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**Developing a community of practice for Trainers:  
Towards a culture of conscience in clinical  
research.**

By

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## Abstract

This developmental research study concerned how trainers, drawn mainly from the commercial (pharmaceutical) sector of the field of clinical research, shared understandings of practice in a professionally localised community, as part of their continuing professional development. Trainers in this community had a heterogeneous range of identities including full-time and part-time trainers: clinical research trainers, training managers; clinical research managers, clinical research associates, compliance managers, auditors and others. The main aim was to explain conditions shaping this community and its concept of practice.

The study involved observing practice from an interlocutory position, using Cultural-Historical Activity Theory (CHAT), to reveal the cultural complexity of the concept of practice within this community.

Two competing rationalities, expressed within contrasting pedagogies with associated cultural standards of compliance or conscience, were established for training:-

- as a restricted technical function focussed on the transmissive delivery of content, or
- as an expansive approach to organisational learning focussed on deliberative enquiry.

These competing rationalities reflected the struggle of an emergent profession to establish autonomy of standards, with implications for the field of practice and wider society: establishing the moral order through a culture of conscience, based on standards of excellence or because a system of regulatory governance dominates the drive to uphold standards through a culture of compliance.

A conceptual-analytical framework, substantiated by empirical evidence, was proposed to describe and analyse the concept of practice embodied in the community's object of activity. Through demonstrating CHAT at the level of declarative conceptions, procedural models, and social discourses/interactions, a link was established between the dominant concept of practice (expressed within a transmissive pedagogy) in the community and the larger socio-cultural context (compliance culture rooted in the system of regulatory governance).

The contribution of this study is to show how CHAT can be applied with theoretically formulated and empirically tested evaluative tools, to reveal the richness of human experience and the complexity of human activity in terms of its cognitive and cooperative social elements, identified as objective regularities unique to the activity system under investigation.

## **PART 1 INTRODUCTION**

## **Chapter 1: Background, outline and structure of the thesis**

# 1 INTRODUCTION

## 1.1 Overview

This research is a study of trainers, drawn mainly from the commercial sector of the field of clinical research, journeying towards becoming a community of practice (CoP). The focus of the study is the concept of practice among this community, formed within the professional body of the Institute of Clinical Research (ICR). Its scope is limited to discussing emergent features of the community, known as the Trainers Forum (TF), in terms of the ‘ecology’ of the commercial sector. This reflects the ICR’s history as a professional association whose members were drawn mainly from the pharmaceutical industry or its associated service industries (recruiters, freelancers, contract research organisations). Observation, questionnaires and interviews further established that members of the Forum were a heterogeneous community of full-time and part-time trainers whose identities ranged from: clinical research trainers, training managers; clinical research managers, clinical research associates; compliance managers and auditors.

As a member of this community, which meets at least three times a year, a contradiction was observed between how community members share ideas, experiences and training methods and how these were frequently talked about. Initial observations suggested that community discourse confused two contrasting pedagogic models, using each of their distinctly defined approaches and associated methods interchangeably. That is, at community meetings, trainer-centred pedagogic strategies routinely used in the act of ‘sharing and discussing’ topical training issues were referred to as ‘learner-centred’.

In this study, pedagogy encompasses not only approaches to the Teaching & Learning (T&L) process, and the associated strategies or methods regarding curriculum content, but also the communicative content of ‘classroom’ talk in terms of its culture, as an element of pedagogy (Alexander, 2005). Hence, for the purposes of this study, in a pedagogic model of *learner centred enquiry*, the approach is defined as learner centred, the process is one of enquiry, and the methods involve collaborative dialogue (sharing and building on ideas). Whereas, in a



*trainer-centred transmission* model, the approach is defined as trainer-centred, the process is one of information transfer, and the methods involve didactic monologue (sharing through delivering information). Consequently, observations suggested that the contradiction is between a practice that emphasises content and transmission, and a discourse that emphasizes process and enquiry, which raised the following questions:-

- Why is a content-driven approach to training, evident in the field of clinical research, dominant in an emergent Community of Practice (CoP)?
- Why do trainers talk about learner-centred approaches but predominantly tend to use trainer-centred methods in this community?

Therefore, this study is based on analysing the ways in which shared understandings of practice are developed within this community. The intention was to explore the concepts, methodology and experiences in the TF in relation to its object of activity. Insights were drawn from observations related to practice in this community, which are explored further via questionnaires and interviews in order understand *what goes on around here* and its implications for *how we do things and why* within a community that, due to its distributed nature, may have wider implications across the field of practice.

### **1.1.1 Problem background**

Training is a fundamental issue that affects the entire field of clinical research (from academia to commercially sponsored research), since the goal of appropriate training in this highly regulated field is ultimately to protect the public from unscientific research that is not conducted to ethical standards. In particular, a quality standard known as Good Clinical Practice (GCP) governs the conduct of clinical research and affects everyone involved in it: subjects, investigators, and sponsors<sup>i</sup>. Protection of subjects' rights, safety and well-being is at the heart of this ethical and scientific quality standard<sup>ii</sup>.

Ongoing regulation in this field means that regulatory inspectors are turning their attention to how organisations sponsoring clinical research demonstrate the effectiveness of their GCP training programmes that support the practice of GCP<sup>iii</sup> among investigators as well as their

own clinical research staff. Such organisations include those in the private commercial sector, ranging from pharmaceutical companies to contract research companies, as well as those in the public healthcare sector (e.g. the NHS) affiliated to academic institutions<sup>1</sup>. Accordingly, as shared at various Trainers' Forum meetings<sup>2</sup>, and in articles published in the ICR magazine<sup>3</sup>, inspection of training records during mandatory GCP inspections by regulators is becoming more of a regular feature.

However, it remains to be seen how trainers or organisations may respond or change their practices as a consequence of inspectors drilling down into training records to find out what is going on in the training process. Generally, it seems that inspectors' focus on training records is limited to concerns about the frequency of GCP training rather than the quality of GCP training (Bringslimark, 2004). However, as reported at the TF, there have been some instances where inspectors have requested to see lesson plans<sup>4</sup>.

An inevitable consequence of this scrutiny has been that organisations concerned about inspectors' expectations with training records have shared their experiences of inspections more widely through publication in order to establish best practices for dealing with inspections generally (Chief Scientist Office, 2005).

Currently, the main implication of these regulatory inspection practices for organisations is the need to be able to demonstrate that not only have employees been trained, but that their training was appropriate and effective. Yet, if regulatory authorities increase pressure on companies to 'practice' accountability with regard to demonstrating the effectiveness of their training programmes, this could challenge under-resourced training departments, especially when training is not necessarily the issue. In particular, in those companies without an evaluative framework it would be difficult to demonstrate that deficiencies in manufacturing

---

<sup>1</sup> i.e. University teaching hospitals within the NHS

<sup>2</sup> TF\_FN\_6/E\_09-05; TF\_FN\_9/G\_05-07.

<sup>3</sup> Hepworth-Jones, 2005

<sup>4</sup> TF May 2007: *When an inspector comes calling*

or clinical research and development processes are addressed effectively through training (Vesper, 2001).

Moreover, if deficiencies are addressed through increasing the frequency of training without paying heed to the quality of that training, then little is accomplished. Therefore, more crucially, success in mediating an effective training process depends on knowing when and how to evaluate different stages and elements of the training process. Otherwise, the status quo is likely to remain unchanged: deficiencies that are not due to lack of training continue to be addressed inappropriately with training; or, deficiencies are addressed with inadequate training. In either case, deficiencies are not remedied. In effect, the potential for GCP non-compliance remains.

Meanwhile, there is no agreement or guidelines about training standards within this field concerning how organisations should demonstrate that their training programmes are effective in assuring regulatory compliance to GCP. At present this is a matter of judgement for individual organisations involved in conducting clinical research. Debate is ongoing in the field regarding the specifics of *how* organisations might train their employees as well as *what* they should learn about the processes involved in clinical research in order to demonstrate compliance with GCP (Zimmerman, 2000a). As a consequence, the need to define training standards is as critical now as when Zimmerman (2000b), an independent trainer, first highlighted this issue:

*“...although the global clinical research community agrees upon basic GCP standards, it has not settled on training standards. At the dawn of the 21st century, GCP training can best be described as a hodgepodge of serendipitous activities of arguable quality. Until the global community identifies and harmonises core GCP knowledge, skill, and behavioural competencies for every position in clinical research, we will all – including the patients whom we strive to help-painfully endure the consequences of GCP non-compliance. And the research community will continue to misuse the minimal funds that management allots for training clinical research personnel.”*

Inevitably, some organisations will excel in the development, delivery and evaluation of their training programmes, whereas others may invest minimal resources in training. Yet, if regulators become involved in defining standards of training, then paradoxically, these may lower quality standards rather than having the desired effect of raising them.

In his time at the Office for Human Research Protections (OHRP)<sup>5</sup> in the USA, Dr Greg Koski recognised the dilemma arising with legislating for quality standards. That is, paradoxically such a legally mandated regime creates the opportunity for competing cultures to develop. Some organisations will do no more than the minimum necessary to adhere to the standards regime (i.e. regulations), thereby creating a *culture of compliance* (Koski, 2001a; Whalen, 2003). Whereas, striving for a *culture of conscience* means standards are driven by a desire to excel in the activities inherent to practice, with full appreciation of the historical context that commands the need for such standards of practice (Koski, 2002:1).

Under Koski's leadership, the OHRP attempted to move from a reactive compliance-focused system of oversight and sanctions in the system of patient protection to a proactive system focused on prevention of harm to subjects—a system in which performance excellence is achieved through education, support and quality improvement. In collaboration with the Food and Drug Administration (FDA)<sup>iv</sup>, the National Institutes of Health and other federal agencies, his office worked "... to identify new opportunities to make the US system for protection of human subjects more efficient and more effective" (Aungst, 2003). Because Koski was acutely aware of the paradox created by more regulations, he was an advocate of proactive training, especially since training is an essential component of quality (Bringslimark, op.cit.). As he recalled in an interview about his time as Head of the OHRP in the USA: -

*"...I never believed that more regulation was the way to go. A "culture of compliance" was not what we wanted. We wanted to build a "culture of conscience" where people didn't do the right thing because it was required by the law, but because of their own sense of moral responsibility and personal integrity – because it was the right thing to do. We emphasized proactive approaches to prevent injury, rather than reactive approaches that would punish someone when something bad happened. Obviously, the goal was, and is, to prevent harm, not to react after harm occurs." (Goldfarb, 2007)*

Similarly, since the introduction of the Clinical Trials Directive (Directive 2001/20/EC) in the European system of clinical research governance, a culturally advanced motive has also been

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<sup>5</sup> The OHRP protects the rights, welfare, and well-being of subjects involved in research conducted or supported by the Department of Health and Human Services (HHS) and helps ensure that such research is carried out in accordance with the regulations described at 45 CFR part 46 of the Code of Federal Regulations, the legislative framework, for the USA.

superseded by a less advanced motive. Compliance with GCP standards is therefore *enforced* with regulations (through mandatory inspections in order to protect clinical research participants) versus *monitored* through voluntary inspections (where organisations were trusted to operate from a sense of “doing the right thing, for the right reasons”). Thus, in the attempt to transform the conduct of clinical researchers, the activity of governance has itself been transformed, through the move from voluntary to mandatory inspections. The main outcome of this transformation is reinforcement of a culture of compliance rather than the intended culture of conscience.

In turn, due to its legitimation in a legal framework, this cultural shift then permeates all clinical research activity operating as a pitfall or double-bind in the struggle to achieve balance in clinical research between quality, time and costs<sup>6</sup>. Conflict then manifests as contradiction whether in the field, the workplace or among training professionals in their community of practice. Hence, in developing a legal framework to enable statutory inspections that uphold and maintain high standards of practice, regulators’ unintentionally may have created the opposite effect through shifting clinical research culture from one of conscience to one of compliance. As Koski states: -

*“...We have gotten to where we are through our own actions. We are going to have to work together now to get back to a place where reason prevails, and we are doing things for the right reasons rather than doing them because we have to.” (Koski 2001b:197)*

Therefore, in the field of clinical research, training is pivotal to helping people do “the right thing, the right way” in the clinical research process, which in the long run satisfies regulatory requirements. Therefore, creating the opportunity for learning lessons where reason prevails depends on identifying the contradictions created by the system of research governance in the field of clinical research<sup>v</sup>, the workplace and at the level of professional practice. Equally, in time, regulatory demands may mean that trainers require formal certification through external

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<sup>6</sup> According to Armstrong and Kaul (2004:191), industry cannot achieve its objectives of providing quicker, better-quality clinical evidence, for regulatory submission, at a lower cost without compromising on cost, quality or time. That is, experience has shown that only 2 of these 3 objectives (described as the 3 sides of an iron triangle) can be achieved simultaneously: “Evidence that is quick and cheap is likely to compromise quality; high-quality research at lower costs is likely to take longer; and quality research in a shorter time is likely to come at a higher price tag.”

qualifications, which has resource implications for both trainers and their organisations, in terms of organisational support for the financial investment and time needed to achieve certification.

Finally, as explained in this outline of issues surrounding training in the field of clinical research, mitigating the risk of regulatory imposition concerning training standards in this field, involves striving to do right things for the right reasons through the pursuit of excellence. Such an endeavour also signals organisations' voluntary commitment to upholding standards in a culture of *conscience* rather than a culture of *compliance*. Moreover, for industry, such pro-activity signals that training is seen as something it 'wants to do' rather than something it 'has to do' (Zimmerman 2000c; 2000d).

In conclusion, the issues can be summarised as follows: -

- Risk of further regulatory imposition if training standards fail to be proactively developed in the field of clinical research
- A standards regime arising from regulatory imposition creates the possibility of standards that are driven by the need to satisfy the regulatory agenda, rather than standards that are driven by a desire to excel
- The need to satisfy an imposed standards regime creates a culture of compliance, which paradoxically may lead only to adherence to minimum standards.

This research therefore, concerns how those working as trainers in the field of clinical research endeavour to uphold standards through developing their shared understandings of practice as part of their continuing professional development (CPD).

### **1.1.2 Problem statement**

#### **Issues:**

- Lack of agreement among organisations in the field of clinical research about the standards/knowledge of training practice e.g. is training mostly about: content or process?  
Which methods are most helpful: trainer-centred or learner centred?

- Role of the Trainers Forum in supporting development of training practice/standards: is there congruence in our *theory-in-action* (Argyris & Schön, 1978) i.e. does our *espoused theory* (what we say we do) match our *theory-in-use* (what we do in actual practice)?

The challenge for the training community is to convince players in the field (i.e. employers - NHS, pharma and CROs) of the need to pro-actively ‘raise our game’ to avoid future regulatory imposition of training standards, which because they are imposed, further reinforces a culture of compliance. Thus, developing knowledge of training process (particularly in evaluation) enables effective demonstration to regulators that personnel are adequately and appropriately trained in GCP. Endeavouring to develop the internal goods of practice founded on the virtues of justice, courage and honesty (MacIntyre, 1985), enables a culture of conscience to flourish (Koski, 2002).

Since 2003, within the Institute of Clinical Research (ICR)<sup>7</sup>, a community of trainers has worked in a group known as the Trainers Forum (TF), with the expressed aims of sharing best practice and discussing topical training issues. This community represented an opportunity to develop training standards through sharing concepts of practice rooted in a *culture of conscience* in the field of clinical research. However, two issues were apparent that could affect efforts to find or provide effective solutions to this cultural challenge. That is, a contradiction was observed in the Trainers’ Forum concerning training practice: -

- While the discourse emphasised learner-centred training (*espoused theory*: our training approach & training methods are learner-centred), the practice of training was about *transmitting* subject matter, since a content-focus was favoured above the process of learning (*theory-in-use*: our approach & training methods are trainer-centred).

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<sup>7</sup> The ICR is a professional body representing clinical research professionals primarily in the UK, but also in Europe and India.

- Training appeared to be driven by a culture of compliance, rather than a culture of conscience in which trainers strive for excellence in the improvement of their practice.

These contradictions were considered as sources of tension driving the community in its learning activities (sharing best practice (BP), discussing topical training & technology issues). In particular, tensions were observed between the desire to excel in practice (operating as a fundamental value providing motivation) and a basic need to ensure standards conform to regulations through delivering content.

## **1.2 Outline of the study**

### **1.2.1 Purpose**

The Trainers Forum represented an opportunity to explore conditions giving rise to the contradiction between discourse and practice amongst trainers (i.e. between *espoused theory* (learner-centred learning approach) and *theory-in-use* (trainer-centred delivery methods)).

It also provided an opportunity to explore, share and develop awareness of reasons for this contradiction. Moreover, since the mission statement of the TF expressed its aims as sharing best practice and discussing training topical issues, the aim of this research was to establish how *we are doing this*. Therefore, the purpose was: -

- To study how the community of trainers, focusing on the Trainers Forum, were developing their professional training practice in response to the *implementation* of state regulation (e.g. mandatory inspections) beginning by exploring what was meant by *training* within this community.
- Given the apparent contradictions between discourse and practice amongst trainers, to study to what extent, and how, have they been able to transform themselves into a community of practice (CoP).



- To explore the activity system – of communication and decision-making – and its social influences that have helped or hindered the development of a community of practice.
- To contribute to practice theory through a critical analysis of the relationship between practice theory and activity theory.

### **1.2.2 Aims**

1. To examine how a group of professional trainers journey towards becoming a community of practice by studying the characteristics of this emergent *professional* community and the conditions that create and sustain this kind of CoP<sup>8</sup>
2. To describe conditions governing practice, which explain the relationship between a compliance culture and the prevalence of a transmissive pedagogy of training within the Trainers' Forum.

### **1.2.3 Objectives**

To explore the workings of the Trainers Forum in order to understand:-

1. How trainers develop their discourse on pedagogy through exploring: the values, purpose and practice of training; the standards of training to be achieved
2. The internal tensions and contradictions between the discourse and practice
3. The social structure of the Trainers Forum: who trainers are; their backgrounds; why they differ in their principal affiliation (to their employers, or to their profession); why they are attached to a particular pedagogy and why they have particular cultural orientations (of training) to regulation (compliance or conscience).
4. The activity system of the TF, in terms of: its division of labour, rules, power and decision-making; its practices of communication (that help or hinder development as a CoP); its practices of agreement making.

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<sup>8</sup> If most communities of practice tend to be those that are distributed across organisations where community members are employed, this kind of *professional* CoP differs in that its members are distributed across a professional institution to which they subscribe, rather than through which they share employment.

### 1.2.4 *Research questions*

Seeking answers to these research questions involved de-constructing: -

- The object of study (the concept of practice in clinical research training) and
- The object of activity within the Trainers Forum (CPD of trainers with practice issues) based on the premise that activity at the TF is guided by its explicitly expressed aims.

The following key and associated questions sharpened the issues to be investigated.

- 
- Research Question 1:** Why is the discourse on pedagogy in the Trainers Forum marked by internal contradictions?
- Why is a content-driven approach to sharing and discussing practice and training issues dominant in an emergent Community of Practice (CoP)?
  - Why are some trainers committed to a transmission model?
  - Is there a relationship between the transmissive pedagogy and the compliance regime? If it exists, how do we explain this relationship?
  - How are trainers working within the Trainers Forum to establish shared understandings about practice/training issues?
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- Research Question 2:** What activities help the Trainers' Forum develop towards becoming a community of practice (and conversely which activities act as a barrier to becoming a CoP)?
- What are the characteristics of activity in the TF? What does practice look like?
  - Why do trainers talk about learner-centred approaches but predominantly tend to use trainer-centred methods in this community?
  - What social processes are moulding the TF (i.e. processes involved in its structuration) e.g. how does the TF run: how is it organised (planning & administration; decision-making; consultation etc.)? Who makes decisions and how

- 
- Research Question 3:** How can the Trainers' Forum realise its potential as a CoP to provide guidance about training standards generally, and evaluation practices in particular, in order to transform training culture from one of compliance to one of conscience?

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Consequently, to gain an insight into the nature of training practices, an understanding of the operational definition of *practice* within this emergent community of practice, spanning this specialised field of clinical research training, needed to be developed. The notion of *best practice* promulgated by this emergent community of practice could then be examined.

Therefore, because the TF represented a developing community of practice within the social setting of a professional society or institution, where trainers met socially and discussed issues of common interest, it provided an opportunity to find answers to the research questions posed in this study.

### **1.2.5 Hypotheses**

As a consequence of initial observations, hypotheses or propositions that will be examined in this thesis are that: -

- If trainers feel divided in their commitments (between their profession, and their employer), then they may speak a language (of process pedagogy) to satisfy their professional peers, but feel forced to deliver cost-constrained training that will satisfy their executive employers
- If the activities of communicative action (dialogue, and giving and taking of reasons to develop dialectical understanding of training) are emphasized within the Forum, then trainers may be more likely to become a community of practice reaching shared understanding about an enquiry-led pedagogy and a culture of conscience in relation to training and ultimately, regulation.

## **1.3 Structure of the thesis**

In this section, the outline of the thesis is provided, which is structured in four parts and split into ten chapters:

### **PART 1 INTRODUCTION**

- Background, outline and structure of the thesis (Chapter 1)
- Review of Literature (Chapter 2)
- Analytical framework (Chapter 3)

### **PART 2 METHODOLOGIES**

- Research Methodology (Chapter 4)
- Research Design (Chapter 5)
- Research Methods (Chapter 6)

### **PART 3 RESEARCH FINDINGS AND DISCUSSION**

- The Subjects: Trainers (Chapter 7)
- Community, Rules & Division of Labour: The Forum (Chapter 8)

- Object & Tools: Purpose & pedagogy of the Trainers' Forum (Chapter 9)

#### PART 4 CONCLUSIONS & RECOMMENDATIONS

- Outcome: Towards a culture of conscience in a developing community of practice? (Chapter 10).
- References
- Appendices.

The background to this research study is provided in Chapter 1. The focus is presented concerning the ways in which shared understandings of practice are developed within a community of practice and why regulatory developments in the field of clinical research may make training problematic.

The literature is reviewed in Chapter 2, exploring where a contribution to knowledge may be situated. This chapter begins by considering the concept and meanings of practice from a number of philosophical, sociological, and educational perspectives to derive an operational definition of practice and to define a conceptual-analytical framework applicable to this object of study. This chapter includes considering reflexivity as fundamental to the analysis of any and all practices, including that of research.

In chapter 3, it is explained how the conceptual framework allows the concept of practice to be viewed as a whole within the Community of Practice (CoP). In turn, the CoP can then be delineated as an activity system with its own rules, community and division of labour. An explanation then follows of how activity can be analysed in terms of the concepts, methodology and experience of training as a practice within the CoP.

Next, the concept of practice is considered in terms of those cognitive and cooperative elements of activity that constitute its objective regularities. This analytical framework is used to analyse observational data, and data obtained from interviews.

The complex nature of activity in the CoP is further distinguished using contrasting epistemological frames of discourse (EFsD) observed within the CoP (i.e. in terms of *saying-*

*writing-doing* and *being-valuing-believing* discourse combinations). These EFsD represent different ways of knowing (received or constructed).

In Chapter 4, Methodology, the pragmatic approach to this research and its ontological structure is described and explained. This provides the background to the research design (Chapter 5) and methods (Chapter 6) that were used to explore elements of practice. These constitutive elements acknowledge the recursive nature of practice, and its institutional arrangement. Methods used to analyse conditions shaping training practices in the field of clinical research within the commercial sector are also outlined in Chapters 3 and 6.

The main analyses are presented in Chapters 7, 8 and 9. To begin, findings are analysed using Wenger's dimensions of community, domain and practice to describe the structure of the Community of Practice, based on individual sessions observed within the Trainers' Forum. Interviews and findings were then analysed using Engeström's activity system model, to explore the social influences of communication and decision making that work to help or hinder the development of the Trainers' Forum as a Community of Practice.

Finally, in Chapter 10, the implications of using activity theory in this study are summarised, concluding with recommendations for future studies of CPD within this field, and other contexts.

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<sup>i</sup> The specialised field of clinical research is subject to complexity and constant challenge. Not least of these challenges, in Europe at least, is the need to comply with an increasing amount of European Regulations and Directives issued by the European Parliament and Council on behalf of Member States of the European Community (EC) (Hooper, 2005; Sweetman, 2003:5).

<sup>ii</sup> The ethical origins of GCP can be traced through the Declaration of Helsinki back to the Nuremberg Code. The Declaration is a code of research conduct binding members of the medical profession to practice ethical principles with regard to the medical care of research subjects. The Declaration grew from the Nuremberg Code, the first internationally recognised code of research ethics established by the Nazi War Crimes Tribunal in 1947 (The Nuremberg Code, 1949), which established the principle of informed consent, whereby participants in research are made aware of the risks as well as the benefits to which they may be exposed by their informed choice of participating in a clinical study.

<sup>iii</sup> GCP was first implemented as a Guideline in the European Community (EC) in 1997. However, individual Member States had their own approach to regulations governing the implementation of GCP in the conduct of clinical trials on medicinal products for human use. So, although it was largely adhered to within the EC, GCP's adoption was neither complete nor uniform, since it was not consistently incorporated into national legislation. In practical terms, regulators' legal powers to seek evidence of GCP compliance through the inspection of relevant sites varied across Europe, ranging from mandatory schemes in the Netherlands and Denmark but voluntary schemes elsewhere (Wilsher, 2002). By contrast, the regulatory authorities in the USA,

namely the FDA, had been conducting mandatory inspections for many years, in Europe such inspections were performed under a voluntary inspection scheme.

Nevertheless, because of past lessons learnt in Europe, including the thalidomide tragedy in the late 1950s and early 1960s, the ethical and moral requirement to demonstrate that patients were protected from participation in ill conceived or inadequately designed studies - indicative of 'poor science' – constituted a basic regulatory obligation despite having no uniform legal framework for adoption. Thus, basic patient protection was achieved through independent review of proposed research protocols by ethics committees, and by obtaining participants' informed consent prior to their participation in a clinical study (van Dongen, 2001). The publication of this legislation as Directive 2001/20/EC in the Official Journal of the European Communities on 1 May 2001 (Fontaine N. and Rosengren B., 2001) has since provided a common legal framework across Member States in the EC for monitoring and enforcing GCP standards applicable to clinical research implementation (Wilson, 2003).

<sup>iv</sup> The Food and Drug Administration (FDA) is an agency of the Federal Government in the United States (US) and part of the US Department of Health and Human Services (DHHS). It became firmly established as a government agency in 1937, to ensure that products with claimed medicinal properties were registered and evaluated for safety, quality and efficacy before licensing. Its firm establishment was triggered by the deaths of one hundred and seven people in 1937 from ingesting a liquid presentation of a drug. The drug, sulfanilamide, had been used without incident in tablet and powder form to treat streptococcal infections. However, following demand for a liquid presentation, the drug was found to dissolve in diethylene glycol, and was developed into a solution, accordingly. The toxicity of this ingredient (which is now used in antifreeze) was overlooked despite warnings in the published scientific literature of the time about its potential to cause kidney damage or failure. Existing regulations extended to testing only for cosmetic aspects such as flavour, smell and appearance. Thereafter, toxicity became a prime concern. Appropriate regulations were enacted the following year, in 1938 (Ballentine, 1981).

<sup>v</sup> Government agencies or regulators are charged with the responsibility of reviewing GCP compliance, with a legal mandate to ensure compliance with GCP standards (Wilson, op.cit.). Since 2004, legislation throughout Member States of the European Union (Directive 2001/20/EC) mandates the monitoring of compliance by regulators through conducting inspections of documentation and procedures at the sites of sponsors, investigators and the Independent Ethics Committees (IECs) involved in reviewing the ethical nature of proposed research (van Dongen, op.cit.). Whereas in the USA mandatory inspections had been conducted for many years, in Europe such inspections were performed under a voluntary inspection scheme prior to the introduction of the Directive. However, directives have to be transposed into national law in each Member State within three years of their publication. Consequently, scope exists for differing interpretations of the intended regulatory requirements such that the goal of harmonisation in terms of approach to clinical research or to standards of GCP is not necessarily achieved (Pinder, 2005).

## **Chapter 2**

### **Theoretical Framework: The Concept of Practice**



## 2 THEORETICAL FRAMEWORK: THE CONCEPT OF PRACTICE

Academic literature specifically ascertaining what constitutes best training practice concerning fellow trainers in the pharmaceutical industry is sparse. Moreover, literature within the field of clinical research about practices that constitute the training process is generally lacking. This gap in the academic literature provides a basic rationale for research in this field of practice.

Meanwhile, the concept and meaning of practice is well established from five theoretical perspectives, outlined as follows:-

- MacIntyre's (1985) concepts of standards (of excellence) within a practice that depend on the relationship between its internal and external goods
- Giddens (1984) structuration theory, where the nature of practice is both shaped by, and depends on, how it is structured by agents according to the rules and resources or sets of transformation relations that constitute the properties of social systems
- Bourdieu's (1990) logic of practice, where practice is considered in terms of agents' embodiment of practical sense for the "rules of the game" (or *habitus*)
- Wells' (2001) theory of dialogic inquiry as a socio-cultural practice of learning
- Engeström's (1987, 2007) development of cultural-historical psychology to generate a theory of activity that informs expansive learning in various fields of societal practice.

Therefore, in order to construct an operational definition of *practice* that has relevance for clinical research training as a field of practice, these perspectives are drawn into an examination of the literature concerning practice, particularly in terms of its professionalism (referred to in terms of quality or standards of practice).

## **2.1 Aim and scope of the Review**

The aim in this review is to consider and examine ways in which practice may be conceptualised and subsequently examined within the context of this research study.

Consequently, the focus is on both theoretical and pragmatic aspects of practice that affect and define its quality. Since the quality of practice concerns the standards that define it, various fundamental perspectives concerning the concept of practice are considered including that of the philosophical (MacIntyre, op.cit.), the sociological (Bourdieu, op.cit.; Giddens, op.cit.) and the educational or socio-cognitive. This latter perspective includes considering learning either as: a social practice of communication (Wells, op.cit.), situated within communities (Lave and Wenger, 1991); or as complex networks of activity each with its own set of contradictions and tensions that drive the process of expansive learning (Engeström, 1987).

Therefore, in the sections that follow, a number of concepts and theories are reviewed, which are central to this research and subsequent analysis of the practice of training: the concept of professionalism; the concept of community of practice; and Activity Theory.

## **2.2 Grounding the concept of practice: professionalism versus professionalism**

The term 'practice' is familiar and well used in a variety of contexts including within traditional and newer professions such as medicine and law, or nursing and teaching.

However, its meaning may have changed reflecting changes within society. For example, in a sociological context, *practice* has been a defining characteristic or feature of professionalization exemplified by the *ability to achieve a definable basis of background knowledge and practice* (Millerson, 1973:6). In this respect, it refers to the everyday conduct of a recognised occupation, where particular ways of behaving or operating are customary. Moreover, in this traditional, idealistic view of professions, they exerted a moral influence in society through their selfless civic-minded service, or altruism (Millerson, ibid.).

From this traditional perspective, one customary defining characteristic of professional practice is that it depends on a university level of education to develop specialised knowledge, and/or passing qualifying examinations for professional membership (Vanderstraeten, 2007; Nicholls, 2001; Goode, 1957). Thus, established professions shared this way of doing things, or common practice, by inculcating members through the basic achievement of academic qualifications representing specialised knowledge (Millerson, op.cit.:13). The challenge is then for members to maintain their professional knowledge at a level that ensures practice is current through the process of continuing professional development (CPD) defined as:-

*...the maintenance and enhancement of the knowledge, expertise and competence of professionals throughout their careers according to a plan formulated with regard to the needs of the professional, the employer, the profession and society. (Madden and Mitchell, 1993:12)*

This definition of CPD infers that *knowledge, expertise and competence* are considered as defining qualities of practice (Lester, 1995:4). With the emphasis on practice, CPD is then about

*...the systematic maintenance, improvement and broadening of knowledge and skill, and the development of personal qualities necessary for the execution of professional and technical duties throughout the practitioner's working life (Lorriman, 1997:2).*

A progressive perspective reflects society's egalitarian quest to involve and recognise everyone's capacity for lifelong learning (Critten 1999). Here, the term *professional practice* encompasses those with experience and knowledge acquired or developed in a variety of contexts: pre-professional training (academic), workplace (vocational) or personal (experiential). Thus, individuals may have developed equivalent levels of knowledge and skill, via different routes, and be capable of applying their knowledge and skill with equal competence. In effect, competency based education and training (or CBET) is based on this particular premise (Bates, 2002). So, now the possibility is considered that regardless of educational background, skill and competence - in effect practice - may be developed effectively in everyone, through a particular process, involving *shared understanding and open dialogue* that encourages professionalism (Nixon, Martin, McKeown & Ranson, 1997; Gilleard, 1996:20).

For example, even if the background knowledge to some professional training practices is not necessarily attained through a university education, practitioners may be assumed to share qualities and standards of skill and competence that define them as professional. Thus, as Critten (op.cit.) states “*we’re all capable of demonstrating professionalism*” such that it may be recognised on the basis of *competence, expertise or conscientiousness* (Chambers Compact Dictionary, 2001). Consequently, such attributes of professionalism are not considered exclusive to those with academic training or status, but are universal to those aspiring to a particular standard or level of conduct. Traditionally that standard or level of conduct concerned integrity where professionals operated according to moral codes of behaviour, at the heart of which was the notion of selfless service for the “public good” (Shirley and Padgett, 2004: 37). According to Evetts, (2003: 396):

*“...there is extensive agreement about the appeal of the idea of profession and professionalism and its increased use in all work contexts. It is used increasingly as a marketing device in advertising to appeal to customers (Fournier 1999) and it is used in mission statements and organizational aims and objectives to motivate employees. It is an attractive prospect for an occupation to be considered a profession and for occupational workers to be identified as professionals. The concepts of profession and professionalism are increasingly used (or misused?) in the organizational, commercial and service contexts in which ‘professionals’ are increasingly employed.”*

Therefore, against the backdrop of changing relations in society, reflected in changing institutional arrangements within society, the changing status of professionals in relation to the nature of their *professionalism* and practice has been extensively studied (Evans, 2008; Bacon, *et al*, 2000; Bellman, 2001:230; Friedson, 1994; Nixon, 1996; Nixon *et al*, op.cit.; Gleeson 2005; Ranson, 2003). In particular, debate concerns whether professionalism may be recognised as a standard of behaviour, or practice rather than as, in Bourdieusian terms - a mark of elitist distinction (e.g. through the acquisition of privileged academic “knowledge” (Catto, 2005; Evans, op.cit.; Svensson, 2006). The specific conditions and characteristics of professional work in education have also been analysed (Vanderstraeten, op.cit.).

However, much of the discourse of past decades about professionalism has focussed on the relationship between the structure of professions and the agency of professionals in terms of a dualism rather than a duality concerning the relational aspects of agency and structure (Grace,

1995). Specifically, professionals are either considered as the recipients of change or the agents of change culminating in polarised camps of theorists who either “privilege subjective agency,” or who elevate “structure over action” (Gleeson, *op.cit.*).

On the one hand, focus is on how market conditions and organisational structure may determine the shape of professional practice, either to the detriment of practitioners through the loss of professional autonomy (Ozga, 2000; Campbell, 2002) or to the benefit of wider society through greater accountability. On the other, practice is emphasised as a reflection of the agency of its practitioners (Knights & Wilmott, 1999). Yet, according to Evans (*op.cit.*:16): “critical analyses of professionalism do not stress the qualities inherent in an occupation”. She contends that because the substance of professionalism – “remains under-examined in the broad sociological field” in terms of what it is, and how it is constituted in the context of education, “this is problematic because without understanding of its substance it is difficult to appreciate how professionalism functions and, therefore, how it may be influenced”.

Yet, in every day society, the idea of professionalism as a particular standard of behaviour operates routinely as a measure of the quality of practice (“he’s a consummate professional”; “he’s an amateur”; “he’s a *cowboy*”). On the one hand, its unconscious adoption may reflect the successful dissemination and distillation of professional attributes throughout society (competence: cowboy; expertise: amateur; and, conscientiousness: consummate professional).

On the other, it may represent the dilution of professional status as the preserve of academically trained professionals. In effect, use of the term *professionalism* is no longer restricted or confined to describe the professions, their professional conduct, or the situation of their practice.

Equally, then Boyt, Lusch & Naylor’s (2001:322) notion that “...professionalism consists of the attitudes and behaviour one possesses toward one’s profession. It is an attitudinal and behavioural orientation that individuals possess toward their occupations” differs from the broad consensus view of professionalism as an “an externally imposed, articulated perception

of what lies within the parameters of a profession's collective remit and responsibilities" (Evans, 2008: 23). In any event, the concept of professionalism has been "significantly affected by social and cultural changes over the past two decades" (Eraut, 1994: 223).

Perhaps then, taking professionalism as a standard of behaviour, related to the generically inherent qualities of a practice, circumvents issues of status associated with the values of particular occupations that are defined by their practices. Accordingly, Evans re-visits Hoyle's (1975) notion of professionalism in relation to teachers' practice, which re-focuses attention on the concept of practice in terms of its quality, and context, since it concerns: -

*"...those elements of the job that constitute the knowledge, skills and procedures that teachers use in their work" (Evans, op.cit.:26).*

After due consideration and analysis, she redefines professionalism as: -

*"...an ideologically-, attitudinally-, intellectually- and epistemologically-based stance on the part of an individual, in relation to the practice of the profession to which s/he belongs, and which influences her/his professional practice" (Evans, ibid.:26).*

Moreover, Hoyle defined professionalism within a continuum or spectrum of standards ranging from restricted behaviours at one end, to extended behaviours at the other. In effect, these behaviours then translate into restrictive or expansive codes defining the quality of practice. Consequently, in his theorised models of *restricted* or *extended* professionalism, he defines *restricted* behaviours as dependent on experience and intuition, guided by a narrow, classroom-based perspective that is concerned principally with the day-to-day practicalities of practice. *Extended* behaviours, by contrast concern the 'bigger picture' and value the theory underpinning pedagogy, adopting a rationally-based approach to the job.

Consequently, the concept of professionalism represents a sea change in thinking about professional practice: -

*"...whereby the claim to professionalism is based not on cultural capital of expert knowledge, but on professionalism as necessarily involving continuous learning. The shift we are trying to define is away from 'professionalism as the ideology of service and specialist expertise; away from 'professionalization' where the status of the occupation is at stake; and towards 'professionalism' which focuses on the quality of practice in contexts that require radically altered relations of power and control." Nixon et al (op.cit:12).*

Therefore, just as professional practice now extends into the commercial world of business and is not restricted to the cloistered world of public service, the concept of professionalism re-directs attention towards standards of practice in recognition of the changing contexts of practice.

However, whereas medics, lawyers, nurses and teachers consider themselves as practitioners in the sense of the everyday conduct of their practice, neither clinical research personnel (i.e. clinical research monitors<sup>9</sup> and managers) nor their trainers seem to refer to themselves in this way, at least not overtly. Yet, in the field of clinical research, regardless of whether commercially based or set in academia, the term *practice* is familiar and used extensively in the guise of *good clinical practice* or GCP. Does this then signify a difference in how clinical research personnel are perceived or how they perceive themselves? That is, does it signify a difference in the state of their professionalization, or their professionalism in terms of their identity?

It may well signal a difference in perceived status as a distinct group within the field of practice (i.e. clinical research), as well as within society at large. In particular, the recognition of an occupation as a profession depends on internal perception by those performing the occupation and on external recognition by those outside it (Millerson, 1973: 6; Nixon *et al*, op.cit.). Hence, the adoption of the term *practitioner* may herald a perception shift for particular occupational groups for both insiders and outsiders (Cochrane-Smith & Lytle, 1993) in terms of appreciation of a particular identity.

That the term *practitioner* has not yet overtly emerged within the industry probably reflects that the discipline of clinical research is in a constant state of flux as opposed to being fully established, as noted in the comments of the editors of the standard industry reference 'Principles of Clinical Research' published by the Institute of Clinical Research: -

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<sup>9</sup> The role of the clinical research monitor involves monitoring clinical research data produced by clinical investigators for integrity and generation in compliance with GCP.

*“...Clinical research is a continually evolving discipline; almost by definition, change is a part of its make-up and could be described as its only constant.” (Di Giovanna and Hayes, 2001:xii)*

In view of this dynamic fluidity, it is then perhaps a little more plausible why practitioners in this discipline are yet to emerge fully-fledged. In particular, the changes that have taken place in clinical research reflect the wider changes in the landscape of pharmaceutical research and development (Fisher, 2005:13), as well as the regulatory landscape.

In addition, general awareness of clinical research, let alone clinical research training as an area of practice, may be low both outside and inside the industry, possibly reflecting the highly specialised nature of the industry. Nevertheless, despite efforts to de-mystify the process of clinical research (Buckland, 2005), the industry's role remains shrouded in mystery, engendering suspicion and mistrust for outsiders (Abraham 2007; Busfield, 2006, 2007), and lacking transparency for insiders (Parrott, 2005).

Nevertheless, as an occupational group, clinical research trainers may share particular characteristics, such as educational background; or, they may share common behaviours and assumptions, adopting particular training strategies influenced by organisational factors such as social and cultural traditions mediating practice. For example, the organisational focus on the evaluation of training may be confined habitually to establishing trainees' satisfaction, rather than on evaluating learning transfer from the classroom back to the job. Rather than basing ways to create learning opportunities for trainees on a participative or deliberative pedagogic model of learning, organisational focus may be on creating materials to convey information underpinned by a transmissive pedagogic model of training.

They may perform similar tasks in a particular way, with different degrees of accomplishment, such that these characteristics of education, behaviours and tasks define their role, its responsibilities and its nature as *professional*. In other words, the complexity of tasks assigned to the training role may require a level of education, skill and accountability, which inherently demands a particular standard of conduct. As MacIntyre (op.cit.:190) states

*“A practice involves standards of excellence and obedience to rules as a well as the achievement of goods. To enter into a practice is to accept the authority of those standards and the inadequacy of my own performance as judged by them. It is to subject my own attitudes,*



*choices, preferences and tastes to the standards, which currently and partially define the practice.”*

Thus, examining these ‘professional’ elements of the training role does not necessarily give a complete understanding of the nature of practice related to clinical research (CR) training, since the standards of excellence associated with practice also partially define it.

Such understanding requires an exploration not only of factors mediating practice within the practice setting, but of the structural elements of practice embodied within a community of practice. Davis and Taylor-Vaisey (1997) frame this as *practice settings* and *practitioner characteristics*, which in their empirical study were common characteristics affecting the adoption of guidelines into practice.

For example, as a constituent of an operational training function the quality of CR trainers’ professional practice and their CPD, or professionalism, has potential implications for the achievement of training goals and their evaluation. For example, the ultimate objective of GCP training programmes is adequate training of suitably qualified staff in the meaning of ethical conduct of clinical research (Armstrong & Kaul, 2004). So, in turn, professional practice refers to a standard of competent ethical conduct of those tasks and responsibilities that define the role of CR trainer. Therefore, standards concern whether the role is commonly defined, or whether it varies depending on a company’s needs, expectations or perceptions of the role. In effect, such standards also concern tacit understanding of the role within the community of practice. It also relates to what extent they can “... *exercise independent judgement and self-regulation*”, which according to Nicholls (op.cit.:78) is representative of professional status and autonomy.

In that sense then, of exercising independent judgement, the professional practice or professionalism of CR trainers may also affect the level of investment in the training process, which ultimately enables those whom they train to comply with regulatory standards for the conduct of clinical research (Zimmerman, 2000e). Therefore, although it may be early days for the recognition of CR trainers as “fully-fledged professionals”, in the traditional sense of a

well-defined occupational identity, nonetheless their role is pivotal to the clinical research process (2000c).

Furthermore, in a clinical research-training context, use of particular language may be an expression of the distinction between training as an activity or as a practice. That is, a session that is *facilitated* may imply a qualitative difference in how information is imparted and shared to build knowledge, from a session that is “delivered”. However, to assess whether a training session is facilitated or delivered requires more than an examination of intent. That is, it requires an examination of teaching and learning approaches and the corresponding methods adopted in order to achieve such an objective. In this respect, artefacts such as training manuals or curricula that encompass particular T & L methods indicate routinisation of the training role within an organisation, and suggest operationalisation of training as a practice.

In order to consider why clinical research personnel do not consider themselves as practitioners, the nature of practice is deliberated in subsequent sections, based on philosophical, sociological and socio-cultural conceptualisations within the literature.

Through distilling the concept of practice from these theoretical perspectives, each provides a particular means to deconstruct the nature of practice.

### **2.3 The philosophical perspective: The definition of practice**

From a philosophical perspective, understanding what *practice* means involves considering the fundamental virtues of courage, justice and honesty guiding it. For example, in considering the nature of the “Virtues”, MacIntyre (op.cit.:187) defines *practice* as

*“Any coherent and complex socially established human activity through which goods internal to that form of activity are realised in the course of trying to achieve those standards of excellence which are appropriate to, and partially definitive of, that form of activity, with the result that human powers to achieve excellence, and human conceptions of the ends and goods involved, are systematically extended.”*

The difficulty with this dense definition, as MacIntyre appreciates, revolves around the philosophical concept of “goods internal to” a practice, and how this concept relates to the notion of virtues arising from practice. He further elaborates:

*“Tic-tac-toe is not an example of a practice in this sense, nor is throwing a football with skill; but the game of football is, and so is chess. Bricklaying is not a practice; architecture is. Planting turnips is not a practice; farming is. So are the enquiries of physics, chemistry and biology, and so is the work of the historian, and so are painting and music.”*

According to this understanding, MacIntyre’s definition of practice uses three criteria to distinguish an activity from a practice. Namely, practice has:

- complexity
- internal goods, and
- standards of excellence.

Accordingly, while engaged in a practice, a practitioner will develop particular skills and qualities in the process of becoming accomplished in the practice, or in the pursuit of excellence. The concept of *goods internal to the practice* concerns the moral dimension of the skills and qualities that are developed while engaged in a practice and through the pursuit of excellence.

MacIntyre’s definition of practice therefore, concerns standards, which are motivated by an appreciation of the nature of accomplishment associated with the practice, which he differentiates into *internal* and *external* goods. At a more pragmatic level, based on Marx’s (1973:89) theory of value, this ‘moral’ dimension concerns the “use” value of such skills and qualities in terms of their ‘greater’ social purpose. *Goods external to the practice* concerns the “exchange” value or material dimension of the skills and qualities so developed, and thus, the economic capital that may be derived from them. Therefore, based on MacIntyre’s (op.cit.) perspective, practice may be considered as those internal (moral) & external (material) goods achieved through a complex activity that is defined by its standards of excellence.

However, as Bourdieu (1977) has considered, other forms of capital can also be associated with attributes of practice namely social, cultural and symbolic capital i.e. the value commonly ascribed in social, cultural and symbolic terms. Consequently, to understand what it means to practice in a sociological context, it is then necessary to consider not only the social, cultural and symbolic derivatives of the ‘goods’ or virtuous qualities embodied within

a particular activity that define it as a practice, but the historical basis of these derivatives. By this means, the social norms that govern the expression of a practice and its social consequences might be more fully appreciated (Levinson, 1998:91). For example, balancing the tension between these two types of goods is necessary if practice is to withstand corruption by the pursuit of external goods, particularly where the exchange value of the practice may eclipse its use value.

Understanding proceeds on the basis that practice refers to the specific way in which a particular activity is conducted and the nature of its internal goods, which help to uphold its continuation, sustain its individual practitioners, and which benefit the wider community (MacIntyre, op.cit.:288). Correspondingly, in a workplace context, a practitioner uses his or her knowledge not just to perform the tasks and responsibilities that define his or her occupational role, but (s)he endeavours to reflect on the nature of intrinsic ‘goods’ within practice of that role, and in so doing strives to achieve standards of excellence.

While so engaged, consideration of ethical relations forms a part of the analysis of the nature of practice (Jones, 2003), since engagement in practice involves the practitioner reflecting on, if not defining, the relationship between self and others, including implications and responsibilities. In this respect, the concept of selflessness is embedded within ethical practice, especially since: -

*“...the moment one is generous in hopes of reciprocity, that relation no longer involve generosity but the commercial relation, the exchange of good behavior” (Levinas, 1999:101).*

Relationships then are considered and negotiated along the lines of *what’s in it for me, you and us*, reflecting the complex stages involved in building trust within modern relationships (Halliday, 2008:5). Hence, MacIntyre’s definition of practice acknowledges the relational element involved in reaching agreement concerning what constitutes the internal goods of a practice, since it involves accepting the authority of defined standards of excellence and constitutive rules associated with their practice. Therefore, achieving the internal goods of practice is contingent on reflecting on the standards of excellence.

The relational element involved in practice is considered in the next section, where attention turns to how *practice* is constituted from a sociological perspective.

## **2.4 The sociological perspective: What constitutes practice and how can it be understood?**

Bourdieu (1990) refers to the structures, laws, and systems that might describe an individual's reality as *objective regularities*. Such regularities are ontological aspects that define an individual's small world of practice, as for example in the context of this study concerning training within either the pharmaceutical industry, or the wider field of clinical research.

However, according to Jenkins (2002:96), Bourdieu (op.cit) makes little attempt with respect to social practice and history, to develop *a theorised model of why people do things, or why things are the way they are* – in order to understand the process and history leading to certain practices (Jenkins,ibid.:96). Yet, Bourdieu's conceptions of *habitus* and *the logic of practice* or *practical sense*, point to a basic framework with which to analyse practice in terms of its objective regularities. That is, *habitus* concerns the embodiment of agents' values and disposition with regard to their perceptions, understandings and actions, which then translate into the objective regularities of practice, determined by their practical sense or *ability to comprehend and negotiate cultural fields* (Webb, Schirato and Danaher, 2002: 49). Hence, to operate within a cultural field (i.e. the site of practice bounded by rules, rituals, conventions, categories) individuals or 'agents' need first to recognise the game that is played out between agents in the field, and need second to learn the rules of that game. This involves:-

*"...a knowledge of the various rules (written and unwritten), genres, discourses forms of capital, values and imperatives which inform and determine agents' practices, and which are continuously being transformed by those agents and their practices. This knowledge allows agents to make sense of what is happening around them, and to make strategic decisions as to how a field or fields should be negotiated – in other words, which practices, genres or discourses are appropriate in certain circumstances." (Webb et al, ibid.:50)*

However, because *habitus* infiltrates practice, agents' actions tend to become routinised in everyday activity (Bourdieu, 1990). Therefore, as Jenkins (op.cit. 96) suggests, mere descriptions of objective regularities does not necessarily explain them. So, describing the structure of the pharmaceutical industry or the field of clinical research, laws governing it and

history forming it, does not help us understand why or how trainers in this field train the way they do. In order for us to do this, we must also consider the conditions that govern practice in a particular situational context.

In Bourdieu's view, the positions of practitioners within the field of practice, both as individuals and collectively, needs to be considered in relation to past and present influences that shape practitioners: their practice and power relations in the field of practice. Perhaps, then, it may be possible to understand *why* CR trainers practice as they do, as well as *how* they practice in their role. Moreover, it should not be assumed that the *why* and *how* elements are related to each other, since accepted or habitual practices might defy or resist rational explanation, having become inviolable customs shaped either by prevailing traditions or by circumstances within a community's cultural environment, or an organisation's. In effect, practices might have developed, or been adopted for political reasons. Orthodoxy may also govern which practices predominate. Bourdieu (1977) frames this as *doxa* – where the core values and discourses articulating the fundamental principles within a field are considered as inherently true and necessary. In practice, this takes the form of *bodily and unconscious submission to conditions that are in fact quite arbitrary and contingent* (Webb *et al*, op.cit.:ix).

Alternatively, Murray and Lawrence (2000: 38) describe conditions governing practice as social norms. In this instance, they are referring to the constraints affecting practitioner-based enquiry, which they consider as a system-based practice. As such, they provide the following explanation:-

*“The concept of ‘system’ suggests constraint. A constraint is a limit on action. It may be self-imposed or it may be externally imposed as in the case of a social norm. A constraint is not only a limit on action, it may also be a sense of restriction on feelings and emotions, and acting in this way sharpens an individual's sensitivity to social circumstances. Constraints produced by and in social structure are said to be ‘normative’. That is, they become transformed into rules which not only publicly define expectations in institutional life, but also contribute to the beliefs and knowledge that people hold about institutional life.”*

Murray and Lawrence's notion of constraint, as self-imposed limits on action, as opposed to an externally imposed norm, implies conscious awareness of effects of constraints on behaviour. Hence, practitioners' self-imposed limits on action are expressed as sensitivity

within their practice and social awareness of how circumstances affect expression within practice. In other words, they have social awareness of constraints within the situation of their practice and consequently they can modify their behaviour in response, accordingly. In Giddens' terms, such rules and resources are structural elements of social practice. Rules may also be culturally bound. Resources are of two types: authoritative – concerning control of people; and allocative – concerning control of things). Consequent social interactions, in terms of rules and resources, and power relations within a community of practice, for example, may then shape (enable/constrain) practice.

By contrast, Bourdieu's concept of doxa implicates habitus, which is expressed through bodily behaviour and not within conscious awareness. Hence, in this view, the response to an externally imposed norm is not a conscious response or conscious modification of behaviour to fit the circumstances. Rather, the notion of 'doxic attitude' is of *unconscious submission to prevailing conditions* (Webb *et al*, op.cit.:xi). Yet, as such, whether the *restriction on feelings and emotions* that Murray & Lawrence (op.cit.) refer to operates at the conscious or unconscious level, the effect on behaviour is the same if it means that potential actions are suppressed through conformity with a social norm.

In practice then, if constraints have effects at both the conscious and unconscious levels, overt or subtle manifestations of the effects on behaviour may nevertheless be considered or examined through deconstruction of objective regularities (i.e. the rules, structures and systems governing an individual's reality). For example, Bourdieu considers the phenomenon of suppression as an inherent element in recognising the game among players in terms of the 'rules of the game' governing linguistic and cultural production in any field of practice. In addition,

*"...In the taking and occupying of positions, what is also at stake is that which cannot be said: suppression and censorship are one of the prime characteristics of the operation of any field"*  
(Jenkins op.cit.:xv)

Consequently, if the tendency of social pressure is to ensure conformity with a given orthodoxy, such pressure also has the potential to ensure certain 'truths' are taken for granted

rather than examined logically or rationally. Any challenge to the scientific credibility or technical expertise of those in positions of power and with a vested interest in maintaining a particular 'truth' is then effectively suppressed (Martin, 1999).

However, this raises the issue of blind adherence to certain practices, implying that practice is static or stagnant, rather than dynamic, since the suppression of challenge or potential conflict means that the opportunity for changed or improved practice is stifled. Moreover, such practice is potentially unethical by virtue of adherents' lack of critical thought, particularly if practice is based on a set of 'taken-for-granted' assumptions. Bourdieu considered this as the ethical imperative of reflexively analysing the history of a practice (Webb *et al*, op.cit : x) in order to recognise that *...our knowledge and actions are bound and liberated by the social contexts in which they arise* (Collier and Toomey, 1997). Yet, regardless of whether practice is theoretically, empirically or culturally-based, to be ethically valid, surely it must be able to withstand challenge?

In effect, Popper (1959) envisaged such challenge as the essence of critical practice, which was subsequently accepted within practice of scientific experimental research. Popper emphasised the 'critical' component within critical enquiry using the principle of *falsification* rather than the principle of *verification*. If after subjecting hypotheses to rigorous testing we cannot show it to be false, then it holds true as a reasonable explanation to our research question, until such time as another theory disproves it. So, if hypotheses withstand the process of critical enquiry, in light of the available evidence, then we can be confident that they provide a reasonable explanation for findings, until shown otherwise. Likewise, Popper's logical imperative holds when applied to educational research, especially when Stenhouse's (1975:156) definition of research is considered i.e. *systematic, critical and self-critical enquiry which aims to contribute to the advancement of knowledge*.

Thus, to consider the automatic or 'taken-for-granted' assumptions on which practice may be based, Bourdieu & Wacquant (1992: 90) refer to the need to reflexively examine the dynamics of the associated field of practice through historical or



*“...genetic analysis of its constitution and of the tensions that exist between positions in it, as well as between this field and other fields, and especially the field of power”.*

Reflexivity then provides the means to overcome tendencies to reproduce assumptions perceived as *common sense* or that infer a rational basis for the development of practice.

Finally, Bourdieu argues that reflexivity begins by forming a *radical doubt* concerning the *values, questions and categories of the field and the society* in which the researcher operates (Webb *et al*, op.cit.:52) such that *the construction of a scientific object requires first and foremost a break with common sense* (Bourdieu op.cit.:235). To make sense of practice, our own and others, we need to contemplate our own social and cultural influences (i.e. categorised as class, religion, ethnicity, age etc.). We also need to reflect on how these factors affect our view of, and participation within, the field, as well as our thinking in relation to practice within the field (i.e. our intellectual bias towards considering practice as an abstract idea originating or pre-constructed within the field, or a problematic issue requiring solution). Consequently, a reflective approach to improving the quality of practice, especially educational practice, is also an approach to social scientific or educational enquiry that addresses the issue of internal goods related to educational practice. Moreover, as a means of self-evaluation it *enables people to hold themselves accountable for what they think and do* (McNiff, Lomax and Whitehead, 2003:14). Thus, as a reflexive methodology, action research is proposed as a means to understanding practice that has far-reaching social consequences beyond that of the immediate benefits gained through improvements to practice for the practitioner or those within his or her sphere of influence:-

*“The idea of social change is embodied in the processes of groups of individuals who are committed to changing the way they think and act. Individual practitioners can become dynamic change agents who can generate wide-scale social change by working together. Action research is a form of personal enquiry, but it is always done collaboratively because it involves individuals working together to achieve commonly agreed goals.” (McNiff *et al*, *ibid.*:14)*

So, through developing the sense of responsibility, and insight, reflexivity has the potential to bring about *emancipation from libidinal, linguistic, epistemic, institutional, or environmental forces that limit our options and our rational control over our lives but have been taken for granted or seen as beyond human control* (Mezirow, 1991:87). As a methodological approach

to improving the quality of practice, the reflective process within action research potentially raises awareness of the issues surrounding knowledge: its validity, utility, value, control and power.

Murray and Lawrence (op.cit.:6) appear less convinced about action research as a democratising and empowering process, as its advocates claim (Carr and Kemmis, 1986; Lomax, 1986; McNiff & Whitehead, 2006). They dispute the internal goods of its constituent reflective process (i.e. its democratising epistemology and empowering nature) that can sustain both practitioners and their communities, on grounds of methodological and intellectual rigour of the action research approach. Subjective attempts to improve one's own practice are considered invalid as a form of research because this approach lacks in objectivity; and because some attempts fail to consider links with the body of knowledge, limiting its general applicability.

Murray and Lawrence's scepticism is grounded in concern for the failure of reflective practitioners to appreciate the intellectual milieu of the practice being reflected upon, in terms of either historical antecedents or theoretical possibilities. They conclude that: -

*"Practitioner research ought to be informed about and by established paradigms or bases of explanation in social and behavioural science. It should also be guided by well-established precepts in the literature." (ibid.:41)*

They emphasise that practitioner research is likely to be sidelined if it cannot keep up with developments in social science (ibid.:40). Hence, they highlight the 'new rules' of social science method (as formulated by Giddens), which includes:

*"...the recognition of power as a crucial, inseparable component of action; the acknowledgement of norms as both constraining and enabling; the idea that the enactment of moral obligations does not necessarily imply moral commitment; and the acceptance of the principle that the production of society is always a skilled accomplishment of its members." Ibid.:41)*

In effect, their argument recognises the effect of social norms and doxa on behaviour. Their concern particularly relates to the recognition that institutional behaviour is constrained by normative beliefs (Murray and Lawrence, ibid.:38).

Hence, in their view, because educational research is bounded within social systems, any examination and analysis of practice in an educational context needs to take account of both historical and current thinking about interpretations of the social world. Such awareness of past and present ideas then enables further building on the foundations provided by social science. In particular, they highlight Giddens' work regarding explanatory theory, where he used the work of classical sociologists such as Spencer, Marx, Weber and Durkheim as his stable benchmarks for explanatory theory. They further advocate that practitioner-researchers be familiar with the ideas involved in this line of descent. For example, one idea concerns the conceptualisation of 'action' which:

*...may be regarded as conduct which is oriented towards norms or conventions. This can then lead in different directions, depending upon whether the analysis concentrates upon actors purposes or motives, or whether the emphasis is placed, as by Durkheim, upon norms themselves as properties of collectivities. (Giddens, 1976:93)*

In conclusion, if we are to interpret the social world, this involves finding a way to de-construct practice in order to analyse it, from both historical and current perspectives and which accounts for the constraints involved. The merits and limitations of such an approach are discussed in the next section.

## **2.5 The socio-cognitive perspective: using CHAT to de-construct practice**

As discussed in the preceding section, in order to develop insight and understanding of practice, such as that of trainers' in the field of clinical research, any critically objective analysis of practice must be more than mere descriptions of the mechanics of practice and the artefacts used to mediate practice. However, the nature and diversity of social and work practices is reflected in their correspondingly diverse interpretation. To be effective, then, the means by which participants interact with each other and through the use of artefacts, must also be considered, which includes examining rules and structures governing practice.

For example, in the field of information systems, or in the field of human-computer-interaction (HCI), lessons have been learned. The failure to understand or appreciate the subtleties of situated work practices, is considered a key reason for end-users' failure to adopt

technological information systems (Nathanael, 2005). In particular, common problems were failure to recognise the contingency of real-life action on cooperation, or failure to capture its complexity through task analysis that focussed on individual users.

Consequently, designers of information systems were encouraged to examine work practices to understand how fundamental patterns of behaviour ultimately determine a technology's intended and unintended consequences (Barley 1988; Blomberg *et al.* 1993; Brown and Duguid 1991; Davenport *et al.*, 1996; Schultze *et al.*, 1998).

The significance of cognitive and social aspects of work practices in this field means that work settings are studied in an effort to learn about what is done today and the reasons why it is being done that way (Nardi, 1996). In this context, this involves considering *the artefacts in use (instruments), the habitual action and communication patterns and the current cognitive ontology*. (Nathanael op.cit.: 66)

However, as acknowledged in this field, a difficulty exists in observing work practices in particular settings (Schultze *et al.*, op.cit.). Namely, neither physical processes nor accompanying technology necessarily define practice settings and their dynamics. Moreover, the stability of either processes or technology may highly constrain individual and collective intentionality. Rather, it is recognised that in certain fields of practice, such as in the service sector:

*"...practice dynamics are more dependent on social conventions, norms and habits of participants than on natural or other causal laws. However, conventions and habits are not as stable as natural or causal laws. Consequently, the structure of domains ... is typically vague, open to situated interpretation and subject to historical evolution."* (Nathanael op.cit.: 66)

Hence, as is appreciated in this particular field, to understand workplace practices, the constituents of social practice and the subtleties of behavioural codes (or culture) governing the expression of particular practices must be explored. The focus of such exploration is on the members of a community of practice and their local habits, assumptions and tacit knowledge. In this context, *local habits* encompass the cognitive and cooperative tasks involved in the activities constituent of particular workplace practices. *Tacit knowledge* describes what is understood and shared within a community of practice. However,

practitioners may not necessarily express this tacit knowledge overtly (Polanyi, 1967). Moreover, in some instances, practitioners may be unable to articulate tacit knowledge (Turner, 1994; Altrichter *et al*, 1993). Despite these limitations, particularly concerning the difficulty involved in defining settings, dynamics or domains of practice, as discussed above, the regularities of practice within the field of information systems have been extensively and commonly defined as:-

- Human agent activity: both co-operative and cognitive elements (as revealed by cognitive task analysis)
- Associated competencies
- Instruments / tools developed to achieve activity

Consequently, Activity Theory (AT) or Cultural-Historical-Activity-Theory (CHAT) has been harnessed in this field to classify the cognitive, physical and social processes involved in performing specific tasks as constituents of complex activity. Human-computer-interaction (HCI) professionals can then understand better, within this descriptive framework, how specific tasks relate to the “bigger picture” of activity (Crawford and Hassan, 2006).

At the same time, due to perceived complexity in defining the unit of analysis, or delineating boundaries between activities and actions (with respect to integrating Leontiev’s hierarchical structure of human activity, shown in Figure 2-1, where “activity is the minimal meaningful context for understanding individual actions” (Leontiev, 1978)), various researchers have developed guidelines or structured methodologies to standardise or help with the application of AT to HCI studies (Crawford and Hasan, *op.cit.*; Mwanza, 2002a, 2002b, 2001; Nardi, 1996). Moreover, in technology-rich learning environments the question of how the “activity” and its constituent actions are identified or how the boundaries of the activity system are delineated from its neighbours has received critical attention. Hall (2001: 208) in particular, has raised concerns about failure to integrate the hierarchical elements of the structure of

activity (shown in Figure 2-1), thereby overlooking the potential sources of contradiction and subsequent transformation through their resolution.

CHAT or third generation Activity Theory was developed by Engeström, and arose out of the work of Vygotsky, Leontiev, and Luria (Engeström, 1990, 1999). First generation Activity Theory (AT) concerned subjects' artefact-mediated and object-oriented action (Vygotsky, 1978:40).

In second generation AT, the concept of collective activity mediated by others through social relations was integrated into Vygotsky's triangular model of action (subject-artefact-object). This was accomplished through incorporating Leontiev's (1981) hierarchical structure of human activity, which distinguished between collective activity and individual action, shown in Figure 2-1, below :-



**Figure 2-1: Leontiev's hierarchical structure of human activity**

Leontiev (1978; 1981) provides an example of a primeval hunt to explain the difference, summarised as follows:-

*Activity is governed by its conscious motive(s): The man is engaged in a communal hunt because he wants to feed his family.*

*Component actions are governed by their aggregate goals (which are subordinate to the main goal or object of activity): The man performs the role of "beater" (the goal being to scare the prey away from himself and toward the other members of the hunting party).*

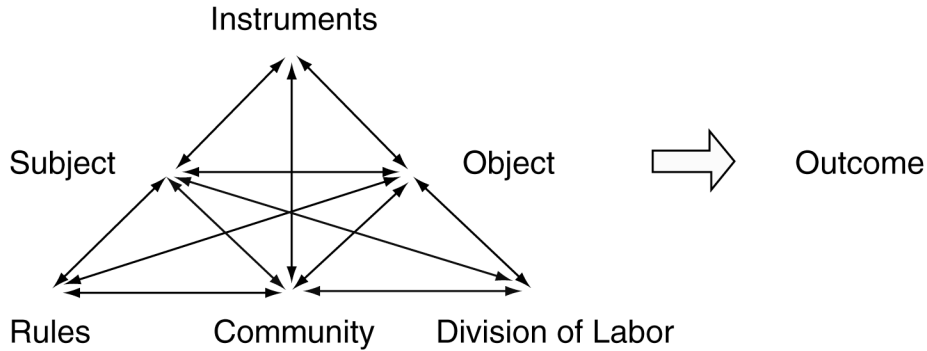
*Operations are governed by the conditions in which component tasks are performed, where operations are the routinised or automated form of the constituent actions within an activity: Operations are governed by the conditions of the hunt. How he carries out the various tasks involved in his role will depend upon the terrain, kind of game-animal sought, wind direction, the weather, the season of the year, etc.*

In effect, Leontiev's conception of the hierarchical structure of activity, and its illustration through the example of the hunt, demonstrates how mediated action has particular social meaning or makes sense in the context of collective activity (Williams *et al*, 2007).

Finally, in the third generation, components that were omitted by Vygotsky to describe the socio-historical aspects of mediation were added, namely: the rules, community, and division of labour (Engeström, 1999). This situates activity within a collective system. Moreover, through analysing different levels of contradictions within and between its elements, the potential for identifying neighbouring systems is also created, such as those that produced the subject, instruments or rules governing the system.

Hence, third generation AT, or CHAT as it is now known, provides a means to explore practice and its constituent elements from shifting perspectives that focus respectively on: the subject, object and mediating artefacts; which transform the object through the activity of the subject (Engeström, 1987, 1990, 1996a). Consequently, CHAT provides the framework for understanding activities, actions and operations - as elements of practice - performed by participants in an activity system. By this means, the collective motives, goals and instrumental conditions within a community may be revealed and understood through the contradictions within and between the elements of the activity system, including its system of rules, and division of labour.

As a theory of expansive learning, Engeström's (1999) model of an Activity System (AS) provides a descriptive and explanatory framework to classify the cognitive, physical and social processes involved in performing a specific task, and to understand how specific tasks relate to the "bigger picture" within a system, or systems, of activity. Moreover, as an applied theory, AT can be operationalised, where "operationalisation means that the framework developed during the conceptual development phase is focused, is specific, and contains unique measurable/observable and understandable elements" (Storberg-Walker (2008: 567). These observable and understandable elements are apparent in Engeström's activity system model, shown in Figure 2-2.



**Figure 2-2: The structure of human activity (Engeström, 1987: 78)**

Thus, in his triangular representation, Engeström provides a unit of analysis that encompasses within its structure the dialectic relationship between subject-object, which is mediated by tools and community (Crawford and Hasan, op.cit.). That is, through this framework, we can attempt to understand the relationships involved in an activity system, and hence to explain their origins, in terms of the conditions giving rise to them, rather than just trying to describe them. As Yamagata-Lynch (2003:104) explains:

*"...The unit of analysis in AT is the mediated action itself (Engeström, 1987; Rogoff 1995; Wertsch, Del Rio & Alvarez, 1995). When conducting research based on sociocultural theory, examining individual behaviour is the gateway for the researcher to enter into and vicariously experience the activity of the subject. Once the researcher identifies the activity, she needs to shift the focus of her examination to understanding the motive-goal-instrumental conditions rather than the observable individual behaviors, and use that information to understand the collective meaning making process."*

The pivotal idea in activity theory is that, individually and collectively, we relate to our environment, or mediate our interaction, with culturally meaningful tools and signs (semiotics).

Hence, language and artefacts created using language (like laws, rules, rituals, textbooks, oral and written discourse, contracts, tests etc.) form the instruments we use to mediate our activities, relationships or interactions, all of which can be defined within social and historical contexts. Use of these instruments is therefore a transformative process, where both the subject and object of activity are transformed.

However, subject, object and the instrument mediating change may be considered simultaneously as stable dimensions within an *activity system*, and as a dynamic three-dimensional (3-D) unit of analysis 'continuously in the midst of transformation' (Worthen,



2000). Moreover, because all elements within an activity system are interconnected, heterogeneous, and multi-voiced, this 3-D unit of analysis unpacks the nature of transformation(s) taking place. In effect, the dynamics within the activity system may be revealed, along with its intended and unintended outcomes.

Furthermore, rather than delimiting context as a container of situationally created experiences with distinct and well defined boundaries, context is visualised as an expansive series of dynamic activity systems that “...tie the actor(s), the outcomes, and mediating artifacts into a unified system of action.” (Halverson, 2003). Hence, in the workplace, engaging in the tasks of work means actors participate in a localised activity system, which interacts with a network of other activity systems. In turn, these are defined, bounded and determined by the activities of various communities to which participants belong, in terms of their division of labour and rules governing practices within them. Although AT cannot predict those actions that may constitute an activity, it can nevertheless explain how one relates to the other, through the motives, goals and conditions within the specific context (Cole, 1996).

AT may then be understood as a social theory of consciousness, where context is socially constructed, and consciousness is defined as “...a product of our social interactions with other people and of our use of tools” (Nardi, op.cit.). Our mental processes of classifying, generalising and abstracting (which are represented by our mental models) are then accessible through the application of AT to our activity, where consciousness is central to its depiction.

The utility of AT, as a means to examine practice has been demonstrated in a variety of contexts, including: education (Meyers, 2007; Blin, 2005; Lim and Hang, 2003; Yamagata-Lynch, op.cit.; Engeström *et al*, 2001); healthcare (Engeström, 2000); organisational learning (Boreham & Morgan, 2004; Daniels and Warmington, 2007; Engeström, 1991).

Thus, in developmental work research (derived from a CHAT approach):

*“practices are analysed as socially distributed collective activities, which evolve over time through tension, contradiction and innovation. New models of practice emerge from the research participants’ experience, similar to action research models of organisational learning (Argyris and Schön, 1996). Solutions are never adopted as prescriptive, but are adapted to individual contexts with the guidance of the researchers” (Meyers, op.cit.:3).*

Engeström's activity system model therefore, provides a means to capture the complexity of systemic relationships transforming training as a practice, within the field of clinical research. These systemic relationships may be internal or external to activity. For example, various institutional systems impinge on practice, such as professional or regulatory bodies, as well as the rules and division of labour within the community in which the activity is situated.

However, the scale and the variety of organisations operating within the field of clinical research make it difficult to observe and to generalise about the everyday context and situation of practice constituted by communities within the workplace. Given this limitation, how then can we analyse practice *in situ*?

## **2.6 The socio-cultural perspective: How can we learn about practice?**

Wenger's (1998) concept of a *community of practice* (CoP) provides a means to contextualise practice within a community. Wenger, McDermott and Snyder (op.cit.) further explain that communities of practice are social structures developing and sharing knowledge, which may differ in attributes such as size, life span, physical boundaries and the extent by which they are recognised in organisations. In addition, "...Knowing the boundaries helps members to decide exactly what's worth sharing, how to present their ideas, and which activities to pursue" (Wenger, McDermott and Snyder, *ibid*: 28). However, all communities of practice are characterised by three fundamental, yet unique structural elements, namely, *domain, community and practice*:

*"...a domain of knowledge, which defines a set of issues; a community of people who care about this domain; and the shared practice that they are developing to be effective in their domain." (ibid.:27)*

The structural features of these elements described further by Wenger *et al*, (*ibid.*) are shown in Table 2-1 at the end of the chapter.

*Community* refers, on the one hand, to the environment in which people interact, learn and build relationships, ranging from professional associations to business organisations (Lesser & Storck, 2001: 832; Gongla & Rizzuto, 2001). On the other, its members "are groups of

people who share a concern, a set of problems, or a passion about a topic and who deepen their knowledge and expertise in this area by interacting on an ongoing basis” (Gongla & Rizzuto, *ibid.*: 4). In effect, because such communities are self-forming and self-governing, identities form or emerge, as do authority relationships, through the interaction around the expertise of members who contribute their time, and their knowledge to engage in developing practice (Monaghan, 2006:13-14; Lessor & Storck, *op.cit.*: 832; ).

*Practice* then, is the set of frameworks; ideas; tools and documents; as well as discourse and its particular *insider* language that community members share (Barton & Tusting, 2005). The *domain* of practice relates to the cognitive or knowledge focus of practice within a given field of practice and may range from mundane know-how to specialised professional expertise. Therefore, communities of practice may be considered as social structures developing and sharing knowledge in organisations (Wenger, McDermott & Snyder, *op.cit.*).

Moreover, if, as Lave & Wenger (*op.cit.*) posited, learning is situated in the context of everyday experience, then a community of practice collectively embodies situated approaches to learning.<sup>10</sup> Hence – a CoP may be a defining component within a social theory of learning, representing a knowledge-based social structure. Building on the concept of situated learning, Wenger regards the concept of a CoP as a means to examine learning - in naturally occurring contexts - as a fundamentally social process that is an inevitable consequence of everyday living, as opposed to its being confined to the artificial setting of a classroom. Hence, the term “Community of Practice”, or CoP, is defined as a component of a social theory of learning, representing a knowledge-based social structure.

Consequently, according to Wenger *et al* (*op.cit.*), the value of such communities concerns the facility to connect the personal development and the professional identity of practitioners to organisational strategy. Whereas their focus mostly concerns the development of communities

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<sup>10</sup> Lave and Wenger (1991) developed the concept of communities of practice to convey the role of activity in binding individuals to communities and to convey the notion of a collective embodiment of situated approaches to learning. For them situated learning took place in the context of everyday experience.

of practice distributed within organisations, which largely encompasses business enterprises such as companies, they also envision the scope of communities of practice to areas of practice within society ‘at large’. Thus, communities of practice external to the work setting may nevertheless impinge upon this process of connecting practitioners to their organisational strategy, albeit at a distance, as in the case of professional body affiliations. Moreover, a study of a *professional* community of practice answers Young and Mitchell’s (2003: 10) call:

*“...to strongly locate the investigation of practice – including the knowledge, documents and tools the community develops – at the heart of their communities of practice: to continue to focus on their practice within their communities of practice”.*

In conclusion, due to its cross-boundary nature within the field of clinical research, a professionally affiliated community of trainers provides a means to analyse training practice *in situ* on the assumption that its members share particular tools that create a sense of identity and common ground. However, whether the construct also provides a comprehensive way to analyse practice as complex activity, as well as learning *in situ* is discussed in the next section.

### **2.6.1 Situating learning and practice within a community**

In a professional community of practice, the endeavour to connect practitioners to their organisational strategy may reveal contradictions between the professional and organisational activity systems in terms of their concepts and models of practice that may unintentionally lead to conflict rather than bring about the desired harmony in operations between practitioners and organisations. Thus, conflicts of interest may be more prominent if not necessarily more problematic in a professional CoP, possibly manifesting as tensions between the internal and external goods of practice.

For example, such tension may be observed in the public spaces within communities of practice, which Wenger *et al* (op.cit.) define as official events organised for all members; private spaces concern one-on-one interaction among members. Consequently, if the express intention within these public spaces is to develop and share knowledge that can be applied in the workplace setting, then it follows that meetings held within communities based within

professional institutions (i.e. like the Institute of Clinical Research) will nevertheless impact upon workplace practice in a CPD capacity, despite being external to the workplace setting. Moreover, such public spaces within a professional setting might be expected to uniquely embody values related to practice, expressed as *professionalism* or a concern for improving the quality of practice through continuous learning. Therefore, in a study of practice, such public spaces provide a focal point for observation. Furthermore, as Giddens (1984: 374) states,

“...the structural properties of social systems do not exist outside of action but are chronically implicated in its production and reproduction.”

Moreover, he defines the duality of structure as *the medium and outcome of the conduct it recursively organises*. Consequently, the forms these meetings take, the ideas or best practices that are shared at them provide a ‘window’ not only into topical issues of concern to members, but into the collective practices and embedded *modus operandi* of trainers made visible within the localised confines of the ‘professional’ public space. At the same time, the sharing of practice may affect an individual member’s *modus operandi* within the wider (clinical research training) community, distributed within individual practitioners’ organisations.

In effect, in this setting, through their habitus, agents participating in the sharing of practice as a learning activity will unintentionally or otherwise, display dispositions towards *certain activities and perspectives that express the culturally and historically constituted field of practice* (Webb *et al*, op.cit.: xiii). Accordingly, the localised confines of the ‘professional’ public space form an intentionally accessible and socially amenable setting within a community of practice for community members to observe how others engage in the activities not only of the community, but also of their professional practice. Thus, in this respect, observation serves as a learning strategy, particularly for peripheral members. Equally, as a tool, it allows researchers to learn more about the CoP, in terms of its role, workings, and collective practices.

Therefore, as Lave and Wenger (op.cit.) intended, the concept of a *community of practice* also conveys the role of activity in binding individuals to their community in keeping with its

theoretical construct as a social theory of learning. However, as a model it is limited as a unit of analysis for examining the constituent elements of *practice*, which is the focus of this thesis.

Nevertheless, it offers a useful guide to analysis of phenomenon within a community (via an ethnographic methodology) including structural features (as outlined in the previous section) and the social processes of learning, which may be understood in terms of relationships through which participants manage their domain, define their practice and interact in their community (i.e. as core, active and peripheral members). As Lave and Wenger suggest, tensions in these relationships may drive the learning process in a CoP. However, although tensions may be observed, identifying their nature by analysing them closely poses a challenge (Barab, 2002), particularly in the absence of a systematic framework.

Therefore, if the CoP construct is conceived as a component of a social theory of learning it might usefully guide phenomenological exploration of a community of practice and its activities, particularly if it is considered as a knowledge-based social structure. But, how might this structure and its potential for causing conflict be explored? For example, what might be considered as the unit of analysis to explore learning in such a structure where “learning is an integral and inseparable aspect of social practice” (Lave and Wenger, 2002:57)?

In this respect, other than specifying the criteria of its structural elements, the construct does not perhaps provide a systematic means or framework to explore the tensions between constituent elements of *practice* despite its relationship to a specific knowledge *domain* within a particular *community*. Nevertheless, in a CoP, the focus is on the relationships between practitioners and how learning depends on, and is facilitated by, these relationships, particularly since learning is theorised as a function of increasing immersion and participation in the practices of the community. In particular, in his original conception of the CoP construct, Wenger (1998) suggests that the potential for learning *in situ* exists through increasing levels of participation in the social structure of the community (moving from the

periphery of the community to become gradually more active)<sup>11</sup>. Yet, the means to analyse how the relationships in the social structure of the community enable or constrain such immersive learning in a CoP is limited to describing the structural features of domain, community or practice, rather than an explaining them.

Therefore, although Wenger's work on Communities of Practice seeks to illuminate the complex relationship between learning, practice, community, and identity (Storberg-Walker, op.cit.), no definitive model exists to operationalise the elements that might serve as a unit of analysis in an applied theory of social learning. In view of this, how then can we address this methodological deficit in order to build up a picture over time of practice and its domain within a community? This question is answered in the next section.

### **2.6.2 Examining a community within an activity system framework**

Cultural- Historical-Activity-Theory (CHAT) offers a way to analyse a community of practice by considering it as an activity system, where the community provides the context of the practice in terms of its constituent complex activities. In such a system, activity is undertaken by a human agent (subject) who is motivated toward the solution of a problem or purpose (object), and mediated by tools (artefacts) in collaboration with others (community). The structure of the activity is shaped and constrained by cultural factors including conventions (rules) and social divisions (division of labour) within the context. Engeström emphasizes the mediational role of the community and that of social structures including the division of labour and established procedures.

Moreover, because activity does not take place within a vacuum, it can be further situated within a network of activity systems, which invariably impinge rules and instruments upon its activities or its operations, the effects and outcomes of which may be perceived to differing degrees of awareness. For example, in the case of the Trainers Forum, its host organisation, the Institute of Clinical Research, has a set of rules for the constitution and conduct of Special

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<sup>11</sup> For example, the novice participant, analogous to an apprentice, may subsequently develop identity through legitimization of his/her participation in meaningful activity in the community and through progressive levels of engagement moving from peripheral to active and core participants.

Interest Groups (SIGs) and Steering Groups (SG). However, members' general awareness of these terms & conditions probably reflect their limited circulation among serving members of SIGs or SGs, but which may shape activity in the TF nevertheless.

Thus, activity theory provides the means to probe the complexity of practice in the field of clinical research training within a community of practice. Subsequently, Engeström's model of an activity system, based on what he refers to as 3<sup>rd</sup> generation activity theory (or CHAT), provides the means for understanding activities, actions and operations performed by participants of a particular community, as elements of practice. By this means, the collective motives, goals and instrumental conditions, within the activity system may be understood.

However, whereas activities-actions-operations are observable, the collective meaning making process may be less transparent since these behaviours are contingent on conditions, goals and means that are perhaps less apparent. Nevertheless, as Yamagata-Lynch (op.cit.) explains:

*"...Examining learning situations using activity systems not only allows the analysis of collective action as a unit of analysis (Cole & Engestrom, 1993; Engestrom, 1987; Engestrom, 1993), but also allows researchers to capture: (a) the dynamic structure of activity, (b) the historical development of activity over time, and (c) the multivoiced nature in the formation of human activity (Engestrom, 1999a)."*

The key strength of activity theory is that it offers the capability to consider various aspects within an activity system (in this case, the TF), including the subject(s) and object(s) of activity, from multiple perspectives. The unit of analysis is then constituted by the relationships formed between these aspects. These include: division of labour, community, rules and instruments mediating the outcome of activity. In effect, as a conceptual theoretical and methodological framework, CHAT transcends the dichotomies between microcosm and macrocosm, subjective and objective, quantitative and qualitative, observation and intervention that pervade methodological debate concerning the choice of appropriate research methods.

In conclusion, the structuration of practice may also be considered in terms of its historical development within an activity system framework in terms of its least meaningful unit of



analysis – activity, or in its entirety (i.e. all 6 components of the AS – subject-tools-object-rules-community-division of labour). The rules, structures, and processes, by which participants in a community interact through their activities, can then be further expanded. For example, activities in the TF concern: -

- how TF members share (i.e. communicate and agree) best practices, or specifically in this context - pedagogies;
- its emergent structures encompassing the planning and decision-making processes; and finally,
- the underlying codes or organising principles indicating how the practices of the TF are constituted by members.

Moreover, as the medium or artefact transforming activity into outcomes, language and its modes of expression are fundamental to understanding the nature of the activities in the TF that may be considered constituent of its practices and pedagogies. The implications of language and its uses in association with particular pedagogies, therefore, will be considered in the next section, particularly in terms of how differences in its expression translate into different actions, and ultimately activities.

### **2.6.3 *Analysing dispositions expressing the culturally and historically constituted field of practice***

Gee (1996:59) encapsulates the focus on language and its modes of expression with the premise that:

*"what is at issue in the use of language is different ways of knowing, different ways of making sense of the world of human experience, that is, different social epistemologies".*

Bourdieu encapsulates these different social epistemologies in his concept of habitus, where agents display dispositions towards *certain activities and perspectives that express the culturally and historically constituted field of practice* (Webb *et al*, 2002: xiii). In addition, as discussed in section 2.2, epistemology also featured in defining an individual's disposition towards their professionalism (or quality of practice).

How then, have these social epistemologies been operationalised and analysed?

These different ways of knowing have been considered further in studies of classroom interactions in terms of exploring the link between teachers' and students' epistemologies. Although empirical studies of this type are limited in number, researchers' interest in this area concerns the use of language as a medium in interactions between teachers and their students and its effect on learning (Johnston, Woodside-Jiron and Day (2001); Wells' (2000; 2001; 2007); Wells & Claxton, 2002). In this context, language is the medium of thought. The focus of such classroom studies is on modes of interaction, associated language, and its effects on students.

In addition, Wells (1999) considers particular approaches to teaching, and their associated vocabularies, as artefacts of a particular pedagogy. That is, teachers with a learner-centred approach tend to adopt dialogic or learner-centred teaching and learning methods; whereas, teachers who use teacher-centred methods in their lessons conduct a monologue in their classrooms, and give students little opportunity to interact.

Johnston *et al* (op.cit) contend that teachers' classroom discourse is the likely mediating variable linking teachers' epistemologies to that of their students. As they explain:

*"Gee (1996) points out that, in literacy, "what is important is not [merely] language, and surely not grammar, but saying-writing-doing-being-valuing-believing combinations," which he calls Discourses. Discourses, he argues, come from, reveal, and produce social epistemologies. The view of epistemology Gee invokes here is consistent with Popkewitz (1998), who uses epistemology "to focus on the rules and standards of reason that organize perceptions, ways of responding to the world, and the conceptions of 'self'" (p. x). These are clusters of beliefs about knowledge and knowing, but also about authority and language. In theory, there should be some systematic connection among the epistemologies of teachers and their students and the discourse in which they are engaged."*

In essence, these *saying-writing-doing-being-valuing-believing* combinations – or epistemological frames of discourse (EFsD) – provide a framework to analyse social epistemologies evident within oral or written discourses. However, such a framework is not limited to understanding the development of literacy, but has applicability to other areas of what is coined as *knowing* and *ways of knowing* (Wells, 2001; Lave, 1996). Hence, if language is the medium by which we communicate, then *who we are* (in terms of our

experience of knowing, and our ways of coming to know) is apparent in the semiotic expression of what we say, write, do, value and believe within our social contexts. Wells (2007) expresses this as

*"...individual persons appropriate the normative values and practices of society and the tools (including language) that mediate their acting, thinking and valuing through their participation in interpersonally performed actions (Vgotsky, 1981). At the same time, since action transforms not only its object but also the persons and artifacts involved, it is through participation in such jointly undertaken actions that individuals instantiate society's normative practices and to some degree transform them".*

Therefore, although Johnston *et al* (op.cit.) acknowledge the lack of consensus that Hofer and Pintrich (1997) observe among researchers in defining epistemology as a construct within studies, they nevertheless simplify it to a dichotomy between constructed and received knowers (terms borrowed from Belenky, Clinchy, Goldberger, & Tarule (1986)). In so doing, Johnston *et al* demonstrate the systematic connection, which Gee refers to, between teachers' epistemological stance, which is reflected in classroom discourse, and their students' epistemological development, since its effect can be seen subsequently in students' discourse and experiential outlook.

For example, teachers who are *constructed knowers view knowledge as constructed by individuals in interaction through language (or semiotic systems)* (Johnston *et al*, op.cit.:7).

On the basis of their study, Johnston *et al* explain how such knowers value discussion as a learning tool, and think of knowledge in the active sense of knowing. Constructed knowers, therefore, view knowledge as being constructed socially through dialogue. Knowledge is viewed as an integral part of experience. They expect to be most engaged by its complexity and ambiguity and rarely view it in simplistic terms of right or wrong. Constructed knowers have an authoritative voice in the building of knowledge, but a non-authoritarian stance. They share a distributed sense of responsibility with other sources of knowledge with whom, or through which, they interact.

Moreover, as Johnston *et al* (op.cit.) describe in their study, depending on teachers' EFD, differences are apparent within the classroom in the type of interactions and activities that take place. A teacher who is a constructed knower will endeavour to create an opportunity for

learning based around a shared experience. For them, the activity of learning encompasses three domains (cognitive, affective and psychomotor) to some degree (Bloom, Engelhart, Furst, Hill & Krathwohl, 1956; Krathwohl, 1964; Dave, 1970; Anderson & Krathwohl, 2001). That is, learning involves thinking, feeling and doing in order for knowledge to be developed effectively, since

*“...real change requires a fundamental shift at each of the three levels. This can be accomplished by designing learning tasks that have cognitive, affective and psychomotor components” (Vella, 2002:18).*

Therefore, how teachers refer to the process of knowing and coming to know through their words and actions not only reflects their entire approach to the experience of *knowing and coming to know*, but determines how they affect their students' subsequent experience of it. Since the act of teaching and learning is learner-centred, the approach is less controlled. Hence, if a trainer facilitates the process of knowledge construction, then both learners and trainers may appreciate knowledge as a unique end-product of a spontaneous and dialectical process of teaching and learning.

By contrast, for *received knowers*, knowledge is “out there” in the sense that it exists separately and distinctly as facts. Someone “in authority” can convey it to them, so that they can learn through its transmission to them. Discussion is not viewed as helpful to learning as any ambiguity that arises is likely to make received knowers uncomfortable, as facts are perceived as right or wrong. Personal experiences and feelings are not considered part of *real knowledge* and are separated from their learning. A hierarchical framework of authority and control is implicit to this perspective. In this schema, knowledge is a commodity that can be transferred from teacher to learner, in the act of training. Thus, the teacher or trainer maintains control of the process of transfer through the teaching and learning methods used (e.g. slides). The act of learning is then implicated predominantly as a listening exercise.

Johnston *et al* (op.cit.) consider that their work fits with the sociolinguistic argument that discourse environments affect more than the acquisition of facts and strategies. Apparently, over time, discourse environments may powerfully affect children's epistemologies, in effect

changing the course of their development (Cazden, 1988; Fairclough, 1992; Gee, 1996). The routines of behaviour, patterns of values, beliefs, roles, identities, and ways of knowing inherent within these discourses may unconsciously affect children's perceptions and ultimately their responses both inside and outside the classroom. (Reichenbach, 1998: 84).

Alexander (2005) highlights the nature of epistemology, as a learned cultural response to our way of understanding the world we know. From his studies of pedagogy he posits that culture and pedagogy are inextricably linked, which he considers unsurprising since "...Vygotsky's claim that 'the true direction of the development of thinking is not from the individual to the socialised, but from the social to the individual'" (ibid.:11). He also considers this to fit with "...Bakhtin's account of social and semiotic influences in the development of thinking" particularly where *dialogue* offers a potent tool for intervening in an individual's progress across the zone of proximal development. His proposition, therefore, is that

*"Pedagogy is not a mere matter of teaching technique. It is a purposive cultural intervention in individual human development which is deeply saturated with the values and history of the society and community in which it is located. Pedagogy is best defined, then, as the act of teaching together with the ideas, values and collective histories which inform, shape and explain that act."* (Alexander, ibid.2)

Although Alexander (ibid.) focuses on pedagogy rather than epistemology, he is in agreement with Johnston et al (op.cit.) that where most of the classroom talk is teacher-dominated, authority and control are either assumed or implicit in the frame of discourse in such classrooms:

*"...teachers rather than learners control what is said, who says it and to whom"* (Alexander, op.cit.:2).

Furthermore, Alexander makes the point that in English culture, considering expository or teacher-centred methods of instruction *didactic* expresses disapproval. Whereas "...elsewhere, *la didactique* and *die Didaktik* celebrate the place in teaching of the subject and its conceptual imperatives" (ibid.:4). Thus, he illustrates how culture affects how we think of our teaching methods, whereas Johnston *et al* explain how it permeates classroom activity through epistemology.

Thus, the changing view of epistemology from a dimension of stage wise intellectual or cognitive development in adolescents or young adults (Belenky et al, op.cit.; Perry, 1970) to that of complex sociocognitive learning has shifted focus to classroom instructional practices i.e. pedagogy (Carlsen, 1997; Gee, 1996; Hofer & Pintrich, 1997; Kardash & Scholes, 1996; Lyons, 1990; Nystrand, Gamoran, Kachur & Prendergast, 1997). Again, such concerns are limited to the effects on the learning processes of young adults as opposed to mature learners. Yet, if epistemology is considered as a dimension within a sociocognitive theory of learning, this changing view of it surely extends focus into how it features in situated learning processes, such as those within communities of practice. However, other than its recognition as a tension driving "...educators towards identifying new theories of, and explanations for, how people learn" and its referencing within acquisition and participation metaphors equating to epistemologies of ownership / participation (Barab, op.cit.), epistemology appears to receive little mention, far less consideration. In addition, as Boreham and Morgan (op.cit.:321) conclude: "... whilst there is an extensive literature on the concept of organisational learning itself, there is a lack of empirical evidence about the practices through which it is brought about, especially its pedagogy".

Finally, Daniels (2007:389) reflects that there is a need to expand the general working hypothesis of learning to include "notions of experiencing and identity formation within an account that includes a systematic and coherent analysis of the wider social structuring of society as an inseparable part of the analysis". He bases this on what he considers as a largely ignored "new unit of analysis, namely, *perezhivanie*" that Vygotsky was focussed on in the last year of his life. This unit of analysis equates to the concept of lived or emotional experience, which began to integrate the cognitive, affective and psychomotor dimensions of learning (developed later in terms of a cohesive approach by Lewin, 1951). *Perezhivanie* represented the unity of psychological development in the study of the social situation of development (Gonzalez-Rey, 2002: 136). In effect, Vygotsky's ideas concerned the largely overlooked role of affect in thinking and action (Mann and John-Steiner, 2002).

Daniels (op.cit.:389) explains the concept of lived or emotional experience further:

*“The emotional experience [perezhivanie] arising from any situation or from any aspect of his environment, determines what kind of influence this situation or this environment will have on the child. Therefore, it is not any of the factors themselves (if taken without the reference of the child) which determines how they will influence the future course of his development, but the same factors refracted through the prism of the child’s emotional experience (Vygotsky, 1994, p. 339)”.*

He also explains that Vasilyuk (1991) refined the idea further “...when he introduced the notion of *experiencing*, defined as a particular form of activity directed towards the restoration of meaning in life” (Daniels op.cit:389).

Therefore, the possibility that epistemology forms through the prism of emotional experience (or affective learning), and thus represents a cultural artefact, either within an activity system or as a sociocognitive dimension within a CoP, apparently remains unexplored. Moreover, according to Davis (2005: 5):

*“Activity Theory has not been used to any great extent to address issues of classroom learning and teaching (Wells, 2002), although it has proved a useful tool for analysing and theorising about workplace activity settings (e.g. Williams, Wake and Boreham, 2001)”.*

However, if a CoP is no less a discourse environment than a classroom, then it follows that the epistemological frames of discourse (EFsD) within them are no less tools of enculturation. Consequently, if members within a CoP view themselves as adult learners, then studying their interactions in terms of the language and behaviour evident as Gee’s (op.cit.) *saying-writing-doing-being-valuing-believing* discourses could elaborate "what is happening" within that CoP. For example, practitioners’ contrasting epistemological stances within the CoP might explain possible tensions or contradictions between what is said and what is done.

Thus, if a link can be demonstrated it may show that members’ approach to learning, and their preferred choice of methods (to have/lead ‘discussions’, or to establish a dialogue, or to give/receive instruction) depends on their enculturation (i.e. as constructed or received knowers), within either the local level of their community’s activity system, or perhaps at an expanded level of interacting activity systems). Thus, a practitioner’s enculturation as a constructed or received knower might also explain their position on Hoyle’s (op.cit.)

spectrum of professionalism, operating either according to restrictive or expansive codes, as discussed in section 2.2.

Accordingly, dialogue and discussion representing particular epistemologies (i.e. constructed knowing versus received knowing) that elicit particular emotional responses then need to be defined, particularly if they are to be operationalised as modes of interaction with an associated language or idiom in the sense of a specialised and shared vocabulary. From his context of pedagogic repertoires within classrooms, Alexander (op.cit.) describes *discussion* as one type of *teaching talk* and defines it as an exchange of ideas with a view to sharing information and solving problems. This definition of *discussion* has pertinence to this study of trainers' embodiment of practice within their community. In addition, he describes *dialogue* as one of five kinds of teaching talk, where the remaining three are rote, recitation and instruction/exposition. Here *dialogue* is defined as "...achieving common understanding through structured, cumulative questioning and discussion which guide and prompt, reduce choices, minimise risk and error, and expedite the 'handover' of concepts and principles"; and instruction/exposition as "...telling the student what to do, and/or imparting information, and/or explaining facts, principles or procedures" (Alexander, *ibid.*: 12).

For the purposes of studying trainers' practice, then, the two types of "teaching" talk that best represent the opposite ends of an epistemological-pedagogical spectrum of adult socio-cultural learning are dialogue and instruction. In this context, *dialogue* represents the tool of choice for constructed knowers and *instruction* or *monologue* the preferred tool of received knowers, since received/constructed knowers will correspondingly use methods that conform to their beliefs about the nature of knowledge and knowing, as described by Johnston et al (op.cit.).

Moreover, learners may receive more than just information communicated via a particular pedagogy, particularly, if as Alexander (op.cit.) has elaborated, culture is an element of pedagogy (i.e. part of the Teaching and Learning approach) that is often overlooked. In effect, they "see" how the process of Teaching and Learning (T & L) is enacted, since teachers' or



trainers' epistemology, inherent in their T & L approach, is subsequently translated through their actions into the activity of T & L (Wells, 2000). That is, a trainer's beliefs about the certainty, simplicity, source and justification of knowledge, which Hofer & Pintrich (op.cit.) define as the key elements involved in knowing and the nature of knowledge or, as Wells (2001) prefers - modes of knowing<sup>12</sup>, is apparent in their T & L approach. This is because

*"...knowing in any mode is not a purely cognitive process. All modes of knowing are embedded in action, and since they are mediated by material tools of various kinds, they involve the body as well as the mind."*

Hofer and Pintrich (op.cit: 120) condense these epistemological constructs into the four elements of certainty, simplicity, source and justification (Table 2-2).

Wells (op.cit.) emphasises an inquiry approach, in terms of pedagogy, as "a means of learning and coming to know" because "...we have to engage in meaningful activities with others, using the relevant texts, tools, and practices, in order to come to understand them". As such, knowledge construction is mediated through dialogue between people engaged in a common endeavour - looking for meaningful answers, where contributions depend on and are determined by participants' *responsivity* to each other's *utterances* (Bakhtin, 1981, 1986). Correspondingly, advocacy of a dialogic approach to teaching and learning is based around analysis of the nature of classroom interactions between teachers and learners, in terms of observing how it operates as a "thinking tool" through language (Lotman, 1988).

As Wells (op.cit.) suggests, therefore, the choice of activities - their form and expression - inevitably affects what is learned and more significantly – how it is learned. Moreover, if language is the medium of expression for thoughts and ideas, which are then translated into actions, then its form and expression inevitably has a bearing on the *experience* of learning as well as what is learned. Furthermore, language is a central tool in Vygotsky's (1978, 1987) concept of artefact-mediated joint activity. Therefore, if language and how it is used is

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<sup>12</sup> Wells refers to theoretical, practical and artistic modes of knowing

fundamental to sense making, then “...*language is the essential condition of knowing, the process by which experience becomes knowledge*” (Halliday, 1993:94).

## **2.7 Conclusion**

As is appreciated from this theoretical exposition based on reviewing the literature, the concept of practice is complex, and subject to wide interpretation. It ranges across philosophical (MacIntyre), sociological (Giddens; Bourdieu) and sociocultural psychological theory (Engeström, Wenger; Wells). These perspectives provide the concepts of: internal goods (MacIntyre); duality of structure (Giddens); habitus and objective regularities (Bourdieu); dialogic inquiry (Wells); and activity (Engeström) as the gateway to understanding expansive learning in various fields of societal practice.

Consequently, a concept of practice, represented in a conceptual model (shown in Figure 3-1 in the next Chapter), is distilled from these theoretical perspectives into the following:-

- Practice concerns those internal (morally driven) & external (materially driven) goods achieved through a complex activity that is defined by its standards of excellence.
- Its structuration depends on those social processes of domination, legitimation and signification, which agents manifest as practical and discursive consciousness in their negotiation of its rules and resources (Giddens, op.cit.) through their habitus.
- Habitus concerns the embodiment of agents’ values and disposition with regard to their perceptions, understandings and actions, which then translate into the objective regularities of practice especially in contexts of situated learning. It manifests through agents’ epistemological frames of discourse (EFsD: *saying-writing-doing-being-valuing-believing* combinations (Gee, 1996) and culminates in monologic or dialogic patterns of interaction (Wells, 2001), particularly in contexts of situated learning (Lave & Wenger, 1991).

- Because habitus infiltrates practice, agents' actions become routinised in everyday activity, which is constituted by both cognitive and cooperative elements. Viewing these familiar elements, some of which may be tacitly understood, as unfamiliar makes them explicit and reveals them as objective regularities of practice.
- As subjects within related activity systems in various fields of societal practice, the complex activity within practice is mediated through artefacts (such as habitus and EFsD) to transform the object (of activity).

Furthermore, the literature has been reviewed for ways to develop an analytical framework that can accommodate these theoretical perspectives while supporting a study of practice among a group of trainers, drawn from the field of clinical research, in their journey towards becoming a community. In particular, if this study evolves from observing *what's going on around here*, how do we explain *how we're doing things* systematically in terms of the concept of practice, in order to understand *why we do things the way we do*? According to these theoretical perspectives, various artefacts (habitus, objective regularities of practice and EFsD) may be considered to mediate complex activity within practice. Therefore, Activity Theory provides the tools to encompass and analyse the concept of practice and its constituent complexities within a specialised community, referred to as the Trainers Forum. It also provides the means to understand the opportunities in the Forum's internal and external contradictions for different features of expansive learning<sup>13</sup> within their related contexts or associated activity systems (Engeström 2004, 2007).

Development of the analytical framework based on the literature is presented in Chapter 3.

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<sup>13</sup> Engeström (2007) characterises these features of expansive learning as *transformative, experiencing, horizontal and dialogical, and subterranean*.

**Table 2-1: Features of the structural elements of a Community of Practice**  
**(Wenger, McDermott and Snyder, 2002)**

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**Domain**

- Creates common ground
- Creates a sense of identity
- Legitimises the community by affirming its purpose and value to members/stakeholders
- Inspires members to contribute and participate
- Guides learning
- Gives meaning to actions

**Community**

- Creates the social fabric of learning
- Fosters interactions and relationships based on mutual respect and trust
- Encourages a willingness to share ideas, expose one's ignorance, ask difficult questions and listen carefully

**Practice**

- Comprises a set of frameworks, ideas, tools, information, styles, language, stories, and documents that community members share
  - Involves the specific knowledge the community develops, shares and maintains
  - Assumes mastery of the basic knowledge of the community
  - Enables community to proceed efficiently in dealing with its domain through body of shared knowledge and resources
-

**Table 2-2: Four dimensions of knowledge and knowing**

Nature of knowledge	Nature of knowing
What is Knowledge?	Where does Knowledge come from and how do we know we know?
<b>Certainty:</b> How sure are we of our Knowledge?	<b>Source:</b> External /internal authority?
<b>Simplicity:</b> What form does it take?	<b>Justification:</b> How are arguments constructed & used?

## **Chapter 3**

# **Analytical Framework**

### 3 ANALYTICAL FRAMEWORK

In Chapter 2, the overlaps between philosophical, sociological and educational perspectives on the concept and meaning of practice were highlighted.

#### 3.1 Overview

Based on these perspectives, for the purposes of this study, practice is characterised as a complex activity defined by its standards of excellence that lead to the attainment of goods inherent to the practice, and constituted by the cognitive and co-operative tasks involved in the activity. The conceptual model of practice derived from these perspectives is shown in Figure 3-1, at the end of the chapter.

Characterising practice as complex activity allows it to be deconstructed within an analytical framework based on what Engeström (1993) refers to as 3<sup>rd</sup> generation activity theory or Cultural-Historical-Activity-Theory, as discussed in Chapter 2. Conversely, the concept of practice guiding activity may be reconstructed through theoretical analysis of the models and concepts employed historically within the system of activity, as well as through empirical analysis of its forms of expression and manifestation.

In this chapter, Cultural-Historical-Activity-Theory (CHAT) is also applied as a conceptual tool in a developmental methodology in order to explain *what goes on around here*” and *“why we do what we do”* within the Trainers Forum (TF).

Because it offers a flexible and expansive approach for researching the dynamics of activity, there are no prescribed techniques and procedures for this type of research. Consequently, the limitations of this approach depend on delimiting the nature and context of the object of research. Furthermore, the conceptual tools for exploring and explaining the object of research are developed and adapted as its specific nature unfolds. Even so, Engeström (ibid.) based the process of developmental research on three foundational principles of activity theory, which involve: -

- Taking as the unit of analysis - the collective activity system comprising 6 components (subject, object, tools, rules, community, division of labour)
- Searching for contradictions manifesting in the form of problems, doubts and uncertainties experienced among the participants of the activity since these disturbances potentially drive innovation and change in the activity system
- Analysing the activity system and its constituent components (including actions and operations) historically.

Consequently, these three principles were applied progressively during the initial, exploratory and confirmatory stages of the research study to elaborate the complex activities constituting practice within the TF. In the initial research phase, Lave and Wenger's (2002.) construct of a *Community of Practice* (CoP) was used to contextualise the concept of practice being explored within the TF, as well as to describe the structure of this community and its domain (Phase 1 analysis). In the second stage, in order to understand “*what goes on around here*” and “*why we do what we do*”, practice was analysed in terms of its objective regularities or cognitive and cooperative tasks constituting routinised actions within this system of activity. By this means, the collective motives, goals and instrumental conditions affecting the activity system could be further elaborated taking the entire system as the unit of analysis.

The analytical strategies conceived within each stage of the study are outlined within a CHAT framework in Figure 3-2. These strategies are described in Section 3.4. Meanwhile, the analytical process involved in CHAT methodology is discussed in section 3.2.

## **3.2 Towards a Cultural-Historical-Activity-Theory Framework**

### **3.2.1 Initial phenomenological analysis of the Activity System**

The process of analysis using a CHAT framework begins by developing a preliminary *phenomenological insight* into the nature of the discourse and problems as experienced by those involved in the central activity being examined, which in this case is the sharing and discussing of practice issues concerning clinical research training. This stage involves



grasping the *need state* and primary contradiction beneath the surface problems, doubts and uncertainties experienced among the participants of the activity.

Contextualising and delineating the activity system under investigation forms the next step, which means explicitly identifying the locus and limits of the activity of interest through modelling the central activity and its components as shown in Figure 2-2, Chapter 2.

By extension, general models of neighbouring activities or systems represent sources of contradiction depending on their neighbouring role with the central activity or system of activity, as shown in Figure 3-3. However, in this respect,

*“...contradictions are not the same as problems or conflicts. Contradictions are historically accumulating structural tensions within and between activity systems. The primary contradiction of activities within capitalism is that between the use and exchange value of commodities. The primary contradiction pervades all elements of our activity systems”*  
(Engeström, 2001:137).

In the first phase of this study, the aim was to explore the TF and to develop phenomenological insight into its context and its activities. At this stage, the CoP construct guided the descriptive analysis of the structural dimensions of the community, its domain and practice. That is, framing *practice* as a structural element in the CoP, contextualised the concept of practice within the community’s structure and its domain. Thus, Wenger’s (op.cit:76) criteria defining the structural features of a CoP were used to descriptively analyse the TF as outlined in Table 3-1.

This phase of research culminated in the delineation of the TF as the AS of interest. Tensions in surface problems or disturbances were also considered as contradictions within or between its elements (subject, tools, object, rules, community, and division of labour). As shown in Figure 3-3: four levels of contradictions within an activity system at the end of the chapter, examining neighbouring activity systems according to their impact on the constituent elements of the central activity system of interest reveals additional sources of contradiction.

Finally, in a CHAT framework the analytical process is accomplished in-depth through three types of rigorous analyses of the activity system, each of which is discussed in the following sections (Holzkamp, 1983 ): -

- the *object-historical* analysis;
- the *theory-historical* analysis; and
- the *actual-empirical* analysis.

### **3.2.2 Object-historical & theory-historical analysis of the Activity System**

Object-historical analysis involves identifying and analysing successive developmental phases of the activity system in terms of the qualitative transformations of the object, which by itself can be appreciated as an activity system. At the same time, the object remains an integral component of the central activity. Identifying and analysing successive developmental phases of the activity system is done by periodising the activity of interest, following its basic temporal structure while simultaneously uncovering secondary contradictions between elements of the activity system driving its transition from one developmental phase to another. In effect, the history of an activity system lies not just in its internal structure and organisation but also in the global history of its tools, procedures, concepts and principles that have mediated the activity. In addition, analysing the impact of neighbouring activities or systems of activity in terms of their role reveals further sources of contradiction, or quaternary contradiction (level 4).

Theory-historical analysis within an activity theory framework involves analysing the concepts and models that constitute the shared secondary or cultural artefacts employed by the activity system in any of its developmental phases. The main aim of this form of analysis is to “identify and trace the formation of the secondary contradictions initiated by or connected to the secondary instruments of the successive developmental periods”. For example, such artefacts “...are embodied in different modalities (i.e. handbooks, working instructions, fixed procedures for classification and diagnosis, etc.), but all are in principle public knowledge, and function as general conceptual instruments of the practical activity” (Engeström, 1987).

More fundamentally, these tools or artefacts will have been “...partly constructed within the central activity”. Understanding these tools means probing the underpinning theories or

models introduced into the central activity, and eventually tracing the instrument-producing activities behind those theories.

Finally, in the last stage of a CHAT methodology, object-historical and theory-historical analyses are complemented by actual-empirical analysis of "...the internalised and invented models professed and actually used, or upheld by the participants of the activity" (Engeström, *ibid*: (5): 6).

The process involved in this last stage is outlined in the next section.

### **3.2.3 Actual-empirical analysis of the Activity System**

Engeström proposes three tenets for the actual-empirical analysis:-

1. If possible, models actually applied in the activity should be analysed on all three levels of activity/motive, action/goal and operation/conditions
2. Models should be analysed as: declarative conceptions; procedural performances; social discourses or interactions; communicational networks; and organizational structures.
3. The results of the historical and theoretical analyses of identified concepts and models (constituting artefacts) should be evaluated using what Engeström (*ibid*: (5): 7) refers to as five general historical types of models (prototypes, classificatory models, procedural models, systemic models, germ cell models).

Thus, consistent with the methodological application of CHAT theory, identification and analysis of models or concepts of practice "professed and/or used" in the activity system calls for the development of an instrument. In effect, this instrument was constituted during the process of both the object-historical and the theory-historical analyses, and was then tested systematically in the actual-empirical phase of analysis. It therefore, simultaneously constituted the outcome of object-historical and the theory-historical analyses, and presented the results of the *actual-empirical* analysis of the object of activity (sharing practice).

Accordingly, this instrument is presented with integrated coding schema as the outcome of analyses in Part 3: Results in Tables 9-1 and 9-2.

Meanwhile, the development of the framework constituting this instrument is explained in section 3.3, and shown in two parts at the end of the chapter in Tables 3-2 and 3-3, respectively<sup>14</sup>.

### **3.3 Operationalising the conceptual framework**

Beginning analysis by illuminating the nature of activity in the Forum eventually delineates its elements and unravels its contradictions. Taking this phenomenological approach to explore the Forum's system of activity develops propositions about the object of activity over time, in terms of the *declarative concepts* of sharing and discussing practice, *procedural models* used and *social discourses or interactions* observed in the Forum regarding this central activity (Engeström, *ibid.* (5):6). In effect, these concepts, models and discourses constitute the tools or artefacts used in transforming the object of activity.

Particular focal questions (shown in Table 3-4) steered the enquiry, guiding analyses of activity within Forum sessions to deconstruct these concepts, models and interactions.

Observing and analysing activity at Forum meetings is based on the understanding that language and its semiotic expression shape our approaches and methods to sharing and discussing practice, either intentionally or unintentionally in terms of perceived shared meanings (Vygotsky 1978; Wells, 1999 & 2001). Consequently, because our epistemological frames of discourse (i.e. our *saying-writing-doing-being-valuing-believing* discourse combinations (Gee, 1996)) reveal how we think of practice, and shape activity at its heart (Gee, *ibid.*), the concept of practice is evaluated in terms of methodologies that stem from it, and how it is experienced through different approaches and methods at the Forum.

For example, methods used to share/discuss practice, patterns of interaction and training idiom, represent regularly occurring features of approaches taken in 55 observed sessions,

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<sup>14</sup> Framework for Objective Regularities of Practice at the Trainers' Forum: Cooperative elements of activity; and cognitive elements of activity.

which operationalise the concept of practice through either a dialogical process of inquiry or a monological process of transfer. From observing activity in 28 sessions in the first few Fora, over a period of 3 years, these familiar elements of practice were theorised as the *objective regularities* of practice. These are ontological aspects observed to define individuals' world of practice in terms of its structures, laws, systems of relationships, etc. (Bourdieu, 1990). In practical terms, these *regularities* concern *what's happening around here* in Forum meetings. As they emerged, regularities were categorised subsequently into cognitive and co-operative elements of complex activity. In turn, these regularities operationalise the concept of practice underpinning the object of activity (sharing practice) i.e. what we say, write and do shows what we believe and value about practice, and determines how we act in relation to our understanding of it.

Pre-defined categories were developed theoretically through a process of open, axial and selective coding of observational data gathered from the first five or six meetings.

That is, data from observed meetings were fragmented progressively into conceptual elements of practice, initially derived from the literature: epistemology, pedagogy, standards of excellence etc. These conceptual elements were then further distinguished as either cognitive or co-operative elements of activity (i.e. what we understand, and how we jointly demonstrate or share our understanding). Core categories and their relationships then emerged through axial coding, corresponding with the guiding questions shown in Table 3-4 (Conceptual matrix).

Through selective coding, cognitive and cooperative elements of activity were aligned with corresponding elements of the concept of practice, which in turn were integrated into core descriptive categories to form the conceptual framework<sup>15,16</sup>.

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<sup>15</sup> Table 3-2: Framework for Objective Regularities of Practice at the Trainers' Forum: Cognitive elements of activity

<sup>16</sup> Table 3-3: Framework for Objective Regularities of Practice at the Trainers' Forum: Co-operative elements of activity

In conclusion, the conceptual framework was developed initially from observing activity in the first 28 sessions. In the process, descriptive/theoretical propositions about the nature of activity involved in the sharing of practice were developed from analysis of qualitative transformations of practice over time (*object-historical* analysis), and from analysing concepts and models of practice (*theory-historical* analyses) used in successive Forum sessions over time.

The final stage of analyses using activity theory culminated in applying the framework as a tool for *actual-empirical* analysis of the object of activity (sharing practice) in the remaining 27 sessions observed. By means of this evaluative tool, core categories were empirically tested and use of the tool validated.

Each of these three stages of analyses built a complementary picture of *what's happening around here* at the Forum through testing and refining the conceptual-theoretical framework in actual-empirical analysis of the object of activity at both initial and later Forum meetings. For example, it allowed the models of practice that were used in the TF and expressed within contrasting pedagogies and associated training idioms to be evaluated against the defined categories of the concept of practice, which have been derived from theoretical perspectives in the literature, as shown in Figure 3-1 at the beginning of this chapter. (Findings are presented in Part 3, Results & Discussion: Chapters 7, 8 and 9.)

Finally, the coding schema representing the activity system elements and their contradictions are shown in Table 3-5 and Table 3-6.

### **3.4 Summarising the Analytical Strategy applied in the Study**

Using these analytic strategies (object-historical; theory-historical and actual-empirical) within a CHAT framework demonstrates how the concept of practice manifests in a community of practice.

The picture built up over time of the complex activities constituting practice within a community of clinical research trainers was progressively analysed using this framework to

explain the conditions that create and sustain this professional community and enculturate its concept of training practice against a backdrop of increasing regulations. Therefore, given the complexity of the object of study (concept of training practice) within the activity system of interest and its evolving context, the analytical strategy suggested by this framework, and subsequently used in the study is summarised in Table 3-7.

The social influences that helped or hindered the development of the Trainers Forum as a community of practice could then be analysed using this strategy.

**Figure 3-1: Conceptual model of the derived concept of practice**

		<u>Elements of activity</u>		
		Cognitive tasks	Co-operative tasks	
<b>Complex Activity</b>		✓	✓	
<i>Defined by:</i>	Standards of Excellence (SoEx)	✓	✓	} Objective regularities of Practice (ObRoP)
<i>Mediated by:</i>	Epistemological frames of discourse (EFsD)	✓	✓	
<i>Leading to:</i>	Monologic / Dialogic interaction	✓	✓	
<i>Resulting in attainment of:</i>	Internal Goods (IG) + External Goods (EG) depending on their value attributes (social, cultural, symbolic & economic)	✓	✓	
		=	Practice	



**Figure 3-2: Analytical strategies in a CHAT framework for examining the concepts, methodology and experience of practice in a *community of practice***

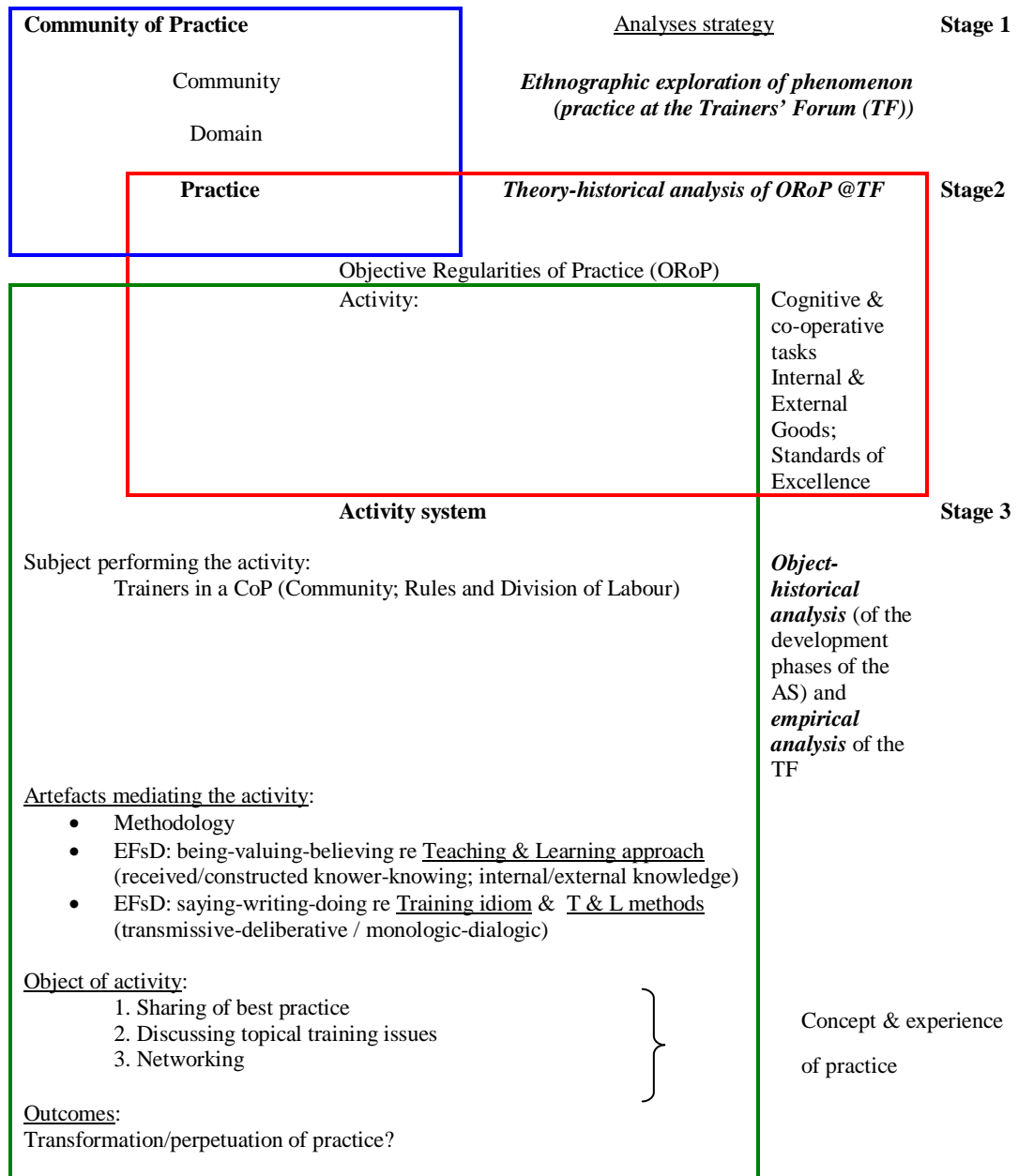
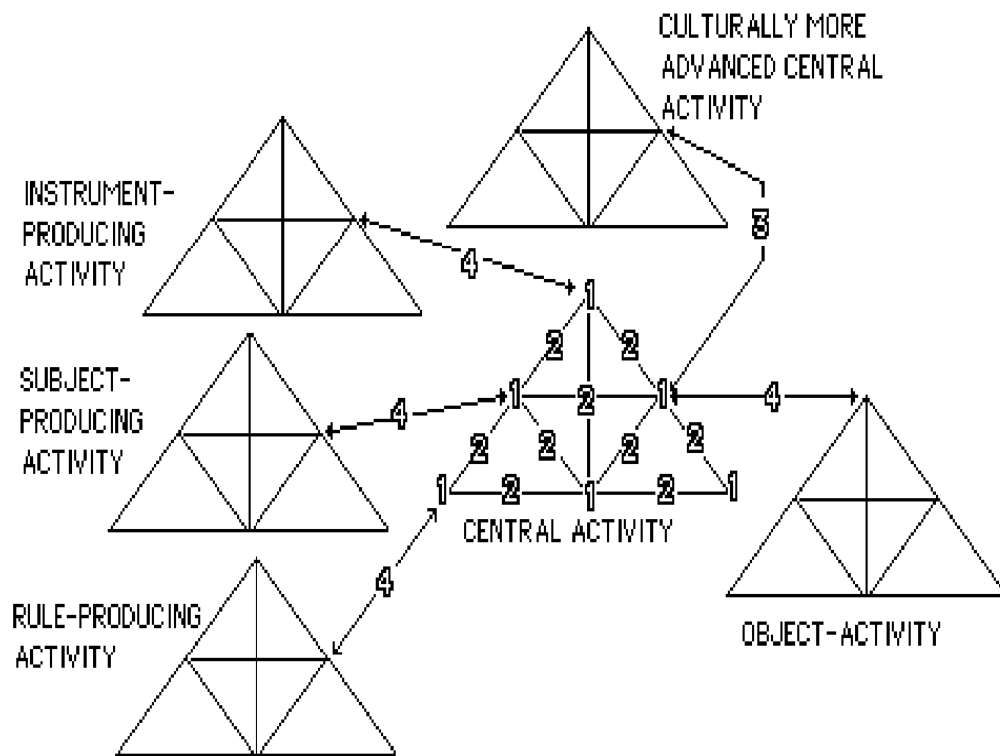


Figure 3-3: Four levels of contradictions within an activity system (Engeström, 1999)



**Level 1:** Primary inner contradiction (double nature) within each constituent component of the central activity.

**Level 2:** Secondary contradictions *between* the constituents of the central activity.

**Level 3:** Tertiary contradiction *between* the object/motive of the dominant form of the central activity and the object/motive of a culturally more advanced form of the central activity.

**Level 4:** Quaternary contradictions *between* the central activity and its neighbour activities.

**Table 3-1: Criteria defining CoP structural elements**

Criteria	Structural element
1. Sustained mutual relationships – harmonious or conflictual	Community
2. Shared ways of engaging in doing things together	Practice
3. The rapid flow of information and propagation of innovation	Practice
4. Absence of introductory preambles, as if conversations and interactions were merely the continuation of an ongoing process	Practice
5. Very quick setup of a problem to be discussed	Practice
6. Substantial overlap in participants' descriptions of who belongs	Community
7. Knowing what others know, what they can do, and how they can contribute to an enterprise	Community
8. Mutually defining identities	Domain
9. The ability to assess the appropriateness of actions and products	Domain
10. Specific tools, representations, and other artefacts	Practice
11. Local lore, shared stories, inside jokes, knowing laughter	Practice
12. Jargon and shortcuts to communication as well as the ease of producing new ones	Practice
13. Certain styles recognized as displaying membership	Practice
14. A shared discourse that reflects a certain perspective on the world.	Community

**Table 3-2: Framework for Objective Regularities of Practice at the Trainers' Forum <sup>17</sup>: Cognitive elements of activity**

Cognitive elements of Activity					
Categories (C <sub>PRACTICE</sub> elements) <sup>18</sup>	CONCEPTS (declarative)	METHODOLOGY (procedural models)		EXPERIENCE (social discourses)	
EFsD <sup>19</sup> : being- valuing-believing	Object of activity?	?	?	?	?
Pedagogy: • T & L approach	?	?	?	?	?
• Culture	?	?	?	?	?
Stds of excellence	?	?	?	?	?
Goods internal to practice	?	?	?	?	?
Discipline knowledge domain	?	?	?	?	?

<sup>17</sup> Objective regularities of practice based on object-historical and theory-historical analysis of observations from eleven TF meetings over a period of five years

<sup>18</sup> C<sub>PRACTICE</sub>: Concept of Practice

<sup>19</sup> EFsD: epistemological frames of discourse expressed semiotically as *being-valuing-believing* combinations through use of language and actions

**Table 3-3: Framework for Objective Regularities of Practice at the Trainers' Forum (TF): Cooperative elements of activity**

Cooperative elements of Activity					
Categories	CONCEPTS (declarative)	METHODOLOGY (procedural models)			EXPERIENCE (interactions)
EFsD <sup>20</sup> : saying-writing-doing	Object of activity?	?	?	?	?
<u>Pedagogy: T &amp; L methods</u>					
• Pattern of interaction	?	?	?	?	?
• Mode of behaviour	?	?	?	?	?
• Training idiom	?	?	?	?	?
<u>Social practice</u>	?	?	?	?	?

<sup>20</sup> EFsD: epistemological frames of discourse actively expressed as *saying-writing-doing* combinations through verbal and written use of language and actions

**Table 3-4: Conceptual matrix**

Focal Questions	Core conceptual categories	Analytic categories
What do we mean by training practice?	} Concept of practice	Object
What are we doing and why?		
What do we do to share it (methods) and how do we do it (approach)?	Methodology associated with the concept of practice	Tools
What happens and why?	Experience of practice depending on the concept	Outcome

**Table 3-5: Codes for describing activity system (AS) elements or contradictions**

Component of AS		Contradiction in AS	
SU 1,2,3...etc.	Subject	L1	1 <sup>ty</sup> internal contradictions within elements of AS
CO 1,2,3...etc.	Community	L2	2 <sup>ty</sup> internal contradictions between elements of AS
OB 1,2,3... etc. MO 1,2,3... etc.	Object Motive	L3	3 <sup>ty</sup> external contradictions between object/motive of the dominant form of the AS (central activity) and the object/motive of a culturally more advanced AS
TO 1,2,3...etc.	Tools	L4	4 <sup>ty</sup> external contradictions between central AS and neighbouring AS
DoL <sub>v</sub>	Division of labour – vertical		
DoL <sub>H</sub>	Division of labour – horizontal		
RU 1,2,3...etc.	Rules		
OU 1,2,3...etc.	Outcomes		

**Table 3-6: Coding scheme for Activity System contradictions**

<b>Codes for identified contradictions: Four levels of contradiction</b>			
<b>Level</b>	<b>Contradiction in AS</b>	<b>Codes for contradictions identified at 1<sup>st</sup>, 2<sup>nd</sup>, 3<sup>rd</sup> and 4<sup>th</sup> levels</b>	
1	1 <sup>st</sup> internal contradictions within elements of central AS	L1SU L1OB L1TO L1CO L1DL L1RU	Subject Object Tools Community Division of Labour Rules
2	2 <sup>nd</sup> internal contradictions between elements of central AS	L2SU-TO L2SU-RU L2SU-CO L2SU-OB L2SU-DL L2DL-OB L2AR-OB L2TO-OB	Subject - Tools Subject - Rules Subject - Community Subject - Object Subject - Division of Labour Division of Labour - Object Artefact - Object Tool - Object
3	3 <sup>rd</sup> external contradictions between object/motive of the dominant form of the AS and object/motive of a more culturally advanced AS	L3OB-OB	Object - Object
4	4 <sup>th</sup> external contradictions between central AS and neighbouring AS	L4SU-AS  L4TO-AS L4OBJ-AS L4RU-AS L4DoLh-AS L4DoLv-AS	Subject producing central activity or Activity System  Tool producing central activity or AS Object producing central activity or AS Rule producing central activity or AS Horizontal Division of Labour producing central activity or AS Horizontal Division of Labour producing central activity or AS



**Table 3-7: Analytical strategy based on a CHAT approach**

Stage 1 analysis
<ol style="list-style-type: none"> <li>1. Outlining and contextualising the phenomenological aspects of the object of study (concept of training practice in the field of clinical research) from the culture of the regulatory environment to the structure of the TF as a vehicle for professional development</li> <li>2. Delineating the TF as the activity system on which the actual-empirical analysis is focused</li> <li>3. Outlining the <i>object-historical</i> development of the TF (i.e. its successive developmental phases) in terms of the qualitative transformations of the object</li> </ol>
Stage 2 analysis
<ol style="list-style-type: none"> <li>4. Closely following <i>object-historical</i> analysis with a <i>theoretical-historical</i> examination of the concept of practice used in the TF</li> </ol>
Stage 3 analysis
<ol style="list-style-type: none"> <li>5. Complementing <i>object-historical</i> analysis and <i>theoretical-historical</i> with <i>actual-empirical</i> analysis of internalised/invented models professed and used in the activity as: declarative conceptions; procedural performances; and, social discourses or interactions</li> <li>6. Illuminating contradictions within the community's objective regularities or dimensions of practice (concept, methodology and experience) by viewing them as pedagogic dualities within constituent elements of the Trainers' Forum activity system</li> <li>7. Identifying and illuminating contradictions between the constituent elements of the Trainers' Forum activity system that may help or hinder its development as a community of practice</li> <li>8. Identifying and illuminating contradictions between elements of inter-related activity systems.</li> </ol>

## **PART 2 METHODOLOGIES**

# **Chapter 4**

## **Research Methodology**

## 4 RESEARCH METHODOLOGY

### 4.1 Introduction

In this chapter, I describe the methodology used to answer my research questions. The ontological features of the object of research in this study are characterised in section 4.1.1.

My methodological framework is presented in Table 4-1, showing the approach, methods and tools used to explore concepts at different stages in this research. My research approach is described in sections 4.2 and 4.3, which includes discussion of methodological issues related to data gathering and analysis, and encompasses problems and limitations. Study Design is explained in Chapter 5, followed by a description of the methods used to gather and analyse data in Chapter 6.

My enquiry is based on analysing concepts, methodology and experiences of fellow training professionals, largely drawn from the public and private spaces within a community of practice and explored in terms of its system of activity. Mixed methods were adopted as being appropriate to explore my object of research for pragmatic rather than philosophical reasons.

For example, in the first phase of the research, the technique of observation, borrowed from ethnographic methodology was used to provide insights about collective understandings of practice: its workings within a specialist forum, together with associated theoretical principles and assumptions. Meetings of the Trainers Forum provided the setting for observing activity as events that "...proceed to a large extent behind the backs or above the heads of the actors" (Engeström, 1987 (4): 48). Documentary evidence, related to training and published in the Institute's magazine, was similarly analysed for common understandings of practice.

In the second stage, a survey questionnaire established the demographic characteristics of trainers, assessing whether respondents had factors in common to their situation.

In the final phase, such factors (including epistemologies, choice of instructional methods, shared vocabulary and common understandings) were explored by means of further observation and via a series of in-depth interviews. In this way biographies, which were built

through interviewing community members at different levels of participation informally and formally over time, served to further illustrate *what was happening* within the community of trainers as a whole, in terms of looking collectively at *how we do things and why*, rather than highlighting individual perspectives.

Eclectic use of mixed methods apparently typifies the general research approach as interpretative educational case study (Bassey 1999; Cohen & Manion (1994); and Verma & Mallick (1999)). Yet, case study implies that the study boundaries are well-defined, which therefore delimits context as a container of situationally created experiences with distinct boundaries. In this study, context is visualised as an expansive series of inter-related and inter-linked systems of activity, which by virtue of their dynamic nature means that boundaries are fluid. In addition, multiple data sources are used, some of which may be located “outside” the specifically observed study setting (TF meetings), but which nevertheless constitute related artefacts of the Trainers’ Forum, both as a community of practice (CoP) and as an Activity System.

As explained in Chapter 2, the nature and diversity of work practices are recognised as socially complex activities, which may be governed or structured by social or cultural factors that in turn moderate institutionalised organisational behaviour. Consequently, due to its structural complexity, the nature of practice is subject to wide interpretation. Thus, the process involved in *de-constructing* the object of research over time depends on the recognition and appreciation of the multi-dimensional layers of social reality constituting the object. As Vella (op.cit.: 16) states, "...as subjects, we evoke the world we perceive".

Accordingly, researchers are advised that the principles underlying the design and form of a research enquiry should reflect the nature of the specific enquiry (Murray and Lawrence, op.cit.:9; Pring, 2000:6). Similarly, verification and validation methods should be in line with the conceptual and methodological approaches selected. Put another way, as Pring (op.cit.:6) states:

*"The nature of the subject matter determines what kind of research is valid or relevant. Or, at least, the nature of that which is to be researched will determine the relevance of different sorts of research and their findings."*

He further elaborates that the decision about which methods to use, or which approach to take, is best made pragmatically and not philosophically. Furthermore, Giddens' (op.cit.) structuration theory provides the means to circumvent what Pring (op.cit.:43) refers to as the *false dualism of educational research* where methodology is determined on an epistemological basis rather than on a pragmatic decision to use methods appropriate for the particular object of educational research.

As Pring argues, there is a significant philosophical tradition that already deals with such fundamental philosophical concepts as

*"...the meaning of what is stated... the truth of what is claimed... the verification of conclusions reached... the conceptualisation of a problem and its solution... the objectivity of enquiry, and ...the knowability of reality." Pring (ibid.: 6)*

Awareness may help to avoid developing potential "blindspots" or biases that may affect data analysis and interpretation arising within particular methodological frameworks. Bourdieu refers to this awareness as the process of critical reflexivity where the interpretative analytical process entails "making the familiar unfamiliar", and as far as possible identifying and challenging cultural or other forms of systematic assumptions (Bourdieu, 1990).

Giddens concept of facticity (op.cit.:331) further relegates epistemological and ontological debate concerning methodology to an irrelevance. To be meaningful, social interactions necessarily invoke the institutional order appropriate to situated action, thereby rendering actions intelligible and coherent. Nevertheless, the capability to interpret contextual meaning of social interactions, so that actions and communication are understood depends on the extent of ontological appreciation and level of epistemological sophistication. The example Giddens gives is one of a courtroom enactment between a judge and defending and prosecuting lawyers, where the actors' interaction is imbued with their common knowledge and assumptive understanding of the institutional order governing their common practice of law. In this circumstance, the practice of law is established both over time and in terms of

place (courtroom) such that it has recognisable structural properties or structured features even to non-practitioners.

However, by contrast with the practice of Law, the structural properties of clinical research training, as coherent institutionalised features, need further elaboration in keeping with the continuing evolution of clinical research as a discipline and the evolving face of the field of practice mirroring constant scientific, technological and regulatory change. In particular, at present these features may appear opaque to practitioners and non-practitioners alike.

Therefore, elaboration of the structural properties of clinical research training began by considering the ontological features of the object of study, which are discussed in the next section.

#### **4.1.1 Object of research: ontological features**

Five layers of social reality were clarified. Each of these layers constitutes an object of study, which further defines the nature of training practice in the UK field of clinical research:-

1. The regulatory environment encompassing and governing clinical research practice
2. Clinical research industry constituting the field of practice
3. Practice settings or sites of practice
4. Professional community of clinical researchers – the Institute of Clinical Research or ICR
5. Clinical research Trainers' Forum (TF) in the ICR.

Therefore, given the complexity of social reality, which these ontological features reveal, the empirical study is focussed on the *concept of practice* as the object of study within the Forum.

This focus assumes that if trainers' everyday habits reflect their operational capabilities or agency, then their community of practice provides a microcosmic view applicable to the macrocosm, both at the *organisational* and *field* level of practice. Therefore, structural elements of practice, the nature and role of which constitute the objective regularities of practice, are examined within the community through posing the following questions: What

form does practice take and how is it defined (concepts)? How is it expressed (methodology) and does it manifest (experience)?

Correspondingly, analysing the effects of regulatory developments on training practices means exploring the elements of practice modelled within the Trainers' Forum as social activities (cognitive and co-operative tasks) and social processes of learning. Study design should then illuminate the local and wider contextual factors mediating or shaping practice *in situ* within this community in terms of concepts, methodology and experience. In effect, de-constructing the structural elements of practice, in terms of its rules and resources, reveals the conceptual instruments that Engeström (op.cit.) explains are partly constructed within the central activity, and partly imported into it as cultural artefacts.

Moreover, the main aim of this study is to explore the processes of learning and inquiry within this community – expressed implicitly within its mission statement - that enable or hinder its progress towards understanding and agreement of best practice (Appendix A). If learning is considered as a social process, then the objective is to explore how the community accomplishes learning as an activity, and to examine what cognitive and co-operative tasks are involved.

As a member of this community, my initial research approach began with observing *the way we do things around here* in order to understand *what* and *how we're doing things around here* and *why*. In turn, observations of Forum activity formed the basis for questions put to community members, both informally at meetings, and formally through pre-arranged interviews and questionnaires. Effectively, *the way we do things around here* captures the cultural expression of activity in terms of the shared values and beliefs about a concept of practice evident in patterns of thought (declarative concepts), behaviour (procedural models), and artefacts (social discourses) that symbolize and give contextual meaning to the activity (Deal, 1985: 605).

In conclusion, the methodology chosen in this study was determined by a research approach that offered the means not only to negotiate the complexities of the five inter-related 'layers'



of social reality, but that provided a sufficiently comprehensive way to analyse the copious amounts of data likely to be gathered. Accordingly, the approach and associated issues in the study are discussed in successive sections.

## **4.2 Research approach**

The various tools and techniques used in this endeavour are shared across various methodologies with their respective traditions. However, the eclectic use of methods in this study is indicative of an approach concerned with exploring the object of research by whatever means are feasible. For example, as an ethnographic tool, observation provides a means to explore practice and its structural elements - the nature and role of which constitute its objective regularities. Although this study relied heavily on the technique of observation, it did not define my approach as ethnographic. Rather it should be seen as a valuable component within the tool-kit and framework of an approach that is developmental in the sense of a theoretical approach, and part of the “methodology for applying activity theory, specifically the theory of expansive learning, in the world of work, technology, and organizations” (Engeström, op.cit.). As Engeström explains (1999b: 9) in this approach,

*“... research aims at developmental re-mediation of work activities. In other words, research makes visible and pushes forward the contradictions of the activity under scrutiny, challenging the actors to appropriate and use new conceptual tools to analyze and redesign their own practice”.*

As an approach, development work research (DWR) or expansive development research (EDR) (Engeström, *ibid.*; 1996b) mainly points to a focus on work activity as the context of application. By contrast, the focus of this research study is on the activity of professional development, which is nevertheless viewed as a sub-sector of work activity in keeping with the idea that professional development is a dynamic process and not a series of static events (Phillips and Friedman, 2001). The research focus is therefore within the refined context of a professional *community of practice* in order to understand the expansive learning opportunities that are afforded through professional development.

Applying a developmental research approach to this context is therefore appropriate since the TF provides a unique opportunity to examine common approaches taken by individual trainers to the activity of training in their respective workplaces. Thus, the TF is a specific setting that resides outside the workplace, inside a professional institution, where professional practice is modelled both intentionally and unintentionally. In reflecting institutional goals of professional development “to share best practice, raise standards and develop the professional” the TF necessarily impacts workplace practice.

The object of activity within the TF activity system (to share best practice and discussion common issues) may differ from the object of activity in the workplace (delivering training – as one component of training practice referred to as the training cycle; see Figure 8-3).

Nevertheless, common approaches to, and problems concerning, the practice of training at the TF are manifested in the embodied activity of sharing practice and discussing common problems.

Thus, observing individual actions of TF members provides insight into the operation of the TF in terms of the conditions giving rise to collective routinised actions, as well as individual goals and collective motives driving activity in the TF. In other words, because agents’ model their practice intentionally or unintentionally within this professional forum, a developmental research methodology provides a context-specific means to examine and perturb basic routinised operations in an effort to constructively pose the questions: (a) why do we do things the way we do and (b) is there a better way?

The challenge of this approach, as a “theoretical investigation moving on the level of categories”, lies in determining “how to select the data; how to process the data into categories; and, how to bring the categories developed into fruitful contact with practice” (Engeström, 1999b:22). These three fundamental methodological questions will be answered in this chapter progressively.

#### **4.2.1 Approach: distinguishing between ethnography or developmental work research**

Traditionally, ethnographic studies within particular cultural contexts capture details of interactions observed, context of interactions, and observers' reactions over an extended period (Hammersley & Atkins, 1995). In addition, traditional ethnography is descriptive (Sierhuis, 1996) both of actions observed and of their context, without which the meaning of actions cannot be interpreted. Accordingly, by providing "thick description" an ethnographer fuses analysis with description (Geertz, 1973; Wolcott, 1987: 47). Thus, the aim of ethnographers is *"to discover how people in the study area classify or label each other, how they find meaning in activities they care about in life and how they engage in processes in which they individually and collectively define (antecedents and consequences of) their situations"* (Gold, 1997:391). As a methodology, ethnography is defined by immersion within the research setting and prolonged engagement in the daily lives of those being observed.

According to Massey (1998), ethnographic research demonstrates seven elements:-

1. Study of a culture, including a work community etc.
2. Multiple methods, diverse forms of data
3. Engagement
4. Research as instrument
5. Multiple perspectives
6. Cycle of hypothesis and theory building
7. Intent and outcome

In contrast, when participant observation involves extensive contact but is deemed less comprehensive, this data collection method is considered an ethnographic tool rather than an approach (Grigg et al 2004; Charmaz and Olsen, 1997).

An expansive developmental research (EDR) approach shares many of these seven elements, but whereas they may define an ethnographic approach, they merely constitute features of an

EDR approach, since EDR is defined as an approach by its potential for expansive learning using activity theory. Modelling the activity system of interest within its network of related activities systems develops an understanding of context as well as cultural factors that impact on activity and its modalities. By this means, we can view and participate in the unfolding microcosm of the TF as “a social testbench and a spearhead of the coming culturally more advanced form of the activity system” (Engeström, 1987, (5):11). The links between the microcosm and the macrocosm of inter-related activity systems are also viewed while unravelling their inter-dependent relationships manifesting as contradictions, disturbances or ‘problems’.

In addition, in EDR or DWR, participant on-site observations form one of many ways in which the researcher may

*“...get a grasp of the need state and primary contradiction beneath the surface of the problems, doubts and uncertainties experienced among the participants of the activity.” (Engeström, *ibid.*: 5, *exp learning*).*

Yet, whether observational data is gathered as part of an ethnographic study or as participant observation in a DWR study, it may be conducted by a variety of means, each of which has practical and ethical implications. Therefore, regardless of whether ethnography is regarded as a tool or as an approach, it presents a range of methodological difficulties, some of which were encountered in the initial and exploratory stages of this study, and which are discussed in Section 4-3.

The concerns that abound are summarised in the following questions:-

1. How does the role of the researcher affect observations (e.g. researcher as complete observer /participant either covertly or openly)?
2. How will the researcher’s role affect access to the research setting? (Is the researcher an insider / outsider?)
3. Will observations interfere with ‘normal’ activities either for the researcher or those being observed, reminiscent of the Hawthorne effect (Mayo, 1933)?

4. How will the rights of those being observed be protected (permissions, confidentiality, anonymity)?
5. How will the researcher's privileges be preserved (to observe, interpret and publish without interference)?

Most of the practical and ethical difficulties encountered in observational research revolve around the researcher's role and relationship to the research participants (points 1, 4 and 5); the research setting (points 1 and 2); and the research object (points 1 and 3).

In my role as an observer, I was challenged to locate my research approach within a particular ethnographic style or tradition. In particular, the complexity of the object of research, and at times my ambivalent relationship to it made this overwhelmingly difficult. For example, I considered myself as an insider to my community. On the one hand, membership provided me with privileged access to a diverse group of people from a variety of backgrounds and workplace settings with a shared interest in training. On the other, despite my claim to be a participant like any other within my community, my research identity distinguished me from other community members.

My insider status meant I had an *emic*- rather than an *etic*-perspective (insider vs. outsider) on the *attitudes, beliefs, behaviours and practices* (TESOL Guidelines on Critical Ethnography, 1996-2007) of my fellow trainers' concept, methodology and experience of their social and cultural world, since this was also my world. Moreover this *emic* perspective appeared to contrast with the *etic*-perspective assumed in traditional (Mulhall, 2003) and critical ethnography styles (Carspecken, 1996).

Yet, as a reflexive practitioner, I was acutely aware of the need for sensitivity concerning expressions of social issues or power relations, not only as other TF participants perceived them but, as I saw them. However, my intent was to develop a perspective on the emancipatory or restrictive potential of culture perpetuated internally within the CoP, as well as externally, and to understand how expression of culture within particular discourses has

implications for learning processes and their products i.e. knowledge (Spradley, 1979; 1980). Consequently, through formulating hypotheses concerning “what is going on around here”, I hoped to develop a critical understanding of the discourse, in terms of the social practices implicated in *the experiential reality of everyday life and the exercise of power* in and around the CoP (Wainwright, op.cit.).

Therefore, it might be considered that situating my research within a social context in order *to consider how knowledge is shaped by the values of human agents and communities, implicated in power relations and favorable for democratizing relationships and institutions* (TESOL op.cit.) differentiates my approach from one of traditional ethnography to one of critical ethnography. Furthermore, as Wainwright (op.cit) states:

*“...For the critical ethnographer, validity depends upon getting beneath the surface appearances of everyday life to reveal the extent to which they are constituted by ideology or discourse.”*

So, given that the focus of my research touches on learning process, which “...becomes situated in the social interaction among the members of the community” (Grossman, 1991; Putnam and Borko, 2000), considering my approach as critically ethnographic might seem appropriate (Carspecken, op.cit.). Moreover, if we are to understand *what goes on around here* within a CoP, then we need “...not only to describe the rules, structures and participants in a community, but the processes by which they interact” (Barab *et al*,2002: 533).

My insider status did not preclude me from asking questions to understand *what was happening around here*, nor did it interfere with my capability to conduct the research. On the contrary, my research ideas were nurtured, developed and crystallised because I was part of a developing community of practice. For example, almost from the start of the TF being established, I observed a contradiction in discourse and within its artefacts. Namely, training was expounded as being learner-centred, but in practice, a pedagogic model of knowledge transmission appeared to dominate discussions about training. This contradiction subsequently offered a challenge to be resolved. However, according to Wolcott (op.cit.: 47):

*“...In and of themselves, ethnographic studies do not point the way to how things can or ought to be improved”.*

Therefore, although my approach may be considered critically ethnographic, identifying contradiction at the preliminary stage of the research is the point of departure at which the study can be characterised as developmental rather than ethnographic. That is, I intended to explore the conditions creating the contradiction between *what we say* and *what we do* in this community of practice by observing, over a period of time, the processes at work (objective regularities of practice) and their structuration (rules and resources). I also hoped to highlight these conditions, in order to focus our efforts on at least recognising what needs changing in order to resolve the contradiction.

Finally, the use of ethnographic methods does not, in this instance, define this study as ethnographic. Nonetheless, such use serves to explore the phenomenological nature of the object of research in-depth where in effect, like grounded theory, data collection continues as long as new insights are being generated that *characterise community life* (Barab et al, op.cit.:496). In conclusion, an expansive developmental research approach was adopted, which allowed me as a core member of my community, to identify opportunities for expansive cycles of learning stimulated by questioning accepted practices, and to gradually expand these opportunities into a collective endeavour to transform practice within the TF.

#### **4.2.2 Stance – participant-researcher or interlocutor?**

As a participant and a researcher in the Trainers' Forum, my role involved me in seeking opportunities for expansive learning. However, I did not act directly as a 'collaborative change agent', but as an interlocutor enabling two-forms of dialogue:-

1. *With* Forum leaders and members about the nature of pedagogy, and
2. *Between* leaders and members about the virtue of jointly deliberating pedagogic reasoning, subsequently developing dialectic practice.

Questioning practice meant highlighting and exploring possibilities for expansive learning in shared practice by seeking evidence of change opportunities through tracing developmental phases of the object of activity (e.g. via successive shifts in the sharing of practice through a transmissive pedagogy to an enquiry pedagogy and back again). An Activity Theory

methodology meant uncovering opportunities to develop practice, and understandings of it, in order to raise its standards. Inherent solutions within the system of activity were traced and analysed through observing and talking with its participants. Crucially, activity was systematically viewed from different participants' perspectives in order to grasp or visualise contradictions within the system, indicative of expansive learning needs (Engeström, op.cit.). Findings were shared progressively with participants thereby routinely validating perspectives during the course of the enquiry (*participant validation*).

Enquiry proceeded through examining *general* aspects of shared practice in order to uncover *particular* reasons for conflict. In this respect, it differs from action research, which stems from seeking to improve a particular aspect of individual practice that, once shared, has potential benefits for all, moving from a study of the *particular* to the *general* (McNiff, Lomax and Whitehead, 2003:14). As change agents, action researchers need to define their social agenda beforehand, in order to demonstrate the effects of their individual agency, following a change in their practice, seeking evidence of its consequences.

By contrast, a developmental researcher has no agenda other than enquiry, based on appreciating, then exploring, social tensions arising from particular group actions that can only be understood in relation to their frequently implicit goals, but which nevertheless manifest through contradiction between systemic elements in the shared activity. As an interlocutor, I sought and shared evidence not of the effects of my agency, but of potential learning opportunities that could initiate systemic transformations of practice. Although I reported my findings about the effects of particular conceptual and procedural models on activity in the system, the transformation of shared practice depended on the joint agency of the community to develop, adopt and apply new models through strategic tasks in the act of sharing practice (Engeström, op.cit. (5):12).

Consequently, the type of evidence sought in this research signifies a point of departure in defining the role of the change agent either as a developmental researcher or as an action researcher. For example, I sought evidence of opportunities for systemic change in practice



rather than evidence of the effects of individual changes in practice. In this instance, the strategy for collecting data was determined by patterns of activity observed within the Forum, which signified contradiction initially between *what we say* and *what we do*. These contradictions were indicative of *tensions* within and between elements in the activity system and its neighbours. Therefore, the process of developing core categories began by theoretically and empirically analysing observational data collected in the research to gradually develop and refine a conceptual-theoretical framework that later served as an analytical tool. In this way, *what's happening around here* in the Forum was explored from an interlocutory position within a developmental research approach.

#### **4.2.3 Methodological considerations in a Cultural-Historical-Activity-Theory (CHAT) research approach**

On the one hand, using critically ethnographic methods meant adopting interpretative analytical techniques within a process of critical reflexivity, such as that advocated by Bourdieu (1990). Bourdieu's intention was to "make the familiar unfamiliar" in order to yield insights about practice, mainly in order for practitioners (as well as researchers) to learn. His intention within such a process was to identify contradictions and thereby challenge systematic assumptions in how and why we do things the way we do.

Bourdieu positions reflexivity as a methodological tool in the examination of the object of study, referring to it as *double objectification*. That is, when the object of study concerns social situations, reflexivity enables the researcher, as an outsider to the experience of the social reality under scrutiny, to acknowledge that his or her interpretations of that reality may not necessarily be the same as an insider's subjective experience of that reality.

Therefore, such double objectification means that a reflexive researcher appreciates that their observations and interpretations of another's social reality depend on their appreciation of their own experiential biases that may distort their capability to make sense of another's social reality. Jenkins (1992:50) describes the method as follows: "First, there is the work done in the act of observation and the objectification or distortion of social reality which it is likely to produce. Second, there is an awareness of that distortion and of the observer as a

competent social actor in his/her own right.” Through appreciating the distortion and the role of the researcher in creating that distortion, the limitations in examining the nature of the object of study are acknowledged along with the recognition that subjective experience of another’s reality can only be approximated.

Yet, in this case, I am not “...an outsider to the experience of the social reality under scrutiny”. I am a participant in that social reality. Moreover, in this situation, my experiential biases are my strength, in that they help me to conceptualise, and therefore objectify, both *what’s going on around here* and *how we’re doing things around here and why*. That is, my experiential and theoretical background is in Learning and Teaching through: being involved in training since 1988; and, taking a PGCE<sup>21</sup> in 1999; followed by gaining a Masters degree in Learning and Teaching, in 2001)<sup>22</sup>. This background enables me to appreciate collective understanding of practice in terms of our shared concepts, methodology, and experiences within a community devoted to our practice, where otherwise I might struggle to make sense of it all in terms of the significance of systemic contradictions.

On the other hand, characterising this research study as developmental in nature, points towards the adoption of a theoretical and methodological framework that encompasses concerns for methodological rigour. Critical reflexivity, reliability and validity are addressed within its developmental principles. Namely, Engeström (2001) summarizes Cultural-Historical-Activity-Theory with the help of five principles, described as follows:-

1. Unit of analysis: a collective, artefact-mediated and object-oriented activity system, seen in its network relations to other activity systems
2. Multi-voicedness: an activity system is always a community of multiple points of view, traditions and interest, where participants’ roles are constructed around the division of labour

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<sup>21</sup> PGCE: Postgraduate Certificate in Education

<sup>22</sup> I am also a professionally qualified scientist having taken my Fellowship examinations in Immunology (1983, Institute of Biomedical Sciences).

3. **Historicity:** activity systems are shaped and transformed over time. Their problems and potentials can only be understood in the context of their own history.
4. **Contradiction:** historically accumulating structural tensions within and between activity systems that constitute sources of change and development.
5. **Potential for expansive transformation:** activity systems move through relatively long cycles of qualitative transformations as individual participants begin to question and deviate from its established norms. “A full cycle of expansive transformation may be understood as a collective journey through the zone of proximal development of the activity.”

These five CHAT principles address methodological rigour in ways that do not conflict with the concerns of critical ethnographers, action researchers or reflexive practitioners on the basis of their relationship to the research setting and research participants. Moreover, the traditional divide between theory and practice is bridged by CHAT. Core conceptual categories are brought into “fruitful contact with practice” as analytical tools in their subsequent adoption within a conceptual-analytical framework (Engeström, 1999b:22). In addition, by this means, core categories may be empirically tested through their application within an evaluative tool, which is subsequently validated.

However, Nardi raised four main methodological considerations based on applying these five CHAT principles to a developmental research project (adapted from Nardi, 1996: 235-246):-

1. Allowing for research time frames long enough to understand subjects’ objects, since changes over time in objects and their relationships must be studied.
2. Paying attention to broad patterns of activity rather than narrow episodic ones that fail to reveal the overall direction and import of an activity.
3. Using varied sets of data collection techniques including interviews, observations, video, and historical materials, without undue reliance on any one method.

4. Committing to understanding things from the subjects' viewpoint –adopting a learner-centric enquiry process.

Thus, in its application as a DWR or EDR methodology, 3<sup>rd</sup> generation activity theory offers many challenges, not least of which are the consequences of these *methodological considerations*. In this study, the main challenge was organising and making sense of the mass of data gathered about training practices in this community over a period of five years, including internal and external artefacts (articles, surveys, evaluations and job advertisements). Reporting this varied and extensive data was an even greater challenge.

However, according to Engeström (1987: 13) this is a common difficulty faced by expansive researchers, since "...reporting and assessing the outcomes of expansive research is not easy". His recommendation for following and recording the "voyage through the zone of proximal development"<sup>23</sup> is by

*"...employing a set of multiple methods, ranging from phenomenological and anthropological observation and historical analysis to rigorous cognitive analysis of performances, conceptions and discourse processes."*

Moreover, he provides a 'simple rule' for reporting, which is to "reproduce the actual course of the expansive transition, following its basic temporal structure. This does not exclude seemingly atemporal excursions and digressions into conceptual, descriptive, statistic, experimental and comparative terrains.

Despite the flexibility offered in this rule, its all-encompassing nature does not simplify the task of reporting. But, again this reflects the challenge of organising a vast quantity of data. Moreover, by virtue of the ethnographic techniques employed, preliminary analysis of the concept of practice could be offered by way of thick description in order to describe *what was happening around here*, in terms of: the common approaches (pedagogies); standards

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<sup>23</sup> In his study of child development, Vygotsky (1978: 87) defined the zone of proximal development as "...the distance between the actual developmental level as determined by independent problem solving and the level of potential development as determined through problem solving under adult guidance or in collaboration with more capable peers.

(internal goods of practice); and language style or idiom (epistemological frames of discourse or EFsD).

The challenge lay in deciding how to structure the presentation of this data, in terms of deconstructing its constituent complex activity, and specifically, how to frame it within the unit of analysis, which in this instance is the TF.

#### **4.2.4 Developing methodological rigour in a CHAT research approach**

##### **4.2.4.1 Analytical strategy**

With hindsight, the starting point of my research concerned “gaining a preliminary phenomenological insight into the nature of its discourse and problems as experienced by those involved in the activity” (Engeström, *ibid.*(5): 5). At this stage, my aim was to highlight primary contradictions “...beneath the surface problems, doubts and uncertainties experienced among the participants of the activity” (Engeström, *ibid.*: 5). Once I accomplished this as the first step in my EDR study, I was then able to delineate the Trainers’ Forum as the activity system under investigation. In effect, this meant specifying the limits and locus of the activity being investigated in terms of the people involved and their location.

Having developed insight into the context of the activity or practice being examined, the next step or phase in EDR involved rigorous analyses of the activity system, namely: -

1. Object-historical analysis of successive developmental phases of the activity system in terms of the qualitative transformations of the object (clinical research training practice)
2. Theory-historical analysis of concepts and models used/professed in the activity system (partly constructed within the activity and partly imported into it)
3. Actual-empirical-analysis of the activity, actions and operations

Accordingly, in this study, CHAT (Engeström, 1987, 1999a, 1999b) encompassed a theoretical framework, and a methodology that guided the development of my analytical

framework concerning the *concept of practice* within an emergent professional community of trainers.

Using this theoretical framework, I sought to pull together a number of seemingly diverse strands of philosophical or sociological debate about the nature of practice. These strands were pulled towards an account of human practices in terms of actual social interaction. In particular, this focus on the relevant associated activity is reminiscent of the *practical turn* away from a metaphysical explanation of human behaviour, which attempts to describe observed effects in terms of *ill defined inherent properties or mechanisms* (Bohman 2008; Jost and Hardin, 1996; Turner 2008). In this respect, any proposed *theory of practice* is not focused specifically on theory as “...a formal system of hypotheses that generate explanations and predictions”. Instead, it encompasses the declarative, procedural or empirical models or concepts of practice observed within a system of activity (Turner, *ibid.*:4), especially since the “situated nature of activity systems indicates that they are rooted in historically developed and conditioned practices” (Meyers, *op.cit.*: 8). Therefore, the tools, concepts and principles that over time mediate activity within the Forum, also reveal its systemic history.

#### 4.2.4.2 Triangulation

As outlined in this chapter, this study was designed to answer the question: *what's happening around here?* Accordingly, observations of Forum activity were used to ask questions of community members, both informally at meetings, and formally through pre-arranged interviews and questionnaires. On this basis, multi-source data was gathered by different methods. Findings were then corroborated across data sets, and interpretations checked for consistency. Therefore, as a consequence of the research design, methodological triangulation may be considered in this study in two ways:-

- First, data was gathered from the same sources (CoP members) using different methods (observation, survey and interviews).

- Second, data was gathered from different sources (CoP members; artefacts from TF meetings; field artefacts: job ads, publications) using the same method (observation).

In addition, categorising trainers according to their level of participation in their CoP, allowed analyses of data gathered from different perspectives (core, active, peripheral members) using different methods (observation and interviews). In effect, analysing these perspectives on the basis of differentiated participation in the Forum acknowledged the multi-voiced constituency of this activity system, according to Engeström's (2001) second principle of CHAT.

Moreover, because of this constituency, the object of activity is "constantly in transition and under construction, and "it manifests itself in different forms for different participants and at different moments of the activity" (Hasu and Engeström, 2000: 4). That is, individual subjects in the community construct the object of activity in myriad ways. How it is shaped reflects their own histories and depends on their relative position in the system of activity (i.e. according to the division of labour). Such shaping is also contingent on the mediating tools available to them (Engeström 1999; op.cit.).

Moreover, interviews serve to deepen and enrich the raw data gathered through observation about the object of study, rather than merely check its coherence or accuracy with CoP participants, since inconsistencies provide an opportunity for further exploration.

Nevertheless, methodological triangulation assumes convergence between "independent measures of the same objective", leading to a *convergence of truth* in the findings (Campbell and Fiske, 1959), which provides more confidence in the credibility of findings, or in the construct validity. That is, when I set out to assess what I defined as "the concept of practice" have I sufficiently demonstrated that this is actually what I am assessing? Moreover, were my methods and instruments suitable for this purpose? In essence, construct validity can be claimed when our observed patterns in data - *how things work around here* are consistent with our theoretical patterns - *how we think the world works* (Trochim, 2006) i.e. in relation to our activity in our CoP and/or our field of practice.

Trochim (ibid.) suggests five criteria to judge research designs: -

1. *Theory-grounded*. Good research design finds its roots in theories, that is, it has the power to test the existing theories as specific theoretical expectations are incorporated in the design.
2. *Situational*. Good research design reflects the setting of the investigation. The design comes up with strategies to cope with situational threats to validity such as "intergroup rivalry, competition".
3. *Feasible*. Good research design takes reality into account. The design anticipates potential problems in implementation, measurement and if necessary, includes additional groups or measurements.
4. *Redundant*. Good research designs duplicate some essential design features.
5. *Efficient*. Good research designs also refrain themselves from overdesign.

Therefore, in the following sections, concerning issues associated with data gathering methods, I will consider how my methodological approach is consistent with the nature of the research, where the aim is to explain the role of social context (i.e. ideology or discourse) on the objective regularities of practice (surface appearances of everyday life) within a community of trainers. Moreover, the issues of reliability and validity are also considered in this research study, which is developmental in nature, in the following terms:-

- Have I asked the right questions, to find answers within my study?
- Have I designed appropriate instruments that each consistently get to the heart of what is happening inside my CoP (e.g. questionnaires, interview schedules and interpretative analytical frameworks)?
- Have I defined my concepts clearly, so that my analytical frameworks are transparent?
- Have my data been gathered in ways that are appropriate for the nature of the research study?



- Will my data be analysed in a rigorous manner that will allow my propositions or hypotheses and conclusions to be judged as trustworthy and credible?

### **4.3 Data gathering methodological issues**

#### **4.3.1 Stage 1 Research: Initial methodological issues**

In the initial stages of my research, I attended Forum meetings initially to access my community of practice. On the one hand, such access presented a useful networking opportunity. On the other, it provided an opportunity to learn about current thinking in training circles, through interacting initially at three levels: (1) informally via conversations with fellow attendees; and (2) formally via sessions run by “speakers”, “presenters” or “session leaders” and (3) formally via leading or presenting a session or sessions. Finally, a fourth level of interaction emerged, following an invitation to join the Steering Group that organised and managed Forum activities.

Therefore, my aims in attending Fora were four-fold, namely:-

- To informally “sound out” topics of common interest or concern within this public space, in order to formulate my research ideas with fellow trainers.
- To establish initial contacts with the intention of identifying prospective interviewees.
- To gather information / data about current perspectives on training issues.
- To explore common understandings of training practices.

Moreover, I considered this as laying foundations and preparing groundwork for my research study, although the focus was still nebulous during this initial phase.

I attended meetings in hopes of sharing experiences with fellow attendees, and perhaps gaining ideas for research. In effect, I hoped to learn through observing and reflecting on the topics under discussion. In particular, I was in a phase within my own practice that involved reflecting on shared elements of practice as well as dissimilarities due to differences in individual practice settings. In addition, I volunteered to lead a session at the fifth Forum on a

topic of intense interest (*What constitutes training records for the purpose of GCP inspections?*) in order to debate how, as trainers, we might consider our standards of practice from a theoretical perspective as well as the usual empirical one. By contrast, all other sessions of this Forum concerned colleagues' feedback from their experience of inspections and inspectors expectations of training standards. The proposition I put forward to the Forum was how we might determine our standards internally for ourselves, rather than accept an externally imposed quantitative model (i.e. for twice yearly GCP training based on inspectors' recommendations). This proposition was also contextualised in my session by explaining that it was part of a research exercise for my doctoral research.

Thus, in all of my interactions at each Forum either as a Forum participant, or on this occasion as a session leader, I declared my role as a researcher to those with whom I interacted, either informally during breaks, or to the wider audience during sessions. I did this openly because of my expressed aim to gather information. The decision to "go public" with my researcher identity, when I first attended the Trainer's Forum, was a conscious effort to start sharing ideas about CPD and training issues, and to announce myself to potential research interviewees. It also began the process of forming relationships.

However, I did not articulate my role at the first few meetings I attended. Principally, this was because I neither defined nor categorised my role as an observer, nor delineated my activity as observation. At this initial stage of research, my focus was on formulating the object of research and not on the methods used to explore it. Nevertheless, observations of fellow trainers' practice and related issues were recorded in field notes. Further, I categorised them initially as field notes because, as well as capturing "snippets" of expressed views and reactions, they contained my reflections on issues discussed at the TF, including instances of contradiction.

In particular, I found that although I had common experience of some of the perceptions held about training among my community of practice, others struck me as odd because they were contrary to my understanding of training process, which intrigued me. Specifically, I

wondered if negative perceptions I observed - about the limited value of evaluation - reflected a particular form of 'organisational' or 'functional' thinking, which I did not share, especially given my status as an independent trainer. I noted these incongruent instances of what I saw and heard, mainly because I was shocked by the apparently consensus view that *evaluating training is a waste of time*, and by the lack of challenge to this view. Rather, in contrast to my expectation of challenge, this negative view was reaffirmed by several speakers, all of whom conveyed their agreement by quoting from Tom Peters, the entrepreneurial management coach "...hire for attitude. Train for skill" (original source: Carbonara, 1996).

Since the process of constructing the object of study is time-bound, my focus developed with progressive clarification, as levels of complexity were appreciated over time such that the multidimensional nature of the object was further refined. In essence, within my field notes, I was following an analytic strategy that involved picking up on paradoxical or incongruent aspects that appeared to 'stand out' for some reason, like the example given previously. These statements or 'incidents' that puzzled or intrigued me were captured initially with quotations, utterances or snippets of conversation, that conveyed the essence of the paradox or incongruity, as I perceived it at the time. These quotations then served as an aide-memoir such that further detail could be further recalled as paradoxical aspects were correspondingly unravelled. As I discovered, this technique offers a way of "mapping the woods" or navigating the research topic such that focus is rapidly refined (Macnaghten and Myers, 2004) as the object of research is conceptualised. In effect, I was collecting "snippets" that I would later conceptualise into categories, and build into my conceptual coding matrix as representations of the objective regularities of practice. By this means data was simultaneously selected and sorted into categories.

Subsequently, over time with continued attendance at various meetings, I appreciated that I was observing the dynamics not only of a community of practice in action but elements of practice being modelled within this dimension, which in turn revealed epistemological beliefs fundamental to the concept of training as a practice. This realisation is consistent with

Wenger *et al*'s (ibid:38) conceptualisation that ...*Through its practice – its concepts, symbols, and analytic methods - the community operates as a living curriculum.* Moreover, as Wenger *et al* (ibid.:9) state, with regard to expertise resident within a community of practice: the knowledge of experts is an accumulation of experience - a kind of “residue” of their actions, thinking, and conversations-that remains a dynamic part of their ongoing *experience*.

It might be argued also, that a community of practice is a type of cultural context, and therefore, public spaces within it are the means by which the community can be observed in action. Therefore, as a consequence, I appreciated that my observations, conceptualisations and resultant insights formed the nub of my research, and thus constituted both raw and analytic data, respectively. At this point, I wondered how I should consider the issue of permissions concerning my observations in a public space, albeit within my professional community of practice. In the first instance, whom might I approach for permission to observe? Was permission actually needed to conduct observation, given that I was already privileged to be a paid-up member of this community within the professional confines of the Institute of Clinical Research? Who should I consult? The answers to these questions are discussed in the next section.

#### 4.3.1.1 Access and permissions

The researcher's insider / outsider status, in relation to the research setting, determines practicalities of access. For example, in this instance, as an insider, there was no need to formally negotiate access to this public space. Attendance is open on a 'first come first served basis' to all members of the Forum, who can book their place, in response to a general e-mail notification alerting all ICR members to the date of the next meeting. Meetings are organised by trainers for trainers, and are positioned as an opportunity to meet and discuss issues of current interest. However, within the Institute of Clinical Research, the TF is constituted as a Steering Group or committee rather a Special Interest Group (SIG), as the latter tend to work closely on special projects with the ICR.

Even if access to my community of practice is not an issue, did this obviate the need to seek permission to conduct my research? Does the omission of this step mean the observational mode was covert, which by implication raises an ethical concern regarding a possible intent to deceive? This depends on the purpose and intent of my research (Mulhall, 2003).

As a member of this community, it was always my intention to build relationships: as a source of research ideas; a source of participants and eventually, a source of data. Besides, my original plan from the outset was to conduct interviews with members of the community about CPD, helped by whatever insights emerged from being part of the Trainers Forum. Moreover, my reflections were constituted by my observations, which were conducted without the intent to deceive - the main ethical concern regarding the covert status of a researcher. As such, my observations did not interfere with the normal activities of the Fora, where members had a choice, like me, to interact within the community and to participate either within this public space or privately.

Yet, if all members are equally entitled to make their own observations within this public setting, on what basis might the researcher be distinguished? In the initial phase of my research, I was open about my researcher status, but I did not articulate the act of observation at this stage since my focus was on understanding the object rather than the methods used to explore it.

However, by the exploratory phase of my research, my engagement, although episodic, which reflected the nature of the research setting, intensified both in terms of my participation and subsequent observations. As the research developed, as a means to tentatively validate my initial insights and observations about the object of research (our shared practice), I shared these with fellow community members, both within private spaces and within steering group meetings. Therefore, immersion within the research setting was indicated by relationships that formed over time with other Forum members.

The process of consultation with the membership about observing “*what happens around here*” was unobtrusive and gradual, like the process of observing itself. From the start I shared

my intent to conduct research with the membership, by sounding out my fellow trainers about the ways in which they might help me. Over time, fellow Forum participants expressed interest and support in my developing articulations. Their willingness to help with the research endeavour was demonstrated by those who later became interviewees. Moreover, my observational data and insights were constituents driving both the questionnaire and the interview schedules. Therefore, by this means of methodological / participant validation, I was testing my hypotheses, derived from my observations.

In addition, by about the third meeting of the TF, I discussed with the ICR Forum co-ordinator the possibility of distributing a questionnaire to the membership, when the time came. The co-ordinator advised that distributing the research questionnaire in person at the Fora was probably the best option since the ICR would claim copyright on my data if an electronic questionnaire was posted via the ICR website.

Therefore, I made no secret of my researcher status. Although I initially articulated my research ideas with fellow TF members in the context of the TF being about CPD, over time the object of study changed as I developed an understanding of the various layers of social reality. Moreover, my developmental approach to the object of research became evident when I volunteered an activity-based session. This was designed around the question of how we can demonstrate to regulatory inspectors that our training is effective through our training records. Once I recognised the role of my observational data in exploring this object, I decided to seek permission to observe formally. However, as I soon discovered, the process of seeking permission from a dynamically heterogeneous community raises its own particular set of issues.

From a practical point of view, seeking permission from individual attendees of each TF meeting, both to observe and to 'go public' with insights via potential publication, was logistically challenging and difficult. Different members attended different meetings over the course of my observations. In effect, this would have meant producing an average of 60 to 80 consent forms for each meeting, assuming a 100% response rate.

As another alternative, within this particular setting, permission might have been negotiated via a 'gatekeeper', whom Wenger *et al* (ibid.) define as the individual who maintains information flow or who determines access and drives activity within the community. However, this assumes the gatekeeper has the power to grant or obtain such permission democratically on behalf of the membership. Yet, during initial observations, there was little evidence of inclusive or democratic processes in play in the workings of the TF. How participants became Steering Group members was unclear: were they elected or self-appointed? Nevertheless, before the start of one particular TF<sup>24</sup>, I approached the 'acting' gatekeeper for advice about how best to circulate my questionnaire and consent form to all participants. The consent form included the request for permission to use data gathered for the purposes of research.

The first issue raised by the gatekeeper concerned the need to avoid conflicting or interfering with the normal 'business' of the TF in circulating these documents. For example, on the occasion I planned to distribute them, a core member was also distributing a GCP quiz, which meant that I risked overloading attendees with 'paperwork'. As such, the concern was that the response rate to both items might be reduced, which in turn could disrupt activities planned for the meeting.

The next issue concerned copyright of session presenters' material, even though presentations were often posted on the ICR website without presenters' express permission, as happened in my own case, although I had no objections. I explained to the gatekeeper and the presenters that I was not interested in specifics but in general issues that arose from discussions. A few of the presenters then completed both questionnaire and consent form. Rather than express an objection to my research some presenters and attendees expressed interest when I engaged them in conversation. A few more attendees also duly completed and forwarded the

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<sup>24</sup>TF held December 2006

questionnaire and consent form. Finally, others remained remote, or disinterested in becoming actively involved in the research. Despite my open pleas for their collective help in completing my questionnaire, the majority (22 out of 28 attendees) preferred to remain uninvolved.

Further discussions established reluctance due to confusion over the purpose of the consent form, or disinterest. However, further unanticipated difficulties in seeking permissions from attendees of specific Fora were then revealed. For example, of the six who completed the questionnaire distributed during the TF, only four returned the consent form. By requesting permission to use “data gathered”, I failed to differentiate whether this concerned data from observations or from the distributed questionnaire. So, were non-responders refusing permission for me to use data gathered from my observations or simply not inclined to respond to the questionnaire?

Rather than speculate on why this happened i.e. why the response rate to both my questionnaire and consent form was not as I had hoped, I established through informal discussions with attendees and presenters, at this and subsequent forums that most felt the questionnaire did not apply to them. Hence, few considered the consent form relevant.

The issue of the questionnaire's relevance revealed that some attendees were involved indirectly with training i.e. as e-learning software programmers, or as administrative members of other professional bodies networking and trawling to enlist “suitable” trainers to help in their organisations. Others had only recently assumed responsibility for training in their role on a part-time basis and felt their lack of experience excluded them as suitable respondents. When I pointed out that the consent form also concerned permission to observe, none had an issue with being observed for the purposes of research. Some then elected to complete the questionnaire but not the consent form, because as they explained to me, completing the questionnaire signified their assent to use the data it provided. I subsequently received these completed questionnaires in the post.



Although access was not an issue in this research setting, I had inadvertently and unintentionally created an ambiguity, by using one combined consent form to seek permissions for use of observational and questionnaire data. In seeking individual consents, I had created an ethical dilemma. How could I use observational data gathered at this particular Forum to take account of whether non-responders were disinterested passive bystanders or because they objected to being observed?

The issue of obtaining consent from survey respondents is equally problematic (Singer, 1978; 2004). For example, informed consent statements may affect perceived risk of breaches of confidentiality such that potential respondents are discouraged from participation. Or, they may be willing to participate in a survey but perceive risk when asked to document their consent with a signature because “they believe that the consent form compromises their anonymity and protects the research organisation rather than respondents.” (Singer, 2004:2).

Therefore, whereas in clinical research, participants must be made aware of the risks as well as the benefits to their health and wellbeing before participating in studies involving experimental treatments, in social or educational research consequential harm is perhaps more nebulous, although no less significant. The key difference is perhaps that risk concerns mainly breaches of confidentiality and their consequences, such as damage to participants’ reputations or consequential material losses.

Paradoxically, too much emphasis on assuring confidentiality, if the risk of breach is minimal, creates suspicion and concern leading to less participation (Berman et al, 1977; Reamer, 1979; Frey, 1986; Singer, Hippler & Schwarz, 1992; Singer, Von Thurn & Miller, 1995). In the context of social or educational research, if the risks to respondents concerning breaches of trust, confidentiality or privacy are minimal, the need for consent may be obviated, since consent is implicit in the act of completing the survey (SRA, 2003). Hence, if questionnaires are returned anonymously and cannot be traced back to the respondent by any means, then respondents’ confidentiality is also seen to be preserved. According to the guidelines of the

Social Research Association (SRA), preserving confidentiality is a core responsibility in the conduct of research, particularly since

*“...The principle of informed consent is, in essence, an expression of belief in the need for truthful and respectful exchanges between social researchers and human subjects. It is clearly not a precondition of all social enquiry. Equally it remains an important and highly valued professional norm. The acceptability of social research depends increasingly not only on technical considerations but also on the willingness of social researchers to accord respect to their subjects and to treat them with consideration.” (SRA, *ibid*: 29).*

So, if obtaining consent to observe from individual TF members was an issue but access was not, could I still justify using observational data? Moreover, did this difficulty suggest a difference between negotiating permission to access a community for observation and seeking consent from individuals to observe? In some instances a distinction may be made between negotiating permission for access and seeking consent (Vinson and Singer, 2004). Hence, in the circumstances of a community of practice, with an assumed shared passion (about training), but possibly diverse interests (in different aspects of training), achieving a consensus for consent proved unrealistic.

As an insider to this CoP, I was uniquely placed to conduct this research. Moreover, as a clinical researcher of twenty years standing, I was acutely aware of my responsibilities to protect the rights of research participants to anonymity without compromise. As an educational researcher I also worked to the revised British Educational Research Association (BERA) guidelines (2004). But, in this research setting and given the unfolding nature of the research endeavour I could not see a way to actively engage the commitment of all who attended each of the eleven Forum meetings I observed. I could only address issues of confidentiality or permissions on an individual basis.

Nevertheless, as explained previously, my intention (to explain the *how*, *what* and *why* of our discussions about topical training issues as a CoP) was not to be deliberately covert.

Moreover, my role as researcher was neither secret nor hidden during my participation at Training Fora. However, in the early stages, my research aims within the TF were less than clear. A lack of transparency in my methods overlapped with lack of clarity in my research

aims, reflecting the cloudiness inherent in the initial stages of research before methodology is articulated.

Yet, even if access to a professional public space, representative of a CoP, is relatively easy to an insider as in this instance, such accessibility does not automatically imply amenability either to the act of observation or to such observations being publicly documented even if the intention is to improve the CPD endeavour for all concerned.

However, in this case, accounts of activities or topics covered or discussed during meetings were openly published in the general magazine of the Institute, which implied that Forum meetings were not considered a protected space within the Institute. In addition, some guest presenters, speakers or session leaders included non-institute members. Again, this implied openness to outsiders, particularly in terms of their 'expert' input, who were then free to relate their experiences of the Forum elsewhere, such as in their own field of practice. The ultimate indicator of this openness to scrutiny was the uploading of a session run by one of the core members to the internet via the publicly accessible You-Tube video website. The link to the videoed sessions was also published by the Head of the ICR membership services, on the ICR website shortly after uploading.

Finally, I was invited into the core membership of the TF after attending only a few meetings, both on the basis of publicly mentioning my research and due to my level of participation. Such admittance suggested acceptance of my researcher status. A few core members were aware of this status from my first attendance of the Forum, because I had discussed it with them in general terms<sup>25</sup>. Moreover, during a steering group meeting, no objections were raised to my declared intention to use feedback, collected by this core group from attendees, for the purposes of my research<sup>26</sup>.

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<sup>25</sup> Initially, my research was explained as exploring the nature of CPD and its implications for practice within the TF.

<sup>26</sup> SGM held after Trainers Forum\_10/H:: 20th September 2007 "Participation: Making Learning the Priority"

Consequently, my decision to use observational data gathered in this naturalistic setting was based on a number of factors, which hopefully resolved ethical issues concerning confidentiality or informed consent:-

- I had no access or amenability issues as an participant-researcher to my CoP
- My intention was not to deceive the CoP but to explore it and contribute to it
- As an participant-researcher, I did not attend the TF under false pretences i.e. solely for the purposes of research; I was also there to network with colleagues as well as contribute to discussions
- My observations were crucial to developing understanding of the object of research as well as to the development of further research tools
- The research findings hopefully will further my contributions as a participant in the CoP
- As an insider, I will remain an active participant in this community after my research endeavour is complete.

### **4.3.2 Stage 2 Research: Exploratory methodological issues**

#### **4.3.2.1 Questionnaire**

The purpose of the questionnaire survey (Appendix B) was to establish demographics concerning practitioners and their practice settings.

Initially, its purpose was explained to potential respondents in a Research Information Sheet (RIS-1: Appendix C) in its wider context of the effects of regulations on training practices including evaluation. When this RIS and Informed Consent form (ICF-1, Appendix D) was circulated at the TF in December 2006, I envisaged my main objective as examining relationships between practitioners' characteristics, practice settings (organisational characteristics, support frameworks and constraining factors) and their training practices. I

also defined my aim as being about identifying the differences trainers make as practitioners to training process, compared to subject matter experts.

Through this explanation, I appreciated the wider context of the research aims, from which alternative propositions would begin to emerge and shape my object of research. Therefore, although my understanding of the object changed, the questionnaire still fulfilled its purpose in gathering information to further elaborate collective understandings of practice. Common understandings of the concepts of reactivity /pro-activity were explored, since these terms were repeatedly used within Forum meetings but without further explanation.

A number of problematic issues related to implementing the questionnaire have already been discussed in the previous section. However, another reason for the vast majority of TF members failing to complete it might have been the large number (thirty-eight) of potentially intrusive question items in the questionnaire. For example, in the same Forum, the response to the GCP quiz, with ten questions, was almost 90%.

With hindsight, the explanation for the purpose of the research was simplified in a subsequent version of the RIS i.e. when the questionnaire was circulated by e-mail in February 2007 (circulated e-mail re RIS-2, Appendix E) and later distributed again at other Forum meetings (Appendix E: RIS-3 May 2007; and RIS 4 March & June 2008). The working title of the research was also modified in the consent form circulated in March & June 2008 consistent with the object of research becoming clearer over time (ICF-2, Appendix F).

After I expressed my disappointment with the response rate following distribution of the questionnaire at the December 2006 meeting (despite it being a response rate of just slightly over 20% of attendees), an administrative liaison of the Institute offered to distribute the questionnaire via e-mail. This generated most of the further responses<sup>27</sup>, bringing the total number of respondents to approximately 25% of the estimated total membership of the Forum

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<sup>27</sup> Circulation at subsequent TF meetings generated five more responses.

(i.e. 31/ 120 based on an e-mail listing circulated in the summer of 2005). Again, as with the response rate at the meeting when the questionnaire was first distributed, perceived irrelevance and disinterest were still possible reasons for this rate of return.

In terms of questionnaire design, unless there is a deliberate endeavour to balance positive and negative statements throughout a questionnaire at the construction stage, difficulties can arise with response sets, or bias (Verma and Mallick (op.cit.:202). According to Bailey, Bemrose, Goddard, Impey, Josyln & Mackness (1995), the main difficulty is with respondents' tendency to agree rather than disagree, so called 'yeah saying', although, 'neay saying' is apparently also possible but less common. However, such conformity possibly presupposes political sensitivity in the question items related to the subject matter being explored. Hence, the challenge in questionnaire design remains that of asking direct questions that are clear and non-leading. In this instance, question items were neither positive nor negative, but open.

As one respondent pointed out, with questionnaire item numbers 4 and 5 regarding methods and strategies — deciding whether to conduct training via the classroom or e-learning is about strategy; and deciding whether to design the training actively using role plays, exercises or passively using lectures is about methods. These item definitions were unintentionally reversed in the questionnaire.

Also in the first draft of the questionnaire, item number 25 asked whether respondents were *graduates* rather than *science graduates*. This item was revised in the second draft together with items 26 and 27, which were amended to request further details of respondents' postgraduate and/or training qualifications. Fortunately, this data was volunteered by the majority and missing for only two of the six respondents who completed the 1<sup>st</sup> draft questionnaires circulated at the December 2006 Forum.

### **4.3.3 Stage 3 Research: Confirmatory methodological issues: Interview schedule**

By the third and final stage of the research, the point had been reached where extensive participant observation and informal interviews had raised issues requiring further examination through formal interviews. However, I had a dilemma over whether to conduct these as open-ended (i.e. unstructured) or semi-structured interviews. Open-ended interviews risked failing to get beneath the surface of participants' accounts of what was happening at the forum due to potential digressions causing the conversation to go "off topic". On the other hand, too focussed adherence to a semi-structured interview schedule could risk missing subtle cues regarding emergent issues raised by interviewees. Thus, the challenge in a semi-structured interview is to find balance between taking and exploring a worldview of the TF and the issues within it, as well attempting to appreciate the TF from participants' perspective. Therefore, the main drawback of this type of interview is that the interviewer fails to register any inconsistencies, discrepancies or incongruities during the interview itself (McAteer, 1999).

Although an open-ended interview might avoid the distracting effect of an interview schedule, it could be argued that even greater interpersonal skills are required to probe and to listen, since both skills affect the interview process (Paterson, 1997). For example, if the interview is 'a conversation between two people working together', then the social interaction is part of the process, particularly when rapport can facilitate discussion about the research topic, and especially in the sense that rapport is "...a basic sense of trust [*which*] allows the free flow of information" (Spradley (1979).

Even so, irrespective of the type of interview, it might be argued that "realness, genuineness and congruency" are the most basic of three essential 'attitudinal' qualities for facilitating the interview process (Rogers, 1983). These qualities may be put into practice provided that the interview schedule is designed with care, thus avoiding phrasing questions in a way that leads interviewees or informants in their responses, a process Lee (1993) referred to as 'transference' and 'counter-transference'.

As a midway position between an open (unstructured conversation with the study participant) and a structured interview (which allows for little deviation from the schedule), the semi-structured interview strikes a balance between:

*“allowing the variety of responses from one interviewee to another and reasonable consistency in the interviewer’s approach” Verma and Mallick (1999:124).*

Such consistency incorporates an element of rigour into the methodology. Therefore, my interview schedule was built around prior analysis of discourse and issues raised through observation. By definition, this composition ruled out an open-ended approach in that interviews were directed at finding out more about interviewees’ understanding of the TF, its purposes, and its leadership.

The original schedule piloted with two informants, consisted of four main sections and totalled almost 60 question items: Employer details & background; concept of practice: activities & standards; TF organisation & processes: how the TF works: common & dominant interests; CoP participation & relationships.

This schedule was simplified and condensed into two main parts comprising two sets of twenty consolidated items, and conducted as two separate interviews. In the first interview schedule, the focus was on the TF participant’s background: employment history, qualifications, training experience; and his/her concept of practice (Appendices G and H). Interviews took anywhere between half an hour to an hour depending on the interviewee.

In the second interview schedule, members’ relationship to the TF and their understanding of how it was organised and how it worked was explored. This interview also lasted between thirty minutes and an hour depending on the interviewee.

Neither schedule was followed in stringent order of the items, reflecting the fluid, flexible and conversational manner in which both interviews were conducted. Hence, if the interviewee raised an aspect, which coincided with a scheduled item, but not necessarily in the scheduled order, it was explored in the order in which it occurred during the interview.



## **4.4 Data analysis methodological issues**

### **4.4.1 Quantitative data analysis issues: Generalisability**

Data analysis methods reflect the nature of the data gathered (GAO/PEMD, May 1992).

A questionnaire-survey was used in this study. However, the data or values gathered were based on categorical or qualitative variables, mainly of the nominal type, with no inherent numerical properties. Although such variables may be quantitated, using Likert scales, nominal data have the least scope for meaningful statistical analysis (GAO/PEMD, *ibid.*). That is, unlike ordinal variables, values assigned to nominal variables cannot be compared or ranked in any meaningful numerical order. An example of a nominal category from my questionnaire is *organisational tendencies* or *organisational characteristics* or *trainer characteristics*.

Accordingly, descriptive and not inferential statistics were used to summarise, describe and explore data, where appropriate.

Consequently, no attempt was made to infer statistical generalisations on the basis of findings concerning causal relationships in this study, since the object of research was not defined and explored in experimental terms, in which such quantitative methodology best applies. Rather, a qualitative methodology was applied. Therefore, because propositions were theoretically derived and empirically tested within a specific context, whether *what happens around here* can be generalised in conceptual terms to other settings and their objects depends on finding similarities in patterns between their features, conditions and circumstances.

### **4.4.2 Qualitative data analysis issues: Study limitations**

The limitations of this research generally depend on the ontological complexity of the object of research, my researcher's capability to delimit its context and the methodology used to examine it. In this study, a conceptual-analytical framework was developed progressively and adopted in order to define, then to illuminate the features of the object of research, which clarified the focus.

Perhaps the main limitation of my research approach in the role of 'participant-observer' is that because of full immersion in and closeness to the research object occasionally I may not be able to "see the wood for the trees". Nevertheless, rather than considering lack of distance in terms of a loss of objectivity, this predicament, of an occasional mental block in the analytical process, is resolved through systematic perseverance, as well as a critically reflexive approach. Furthermore, processing raw data from fieldwork through open coding, then conceptualising it as categories is a laborious technique (Strauss and Corbin, 1990) that develops, if not demands, a level of familiarity, with the object of study in all its dimensions. By this means, through recognising concordances, discordances or discrepancies, the *familiar* can also be rendered *unfamiliar*.

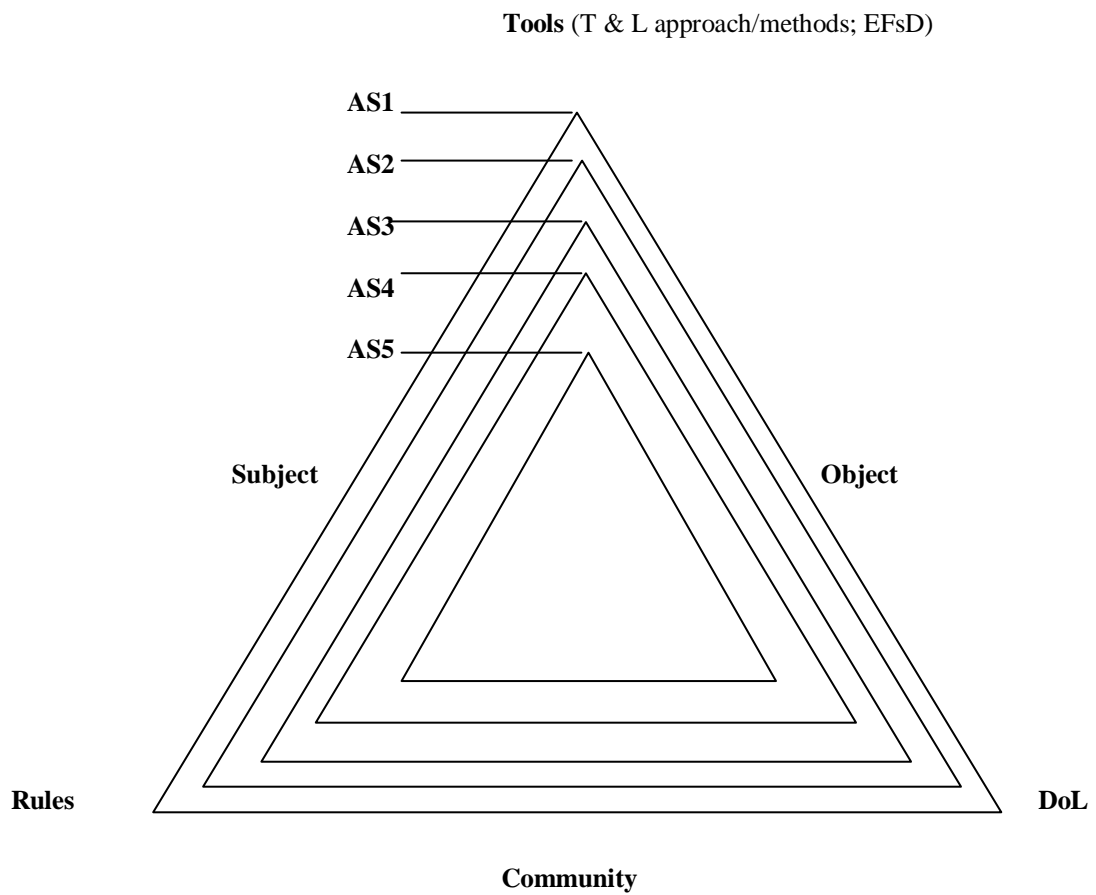
In addition, such concepts grounded in the data are rigorously tested through constant comparison, with theoretical sampling of data gathered by different techniques from a variety of sources. So, for example, in my study, the initial raw data (which started with field notes where 'live' snippets of conversation or utterances were collected during meetings) were progressively conceptualised into categories. These categories were then refined through progressive comparison eventually with data gathered and coded from transcribed digital recordings of entire meetings. By this means, concepts were firmly bedded or grounded in data that were captured in varied ways, from varied sources, reinforcing the methodological validity of the research design and the theoretical consistency of propositions that emerge through that design.

Mind mapping software was used to closely manage the coding process due to the volume of the data corpus, highlighting that being overwhelmed by data is a potential limitation of an EDR approach. Mind mapping provided the means to visually organise concepts and to visualize relationships between categories and sub-categories. What emerged from the coding process were the core categories of *concept*, *methodology* and *experience* of practice. These categories were then framed using an AS model to examine *what happens around here*

shown in Table 4-2. Meanwhile the TF was delineated as an activity system shown in Figure 4-1.

In effect, using EDR, the TF was approached as a nested activity system, where the link between the concept of practice (expressed within contrasting pedagogies and their associated idioms) in the Trainers' Forum and the larger socio-cultural context was explored in order to further understand “*why we do what we do*”. The research design and methods used to explore the Trainers' Forum are described in Chapters 5 and 6 respectively.

**Figure 4-1: Modelling the TF as a nested Activity System with five ontological layers**



Key

- AS 1: The regulatory environment
- AS 2: The field of practice
- AS 3: The workplace
- AS 4: Institute of Clinical Research (ICR)
- AS 5: Clinical research Trainers Forum (TF) in the ICR

**Table 4-1: Methodological framework showing the approach, methods and tools used to explore concepts in different phases of research.**

#	Phase of Research	Exploratory Concepts	Research Approach	Methods for gathering evidence	Tools for gathering evidence	Data Source
1	Initial	Formulation of research ideas re Community of Practice (CoP):- Community Domain Practice	Developmental using CHAT:  Object-historical stage of analysis	Participant observation  Constant comparison	Field notes; filed notes/reflective diary  Analytic memos	Discourse at Training Fora (TF) & artefacts:-  ICR magazine (CRf) & website: articles re TF sessions; TF presentations/handouts; general training articles; job advertisements; Discourse extracts incl. quotations from participant observations
2	Exploratory	Concept of Practice & its Objective Regularities (ORoP):- Structure of practice (Rules & resources) Stds of Excellence defining training Internal/external goods of practice	Developmental using CHAT:  Theory-historical stage of analysis	Participant observation  Questionnaire survey  Informal interview	Field notes; filed notes/reflective diary  Questionnaire  Field notes	Discourse within TF sessions & artefacts including:-  Collated Forum participant feedback concerning specific sessions and Forum sessions generally;  Written discourse produced by CoP members from TF meetings, published in the Research Questionnaire responses TF survey responses
3	Confirmatory	CoP as an Activity System with complex activity: Cognitive & Co-operative tasks	Developmental using CHAT:  Actual-empirical stage of analysis	Participant observation  Initial & Follow-up Interviews	Field notes; filed notes/reflective diary; TF session transcripts  Semi-structured interview schedule	Interview transcripts from trainers at different levels of participation in the TF:- Core members Active members Peripheral members Discourse at TF & artefacts

**Table 4-2: Modelling core categories as Activity System (AS) elements**

Core categories from qualitative analysis	Modelling core categories as AS elements	
Concept(s) of practice	Sharing best practices & discussing ideas about topical training issues	Central activity
	Trainers with practice issues	Object of activity
Methodology of practice	T & L approach/methods; EFsD	Tools used to mediate activity
Experience of practice	Transfer of information/co-construction of knowledge	Outcome of the activity

# **Chapter 5**

## **Research Design**

## 5 RESEARCH DESIGN

### 5.1 Overview

The focus of this study was on a community of trainers (Trainers' Forum) spanning a field of practice rather than any individual organisation. The aim was to explore "what goes on around here" and to clarify how and why things happened the way they did in the community through theoretical and empirical study.

Focussing on the Training Forum (TF) enabled detailed examination of the activity system of trainers, and of the extent to which it made progress towards becoming a Community of Practice. Therefore, the setting for the study was within the public spaces of this putative or emergent Community of Practice (CoP), in the form of TF meetings. Thus, the study was designed to answer research questions through observing meetings and by surveying and interviewing TF members. The following goals guided the respective parts of the study:-

#### Through observation

- To describe how things were done by trainers in terms of the concept of practice and its objective regularities
- To explain why things happened as they did in terms of the TF being an activity system.

#### Through surveys

- To establish demographic details of trainers' background, qualifications and workplace settings
- To discover their experiences/responsibilities related to training practice, course design, delivery and evaluation; and their definition of reactive and proactive training.

#### Through interviews



- To find out how members made sense of it all depending on their epistemological frames of discourse or EFsD (*saying-writing-doing-being-valuing-believing* (Gee, op.cit.): how they ‘saw’ what went on at the TF.

Data was also gathered in the TF from participant feedback to particular TF meetings, and from artefacts produced from the Forum (published meeting reports).

Ultimately, the aim was to examine the constitution of training practice (in terms of its constituent complex activities) via examining artefacts, observing embodied practice, surveying and interviewing members of the community of trainers in order to analyse how agents are capable of transforming practice (collective activity) through mediated action. The study was correspondingly designed to analyse data gathered about what happened at the TF as an activity system, and to examine elements involved. Study design is described in subsequent sections.

### **5.1.1 Phases of Research**

The research was designed and conducted as follows:-

#### Phase 1 Initial

- Informal observation (field notes; journal articles, adverts) to examine the structure of the community and its domain

#### Phase 2 Exploratory

- Formal observation (digital recordings)
- Questionnaire survey
- Informal discussions/conversations to determine “what goes on around here” in terms of practice, methodology and experience within the CoP

#### Phase 3 Confirmatory

To clarify how and why things happen the way they do in the CoP:-

- Formal observation (digital recordings)

- Informal discussions/conversations: in person and via e-mail
- Initial and follow-up interviews.

### **5.1.2 Setting and study population**

The setting for the study was within the public spaces of an emergent Community of Practice (CoP): Training Forum (TF) meetings. Members of the TF formed the study population, some of whom participated/attended meetings on a regular, occasional or infrequent basis. The sample of interviewees was drawn from this population, estimated as totalling almost 120<sup>28</sup>.

Members contributions within the TF were considered in terms of their observed participation status, categorised respectively as: core, active and peripheral, according to Wenger et al's classification (2002:56). The intention was to select a cross-section of interviewees from: those questionnaire respondents who volunteered; and, from those members whose participation was defined as core, active or peripheral in order to:-

- Gain understanding of the experience of core, active or passive participation;
- Build biographies of TF members at different levels of participation; and
- Develop understanding of the learning experience – i.e. how and what do they learn from participating in the TF?

In effect, differentiating agents at different levels of community participation was intended to provide a comprehensive perspective and understanding of concepts, methods and experience of training as a practice within the community.

The categorisation of members of the community according to their participation status is described in the next section on Design Strategy.

### **5.1.3 Design strategy**

If the TF is considered as an activity system: the community was formed by all who are Training Forum members, with individual trainers as subjects. The object of the activity was

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<sup>28</sup> Based on the number of TF members' e-mailed in a call for suggestions for contributors to the September 2005 Forum.

*the sharing of "best" practice and the discussion of topical training issues.* The division of labour in relation to the achievement of the activity in this particular system was compartmentalised on the basis of members' participation status as core, active or peripheral members of the CoP. That is, interviewees were selected to ensure the sample included those members observed at Forum meetings: listening, questioning, speaking, presenting, facilitating, or steering or organising meeting content. Hence, the design strategy subdivided members within the TF, according to their participation status (core, active and peripheral) as shown in the Table 5-1.

Initially, products of participation, such as discourse, TF discussion dialogue, or TF topic leaders' comments were analysed as textual artefacts in light of the participation status of contributors (core, active, peripheral).

Further to subdividing members according to their participation status, the design strategy took account of different attendance patterns among members at each of these levels. That is, where possible, interviewees were subdivided according to their attendance record: *regular*, *occasional* and *infrequent*.

Regular attendees were those members who attended more than 8 out of 11 TF meetings (or almost two thirds) held since inauguration of the Community in 2004. Occasional attendees were those attending more than 6 but less than or equal to 8 meetings (i.e. more than half but less than two-thirds). Infrequent attendees were those attending less than 6 meetings (less than half).

The intention of these differentiation strategies was to determine how attendance patterns of members at different levels of participation affected the predominant EFD at the TF. For example, within the conceptual-analytical framework, language was a mediating artefact that revealed not only a contradiction within the CoP, but contrasting epistemological frames of discourse (between *received* or *constructed* knowers). Therefore, the idiom used in relation to

training practices generally or about evaluation specifically, from both stages of the study (i.e. theoretical analysis and empirical study) formed part of the analyses.

Finally, the public space in which observation took place was constituted by the individual sessions within meetings of the Forum. The private space in which observation also took place was constituted by meetings within the Steering Group.

#### *5.1.3.1 Criteria for participation status categories*

Steering group members were those observed to actively engage in the inception stages of organizing the Training Forum. Steering group members were also those subsequently engaged in driving the TF and its topic focus. This type of member formed the *core* category co-opting other TF members or non-members to present topics or to lead sessions or they volunteered themselves to do this.

*Active* members were those who attended TF meetings regularly, occasionally, or infrequently, asking questions and participating in Forum discussions, presenting or facilitating topic discussion. This group also included those who may have been involved in Steering Group (SG) activities at one time, but who at the time of their interviews had stepped down from this level of participation, consistent with the fluid and dynamic nature of participation (Wenger, 2002).

*Peripheral* members of the TF were those who seldom actively participated in discussions in this public space i.e. a peripheral member may not have asked questions, or only asked one question in the course of Forum attendance.

Although data was gathered from the same sources (the members) using different methods (observation, survey and interviews), it was intended that differentiating agents at different levels of community participation, would provide a comprehensive perspective and understanding of concepts, methods and experience of practice in the Trainers' Forum.

External "guests" were not selected for interview, although their comments or artefacts were analysed as part of the discourse within the CoP and in terms of members' reactions.

Where possible, on the basis of observation, questionnaire and informal / formal interview, members were further classified according to characteristics, identified within literature as affecting structuration of practice, or affecting levels of participation. For example, the *scale of operations* affects the control of material resources (people, things) and depends upon processes or structures being implemented to manage these resources (Nixon *et al*, 1997). Such processes might include the specification of a training process, as a separate function within clinical operations. Its implementation may also indicate the level of economic investment made by an organisation in terms of time and money spent on developing processes.

Alternatively, in smaller organisations, with a sole trainer, training process may be less defined or informal. Hence, at the level of the individual, a trainer's knowledge and experience (concept of training and evaluation practice) may be shaped by their exposure (or lack thereof) to a formally specified system of training evaluation (methodology). In turn, their experience of the training process may depend on the scale of operations or the *type of practice setting* (CRO, pharma or ITP) determining specifications of the training process.

The possession of *qualifications* may be anticipated to signal individuals' resources of basic discipline knowledge, and to signify their cultural capital (Bourdieu, 1991). The *type of practice setting* may then affect the epistemological expression and application of this discipline knowledge both within situated practice, and by extension through the embodiment of practice, within a CoP, depending on the influences from either an external 'professional' culture or an internal organisational culture (Alexander, *op.cit.*).

Therefore, by interviewing members selected according to their degree of participation in the TF as core, active or peripheral members and their frequency of attendance (regular, occasional or infrequent) these assumptions would be tested. Their workplace practice settings and whether they possess training qualifications would also be considered in the analysis in terms of their effect on participants' EFD, knowledge and experience.

### 5.1.3.2 *Interview Plan*

Community members were approached, on an informal basis as part of the process of building biographies of TF members at different levels of participation over a period of time, and in order to develop understanding of how and what is learned from participating in the TF. The final numbers formally interviewed depended on the availability of community members matching each of the criteria shown in Table 5-1, and on reaching saturation point for theoretical sampling of data, gathered by different techniques, from a variety of sources.

The plan was to interview Forum members according to their employment profile, participation status and attendance record for meetings held from 2004 to 2008 (Table 5-2).

After the first set of formal interviews, designed to establish members' background, interviewees were then subdivided according to their emergent epistemological frame of discourse (EFD) revealed either during interview or from previous observation. That is, they were categorised, either as constructed or received knowers, into three groups as follows:-

- Constructed or received knowers who were core members
- Constructed or received knowers who were active members, and, finally
- Constructed or received knowers who were peripheral members.

These two groups were then interviewed on one further occasion to establish their concept of practice and their perspectives on common and dominant interests in the TF.

## **5.2 Analyses Plan**

The analysis plan is shown in Table 5-3 (Research analyses plan), at the end of this chapter.

Each stage of analyses reflects the design of the study, in its three distinct research phases: initial, exploratory and confirmatory, as described in section 5.2.2.

The analytical strategy applied in the study is described fully in Chapter 3, section 3.3.

**Table 5-1: (Participation categories)**

Participation status	Category of participant
Topic/session leaders who are Steering Group members	Core
Meeting organisers/leaders who are Steering Group members	Core
Questioners who are Steering Group members	Core
Topic/session leaders who are not Steering Group members	Active
Regular questioners who are not Steering Group members	Active
Listeners and occasional questioners who are not Steering Group members	Peripheral

**Table 5-2: Interview Plan**


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Contexts of participation (2004 -2008)

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Employment Profile	CRO	PHARMA	ITP	
Attendance record	Participation status			Sub-totals
	Core	Active	Peripheral	
Regular [Attended >two-thirds of meetings]	1	1	1	3
Occasional [Attended >half of meetings]	1	1	1	3
Infrequent [Attended $\leq$ half of meetings]	1	1	1	3
Sub-total	3	3	3	
Total				9

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**Table 5-3: Research analyses plan**

Research phase	Aim	Analytical framework	Form of CHAT analyses
1. Initial	Examine structure of the Community and its Domain	Community of Practice Community Domain	Phenomenological  Theory-historical
2. Exploratory	Determine “what goes on around here” by defining the ORoP	Practice  Objective Regularities of Practice (ORoP) Activity: Cognitive & co-operative tasks; Internal Goods & External Goods; Standards of Excellence	
3. Confirmatory	Clarify how & why things happen the way they do in the CoP	Activity system Subject performing the activity: Trainers in a CoP Community shaping the activity through DoL & Rules Tools mediating the activity: <ul style="list-style-type: none"> <li>• Methodology - pedagogy (transmissive/deliberative)</li> <li>• EFsD: being-valuing-believing regarding : Teaching &amp; Learning approach (receiving-conveying knowledge/constructing knowledge)</li> <li>• EFsD: saying-writing-doing regarding T &amp; L methods (monologic/dialogic)</li> </ul> Object of activity: (Concept & Experience of practice) <ol style="list-style-type: none"> <li>1. Sharing of best practice;</li> <li>2. Discussing topical training issues;</li> <li>3. Networking</li> </ol> Outcomes: Transformation/perpetuation of practice?	Object-historical Actual-empirical

# **Chapter 6**

## **Research Methods**

## 6 RESEARCH METHODS

### 6.1 Overview

A developmental research approach was adopted to study the activity system of the Trainers' Forum (TF). Engeström's activity system model was used within a CHAT framework, to analyse the embodiment of the concept of practice, in the activity of sharing and discussing the practice of clinical research training.

The research was conducted in three distinct phases as shown in Table 5-3 (Analyses Plan) at the end of Chapter 5 (Research design). Qualitative and quantitative methods were used to gather data, which included: participant observation; questionnaires and interviews. Because the study concerned a community of trainers and its practices, data sources were varied. For example, texts included interview transcripts, documents & written discourse as detailed in Table 4-1 (Methodological framework: Data sources).

The coding conventions for the varied sources of data are shown in Appendix I. These conventions are used in the footnotes of the three findings chapters 7, 8, and 9 respectively, to indicate data sources.

Each stage of analyses (object-historical, theory-historical and actual-empirical) was conducted using an interpretative framework based on CHAT, as described in Chapter 3, section 3.3: Operationalising the conceptual framework. This framework developed progressively through each phase of the research (initial, exploratory and confirmatory).

Finally, the concept, methodology and experience of practice within the TF were explored by applying this conceptual-analytical framework as an evaluative tool.

## **6.2 Data collection methods**

In the initial phase, research began with an ethnographic and critically reflective approach. A questionnaire was distributed in the exploratory phase<sup>29</sup> of the research. The final confirmatory phase involved conducting interviews. Each of these research phases, with associated methods and data collection tools, is described in the following sections.

### **6.2.1 Phase 1 Initial research method: Retrospective participant observation**

The empirical work involved episodic, longitudinal, observation of public spaces within a community of practice, whose members ranged in their levels of experience and expertise. It took the form of participant observation at scheduled meetings of the Trainers' Forum lasting 4 to 6 hours and held two or three times a year. Observations took place over a period of five years from the second meeting after inception of the Trainers' Forum in December 2003.

Field notes were written at TF meetings.

Notes were written as soon as possible thereafter in a reflective diary to capture utterances, initial thoughts, feelings, and impressions related to observations at the Forum and from further analysis of field notes. Both field notes and reflective diary extracts were later transformed into analytic memos or *filed notes* for formal data analysis and collated into mind maps.

### **6.2.2 Phase 1 Data gathering instruments**

Field notes included: -

- Agenda with topics and number of attendees
- Brief notes about session topic & content/format
- Individual agenda sessions categorised according to Teaching & Learning approach / methods in evidence at each session (monologic: talk/presentation with Question & Answer (Q&A); dialogic: facilitated exercises including discussion)

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<sup>29</sup> Second stage

- Observations during meetings, including quotations/utterances capturing initial contradictions to be explored
- Spontaneous reflections during meetings

Reflective diary included: -

- Ongoing spontaneous reflections critically analysing (Minton, 2005):-
- Behaviour: what was surprising?
- Learning/teaching activities: what went well/badly
- General insights

Documentary evidence included: -

- Job advertisements for positions with training responsibility
- Articles published in the ICR Journal (CRfocus) related to either Training Forum activities or training issues in general
- ICR TF mission statement published on the ICR website
- TF presentations published on the ICR website.

### **6.2.3 Phase 2 Exploratory research methods**

#### **6.2.3.1 Informal interviews**

TF participants were interviewed informally either during breaks or at the end of meetings to initially establish background, role and involvement in TF activities/ sessions/meetings.

#### **6.2.3.2 Survey**

The questionnaire survey was designed to establish demographics concerning trainers and their workplace practice settings. It was also intended to further elaborate collective understandings of practice in terms of concepts and methodology used in everyday practice (e.g. evaluation) by trainers because, as tools, such artefacts represent common understandings of practice.

Common understandings of the concepts of reactivity/pro-activity were also explored since these terms were frequently used within various Forum meetings, but without further explanation.

The questionnaires were distributed in three main ways:

1. Actively at one particular training forum (December 2006): by distribution to all attendees; or
2. Passively making them available at three subsequent Forum meetings to attendees (i.e. allowing attendees to complete/collect a questionnaire voluntarily at the meetings in May 2007, March 2008 and June 2008).
3. Using e-mail via the ICR (i.e. Forum liaison personnel distributed the questionnaire via e-mail to all Forum members (February 2007).

## **6.2.4 Phase 2: Data gathering instruments**

### **6.2.4.1 Informal interview tools**

In this phase of the research, interviews with TF participants were conducted informally i.e. on a spontaneous basis as the occasion arose. Accordingly, no formal interview schedule was used. However, participants were each asked similar questions to establish *what is going on around here:-*

- Why are you here today?
- How are you involved?
- What's the history of your involvement?
- What did you think of session X?
- What did session X mean for you?

Personal communications by e-mail were also collated for later analysis with participants' permission.

#### 6.2.4.2 Questionnaire

Respondents were asked to reply to 38 statements concerning their background, qualifications and workplace settings; their experiences related to training practice, course design, delivery and evaluation; and their definition of reactive and proactive training.

Statements were divided into three sections: Role & responsibilities (questions 1–10); Organisational tendencies (questions 11 – 21); and, Demographics (trainers' and organisational characteristics) (questions 22 – 38). Responses to questions 1 to 21 were gathered and scored using the following Likert rating scale:-

1. Strongly disagree
2. Tend to disagree
3. Tend to agree
4. Strongly agree.

The questionnaire (shown in Appendix B) was arranged into sections with questions gathering information about roles, responsibilities, and organisational tendencies, as outlined in Table 6-1. Respondents were then categorised according to demographic characteristics into qualified trainers and non-qualified trainers within four types of organisation<sup>30</sup> of different size.

Associated research information sheets (RIS 1 & 2) and informed consent forms (ICF 1 & 2) are shown in Appendices C, D, E & F.

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<sup>30</sup> Pharmaceutical company (pharma); Contract Research Organisation (CRO); Independent Training provider (ITP); Other.

### **6.2.5 Phase 3: Confirmatory research methods**

#### **6.2.5.1 Observation**

Observation in this phase of the research differed from the initial phase, in that meetings were digitally recorded and later transcribed, as well as captured in field notes. Feedback records were also gathered from five Trainers' Fora: September 2005, September 2007; February 2008; June 2008 and October 2008 for later analysis.

#### **6.2.5.2 Interviews**

In order to gather data representing different levels of participation within the community interviewees were selected from two sources. These two sources included:-

- Questionnaire respondents who provided contact details and
- Opportunity sample of interviewees selected from earlier participant observations.

The opportunity sample included steering group members, other experienced members and less experienced or less involved members classified respectively as core, active and peripheral participants, as explained in Chapter 5, section 5.1.3.1.

### **6.2.6 Phase 3 Data gathering instruments**

#### **6.2.6.1 Interview schedules 1 and 2**

During the final phase of the study, two rounds of formal interviews were planned that built on informal interviews conducted in the first or second stages of the research. Initially, approximately six to eight interviewees from each category of Forum participant (core, active and peripheral) were approached in person, and then followed up by e-mail. Fifteen members were informally interviewed in person during breaks or after meetings. Of those who agreed to be formally interviewed, four belonged to the peripheral group, with three each from the active and core groups. In total, eighteen interviews were conducted by telephone: nine in-depth initial interviews, and nine in-depth follow-up interviews. Both sets of interviews lasted for approximately one hour, producing transcripts ranging from 8 to 36 A4 pages, and



the form of interactions (trainer vs. audience or facilitator and participants) differed based on a monologic or dialogic approach to the activity of sharing / learning. Thus, two different ways of communicating and sharing/learning ideas (based on didactic or dialectic principles) were also apparent in these two different approaches, which it was proposed depended on the dominant epistemology of participants. Consequently, the first interview schedule was designed to determine participants' epistemological beliefs about knowledge in relation to the cognitive, affective and psychomotor domains of Teaching & Learning. That is, epistemological beliefs determining the approach to the activity of training (as a content-driven activity with the objective of transferring information or a learning process with the objective of building or increasing knowledge) were explored.

The following aspects were also explored in the first interview:-

- TF participant's background: employment history, qualifications, training experience
- Concept of practice: what is training?
- What does training mean/involve (cognitive domain)?
- What does it feel like (affective domain)?
- What does it look like - what happens (psychomotor domain)?
- Epistemology: what is our approach to training: how do we talk or write about training, or do it? How is our discourse about training framed in terms of our theory of knowledge? How are our theories embodied in how we are, what we value and what we believe?

In the second schedule interview, members' relationship to the TF and experience of it were explored. Epistemological aspects of the concept, methodology and experience of practice were also explored as shown in Table 6-2, at the end of the chapter.

Exploring these aspects was intended to examine the relationship between participants' EFD<sup>31</sup> and the structuration of practice, which manifested in the form of training idioms, interactions and structure of practice at the TF. Thus, as well as examining the influence of personal epistemology in particular manifestations of practice, I also hoped to examine the conditions governing practice (i.e. rules and resources; whose interests dominate: who leads, who has power?).

## **6.3 Data analyses methods**

### **6.3.1 Overview**

The analytical strategy for the study is shown in Figure 3-2, in Chapter 3, which in turn corresponds with the research analysis plan shown in Table 5-3, in Chapter 5.

In the first phase of analyses in this research study, *what is going on around here* was observed. First, Lave and Wenger's (2002) *community of practice* construct was used to contextualise activity; and second, activities, actions, operations were framed using Engeström's CHAT, having delineated the TF using his activity system model (shown in *Figure 2-2*, Chapter 2). Moreover, *how we are doing things* was considered in terms of the concept of practice, in order to understand *why we do things the way we do* and to determine the need state and primary contradictions in this system of activity. In effect, the concept of practice was the main focus of the study framed within the dimensions of concept, methodology and experience.

Observations were compared in a number of ways to identify a concept of practice over a period of time (Mar 2004 – Oct 2008): -

- Within different sessions in the same TF meeting
- Between sessions across different TF meetings
- Between TF sessions and particular artefacts produced from these

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<sup>31</sup> EFD: epistemological frame of discourse

sessions (handouts, presentations, published reports of the gatherings)

- Between TF sessions, their artefacts and field artefacts (job advertisements, general training articles)
- Between various TF meetings and artefacts produced across these meetings (documents: handouts, presentations, published reports of the gatherings).

In observing and participating in these patterns of activity, the successive developmental phases of the activity system were identified and analysed as part of the object-historical analysis of how the object of activity in the TF (sharing practice, discussing training issues and networking) developed. This constituted part of the rigorous analyses of the activity system. Next, during theory-historical analysis, activity was further framed in terms of declarative concepts, procedural models and social discourses and interactions, using observations and discussions in interviews about its dimensions of practice (concept, methodology and experience). Finally, after an extended period of engagement within the TF, through this process of constant comparison, the conceptual-analytical framework was further developed and tested during actual-empirical analysis, as explained previously in Chapter 3, section 3.2.

Observations were also used to ask questions of fellow community members, both informally at meetings, and through pre-arranged interviews in order to understand the rules, structures, and processes or activities governing our interactions. By this means, the intention was to reveal and analyse the collective motives, goals and instrumental conditions within this community that affected practice.

Although the process of analysing data gathered longitudinally (over a period of five years) was continuous, it is explained in three phases of initial, exploratory and confirmatory research, each of which reflects the design of the study, in its three phases.

### **6.3.2 Phase 1 Initial method of analysis**

In the first phase of the research, the construct of CoP guided descriptive analysis of the structure of the community and its domain. *Practice* was also framed as a structural element based on identifying certain behaviours as shared repertoires and shared resources such as particular language idioms, jargon or tools. In effect, observational data was analysed based on identifying the features and associated characteristics that suggest a CoP, as described in Chapter 2, section 2-6 and Table 2-1 (Wenger, op.cit.:76):

- mutual engagement;
- joint shared enterprise; and,
- shared repertoire of negotiable resources accumulated over time.

These features and characteristics were then applied to the analysis of the community of trainers by way of thick description as part of the phenomenological exploration of the Trainers' Forum and its activities, which constituted the initial analysis of the features of TF as an activity system. In addition, the criteria listed in Table 3-1 (Criteria defining CoP structural elements) Chapter 3, which Wenger also proposed (op.cit.:130–31), were applied to the TF to identify more specific features of structural elements within a CoP.

### **6.3.3 Phase 2 Exploratory method of analysis**

In the second phase, an analytical framework representing the conceptualised dimensions of practice (concept, methodology and experience) emerged during the phenomenological exploration of the Trainers Forum. These dimensions constituted the objective regularities of practice (ORoP) observed in the TF. Methodology and experience were framed in terms of two differing core epistemological beliefs within the concept of practice, which operated as cognitive elements within the activity of training (i.e. as a process of information transfer or as a process of inquiry/deliberation). These differences emerged within contrasting epistemological frames of discourse (EFsD).

This conceptualised framework of the ORoP also formed the coding matrix for analysis of multi-source data<sup>32</sup>. That is, data gathered from TF artefacts, observations and interviews were compared, coded, categorised and analysed progressively to develop this interpretative framework. In effect, it was developed through three stages of analyses corresponding to object-historical, theory-historical and empirical (Engeström, 1987) analyses of activity in the TF.

#### **6.3.4 Questionnaire data analysis**

Descriptive statistics were used to present qualitative (categorical) variables gathered using the questionnaire. For example, survey participants were classified according to particular demographic categories, such as their educational background. Different proportions for each demographic category were then tabulated accordingly.

### **6.4 Phase 3 Confirmatory method of analysis**

#### **6.4.1 Empirical analysis of the activity system (the unit of analysis)**

How and why *things happen the way they do* were clarified through empirical study of activity within the TF using Engeström's activity system model to underpin interpretative analysis. That is, the *community* was framed as a constituent within an activity system in order to analyse its activities, *division of labour* and *rules*. Trainers were the *subjects* who constructed and shaped the *object* of activity within this system depending on the *tools* available to them.

Questions guiding the identification of activity system elements in interview and observational transcripts are shown in Table 6-3. Identified elements and their contradictions were then coded according to the schema shown in Table 3-5<sup>33</sup> and Table 3-6<sup>34</sup> in Chapter 3.

Through modelling the TF as an activity system, various levels of contradiction were identified, then analysed (primary, secondary, tertiary and quaternary), as explained in

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<sup>32</sup> Type of data and sources were outlined in Table 4-2: Methodological framework showing the approach, methods and tools used to explore concepts at different stages of research, Chapter 4.

<sup>33</sup> Table 3-5: Codes for describing Activity System elements or contradictions

<sup>34</sup> Table 3-6: Coding scheme for describing Activity System contradictions

Chapter 3, section 3.4 and Figure 3-3. Identifying and tracing the conceptual models that were partially imported into, and partially invented within, this activity system explained contradictions in terms of conditions that created and sustained this professional community. In turn, these conditions explained the enculturation of its concept of training practice. Moreover, through applying CHAT in a conceptual-analytical framework, the concept of practice was analysed as a whole, in terms of trainers' (subjects) concepts<sup>35</sup>, methodology (artefacts/tools) and experience of training as a practice within the TF (activity and outcomes), by viewing it as an activity system with its own rules, community and division of labour.

Therefore, the conceptual-analytical framework of complex elements of activity constituting practice was formed through teasing out, classifying, re-classifying, categorising and organising the objective regularities of practice that emerged from observing Forum sessions and interviewing Forum participants. It was then applied, during the *actual-empirical* stage of analysis, to systematically code observational data gathered during sessions, as well as interview transcripts. Accordingly, conceptual models of practice used in the Forum (i.e. transmission vs. enquiry) were evaluated through features observed in session activity to typify procedural models and social discourses/interactions as either didactic monologue or dialectic dialogue. In total, 55 sessions lasting almost 50 hours were observed and analysed at 11 separate meetings of the Trainers' Forum held over a period of 5 years. Collated data (from field notes/transcribed digital recordings) were then analysed to characterise predominant conceptual/procedural models and social interactions/discourses in Forum activity<sup>36</sup> to explain *what's happening around here* and *why*.

Finally, in the next three chapters, phenomenological and empirical findings are reported and discussed, and supporting data is presented, about each of the elements of the Activity System

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<sup>35</sup> declarative/procedural and social interactions/discourses concerning the object of activity

<sup>36</sup> Table 8-5: Predominant conceptual/procedural models of practice characterising Forum activity

of the Trainers' Forum: subject (Chapter 7); community, DoL, rules (Chapter 8) and finally, object and tools (Chapter 9).

**Table 6-1: Training roles, responsibilities, organisational tendencies and****Demographics****Responsibilities of trainer's role**

Current practice regarding course design i.e. autonomy to decide: Teaching & Learning strategies (classroom versus resource-based learning or e-learning; methods (PowerPoint presentations; role plays; case studies)

Current practice and experience of using evaluation tools (type of tools used or available for implementing evaluation strategies)

Common understandings of the concepts of reactivity / pro-activity

**Organisational tendencies**

Current practice re evaluation strategies (levels commonly used and forms of assessment).

**Demographics**

Characteristics of practitioners as:

Subject matter experts (SMEs) i.e. qualifications / experience related to clinical research practice

Professional trainers i.e. qualifications/experience related to training practice

**Characteristics of practice settings:**

Type: Pharmaceutical company (pharma); Contract Research Organisation (CRO); Independent Training provider (ITP)

Size: micro/small/medium/large enterprise as per EU Directive criteria<sup>37</sup>

**Key**

Micro: A micro organisation refers to those with 10 or less employees (Liikanen, 2003).

An enterprise with less than 50 employees is categorised as small (Liikanen, 2003; Loecher, 2000).

A medium enterprise is one with at least 50 employees, and more than 20 (Liikanen, 2003; Loecher, 2000).

A large enterprise is defined as 50 or more employees (Liikanen, 2003; Loecher, 2000).

<sup>37</sup> Although there is no universally accepted definition for the size of a business, one criteria used by the EU is the number of employees (SBS Stats, 2004).



**Table 6-2: Questions of epistemology – the nature of knowledge and knowing**

<b>Interview schedule</b>	<b>Concept</b>	<b>Explorative questions</b>	<b>Epistemological aspect</b>
1	Concept & methodology of practice	What is training? How can/do we share our ideas to learn from each other?	Nature of Knowledge (certainty & simplicity)
2	Concept, methodology & experience of practice	What happens at the TF? Activities: what do we do? What cognitive & cooperative tasks constitute these activities?	
2	Community of practice: Concept of power	Organisation & processes: Who runs the TF; how's it run? What happens at the TF & why? Common interests: Who benefits – what do we get out of the TF? What motivates us to be involved at diff levels of participation? Dominant interests: Who leads the TF & why? (Who is perceived to have authority?) Participation status: attendance record & level of interaction	Nature of Knowing (sources & justification: external/internal; type of evidence/application)
2	Rules of operation	How does the TF work? Does it help us, and if so how?	Nature of knowing & knowledge

**Table 6-3: Questions guiding identification of activity system elements<sup>38</sup>**

<b>Activity</b> (individual/group actions)	What sort of activity does the agent/interviewee refer to and which Activity System does it concern?
Object(ive)	What is the purpose of the activity agents refer to or perform?
Subjects	Who is involved in the activity agents refer to or perform?
Tools	What means do they use or refer to in the performance of the activity?
Rules & regulations	Do they refer to, exhibit or conform to any norms, rules or regulations?
Division of labour	Who is responsible for what, and are those rules organised?
Community	What is the environment in which this activity is being carried out?
Outcomes	What is the desired outcome?

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<sup>38</sup> Adapted from Mwanza and Engeström, 2005: 459

## **PART 3 RESEARCH FINDINGS AND DISCUSSION**

## **Chapter 7**

### **The Subjects: Trainers**

## **7 THE TRAINERS: SUBJECTS**

### ***7.1 Who are the participants in the Forum?***

In activity theory, the significant dimensions of the system being studied comprise: subject, object, tools, community, division of labour and rules. Hence, in this study, the Trainers' Forum provides the activity system and setting for investigating those elements of trainers' practices that illuminate training activity in the wider context of the field of clinical research.

Findings are reported in the following three chapters based on viewing the Forum as a practice focussed activity system in its entirety (e.g. subject, object, tools, etc.). In effect, the Forum is the unit of analysis providing the "minimal meaningful context for an activity" (Hall, 2001: 208). That is, the Trainers' Forum is the context in which the complex activity constituting the sharing and discussion of trainers' practice was observed.

Viewing activity from the perspective of respective actors in the system of activity enables a comprehensive picture to be built of the systematic elements involved. In addition, according to Lave and Wenger (op.cit.), the identity of members in terms of who they are, and what they do, is bound up with the activity or practice that defines them as a community. Consequently, describing who the subjects are within the system of activity, and the tensions between them, provides an insight into the social structure of the activity system in terms of the features of their shared practice, such as: a shared language (training idiom); ways of doing things (methods and patterns of interaction); or cultural traditions or orientations (conscience versus compliance). Some of these aspects, which define the social structure of the community, are addressed in the following sections and subsequent chapters using a series of questions to lead the enquiry and to illustrate identified tensions.

#### ***7.1.1 Characteristics of Trainers***

As indicated in the research questionnaire, experience varied among Forum members, and in those surveyed (n=31) it averaged 7.95 years and ranged from less than a year to 37 years.

The total number of women respondents greatly exceeded the number of men (87%: 13%;

27:4) as shown in Table 7-1 at the end of the chapter, which generally reflects the greater proportion of women in clinical research.

## ***7.2 The heterogeneity of the training community: Identity***

From observation, questionnaires and interviews, it was apparent that the trainers who formed the membership of the Forum were a heterogeneous community with a range of identities including full-time and part-time trainers: clinical research trainers, training managers; clinical research managers, clinical research associates, compliance managers, auditors and others.

### ***7.2.1 Organisational contexts: diversity or uniformity?***

Such heterogeneity is a reflection of the variety of organisations and the diversity of their structures. Thirteen trainers (42%) worked in pharmaceutical companies, ten (32%) of which were classified as large, two (6%) as medium and one as micro (3%), according to the classifications given in Table 7-1 (Trainers' responsibilities within micro, small, medium and large organisation) at the end of the chapter. Eleven trainers were employed respectively in seven (23%) large clinical or contract research organisations (CROs), one medium sized CRO (3%) and finally, three small CROs (10%). Seven (23%) remaining trainers were employed either in large organisations (10%): a university, a biotechnology company and a medical device company, respectively; or in four micro organisations as independent training providers (13%).

The diversity of organisations and variety in roles reflects the structure of the field of clinical research, specifically reflecting changes in the business model for the pharmaceutical industry. That is, CROs were unheard of until the 1980s. Various referred to as either clinical or contract research organisations, they introduced a new business model or concept for the conduct of clinical research – the service provider. In essence, these organisations compete for the business of industry sponsors of clinical research. Winning the contract entails anything from progressing an investigational medicinal product or a medical device through various stages of development to overseeing final submission of the dossier to

regulatory authorities. A successful outcome results in the sponsor being granted a marketing authorisation or license to market the product to the medical profession to treat patients with specific disease indications.

Due to increasing competition in healthcare markets through generic competition with loss of patents, sponsors need to shorten their development timelines in order to achieve a faster return on investment (ROI) for investors, contingent on licensing and successful marketing. Sponsors also need to maintain a product pipeline, securing the future of the company from the threat of mergers or acquisitions. Therefore, the aim of outsourcing their clinical research projects to CROs or to hire in contract staff was, and is, to rationalise shrinking budgets and timelines without compromising quality. Consequently, over the last twenty or so years, as the clinical research process has been streamlined and outsourced, new specialisms have developed mirroring a refinement in focus, particularly in clinical research, training and project management (Hayes, 2008).

For example, 'sales' refers to the functional specialism of *business development* within CROs, where business development executives compete for the business of sponsor pharmaceutical companies. This usually involves preparing and submitting *tender quotations* based on the prospective client's brief. The client may pick and choose, then negotiate the services required based on the fixed and pass-through costs outlined for conducting specific elements of the clinical research project.

While clinical research associates (CRAs) and senior CRAs manage investigators and their conduct of clinical research, their managers in turn, gather metrics concerning both the CRA's performance, and that of the research sites for which they have monitoring responsibility. Either CRAs or CRA managers (CRM) may be employed directly within pharmaceutical companies or within CRO, or outsourced from the latter. That is, a CRO may supply the headcount resource (a CRA, CRM or a project manager). Although the person occupying this position then fits inside the sponsor company's structure for the duration of the clinical study or project, or business relationship, they are employed by the CRO. Alternatively, a CRO may

develop a partner relationship with the sponsor company, where the CRO and the sponsor jointly or separately manage resources.

The growth in CROs and increasing acceptance by sponsors of the change they have forged in the business model has also created opportunity mainly for experienced clinical research associates and trainers to offer their services independently. Some do this as freelancers, sub-contracting their services to client companies (sponsors or CROs). Or, some establish service companies providing a range of monitoring services in clinical research, or offer a greater choice of training courses to customers across the field of clinical research. As independent trainers their primary object is to develop business opportunities in order to maximise their earnings/profits. Their secondary aim is to facilitate learning through a training process.

Hence, members of the Trainers Forum are drawn from a variety of different practice locations, with different circumstances, where their everyday practice is situated. For example, some trainers work in companies with dedicated training departments. Others are the sole trainer, within the whole company, or its regional subsidiary. Those trainers operating as independent training providers (ITPs) may hire out their own or others services to client companies (pharmaceutical or contract research). Or, some may work within contract research organisations (CROs), which in turn, hire their services out to client pharmaceutical companies, directly or indirectly. The remainder is mostly employed within pharmaceutical companies, which engage in research and development, within the pharmaceutical sector. However, some may also work in biotechnology or medical device companies. Hence, the predominant types of organisations (CROs and pharma companies) are variously categorised as micro, small, medium or large enterprises. A smaller proportion of members is employed within the health service or associated academic units situated within Hospital Trusts.

In both CROs and sponsors, depending on their size or resources allocated to training, the activity of training may be situated within training departments, or be the responsibility of single dedicated trainers (full-time role), or be a devolved responsibility (part-time role) shared out among personnel with principal roles as clinical researchers or quality assurance



managers etc., spread out over different departments (Clinical Research; Quality Assurance or Compliance; Pharmacovigilance; Human Resources).

Therefore, just as there is diversity of organisational structure across the field of clinical research, there is inconsistency in how the training function is supported, since resources allocated vary across organisations. In addition, there is no uniformity in how the role manifests, other than its being either a dedicated or a shared role.

### **7.2.2 Resourcing of Training: cost or investment?**

Levels of organisational support given to both the training function and to the CPD of trainers were considered inadequate when discussed at the 2<sup>nd</sup> and 3<sup>rd</sup> Fora. The predominant view among members in attendance at each of these meetings was that the training function is reactive and not proactive in its training strategies, which was agreed as being due to a general reluctance of employers to adequately resource the training function. In turn, this reluctance was considered to be due to senior management's general perception that training is a cost and not an investment, based on a belief that its benefits cannot be demonstrated in terms of a return on investment. A few trainers attested privately in conversation to their personal struggle to secure either time or financial support from their employers when seeking a training qualification:

*"...I really had to make a strong business case, to show that the organisation would reap the benefits as well as me, if I knew more about how to do my job..." (Molly<sup>39</sup>).*

*"...I was determined to do it, even if it meant taking days off as holidays to go on my course. In the end, they gave in..." (Liz<sup>40</sup>).*

As discussed at these two meetings, training responsibilities generally depend on how the training role is specified either on a proactive basis "...to meet strategic needs"<sup>41</sup> or on a reactive basis to address individual needs or operational issues. In effect, as explained at both these Fora, a strategic trainer helps drive business objectives forward through developing strategic training plans and programmes; whereas, an operational trainer delivers rather than

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<sup>39</sup> FN-PC\_Interviewee9\_core\_EFDc\_TF\_2/A\_05-04

<sup>40</sup> FN-PC\_peri\_Liz\_EFDr\_TF\_2/A\_05-04

<sup>41</sup> TF\_FN\_2/A\_05-04; 3/B\_09-04\_CRf 2004, 15(9): 18

develops the training programmes that are intended to accomplish business goals. Operational trainers also react to needs and operational issues at a local (or non-strategic/reactive) level.

Yet, according to the research questionnaire, 80% considered that their organisational training strategy was pro-active versus 20% who did not. At the same time, 83% viewed it as reactive versus 13% who did not. Such a mixed picture has three possible interpretations. First, most organisations are hard at work implementing their strategic business plans through their training programmes. Second, as well as addressing operational needs as planned, organisations are also addressing individual needs as they arise. Finally, those trainers who were surveyed have different individual understandings of the nature of proactive and reactive training in their organisations, compared to the meanings clarified in group discussion at the 2nd and 3rd Forum meetings.

The findings from the research questionnaire, shown in table 7-2 (Trainers definitions of proactive and reactive training) suggest that the latter interpretation is likely. Of those surveyed whose functional specialism was training (n=15), 29% gave no definitions; 21% gave similar definitions for proactive and reactive training; and 50% gave definitions that corresponded with the definitions agreed in the 2<sup>nd</sup>/ 3<sup>rd</sup> Fora. Of those whose specialism was clinical research (n=8), 44% gave no definitions; 22% gave incorrect definitions of proactive; and, 33% gave similar definitions to those agreed at the 2<sup>nd</sup>/ 3<sup>rd</sup> Fora. Of the remainder (n=8), 71% had definitions that agreed with the common definitions; and, 29% gave incorrect definitions of proactive.

The functional group with the clearest understanding of strategic training are those involved in Quality Management, as opposed to trainers or clinical researchers, which is consistent with the strategic nature of the Quality Management role in ensuring that processes/products are conducted/produced according to the required standards (GXP<sup>42</sup>: GMP, GLP, GCP etc.)

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<sup>42</sup> Good Laboratory Practice, Good Manufacturing Practice and Good Clinical Practice are collectively known as GXP.

### **7.2.3 Roles and responsibilities: full-time dedicated or part-time shared?**

As shown in Table 7-3 (Features of trainers' organisational location), trainers occupy a variety of roles. Fifteen respondents out of thirty-one were classified as full-time trainers (48%), and sixteen as part-time (52%). Of the 15 whose role was dedicated to training, 26% worked in pharma companies, 16% in CROs, 3% in some other type of organisation, and 3% were independent training providers. In terms of size, 3% of these organisations were classified as small, 13% as medium and 32% as large.

Eight (26%) respondents based in clinical research with training responsibility were represented across the range of organisations, but split between micro (10%) and large (16%) organisations. Likewise, those in quality management from pharma (10%) and CROs (16%) were also split between the two ends of the size spectrum with 3% in micro sized companies and 13% in large companies. Those whose main role was in project management were evenly split between a small (3%) and a medium CRO (3%).

The greatest proportion of trainers worked in large companies (65%) with roles split evenly between dedicated/shared (32% versus 32%). These findings indicated that trainers in shared roles were distributed across the same type and size of companies as those who were in dedicated-trainer roles. Therefore, due to the structural diversity of organisations in the field of clinical research, at the very least it can be concluded that trainers attending the Trainer' Forum share an interest in training, if not a similarity in job title or organisational structure.

However, as confirmed in the research questionnaire, first circulated in December 2006 at the 8<sup>th</sup> meeting of the Forum, training responsibilities differ in the workplace for some or all aspects of the training process, which reflect perceived strategic differences in the role within organisations.

For example, as shown in Table 7-2 (Trainers' responsibilities) in seven cases (23%), the trainers either took or were given responsibility for establishing training needs. For the remainder, in those organisations where TNA were conducted, it is possible that their line managers assumed this responsibility. The vast majority were able to plan their courses and

their content (97%), as well as choose their methods of delivery. But, in two exceptional cases (6%), respondents stated that they were unable to decide training strategy i.e. via classroom or via e-learning. In one case, the respondent was unable to choose the methods e.g. presentation/lectures, role- plays and exercises. Finally, one respondent stated that s(he) was unable to decide learning objectives for the training.

#### **7.2.4 Job status: dedicated roles versus part-time duties**

The difference in the circumstances and situation of members practice was raised as a concern by the leadership of the Trainers' Forum and discussed in September 2007, after the Forum (*Making learning the priority*) at a Steering Group meeting. Through a show of hands at this Forum it was established that a substantial proportion of members in attendance were "part-time trainers", which was then captured in the minutes<sup>43</sup>. The Steering Group debated, in private, the challenge presented by having a "mixed" audience. In particular, it was generally assumed that part-time colleagues had limited experience compared to their full-time colleagues on the basis of the type of questions they asked during the meeting. A Steering Group member commented that their questions indicated that they had yet to "face the mountains already climbed" by their full-time colleagues<sup>44</sup>. For example, one session, where the use of *role playing* was demonstrated, stimulated a number of questions about when and how to apply this teaching and learning method to the field of clinical research training:

*Diane: "...how do we make trainees feel comfortable enough to take part in a role play? A lot would find it intimidating to 'act out' a part in front of their colleagues..."*

*Lesley: "...perhaps role play is best for trying to change behaviours...but, surely it's a bit limited when it comes to getting information across, which is really what we're concerned with most of the time..."*

*Ruth: "...how do we convince management that this is a useful way to spend our time? Not easy to evaluate the results..."*

As a result of this line of discussion in the Forum, Jennifer<sup>45</sup> proposed a new model of Forum activity in the de-brief meeting:

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43 SG\_Mins\_TF\_10/H\_09-07

44 SG\_FN\_Jennifer\_EFDr\_10/H\_09-07

45 SG\_FN\_Jennifer\_EFDr\_10/H\_09-07

“...after the initial presentations at the next Forum, it would be good to split into full-time and part-time workshops to cater properly for both groups”.

Her idea was discussed by the Steering Group in terms of the logistics and practicalities of dealing with two separate groups, and eventually rejected mainly on the grounds of feasibility. Moreover, on the one hand, it was also acknowledged that part-timers would probably gain more by being part of the whole, since “...we have to cater for everyone’s needs” (Molly) and it was agreed that “...the Forum meetings provide a good support mechanism for part-time trainers and so, we should continue to support them the way we do” (Molly and Peter). On the other hand, it was concluded that while the group empathised with the challenges faced by part-time trainers, the Forum was “...still not the place for them to *learn the basics* about training” (Jennifer). This conclusion indicated two levels of contradiction affecting operations within the TF: -

1. Primary contradiction within the element of subject (L1SU): Cross-functional part-time trainers were differentiated from dedicated full-time trainers on the basis of having different levels of experience and needs.
2. Secondary contradiction (L2SU2-RU1): The needs of part-time trainers were subsumed by the needs within the greater whole, on the grounds of not getting involved in ‘Training the Trainer’ (i.e. not challenging this rule).

These contradictions can be considered as tensions driving activity, or the development of practice, within the community. Such contradictions also reveal trainers’ predicament with their CPD: all are full-time employees who have to fulfil particular expectations regarding standards of training (i.e. to demonstrate its effectiveness). Yet, being a part-time trainer referred to a functional role split rather than a description of employment status. Part-time trainers were full-time employees whose role is split between their main function and training duties. However, those whose training duties were “tagged on” to their main functional role

were not afforded the same opportunities or time to develop their training knowledge or skills as their fellow Forum members in dedicated training roles<sup>46</sup>.

As discussed in meetings held in 2004 and 2005<sup>47</sup>, and noted from the research questionnaire results, presented in Table 7-4 (Features of trainers' organisational location), the working environments of Forum participants are non-uniform in terms of diversity in the type and size of their workplace structures.

Moreover, the range of job titles can be grouped into 5 different functional areas: Sales, Clinical Research, Project management, Quality management and Training (shown in Table 7-5: Job functionality defined by job title). However, despite describing functional areas, job titles give no indication of associated responsibilities. That is, regardless of whether trainers' roles are dedicated or shared they may nevertheless share similar responsibilities to a greater or lesser degree. In addition, as shown in Table 7-2, this functional split between dedicated and shared roles occurs in similar proportions across the various organisations of different types (pharma (26%:16%); CROs (13%:23%); and ITPs (6.5%:6.5%)) and sizes (micro, small, medium, large). However, in pharmaceutical companies there are nearly twice as many dedicated trainers as those in shared roles (26% vs. 16%). In CROs, the situation is reversed, with almost twice as many trainers in shared roles versus those in dedicated roles.

Finally, as shown in Table 7-1, these results show that respondents (n=31) with dedicated training responsibility (48%) have a similar mean (9 years) and range of service (0.5 – 27 years) as their clinical research colleagues (26%) with training responsibility (mean = 6.7 years; range = 2 – 20). Forum members whose main role is in quality management (16%) had the greatest range of service (1-37 years). The average length of time with responsibility for training on a part-time basis was similar (10 years) to those in dedicated training roles (9 years). Nevertheless, as indicated by the discussion among Steering Group members after the 10<sup>th</sup> Forum meeting, duration of service is not considered a measure of equivalent experience

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<sup>46</sup> Interviewee #1\_peri\_EFDr; Interviewee #4\_peri\_EFDc

<sup>47</sup> TF\_2/A\_05-04, TF\_3/B\_09-04; and TF\_5/D\_05-05

between part-time or full-time trainers'. In effect, the Steering Group discussion revealed an assumption that part-time and full-time trainers do not share equivalent status on the basis of "time served", irrespective of members' qualifications as trainers, or career choices. At the time of the survey, with the exception of myself all members of the Steering Group were trainers in dedicated full-time roles.

Yet, like their part-time colleagues, dedicated full-time trainers may be equally limited in their capacity to develop experience and requisite skills as professional trainers. For example, from the research survey, it was apparent that resources available to trainers to evaluate the effects of their training strategies, methods and courses on trainees' behaviours and achievement of personal and business goals varied. In particular, few respondents performed evaluation at all five levels defined by Kirkpatrick (1975). As shown in Table 7-2, at level one, most had tools available to them to assess trainees' satisfaction with training course content and delivery (n=27; 87%). By contrast, less than half (n = 14; 45%) had tools available to assess changes in knowledge before or after a training intervention (level two). Even fewer still had access to tools to assess at level three: the impact of the training on trainees' behaviour or attitudes (n=11; 36%); or at level four, to assess the effect on trainees' achievement of performance-related goals (n=10; 32%); nor finally, at level 5, to assess the impact of training on achievement of business goals (n=10; 32%). Therefore, these findings are consistent with the consensus view at the 2<sup>nd</sup> and 3<sup>rd</sup> meetings of trainers' struggle to demonstrate the effectiveness of the training process in facilitating an organisation's business strategy. Moreover, such findings suggest a limited focus in the workplace on the expansive capabilities of training as a function.

This struggle was described as "the conflict between external forces and internal resources"

<sup>48</sup>. That is, trainers struggle to develop an evaluation methodology to satisfy "corporate managers demanding a return on investment (ROI)" while

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<sup>48</sup> TF\_2/A\_ FN\_05-04; 3/B\_09-04\_CRf 2004, 15(9): 20

“... many evaluations will invariably meet with noise that cannot be eliminated (e.g. internal resources, external forces) and trainers may find themselves with a great many ifs, buts and maybes” (Hayes, *ibid*:22<sup>49</sup>).

At the 3rd meeting, it was explained that finance and human capital represented the internal resources inside an organisation, whereas the external forces concerned a mixture of pressures arising from sociological, environmental, political, technological and competitive sources in the marketplace. For example, regulatory demands on organisations in the field of clinical research represented external forces. As will be explained further in Chapter 8, these forces operate in neighbouring activity systems, including the TF and the workplace, and are revealed as quaternary contradictions. For example, as was understood at the TF, organisations need to demonstrate that their clinical research personnel are adequately and appropriately trained in GCP, thereby demonstrating that they have processes in place that ensure compliance with regulatory requirements.

However, as revealed at this meeting, trainers were challenged to demonstrate the effectiveness of their training processes at local or strategic levels through lacking the necessary tools. As will be discussed further in section 7.2.5, this lack of tools may be explained by employers’ tendency to recruit clinical research subject matter experts (SMEs) with in-depth knowledge of GCP, rather than training professionals with knowledge and experience of training process. Thus, if training qualifications are not regarded as essential, then subject matter experts develop professional training practice through trial and error, rather than by design. In a quality conscious climate, this predicament raises the curious paradox that the continuing emphasis in organisations to hire subject matter experts may perpetuate the conflict between internal resources and external forces.

Moreover, *best practice* is a familiar term in common use in the field of clinical research. However, in the Forum, trainers appeared to take either a local or a strategic view of what *best practice* meant in relation to the requirements of the training role in the workplace. For

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<sup>49</sup> TF\_2/A\_FN\_05-04



example, Peter<sup>50</sup>, a full-time trainer based in a CRO, often used the term *best practice* in a local sense with regard to specific methods (from line 125):

*“... there are different approaches within different companies and we have to work within those parameters ... you know, like in one company we ... we may discuss what is best practice in classroom training and ... and in another company may not have the opportunity to do that. They just don't do it, so it doesn't work for them.”*

Yet, in the Trainers' Forum, the issue of what it means to be a trainer was first raised at the 2nd meeting in 2004, and again at the 3<sup>rd</sup>, 4<sup>th</sup>, 5<sup>th</sup>, 8<sup>th</sup> and 9<sup>th</sup> meetings. In particular, discussion in the early meetings (and reports) focused on how to impress the need upon corporate management to maintain a balance in training delivery through use of “blended” methods (i.e. using the internet to deliver materials as a support to classroom training and not as a substitute for it<sup>51</sup>). Moreover, in the 2<sup>nd</sup> and 3<sup>rd</sup> meetings, Forum participants agreed that a trainer needs to be, at the very least, a balance between an engaging *knowledge-based* presenter and a mindful *facilitator* (as these contrasting elements of the training role were coined at these meetings)<sup>52</sup>.

However, as was also discussed, trainers needed to develop insight concerning the strategic purpose of facilitative training. It was also agreed that strategic capabilities were needed to conduct training needs analysis and evaluation in order to deliver strategic outcomes, and to justify to management the necessity for continued classroom delivery of training. But, qualifications were not perceived as helpful in developing this strategic expertise. For example, Peter, who had more than a decade's experience as a trainer, with at least four spent at director level managing a training department in a CRO, saw no need for them.

*Question: Would you be interested in a qualification?*

*Peter (from Line 30): No. In a word. No.*

*Question: Why?*

*Peter: I don't think it's necessary for me to do the job that I do... it might give me more credibility in the external training world. In fact, you were at the last meeting weren't you... where one guy asked about qualifications?*

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<sup>50</sup> Interviewee-5\_core\_EFDr

<sup>51</sup> TF\_FN\_1/U\_12-03;TF\_rep\_CRf\_Montgomery, 2004

<sup>52</sup> TF\_FN\_3/B\_09-04; and TF\_rep\_CRf\_Hayes, 2004b

*I don't think qualifications make a good trainer. I don't think you need qualifications to be a good trainer or a good training manager. But at the same time it won't hurt to have a qualification.*

*Question: So what does make a good trainer then?*

*Peter: I would say someone who has a very good knowledge of regulations and drug development, drug discovery...the subject in general. I think... background knowledge has got to be there.*

Likewise, Jennifer was an experienced trainer who decided to take a qualification via the CIPD<sup>53</sup> route, after more than a decade of experience: "... Although I enjoyed it, I didn't learn anything really new, as such. It just put a different slant on things"<sup>54</sup>. Gayle, a senior training manager, also found the CIPD certificate course, which she was required to take "...a complete waste of time. The course was a shambles; badly organized. Couldn't wait to get it over with."<sup>55</sup>.

By contrast, Sally<sup>56</sup>, a peripheral member of the Forum, had a more strategic view. As a relatively experienced full-time trainer of 4 years standing in a CRO, she explained that helping trainers to gain qualifications or to attend courses is not an easy task due to a lack of strategic perspective concerning the training role:

*From Line 466: I would say that the trainers that we have within our company have come from a subject matter expert arena and our difficulty has been to give them the trainer skills to build on their natural ability ... and to give them some specific training skills ..... because of ... well, as you know, what I described to you ... the fact that there isn't a formal programme for being qualified as a trainer.*

### **7.2.5 The background of trainers: qualified trainer or subject specialist?**

In terms of backgrounds, although the vast majority have science qualifications, only slightly more than a third has qualifications that relate specifically to training (35%). This finding is consistent with the emphasis on recruiting subject matter experts into the training role as indicated in a review over a period of three years<sup>57</sup> of ten job advertisements for trainers presented in Table 7-6: Role requirements/specifications in job adverts for trainers.

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<sup>53</sup> Chartered Institute of Personnel and Development

<sup>54</sup> TFS\_FN\_8/F\_12-06-2\_core\_EFDr

<sup>55</sup> TFS\_PC\_5/D\_05-05\_peri\_EFDr

<sup>56</sup> Interviewee 4\_peri\_EFDC

<sup>57</sup> October 2005 – November 2008

The majority of these adverts specify that subject matter experience is essential. In effect, this means that the candidate should have previous experience of working in the clinical research industry (90%; n=9). Subject matter qualifications and knowledge of GCP are also specified as essential in 60% of the adverts, but training qualifications however, are not specified in any (0%). Previous experience of developing or delivering training is specified as required in 60%. However, only one advertisement for “Training Manager” (advert #1) indicates that being able to engage trainees is considered an essential skill. Yet, curiously no previous experience as a trainer is required for this particular role. By contrast, this advert, and one other (#4), actively specified that previous training experience was not required (25%). In the latter case, the role of trainer required written and oral communication skills together with IT and presentation skills. In two cases (#2 and #9), the candidate was expected to assume the administrative tasks of quality controlling the training records (25%) and/or establishing a training management system (#9 and #3).

Consequently, research questionnaire findings are consistent with the profile of candidates specified in these adverts. For example, the vast majority of Forum members who responded were science graduates (28 versus 3 non-graduates or 90% vs. 10%), with far fewer having training credentials. Sixteen were post-graduates, five of which were PhDs. Of the eleven (35%) who had credentials as trainers, six were full-time (19.5%) and the remaining five (16%) had their roles split between part-time training and their main function (clinical research associate, manager etc.).

Types of training credentials were also varied (shown in Table 7-7: Training credentials), ranging from Train the Trainer courses (2/11; 18%) to traditional teaching qualifications awarded by universities (postgraduate certificates or diplomas in education: 4/11; 36%) or professional certificates and diplomas in training awarded by professional institutes (Chartered Institute of Personnel and Development or CIPD: 2/11; 18%) or other in-house course for university staff (CPD certificates: 1/11; 9%). The nature of credentials was not specified in two cases (3/11: 27%).

Therefore, the current trend in the field of clinical research (AS2) is to emphasise in job advertisements for the role of clinical research trainer that job applicants must be subject matter experts (SMEs) in clinical research, with qualifications and experience reflecting such expertise. Conversely, previous experience or a training qualification is occasionally listed as an advantage, but is not specified as essential. This trend is reflected and consistent with the finding that the minority of respondents had training qualifications (11/31 or 35%).

As will be discussed further in Chapter 9, this practice of hiring SMEs in the workplace has an impact on the neighbouring activity system of the Trainers' Forum (AS5), in that it creates a quaternary contradiction (LASU-AS2), as illustrated in Figure 7-1, and outlined in Table 7-8 in terms of the role of the regulatory environment (AS1) in its capacity as a neighbouring rule-producing activity system. In particular, the focus of knowledge-based trainers is on delivering technical content in accordance with the objectives of senior management in the workplace (AS3). Thus, in the Forum their object-activity is consequently restricted out of habit to the task at hand: delivery of an agenda.

As explained in Chapter 1 (problem statement), the tendency to hire mainly clinical research SMEs as knowledge-based trainers, whether in CROs or pharmaceutical companies, is a response to the demands of the regulatory environment (AS1) in the field of clinical research i.e. that personnel are "adequately qualified" to do their jobs. Hence, this practice assumes SMEs have the requisite knowledge needed that can then be "shared" with others in the organisation.

However, if conditions in the workplace regarding professional development for SMEs as trainers encourage their transformation into knowledge-based trainers, rather than into facilitative trainers, which the findings in the chapter indicate, such sharing in the workplace and Forum takes the form of knowledge delivered as content, rather than co-constructed. At this level of rationality, the identity of the 'trainer' remains poorly defined, particularly where training responsibility is delegated to 'part-time' trainers. Correspondingly, as suggested by the findings presented in Table 7-3, training resources remain limited or continue to be given

low priority. That is, a minority of survey respondents had training qualifications (11/31 (35%)), and yet almost half were full-time trainers (14/31 (45%)). Moreover, in explaining why they did not consider the research questionnaire (circulated at the Forum on four separate occasions<sup>58</sup>) as relevant to their situation, potential respondents stated: -

*“...I’m only part-time...”*

*“...actually I’m a CRA/manager/project manager, but I do some training...”*

Such responses suggested that those who shared the burden of this role barely identified with it. Hence, whereas subject specialists may look to their occupation for their identity, it remains to be seen where they search for their identity as trainers. It may be that they seek it through social networks established at the Trainers’ Forum to sustain this dimension of their identity. Furthermore, the results of the research questionnaire, presented in Table 7-2 (Trainers’ responsibilities), showed that irrespective of job titles and regardless of how their role was defined, individuals had responsibility for planning (97%) as well as delivering of content (90%). However, a minority show of hands<sup>59</sup> in response to: “how many here today are Trainers?” asked at two Forum meetings where the questionnaire was circulated in 2008, about *How we train others in SOPs*<sup>60</sup> and about *How we train our project managers*<sup>61</sup>, also suggested that even those who trained others on their organisations’ Standard Operating Procedures (SOPs) or who trained project managers, did not view themselves as trainers. Moreover, as shown in Table 7-6 (Role requirements/specifications) job titles did not necessarily give any indication of the range or level of training responsibilities that could be specified for full-time training roles. For example, job advertisements 1, 6, 7, and 9 are for ‘managers’. Yet, in the case of #1, this management position required ‘management’ skills, but did not further specify budgetary control or man management as requirements for this position, despite these being two of the usual responsibilities of managers. By contrast,

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<sup>58</sup> TF\_8/F\_12-06; TF\_9/G\_05-07; TF\_11/I\_03-08; TF\_12/J\_06-08

<sup>59</sup> Approximately one fifth of the 76 and 61 attendees respectively at both meetings

<sup>60</sup> TFS- DR\_11/I\_03-08-1\_EFDr

<sup>61</sup> TFS- DR\_12/J\_06-08-1\_EFDr

positions 2 and 9 required people mentoring and management skills, as did positions 6 & 7.

Yet, the job title of position #2 did not appear to be for that of a manager.

In conclusion, findings presented in Tables 7-6 and 7-2 (Trainers' responsibilities) together with the variation in job titles among respondents of the research survey (shown in Table 7-5: Job functionality or responsibility), suggest that presently the role of a clinical research trainer is not standardised and ranges from a part-time shared responsibility to a dedicated function ranging from addressing local training needs on a reactive basis to proactively ensuring that business objectives are achieved through ensuring that personnel are adequately and appropriately trained in GCP.

As results in Table 7-2 show, the majority of trainers were involved with planning and delivery, and only a minority were involved with evaluating the impact of training on: trainees' behaviour (n=11; 36%); achievement of performance-related goals (n=10; 32%); or, the impact of training on achievement of business goals (n=10; 32%). Such findings therefore support the conclusion that workplace training is a restricted technical function focussed principally on the delivery of technical content, regardless of its effectiveness.

In addition, research findings shown in Table 7-3, indicated that the minority of trainers, whether dedicated or in a shared-role have qualifications (11/31 or 35%), and of those, nearly half (40%), could not differentiate between pro-active and reactive training strategies.

Therefore, it appears that these particular qualifications do not necessarily help trainers to distinguish between strategic and operational training needs. Nevertheless, as revealed in a Forum survey of Trainers' Forum members<sup>62</sup>, clinical research trainers "have a conscious incompetence" concerning their desires and abilities to complete both ends of the training cycle, namely training needs analysis and evaluation.

Therefore, the role of the Forum in helping to resolve or transform trainers' conscious incompetence into conscious competence - the next stage in this particular skills learning

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<sup>62</sup> Results presented and discussed at the third Trainers' Forum in May 2004 and reported in CRf (Hayes, 2004a:22).

model (Howell, 1982) - will be examined subsequently in Chapter 9 (Purpose and pedagogy of the Forum). In particular, despite recognising the need to adopt a facilitative model in the workplace, collectively trainers have yet to give it predominance in the Trainers' Forum. Even so, despite being in the minority in the Forum, as will be further revealed in the next chapter, facilitative trainers maintained their focus on developing the expansive goals of organisational learning, which they then shared, in keeping with their individual object-activity of developing professionalism. This revealed the foremost primary contradiction in the subject element in the activity system of the Forum (L1SU). That is, trainers in the Forum divided into two groups: facilitative or knowledge-based trainers (KBTs). Within either of these groups trainers were either dedicated full-time trainers or cross-functional part-time trainers, as illustrated in Figure 7-2.

In conclusion, although the trainers differed in the circumstances and situation of their practice, at a minimum, each had common interests, experiences and problems in his or her role as a trainer as shared and discussed in the 55 sessions observed in 11 separate meetings of the Forum over a period of five years. Yet, despite the heterogeneous nature of the community, certain characteristics typified the circumstances and situation of the members of the Trainers' Forum, which also captured the contradictions inherent within their position as subjects in this activity system as modelled in Figure 7-1.

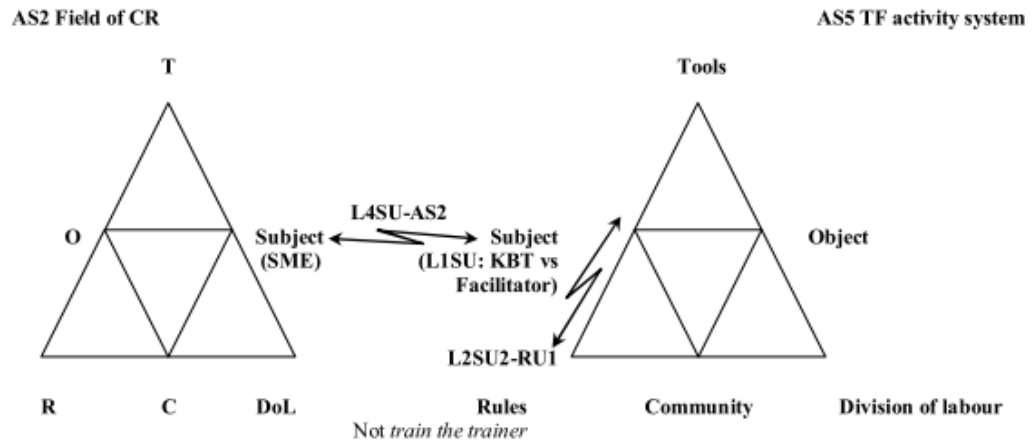
That is, although the community was made up of subjects with a range of skill sets across two differing knowledge domains (clinical research and training) they were typically employed either as dedicated 'full-time' trainers or as cross-functional 'part-time' trainers. However, within these organisational groupings, two differing rationalities manifested in discussion, as the local functional concerns of KBTs, or the strategic organisational concerns of facilitative trainers<sup>63</sup>, which will be elaborated further in Chapter 8. In particular, trainers differentiated their status on the basis of their dedicated or cross-functional roles, rather than their

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<sup>63</sup> TF\_FN\_2/A\_05-04; TF\_FN\_3/B\_09-04

rationality. Accordingly, the implications of these findings on the structure of the Forum as a community, its division of labour and rules governing behaviour are presented in Chapter 8 (The Forum: Community, rules and division of labour).





**Key**

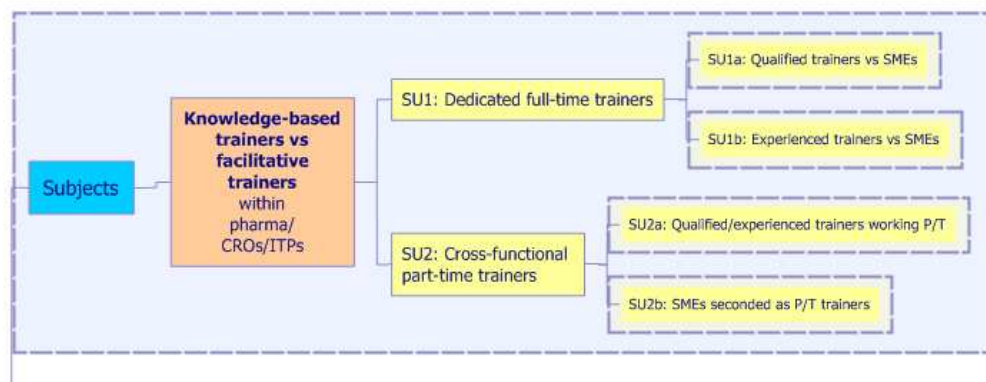
**L1SU:** Trainer as Knowledge Based Presenter vs Facilitator

**L2SU2-RU1:** The needs of part-time trainers are subsumed by the needs within the greater whole, on the grounds of not getting involved in 'Training the Trainer' (i.e. not challenging this rule).

**L4SU-AS2:** The practice of hiring predominantly SMEs in the field of clinical research, who then develop as knowledge-based trainers, is the subject-producing activity that affects the focus and rationality of practice in the TF.

**Figure 7-1: Modelling primary, secondary and quaternary contradictions in the Activity System of the Trainers Forum (AS5)**

**Level 1 contradictions (within Activity System elements)**



**Figure 7-2: 1ry contradictions in the element of subject in the TF (AS5)**

**Table 7-1: Demographic characteristics of Training Forum participants**

FUNCTIONAL ROLE	Trainer Characteristics (n=31)							
	Respondent id #	Experience (Yrs)	Gender		Dedicated vs. shared role		Qualifications	
			M	F	FT	PT	Training	Science
Sales (business development)	31	5	-	(1)	(1)		(1)	
				3%	3%		3%	
Clinical Research	9,12,15,18, 20-23; 30	6,20,3,6,6,6,4,2,7,8	-	(9)	-	(9)	(2)	(7)
			-	29%	-	26%	6%	23%
Project Management	10,28	3½; <1	-	(2)	-	(2)	-	(2)
			-	6%	-	6%	-	6%
Quality Management	11,14,16,19, 27	1,3,7,4,1½,12	(2)	(3)	-	(5)	(2)	(5)
			6%	10%	-	16%	6%	16%
Training	1-8; 13, 17, 24-26; 29	15,½,12,15,15,3,15, 3,7,2,3,<1, 27	(2)	(12)	(14)	(0)	(6)	(14)
			6%	39%	35%	0%	19%	45%
	<b>31</b>		(4)	(27)	(15)	(16)	(11)	(28)
<b>TOTALS</b>	<b>100%</b>		<b>13%</b>	<b>87%</b>	<b>48%</b>	<b>52%</b>	<b>35%</b>	<b>90%</b>

**Table 7-2: Trainers' responsibilities within micro, small, medium and large organisations**

Identity	Full-time Trainers (n= 15)					Part-time Trainers (n= 16)					
	N= (%)	Micro	Small	Medium	Large	Sub-T	Micro	Small	Medium	Large	Sub-T
		1-10	11-50	51-250	251+		1-10	11-50	51-250	251+	
Affiliation											
Pharma	13 (42%)	-	-	2	6	8 (26%)	1	-	-	4	5 (16%)
CRO	11 (36%)	-	1	1	2	4 (13%)	-	2	-	5	7 (23%)
ITP	4 (13%)	2	-	-	-	2 (6.5%)	2	-	-		2 (6.5%)
Other	3 (10%)	-	-	-	1	1 (3%)	-	-	-	2	2 (6.5%)
Responsibility											
TNA done by trainers	7 (23%)	-	1	1	1	3 (10%)	-	-	1	3	4 (13%)
Assessed via audit reports	21 (68%)	-	1	1	5	7 (23%)	3	1	2	8	14 (45%)
Assessed via O-T-J resources	18 (58%)	1	1	1	5	8 (26%)	2	1	1	6	10 (32%)
Planning	30 (97%)	2	1	3	9	15 (48%)	3	2	-	10	15 (48%)
Delivery	28 (90%)	2	1	3	8	14 (45%)	2	2	-	10	14 (45%)
Levels of Evaluation											
Evaluation L1	27 (87%)	1	1	3	9	14 (45%)	2	2	-	9	13 (42%)
Evaluation L2	14 (45%)	-	-	3	6	9 (29%)	1	1	-	3	5 (16%)
Evaluation L3	11 (36%)	-	1	2	4	7 (23%)	-	1	-	3	4 (13%)
Evaluation L4	10 (32%)	-	1	1	4	6 (19%)	-	1	-	3	4 (13%)
Evaluation L5	10 (32%)	-	1	1	4	6 (19%)	-	-	-	4	4 (13%)

**Table 7-3: Trainers definitions of proactive and reactive training**

Respondent id #	Definition 'Proactive ' 'Reactive'		Functional specialisms	Years of experience	Training qualification
29	R	R	Training	27	Y
26	R	R	Training	0.25	N
25	-	-	Training	3	N
24	P	R	Training	2	N
23	-	-	Training	7	N
17	P	R	Training	7	Y
13	P	R	Training	3	N
8	P	R	Training	15	Y
7	R	R	Training	3	N
6	-	R	Training	15	Y
5	P	R	Training	13	Y
4	P	R	Training	12	Y
2	P	R	Training	0.25	N
1	P	-	Training	15	N
30	R	-	Clinical Research	8	Y
22	-	-	Clinical Research	2	N
21	-	-	Clinical Research	4	N
20	P	R	Clinical Research	6	N
18	P	R	Clinical Research	6	N
15	P	R	Clinical Research	3	N
9	R	R	Clinical Research	6	Y
3	-	-	Clinical Research	2	N
12	-	-	Clinical Research	20	N
27	P	R	Quality Management	12	Y
19	P	R	Quality Management	1.5	N
14	P	R	Quality Management	37	Y
11	P	R	Quality Management	1	N
16	R	R	Pharmacovigilance	4	N
28	P	R	Project Management	0.5	N
10	R	R	Project Management	3.5	N
31	P	R	Sales	5	Y

**Key**

Proactive column: 'P'	Definition of <i>proactive</i> corresponds with that agreed at 2 <sup>nd</sup> / 3 <sup>rd</sup> Trainers' Fora to mean proactive training, which is performed “...to meet strategic needs”.
Proactive column: 'R'	Definition of <i>proactive</i> corresponds with that agreed at 2 <sup>nd</sup> / 3 <sup>rd</sup> Trainers' Fora to mean reactive training i.e. that training performed to address individual needs or operational issues.
Reactive column: 'R'	Definition of <i>reactive</i> corresponds with that agreed at 2 <sup>nd</sup> / 3 <sup>rd</sup> Trainers' Fora to mean reactive training i.e. that training performed to address individual needs or operational issues.
Either column: '-'	No definition given for either <i>proactive</i> or <i>reactive</i> .

**Table 7-4: Features of trainers' organisational locations**

Functional Area	Type of Organisation				Size of Organisation				Gender	Training Role		
	Other	Pharma	CRO	ITP	Micro	Small	Medium	Large			M:F	FT:PT
									1-10	11-50	51-250	251+
Training									2:13	15:0		
15	1	8	5	1	-	1	4	10				
48%	3%	26%	16%	3%	-	3%	13%	32%				
Clinical Research									0:8	1:7		
8	1	2	2	3	3	-	-	5				
26%	3%	6%	6%	10%	10%	-	-	16%				
Project Management									0:2	0:2		
2	-	-	2	-	-	1	1	-				
6%	-	-	-	-	-	3%	3%	-				
Quality Management									2:3	0:5		
5	-	3	2	-	1	-	-	4				
16%	-	10%	6%	-	3%	-	-	13%				
Sales									0:1	0:1		
1	1	-	-	-	-	-	-	1				
3%	3%	-	-	-	-	-	-	3%				
<b>Totals</b>	<b>3</b>	<b>13</b>	<b>11</b>	<b>4</b>	<b>4</b>	<b>2</b>	<b>5</b>	<b>20</b>	<b>4:27</b>	<b>16:15</b>		
	10%	42%	35%	13%	13%	6%	16%	65%				

## Abbreviations

FT	Full-time
PT	Part-time
M	Male
F	Female
CRO	Contract Research Organisation
ITP	Independent Training Provider

**Table 7-5: Job functionality defined by job title**

Shared responsibility (PT)		Shared function (PT)		Dedicated function (FT)
Sales	Clinical Research	Project Management	Quality Management	Training
Business Development Executive	CT Coordinator	Clinical Project & Training Manager	Snr QA Auditor/Training Facilitator	Training Coordinator
	Freelance CR Trainer		Compliance & Training Advisor	Trainer Advisor
	CR Consultant		Pharmacovigilance Standards Manager	Clinical Trainer
	Snr CRA		Compliance Manager	Snr Lecturer
	Protocol lead CRA & Dept Training Representative		QA Manager	Principal Education Advisor
	CR Monitoring Manager			Manager, Clinical Research Training
				Training Manager R&D
			Snr Clinical Training Manager	
			European Training Manager	
			Manager, Global Training & Development	
			Global Clinical Training Manager	
			Head of Training & Personal Development	
			Director	
			Managing Director	

Abbreviations

CT	: Clinical Trial
CR	: Clinical Research
Snr	: Senior
CRA	: Clinical Research Associate
CR	: Clinical Research
QA	: Quality Assurance
R&D	: Research & Development
FT	: Full time
PT	: Part time

**Table 7-6: Role requirements and specifications in job advertisements for trainers**

Job advertisement	#1	#2	#3	#4	#5	#6	#7	#8	#9	#10
Date	Oct 05	Nov 05	Dec 05	Oct 06	May 07	Sep 07	Sep 07	Oct 07	Jan 08	Nov 08
Position	Manager	Trainer	Training Consultant	Trainer	Training Consultant	Snr. Manager	Manager	Training Exec	Training Manager	Snr.Trainer
<b>Job specification</b>										
UK responsibility	-	✓	✓	✓	✓	✓	✓	✓	✓	✓
Global: European	-	✓	-	✓	✓	✓	✓	-	✓	-
Global: US	✓	-	-	-	-	-	✓	-	-	-
SM Qual	✓	✓	✓	✓	-	✓	-	✓	-	-
<b>SM Knowledge</b>	✓	✓	✓	-	✓	✓	✓	✓	-	-
CR processes	-	✓	✓	-	✓	-	✓	✓	-	-
GCP	-	✓	✓	-	✓	✓	✓	✓	-	-
Regulatory reqmts	-	✓	✓	-	✓	✓	✓	✓	-	-
SM Experience	✓	✓	✓	-	✓	✓	✓	✓	✓	✓
pT Quals	-	-	-	-	-	-	-	-	-	-
<b>pT Skills</b>	✓	✓	✓	-	-	-	-	✓	-	-
Written comm skills	✓	✓	-	✓	-	-	-	✓	-	-
Oral comm. Skills:	✓	✓	-	✓	-	-	-	✓	-	-
Presentation	✓	✓	-	✓	-	-	-	✓	-	-
Coaching	✓	✓	-	-	-	-	-	-	-	-
<b>IT skills</b>	-	-	-	✓	-	-	-	-	-	-
<b>Provide engaging trg interventions</b>	✓	-	-	-	-	-	-	-	-	-
<b>pT Experience</b>	✘	✓	-	✘	✓	✓	✓	✓	✓	-
Developing courses	-	✓	-	-	-	✓	✓	-	-	-
Delivering courses	-	✓	-	-	-	✓	✓	-	-	-
<b>Responsibilities</b>	✓	✓	✓	-	✓	✓	✓	✓	✓	✓
TNA	✓	✓	-	-	-	-	-	✓	✓	-
Planning & prep	✓	✓	-	-	✓	-	✓	✓	-	✓
Delivery	✓	✓	✓	-	✓	-	-	✓	-	-
Provide 'hands-on'	-	-	-	-	-	-	-	-	✓	-
Organise delivery	-	-	✓	-	-	-	-	-	✓	-
Evaluation / Implementation	✓	-	✓	-	-	✓	✓	-	✓	-
L1	-	✓	-	-	-	-	-	-	-	-
L2	-	-	-	-	-	-	-	-	-	-
L3	-	✓	-	-	-	-	-	-	-	-
L4	-	✓	✓	-	-	-	-	-	-	-
L5	-	-	-	-	-	-	-	-	-	-
<b>Management skills:</b>	✓	✓	-	-	-	✓	✓	-	✓	-
Budget	-	✓	-	-	-	-	-	-	-	-
QC training records	-	✓	-	-	-	-	-	-	✓	-
Establish a TMS	-	-	✓	-	-	-	-	-	✓	-
People mentoring	-	✓	-	-	-	-	-	-	✓	-

Key: ✓ = specified as an essential requirement; ✘ = specified as non-essential or not required; - = not specified or mentioned

Abbreviations: Trg = training; SME = subject matter; pT = professional training; IT = information technology; TNA = training needs analysis; QC = quality control; TMS = training management system; L1-5 = Kirkpatrick's evaluation levels

**Table 7-7: Training credentials of respondents**

Respondent id #	Training Credential
4	? unspecified
5	? unspecified
6	CIPD Diploma Training Practice
8	PGCE
9	CIPD Cert Training Practice
14	CPD: L&T for General Teaching Associates
17	PGTC/Dip Ed
27	PGCE
29	PCGTHE
30	Train-the-Trainer course
31	Adult Learner Support
11	11



**Table 7-8: Role of neighbouring activity systems on the Trainers Forum**

AS	Locus	Subject	Object	Central Activity	Motive	Tools	Rules	Actions	Operations	Outcome	Neighbouring Role	L4 Contradiction with TF (AS5)
1	Regulatory Environmt	Inspectors	Inspecting Clinical Research (CR) process	Ensuring safety of CR (CR governance)	To enforce vs. monitor GCP compliance	Directives ; Compliance culture	Compliance	Inspections	Statutory inspections (previously voluntary <sup>64</sup> )	Patient protection via enforcing vs. raising standards	Rule-producing activity	Culture of compliance vs. conscience
2	CR field	Managers	Training	Managing CR Training	Satisfying Training Needs (TNs) re GCP compliant behaviour	Pedagogy & idiom	Hire SME vs. PTs  Develop Subject Matter Expertise vs. Professional Training Skills	Expedient, cost-effective delivery of content; evaluating trainee knowledge (K)	Stage 3 - T/cycle (i.e. delivery); L1& 2 evaluation <sup>65</sup>	Trainees demonstrated to: have received requisite GCP “K” (i.e. information) vs. Demonstrated to have capability re GCP compliant behaviour	Subject-producing activity	CR trainers who are mainly SMEs not PTs

64 Before the introduction of Directive 2001/20/EC, on 1 May 2001, inspections by regulators took place on a voluntary basis)

65 L1 evaluation: checking trainee satisfaction with content, delivery methods etc.; L2 evaluation: assessing trainee knowledge before and after a training intervention

## **Chapter 8**

### **The Forum: Community, Division of Labour and Rules**

## **8 THE FORUM: COMMUNITY, DIVISION OF LABOUR, RULES**

The Trainers' Forum is viewed as an activity system (AS) in its entirety through considering the continuous patterns of activity within sessions of Forum meetings. However, in order to proceed with analyses at the level of the declarative, procedural and social interactions/discourses that Engeström suggests are necessary for actual-empirical analyses, the community, its rules and division of labour are foregrounded. The object of activity can then be analysed subsequently in light of the conceptual models that have emerged in the Forum. Findings concerning the object of activity are therefore presented last in Chapter 9, in order to conclude discussion of the object of activity - and the thesis argument - in terms of how particular conceptual models are associated with a particular rationality of practice and professionalism.

### **8.1 Community: What is the Trainers' Forum (TF)?**

As a component of this AS, the concept of *community* is pivotal to analysis of the Trainers' Forum - both as a Community of Practice and as an AS - since describing structure of the Forum elaborates the community formed by its members. Moreover, the structure of the community is bound up in the activity within the public and private spaces across which members' practice is shared, providing the context for analyses of the hierarchical structure of human activity, as shown in Figure 2-1, Chapter 2.

Understanding the meaning of the activity, actions and operations of the Forum depends on understanding who subjects are (in this case - participants in the Trainers' Forum), and how they cooperated in their object of activity. Who they are was presented and discussed in Chapter 7. How they cooperated is considered in this chapter with findings reported about the community forming this system of activity, its rules and division of labour.

Analysing the social practices of the Forum before presenting in-depth analyses of the object of activity and the tools used to achieve it, unravels the conditions, goals and motives affecting and driving participants' actions. It also gives further meaning to the object of

activity in terms of the concept of practice, methodology and experience of the subjects within the system of activity. Preliminary analysis of the object of analysis, also takes place at this point.

Finally, findings are reported and discussed in this chapter about the community, its rules and division of labour on the basis of observing 55 sessions of the Trainers' Forum, and from gathering data from informal and in-depth interviews with 15 members of the Forum together with examining artefacts produced for and from the Forum. Interviewees' profiles are presented in Table 8-1.

### **8.1.1 *The TF: A hosted specialist group constituted within the ICR***

The Trainers' Forum is a cross-boundary structure that constitutes one of the many specialist groups within the professional body of the Institute of Clinical Research (ICR). These groups are collectively known either as Forums or as Special Interest Groups or SIGs. Members of the TF community may also belong to ICR special interest groups (SIGs), or they may sit on the Board of the ICR.

According to the ICR, the key difference between a Forum and an SIG is that the former concerns an area of interest, while the latter is "...generally constituted to deal with a specific role or activity within clinical research" (Noble, 2008: 38). Yet, even as a Forum, the TF serves as a model of professional development for trainers, since it fulfils the criteria of the ICR to act as a vehicle for sharing best practices, raising standards, and developing the professional.

The community forming the Trainers' Forum is drawn mainly from the commercial sector of the specialised field of clinical research. Nevertheless, it also encompasses the public sector (i.e. the National Health Service (NHS), which includes academic units operating within its Trusts). However, such members represent a minority, reflecting the ICR's history as a professional association whose members were mostly employed within the pharmaceutical industry or its associated service industries (recruiters, freelancers, contract research organisations).

Nevertheless, over time it has been recognised that the professional affiliations of members extend beyond these private sectors into the public sectors of academic research and the NHS, where clinical research is also conducted. However, because the focus of this study mainly concerns those members of the community from the private commercial sector, the scope of the study is limited to discussing emergent features of the community in terms of the ‘ecology’ of the private sector. Therefore, the characteristics of Forum members, mainly drawn from this commercially employed *community* of trainers, were described in Chapter 7.

### **8.1.2 The TF: A vehicle for CPD constituted within the ICR**

The Institute of Clinical Research (ICR) was originally founded in 1978 as an association<sup>66</sup>. In 2000 it changed its status to become the Institute of Clinical Research representing the interests of members in the field of clinical research.

The ICR offers CPD programmes for clinical research personnel, which includes specific formal qualifications in clinical research run previously in conjunction with John Moores University, and now with Cranfield University (Scott *et al*, 2000). As yet there are no equivalent academically certified courses offered under the Institute’s umbrella specifically for trainers to develop or improve their professional training skills. ICR’s principal academic focus appears to be on developing the knowledge and skills of clinical researchers, monitors and administrators, etc.

This may reflect early days in recognising the professionalisation of clinical research (CR) trainers. Or, it may simply reflect that other professional bodies fill the specialist needs of trainers. For example, as explained at the 8<sup>th</sup> Forum held in May 2007<sup>67</sup>, trainers may turn to the Chartered Institute of Personnel and Development (CIPD), which offers the Certificate (foundation level) and the Diploma in Training and Development (advanced level). By contrast, as discussed at the 12<sup>th</sup> Forum in June 08, certain professional qualifications are

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<sup>66</sup> The ICR was originally founded as ACRPI (The Association of Clinical Research for the Pharmaceutical Industry). According to the ICR, it is well established as the largest clinical research body in Europe and India. It is a not-for-profit organisation, guided by a Board of Directors who are elected by the membership and is based at its Head Office in Buckinghamshire, UK.

<sup>67</sup> TF\_rep\_8/F\_12-06\_Crf\_18(5):30\_May07

regarded as necessary requisites<sup>68</sup> in some roles such as Project Managers). Such requirements indicate a standard is being set for formal evidence of CPD, shifting it from voluntary to mandatory.

As yet, it remains to be seen whether, or how, this trend will affect CR trainers, or what the implications might be for their future professional and career development, especially given the increasing regulatory requirements in clinical research. In particular, it seems that the contradictory response to ensuring that organisations satisfy these regulatory demands is to ensure trainers with a particular level of experience and knowledge in clinical research are recruited, regardless of their experience or knowledge of training process, as discussed in Chapter 7. Thus, as indicated in Table 7-6 (Role requirements and features in job adverts), the trend continues among employers to hire SMEs as trainers.

Meanwhile, the Institute revised their CPD scheme in 2007. Accordingly, since 2008, going to the Forum leads to the award of three CPD points in a formal certificate of attendance, which members retain for their personal records (Fitzpatrick, 2008). Hence, the Forum is recognised as a vehicle for CPD by its host organisation, the ICR.

### **8.1.3 The TF: Public and private spaces constituted within the community**

The Trainers' Forum is open to anyone with an interest or passion in training, who is a member of the ICR, as reflected in the mission statement published in the Institute magazine (February 2004)<sup>69</sup> and again on the Trainers' Forum page of the Institute's website (June 2005)<sup>70</sup>. Non-members of the Institute are also able to attend meetings, for a small fee.

Trainers' Forum meetings are official events held at least three times a year and hosted by the ICR for members with responsibility for training who wish to pursue their CPD. The Fora represent the public space within this particular community of practice, where members

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<sup>68</sup> Project managers tend to turn to the Project Management Institute, a global organisation established since 1969, to gain accreditation of their knowledge and skills as a Project Management Professional, an accredited qualification obtained by examination and requiring re-validation every three years, as explained by Shirley, a project manager in a large CRO, at the Trainers Forum in June 08 (TF\_DR\_12/J\_06-08-4\_EFDr).

<sup>69</sup> TF\_1/U-12-03\_CRf\_15(1): 34-35\_Hepworth-Jones, 2004

<sup>70</sup> TF-pu\_ICR-website\_06-05; Appendix A

gather. It is possible to analyse the social processes that shape or affect this ‘public’ space through Wenger’s model of a *Community of Practice* (1998). However, the model also concerns private spaces where individual practitioners interact within ‘private’ spaces, and which are not necessarily visible to the rest of the membership. For example, in the Forum, ‘private’ interactions are neither shared nor accessible to the wider distributed community, such as when members of the Steering Group (SG) meet in person or meet virtually by teleconferences or communicate by e-mail.

Nevertheless, these established relationships were evident within the public spaces and impacted upon others, intended or otherwise. In particular, peripheral members felt excluded from proceedings since the core group spent time catching up and talking among themselves and not necessarily networking to welcome newcomers, an aspect that Sally<sup>71</sup>, a newly appointed trainer at her first Forum, touched on in her first interview:

**From Line 376:** *I didn’t get as much out of the sort of networking aspect. I think I would have preferred a more workshop-type forum, because there was obviously groups of people who came regularly, who knew each other well, who sat together and caught up with each other.*

*Coming in as somebody new into that Forum, it was difficult to slot into a group. Then, are you just there to have a nice day out - to realise that you’ve got similar issues to somebody else? But, never really saying: well, what do you do about it, how do you sort that out?*

Sally’s comments typified peripheral interviewees’ expectations regarding the networking opportunity. In particular, Mary<sup>72</sup>, an experienced part-time trainer and clinical research administrator, shared her expectations as follows:

**From Line 78:** *I wanted an insight into what’s happening in training in the industry and I wanted to meet some trainers and see how many full-time trainers dabble in it. How many do it because they have to ... and to benchmark me as well. To find out, is it an area I want to carry on in, or not carry on in? What support is there in the industry? So, if I choose to carry on, can I go back to the Forum and say: Help, or can I network with the Forum and say: you know, what should I do now? Or, some advice, I suppose, just advice, really.*

**Question:** So did you achieve that?

**From Line 86:** *Mm, no. But. I went there to see if that was there ... yeah?*

*I networked and talked to a number of people and yeah, that did make me feel that I have a place somewhere, in training in the industry, if I want it. But then it’s up to me to find out how I go about doing that.*

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<sup>71</sup> Interviewee-4\_peri\_EFDc

<sup>72</sup> Interviewee-2\_peri\_EFDc

Other interviewees were disappointed that due to the very short tea break they did not talk to more people or have more opportunity to talk. The unfulfilled need to talk both within the public and private spaces was a common thread, typified by Deirdre's comments<sup>73</sup>, below:

**From Line 127:** "...I thought I'd be able to chat more with others and share experiences. Instead, I got chatting with another trainer who'd been at the meeting<sup>74</sup> on the train on the way home. To be honest, we both felt that we didn't get much that was of use for us."

Mary, who was new to the Forum, also felt that rather than relegating networking to coffee-breaks and lunch, sessions should also offer more opportunity for this:

**From Line 24:** I think there could have been a bit more gelling earlier on. People warmed up later on in the afternoon and I think there could have been a bit more interaction ... earlier on. People were very shy at the individual tables: some gelled, some didn't. I mean, on my table, they kind of all stared at each other.

On the one hand, the limited time available to network, particularly in meetings prior to 2008, reflected the way in which meetings were structured, in an ordered and controlled way, adhering to a scheduled agenda. In the first few years of meetings, guest speakers, and occasionally some core members, arrived just in time for their allotted slot, and left shortly after, due to other commitments, even though these meetings generally only lasted from 10am until 1pm.

Progressively, the networking model was modified. The Steering Group noted members' need for more time to socialise, particularly over lunch. The structure of the meetings was gradually extended, as shown in Table 8-2<sup>75</sup>. By May 2007, meetings routinely ran from 10am until 3pm. In terms of the format for the day, the habit was to launch straight into outlining the agenda, then to introduce the first speaker/leader. Forum participants were not in the habit of introducing themselves when asking questions or during exchanges.

On the other hand, it could be argued that newcomers to the Forum, particularly those who are also newly appointed trainers, lacked sufficient confidence either to introduce themselves, or to interact with other members, let alone core members<sup>76</sup>. Such members, fitting with

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<sup>73</sup> Interviewee-1\_peri\_EFDr

<sup>74</sup> TF\_10/H\_09-07

<sup>75</sup> Table 8-2: Outline of meeting themes and session topics.

<sup>76</sup> In my own case, at the first meeting I attended (18<sup>th</sup> May 2004), I directly approached those acting as 'organisers', who were recognisable by their demeanour of confidence, familiarity and authority. Even before I had any clear



Wenger *et al's* (op.cit.) description of those on the periphery, appeared inhibited by the type and level of interactions, and some commented on refraining from intruding upon apparently 'established' relationships. Hence, relationships between core members were apparent, in that they knew each other, and talked to each other. As a peripheral member on her first visit to the Forum, Sally spoke of being relieved to meet one other person she already knew from outside the Forum, given that it had been her turn to go to the Forum:

**From Line 396:** *I really felt that it was a networking environment to share good practices and maybe some discussions with people. And it was. But, I was always hoping that I would be able to meet up with some of the people that I knew and I did. One of my old colleagues from XYZ Ltd was at one of the meetings, and presented, and that was a nice opportunity. But, I think people's attendance was quite sporadic as well. I certainly know, for us, within our group, we had only allowed one person to go. So, there was probably three of us who were based in the UK and showed an interest. So you know - we take it in turns really.*

Sally's comments were echoed in the general awkward behaviour of newcomers who appeared not to know anyone, especially when the numbers attending the Forum began to double and treble. This was particularly evident when the ICR moved to bigger premises, where the meeting and general congregation rooms were quadruple the size of the previous rooms. At the start of the meeting in March 2008, many newcomers stood around looking awkward, or they pre-occupied themselves with getting drinks, or watching the preparation to start up the meeting<sup>77</sup>.

Yet, in this next extract, Mary, an experienced trainer, describes how she found herself constrained in making connections at this same meeting, not because she lacked confidence at networking, but due to her experience of the predominantly monologic structure of the Forum, despite the first session starting with an interactive juggling exercise.

**From Line 155:** *I met new people. That was good. It does make you feel part of the bigger picture, doesn't it, when you meet other people? ... 'Cause we're all doing the same thing. Laughter*

**From Line 370:** *I was very much an observer, because there wasn't an opportunity for me to do anything. On our table for example, we did say each others' names...to first introduce. But we didn't really gel, because there were two or three just writing very copious notes the whole time. I think these people may have to go back and present to their companies. That's quite*

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ideas about my research, I wanted to know more about what was going on, who these organisers were, how they got involved and why the TF was established. In other words, I was curious regarding their mandate and interested in joining forces to expand my social network among like-minded professionals.

77 TF\_FN\_11/I\_03-08

*evidently what people do, if you're released for a day to go on a training course. You have to go back and present the training ... of what you did. So we didn't gel.... you know? I was just an observer, definitely a listener – talker.*

*I think if you get the chance to have the breakout ... quite early in the day, because that's when everybody starts to get to know each other. Not last thing before you go home ...and then you get more of a buzz in the afternoon.*

As Mary observed, the monologic structure of the Forum inhibited her ability to network or learn through socialising.

As the criticism of how the networking opportunity was managed in the Forum indicates, networking was a key factor for trainers going to the Forum, as exemplified by Donald, Michael, Peter and Molly, when asked why they took part.

Line 60.	Donald <sup>78</sup>	<i>Primarily, I think it was because it was a way of talking to other people, who were doing a similar job to mine ...</i>
Line 55	Michael <sup>79</sup>	<i>What I need - is to mix with people. You get more from the lunch breaks and coffee breaks than you do from the sessions...</i>
Line 66	Peter <sup>80</sup>	<i>I think it's given me a really good network of contacts within training in the pharma industry...</i>
Line 313	Molly <sup>81</sup>	<i>I guess I see the Trainers' Forum more as networking, and me being able to contribute...</i>

For Evelyn<sup>82</sup>, a core member of the Forum, it also helped her to feel less isolated and more confident:-

**From Line 112:** *Because I was working solo. I'd moved from a big team. And so being in a big team and suddenly going to being sort of the training department, I felt quite isolated. And it was really the network. That was the real reason, you know, to make sure that I could provide [company name] with the best training ... and by doing that, I felt I needed to do some networking.*

**From Line 124:** *It sort of helped build my confidence actually. That what I was doing was the right thing. It helped give me confirmation that what I was doing was OK. And, it gave me pointers for other things that I could be doing.*

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<sup>78</sup> Interviewee-8\_act\_EFDc

<sup>79</sup> Interviewee-7\_act\_EFDc

<sup>80</sup> Interviewee-5\_core\_EFDr

<sup>81</sup> Interviewee-9\_core\_EFDc

<sup>82</sup> Interviewee-6\_core\_EFDr

However, it could also be argued that with the passage of time, as relationships become more established between Steering Group (SG) members, and thus more apparent, it becomes even more difficult for newcomers to break into this group. In particular, new members found these established relationships a little intimidating, especially as SG members were not introduced to other members in a formal capacity at meetings as a way of breaking the ice.

Yet, membership of the SG did not remain static. As new members joined, some core community members stepped down formally (Michael<sup>83</sup>; James<sup>84</sup>). Others simply dropped out of the Forum (Leanne<sup>85</sup>). Or, in Michael's case, his attendance became intermittent due to a change in his priorities (Line 2):

*"In the last year, I stepped off the steering group to let other people have a shout; and also because by then I was on the Board."*

Therefore, participation within the public and private spaces was dynamic, with movement between them, at active and core levels, as members joined, then informally dropped out or formally stepped down from the Steering Group. However, the tension in this movement between participation levels surfaced in the experience of one member, Leanne, who expressed an interest in joining the SG. Once 'on board', during a Steering Group conference call, she voiced her concerns over its non-inclusive processes. Discussion was reported in the meeting minutes as:

*"...It was agreed that we need to look at the structure of the group, and the way forward and ways to bring in "new blood..."<sup>86</sup>*

Subsequently, after participating in one SG meeting, this member then dropped out of the Forum completely, to pursue her CPD commitment elsewhere, as she explained:

*"I started the CIPD Certificate in Training Practice in March and it was taking up so much time that I felt I couldn't give what was needed to the Trainer's Forum. I'm hoping to go back next year if there's still a gap..." Leanne<sup>87</sup>.*

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<sup>83</sup> Interviewee-7\_act\_EFDc

<sup>84</sup> Interviewee-10\_core\_EFDc

<sup>85</sup> Interviewee-15\_active\_EFDc

<sup>86</sup> SG\_FN\_TC\_Pre\_10/G\_07-07

<sup>87</sup> PC\_e-mail\_09-06-08\_catch-up\_Leanne\_act\_EFDc

A few months later at the next meeting of the Steering Group (September 2007), Michael and James announced their decisions to step down to make-way for new blood. The timing coincided with James' new business venture as a freelance trainer. However, his sensitivity to Leanne's critique of the SG's leadership style played its part in the timing of his decision to step down, as he explained:

*"It feels like a thankless task at the best of times...then when you're accused of being too cliquy...there's no pleasing some people...so what's the point? I've got my own concerns to deal with, so that's it. I'm leaving the field clear..."<sup>88</sup>.*

In terms of taking the group forward with new blood, this became the regular focus of meetings that followed, until new members were proposed, who subsequently joined in 2008. From the point at which feedback forms were introduced routinely after Forum meetings in May 2007, thirty-one Forum participants had volunteered to join the Steering Group. Three members each volunteered on two separate occasions. Two who volunteered their services on only one occasion, but who were already known to SG members, subsequently joined the SG (Table 8-3<sup>89</sup>).

Therefore, the main tension identified within the community, concerns movement of core and active members between its public and private spaces. Likewise, the community was in a constant state of turnover of peripheral members with a minority of the same peripheral members in attendance. Since the numbers going to the Forum increased, more and more new participants attended only once.

The relationship between this tension and the control of the agenda by the Steering Group will be discussed further in section 8.2 along with role of the Steering Group.

## **8.2 Practices of the Forum: Historical Division of labour**

In keeping with the constitution established by the ICR, members of a Forum can fulfil two possible roles: Steering Group members; and TF members, who become active or peripheral

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<sup>88</sup> PC\_FN\_TF\_10/H\_20-09-07\_Interviewee-10\_core\_EFDc

<sup>89</sup> Table 8-3: Steering Group recruiting opportunities.

members depending on their level of participation. A Steering Group has a chair, a minimum quorum of four members, and a maximum of fourteen<sup>90</sup>.

Consequently, the vertical division of labour (L1DoL1<sub>v</sub>) in the Trainers' Forum meant that the Steering Group made decisions about what happened in Forum meetings, how often meetings took place, and their themes. Steering Group members, therefore, decided how often to re-visit a topic or whether to have similar progressing themes in successive meetings. The SG were also in a position to develop an inclusive or exclusive leadership approach towards Forum participants.

The roles of the Steering Group, and active or peripheral members are discussed in the next sections.

### **8.2.1 Roles in the Community: Who did what?**

In the 1990s, trainers formed an informal network, which later dissolved. Another few years later, members approached the ICR to suggest that a trainers group be re-established, this time under the Institute banner<sup>91</sup>. In 2003, a general invitation was circulated by the ICR to members to form the Steering Group for the Trainers' Forum<sup>92</sup>. Hence, those who responded to the invitation formed the original SG members. Thereafter, members of the Forum joined the SG in a number of ways described in the following section.

By virtue of their assumed role as organisers, SG members took part in telephone conference calls to discuss the agenda for future meetings. However, this model of communication between SG members was not introduced until 2006, as an alternative to planning meetings face to face. In the early days, SG planning meetings were held after the regular meeting had closed, but were not formally announced as such. Nevertheless, to those who remained to chat in the coffee room, it was clear that "something" was going on, if not exactly clear what. Communication between the SG also took place by e-mail. From these private discussions,

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<sup>90</sup> Steering group terms & conditions, circulated after a SGM in July 2007

<sup>91</sup> TFpu\_1/U\_12-03\_CRF\_15(1)\_Feb04

<sup>92</sup> Eveyln\_Interviewee-6\_core\_EFDr

SG members then contacted either external people or active members to invite them as "speakers" in forthcoming planned meetings.

Therefore, as a rule, active and peripheral members were excluded from planning arrangements (L1RU3). Moreover, the process involved in planning agenda was not accessible to these members, nor were they expected to contribute to the organisation of the Forum. However, on one occasion, for the regulatory inspection meeting, the Chairperson sent out an e-mail via the ICR "calling for suggested speakers" to all members who had registered an interest in attending the Trainers' Forum.

This call from the SG to the Forum membership for 'help' represented a new model of communication. It presented an opportunity for a horizontal division of labour (L1DoL<sub>H</sub>) through a model of collaboration, which assumed some equality between participants in the Forum irrespective of their status as core, active or peripheral participants in the community.

However, this was the first and last time that the distribution list of 118 members of the Trainers' Forum was made visible to all. Presumably, this visibility had been intended to stimulate a response rather than a discussion, since no SG members engaged with the brief e-mail trail that arose among active TF members, in response to a suggested session from an active member<sup>93</sup>. By 2008, the Data Protection Act was quoted by the ICR as a reason for not having a visible membership or not being able to provide estimates of the TF membership:

*"...we are limited as to how much information we can give out about our members due to data protection, we are also pretty rushed off our feet at the moment..."<sup>94</sup>.*

Subsequently, a vertical division of labour through which the community mediated its activity was maintained (L1DoL<sub>V</sub>), reinforcing the status of the participants as core, active or peripheral, and highlighting the distribution of power between them. Active and peripheral

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<sup>93</sup> In order to open up the discussion among members, I copied my response to this e-mail to the other 117 Forum members listed. In effect, the level of need among the members for the proposed topic was canvassed. This action also made visible support for proposed methods to share the topic. It also provided an opportunity for members to make further suggestions.

<sup>94</sup> PC\_e-mail\_28-02-08\_data protection\_Vivienne

members were excluded from controlling the agenda, with their input limited to providing suggested topics via feedback forms. Although core members briefed guest session leaders / presenters, they did not control how these individuals chose to deliver their topic or the exact nature of the content. Occasionally this lack of control raised comment after a meeting, about a particular topic's 'fit' within the overall theme, or about the amount of overlap in presentations. Dissatisfaction was apparent in the Forum feedback about *how we train our investigators* in October 2008. The issue of how presentations were vetted prior to the meeting was raised by Forum participants in the then routine feedback forms circulated after the meeting (shown in Table 8-4: October 2008 Forum Feedback). Consequently, it was noted in the SG minutes that:

*"...for future events we need to be more insistent about having slides in advance in order to check that the content is what we are looking for and that there is no/very little overlap between presentations"<sup>95</sup>.*

#### **8.2.1.1 Steering Group members: volunteer or elected leaders?**

Steering Group members arranged and led meetings, and were responsible for agreeing an agenda, deciding and organising its content and for making it happen. Given their level of participation in organising the Forum, by definition, Steering Group members were core members of the community. In addition, most had a generally visible and audible presence in terms of their contributions at meetings, making them recognisable as experienced Forum members to others.

However, as a consequence of recognising the need for new blood raised during a SG conference call in July 2007, rules were instituted after the September 2007 meeting, using the ICR framework for Steering Groups to propose and appoint TF members to the SG. Therefore, over time, as the ICR's processes developed, recruiting members to the Steering Group was gradually formalised. By October 2007 it was described as follows by the ICR coordinator in response to a core member's query about how to introduce members into the SG:

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<sup>95</sup> SG\_mins\_13/K\_10-08

*"...I will forward an application form and info booklet. They complete the application and forward it back to me with a current CV and then it goes to the Chair and Vice Chair. If accepted the person will be invited to the next meeting as an observer and if everyone is happy will become a fully fledged member after that"<sup>96</sup>.*

By contrast, prior to the introduction of this process, becoming a SG member was an informal process:

*"So, I went along to a meeting and ... Michael Campbell was at the meeting, as well, and I was just chatting to him. He decided that I needed to be on the Steering Committee. In those days, it was all very kind of informal, I mean ... it was ... 'Oh, I think you should be on the Steering Committee, don't you?' 'Oh yes, that would be a good idea' ... 'OK, you're on, then!'" Molly<sup>97</sup>.*

Thus, the Steering Group started as a self-selected core<sup>98</sup>. As the Forum developed, SG members – as core members of the community – generally recognised other members' active contribution during meetings. Subsequently, the active Forum member was then invited to join a Steering Group meeting, after a Forum meeting.

#### **8.2.1.2 Who are the peripheral and active members?**

As originally intended by the Steering Group, Forum meetings were generally held two to three times a year and were organised by trainers for trainers. Most attendees considered the meetings as networking opportunities. In this sense, as members of the Forum, trainers constituted a widely distributed community, the visibility of whose members gradually increased at successive Fora.

Since inception in December 2003 to Oct 2008, attendance numbers varied at each meeting.

In the early meetings, numbers averaged from 25 to 30. By 2005, numbers increased to around 40, steadily increasing to around 60 by 2007, and peaking at almost 80 by 2008.

However, an indication that the community was much larger than indicated by attendance numbers, first came from the e-mail circulated to members by the ICR on behalf of the

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<sup>96</sup> SG\_e-mail\_07-10-07\_SG joining process

<sup>97</sup> Interviewee-9\_core\_EFDc

<sup>98</sup> Similarly, at the end of the Forum on a day in the life of a pharmaceutical trainer, I was invited by a Steering Group member to sit in on the SG meeting held afterwards. I had also contributed actively at previous meetings, by asking questions and discussing issues in the public and private spaces of the Forum with both Steering Group members and fellow Forum members. Subsequently, I volunteered to run a session on evaluation at the Forum on *how to prepare for a regulatory inspection* (held in September 2005), in response to the e-mail I received along with the other 117 registered members of the Forum.



Steering Group, in a call for speakers for the September 2005 Forum. The distribution list on this e-mail included 118 members, identified on the basis of their having previously registered for meetings, with their details kept by the ICR<sup>99</sup>. Thus, from the developmental research questionnaire, which was circulated on 5 occasions<sup>100</sup>, the 31 respondents represented slightly more than a third of the community members who had ever attended the Forum (31/80), but approximately a quarter of the visible membership (31/118).

From observation, with each successive meeting, approximately a dozen or so of the same active and core members attended meetings on a frequent or regular basis. Peripheral members had the greatest turnover in attendance, although one or two active members who briefly joined the steering group subsequently stopped attending the Forum. Hence, from 2003 to 2008 the community was in a constant state of turnover of participants.

For peripheral members, the reasons for turnover were threefold. First, the Forum did not meet their expectations; second, as a consequence they could not make a business case to justify their attendance; third, they had a specific interest in only one particular session or Forum. Or, finally, as in the case of Donald, an experienced active member of the Forum who provided three sessions on three different occasions, work commitments did not allow him to take his participation to the next level – becoming a core member, through joining the

Steering Group:

*From Line 47: It's part of our values and culture that we should be involved in external organisations and wherever possible, we should be given the opportunity to represent the company externally ... So, you know, that has been formally recognised. It's whether or not my line manager would be happy for me to do that, and I'd obviously need to know what it would involve... and how much time would it involve.*

### **8.2.2 How are meetings organised?**

The structure of the TF meant that meetings were held at least 3 times a year on topics the SG deemed appropriate. Continuity was provided in terms of the SG who organised each event.

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<sup>99</sup> TF\_pu\_e-mail\_14-06-05\_call for speakers

<sup>100</sup> Questionnaire distributed four times at meetings: TF\_8/F\_Dec06; 9/G\_May07; 11/I\_Mar08; 12/J\_June08; and once via e-mail in Feb 2007

However, as Evelyn<sup>101</sup> explained achieving a consistent presence in the Steering Group depended on the individual commitments of its members:

*Line 296: "It's one of those things. You know yourself how it is, really. You know, we all say, we'd sort of like to help, but it's very difficult ..... you know, squeezing it into your own job. Now I'm freelance, in some respects, the pressures are less, because I'm not working full-time. So, potentially I would have more ... So, for instance, I've got more opportunity. Had I been in my, you know, last job, I might really have struggled you know, to do these telephone interviews with you."*

On the other hand, Peter<sup>102</sup>, a core member of the Forum almost since the beginning, expected those who were fully committed at a core level to get involved in the Forum, regardless of their other responsibilities:

*Line 159:: "... there are people who are quite willing to give their time up to these sorts of things ... There's a huge amount of people who're not. And some people might feel like they should be involved ... a bit like Leanne: they come along once or twice and in the end they just decide "...Ah no, can't be bothered". There's always that element - that someone else will take care of it ... and "it's not my problem", sort of thing. And I suppose what makes the difference - for you and me - is we've got an interest in it. And therefore, we're involved.*

*Presumably other people know who you are. Or, is it just a case of: well, they've figured out that you were involved in it, so they come up and have a moan at you? "*

From Peter's perspective, the shaping of the agenda by core members was both an onus and a right foregone by less committed Forum members whose constructive criticism was perceived as 'moaning'.

### ***8.2.2.1 Planning the meeting: How is agenda content decided and arranged?***

When planning a meeting, the first task of the Steering Group was to decide the theme for the meeting agenda content and to discuss session topics. In effect, producing an agenda was the first instrument producing activity of SG members.

The content of meetings was generally decided in various ways:-

1. On the basis of whether an agenda flowed fairly effortlessly from ideas and suggestions within the group, indicating that "*...the topic has enough substance to drive the agenda without being forced, or being directionless...*"<sup>103</sup>.

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<sup>101</sup> Interviewee-6\_core\_EFDr

<sup>102</sup> Interviewee-5\_core\_EFDr

<sup>103</sup> SG\_FN\_post\_6/E\_09-05\_agenda discussion

2. Occasionally re-visiting the expressed goals of the Trainers' Forum – to share best practice and to discuss topical issues<sup>104</sup>.
3. On the basis of gathering participants' forms at the end of meetings and sifting through feedback to decide which topics were feasible to deliver, rather than feasible to discuss.
4. On the basis of whether SG members could suggest, agree and organise speakers for each particular aspect of the topic to be "covered". Occasionally, SG members volunteered to lead sessions, particularly if as Molly<sup>105</sup> explained "*...it was a case of nobody else was available to do it!*" (Line 24).

Achieving the task of agenda planning, therefore, depended on who SG members knew could deliver a particular topic. In the first instance, their social connections had greater significance than any knowledge of the topic that might be contributed. This set the tone for 'delivering' the agenda as a product rather than using it as a discussion tool for the goals of the meeting. The declarative model in use concerned *who you know* rather than *what you know*<sup>106</sup>. On more than one occasion<sup>107</sup>, Jennifer defended the associated procedural model of slide presentations in response to suggestions that more active and less passive approaches to sharing experiences might generate more interest and discussion. When a workshop approach was proposed as an alternative for the next Forum meeting, she related experience from her own practice:

*"...with [slide] handouts, it's something concrete to take away with them...especially... with non-native English speakers... they're mainly...a really useful aide-memoire...with all the information...can't be easy...dealing with a foreign language"*<sup>108</sup>.

On at least three occasions in SG meetings, an alternative workshop approach was proposed in order to increase the level of discussion from the usual 90% presentation versus 10%

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<sup>104</sup> SG\_mins\_post\_10/H\_20-09-07

<sup>105</sup> TF\_Interviewee-9\_core

<sup>106</sup> In contrast, *what you know* rather than *who you know* underscored the session I volunteered for the September 2005 meeting.

<sup>107</sup> SG\_FN\_TF\_10/H\_09-07; SG\_FN\_TC\_pre-11/I\_Nov07; SG\_FN\_13/K\_Jun08)

<sup>108</sup> SG\_FN\_TC\_pre-11/I\_27-11-07

discussion model. However, on the first occasion this suggestion was met with silence<sup>109</sup>. It was rejected on a second occasion at another SG meeting when the topic of inspections was being re-visited as the next possible meeting theme, on the grounds of insufficient time to plan accordingly<sup>110</sup>. Later, in the same meeting, the idea was again rejected, this time after feedback gathered from TF members was presented about the need for “...more participation – to get discussion going, rather than just listening to others ideas...”. In this instance, it was rejected in relation to the topic being discussed – sharing experiences about inspections – on the grounds that participants would not be able to openly discuss their experiences due to confidentiality issues.

Finally, at the third attempt, the alternative model for generating discussion at the Forum was accepted as being appropriate for the theme of *how we train our investigators*. This topic provided a thematic continuity following on from the previous two Forum meetings (*how we train our project managers; how we train our SOPs*), and consistent with the earlier pattern of thematic continuity in the topics discussed (i.e. training needs analysis, evaluation methods, Teaching & Learning methods), where the focus was on sharing methods and problems (see Table 8-2).

#### 8.2.2.2 Process model for involving Forum members in its organisation: inclusive or exclusive?

Because the agenda served as the expression of the TF’s goals (to share BP and discuss topical training issues), setting the meeting agenda represented the first opportunity to involve community members in reaching shared understanding and agreement about training practice, as a collaborative activity. In the first Forum meeting in December 2003, this process began with agreeing what issues were topical and which related aspects of practice were of concern, or needed to be discussed and shared. This approach was reported in the Institute magazine, Clinical Research Focus (CRF), by the Chair of the Trainers’ Steering Group:

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<sup>109</sup> SG\_DR\_TC\_pre\_11/I\_27-11-07

<sup>110</sup> SG\_mins\_post-12/J\_11-06-08

*"...Feedback at the meeting suggested that the steering committee is on the right lines to meet trainers' needs. A lunchtime session for networking was suggested for the Spring meeting, together with three fora per year..... I hope to welcome you to a future Trainers' Forum meeting. The steering committee will be meeting early in 2004 to plan the 2004 meetings and would welcome your contribution..."<sup>111</sup>.*

Thereafter, up until September 2005, the model for seeking input or for active and peripheral members of the Forum to give feedback was not visible, and therefore, the organisation of meetings appeared to exclude their input. However, at this September 2005 Forum, a feedback form was introduced at the end of one session, serving as a model of best practice<sup>112</sup>. Eventually, from May 2007 onwards, feedback forms were distributed routinely at meetings, and the collated feedback circulated to SG members by e-mail.

In addition, prior to July 2007, the working 'notification' model used by the ICR to alert members of forthcoming events involved distribution lists. These lists contained the e-mail addresses of individual members who had previously registered their interest in joining a particular group, whether a forum or a special interest group (SIG), when its formation was originally announced:

*"...If you would like to receive advance notice of these, then contact [named contact] ...to add your e-mail details to the Trainers' Forum mailing list..."<sup>113</sup>.*

Members then had the opportunity to respond to the alerting e-mail, and to reserve a place at the meeting on a first come first served basis. The existence of these lists signified that in their administrative procedures the ICR categorized members according to the expression of their interest. Less active or conversely more passive members of the Institute would thus likely miss out on this type of specialised event notification.

However, this model changed when a new Institute website was introduced in 2007 and all ICR members received notifications by e-mail of all forthcoming events advertised, hosted or charged by the ICR. Consequently, by automating the notification system so that all members

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<sup>111</sup> TF\_rep\_1/U\_12-03\_CRf\_15(1): 35\_Feb04

<sup>112</sup> I announced that this feedback form served two purposes: (1) to help me evaluate the effectiveness of my session and (2) in order to demonstrate best practice.

<sup>113</sup> TF\_rep\_1/U\_12-03\_CRf\_15(1): 35\_Feb04

received announcements of meetings of training events, forum meetings, SIG meetings etc., every member of the ICR had the opportunity to attend the Trainers' Forum. Members then registered their intention to attend by completing an online form. Prior to the March 2008 Trainers' Forum, the ICR limited the numbers attending, on a first come first served basis, due to restricted meeting room sizes in their previous offices. Hence, this was no longer an issue once the ICR located to new premises in October 2007.

Paradoxically, in becoming more proactive and inclusive, since automating their systems to provide blanket notification of events to all members, the ICR rendered its members as passive recipients. Moreover, Sally's view of the barrage of constant e-mails - as a nuisance – summed up peripheral TF participants' attitudes:

*Line 374: "I mean, one of the things that I've noticed is that there seems to be a heck of a lot of e-mails that come out of ICR and I just delete them now as I've got sick of them. It's just another thing landing in your inbox, you know ... courses ... courses that you know you'll never be able to go on."*

### **8.2.3 What is the focus of professional expertise in meetings?**

As Wenger *et al* (op.cit.) define it, the domain of practice relates to the cognitive or knowledge focus of practice within a given field of practice, ranging from mundane *know-how* to specialised *professional expertise*. Describing the domain contextualises the activity of the CoP and defines the interest or passion of its participants. Hence, in this case, according to the expressed aims of the Trainers' Forum, the domain of practice specifically concerns *best practice, and topical issues related to training process*.

The expressed aims from its mission statement, on the Institute's website that "*the purpose of the Forum will not be to Train the Trainer*" encapsulated the community's desire to focus beyond the basics of training<sup>114</sup>. Nevertheless, even if the community's intention was to move beyond the basics, implicit within the mission statement was the assumption that

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<sup>114</sup> Appendix A: Trainers' Forum mission statement

members would share and discuss knowledge and experience of training process, defined as four stages within the training cycle<sup>115</sup> and shown in Figure 8-3 (Training cycle stages).

At the various meetings over the years, the domain focus switched between practice issues related to the training cycle (training process expertise) and practice issues concerning the field of clinical research (subject matter expertise). For example, topical issues included: GCP training and inspections; training needs analysis; evaluation process and planning; how clinical research associates, investigators and project managers are trained; and, how to prepare for regulatory inspections (see Table 8-2<sup>116</sup>).

In addition, as the SG's survey revealed, despite agreement among trainers of the need to move beyond the basics, few achieved this in practice (i.e. few evaluated whether individual performance goals or business goals were achieved through particular training strategies). Therefore, the challenge for members to share their practice in order develop their training expertise within the Forum was clear, even if the consensus on how to develop this opportunity was less so.

For example, at first glance, findings shown in Table 8-5<sup>117</sup> indicated that the domain focus mostly concerned training process: i.e. nineteen sessions focussed on subject matter issues (i.e. clinical research field or workplace issues) versus thirty-six dedicated to training process. However, deeper examination of the divide in the domain focus between training expertise and subject matter expertise revealed differences in trainers' concept of sharing and approach to discussion that was apparent within Forum activity.

In particular, session leaders' epistemological frames of discourse (saying-writing-doing-being-valuing-believing) revealed their choices and applications of methods to share 'knowledge', resulting in particular patterns of interactions. Pedagogical approaches to the

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<sup>115</sup> TF\_FN\_05-04 and TF\_FN\_09-04

<sup>116</sup> Table 8-2: Outline of meeting themes and session topics.

<sup>117</sup> Table 8-5: Predominant conceptual/procedural models of practice characterising Forum activity

activity of sharing practice and discussing topical training issues - constituted by choice of method, application and interaction outcomes (monologue or dialogue) - are shown in Table 8-5. The behavioural consequences of these pedagogical approaches, and their associated epistemological frames of discourse, are described and discussed in the next section, in terms of the rules emanating from these choices that subsequently governed how the Forum worked.

### **8.3 Rules: What common behaviours do participants in the Forum share?**

The host organisation of these professional Fora - the ICR - provided for the constitution of the Steering Groups that planned them. Nevertheless, its participants were free to determine the organisation of the Trainers' Forum, to run it as they saw fit. Thus, by virtue of their epistemological frame of discourse (saying-writing-doing-being-believing-valuing) session leaders either used a monologic procedural model based on a transmissive conceptual model of practice, or they led sessions using a dialogical model based on an enquiry-led conceptual model of practice (L1TO2a). Consequently, the rules of conduct that emerged in the Forum depended on the procedural models adopted. These are described in the next section.

#### **8.3.1 Procedural approaches to sharing: monologue versus dialogue**

As shown in Table 8-2 (Outline of themes and topics) and summarised in Table 8-6

(Consistency of procedural model distribution among session leaders), received knowers (EFDr) tended to consistently give content driven presentations regardless of whether the domain focus concerned clinical research issues or training process issues. Moreover, as a direct consequence of this approach to sharing a topic or issue, discussion was controlled.

Responses to 'interruptions', such as questions, were diverted to the end of presentations. In two sessions on two different occasions, such control interrupted the flow of proceedings, more perceptibly than usual, either curtailing the level of interaction from questioners, or causing the speaker to lose his concentration. In the first case<sup>118</sup>, the Chairperson curtailed

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<sup>118</sup> TFS\_FN\_5/D\_05-05-4\_EFDr



questions being asked in order to “...keep the proceedings to schedule”. In the second instance, using this technique, the ‘speaker’ avoided a direct question that challenged his viewpoint about how to demonstrate the effectiveness of training, through its either being ‘dropped’ or forgotten (George<sup>119</sup>). This approach maintained the status quo of the presenter as the controller of the ‘knowledge’ being shared, as a commodity or product transferred between parties, evident in how slides were used as artefacts mediating the sharing of information. This authoritarian approach to controlling how knowledge was shared typified a trainer’s EFD as *received*.

By contrast, constructed knowers (EFDc) showed how to ‘deliver’ content through a process-driven learning experience involving participants in cognitive, affective and psychomotor learning domains. In these instances, a dialogic procedural model corresponded with an enquiry-led conceptual model of practice. In these types of sessions, questions were welcomed from participants and actively used by session leaders to guide or direct discussion. Finally, on more than one occasion trainers consistently used the same procedural models either to open deliberations or convey information (Table 8-6: Consistency of procedural model distribution among session leaders).

Therefore, by virtue of the methods they used, received knowers tended towards a monologic pattern of interaction and constructed knowers tended towards a dialogic pattern. Very occasionally, however, monologue was of a deliberative nature, in that rhetorical questions were used as a technique to stimulate thinking, if not interaction, especially in instances when time keeping was of the essence, due to the amount of information that was conveyed in the allotted time.

In a monologic style of session, in the act of presenting his or her material, trainers cast participants in the role of listeners or audience to the presentation. Both then shared a sense of urgency about the presenter’s challenge to keep to the schedule, avoiding being diverted ‘off

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<sup>119</sup> TFS\_FN\_6/E\_09-05-1\_EFDr

topic' through interruptions (RU2b), in order not to encroach upon the allotted time for the next session. As encapsulated in the following comment, Brian<sup>120</sup> glossed over detailed information contained in his slides about a particular project management system because: "...there's not enough time to go through all of this – so, I'll skip these slides".

This time keeping rule (RU2a) was rigidly followed in meetings where time was short but many sessions were planned (i.e. five or more planned in three and a half hours). Animated discussions during and between sessions were curtailed in order to "keep on track"<sup>121</sup>.

However, in the case of the September 2005 meeting about *preparing for regulatory inspections*, normal adherence to these rules was suspended (L1RU2a). As before, discussions and exchanges between session leaders were extremely involved, with active members competing to ask questions. This meeting also differed in size with two to three times the usual numbers attending (60 people). Consequently, because members wanted answers, the moderator had no choice but to allow the natural discussions to run their course. Sessions over-ran considerably. Lunch was scheduled for 1pm. However, rather than extend the meeting as a result of its highly participative nature (RU2b), lunch was delayed until after the final session of the meeting. This dialogic session<sup>122</sup> was started 40 minutes late and curtailed fifteen to twenty minutes later, by the Chairperson, to accommodate the growling stomachs of the hungry participants.

This meeting highlighted that members wanted answers, needing to discuss topical issues as they arose. However, the following feedback<sup>123</sup>, typified the discomfort raised by the less controlled, but increased level of interaction:

*"The group were hot, and hungry, for lunch and blood. They had given previous speakers really quite a hard time, and to be honest I was embarrassed at the lack of manners and professionalism of the participants. If they were my group of trainees, I'd have called them a difficult group and I will be letting ICR know of my concerns of the group behaviour" (Kathy<sup>124</sup>).*

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<sup>120</sup> TF\_DR\_12/J\_06-08-1

<sup>121</sup> TF\_FN\_2/A\_05-04; 3/B\_09-04; 5/D\_05-05; 6/E\_09-05

<sup>122</sup> I planned and ran this session as a participative exercise to illustrate sources of evaluative training tools

<sup>123</sup> Collected from my session, in the September 2005 meeting.

<sup>124</sup> Interviewee 13\_peri\_EFDr

From Kathy's perspective, the driving demand among the group for definitive answers from 'speakers' made this group "difficult". That is, their constant interruption of speakers constituted a lack of the normally "ordered" behaviour in the Forum, which Kathy found unacceptable.

Nevertheless, although the Steering Group at this meeting obtained no formal feedback, feedback from subsequent meetings (i.e. May 2007 onwards) indicated that participants wanted more of a balance between presentations and discussion (Table 8-7: Overview of Forum feedback (2007-2008)). Some felt strongly enough to give further comments on the forms about the need to share, and in one case, about the need to further define standards (Table 8-8: Overview of Forum feedback comments (2007-2008)).

Furthermore, in her review of Forum feedback, Elspeth's e-mail to other members of the Steering Group highlighted the normative bias against the time involved in organising or providing practical sessions:

*"...the feedback from the last meeting indicated interest in a number of other topics – I've included a summary of the feedback under these categories below. It would be good to cover more than one area. There was also a comment that mixing theoretical and practical sessions would be good but I am not sure how realistic this is in the time available..."<sup>125</sup>.*

Despite this feedback, the Forum continued to be moderated according to the timed schedule, although with a more light-hearted approach. In particular, a new "traffic light" model for monitoring the passage of allotted time per session was introduced in 2008, where speakers/session leaders were advised of how they were "doing for time" using a 'traffic light' flag system as a visual cue. Prior to this system of time monitoring, previous Forum moderators interrupted session leaders five minutes prior to the end of their allotted time, which was more intrusive for all concerned.

Therefore, because of these differences in approach to sharing practice and discussing issues related to training, the domain was split between subject matter experts sharing their

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<sup>125</sup> SG\_TC\_pre\_10/H\_09-07-07

knowledge about aspects of the field of practice (referred to as *knowledge-based trainers* at the 2<sup>nd</sup> Forum), and trainers who led deliberations about training process or issues (the new model of *facilitator* discussed at the 2<sup>nd</sup> Forum). In particular, at the 12<sup>th</sup> Forum, which concerned what the chairperson envisaged as “sharing theory and practice”<sup>126</sup> of *how we train our project managers*, sessions were content-driven presentations given by subject matter experts (i.e. project managers) about the structure of career development pathways for project managers within different organisations<sup>127</sup>.

Each subject matter expert who spoke at this Forum provided an insight into how the field of clinical research compared with other industries in recognising that project management is a separate discipline, with its own accreditation pathway to develop knowledge and skills. The mechanics or methods involved in training project managers, however, were not discussed. The feedback from attendees at the June 2008 meeting<sup>128</sup> indicated that the content and monologic delivery methods of sessions appealed to some more than others, according to their varied needs or expectations as expressed in their epistemological frame of discourse. Subsequently, these reactions were used to categorise them as received or constructed knowers, as shown in Table 8-9 (June 2008 Forum feedback).

Constructed knowers (EFDc) either directly expressed their appreciation of the *information* shared about project management (i.e. differentiated it from knowledge), mainly from a Contract Research Organisation (CRO) perspective, or implied its value (Participants 6 & 12), while gently suggesting the need for discussion and interaction. Received knowers (EFDr) also expressed their enjoyment of the information shared, without differentiating it from knowledge, and without commenting on the need for more interaction. One complained about lack of direction (participant 1). Another complained of the lack of examples from a pharmaceutical company perspective (participant 4).

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<sup>126</sup> SG\_FN\_pre\_12/J\_FN\_05-03-08

<sup>127</sup> TFS\_DR\_12/J\_10-08

<sup>128</sup> SG\_Fdbk\_12/J\_10-08

As this feedback demonstrates, the practice modelled within the public space inside this community, and the form and scope of domain topics discussed, directly and indirectly reflected contrasting collective theories-in-action about what it means to share and discuss practice: -

- giving or listening to a presentation (Participants: 3,4,7,11,13);
- having an interactive discussion (Participants: 5,6,8,9,10); focussing on developing skill sets (Participant:12);
- receiving /developing ‘take home’ messages for individual practitioners (Participant:1,2,9).

Therefore, if the intentions expressed within the Forum’s mission statement as *sharing of best practice, discussion of new technologies and discussion surrounding topical issues*<sup>129</sup> represented collective espoused theories-in-use, then a lack of further definition enabled contrasting theories-in-action to emerge (Argyris and Schön, 1978). Thus, exploring contradiction between these concepts reveals how the relationships between the different elements of this activity system, and ultimately its neighbours, affected the structuration of practice, in terms of the constitutive role of objective regularities. Consequently, these relationships will be elaborated further in Chapter 9 (The object of activity in the Forum) and in Chapter 10, Conclusions.

Finally, if *skills, behaviours and attitudes* in operation during Training Fora sessions correspondingly model the practice of training as a commonplace activity, their analysis reveals the constituent cognitive tasks that are an everyday regularity of sharing training practice, and which are associated with this human agent activity. In particular, if the Forum is about *sharing best practice*, then not unreasonably, trainers might be expected to mirror their usual training behaviour and thus, “show how it’s done”. In this case, the time keeping rule (RU2a) is indicative of the workplace emphasis or object to conduct courses in an

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<sup>129</sup> Appendix A: TF mission statement, ICR website June 20<sup>th</sup> 2005

effectively expedient manner. By contrast, expediency serves no particular purpose in the Forum – meeting rooms are booked for an entire day. Therefore, as each Forum agenda with timed slots continued to demonstrate, this workplace object remained in place, having been transformed into a rule of expediency in the TF. However, because the agenda was not usually organised based on what Steering Group members knew about training (e.g. cognitive domain) but was based, in the first instance, around who they knew (i.e. contacts in their social domain)<sup>130</sup>, this rule of expediency enabled accommodation of guest ‘speakers’ or session leaders participation according to their commitments. Hence, because the SG differentiated its division of labour based on a social rather than a cognitive domain (DoL<sub>2H</sub>), those core members with the greatest number of contacts had the most power to influence the agenda.

This fixation with a time-bound training syllabus is a feature of the dominant knowledge-based model of training, which is susceptible to direct pressure in the workplace to deliver training expediently, due to budgetary constraints imposed by management, irrespective of the results obtained. As the survey results discussed in the 3<sup>rd</sup> Trainers Forum indicated, and as Forum discussion supported, this susceptibility stems from implementing a limited evaluation process, thereby failing to demonstrate training effectiveness to senior management. In turn, the vicious cycle is started and completed due to the predominance of senior management’s received wisdom about the difficulties involved in measuring the impact of training on the organisation’s bottom line using financial measures. Consequently, as mentioned in Chapter 7 section 7.2.5, until the *conscious incompetence* of trainers raised at the 3<sup>rd</sup> Trainers’ Forum, “in completing both ‘ends’ of the training cycle”<sup>131</sup> is addressed, *knowledge-based* trainers will remain challenged to break this vicious cycle and in making their business case to convince senior management that training is an investment and not a cost (outlined further in Chapter 9, Figure 9-4).

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<sup>130</sup> Division of labour in the Steering Group determined by socially- vs. cognitively-based domains

<sup>131</sup> TF\_rep\_3/B\_09-04\_CRf\_15(9): 19\_Nov04

In conclusion, although the workplace conditions that demand training is expedient did not operate in the Trainers' Forum, the object of expediency was nevertheless carried forward as a rule, which was subsequently transformed back into an objective. As such, this highlighted two quaternary contradictions: one between the object in the workplace and in the TF; and, that between tools used in the workplace and those used in the Forum (L4TO-AS3). Both of these contradictions explained the temporal inflexibility of a highly structured agenda (RU2) over which active and peripheral participants in the Forum had no input (RU3) and hence, no control (DoL1<sub>v</sub>). In effect, these contradictions highlighted the recreation of conditions emulating trainers' lack of control over the conditions imposed by senior managers in the workplace. As a consequence, by adhering to the expediency rule, the procedural model of transmissive pedagogy commonly used in the workplace was also incorporated into the TF.

In conclusion, the effect of the workplace, as a rule-producing, object-producing and instrument-producing activity, on the TF's activity is presented in Table 8-10.

### **8.3.2 Professional affiliations: colleagues, clients or competitors?**

In terms of their approach to each other in the Forum, as the subjects participating in an activity system, particular attitudes emerged among trainers in the act of sharing practice suggesting differing rules of conduct associated with the contrasting dialogic or monologic behaviours that were observed (i.e. inclusiveness and exclusiveness: L2RU3-TO2a & c). These rules are modelled in Figure 8-1.

On the other hand, these attitudes oscillated between a sense of competition and a sense of cooperation, as recalled by Michael, a core member, who explained the original brief of the Trainers' Forum, by describing its history, including its first incarnation, when asked about its purpose:

*From Line 14: Mmmm...benchmarking quality, sharing best practice in that sense...recognising that it was still allowed to be competitive. There was always a delicate balance of people from one company knowing more than others in another company, and in bringing others up to speed, and people stealing materials. It was a significantly different bunch of people. Mostly pharma rather than CRO, who at the time were very much "... we'll come along and steal everything". There were lots of perceptions about that across the industry, not just training.*

*There wasn't any representation from freelance trainers because in the late 90s they were a separate unique identity, just maybe starting off. There were freelancers as CRA's. But, there weren't any freelance trainers -consultant trainers - whatever you want to call them. So, it was Pharma sharing inside ideals from very similar backgrounds... But then it got diluted by people's commitment by the first three meetings*

*But, mid 90s late 90s, stuff - as collaborative stuff - really worked. The idea was - other groups within the Trainers Forum would develop in other sessions. But no one had the same.... I don't know. It just didn't happen...whether they couldn't get together...*

In another instance, Molly, a qualified independent trainer, raised the notion of the Forum being in competition with its host, the ICR, when asked about the *not training the trainer* rule in the Mission Statement:

**From Line 87:** *I guess being cynical... laugh... you could say that it would have an impact on ICR's business, because they offer training ... I don't know whether that's the reason why they went down that route or not ... because ICR offers training now for a train-the-trainer course. And they offer training for clinical research. So...if one of their forums is providing training for trainers, then it's in competition with them, basically.*

At the start of the Forum on *preparing for regulatory inspections* (9/G), in May 2007, this competitive attitude also manifested but this time with respect to the need to protect employers' interests versus the need to develop professional interests<sup>132</sup>. For example, it was announced that: "...we can't make slides available because legal departments of companies have deemed the information confidential and sensitive". As a result, no handouts of slide presentations were provided, as was usually the case at most meetings. Nor, did the Institute post slide sets on the Institute's website as was often the case, due to concern for sharing 'information' about how different organisations had prepared for inspections.

Consequently, this statement placed a value on the handouts/slides concerning the information that would be revealed, inferring that the information they contained had commercial/proprietary value worth protecting legally. Yet, no such prohibition could be applied to what participants said, heard, or wrote down, revealing the contradictory nature of this duty-bound concern for confidentiality in order to protect employers' interests in terms of the information shared. Moreover, this concern for the sensitivity of information illustrated the transmissive conceptual model in use at the Forum, in terms of the value ascribed to the

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<sup>132</sup> LICO.



information imparted by this means. In a question about how trainers can demonstrate adequate GCP training, put to a core member acting as a ‘speaker’, the embedded nature of the transmissive model within speech idioms, or epistemological frames of discourse, was encapsulated in the response: “...there is only so much we can *say* about GCP (Good Clinical Practice) and only so many ways we can *say* it” (Evelyn<sup>133</sup>). In this model, GCP was referenced as a finite set of 13 principles, rather than considered in terms of its infinite applications within the domain of clinical research. Moreover, this response was not challenged.

The content shared at this Forum concerned: how inspectors make contact; what they decide to inspect; their questioning techniques; how companies prepared for the inspection; and finally how they each responded. Similar general information can be found on regulators websites or in other published sources<sup>134</sup>. No ‘sensitive’ details of inspectors’ material findings within particular organisations were shared. However, in sharing their experience of particular regulatory practices, trainers were drawn together as colleagues being helped to prepare for their turn at being inspected, as rather than as competitors, who might gain an edge as a result.

Yet, as this example suggests, in this public space within a professional community, the rules of a neighbouring activity system (L4RU-AS3), the workplace (to treat or commodify information as inherently valuable, regardless of its content or context), impinged on the object of activity in the Forum (to share practice and discuss issues). Hence, by placing limits on what can and cannot be shared or discussed at the TF, this rule of commodification (RU3a) conflicted with its object of sharing and discussing practice for the purposes of CPD, and introduced a secondary contradiction (L2RU-OB).

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<sup>133</sup> TFS-9/G\_DR\_05-07\_3\_Interviewee #6\_EFDr: [Trans-Mdol-r]

<sup>134</sup> Journal of Good Clinical Research Practices; Quality Assurance Journal; Research Matters. Newsletter of the Chief Scientist Office. Issue 29 (Summer): 3-5.

Moreover, this controlling action is characteristic of a received epistemology. Otherwise, in a constructed epistemology, Forum participants were free agents to institute or follow rules agreed as appropriate in this community. This 9<sup>th</sup> Forum was the most explicit occasion, but not the only instance, where employers' interests were positioned ahead of trainers' professional interests. So, despite the intended focus of the meeting on the role of the trainer in preparing for inspections, the "sensitive" nature of the topic's subject matter (regulatory inspections) gave priority to employers' interests. In the process, Forum members were reminded that their fellow trainers were potential rivals, not only in the clinical research market place, but also in knowing how to handle regulatory inspections on behalf of their respective employers. Nevertheless, a cooperative atmosphere prevailed, possibly because trainers were united in their mission to share information about regulatory practices and motivated to learn from each other's experience.

Some may also have recalled, from the 2<sup>nd</sup> and 3<sup>rd</sup> Forum meetings, agreeing the need to redefine their role from *knowledge-based trainers* to *facilitators of learning in the organisational strategy* in order to develop their professional interests. At these meetings, the necessity of developing specialist knowledge was also acknowledged. It was agreed such expertise would position trainers as professionals traditionally placed to maintain the highest standards of practice through the exercise of conscience and therefore in control of their practice (Goode, 1957; MacIntyre, 1985):

*"Clearly proactive themselves, the audience of trainers were encouraged by the models discussed and, in many senses, a number of the trainers had such a philosophy already in mind. Of course, the integrated facilitating trainer will be better for the company than the administrative trainer left in isolation ticking*

*boxes. Yet it may take one huge leap of faith in corporate culture to ignite such proactive training strategies. The importance of the training cycle and the virtues of continual training needs analysis were seen as key to implementation of*

*change. These will be challenged in the crucible of experience and reality at the next Trainers' Forum. Only with these in place and working well can real progress be made"<sup>135</sup>.*

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<sup>135</sup> TF\_rep\_2A\_05-04\_CRf\_15(6): 26\_Jul04).

Therefore, those trainers in the community whose sessions were deliberative exemplified this facilitative style, in an effort to foster a cooperative atmosphere: using their discretion to decide what they wanted to talk about, and how they wanted to talk about it (signifying use of an enquiry-led practice model to discuss professional concerns). Each had shared examples of best practice adapted from ‘real life’ cases first by demonstrating, then theorising them (John<sup>136</sup>; Molly<sup>137</sup>; Jill<sup>138</sup>; Marie<sup>139</sup>; Norman<sup>140</sup>; James and Jessica<sup>141</sup>; Matt<sup>142</sup>; Donald<sup>143</sup>). All except Jill and Donald were independent training providers. Jill, however, had been a qualified teacher before becoming a clinical research trainer in a contract research organization (CRO). In addition, all were qualified as either teachers or trainers. Unlike the others, John, Norman, Jessica and Matt were external ‘guest’ trainers invited into the Forum, and not bound by the rules or regulations of the field of clinical research. Each shared a concern for professional practice in this professional community.

Nevertheless, despite these trainers having modelled a deliberative practice at the TF on a number of different occasions, a transmissive conceptual model with a corresponding monologic procedural model for sharing and discussing practice predominated in the Trainers’ Forum, as shown in Table 8-5 (36 monologic vs. 19 dialogic sessions). Therefore, for those bound by the regulations (concerning GCP) within this field of practice, the conflict between professional and employers’ interests represented an opportunity within the TF to discuss whether the dominance of transmissive pedagogy addressed the principles of conscience intended to achieve the highest standards of patient protection in clinical research (i.e. the Declaration of Helsinki). By extension, it also represented an opportunity to reflect on how the highest standards of professional practice might be addressed.

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<sup>136</sup> TFS\_FN\_4/C\_12-04-1

<sup>137</sup> TFS\_FN\_4/C\_12-04-3

<sup>138</sup> TFS\_FN\_6/E\_09-05-3

<sup>139</sup> TFS\_FN\_6/E\_09-05-5

<sup>140</sup> TFS\_FN\_8/F-FN\_12-06-4

<sup>141</sup> TFS\_DR\_10/H\_09-07-3

<sup>142</sup> TFS\_DR\_11/I\_03-08-1

<sup>143</sup> TFS\_DR\_11/I\_03-08-6

However, this issue of whose interests were at stake brought another dimension (or, object) to the Forum, which was another source of conflict, contradiction and mistrust. That is, whereas the goal-directed action of networking for social collaborative learning purposes was driven by concerns for the professionalism of training practice, networking to develop business opportunities was the perceived dominant motive. In particular, it manifested regularly in feedback, as criticism of sessions run by independent training providers (ITPs) or CROs, for coming across as “sales pitch”<sup>144</sup>.

Such feedback reflected the heterogeneous nature of the community: industry colleagues - whether based in pharma or CROs or independent trainers – recognised each other respectively as potential competitors or clients. So too ITP’s acknowledged other ITP’s, or even the ICR itself, as potential competitors in the bid to provide training services to their target market (pharma and CROs) who were represented within the Forum. Thus, the primary contradiction in the community was revealed in the relations between TF participants: as competitors/clients versus colleagues. Moreover, the financially motivated object - to network for business opportunities – created tension and mistrust in the motives of those running sessions. Consequently, this tension highlighted a tertiary contradiction in the TF (L3OB-OB). That is, networking for business opportunities was in opposition to the more culturally advanced motive of developing relationships for the purpose of socially collaborating for CPD. In conclusion, these conflicting conditions, goals and motives will be elaborated further in Chapter 9 through examining the object of activity in the Trainers’ Forum.

In conclusion, the elements of the activity system examined and contradictions analysed in this chapter are modelled, depicted and summarised respectively in Figures 8-1 and 8-2, in terms of the community constituting the Forum, the division of labour within it and the rules affecting its activity and individual chains of actions. The object of activity has also been introduced and briefly discussed in this chapter. Consequently, it is also modelled in Figure 8-

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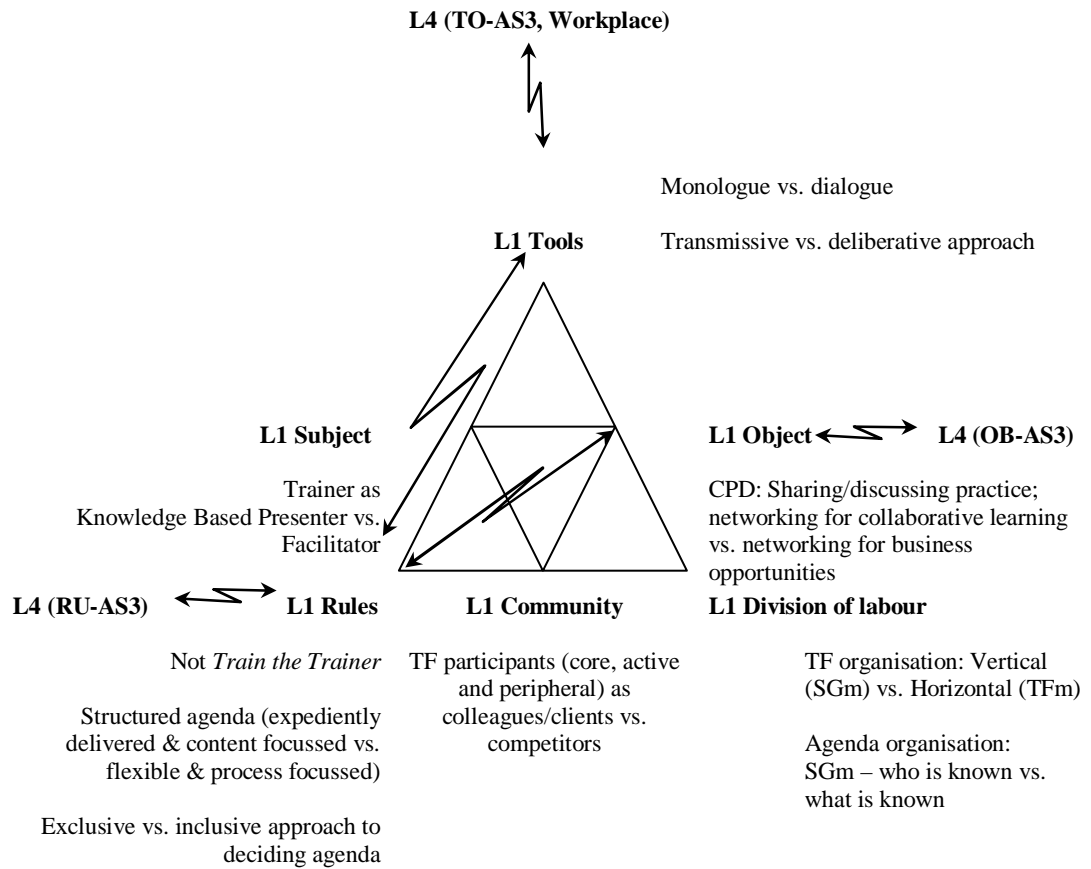
<sup>144</sup> TF\_13/K; TF\_12/J\_4,5,6; TF\_10/H\_3; TF\_8/F\_4; TF\_6/E\_5

1. Moreover, the role of the workplace (AS3) has been revealed in the chapter, in its capacity as a neighbouring rule-, instrument- and object-producing activity system. This is shown in Table 8-10 (Role of neighbouring activity systems on the trainers' Forum) with its respective systemic elements. The ICR is also shown as the system that 'dictates' the division of labour within the Forum.

Finally, in this chapter it has been explained through quaternary contradictions, evident between the TF and the workplace, how and why the circumstances that trainers endure in their own practice are replicated in the Forum. That is, a time-bound, content-driven agenda predominates in the Forum as a feature of transmissive pedagogy; the dominance of which trainers appreciate is problematic both for organisational learning strategy and their role as *facilitators*. Nevertheless, despite awareness of a need for a more facilitative model of training, the rules of conduct that emerged in the Forum reflected the declarative and procedural models imported and adopted from the workplace.

In the next chapter, the purpose and pedagogy of the Forum is unravelled and framed in terms of the *object* of its members and the *tools* available to them in the Forum.

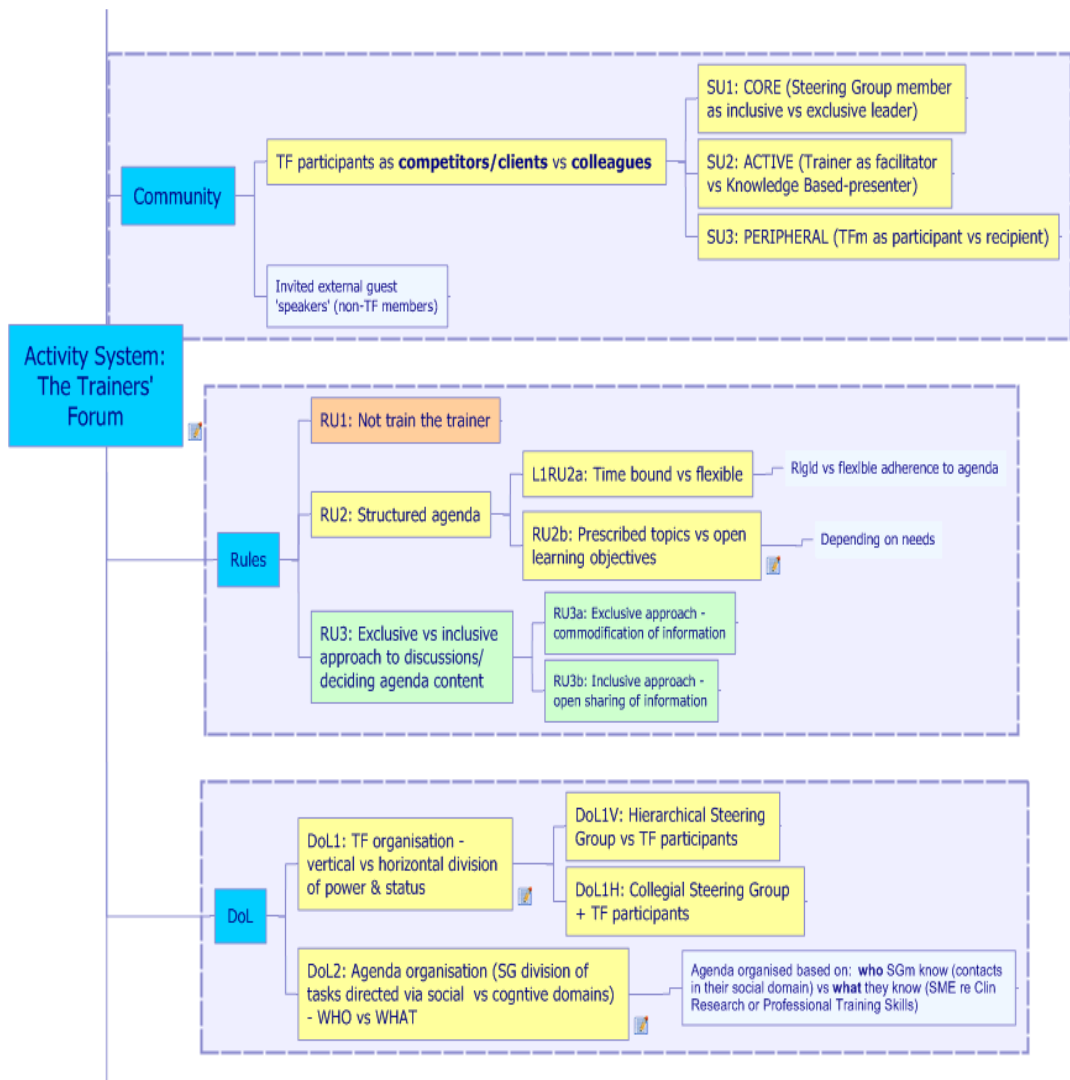
**AS5 TF activity system**



**Key to contradictions**

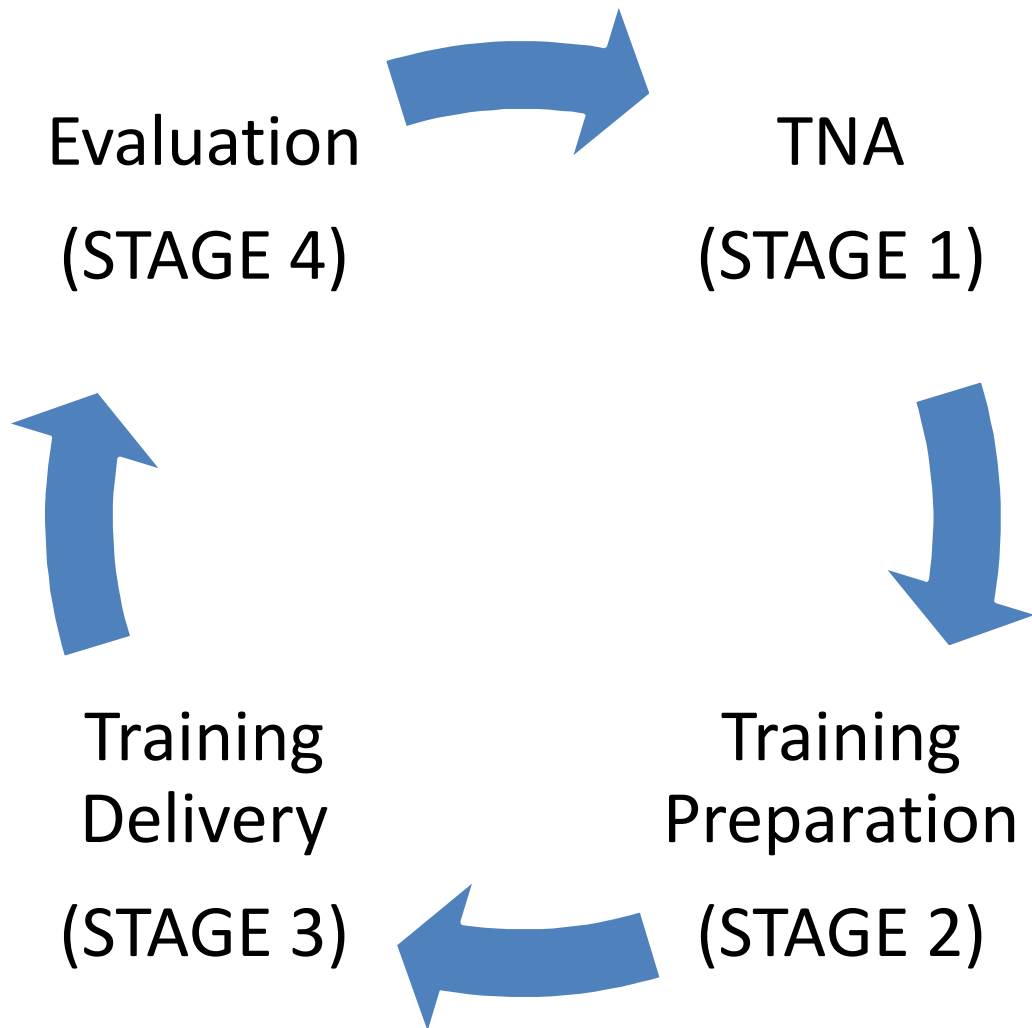
- L2RU-OB: Rule of *not training the trainer* restricted the object of “sharing” practice for CPD
- L2RU-OB: Rule of commodification conflicted with TF object of freely sharing and discussing practice for CPD
- L2RU-TO: Rule of expediency restricted the mode of interaction to monologue
- L2RU3-TO2a & c: Exclusive/inclusive rules of conduct governed patterns of interaction (behaviours)
- L3OB-OB: Object of networking for business opportunities opposed culturally more advance object of networking to collaborate over CPD
- L4RU-AS3: Information in the TF commodified due to the general predominance in the workplace of received epistemology about its inherent value
- L4OB-AS3: Workplace object of expediency carried forward into the TF as a rule and subsequently transformed back into an object
- L4TO-AS3: Transmissive pedagogy imported from the workplace as the dominant instrument for sharing information via monologue

**Figure 8-1: Modelling primary / secondary contradictions within and between elements in the Trainers Forum (AS5): community, rules and division of labour**



**Figure 8-2: Primary contradictions illustrated within the elements of community, rules and DoL**

**Figure 8-3 Training cycle stages**



**Key**

Stage	Description
Stage 1	(Training needs analysis);
Stage 2	(Training preparation: content: learning objectives & training materials; location etc.);
Stage 3	(Training delivery: teaching and learning methods);
Stage 4	(Training evaluation: content, materials, delivery methods; learning transfer; training impact).



**Table 8-1: Interviewees profiles**

Interviewee id #	Pseudonym	Interview type			Community status	Training qualifn	Position
		Informal	Formal				
			Initial	Follow-up			
1	Deirdre	✓	✓	✓	Peripheral	None	Snr CRA
2	Mary	✓	✓	✓	Peripheral	HE Certificate	BD Exec
3	Gary	✓	✓	✓	Peripheral	CIPD	QM
4	Sally	✓	✓	✓	Peripheral	None	TM
5	Peter	✓	✓	✓	Core	None	TD
6	Evelyn	✓	✓	✓	Core	None	ITP
7	Michael	✓	✓	✓	Active	None	TD
8	Donald	✓	✓	✓	Active	Certificate	TM
9	Molly	✓	✓	✓	Core	CIPD	ITP
10	James	✓	-	-	Active	PGCE	ITP
11	Jennifer	✓	-	-	Core	DIPD	T
12	Helen	✓	-	-	Active	None	T
13	Kathy	✓	-	-	Peripheral	HE Certificate	Snr CRA
14	Leanne	✓	-	-	Active	CIPD	T
15	Linda	✓	-	-	Core	CIPD	T

**Key**

SNR CRA	Senior Clinical research Associate
BDE	Business development executive
TM	Training manager
TD	Training director
ITP	Independent trainer
T	Trainer

**Table 8-2: Outline of meeting themes and session topics****Key**

E= External; C = Core; A = Active;

dM = deliberative monologue; M – content driven monologue; D = dialogue;

F/cht = flipchart; Q's = questions; h/out = handouts; Q&amp;A = question &amp; answer; Demo = demonstration

TP = training process; SM = subject matter

Mtg #/ID	Date	Meeting Theme	CoP status	Procedural approach		Domain focus
				Methods		
<b>1/ U</b>	<b>3<sup>rd</sup> Dec 2003</b>			<b>Inaugural meeting</b>		
<b>2/A</b>	<b>18<sup>th</sup> May 2004</b>			<b>Formulating your training strategy</b>		
10.00	1.	Trainer as team facilitator	E	dM	Speaker Crib notes	TP
11.15	2.	Reactive training strategies		M	Slides	TP
11.30	3.	Training in CROs vs. Pharma		D	F/cht & open Qs	TP
11.45	4.	Learning strategies vs. training strategies		dM	Slides	TP
12.00	5.	KM and learning reviews (eval)		M	Slides	TP
12.30	6.	Training strategies for teams		M	Slides	TP
12.45	7.	CPD		M	H/out	CPD
1.00		Close				
<b>3/B</b>	<b>13<sup>th</sup> Sep 2004</b>			<b>Evaluation methods &amp; Training Needs Analysis</b>		
10.00	1.	TNA and Eval Survey results	C	M	Slides/h/out	TP
11.00	2.	TNA	E	M	Slides; h/out	TP
12.00		Lunch				
12.45		TNA continued				
1.30	3.	The bad, the ugly and not so bad	A	M	Slides	TP
1.45	4.	Real vs. perceived training needs	C	dM	Video – remote voice over slides	TP
2.00		Close				

**Table 8-2 continued: Outline of meeting themes and session topics**

<b>Mtg #/ID</b>	<b>Date</b>	<b>Meeting Theme</b>	<b>CoP status</b>	<b>Procedural approach</b>	<b>Methods</b>	<b>Domain focus</b>
<b>4/C</b>	<b>6<sup>th</sup> Dec 2004</b>	<b>Innovative Training Techniques</b>				
10.00	Welcome & Introduction			-		
10.20	1.	Interactive training strategies	E	D	Dialogue F/cht Exercise	TP
11.20	2.	Applying theory in the workplace:				
	3.	SOP training – the Challenges and possible solutions	A	D	F/chart Exercise	TP
	4.	Clinical research training: avoiding death by PowerPoint	2 x C	D	F/cht	TP
12.00	5.	Sharing ideas		D	F/cht	TP
12.30	Summary of key messages		C			
12.45	Lunch			-	-	
2.30	Meeting close			-	-	
<b>5/D</b>	<b>10<sup>th</sup> May 2005</b>	<b>A day in the life of....a trainer in the pharmaceutical industry</b>				
10.00	Welcome & Introduction		C	D	Warm-up exercise (speaking Japanese)	
10.10	1.	Survey results	C	D	Show of hands	TP
11.20	2.	Who is responsible for training?	C	D	Dialogue; Q&A Handout	TP
11.40	How the training function is organised. Perspectives from a:					
	3.	training manager	A	M	Slides	SM
	4.	technical trainer	C	M	Slides	
	5.	freelance trainer	A	M	Monologue	SM
1.00	6.	OTJ trainer	A-P	M	Slides	SM
1.15	Summary of key messages		C			
2.30	LUNCH & Meeting close					

**Table 8-2 continued: Outline of meeting themes and session topics**

Mtg #/ID	Date	Meeting Theme	CoP status	Procedural approach		Domain focus
					Methods	
<b>6/E</b>	<b>20<sup>th</sup> September 2005</b>	<b>Preparing for regulatory Inspections</b>				
10.00		Welcome & Introduction	C			
10.10	1.	Training and Fitness to do the Authorised Job <ul style="list-style-type: none"> <li>• Essentials of Quality</li> <li>• Starting Point - What do the Regulations say?</li> <li>• Summary of the Regulations</li> <li>• Checking for Evidence of Fitness to ----</li> <li>• Examples of Audit and Inspection Findings</li> </ul>	A	cdM		SM
11.00	2.	Training and Inspections	A	cdM		SM
11.20	3.	Surviving an inspection: the trainer's supporting role	A	D	Exercise Dialogue via open Q's	TP
11.40		Stretch break				
11.50	4.	Do your training records measure up?	A	M	Slides	TP
12.10	5.	The training record - product or process?	A	D	Slides; exercise; open Q's	TP
12.40		Review of the meeting	C	M		
13.00		Lunch				
14.30		Meeting close				
<b>7/U</b>	<b>20<sup>th</sup> September 2006</b>	<b>Learning Management Systems</b>				
<b>8/F</b>	<b>8<sup>th</sup> December 2006</b>	<b>Are you fit for purpose? Developing the trainer</b>				
10.00		Welcome & Introduction	C			
10.10	1	Managing the training function	C	M	Slides	SM
10.50	2	CIPD & Training Qualifications	C	M	Slides	SM
11.00		Coffee				
11.20	3	Trainers Toolkit	C	D	Exercise	TP
11.50	4	Getting the message across with cartoons	E	D	Whiteboard; f/cht; exercise	TP
13.20		Summary				
13.30		Meeting closed				

**Table 8-2 continued: Outline of meeting themes and session topics**

Mtg #/ID	Date	Meeting Theme	CoP status	Procedural approach		Domain focus
				Methods		
<b>9/G</b>	<b>3rd May 2007</b>	<b>Regulatory Inspections: The role of the trainer</b>				
10.00		Welcome, introductions	C			
10.15	1	MHRA inspections - the trainer's perspective in a large pharmaceutical company	A	M	Slides	SM
11.15		Coffee Break				
11.30	2	MHRA inspections - the perspective of a large biotech company	E	M	Slides	SM
12.30		Lunch, networking				
13.30	3	MHRA inspections - the perspective of a small-medium pharmaceutical company	C	M	Slides	SM
14.30	4	Recent FDA, BfArM and affssaps findings	A	M	Slides	SM
15.00		Close of meeting				
<b>10/H</b>	<b>20<sup>th</sup> September 2007</b>	<b>Participation: Making Learning the Priority</b>				
10.00		Welcome, introductions	C			
10.15	1	Trainer's Toolkit Session	C	D	F/cht	TP
10.45	2	Boundary Spanning – Using non-trainers to do your training	C	D	F/cht ; exercise	SM
11.15		Coffee break				
11.30	3	Role Playing – imagination, creativity, innovation	E	D	Role play	TP
12.30		Lunch & Networking				
13.30	3	Role Playing – imagination, creativity, innovation (continued)		D	Role play	TP
14.00	4	Inspiring the Trainee – making motivation matter	E	M	Slides	TP
15.00		Close of meeting				

**Table 8-2 continued: Outline of meeting themes and session topics**

Mtg #/ID	Date	Meeting Theme	CoP status	Procedural approach		Domain focus
				Methods		
<b>11/I</b>	<b>5<sup>th</sup> March 2008</b>	<b>SOP Training: Same Old Powerpoint vs. Some Other Possibilities</b>				
10:00-10:15		Welcome and introduction	C			
10:15-11:15	1	Keynote presentation - Learning Styles	E	D	F/cht; h/out; exercise	TP
11:15-12:15	2	SOP training strategy session 1 – The use of mind mapping techniques	A	M	F/chrt; demo	TP
12:15-13:00		Lunch				
13:00-13:30	3	SOP training strategy session 2 - Comply, Concentrate and Confer	A	M	Slides; MCQ	SM
13:30-14:00	4	SOP training strategy session 3 - a Japanese company perspective	A-P	M	Slides	SM
14:00-14:30	5	SOP training strategy session 4 - eLearning	A	M	Slides	SM
14:30-15:00	6	SOP training strategy session 5 - do we have a choice?	A	D	Fchart; open q's	TP
15:00		Close				
<b>12/J</b>	<b>11 June 2008</b>	<b>Training our Project Managers – Budgets, Timelines &amp; Quality</b>				
10:00		Welcome and introduction				
10:10	1	General overview of project management within the pharmaceutical industry	A	M	Slides; short ex	SM
11:00		Break				
11:10	2	What's in the technical and interpersonal skills toolkit of good project managers?	E	M	slides	SM
12:00		Lunch				
13:00	3	How are PMs in the industry being trained?				
13:00	4	Case study 1	E	M	Slides	SM
13:30	5	Case study 2	E	M	Slides	SM
14:00		Break				
14:10	6	Case study 3	E	M	Slides	SM
14:40	7	Thoughts and experiences from the audience				

**Table 8-2 continued: Outline of meeting themes and session topics**

Mtg #/ID	Date	Meeting Theme	CoP status	Procedural approach		Domain focus
					Methods	
<b>13/K</b>	<b>8<sup>th</sup> October 2008</b>	<b>The Who, What, Where, When and How of Investigator Site Training [85]</b>				
10:00		Welcome and introduction	C			
10:15	1	General Overview of Investigator Site Training	C	M	Slides	SM
10:55	2	An Academic Research Centre Perspective	E	M	Slides	SM
11:30		Refreshment Break				
11:50	3	A CRO Perspective	E	M	Slides	SM
12:20	4	Virtual Alternatives for Investigator training	C	M	Slides	SM/T P
13:00		Lunch				
14:00	5	Investigator Training Workshop	All	D	F/cht	SM/T P
		Review of what we are currently doing in practice				
		Group 1) The pros and cons of the classic Investigator Meeting				
		Group 2) How are we providing on-going training to Investigator sites after the initial start up training effort?				
		Group 3) Alternative methods for training Investigator site staff				
15:30		Close				

**Table 8-3: Introducing new blood: Steering Group recruiting opportunities**

<b>Meeting ID</b>	<b>Meeting date</b>	<b>Proportion of volunteers<sup>145</sup>: participants</b>	<b>% of volunteers</b>	<b>Recurrent volunteers</b>	<b>Selected volunteers</b>
9/G	3 <sup>rd</sup> May 2007	7 : 56	12.5%	A, B, C	
10/H	20 <sup>th</sup> Sep 2007	2 : 40	5%	C	
11/I	5 <sup>th</sup> Mar 2008	10 : 76	13%	A	D
12/K	11 <sup>th</sup> Jun 2008	10 : 61	16%	B	E
13/J	8 <sup>th</sup> Oct 2008	2 : 85	2%	-	
<b>Totals</b>	<b>5 meetings</b>	<b>31 volunteers</b>		<b>3 recurrent volunteers</b>	

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<sup>145</sup> Volunteers who provided contact details on Feedback forms



**Table 8-4: October 2008 Forum Feedback**

<b><u>Participant #</u></b>	<b><u>Feedback</u></b>
Participant 1.	"An Academic Research Perspective" - The speaker obviously didn't understand what was required!!!
Participant 2.	Might be worth reviewing guest speakers presentations a day or two before the event to ensure they understand and then give/deliver appropriate presentations
Participant 3.	I think Academic Research Site presentation was not relevant to this meeting. Did not mention how they find sponsor training
Participant 4.	Did you review slide content prior to the day? They weren't all very relevant & came across as sales pitch
Participant 5.	GENERALLY GOOD THANKS!!!!!!
Participant 6.	Some presentations contained rather too much "sales pitch". It would have been more appropriate to place a higher emphasis on methods of training rather than facilities or products.
Participant 7.	I am working in Animal Health Clinical, so some of this was not that relevant
Participant 8.	Would have liked site perspective to cover training received from sponsors/CRO's - GOOD DAY - THANK YOU!!!!
Participant 9.	First 20 mins. of Surrey CRO presentation not relevant at all to to-days topic, more them touting for business!
Participant 10.	An Academic Research Centre Perspective presentation was 80% irrelevant, sadly both this and PharmaEd presentations, although interesting, did come across as a sales pitch. Good CRO perspective presentation and thought stimulating general overview
Participant 11.	More training further North and Scotland
Participant 12.	An academic Research Centre Perspective wasn't really relevant and didn't really cover any general info in relation to GCP training, interaction with sponsor etc, would have preferred to hear about NHS perspective
Participant 13.	ARC presentation - too much info on what unit does, not a lot of content on training
Participant 14.	Didn't touch much on Web Conferences for delivering of IM, mostly covered F2f vs. Recorded meeting/online learning
Participant 15.	Presenters should be asked to repeat questions raised by audience, as not everybody could hear the questions

**Table 8-5: Predominant conceptual/procedural models of practice characterising Forum activity**

Mtg ID #	Date of Meeting	Meeting Title	Duration	# of attendees/sessions	Method artefacts						Procedural model		Domain focus		Conceptual model
					Slides	Q & A / discussion	Ex	H/out	Flip-chart	Mono-logue	Dia-logue	SubjMatter vs. Training process	Transmissive	Enquiry-led	
					Formal 146	Informal 147									
2/A	18 <sup>th</sup> May 2004	Formulating your training strategy	4 hrs	26/7	3	7	2	0	0	2	6/7	1/7	0:7	6	1
3/B	13 <sup>th</sup> Sep 2004	Evaluation methods & Training Needs Analysis	4 hrs	25/4	4	4	0	0	2	0	4/4	0/4	0:4	4	0
4/C	6 <sup>th</sup> Dec 2004	Innovative training techniques	4.5 hrs	26/4	0	1	3	2	3	4	0/4	4/4	0:4	0	4
5/D	10 <sup>th</sup> May 2005	Day in the life of a trainer in pharma	4 hrs	38/6	2	1	3	1	1	0	5/6	1/6	0:6	5	1
6/E	20 <sup>th</sup> Sep 2005	Preparing for Regulatory inspections. Training records	4 hrs	42/5	5	5	5	2	1	1	3/5	2/5	3:2	3	2
8/F	8 <sup>th</sup> Dec 2006	Are you fit for purpose? Developing the trainer	3.5 hrs	29/4	2	2	2	2	1	2	2/4	2/4	2:2	2	2
9/G	3 <sup>rd</sup> May 2007	Regulatory inspections. The role of the trainer.	5 hrs	56/4	4	4	1	0	0	0	4/4	0/4	3:1	4	0
10/H	20 <sup>th</sup> Sep 2007	Making learning the priority (Trainers Toolkit)	5 hrs	40/5	1	1	4	3	1	2	1/5	4/5	1:4	1	4
11/I	5 <sup>th</sup> Mar 2008	SOP Training: Same Old PowerPoint	5 hrs	76/6	4	2	4	2	3	3	3/6	3/6	3:3	3	3
12/J	11 Jun 2008	Training our Project Managers: Budgets, Timelines & Quality	5 hrs	61/5	5	1	5	1	1	1	5/5	0/5	5:0	5	0
13/K	8 <sup>th</sup> Oct 2008	The Who, What, Where, When and How of Investigator Site Training	5.5 hrs	85/5	4	4	1	1	1	1	3/5	2/5	2:3	3	2
			49.5 hrs	504/13 = 39	34	32	30	14	14	16	36/55	19/55	19:36	36	19

146 Formal: Questions & Answers – directed to the end of the session, as planned, subsequent discussion treated as interruptions by ‘speaker / session leader’ or chairperson &  
 147 Informal: Q&A – ‘speaker / session leader’ responds to spontaneous questions from Forum members during the session engaging in dialogue (discussion).

**Table 8-6: Consistency of procedural model distribution among session leaders**

Procedural model	Session leader	Meeting number and coding reference											
		2/A	3/B	4/C	5/D	6/E	8/F	9/G	10/H	11/I	12/J	13/K	
Dialogic	Donald	✓		✓						✓			3
	Molly			✓					✓			✓	3
	James			✓	✓				✓				3
											<b>Total</b>	<b>9</b>	
Monologic	Peter	✓			✓			✓			✓		4
	Jennifer	✓	✓		✓			✓					4
	Susan		✓		✓							✓	3
	Brian					✓			✓				2
	Evelyn							✓	✓				2
	Jan								✓		✓		2
	Robert		✓								✓		2
											<b>Total</b>	<b>19</b>	

Table 8-7: Overview of Forum feedback (2007-2008)

		Training Investigators		Training Project Managers		SOPs: Same old P/Point		Making learning the priority	
		TF_13/K 08Oct08		TF_12/J 11Jun08		TF_11/I 05Mar08		TF_10/H 20Sep07	
# of Participants : Respondents		n =85 : 45 [53%]		n =61 : 55 [90%]		n =76 : 51 [67%]		40 : 16 [40%]	
		%	n =	%	n =	%	n =	%	n =
<b>How did you find the content of this forum?</b>	Excellent	12%	10	28%	17	30%	23	20%	8
	Useful	32%	27	54%	33	32%	24	12.5%	5
	Adequate - Disappointing	5%	4	3%	2	5%	4	0%	0
	Not relevant	0%	0	0%	0	0%	0	0%	0
<b>What format would you prefer the future Forums?</b>	Presentations only	0%	0	5%	3	1%	1	0%	0
	Workshops/Debate Style	8%	7	15%	9	12%	9	7.5%	3
	Discussions only	1%	1	0%	0	0%	0	0%	0
	Mix of presentations/discussions	44%	37	71%	43	49%	37	32.5%	13
	Other	0%	0	0%	0	1%	1	0%	0
<b>How many forums would you want ICR to organise a year?</b>	Once a year	0%	0	0%	0	3%	2	0%	0
	Twice a year - Depending on content	15%	13	31%	19	24%	18	10%	4
	Three to four times a year	31%	26	52%	32	29%	22	27.5%	11
<b>How did you hear about this event?</b>	Colleague/ICR Member	13%	11	16%	10	0%	0	25%	10
	CRfocus	3%	3	3%	2	0%	0	5%	2
	Email	25%	21	61%	37	0%	0	7.5%	3
	Website	2%	2	7%	4	0%	0	0%	0
	Other	1%	1	0%	0	0%	0	0%	0
<b>Would you be interested in joining the Steering Group?</b>	Yes	2%	2	16%	10	1%	1	5%	2
	Maybe	7%	6	0%	0	12%	9	0%	0
	No	0%	0	0%	0	32%	24	0%	0

**Table 8-8: Overview of Forum feedback comments (2007-2008).**

<b>Date of Forum</b>	<b>Participant #</b>	<b>Comment</b>
May 2007	Participant 1	I would not mind if the Forum lasted until 4pm if there was more time for workshops
Sep 2007	Participant 1	More Time
Mar 2008	Participant 1	Last presentation very good. Is a good idea to bring people together as group and share thoughts and act as one unit
	Participant 2	Would have liked a workshop to create a list of ideas for things to try – sharing experiences of all in the room
	Participant 3	These Forums could do more of this to collect experiences and facilitate even greater sharing of experiences and ideas
	Participant 4	Defining some "Standards" for our profession - How far beyond read / certify do we go? e.g. What is acceptable GCP training content.

**Table 8-9 : June 2008 Forum feedback**

<b>Participant #</b>	<b>EFD</b>	<b>Feedback</b>
Participant 1.	EFDr	Brian's presentation could have been better if it had focused on what project management is in Pharma, rather than educating us on PRINCE2.
Participant 2.	EFDr/c?	Difficult to make these sessions relate to ones own area of working.
Participant 3.	EFDr	Useful session!
Participant 4.	EFDr	Course was really good - felt it focused a lot on project managers from a CRO. Would be good if it was more of mixture.
Participant 5.	EFDc	Try and ensure a balance between interactive discussions and presentations. Probably too many presentations and not enough interaction today.
Participant 6.	EFDc	Would have been useful to have copies of all presentations. Some discussions would have been good!
Participant 7.	EFDr	New subject area for me and I found it really interesting and inspiring. Thanks
Participant 8.	EFDc	Very informative session - could be improved with interactive activity after lunch
Participant 9.	EFDc	An interactive expert panel session would add value
Participant 10.	EFDc	Good mix of presentations - maybe more time for group discussion
Participant 11.	EFDr	I really appreciate the mix of these sessions - I find it very useful to share information. Often trainers don't get training so it's a nice opportunity.
Participant 12.	EFDc	As well as the current information courses, it would be useful to have 2 sessions a year on developing our skill set.
Participant 13.	EFDr	Really enjoyed it - thank you!

**Table 8-10: Role of neighbouring activity systems on the Trainers Forum**

AS	Locus	Subject	Object	Central Activity	Motive	Tools	Rules	Actions	Operations	Outcome	Neighbour'g Role	L4 Contra'dn with the (AS5)
3	Clinical Research workplace	Senior Managers	Clinical Research process	Managing Clinical Development Programme (CPD)	Following GCP	Operational structure; GCP-SOPs; Project management	Deliverables produced on time to budget and to GCP stds; compliance culture	Managing studies to timelines & budget	Conducting Clinical Development Programme to GCP-SOPs	ROI; GCP compliant procedures	Rule-producing activity	Culture of compliance vs. conscience (related to the internal goods of practice)
3	Clinical Research workplace	Senior Managers	Achieving business goals	Controlling training budget	Ensuring training needs (TNs) satisfied according to business goals	EFsD (received)	Financial measures of training effectiveness (training as a cost vs. investmt) NOT training eval'n model (Kirkpatrick's 5 levels)	Allocate resources for proactive training	Limit expenditure to proactive training	Routine delivery of proactive training; Missed opportunity to routinely evaluate achievement of business goals/effectiveness of proactive training	Rule-producing activity	Predominance of received vs. constructed knowing about the value of training or information
3	CR workplace	Trainers	Expediently trained trainees	Planning and delivery of expedient training	Satisfying TNs according to individual needs	Pedagogy (transmissive)	Expediency  No valid way to measure training effectiveness	Expedient conduct of S3-T/cycle (delivery); L1&2 eval	Conditions: Routine expedient performance of S3-T/cycle (delivery); L1&2 eval	Routine delivery of reactive training	Object-producing activity Instrument-producing activity	Use of expedient vs. deliberative methods Use of transmissive vs. enquiry led pedagogy
4	ICR	ICR members	Professional practitioners in the field of CR	CPD: Sharing BP; raising stds; develop'g individual	CPD of all members	SIG/SG constitutions; formal prof perform'ce stds for CR	CPD points for attendance	Host SIGs and Fora	Admin: notify members of meetings; organise bookings etc	CPD	DoL-producing activity i.e. constitution of SG/ SIGs	Structure of labour in TF: vertical vs. horizontal

## **Chapter 9**

# **The Purpose and Pedagogy of the Trainers' Forum: Object and Tools**



## 9 THE PURPOSE AND PEDAGOGY OF THE TRAINERS' FORUM: OBJECT AND TOOLS

The community constituting the Forum, the division of labour within it, and the rules affecting its activity and individual chains of actions were described and analysed in the previous chapter. Analyses revealed that trainers replicated the circumstances that they endured in their workplace through the predominance of a time-bound, content driven agenda, driven by a compliance culture that can be traced to the workplace, where it operated as a rule. In turn, this rule was traced to another neighbouring activity system, the regulatory environment, where compliance culture is used as a tool to enforce adherence to GCP standards (L1TO2d).

In this chapter, the object of activity in the Trainers' Forum and the tools used to transform it into outcomes are analysed.

### 9.1 Purpose of the Forum: Object

As discussed in Chapter 4, developmental research presents a number of methodological challenges, not least of which is the gathering, selection and analyses of data for examination due to the vast quantity available. However, the final challenge lies in reporting analyses in order to make sense of historical, expansive and occasionally retrograde developments. In general, this means specifying the limits and locus of the activity being investigated in terms of the people involved and their location. In this study, it also entails unravelling the ways in which activities shape and are shaped by their different levels of context. Only then does it become possible to understand how a concept of practice has developed, since:

*“...To analyze human social activity, development, and learning across multiple time scales, we must be as willing to look at biography and history as at situations and moments, as methodologically and theoretically prepared to study institutions and communities as to study students and classrooms” (Lemke, 2001: 25).*

Thus, the Trainers' Forum is the context in which the complex activity constituting the sharing and discussion of trainers' practice was observed, for almost fifty hours, over a period of five calendar years, supplemented by interviews of those involved in the activity (e.g.

members of the community according to their levels of participation or the division of labour in relation to the activity).

Activity Theory provides the framework for understanding activities, actions and operations - as elements of practice - performed by participants in this activity system. Moreover, if the unit of analysis concerns the systematic activity of the Forum in its entirety, then an individual session within each meeting is the object-unit, which "...provides a strategic lens or magnifying glass through which the inner movement of the activity system becomes visible" (Engeström, 1987 (5):7. Consequently, the collective motives, goals and instrumental conditions that drive activities, actions and operations, respectively, in this system of activity may be understood by considering how each of the parts or sessions contribute to the Forum's purpose as a whole, following Leontiev's (op.cit.) hierarchical structure of activity, as discussed in Chapter 2:-

*Activity is governed by its conscious motive(s).*

*Component actions are governed by their aggregate goals (which are subordinate to the main goal or object of activity.*

*Operations are governed by the conditions in which component tasks are performed, where operations are the routinised or automated form of the constituent actions within an activity.*

The object of activity or purpose of the Trainers' Forum may be understood through analysing the historical development of the central activity in the Trainers' Forum i.e. the sharing of practice and discussion of issues. Through observing participation in eleven meetings of the Trainers' Forum and observing the patterns of activity within and between fifty-five constituent sessions, the successive developmental phases of the Forum as an activity system were identified. These phases are presented in the following sections as part of the object-historical, theory-historical and actual-empirical analysis i.e. revealing how the purpose and consequent object of activity in the Forum developed.

Three stages of historical development were identified:-

Stage 1. Defining issues: agreeing the need to redefine the traditional role of the trainer

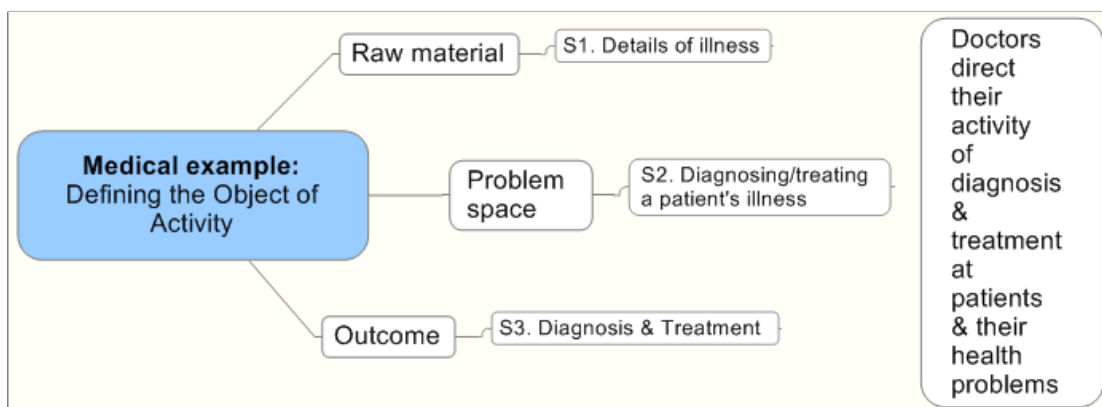
Stage 2. Defining problems and challenges: the conflict between internal resources and external forces in re-orienting towards learning

Stage 3. Sharing approaches to practice problems and challenges: defining strategy and solutions

Each of these stages is discussed in subsequent sections, with analyses proceeding through the voices of the Forum's participants to elaborate how the object of activity was transformed into outcomes in the Forum using the tools available.

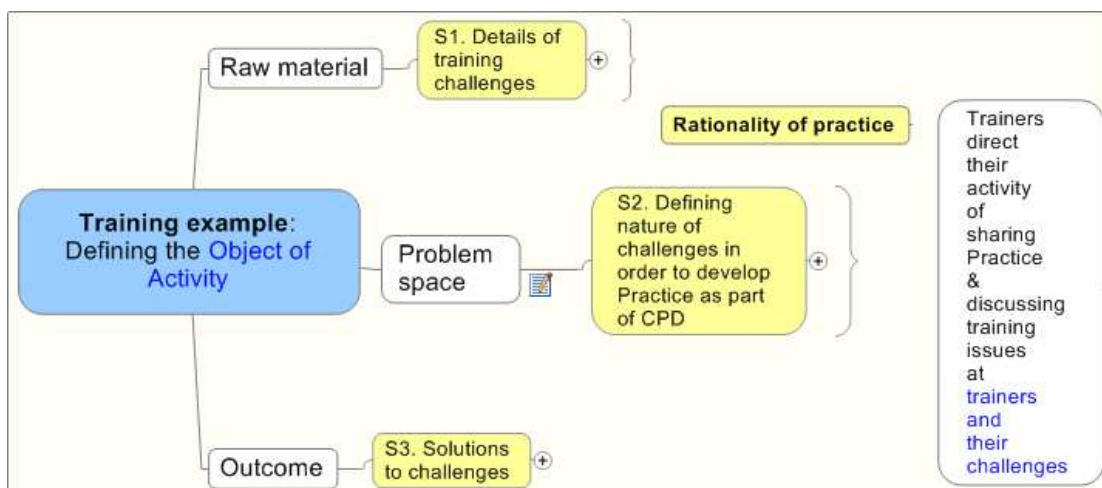
## 9.2 Historical development of the object of activity

Engeström defines the object of activity as the raw material or problem space at which activity is directed, using medical practice as an example, shown in Figure 9-1, below. In effect, each of these components reflects the first, second and third stages of historical development of the object-activity (S1, S2, S3).



**Figure 9-1: Object of activity in medical practice**

The object of activity at the Trainers Forum is correspondingly defined and illustrated in Figure 9-2, below.



**Figure 9-2: Object of activity in trainers' practice at the Forum**

In keeping with Wenger *et al's* (2002:56) ideas, the participation status of Forum members reflected their degree of involvement as subjects in this activity system. Thus, *core* members were differentiated on the basis of those who steered the community in its activities: they were involved in its leadership, acting as auxiliaries to the community coordinator. They identified topics to be addressed; and finally, they helped to move the community along its learning agenda. In the case of the Trainers' Forum, the coordinator role was split between two functions:-

1. An ICR employee, who coordinated steering group activity: getting everyone together for planning meetings; writing and sending out the minutes; and circulating notices, and e-mails etc.
2. The Chair of the Steering Group, who guided discussion and decisions about meeting content, and co-ordinated steering group members' activities during the planning stage.

According to Wenger, the core in a community of practice is small and typically made up of around 10 – 15% of the whole community. In the case of the Forum, with attendance numbers ranging from 26 to 85 and averaging 39 per meeting, at least 4 or 5 core members regularly attended meetings, and another 3 or 4 attended occasionally.

The next level outside the core, is the active group "...these members attend meetings regularly, and participate occasionally in community forums but without the regularity or intensity of the core group". Active members in the TF were those who regularly asked questions, or made comments, or, as in Donald's case – were invited to lead sessions by core members. According to Wenger *et al* (op.cit.), this group is formed by 15 to 20% of the whole community. The final portion of the membership is described as peripheral. These members keep to the sidelines, watching the interactions of the core and active members, and rarely contribute themselves. However, this passivity does not imply that they are not learning or gaining insights from observing others exchanges, which they may put to good use.

On the one hand, in the TF, some community members did not contribute or were unwilling or unable to get further involved due to the time investment. On the other hand, due to their relative inexperience or lack of confidence or authority in the role of trainer (dedicated or shared), trainers like Deirdre, did not participate because they felt their observations were contextually inappropriate or carried no weight: "I don't think I know enough to pitch in...maybe when I've been doing it for a few more years. I don't have the experience to contribute at that sort of level"<sup>148</sup>. Nevertheless, as an emerging community of practice, this social space provided an opportunity for learning such that members' participation in the community affected not only their own learning but that of their fellow trainers.

Consequently, observing participation in meetings of the TF<sup>149</sup> and observing the patterns of activity within and between constituent sessions, revealed the successive developmental phases of the Forum as an activity system. These phases are presented in the following sections as part of the object-historical, theoretical and empirical analysis i.e. revealing how the purpose and consequent object of activity in the Forum developed.

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<sup>148</sup> Interviewee-1\_peri\_EFDr\_Line 260

<sup>149</sup> from May 2004 until Oct 2008

### 9.2.1 Stage 1: Defining our issues – agreeing what is best practice

From the beginning, the collective focus of the Trainers' Forum's central activity was on sharing practice & discussing issues with the object of learning new ideas; benchmarking standards and practice in order to raise standards, as affirmed by individual trainers.

In the first stage of development, the focus of Forum activity was on defining best practice, opening debate about the need for new models of training from “knowledge-based” to “facilitative”, as discussed in Chapter 8. This stage of development, concerned the rationality of practice, and took place over the first two to three meetings<sup>150</sup>. It was expressed as the need “...to redefine the role of the trainer...advocating that the trainer puts complete emphasis on facilitation, almost as a new role” (Hayes, 2004a:23)<sup>151</sup>. In particular, how the role of trainer was operationalised and perceived was discussed at the 2nd Trainers Forum meeting in 2004. In his session on the difference between training in CROs and pharma, Donald, an active member of the Forum, and a full-time dedicated trainer remarked that

*“...there is an industry shortage of trainers who have both subject matter expertise combined with training skills”<sup>152</sup>.*

The impact of this shortage was discussed in terms of how it “...immediately limits fulfilment of training strategies...” in that “...a five-year training strategy, aligned with corporate strategy, is the preferred option for both small and large companies. However, it is rarely seen...” (Hayes, *ibid.*:24)<sup>153</sup>.

Problems with image and credibility generally in the training function were attributed to failure of organisational strategy to implement the concept of the trainer as a facilitator in the process of organisational development, because:

*“Mark: ...Training linked to Human Resources is dangerously close to being an administrative function... it's too generalized because it's not focused on functional groups...and stuck in a rut, because it's not effective...”<sup>154</sup>.*

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<sup>150</sup> TF\_1/U\_12-03; TF\_2/A\_05-04;TF\_3/B\_09-04

<sup>151</sup> TF\_rep\_2/A\_05-04\_CRf\_15(6):22-26.

<sup>152</sup> TFS\_FN\_2/A\_05-04-3\_EFDc

<sup>153</sup> CRf\_05-04\_2/A

<sup>154</sup> TFS\_FN\_2A\_05-04-1\_EFDr

No one disputed this statement and some nodded their heads in agreement. In addition, further comments revealed how project managers were perceived as having more influential roles compared to trainers, which, it was remarked, was ultimately reflected in their greater career advancement within the organisational management structure. Some of the reasons for the greater influence of project managers were also indicated in the following exchange:

*"...as trainers, we don't even get a whiff of the business plan, far less get involved with it... whereas, project managers are automatically feeding into it during the course of the project, in case contingencies are needed for critical timelines, or budget over-runs etc..." (Robert<sup>155</sup>).*

*"...yeh...project management is an automatic stepping stone into senior management. The same can't be said for training because it's hard to define what we contribute to the business. With project management it's obvious, either the project is delivered on time, and on budget, or it's not. Even the reasons for drift can be analysed..." (Bill<sup>156</sup>).*

In voicing their frustration about the perceived low status of trainers, the issue of why trainers felt unable to change the status quo began to emerge, summarized in the Forum report published in the Institute of Clinical Research magazine, Clinical Research Focus (CRf) as:

*"...industry is being pragmatic when it trains for compliance reasons, and therefore can be seen as reactive..."*

Each session speaker in the 2<sup>nd</sup> Forum touched upon a different aspect of the status of training and trainers, sharing a concern to raise the profile of training as a strategic function that enables the organization to achieve its business goals. Trainers at the Forum were challenged to think about the ways in which this aim might be achieved, with the following questions put to them by Peter<sup>157</sup>, a full-time trainer in a CRO, in his session on *reactive training strategies*:-

"...Is your training remit defined by you or for you?"

"...Is your training strategy what you want it to be?"

"...How is your training group positioned in process development: is it managed or is it mayhem?"

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<sup>155</sup> TFS\_FN\_3/B\_09-04-3\_EFDr

<sup>156</sup> TFS\_FN\_3/B\_09-04-3\_EFDr

<sup>157</sup> TFS\_FN\_2A\_05-04-2\_EFDr

In her session on *learning versus training strategies*, Julie<sup>158</sup>, a full-time freelance trainer, suggested that the hiring of Chief Learning Officers, whose aim was to change corporate culture to make it easier for trainers to influence corporate *learning* strategy, was having the effect of re-positioning training as a corporate “learning endeavour”. This was the first explicit mention of the need to re-direct culture from compliance to conscience (LITOd), particularly in small companies within other industries in which she also worked. She qualified her observations of small companies’ approach to corporate learning strategy by stating that in her experience: “...*writing it is one thing. Doing it is another*”. Nevertheless, Julie stated that, as a function, training was more likely to be adequately resourced to fulfil its strategic purpose of proactively helping employees develop their knowledge, skills and behaviours in order for the business to achieve its goals, if senior managers were able to “...*see the business value of clinical training through evaluation.*” She recommended that such evaluation be promoted in terms of:

*“...as a consequence of this training, this is where we are now in the clinical development process. This is how much time we’ve shaved off project X”.*

In effect the message, from Mark in the first session, for trainers to “...*challenge the need to put prescriptive technical knowledge at the top of the training agenda*” was echoed throughout the six sessions that followed. Forum participants were reminded to consider the value to their organisations of changing behaviours and attitudes. Ways to demonstrate that value through the implementation of new models were also suggested mainly by re-evaluating the role of the trainer not as a deliverer of formulaic “...*knowledge-based training*”, but as a “...*facilitator of learning in the organisational training strategy*”<sup>159</sup>.

Despite the general agreement and support at this 2<sup>nd</sup> Forum of the need to develop the “new” model of trainer as *facilitator*, the entrenched nature of the *knowledge-based* model of the trainer persisted through subsequent Fora culminating in its re-definition at the 5<sup>th</sup> meeting in May 2005. Jennifer, a full-time trainer, explained that her role was that of “technical trainer”.

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<sup>158</sup> TF\_FN\_2A\_05-04-4\_EFDc

<sup>159</sup> TFS\_FN\_2/A\_05-04-3\_act\_EFDc; TF\_rep\_2/A\_05-04\_CRf, 2004, 15(2):23-24.



It mostly involved "...delivering training modules..." selected from an established module bank and delivered either via e-learning or occasionally via instructor-led video link. For her, one disadvantage of being a technical trainer was "...becoming very specialised in subject matter" as well as "travelling a lot"<sup>160</sup>.

Yet, vestiges of the support for the new model also persisted in subsequent meetings, encapsulated as "...*the guide on the side versus the sage on the stage*" by James, a qualified trainer. Since first quoting this in his report of the inaugural Trainers' Forum from the work of Alison King (1993), James re-iterated this mantra at every opportunity to open up debate about the over-reliance of the knowledge-based trainer on PowerPoint slides to "transfer knowledge" to trainees<sup>161</sup>. Allegiances to one or other model emerged in discourse of the 4<sup>th</sup> Forum, and re-surfaced in the 5<sup>th</sup> meeting<sup>162</sup>. In particular, the 4<sup>th</sup> Forum was dedicated to demonstrating "innovative training methods" and debating the merits of particular training methods e.g. role plays, PowerPoint slides. The concept of "swiped" exercises 'borrowed' from other settings or industries and adapted to suit the trainer's particular purposes was also introduced at this Forum.

Within the community, allegiances emerged in various sessions of Forum meetings. That is, *knowledge-based* trainers modelled their definition of practice in their use of PowerPoint slides to communicate information in the act of sharing knowledge. Similarly, facilitative trainers modelled a deliberative practice, where slides were used as a tool within an enquiry-led session to discuss, summarise or make key points before, during or after participants performed an activity. The different methods used in these transmissive and enquiry-led approaches were shown in Chapter 8, Table 8-5<sup>163</sup>. Meanwhile, pedagogical and epistemological implications of the types of practice modelled are discussed further in this chapter.

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<sup>160</sup> TFS-5/D\_FN\_05-05-4\_EFDr

<sup>161</sup> TFS-4/C\_FN\_12-04-4; TFS-5/D\_FN\_05-05-3;TF\_ 6/E\_FN\_09-05-P1

<sup>162</sup> TFS-4C\_FN\_12-04-1 and 4; TFS-5D\_FN\_05-05-3

<sup>163</sup> Table 8-5: Predominant conceptual/procedural models of practice characterising Forum activity.

For example, over time, the tension and contradiction between these two models of practice became apparent in the frequent re-iteration from transmissive pedagogues that "...we are not here to show people how to *present*" despite habitually delivering presentations. This expression re-surfaced regularly when the mission statement of the Forum not to *train the trainer* was questioned or discussed by deliberative pedagogues at various SG meetings<sup>164</sup>. As Evelyn remarked in her interview on this point:-

**Line 153:** *I've felt that I've received - you know, trainers are usually the last people to attend any training - so I used to see my participation on the Committee and the delivery of the Forums as some sort of training...*

**Line 167:** *"But, it is quite confusing and I think ... everybody's got different interpretations and it often comes up: oh well, we're not doing train the trainer. I think it's this sort of meaning ... that we're not gonna do the basics of learning styles and ... um ... how to set up a room. But, the fact that we've covered ... like this year we did SOP training - I mean we had speakers on the way we present SOP training - and that is helping trainers to train people. So it is a bit confusing. I think it's never been kept in its pure form as not training the trainer. So actually, I remain a bit confused, but I think it's because people have different perceptions of what that statement actually means."*

Although discourse in the TF and SG meetings demonstrated an understanding that presentation skills constituted the most basic aspect of a trainer's role, it also revealed the perceived obstacles challenging trainers to develop their facilitation skills (the "conflict between internal resources and external forces" first raised at the 3<sup>rd</sup> Trainers' Forum<sup>165</sup>). Moreover, the notion that such skills were implicitly demonstrated in the TF was never directly addressed, although core members had reflected on this aspect during their interviews,<sup>166</sup> as exemplified by Evelyn's comments. However, by constantly rejecting requests to review why the Forum did not consider *training the trainer* part of its mission, an opportunity to address the needs of members and to reach a common understanding of the goals of the Forum was overlooked (L2RU-OB, illustrated in Figure 9-11: Modelling 1<sup>ty</sup> and 2<sup>ty</sup> contradictions within the elements of tools & object). Consequently, an opportunity to develop understanding and therefore to build commitment to the Forum from both its members and leaders, who occasionally bemoaned its lack, was also overlooked. Instead, the

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<sup>164</sup> SG\_FN\_10/H\_09-07\_Jennifer; SG\_FN\_Pre\_TF\_11/I\_03-08; PC\_e-mail\_31-10-08\_catch-up\_James; SG\_mins\_13/K\_10-08

<sup>165</sup> TFS\_FN\_3/B\_09-04-2\_EFDr

<sup>166</sup> As presented in Chapter 8, section 8.3.2 (Molly – interviewee 9\_core\_EFDc).

divisions in contrasting pedagogies remained between trainers due to this double-bind in the situation of their practice in the workplace i.e. caught in the conflict between internal resources and external forces. That is, since KBTs were most likely to have appropriated the tools available to them in the workplace (transmissive pedagogy), they were most vulnerable to the regulatory compliance culture that dominated the workplace.

As described in Chapter 8, section 8.1.1, the Trainers' Forum was established by the ICR to serve as a vehicle for CPD through sharing best practices, raising standards, and developing the professional. By implication, if an activity is considered a form of *doing directed to an object* (Kuutti 1996: 27), then from discussion at the second Forum, trainers' object-activity was to share a facilitative model of training in order to learn which aspects of their practice needed developing.

However, until the ICR re-structured its framework for CPD in 2007, Forum participation was not officially recognised to serve this purpose. Consequently, when the Forum was established in 2003, participants may have differed in their conscious awareness of CPD motivating Forum activity, depending on their level of participation. In contrast, in forming the SG, core members were not only aware of its purpose, but helped to formulate it within a mission statement, subsequently posted on the ICR website (June 2005). The mission statement was also publicised in the February 2004 report of the inaugural meeting held in December 2003<sup>167</sup>.

The role of the SG in suggesting "possible topics of interest to trainers" was outlined in the inaugural report by a core member of the Forum. (Subsequent reports of meetings were written by various core members). This report also revealed the model format for discussions as "steering group members identified an excellent panel of speakers"<sup>168</sup>. Moreover, the goal of future Forum meetings was reported as being decided in the final session of the day, when a core member "...led discussion on meeting our training needs and identified key topics for

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<sup>167</sup> TF\_rep\_1/U\_12-03\_CRf 2004, 15(1):34.

<sup>168</sup> Illustrated as DoL in Figure 8-1.

future forum meetings – evaluation looks like the current hot favourite! Feedback at the meeting suggested that the steering committee is on the right lines to meet trainers' needs." Although the report provided an overview of proceedings, what those needs were, or how they were to be addressed was not explicitly mentioned.

A second report published in the Institute magazine, CRf, focussed on the inaugural meeting's content, which concerned the topic of e-learning. It highlighted that trainers' need "...to consider how people learn..." and develop "...approaches to training which place the learner rather than the trainer at the centre..." especially since "...the sheer volume of content on which trainers are asked to 'train' others is overwhelming and can prevent us from adequately considering how people learn"<sup>169</sup>.

This report also highlighted the challenge that "*re-orienting towards learning*" presents for clinical research trainers, because "...many people may have a tendency to be passive when learning as a result of the schooling they received, and so can be reluctant to become more active." Moreover, it emphasised that trainers had a further predicament since "...in the highly regulated world of drug development there is much need both for all of us to be kept up to date and for this process to be recorded."

Thus, from the beginning, the contradiction in how the community might meet trainers' needs was apparent in the desire to "...have a forum ...to share ideas and best practices, perhaps to compare our clinical training and brush up skills... and simply to feel less isolated (many clinical trainers work alone)"<sup>170</sup> but without "*training the trainer*". In addition, the second report mentioned, in passing, that the ICR provided *Train the Trainer* courses:

*"...To its credit, the Institute of Clinical Research has recently initiated a CPD scheme and does run Train the Trainer courses. However, it has not yet developed its own qualification to address the competencies, rather than the content, required for training today – perhaps it is time it did so?"<sup>171</sup>*

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<sup>169</sup> TF\_rep\_1/U\_12-03\_CRf, 2004, 15(2):25.

<sup>170</sup> TF\_rep\_1/U\_12-03\_CRf 2004, 15(1):34.

<sup>171</sup> TF\_rep\_1/UF\_12-03\_CRf, 2004, 15(2):26.

In commending the ICR for introducing a CPD scheme, it was gently reminded of an educational / professional need for accredited courses that by implication *Train the Trainer* courses did not address.

This need to demarcate that *training the trainer* was the chargeable domain of the ICR, rather than an automatic by-product of CPD within a community of practice, points to a history. As Jennifer<sup>172</sup> explained:

“...Back in the 90s, a similar group was set up. At the same time, some of the trainers were also helping out the ICR with running courses. So, when they set them up and began charging for them, it caused a bit of bad feeling. People were giving up their time for free, but not getting anything back. So once the Forum was set up this time, it was decided to steer clear – so people wouldn't feel like they were being asked to deliver something for free. The Forum is about sharing ideas not running courses.”

Hence, the political boundary between the chargeable ‘arm’ of the ICR’s operations and its CPD ‘arm’ may have been publicly declared in Forum artefacts (mission statement; reports) and clarified privately, in order to pacify SG members about what was expected of them. However, this historical demarcation that the Forum was not about *Training the Trainer* had no relevance or meaning either for Forum participants or for SG members, who were unaware of the history that led to it, or its consequent political significance as a source of tension between the Forum and the Institute. Rather, their expectation as prospective participants at the Trainers’ Forum, remained to learn more about being trainers, ranging from “how to present training material” (Deirdre<sup>173</sup>; Sally) to “benchmarking practice” (Donald, Evelyn, Molly).

Both peripheral and active members attested their disappointment that this expectation was not met, particularly since the reasons for it not being *train the trainer* remained unexplained. For example, in attending her first Forum, Deirdre, a newly appointed part-time trainer and peripheral member, talked about how she was attracted by the Agenda title, but soon realised that the meetings content did not fulfil her need to “... share ideas of the different ways of presenting training material – via groups or one-to-one interaction. And the different ways

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<sup>172</sup> PC\_FN\_Jennifer\_core\_EFDr\_4/C\_12-04.

<sup>173</sup> Interviewee 1\_peri\_EFDr: excerpted from line 24 – 35.

you can actually give the material over to the trainees” which she had “...expected to be one of the topics. But it was different from what I understood it to be”. Deirdre was particularly puzzled that the Forum was not about *training the trainer* since “...that was my reason for going - a trainers’ toolkit for me is something you can use...it’s strange”. Her main reason for going to the Forum was to learn how to handle different elements of her new role through sharing the received ‘wisdom’ of others.

By contrast, Mary<sup>174</sup>, an experienced part-time trainer, also attending her first Forum, as a peripheral participant, was a little more cynical in her outlook regarding what to expect, based on her appreciation of the limitations of transmissive pedagogy:

*From Line 440: It's the same, every training event... People go along with expectations: they're going to come out with some practical knowledge – ‘...now I can go back and do that’. It's not. It's just a bit of information.*

Yet, for Evelyn, an experienced but unqualified trainer<sup>175</sup>, attending the Forum fulfilled a need for reassurance that her experience compared favourably with others. It subsequently encouraged her to add her contribution, based on her growing sense of familiarity about the topics being ‘shared’:

*From Line 130: I think it's the topics that we chose. Especially ones I had some sort of familiarity of, and thought: oh, yes I can contribute. I remember feeling at the beginning it was a bit intimidating, 'cause we had a few sort of quite mouthy people, which you'll always get amongst trainers. So that was, you know, something to get over that. But yeah, everybody does. So, it was really good to meet other trainers and trainers from big departments, like Margaret and ... um ... trainers from small departments, like me. And, I think there were a few other people that sort of dipped their toes in and out of the Forum, like me from small companies.*

*I mean, when I think of when I first joined... I used to go along and I didn't used to speak up as much. Although, perhaps I'm not always that confident, it's one of those trainer tricks. You know, that you're not more confident than you are? But, that was five years' ago. And I know at the beginning, I know I used to be one of the quieter ones at the Forum but now I'm used to it. So, perhaps it's my personality. But, if you're not going to turn up and even try, you'll never find out.*

Other trainers like Donald and Sally, saw the Forum’s potential as a “centre of education”

(Donald<sup>176</sup>) with trainers as “champions working out solutions” (Sally<sup>177</sup>) to the challenges

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<sup>174</sup> Interviewee2\_peri\_EFDc

<sup>175</sup> Interviewee 6\_core\_EFDc

<sup>176</sup> Interviewee 8\_act\_EFDc

<sup>177</sup> Interviewee 4\_peri\_EDFc

they faced with implementing effective training strategies. As an experienced qualified trainer, Donald's participation in the Forum was active, having occasionally led Forum sessions over the years, and contributing to others sessions through discussion. In contrast, Sally joined the Forum as a relatively inexperienced and unqualified trainer. Her participation was typically peripheral, in that when she attended meetings she talked to fellow trainers privately, but not publicly.

Nevertheless, the gap in expectations over the purpose of the Forum, and in the role of its Steering Group was the double bind of the situation in the Forum regarding the object of activity. That is, the stipulation by the SG that 'training the trainer' was not an aim of the Forum reflected, yet constrained, its depth of focus and subsequent development as a vehicle for CPD, especially if CPD was defined as helping trainers further develop their skills. This next extract from a Steering Group e-mail about a pending conference call illustrates this point:

*Tomorrow we should focus on the agenda for 20<sup>th</sup> September. As a reminder to all, from the discussions we've had in the past, the Forum as a whole is a place to share best practice, or showcase new ideas, or problem solve a current issue, yet not intended to be somewhere trainers come to be trained. Although, the 'toolbox' session has been added to give something personal, in terms of tips and techniques for attendees.<sup>178</sup>*

This double bind illustrates the primary contradiction in the object-activity (L1OB) at the Forum: participation served as CPD but did not serve to *train the trainer*. Nevertheless, the Forum provided a business opportunity for colleagues and competitors alike to gain advantage, free of charge.

Accordingly, resolving this contradiction involved moving on from this history to address the gap, as suggested by its active and core participants:-

Line 559.      Donald      *I think you have to start from the beginning, I mean, I'd like to see the Training Forum go back to the very beginning, go back to basics ...*

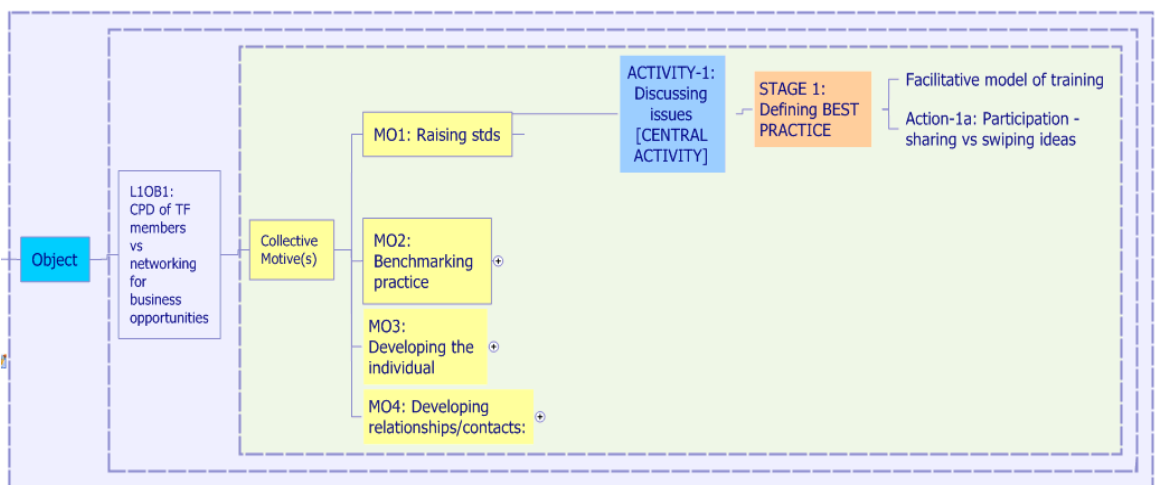
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<sup>178</sup> SG\_e-mail\_12-07-07\_preparation

- Line 21. Michael *...I think it was probably the best forum that sat inside ICR's three statements: sharing best practices, raising standards, and developing the professional. And I don't know whether it has lost its way. But I just have had other things on my plate. So, I haven't been to steering group meetings. I haven't seen what people have been wanting to do...it goes on.*
- Line 165. Molly *I think it's lost its way a bit ... a couple of years' ago when we were kind of repeating the same things over and over again, and maybe not quite covering the topics that people wanted to hear about...*

Unusually perhaps, at the collective level of activity (which involved sharing practice through discussing topics and issues related to training) the collective motives of the Forum, as a vehicle for CPD, were clear to most participants. Moreover, these motives (shown in Figure 9-3 below) were shared with the ICR, its host organisation: to raise standards of practice and to develop the professional.

Yet, irrespective of the extent to which participants were aware of the Forum's history or its collective motives, the outcome of collectively motivated activity depended on its translation through the use of contrasting pedagogies into individual actions and associated goals. Consequently, at this level (i.e. of the epistemological frame of discourse) the nature and source of the double bind of the situation at the Forum was further revealed. Therefore, in subsequent sections, the nature of the contradiction in how the object of activity translated into action through particular pedagogies and frames of discourse is elaborated.



**Figure 9-3: Motives embedded in the object (CPD of Trainers)**



### **9.2.2 Stage 2: Defining our problems and challenges – changing traditional models of training practice**

In the second stage of the Trainers' Forum historical development, the problems and challenges involved in changing the model of training from knowledge-based, to one that was facilitative were defined<sup>179</sup>. In the third and fifth meetings, the problems were agreed to concern: -

- Restricted resources due to senior management's belief that "training doesn't work"
- Lack of models for measuring/quantifying benefits of training to trainees, or value to company. Therefore, it's pointless trying to do this" (Jack)<sup>180</sup>.

A consensus of opinion at both meetings was that as a consequence of these perceptions and conditions (lack of resources), training generally had low status as a function. It was also agreed that as a result, the most expedient means of 'delivering' and evaluating training were often adopted, limiting diversity in both training approaches and training roles. These group observations agreed with the findings of the research questionnaire.

For example, as shown in Table 7-2 (Trainers Responsibilities), Chapter 7, regardless of whether their role was dedicated or shared (45% vs. 42%), a majority of trainers (87%) evaluated at Kirkpatrick's level 1, in effect simply establishing trainees responses to training. By contrast, 29% and 23% of dedicated-role trainers versus 16% and 13% of shared-role trainers evaluated at levels 2 and 3 respectively, to establish what their trainees had learned (45% in total) and what difference the training made to their personal goals (36% in total). At levels 4 and 5, mainly in large organisations, 19% versus 13% of dedicated- and shared-role trainers were involved in assessing the impact of training on the achievement of strategic business goals, and in terms of financial implications.

Moreover, these research questionnaire results for evaluation levels 1 and 2 were relatively consistent with a Forum survey, presented and discussed at the third Trainers' Forum of the

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<sup>179</sup> TF\_3/B\_09-04; TF\_5/D\_05-05

<sup>180</sup> TFS\_FN\_3/B\_09-04-2\_EFDr

Institute of Clinical Research (ICR) in May 2004. Capabilities to perform such evaluations were concluded to vary, and it was agreed that:

*...the traditional training cycle process within our clinical research environment was far from being realised<sup>181</sup>.*

This survey was circulated to attendees of the previous Forum (n=26), of whom 19 responded prior to attending the 3rd Forum. Results are shown below in Table 9-1.

**Table 9-1: Frequency of evaluation levels used**

<b>Evaluation level</b>	<b>1</b>	<b>2</b>	<b>3</b>	<b>4</b>
<b>Rating</b>	<b>Response (%)</b>			
<b>5</b> (Always used)	63	5	10	5
<b>4</b>	21	16	16	10
<b>3</b>	5	16	16	16
<b>2</b>	-	10	16	10
<b>1</b> (Never used)	-	5	21	37
<b>Totals</b>	<b>89</b>	<b>47</b>	<b>58</b>	<b>41</b>

According to the Forum survey respondents, 89% (n=17) always used level 1 evaluation. At level 2, this dropped to 47% of respondents (n=13). By comparison, 58% (n=11) of the Forum respondents revealed that they used level 3 evaluation, which was a greater proportion compared to the research survey respondents (35%). Similarly, a higher proportion of the Forum survey respondents stated that they used level 4 evaluation (41%; n=8 vs. 32%, n= 0).

Based on these Forum survey responses, it was concluded at the meeting that with respect to benchmarking practice, clinical research trainers “have a conscious incompetence”<sup>182</sup> concerning their desires and abilities to complete both ends of the training cycle, namely training needs analysis and evaluation. On the basis of this survey and attendees' experience,

<sup>181</sup> TF\_rep\_3/B\_09-04\_CRf, 2004, 15(9):18.

<sup>182</sup> TF\_rep\_3/B\_09-04\_CRf, 2004, 15(9):19; TF\_FN\_3/B\_09-04-1\_core\_EFDr.

it was generally agreed at the meeting that this state of affairs could be attributed to the level of organisational support given both to the training function and to the CPD of trainers in the workplace. Demand for return on investment and expedient training by corporate management were agreed as compounding conditions. At this stage, no distinction was made between the situation of dedicated-role and shared-role trainers.

As an illustration of raising awareness of this competence issue, and presenting lessons learned, one session leader, Robert, an active, non-qualified trainer shared his organisation's perceived 'problems' with conducting a training needs analysis (TNA), using questionnaires<sup>183</sup>. Robert summarised his organisation's issues as follows:-

- Difficulty with constructing questionnaires (i.e. methodological issue regarding how to ask open / non-leading questions)
- Difficulty in being able to organize, categorise or quantify the vast amount of data obtained
- Difficulty interpreting data gathered from surveys
- Lack of appropriate quantitative framework to analyse data

On the one hand, an over-reliance on statistical methods to analyse data was admitted. This was unsurprising since Clinical Research methodology is traditionally based on making statistical generalisations. On the other, it was concluded that without focussed questions surveys generally produce meaningless extraneous data or background 'noise' that is impossible to interpret or quantify. The difficulty with the first attempt at surveying training needs in Robert's organisation was later summarised as follows in the meeting report:

*"... with around 2000 pieces of data to be analysed and much of the data given in open text, there was "stagnation of analysis" and as a result raised expectations of forthcoming training opportunities that were largely unsatisfied" 184.*

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<sup>183</sup> TF\_FN\_3/B\_09-04-3\_act\_EFDr

<sup>184</sup> TF\_rep\_3/B\_09-04\_Crf, 2004, 15 (9):23.

On the second attempt at surveying training needs, 8000 pieces of data resulted from targeting 400 employees in 23 countries with detailed questionnaires. When publically challenged in this early Forum meeting about the nature of the difficulty with analysing this 'rich' data<sup>185</sup>, Robert revealed that without producing meaningful *need to know* results through statistical analysis, the huge amount of qualitative data gathered, although interesting and *nice to know*, could not be interpreted and was effectively of no value.

Subsequent discussion around the significance of analysing this 'rich' data using qualitative methods revealed a lack of familiarity with qualitative analytical methods, regarding how to code or thematically analyse this type of data in order to identify common themes or trends. Nevertheless, as Sally<sup>186</sup> commented in her first interview, reported in Chapter 8 section 8.1.3, finding that you have "issues in common with others" is one thing, but "sorting them out" is another. Moreover, despite acknowledging the need to develop TNA and evaluation methodology further, the status quo concerning routine use of L1 and L2 evaluation standards remained largely unchallenged<sup>187</sup>.

Meanwhile, by the end of this 3<sup>rd</sup> Forum meeting, the issue of how to manage "corporate managers demanding a return on investment"<sup>188</sup> was acknowledged as representing a different expectation from that of trainers concerning the measure of training effectiveness or success in the workplace. In particular, the need to demonstrate the effectiveness of facilitative training through the implementation of TNA and evaluation was agreed as being a solution, and a strategy to the defined challenges faced by trainers due to "the conflict between external

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<sup>185</sup> My challenge to Robert was intended to clarify whether the difficulty concerned a lack of conceptual / analytical frameworks to sort and analyse 'rich' qualitative data, which was subsequently confirmed.

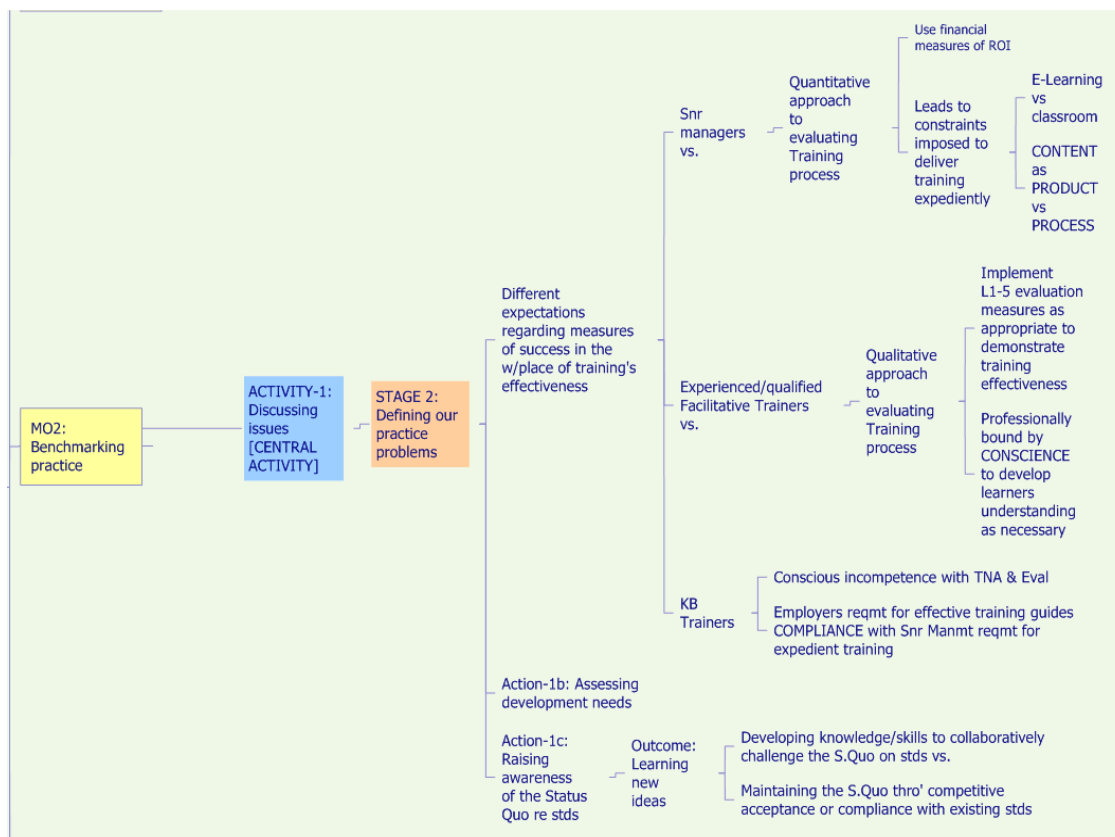
<sup>186</sup> Interviewee 4\_peri\_EFDc, line 376

<sup>187</sup> TF\_FN\_6/E\_09-05\_5\_act\_EFDc. The topic was not further discussed until one year later, when I introduced a brief exercise in my session during the sixth Forum, to illustrate how commonplace management tools in organisations serve as evaluation tools

<sup>188</sup> TF\_3/B\_09-04\_CRF, 2004, 15 (9): 22.

forces and internal resources<sup>189</sup>. However, the topic was not further discussed until one year later<sup>190</sup>.

The contradictions that emerged within this stage of Forum development are summarised in Figure 9-4 below, in terms of the collective motive of benchmarking practice.



**Figure 9-4: Primary contradictions in Stage 2 of the development of the object of activity in the Trainers' Forum**

**9.2.3 Stage 3: Sharing our approach to problems and challenges - defining strategy and solutions**

At the 4<sup>th</sup> Forum, development of its object moved into the next stage, where participants shared their approach to their problems and challenges. In particular, trainers - based inside and outside the field of clinical research - shared their facilitative approaches, demonstrating how to move away from the knowledge-based model. However, between the 5<sup>th</sup> and 9<sup>th</sup> meetings (15 out of 24 sessions), and between the 11<sup>th</sup> and 13<sup>th</sup> meetings (11 out of 16

<sup>189</sup>TF\_FN\_3/B\_09-04-2; 3/B\_TF\_09-04\_CrF 2004, 15 (9): 20.

<sup>190</sup> One year later, when I introduced a brief exercise in my session during the sixth Forum in September 2005, to illustrate how commonplace management tools in organisations serve as evaluation tools.

sessions), the sharing and discussing of practice operated mainly in “delivery of content” or transmissive mode, typical of the “knowledge-based” model of the training role. Yet, in Stage 1, it had been agreed that a facilitative model of organisational learning was needed. The dominance of the transmissive mode was typified by Deirdre’s<sup>191</sup> view of her role as a newly appointed part-time trainer:

*“My role is as a trainer, not a developer. I deliver the content”.*

As Sally, also a peripheral member of the Forum, but a more experienced full-time trainer than Deirdre explained in the excerpt in Chapter 7 (section 7.2.4), part of the reason for this narrow perception of the role is because few have the opportunity to learn how to best use their subject matter expertise in their new role via *train the trainer* courses. Instead, most learn on the job to maintain a local focus on achieving the task of delivering content, rather than developing a strategic focus on how the task may be achieved. As Deirdre herself mentioned, because she “...missed out on going on a course” the opportunity was unlikely to arise for her again. Thus, as a subject matter expert, Deirdre was guided by the instruments available to her in the workplace (transmissive pedagogy). As her idiom and earlier declaration indicated, such instruments maintained her focus on delivery of content (instrument-producing activity).

Accordingly, as Donald remarked, after twenty years as a full-time trainer in the workplace, he noticed that despite awareness of how to make training effective, basic training principles are not implemented in the workplace:

*From Line 545: All the pieces of the jigsaw need to be there and that ... to me, that's best practice... ...if you follow principles. You know, we've got all these models ..... instructional designers, you know, people that (sic) know everything there is to know about learning and adult learning and pedagogical approaches ... we've got all of that, that's fantastic “Gosh, you're so clever”. But, those principles are very rarely followed.*

Consequently, fulfilling the Forum’s potential or object to change the model of the trainer from one that is *knowledge-based* to one that is *facilitative* has depended on how the publicly

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<sup>191</sup> Interviewee 1\_peri\_EFDr: line 90

attested motives (to raise standards and develop the individual) have driven Forum activity (shown in Figure 9-5: Motives driving activity). Likewise, as mentioned at the end of Chapter 8, the tension between networking for business opportunities and networking for the purpose of socially collaborating over continuing professional development has affected the development of the central object of activity, as shown in Figure 9-6 (Primary contradiction in networking object). This latter reason for networking constitutes a more culturally advanced motive for developing relationships and introduced a tertiary contradiction in the TF (L3OB-OB), related to the strategically goal-directed actions of facilitative trainers concerned with the professionalism of training rather than its functionality.

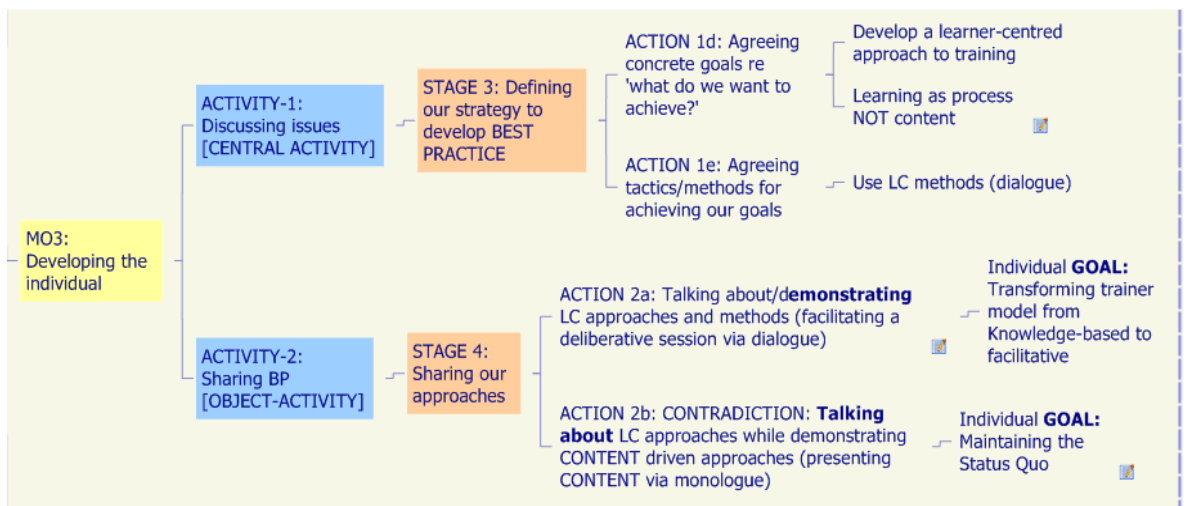
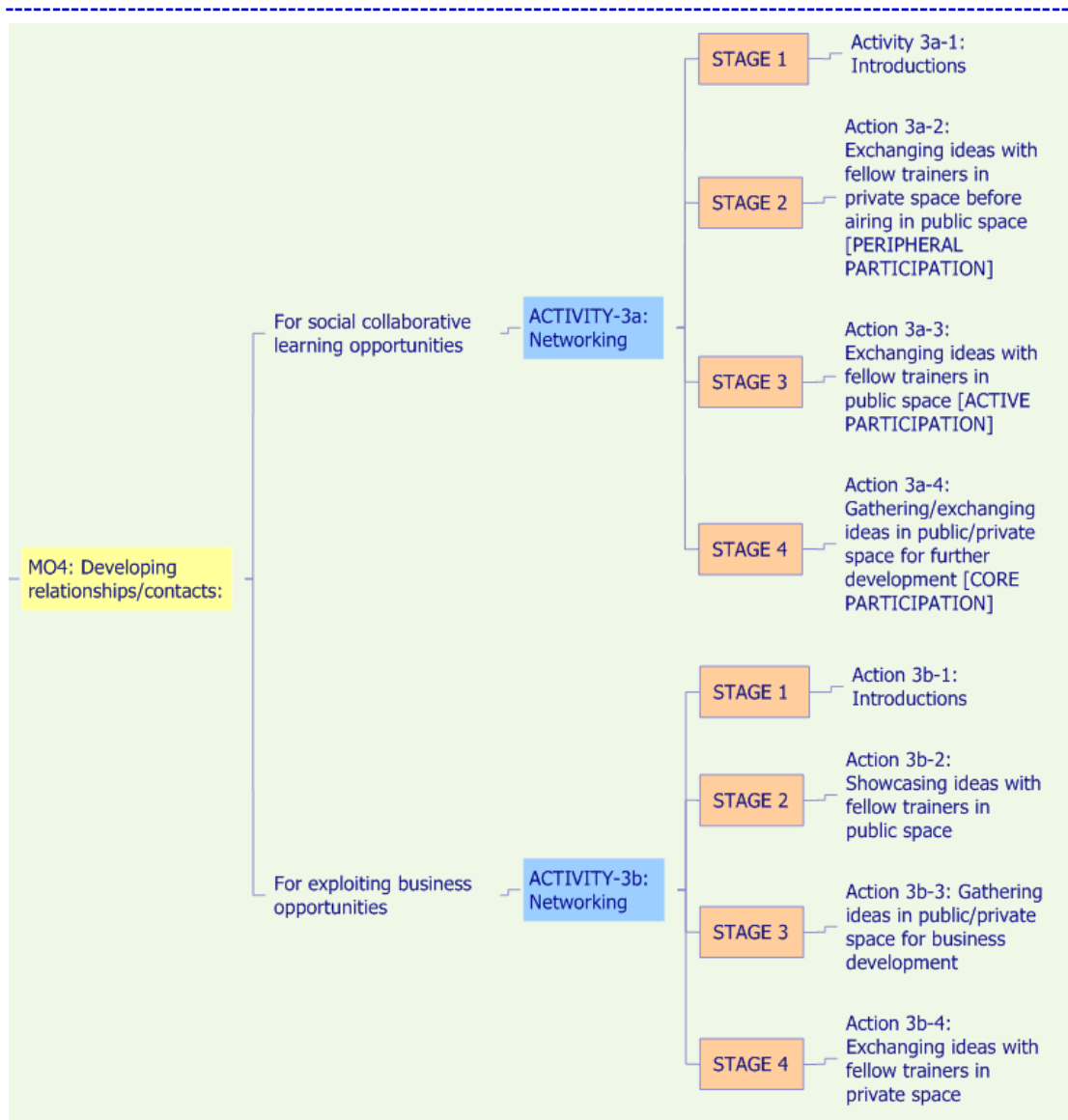


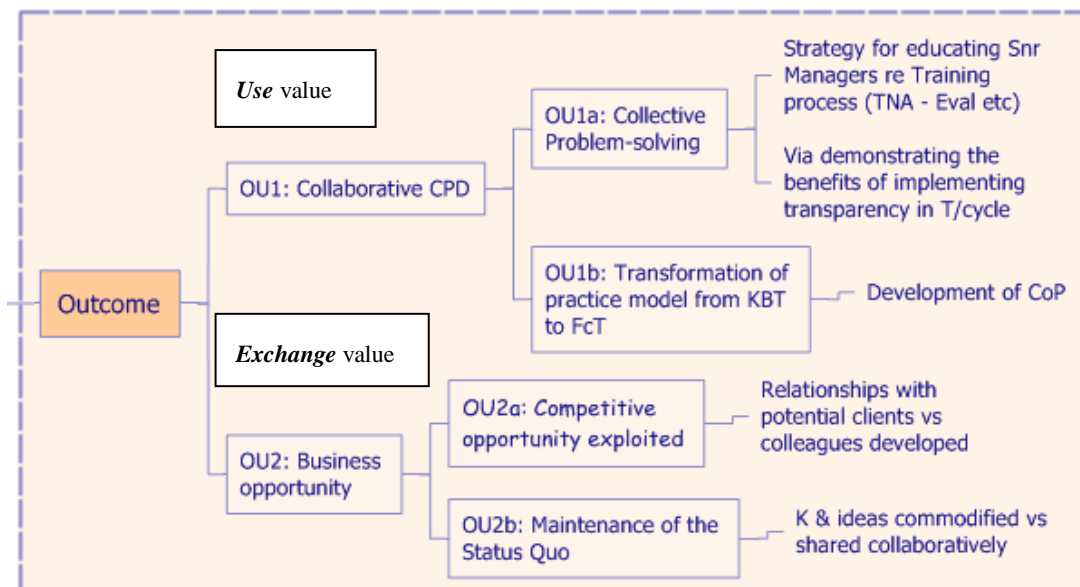
Figure 9-5: Motives driving activity



**Figure 9-6: Primary contradiction in networking object**

In turn, if the purpose of sharing practice was to raise standards, and similarly, the motive guiding discussion of topical issues was to develop the individual, then how these motives translated into individual goals / actions depended on the tools mediating activity, and the subjects using them. Similarly, how these tools affected transformation of the object of trainers' activity into outcomes is shown in Figure 9-7. Consequently, these outcomes of Forum activity reflected the primary contradiction arising between the use and exchange value in the object of this system of activity (CPD vs. business opportunity).



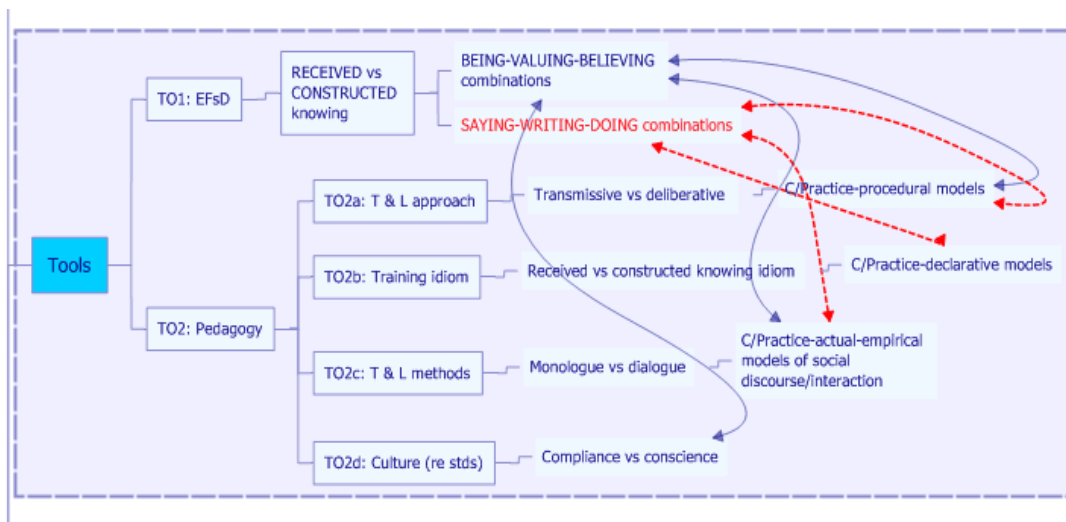


**Figure 9-7: Outcomes**

These tools mediating the object of activity in the TF are elaborated in section 9.3 through two excerpts discussed in the next section. These examples illustrate how contrasting conceptual models of practice used in the Forum (i.e. transmission vs. deliberative enquiry) were evaluated through features observed in session activity to typify procedural models and social discourses/interactions as either didactic monologue or dialectic dialogue.

### **9.3 Translating motives, goals and conditions into activity, actions and operations through contrasting pedagogies: Tools (I)**

As outlined in the previous section, in the third developmental stage of the object of activity (sharing our approaches to practice and training issues), tension arose in the Forum because of the different ways in which participants translated the object of activity into outcomes due to their contrasting pedagogies, illustrating a secondary contradiction between the subjects in the system and the tools they used to mediate their activity (L2SU-TO). These tools, which participants bring with them into the Forum either from their experience in the workplace or from development of their professionalism as trainers, are outlined in Figure 9-8, below. Hence, transmissive pedagogy was brought to the TF by KBTs and deliberative pedagogy by facilitative trainers.



**Figure 9-8: Primary contradictions in tools within the Trainers' Forum**

Key

- - - - - indicates relationships between pedagogical elements and *saying-writing-doing* epistemological discourse combinations that demonstrate constructed / received knowing
- indicates relationships between pedagogical elements and *being-valuing-believing* epistemological discourse combinations that demonstrate constructed / received knowing

In addition, examining expectations and attitudes towards the role of the steering group reveals not only how participants view *what* happens at the Trainers' Forum but also their understanding of *how* it happens. For example, the difference in members' expectations of what happens at the Forum reflects a qualitative difference in their conceptual and instrumental translation of the object of activity in the Forum - sharing practice, as well as the central activity of discussing training issues, through: a content-driven process of information transfer, or a process-driven method of enquiry. Moreover, because of these differences in understanding of the object of activity at the Forum, activity mediating the transformation of the object (technical knowledge-based practice) into an outcome (facilitative practice) translates into contrasting individual actions and goals: -

- instrumental delivery of information about topical training issues, in order to expediently share 'knowledge' or

- deliberative discussion about topical training issues in order to address the CPD challenges facing trainers in the field of clinical research.

Thus, sharing practice through discussing topical training issues means different things to different members of the Forum, depending on their background and experience as trainers. In turn, this determines the conceptual/procedural models that they bring to the Forum and adapt within it. As a consequence, trainers have been observed to differ in their approach and choice of methods to the task of sharing practice and discussing issues, as well as the idiom that they have adopted as shown in Table 8-5, Chapter 8.

Therefore, models were theorised within an evaluative instrument through observing their emergence over time, as discussed and outlined in Chapter 3 (Analytical Framework). Subsequently, this instrument was tested in the course of identifying these models in Forum sessions as declarative conceptions (concept of practice); procedural performances (methodology) and social discourses or interactions (experiences). By this means, practice was elaborated in terms of its objective regularities or cognitive and cooperative tasks constituting routinised actions within the activity system, as shown in Tables 9-2 and 9-3 (Objective Regularities of Practice at the Trainers' Forum - Cognitive / Cooperative elements of activity).

Moreover, in the case of this research, through the language and behaviour observed at the TF, such an instrument links elements of pedagogy (approach, methods, culture and idiom) to trainers' epistemological stance (knowledge: constructed or received) or EFsD (*saying-writing-doing* and *being-valuing-believing*). That is, *saying-writing-doing* discourses were observed at the Trainers Forum to concern how we talk about training while in the act of discussing and sharing our practice. Meanwhile, *being-valuing-believing* discourses were revealed in our approach to the task of sharing & discussing practice: as content (information transfer) or as process driven (enquiry-process). Thus, talk about "covering content", or "getting through the material" during presentations delivered as monologue with questions reserved until the end of the presentation, categorised the EFD as "received".

Therefore, taken together, the approach, methods, culture and idiom used to share practice operationalised key elements of the concept of practice. The standards of practice that followed were contingent on (and thus defined) the concept of practice illustrated through these elements. For example, in a transmissive pedagogy the standard guiding practice concerned the delivery of content (presentation skills) and communication of 'information' (communication skills) so that it may be received and processed to become 'knowledge'.

By contrast, in those sessions where an enquiry-led pedagogy was used, participants were encouraged to actively develop particular skills and attitudes by engaging with subject matter through a facilitated process, which effectively encompassed different elements of the cognitive, affective and psychomotor learning domains. Thus, these contrasting pedagogies suggest different rationalities of practice. At one level, a focus on expedient delivery of content (monologic transmission) concerns the functionality of training i.e. where the measure of success is expedient delivery. At another, it concerns the development of an emergent profession, which has the capability to mediate the moral purpose of organisations contributing to the public health of nations through dialogic enquiry.

In the following two sections, two sessions are analysed as examples of these contrasting pedagogies and to illustrate the differences in the rationality of practice expressed in associated epistemological frames of discourse.

### **9.3.1 *Deliberative pedagogy: Modelling a dialogic approach to address the CPD challenges facing trainers in the field of clinical research***

In Appendix J, an excerpt from the 4th Forum held in December 2004 is analysed as a typical example of the dialogical, enquiry-led approaches to sessions listed in Table 8-5, Chapter 8). Elements that illuminate theoretical propositions concerning *what is happening around here* are underlined and coded in each segment (S1, S2 etc) in terms of the declarative and procedural models, and types of social discourse/interactions as shown in Tables 9-2 and 9-3 .

The session, entitled *Interactive Training Strategies* was lead by John, a qualified education and training consultant. Almost 30 participants were present, with the room laid out in classroom style (tables grouped in hubs).

By writing on the whiteboard to open his session, John grabbed participants' attention, raising curiosity about what would happen next. He invited discussion about what was meant by *innovation*, engaging participants in dialogue. He changed the pace and form of interaction from leading discussion through open questions, to facilitating participants' learning through an activity about how the agreed definition of *innovation* applies as *appropriate novelty*.

John explained that he adapted the exercise, from elsewhere, to encourage participants to think about Teaching & Learning process from a different perspective – in a new or novel way, demonstrating that methods can be adapted to suit content and purpose. From the start of the session, he engaged participants since his choice of methods facilitated discussion i.e. no slides were used in this one-hour session.

The standards guiding his practice were contingent on the concept of practice that John illustrated through elements of his practice, to facilitate discussion and engagement with session content. For instance, he used a flipchart, a whiteboard, a pen, and open questions as tools to guide discussion. He encouraged reflection on his session's content in terms of its relevance and applicability to Forum participants' circumstances by posing probing yet open questions. His methods enabled participants to internalise knowledge constructed during their engagement with his session content and with each other.

Consequently, participants revealed their challenge to develop learners' analytic and evaluative skills because of the quantity and complexity of information that learners are "required to know" in the clinical research environment. This problematic issue was first raised at the inaugural Forum meeting because the "sheer volume of content on which trainers

are asked to 'train' others is overwhelming" and diverts attention from "considering how people learn" (Montgomery, 2004: 25<sup>192</sup>).

The exchange that followed highlights the dilemma trainers have: how to satisfy regulatory requirements to ensure trainees are appropriately "knowledgeable" either by focussing on a method that delivers complex information quickly (PowerPoint slides) or by focusing on how to apply or adapt training methods in line with training purposes.

Closing the session by asking participants to analyse *what has happened* in terms of its purpose, John illustrated how a reflective, process-driven trainer pushes learners to develop analytic and evaluative skills to reach common understanding, by modelling a dialogic approach to the teaching and learning principles underlying the entire session.

### **9.3.2 Transmissive pedagogy: Modelling a monologic approach to share "knowledge" expediently**

An excerpt from a session held at the 13<sup>th</sup> Forum held in October 2008 is analysed and shown in Appendix K. This extract is presented as an example of the monological, transmissive approaches to sessions listed in Table 8-5, Chapter 8). As before, elements are coded in each segment (S1, S2 etc), as shown in Tables 9-2 and 9-3.

This session was videotaped and the edited results made available by the ICR coordinator through a link to two websites<sup>193</sup>. Throughout this session, *information delivery* was treated as synonymous with *knowledge acquisition* or *knowledge transfer*. Yet, according to Bloom's Taxonomy Of Educational Objectives' (Bloom *et al* 1956), personal development based on mastery of a subject (i.e. how to be a facilitative trainer), involves more than the basic levels of the cognitive domain (fact-transfer and recall).

As well as referring to ways of transferring knowledge and to measuring the effectiveness of that transfer, the video of this session is a demonstration of how such knowledge transfer may

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<sup>192</sup> TF\_rep\_1/U\_12-03\_CRf, 2004, 1592): 25-27.

<sup>193</sup> This session was provided by Linda, an independent training provider. A link to her video on her business website<sup>193</sup> and on YouTube was made available by the ICR coordinator.

be conducted asynchronously i.e. at the convenience and demand of the individual learner, which is referred to as “on demand”. However, as the video illustrates through editing out discussion, this vital aspect of the social learning process fades from view, in the process showing how dialogue is overlooked as a teaching and learning method. As shown in this transcribed extract, resisting adoption of modern technology as a means to applying non-participative monologic methods is referred to as “luddite”<sup>194</sup>, further illustrating how social learning methods i.e. dialogue are under-rated or devalued.

#### **9.4 Understanding the object of activity through contrasting epistemological frames of discourse: Tools (II)**

As explained in Chapter 2, *saying-writing-doing-being-valuing-believing* combinations provide a framework to analyse social epistemologies. In the Forum, trainers' declarative models or concepts of practice are evident in what they say, write and do. Their procedural models are also revealed by their mode of interaction with fellow participants in the Forum through monologue or dialogue. Thus, knowledge-based trainers who have tended to give presentations demonstrate their belief that knowledge is a concrete, fixed commodity that can be exchanged or transmitted. Whereas, by contrast, facilitative trainers demonstrate their belief that knowledge is a fluid and dynamic construction, which depends on establishing a shared understanding of meaning contingent on a knower's perspective.

Hence, as illustrated in Tables 9-2 and 9-3, knowledge-based trainers and facilitative trainers tend to operate in different ways as a result of their contrasting beliefs about knowledge and knowing: through giving and receiving information, referred to as sharing “knowledge” or challenging Forum participants to think about issues from a different perspective.

However, regardless of the contrasting transmissive or enquiry-led approaches taken by individual trainers, and irrespective of their levels of participation (core, active or peripheral),

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<sup>194</sup> Historical reference to the Luddite movement around 1811, in which hand loom weavers resisted progress during the industrial revolution, burning mechanised looms.

there is consensus among participants in the Forum that the role of the steering group in directing activity towards the object of activity or “the problem space or raw material” is pivotal (Engeström, 1987).

For example, during the period she attended the Forum (2005-2006), Sally, a full-time trainer, developed experience in her role. For her, as a peripheral member of the Forum, the responsibility for deciding topics of interest in meetings should be a joint effort between the steering group and Forum participants:

*From Line 346: Um, I think ... I think that people who are involved in the Trainers' Forum, who attend regularly the meetings and who feel that themselves are kind of champions of them, can benefit from them and they're the people to run them ... or to... at least to suggest what would be good topics, and what are topical issues, for example.*

*I think the organization, as it's falling under ICR, has been very good ... um ... and I think they've certainly got a very strong ... you know ... a strong following as it were. But, I think it does need to come from ... you know, from trainers themselves ... to say, you know, this is what's actually interesting us.*

Likewise, Donald, an active member, had very firm ideas about the Forum's purpose:

*From Line 7: Um ... I think personally, I think the networking's fantastic ..... talking to people informally is really, really good. Obviously you can't say ... you know, you can't use that as the main purpose of the Forum ... but I do think it ... it's a really, really important part. I think ... um ... I've got a number of things in my mind about the Forum. One is to communicate about what you're doing. Don't call it best practice. Just say “let's hear about what others are doing”. If you like, a forum is benchmarking. You know, it's a way of benchmarking ourselves. I think that leaders and managers will feel that that is useful: “Where do we sit in relation to similar groups in other companies?” That's free information you're getting in that.*

*So, I see that as being a very important thing, but I also ... I think the primary thing is that the Forum should be a centre of education for the industry. How can we promote the way that training should be done ..... within the industry? Best practice jargon, let's talk about ... what are our foundations? What are the principles against which we can deliver really effective training? And how can we help the industry to implement those principles? That's it to me.*

Sally and Donald's views, respectively as peripheral and active members of the Forum, reflect a participative model, where trainers decide among themselves what aspects of practice to share and what topics to discuss. Donald also alluded to the use-exchange value of the object of activity (i.e. freely sharing information). From the *Center for Activity Theory and Developmental Work Research* (at the University of Helsinki) website, we are reminded that this value is a source of contradiction since “...the primary contradiction of all activities in capitalist socio-economic formations is that between the exchange value and the use value within each element of the activity system”. The conflict caused by independent trainers



viewing their fellow trainers as potential clients, which was discussed in section 8.3.2, Chapter 8 illustrates this point.

Equally, for Molly<sup>195</sup>, a full-time, experienced and qualified trainer, who often provided sessions at the Forum, the role is clear-cut and without ambiguity:

*From line 185: It's always a bit hard to mouth, isn't it? It's always panicking to find speakers. But, I think ... I think ... I think we do a good job now. I think we do a very good job. .... it's obviously up to the steering committee to decide what we cover when (Trans-Id-r), and to organise the meeting. That is their role. But ... um ... I think, you know, asking the members what they wanted is a good idea (Incl-Mdol-c) ... and I think that's a standard question now on the feedback form ... "are there other topics that you'd like to see covered?" (Trans-Id-r). So, we're getting a continual stream of new ideas coming through ...*

As a core member of the Forum, Molly revealed that she considers having input from the membership valuable. Yet, by inference from her comments about the Steering Group's level of control, the value she assigned this input is not because it gives participants a voice, but because it takes the onus off the group to come up with new ideas. Instead, Forum participants provide a steady source of raw material (i.e. new ideas) around which the steering group can build meetings, based on identifying appropriate "speakers" to cover the requested topic. As Molly revealed, the steering group previously relied on each other for ideas, rather than seeking feedback from TF members. However, as Peter explained "...we've kind of dried up in terms of the major topics"<sup>196</sup>. Hence, a lack of ideas among the steering group was the springboard for finding a new way of coming up with topics for meeting content.

Consequently, the form Molly referred to was a new instrument designed to keep the activity system 'going'. Therefore, the division of labour, in the action of seeking topics, shifted from the steering group to the TF members.

Yet, as an example of her *saying-writing-doing* discourse combinations, Molly's comments also revealed discordance in her epistemological frame of discourse, particularly with her

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<sup>195</sup> Interviewee 9\_core\_EFDc

<sup>196</sup> (line 146, interview 2)

*being-valuing-believing* combinations. This discordance will be analysed further in section 9.5.

Like Molly, Peter's view on the role of the steering group was clear-cut. For him, the Steering Group had the onus or responsibility to decide meeting content. As this next extract shows, such responsibility was based on the capability to determine 'suitable' topics for discussion, by reviewing Forum participants' suggested topics in the now routinely circulated feedback forms.

*From line 226: I think as a Steering Group, you know, we're the people, who are devoting our time, our energy and are interested in this. Therefore, I think we should have – (we probably have got the right knowledge levels) - experience to know what is going to make a good topic for the meeting.*

*You know, the evidence is there if you look at some of the stuff that people want covered - ludicrous stuff: ...um ... "effective training in global terms; how to make your training system as robust as possible; training on investigator-led studies ; how to write the perfect SOP".*

*I mean, it's just terrible. There are some good ideas there, but I think it's like any committee: they have to look at all the ideas that come through, and then weed out the clearly ridiculous, and then concentrate on the ones that do look interesting. And the other problem we face on the Committee as well is that, there may be some individual things that are really interesting, but it's really how to build it into a topic for the whole meeting.*

*And this year, we've picked on SOP training. There's lots of stuff that goes under that. Then we looked at project management training. And then - you were there -you know: at the session we had last time, when we were trying to think of topics for October and then all of a sudden, topics just came in - investigator training. Wow! I kind of shudder to think what we're going to do next year.*

Therefore, according to interviewees, being a Steering Group member predominantly concerned the expedient delivery of a 'product' through deciding the agenda and organising others to deliver its content. Although this task was performed on behalf of the membership, it involved canvassing members for 'sensible' ideas to take forward. However, as Peter explained finding appropriate 'speakers' to deliver on these ideas/topics was problematic:

*From line 268: What I didn't want to happen was to have to stand up there in front of 80 people and it would be a total flop. That to me would be a disaster.*

*I guess if I was to say what has been the main problem - it's been that ... um ... .. um ... I think superficially people will be happy to go and contact others. You know - possible speakers. It's when you get: "sorry, they didn't want to do it". It's then. You know. It's the next step after that.*

Peter's fear was that failure to find speakers meant a loss of structure in the carefully planned agenda. It also risked a failed opportunity to 'deliver' tangible content, rather than a flexible

opportunity to participate in discussion. Jennifer<sup>197</sup>, another steering group member, summarised these concerns as follows:

*"...some members have to make a strong business case to come along to the meetings. The least we can do is make it worthwhile by giving them something tangible to take away with them. For many English isn't their first language...handouts then come in handy as an 'aide memoire' to what's been covered. I can barely remember anything that's covered. So, goodness knows how they manage".*<sup>198</sup>

With the exception of Molly and James, most interviewees made similar comments about the onus on the group to make each meeting a success as a consequence of members' need to justify their attendance at the Forum.

In Steering Group meetings, attempts to suggest that such potential 'disasters' represented an opportunity for goal-directed discussion, driven by participants, were repeatedly resisted. Instead, the focus was on ensuring meeting attendees received their "money's worth" rather than "start going into discussion about something ...that's all very nebulous (Donald<sup>199</sup>).

Although, as Donald pointed out, nebulous discussion might be avoided by also having "...someone there ... or whoever it is, who's chairing sessions or chairing discussions ... to make sure we stay on the straight and narrow"<sup>200</sup>.

Given that attendance/participation at Forum meetings was free at this time, a pre-occupation with "delivery of value for money" is a carry-over effect from such emphasis in the workplace (i.e. where the expedient delivery of a fully organized agenda fulfils senior managers' demands to minimise costs), despite it being agreed at the 3<sup>rd</sup> Trainers Forum, that:

*"...learning and development should not be a cost. If it were, it would be cut; it must be considered an investment" (Hayes, 2004: 21).*

Moreover, the general reluctance in the Steering Group to take a less structured or controlled approach to the agenda through developing more of a workshop approach to meetings, illustrates a common attitude to sharing the responsibility for the outcome of the meeting with Forum participants: having discussion groups is a risky strategy, particularly if it lacks focus.

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<sup>197</sup> SG\_TC\_FN\_pre\_11/I\_27-11-07

<sup>198</sup> SG\_TC\_FN\_pre-11/I\_27-11-07

<sup>199</sup> Line 597, Interviewee-8\_act\_EFDc

<sup>200</sup> Line 587

The number of people at the meeting was also seen as a limitation to running it in a workshop style. Too many people would mean that exercises would "...take too long to do" and in turn, there would not be "...enough time to facilitate it". Debriefing on the outcomes of a group exercise by discussing and sharing what happened through the exchange of reasons was considered too time intensive by Peter:

*From line 63: ... The last two groups we've had have been in the 70 - 80 numbers. If you're going to do any sort of interactive exercise with that amount people – you need 30 to 40 minutes, at least: in order to tell them what they're going to do; get them doing it; giving them time to do it; go around and monitor; and then, whatever feedback you're going to be doing. You're never going to do that in less than 30 or 40 minutes. That's all we allow for each of the case studies.*

Question: Would it be a risk if we actually decide: okay then we're going to give people an hour to get something out of this?

*That's where it was easier for me to think let's have a couple of hours of theory, and three case studies in two hours. Time is bound to run over in one or two of them, so that will fill up the two hours.*

Despite Peter's concern to "fill" gaps in content, discussion on various occasions<sup>201</sup> was curtailed. Regardless of its quality or relevance, the chairperson would usually end discussion if it over-ran into another 'speaker's' slot. Such actions illustrate that discussion was treated as time-intrusive on the delivery of agenda content and a secondary goal, rather than the primary objective of meetings.

Finally, in one Steering Group meeting<sup>202</sup>, an idea to run a workshop based on asking participants to put forward examples of inspectors' findings in relation to training was rejected since:

*Peter: "...in my company, the legal department would clamp down on that. The 'problem' owners wouldn't be able to own up and give us any feedback on how they handled it".*

*Marie: "Ok. But, it would still make be a great way to discuss these issues, even if we did it hypothetically...the owners could provide their solutions on paper, anonymously, and one of us could provide it...we could then*

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<sup>201</sup> TFS\_FN\_3/B\_09-04-3\_EFDr\_Robert;TFS\_FN\_5/D\_FN\_05-05-4\_EFDr\_Philip;TFS\_DR\_9/G\_05-07-1\_EFDr\_Jan; TFS\_DR\_9/G\_05-07-4\_EFDr\_Brian; TFS\_DR\_11/I\_03-08-1\_EFDc\_Matt; TFS\_DR\_11/I\_03-08-6\_EFDc\_Donald.

<sup>202</sup> SG\_FN\_TC\_pre13/K\_11-06-08

*discuss how it was handled, as well as the original finding...*

*Peter: "Nope. Too risky. Too complicated. Forget it."*

Again, as discussed in Chapter 8, employers' interests were placed ahead of any professional interest or need to share experiences concerning the type of findings about training, or more crucially to share how such findings were handled.

Therefore, for Peter, the conditions governing the routine operation of Forum planning and delivery included: risk of failure to deliver tangible content; agenda time constraints; numbers of participants; and, last but by no means least, the need for deference to employers' interests in deciding agenda content.

Yet, the risk taking strategy of devolving responsibility for the outcome of Forum meetings to all its participants was taken in at least two meetings: Innovative Training Methods and Trainers Toolkit, which were the 4<sup>th</sup> and 10<sup>th</sup> meetings, respectively. In the latter meeting, participants were invited to write responses to various questions posted around the meeting room on flipcharts, which it was hoped could then be discussed. However, few responded to the invitation or were prepared to enter into discussion. This minimal participation may have been due to lack of familiarity with this approach, or reflected the nature of the questions posed: -

- What do you want out of today's Forum?
- Is your laundry list of wants the same as your needs?
- How do adults learn best?
- What makes training great?
- What makes training poor?

This direct approach or model of a steering group member as a facilitator of a deliberative process was a departure from predominant approaches. In this model, participants were invited to agree the objectives and content (if not the format and delivery of the agenda) using

a deliberative pedagogy. James, an experienced, full-time and PGCE qualified trainer, who led this Forum (and played a key role in organising the 4<sup>th</sup> Forum), also asked some specific questions, which again generated a small amount of discussion: -

- What is reflective practice?
- Is e-learning a method or a delivery system?
- Why do people come to GCP courses?

James argued that in the latter case, organizations insistence that staff attend GCP courses on a “mandatory” basis guarantees little more than reluctant attendance instead of willing participation or engagement, since compelling them to attend sets the wrong ‘tone’ or attitude before the training has taken place. Accordingly, this contention stimulated participants to respond with a variety of questions and statements, which suggested that experience was limited: -

<i>Participant 1</i>	<i>“So how <u>do</u> we get them to attend?”</i>
<i>Participant 2</i>	<i>“If attendance isn’t mandatory, then they won’t bother coming...”</i>
<i>Participant 3</i>	<i>“If we shouldn’t say it’s mandatory, then what’s your suggestion?”</i>
<i>Participant 4</i>	<i>“How do we make GCP interesting...say for Senior Managers who are too busy to come to yet another training course?”</i>

James suggested that prospective trainees want to know *what’s in it for me*. Consequently, arousing their interest and curiosity sets a different collaborative ‘tone’ as opposed to one that is demanding and authoritative. Discussion ensued around the use of the word ‘*mandatory*’ regarding its implications about how it either commanded obedience or disregard depending on the beholder’s attitudes to authority (i.e. their epistemology as received or constructed knowers, respectively).

A feature of James participation at the Forum, as illustrated in his leadership of this 10<sup>th</sup> meeting, was his tendency to play devil’s advocate by posing provocative questions both in the public and private spaces of the Forum. In particular, on yet another occasion the ‘no

training the trainer' rule was opened up for discussion in the steering group by an e-mail from Peter to the group<sup>203</sup>:

*Peter: Since we began this forum, our view was we should not concentrate on how to train - we may need to rethink this and dedicate 1, maybe 2 of next year's sessions to these since the demand is clearly there.*

*James: Quite a challenge bearing in mind the "trainers" in question range from Clin ops managers to fulltime trainers i.e. less than 0.1 FTE to 1FTE204 - weaning the former off the weapons of mass instruction such as PowerPoint and encouraging them to become more learner centred and/or aware of adult learning principles by developing session plans, learning objectives. Indeed, this may prove to be a bridge too far bearing in mind the time they would have for this commitment. Mind you, there is the potential to do some interesting stuff e.g. around Eliot Masie's suggestions for developing and supporting e-learners...and we must strive to meet the needs of our punters.*

*But this is in your (collective) hands now as I'm stepping down at the end of 2007.*

*James.*

James had already announced to the group his intention to step down at a previous Steering Group meeting. However, in private he admitted that in light of criticism in the late summer of 2007 of the Steering Group's lack of inclusiveness, he felt it appropriate to "...make way for new blood"<sup>205</sup> especially as his involvement felt like a "thankless task".

Despite James' stepping down, the Steering Group eventually moved towards a more inclusive participation model by the final meeting observed in this study (Investigator site training<sup>206</sup>). The feedback from the previous meeting (training our project managers<sup>207</sup>) had a bearing on this, since, in my role as interlocutor, I brought it to the attention of the Steering Group that compared to other meetings a far greater proportion of members had expressed a desire for more discussion (i.e. 71% compared to 44%; 49% or 32.5%)<sup>208</sup>.

## **9.5 Analysing contradictions in the object of activity at the TF**

On the one hand, as described in Chapter 8, Molly's approach and choice of methods during sessions was indicative of a constructed knower (*being-valuing-believing*), often using simple

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<sup>203</sup> SG\_e-mail\_20/11/07\_ideas for discussion

<sup>204</sup> FTE = full time employee

<sup>205</sup> SG\_FN\_James\_core\_EFDc\_10/H\_09-07

<sup>206</sup> Table 8-2: TF\_13/K\_10-08

<sup>207</sup> SG\_Fdbk\_TF\_12/J\_06-08

<sup>208</sup> Table 8-7: Overview of Forum feedback

exercises to support her arguments. On the other, as the extract in section 9.4 (from line 185) exemplifies, her idiom and authoritative attitude, representative of her declarative model of practice in her *saying-writing-doing* discourse combinations, were not quite consistent with her actions that were representative of her procedural models and demonstrated in her *being-valuing-believing* discourse combinations (i.e. talking about *covering* topics as opposed to actually *discussing* them).

Despite her repository of practical experience in clinical research before becoming a trainer, as well as having a qualification in training (CIPD), use of this idiom is not representative of facilitative methods, as part of a deliberative pedagogy. This inconsistency illustrates the primary contradiction in the tools available within the TF (Figure 9-8: L1TO1; L1TO2a and L1TO2b). For example, the discordance in Molly's EFD may reflect her position as an independent training provider: on the one hand, the Forum is a place where she "can actually contribute"<sup>209</sup> on the other, it provides her with "...a marketing opportunity"<sup>210</sup>. Molly's situation is representative of the dilemma faced by independent training providers, which is illustrative of contradictory motives (Figure 9-4; 9-5 and 9-6). Ultimately, these affect the object of activity and its outcomes at the TF through the individual actions that determine collectively what constitutes CPD (Figure 9-7). Consequently, Molly may use the idiom she does to fit in with – or unconsciously mirror - her prospective clients depending on the circumstances, since it reflects the predominant transmissive idiom in use at the Forum. Accordingly, using familiar idiom wins trust by presenting no threat to the conceptual models held by knowledge-based/transmissive trainers.

Like Molly, Donald also used active methods, ranging from exercises to open questions. Jennifer, by contrast, used passive methods in her presentation of content. However, both Jennifer and Donald, who had similar backgrounds and CIPD qualifications, often used a similar idiom concerning "covering" content or "...doing GCP training to brand new

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<sup>209</sup> line 317

<sup>210</sup> line323



starters”<sup>211</sup> possibly because, as Donald explained, in his experience, the organisational focus on expedient delivery means: “...when it comes to compliance training and regulations ... we’re looking at ticking the box. That’s what managers look at – ...*have you done it yet? Great. Move on*”<sup>212</sup>. As Donald described earlier, such singular focus means that: “...learners are not followed up adequately in the workplace and they’re not given the opportunity to implement what they learned in the workplace. Their ability to transfer that learning into skills and behaviours is not evaluated”<sup>213</sup>.

In contrast to Molly and Donald, in his sessions, Peter, an experienced full-time trainer, talked as if he is a constructed knower, referring to learner centred strategies, such as case studies, as this next extract illustrates. But Peter behaved as a received knower through his routine use of monologue, and rhetorical questions, which revealed a contradiction between his theory-in-use and his theory-in-action. PowerPoint slides were also his method of choice when ‘discussing’ topics at the Forum. His understanding of sharing practice was for speakers to give accounts of their practical experience in their organizations, rather than to illustrate that experience with practical demonstrations from their organisations, which might match the expectations of peripheral members as expressed by Sally, Deirdre or Mary in Chapter 8.

*From line 59: I think what I’ve tried to do is make the two sessions I’ve run a mixture of the theory of the particular topic and then what I really like doing is seeing what people are actually doing in practice. It’s all well and good talking about – what we shouldn’t be doing...and these models say this is what should happen. What is actually happening when we come to look at how companies are doing this? I find strategy is great. It’s fine and you need a strategy. But strategy is worthless if you can’t actually do it...*

*What I tried to do in the Forum was look at what the theory it is out there, with these wonderful models that get written up in all these books. But at the same time, we don’t just want to walk away from these Forums knowing the theory – we want to actually see how people are putting this into practice.*

Peter, often referred to “looking at what people are doing putting theory into practice” as a case study approach. The “case” usually involved the speaker giving an account of practical experience in his or her organization, predominantly via a monologue, rather than providing a

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<sup>211</sup> from line 379

<sup>212</sup> from line 485

<sup>213</sup> from line 130

case study for participants to review, then discuss or analyse in terms of its strengths, weakness, opportunities or threats, often referred to as a SWOT analysis.

Thus, as illustrated by these examples, the training idiom used in the Forum by individual trainers seemed to reflect not only their pedagogy (approach and methods), but the conditions in which they worked or practiced. Hence, an EFD (“received wisdom”) in the workplace concerning the limited value of training drove its expedient delivery to become habitually transmissive. In turn, such conditions impinged on the TF’s activity in terms of how the object to share/discuss practice was mediated i.e. predominantly through monologue rather than dialogue, highlighting a secondary contradiction between the object of activity in the TF and the tools used to achieve it (L2TO-OB), particularly if *sharing* is assumed to be a two-way process.

During interview, Donald referred to some of the representative causes and consequences of this dominant pedagogy in his organisation (extract<sup>214</sup> shown in Appendix L). He suggested that trainers needed to challenge the orthodoxy that organisational problems involve training or that “delivering” training automatically leads to trainees’ compliance with organisational procedures. Moreover, his reference to a “tick-box exercise” encapsulated a common awareness of the dominant culture of compliance, originating from the regulatory system (AS1) and its effects as a rule-producing activity system (L4 RU-AS1) on the workplace, as exemplified in this extract from one of the handouts provided in a facilitative session (Appendix M):

*“SOP training is not just about ticking boxes so that the regulator can see that there has been compliance, it is about engaging the audience, informing and inspiring them so that current SOPs are bought into at the level of hearts and minds. And yet still so much of SOP training relies on PowerPoint based presentations.”<sup>215</sup>*

Frequent reference to “ticking the box” throughout Forum meetings illustrated the tension between the demand on trainers to deliver cost-constrained training that satisfied their

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<sup>214</sup> Appendix L: Interviewee 8\_act\_EFDc: line160

<sup>215</sup> Appendix M: TF\_ artefact from session 1\_11/I\_TF\_03-08\_1\_EFDc

executive employers' need to demonstrate regulatory compliance, and their professional need to know how to be effective trainers.

Furthermore, James contemplated the entrenched nature of compliance culture and its effects throughout the workplace, and more crucially within the Forum, one year after he stepped down from being a core member, in a personal communication (analysed in Appendix N). His colloquial and formal training idioms exemplify recognition of contradictions inside and outside the Forum that affected its outcomes. Taken together with observation of his procedural models demonstrated at the Forum (Table 8-6), this communication illustrates that James' conceptual model of practice is deliberative, based on an epistemological frame of discourse (EFD) typical of a constructed knower (Tables 9-2 and 9-3). Furthermore, unlike Donald, Molly or Peter, James *saying-writing-doing* and his *believing-valuing-being* discourse combinations were not compromised by inconsistency. Moreover, as James appreciated, the consistency in his message and methods ("telling ain't the same as training") caused tension due to his uncompromising commitment to promote professionalism over employer's/clients functional demands or interests, highlighting the divisions in trainers commitments.

Nevertheless, even if members of the Forum were only beginning to appreciate its contradictions, object-historical analysis in this chapter has shown that they appreciated the need to change the rationality of their practice, as illustrated in Figure 9-10. However, given the pivotal role of the Steering Group in the Forum, challenging the *tick-box* mentality depends on more core members recognising: how equivocal discourse combinations among core members affect the mediation of Forum activity within the community; and, the effects and consequences of transmissive pedagogy in maintaining the status quo not only in the TF but in the workplace, and vice versa.

In particular, object-historical analysis of the development of our object of activity in the TF has shown that our need state – concerning issues, problems and challenges with moving from a traditional knowledge-based model of training to a progressive facilitative model of training

- was defined and agreed across the first three TF meetings. By the 4<sup>th</sup> Forum, dialogic methods were shared as solutions to lead this change. However, a rule about *not training the trainer*, which was originally instituted in the TF's mission statement, was upheld in subsequent meetings, which discouraged the use of dialogic methods and allowed monologic patterns of interaction to re-emerge and predominate. Consequently, further discussion about how we might have moved from a knowledge-based model of training to a more facilitative model was forestalled, despite occasional demonstrations of a facilitative model of deliberative practice. That is, this rule affected the development of the object of activity (i.e. by affecting how practice was interpreted, shared and discussed), such that the status quo of a traditional training model was maintained.

To conclude, understanding the Forum's purpose has meant analysing the activities, actions and operations within the Forum, as well as appreciating the motives and goals of participants that drive them, and the instrumental conditions inside and outside the Forum that shape them, in order to understand how the subjects in this activity system mediated their activity through use of particular tools to achieve outcomes:-

- *Activity is governed by its conscious motive(s):* We attended the TF to share practice and discuss topical training issues as part of our CPD.
- *Component actions are governed by their aggregate goals (which are subordinate to the main goal or object of activity):* TF members gave/listened to monologues in order to expediently share information by hearing from others; or they participated in dialogue in order to collaboratively learn and share the concept, methodology and experience of training (because the main goal was CPD).
- *Operations are governed by the conditions in which component tasks are performed, where operations are the routinised or automated form of the constituent actions within an activity:* TF members routinely performed the role of speaker/listener, only occasionally acting as participants in dialogue. This was because giving/receiving monologue was perceived as a more expedient delivery method, with tangible artefacts

(i.e. slide handout) consistent with employers' focus on the functionality of training.

Therefore, due to the prevalent culture to satisfy employers' need to comply with regulations, trainers' focus on professionalism was subsumed (L1TO2d).

Finally, therefore, the elements of the activity system examined and the primary and secondary contradictions that were analysed in this chapter are modelled in Figure 9-11 in terms of the object of activity in the Trainers' Forum, and the tools used to transform it into outcomes. The system of activity in the Trainers Forum is also summarised in terms of its contradictions in Table 9-4.

In the next chapter, it will be considered how findings from each of the results chapters 7, 8 and 9 address research questions and hypotheses.

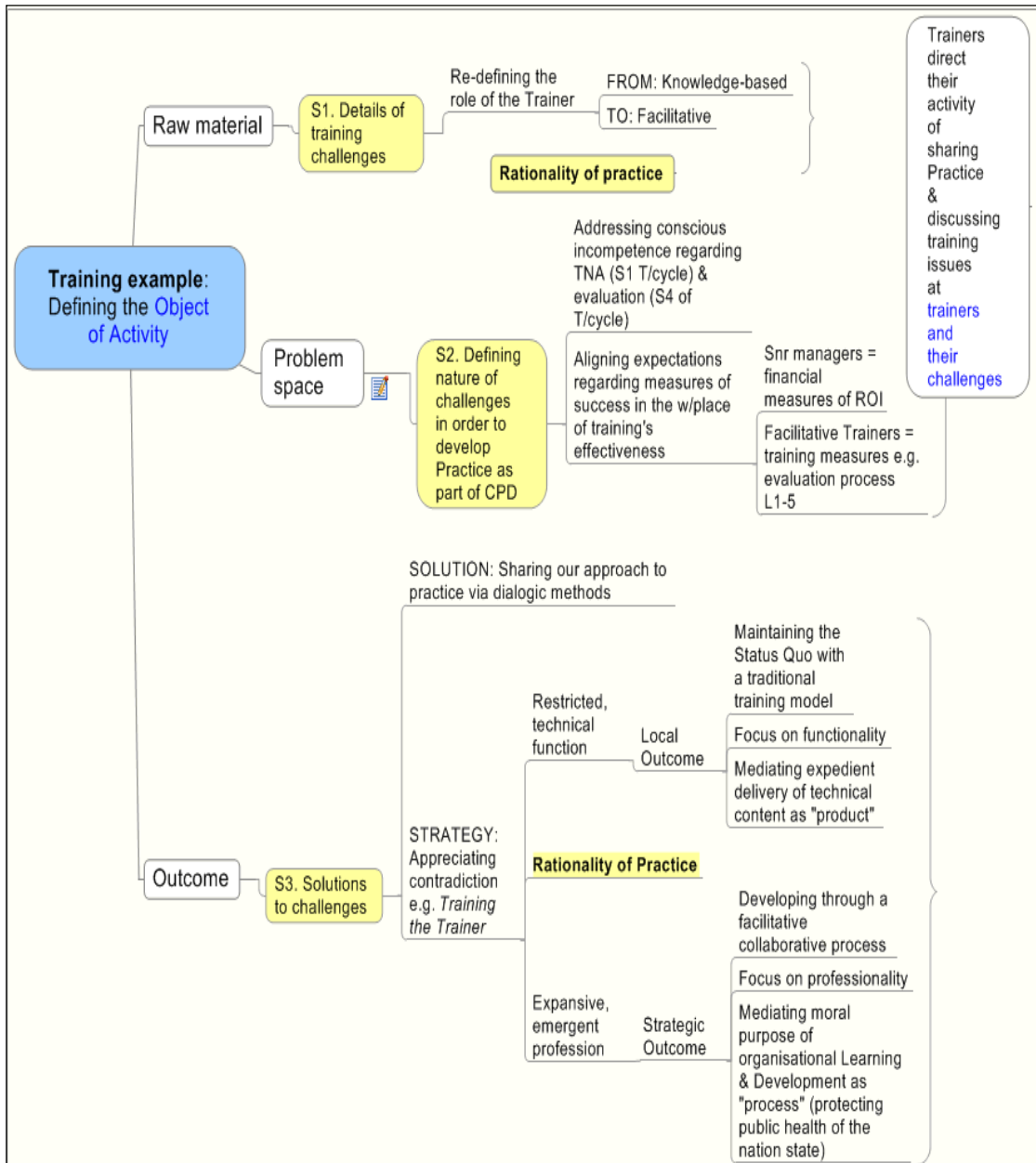
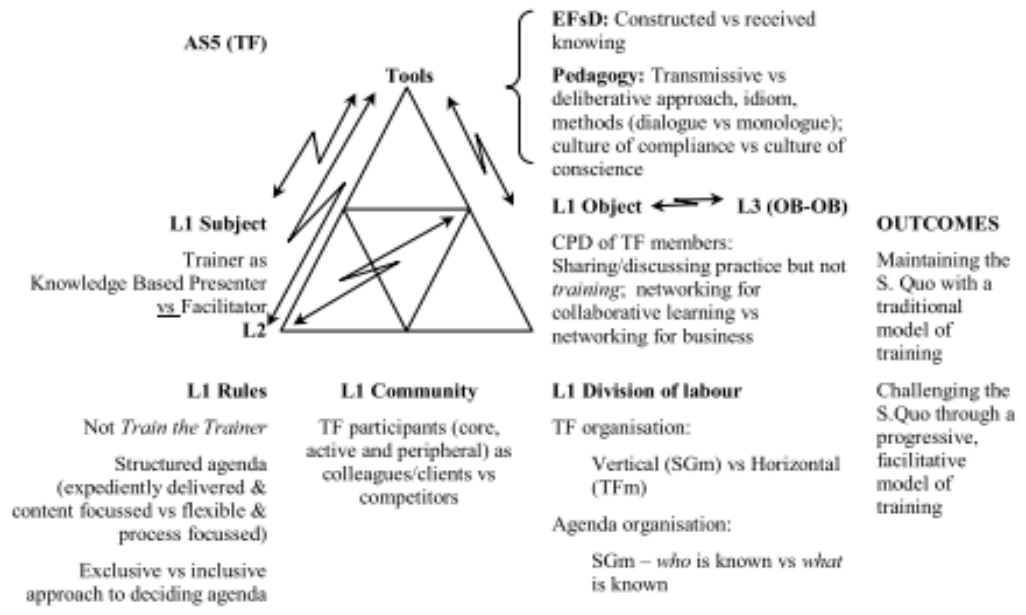


Figure 9-10: Expanded object of activity in trainers' practice at the Forum



**Key to contradictions**

- L2RU-OB: Rule of not *training the trainer* restricted the object of “sharing” practice for CPD
- L2TO-OB: Achievement of the object of “sharing” practice limited through using monologue as mediating tool
- L2TO-SU: Tools used to mediate activity introduced from the workplace by KBTs, or from development of professionalism by facilitative trainers
- L3OB-OB: Object of networking for business opportunities opposed culturally more advance object of networking to collaborate over CPD

**Figure 9-11:– Modelling primary / secondary contradictions within and between elements in the Trainers Forum (AS5): Tools and Object**

**Table 9-2: Objective Regularities of Practice at the Trainers' Forum<sup>216</sup>: Cognitive elements of activity & Coding Scheme**

Categories (C <sub>PRACTICE</sub> elements) <sup>217</sup>	Cognitive elements of Activity				
	CONCEPTS (declarative)	METHODOLOGY (procedural models)		EXPERIENCE (social discourses)	
EFsD <sup>218</sup> : being-valuing-believing	Sharing best practice & discussing issues	Conveying knowledge	Jointly constructing knowledge	Received knowing	Constructed knowing
Pedagogy: • T & L approach	Learning vs. training methods & strategies [Peda_T-meth-r vs. Peda_L-meth-c]	Transmissive: Trainer-centred (Knowledge-based training) [Trans-Mdol-r]	Enquiry-led: Learner-centred (Facilitative training) [Enq-Mdol-c]	Process of transfer (Content driven) [Trans-Exp-r]	Process of inquiry (Process driven) [Enq-Exp-c]
• Culture	Compliance vs. Conscience [CU-comp-r vs. CU-cons-c]	Quantitative measures of performance [Comp-Mdol-r]	Qualitative measures of performance [Consc-Mdol-c]	Compliance: Complying with externally imposed system std [Comp-Exp-r]	Conscience: Defining stds of professional practice [Consc-Exp-c]
Std's of excellence	Competency framework [K <sub>CR-r</sub> vs. K <sub>T-c</sub> ]	Presentation skills: delivery of subject matter content; voice, pacing etc. [Pres-Mdol-r]	Facilitation skills: engaging participants through cognitive, affective & psychomotor learning domains [Fac-Mdol-c]	Information delivery / covering content [Info-Exp-r]	Increased understanding & participation through creation of a joint learning opportunity [U-Exp-c]
	Performance framework [Content-r vs. Process-c]	Quantity of content delivered [Quant-Mdol-r]	Quality of engagement with content: synthesis, analysis, evaluation [Qual-Mdol-c]	Reinforcement of orthodoxy [Ortho-Exp-r]	Challenge of perceptions (heterodoxy) [Het-Exp-c]
Goods internal to practice	Soft skills [So-sk]	Communication skills [Comm-Mdol-r]	Reflective skills [Ref-Mdol-c]	Sharing information [SI-Exp-r]	Facilitating joint understanding [FJU-Exp-c]
Discipline knowledge domain	Topic /theme focus [Foc]	Curriculum subject matter (CSM): CR [CSM-Mdol-r]	Training cycle: TNA/ Planning & prep/ Delivery /Eval [TC-Mdol-c]	CSM: Clinical Research [CSM-Exp-r]	T/cycle [TC-Exp-c]

<sup>216</sup> Objective regularities of practice based on object-historical and theory-historical analysis of observations from ten TF meetings over a period of five years<sup>217</sup> C<sub>PRACTICE</sub>: Concept of Practice<sup>218</sup> EFsD: epistemological frames of discourse semiotically expressed as being-valuing-believing combinations through use of language and actions



**Table 9-3: Objective Regularities of Practice at the Trainers' Forum (TF): Cooperative elements of activity & Coding Scheme**

Cooperative elements of Activity					
Categories	CONCEPTS (declarative)	METHODOLOGY (procedural models)		EXPERIENCE (interactions)	
EFsD <sup>219</sup> : saying-writing-doing	Sharing best practice & discussing issues	Conveying knowledge	Jointly constructing knowledge	Received knowing	Constructed knowing
<u>Pedagogy</u> : T & L methods					
• Pattern of interaction	Discussing topical issues	Conveying/receiving information	Facilitating / discussing learning and understanding	Passively submitting to didactic monologue	Dynamically engaging in dialectical dialogue
		[Info-Mdol-r]	[U-Mdol-c]	[Mono-Exp-r]	[Dial-Exp-c]
• Mode of behaviour	Sharing practice	Presenting / Listening	Jointly participating	Mimetically reproducing/ watching presentation skills	Modelling/ appreciating facilitation skills
		[PresLi-Mdol-r]	[Par-Mdol-c]	[Rep-Exp-r]	[Mod-Exp-c]
				Using rhetorical questions with no expectation of interaction	Using open questions to encourage discussion
				[Rhet-Exp-r]	[Open-Exp-c]
• Training idiom	Training "talk"	Covering, giving; receiving	Thinking; discussing	Getting, telling, giving, covering (information)	Thinking, learning, applying, doing
		[Cov-Mdol-r]	[Think-Mdol-c]	Trans-id-r	Del-id-r
<u>Social practice</u>	Networking	Exclusive	Inclusive	Randomly interacting - depending on individuals	Organised interaction -with a collective/ group focus
		[Excl-Mdol-r]	[Incl-Mdol-c]	[Rand-Exp-r]	[Org-Exp-c]

<sup>219</sup> EFsD: epistemological frames of discourse actively expressed as *saying-writing-doing* combinations through verbal and written use of language and actions

**Table 9-4: Summarised analysis of the system of activity in the Trainers Forum**

AS	Locus	Subject	Object	Central Activity	Motives	Tools	Rules	Actions	Operations	Outcome	Neighbouring Role	Main Contradictions
5	TF <sup>220</sup>	Knowledge-based vs. facilitative trainer	CPD of professional colleagues vs. Networking for business opportunities	Discussing common issues & sharing practice (= object-activity)	<b>Benchmarking</b> practice thro': competition or cooperation; <b>networking</b> for business developmt vs. for collegial help	Pedagogy (C <sub>p</sub> ) & idiom	Strict vs. flexible agenda structure (temporal/content)  Not train the trainer  Exclusive vs. inclusive approach to agenda setting	KB-Presenting vs. facilitating	Didactic monologue vs. dialectic dialogue	Expansive CPD & problem-solving vs. static repetition of information & reinforcement of systemic orthodoxy	Central activity: sharing & discussing practice	<b>L1TO:</b> Modelling monologue vs. dialogue as BP  <b>L2RU1-OB:</b> distinguishing <i>training the trainer</i> as being something outside the domain of the Forum and different from sharing and discussing practice  <b>L3OB-OB:</b> networking for business opportunities – as opposed to developing collaborative relationships to promote social learning (CPD)

<sup>220</sup> Abbreviations: TF – Trainers Forum; CPD – continuing professional development; C<sub>p</sub>– concept of practice; KB – knowledge-based; BP = best practice

## **PART 4 CONCLUSIONS AND RECOMMENDATIONS**

## **Chapter 10**

### **Outcome: Towards a culture of conscience in a developing community of practice?**

## **10 OUTCOME - TOWARDS A CULTURE OF CONSCIENCE IN A DEVELOPING COMMUNITY OF PRACTICE?**

### **10.1 Overview**

In this chapter, the purpose, research questions and hypotheses of the thesis are revisited in the process of drawing conclusions. In addition, a critique of the methodology used in this research is offered to assess the contribution to knowledge.

The overall aims of this research study were: to explain the conditions creating and sustaining a professional community of trainers and its concept of training practice against a backdrop of increasing regulation; and, to understand the effects of compliance culture on the sharing of practice and development of shared understandings in this community. The pertinent questions posed in line with these aims are addressed in subsequent sections.

Because it offered a pragmatic, flexible framework for analyzing the activity of trainers *in situ*, CHAT was applied to demonstrate how the concept of practice manifested in this community. Moreover, as shown in Chapter 3, AT bridges the traditional divide between theory and practice offering CoP researchers a model of contextualised activity, which can be theorized and tested through the development of an instrument. This instrument also serves as a conceptual framework and an evaluative tool, in this case for the concept of practice.

Therefore, gaining phenomenological insight into the concept of training practice involved recasting the five layers of social reality identified in this study as inter-dependent activity systems within the field of clinical research. In effect, these five levels represent a set of nested activity systems (AS): -

AS1. Governance:

- The regulatory environment encompassing and governing good clinical practice (GCP), which concerns practice in the field of clinical research - activity of governance with the object of ensuring compliance with regulations

AS2. Field:

- Clinical research industry constituting the field of practice i.e. pharma, CRO, ITP, NHS, academia - activity of clinical research with the shared object of conducting clinical research in compliance with regulations

AS3. Organisational:

- Clinical research training practice settings within various non-uniform functional workplace structures: training departments, single dedicated FT trainers, or PT trainers in shared roles - activity of clinical research training with the object of expedient training

AS4. Professional:

- Professional community of clinical researchers i.e. the Institute of Clinical Research (ICR) - activity of CPD with the object of sharing best practices, raising standards and developing the professional

AS5. Community:

- Clinical research trainers group within a cross-boundary structure (Community of Practice) i.e. the Trainers' Forum (TF) within the ICR - activity of sharing practice & discussing issues with the object of learning new ideas, benchmarking practice and raising standards

Appreciating the quaternary contradictions in the Forum arising through each of these levels or systems provided an understanding of the place and pivotal role of training in the clinical research process. For example, on the level of AS5, this entailed analysing the concept of practice as it related to training process (partially imported model), and as it manifested within the community of trainers (partially constructed model). On other levels (AS1–4), it involved exploring the socio-cultural underpinnings within the wider contextual framework that influenced the concept of practice. Examining the concept of practice at these different levels revealed the models/concepts that were partially constructed within, and partly imported into the activity system of interest i.e. the TF. Moreover, their functions as tools

were then evaluated in terms of declarative and procedural models, as well as experiences or outcomes in the TF. In effect, analysing each inter-related or neighbouring activity system at a *theory-historical* level provided further layers of context that served to illuminate the inner workings of the TF as an activity system.

Yet, in practical terms, the complexity of each of these layers or neighbouring activity systems, necessitated limiting the main empirical focus of this thesis to the final level: the professional community of trainers (TF) and their activities of sharing practice and discussing issues related to CR training practice. Meanwhile, movement back and forth between all levels in terms either of analysing *object-historical* developments or *theory-historical* perspectives was necessary to understand the activity and actions from a ‘social-ecological’ perspective within the specific level of the TF (Lemke, 2001: 17-18). The multi-voiced nature of longitudinal participant observations and interviews provided a further empirical dimension to analyses of *object-historical* developments and *theory-historical* perspectives within neighbouring activity systems.

Thus, by means of moving back and forth between the inter-dependent layers of activity systems, the effects of regulatory developments (signified by the switch from voluntary to mandatory inspections) on the constitution of practice within the TF were analysed. That is, the relationship between trainers’ concept of practice within the TF (AS5) and a *culture of compliance* was traced through the workplace (AS3), wider field of practice (AS2) and the system of governance (AS1).

Hence, the study addressed the research questions by identifying, describing, and interpreting the socio-cultural elements that perpetuated or transformed the concept of training practice in the Trainers’ Forum (TF) and its neighbouring systems.

A detailed picture was built over time by using ethnographic techniques within a developmental research approach. Moreover, in order to describe *the way we do things around here* the concept of practice (declarative concept) was linked with particular pedagogic activities and training idioms (procedural models). In turn, through situating these

concepts, pedagogies and idioms within their larger socio-cultural context, it became possible to appreciate why the participants of the TF approached their activity - of sharing practice and discussing topical training issues - as they do, with respect to how their activities and actions as trainers are sustained by their larger socio-cultural context, and what problems are encountered as a result.

For example, as revealed in Chapter 7, job adverts for trainers in this field revealed a bias towards hiring subject matter experts (SMEs) with expertise in clinical research as the knowledge domain, rather than professional training expertise. In accordance with senior management's objectives in the workplace (AS3) to demonstrate regulatory compliance, the focus of these SMEs was on the functional task of delivering technical content, guiding their development as knowledge-based trainers, and reflecting a restricted rationality of training practice.

Moreover, in Chapter 8 it was revealed that members of the Forum had different expectations of what should happen there. Thus, in looking at TF interactions from a critically ethnographic perspective - two types were apparent: based on either a monologic or dialogic approach. In the first approach, the roles of participants were well defined and their expectations were clear: the "speaker" talked and the audience "listened". With a dialogic approach - everyone had an opportunity both to speak and to listen, but perhaps with a less predictable or routinised form of interaction, or outcome. However, monologic interaction predominated.

In Chapter 9 it was shown that this difference in expectations reflected a qualitative difference in trainers' conceptual and instrumental translation of the object of activity in the Forum i.e. sharing practice, as well as the central activity of discussing training issues, through: -

- a content-driven process of information transfer via monologue, or
- a process-driven method of enquiry via dialogue.



In effect, these differences were representative of contrasting pedagogies, which differentiated trainers as either knowledge-based or facilitative. Therefore, in light of these findings it is now possible to answer the research questions posed in Chapter 1 in subsequent sections.

## **10.2 Re-visiting the three research questions**

### **10.2.1 Research Question 1: Why is the discourse on pedagogy in the Trainers Forum marked by internal contradictions?**

The first research question is addressed in this section through a series of four associated questions.

*RQ1a: Why is a content-driven approach to sharing and discussing practice and training issues dominant in an emergent Community of Practice (CoP)?*

Preliminary analysis of activity at the Forum revealed that trainers appreciated that they had a conscious incompetence concerning how to evaluate the effectiveness of their training programmes. They also appreciated that strategically focussing on their professional development meant developing their role from that of knowledge-based trainers to facilitators of learning. However, when efforts were made to change the transmission model, it entailed promoting them as innovative training methods<sup>221</sup> as discussed in Chapters 7 and 8. Nevertheless, despite an awareness of the need for change in the workplace, a transmissive model of practice predominated in the Trainers' Forum. The reasons for this are explained as follows.

In the system of governance (AS1) GCP operates as a tool, in that inspectors use it as the performance standard in clinical research conduct against which clinical researchers are measured. In the field of clinical research (AS2) and in the workplace (AS3) this tool has become a rule of conduct, known as "GCP compliance". Therefore, the activity of the regulatory system (inspecting statutory compliance with GCP) has produced an object and a

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<sup>221</sup> TF\_FN\_4/C\_12-04-1

rule that governs the activity of these two related neighbouring systems (to comply with regulations founded in GCP). In socio-cultural terms this rule of conduct is transformed into a culture of compliance, which then operates globally in the field (AS2) and locally in the workplace (AS3).

In training terms, as shown in the findings in Chapter 7, this ruling culture of compliance in the field of clinical research (AS2) translates into a bias towards hiring predominantly clinical research subject matter experts (the subject-producing activity) to perform as knowledge-based trainers in preference to specialised training professionals. Subsequently, for knowledge-based trainers (KBTs) in the workplace (AS3), compliance culture becomes a rule of conduct (expedient delivery of technical content), or an operational standard of behaviour (compliance with senior management's objectives (shown in Table 8-10), based on a restricted rationality concerning the limited value of training to the organisation). Thus, because focus in the workplace is mainly on curriculum delivery (i.e. stage 3 of the training cycle (Figure 8-3)), both full-time and part-time KBTs are limited in their opportunities to become sufficiently versed in all aspects of their 'trade', namely evaluation, as revealed by the Forum survey (Table 7-2: trainers' responsibilities). So in an everyday epistemological sense (Bourdieu, 1990; Webb *et al*, 2002), as practitioners, they may lack the 'practical tools of the trade' to fully 'play the game' in their organisations and consequently secure appropriate training budgets. In turn, this evaluative capability is dependent on recognising the difference between conveying information and creating an opportunity for trainees to develop knowledge i.e. to learn where "*...knowledge is the uniquely human capability of making meaning from information - ideally in face to face relationships with other human beings...*" Miller (2002:1).

Therefore, through these conditions, because the dominant rationality in the workplace concerns the expedient delivery of content (technical information), KBTs are habituated to a transmissive pedagogy. Subsequently, in the Forum, because KBTs comprise the majority, the dominance within the community at large of the content-driven, trainer-centred transmission

pedagogy over the process-driven learner-centred enquiry pedagogy is perpetuated through this bias.

*RQ1b: Why are some trainers committed to the transmission model?*

In turn, because subject matter experts in the role of trainer are encouraged to develop professionally as KBTs, rather than as facilitative trainers, transmissive pedagogy remains the dominant concept of practice imported from the workplace, guiding trainers in their discussions in the TF. In effect, because the workplace object of expedient delivery was transformed into a rule of expediency that subsequently became a pedagogical tool of convenience (monologue) in the Forum (AS5), Forum activity is restricted mainly to monologic interaction.

The majority commitment to this model of practice was then reinforced in the Trainers' Forum because, as discussed in Chapter 7, it serves as a model of professional development. Moreover, it helps to explore identity, consistent with it being a Community of Practice (Meyers, op.cit.) consisting of "groups of people who share a concern, a set of problems, or a passion about a topic and who deepen their knowledge and expertise in this area by interacting on an ongoing basis" (Wenger, McDermott and Synder (op.cit.:4). That is, the three identifying features of Wenger's CoP (op.cit.:76) in terms of the dimensions of its practices that are implicated in a sense of identity were also fulfilled in the Trainers' Forum, as follows: -

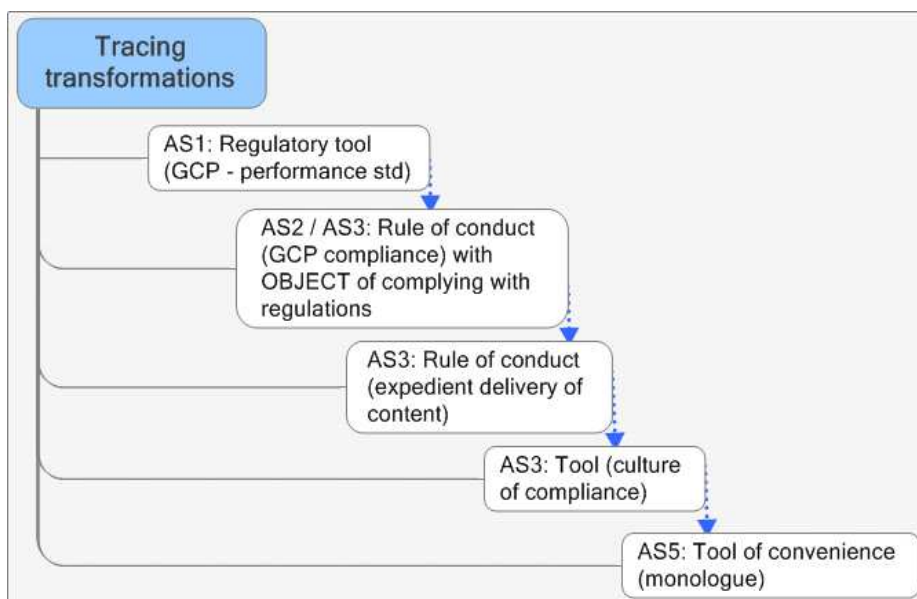
- Mutual engagement (attendance and participation as core, active, and peripheral members)
- Joint shared enterprise (common endeavour to share and discuss ideas predominantly via monologue)
- Shared repertoire of negotiable resources accumulated over time (common resources of language style by means of which members of a particular community express their identity (Bourdieu, 1998): as transmissive or deliberative pedagogues).

Thus, through modelling their shared understandings and common resources (such as EFsD, language style or idiom and similar approaches to issues or problems) members of the TF expressed or developed their sense of identity and belonging on basis that the majority were transmissive pedagogues.

*RQ1c: Is there a relationship between the transmissive pedagogy and the compliance regime?*

*If it exists, how do we explain this relationship?*

In answering RQ1a, the relationship between the compliance regime in the governing system of regulation and transmissive pedagogy in the TF was explained and traced throughout neighbouring systems in its various transformations from tool to rule and so forth, as represented and summarised in Figure 10-1.



**Figure 10-1: Tracing transformations**

In addition, in Chapter 8 (Table 8-10) role of the workplace as a rule-producing and instrument-producing system of activity was discussed in terms of the effect on how practice is shared and discussed (the central activity) at the Forum, to explain why the discourse on pedagogy is marked by internal contradiction (RQ1). That is, depending on the tools available to them (EFsD and pedagogy) and through their habitual use in the workplace, trainers in the Forum behaved either as traditional, knowledge-based presenters or as progressive facilitators. By implication, even in the TF, the motives of SMEs hired as KBTs in the field of

practice, differed from training practitioners. The focus or goal of the former group was on achieving the task of expediently delivering content, rather than on how the task was achieved.

By contrast, the goal of those demonstrating a facilitative practice was driven by standards of conscience as part of the internal goods of practice to lead a deliberative enquiry, in order to generate common understanding through shared meaning (as exemplified in an extract from one of the artefacts produced by a facilitative trainer, shown in Appendix M). Therefore, despite apparently having the freedom to choose how to share and discuss practice, the choice of monologic methods reflected the dominant rationality through conformity to the workplace rule of expedient delivery.

**10.2.2 Research Question 2: What activities help the Trainers Forum develop towards becoming a community of practice (and conversely which activities act as a barrier to becoming a CoP)?**

Each of the associated questions are answered in this section.

*RQ2a: What are the characteristics of activity in the TF? What does practice look like?*

As discussed in the previous section, a culture of compliance, which originates in the regulatory environment (AS1), has taken root within contrasting epistemological frames of discourse (EFsD) that were observed in the TF. In turn, these EFsD shape the concept of practice i.e. due to core epistemological beliefs, which operate as cognitive elements within the activity of training (i.e. training as information transfer, or as a process of inquiry).

Therefore, in the TF *saying-writing-doing* discourses concerned how we talk about training while in the act of discussing and sharing our practice. Meanwhile, *being-valuing-believing* discourses were revealed in our approach to the task of sharing & discussing practice: as content (information transfer) or as process driven (enquiry-process). Thus, talk about “covering content”, or “getting through the material” during presentations delivered as monologue, with questions reserved until the end of the presentation, categorised the EFD as “received” and characterised activity as monologic.

Therefore, taken together, the approach, methods and idiom used to share practice operationalised key elements of the concept of practice. The standards of practice that followed were found to be contingent on (and thus defining) the concept of practice illustrated through these elements. For example, in a transmissive pedagogy the standard guiding practice concerned the delivery of content (presentation skills) and communication of 'information' (communication skills) so that it could be received and processed to become 'knowledge'.

By contrast, in an enquiry-led pedagogy, participants were encouraged to actively develop particular thinking skills and attitudes by engaging with subject matter through a facilitated process of dialogue, effectively encompassing different elements of the cognitive, affective and psychomotor learning domains.

*RQ2b: Why do trainers talk about learner-centred approaches but predominantly tend to use trainer-centred methods in this community?*

This contradiction may be explained by:-

- Lack of awareness of the contradiction between Teaching & Learning approach espoused and Teaching & Learning methods applied in the TF.
- Dominance of a pedagogic model of 'knowledge' transmission imported from the workplace.

As summarised in Table 8-10 (Chapter 8), the domination of habitually transmissive pedagogy<sup>222</sup> in the Forum highlighted several instances of quaternary contradiction. That is, although trainers could decide for themselves in the Forum which topics to discuss and how to discuss them, the restrictions imposed in the workplace (L4 RU-AS3) to deliver or transmit content expediently (L4 OB-AS3), through monologue (L4TO-AS3) were perpetuated in the

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<sup>222</sup> 39 transmissive:18 deliberative, as shown in Chapter 8, Table 8-5: Predominant conceptual/procedural models of practice characterising Forum activity

Forum. Consequently, despite their object to collectively share and discuss practice in the Forum, tension arose when trainers' efforts in the Forum to lead deliberative enquiry through dialogue, deviated from the predominant transmissive pedagogy to "deliver" agenda content. Inconsistencies in discourse combinations i.e. talking about learner-centred strategies while demonstrating trainer-centred methods were indicative of divisions in trainers' commitments to develop their professionalism, business opportunities, or protect their employers' interests and as reflected in contradictions within and between their object and its mediating tools .

*RQ2c: What social processes are moulding the TF (i.e. processes involved in its structuration) e.g. how does the TF run: how is it organised (planning & administration; decision-making; consultation etc.)? Who makes decisions and how*

Despite the acknowledged need state expressed from the beginning of the TF to develop from KBTs to facilitative trainers, the identity of trainers in the Forum was not defined explicitly in terms of pedagogic rationality. Rather, trainers were routinely differentiated in the Forum on the basis of their functional status as cross-functional PT or dedicated FT trainers and location of their practice (pharma, CRO, ITP), as a means to identify their competing interests within the community i.e. as colleagues, clients or competitors . As revealed in Chapter 7, this level of differentiation reflected the heterogeneity of trainers in the field of clinical research and the lack of uniform structure in the workplace.

Nevertheless, such differentiation of status, on the basis of the FT or PT nature of the role, was based on the assumption that regardless of duration of service and irrespective of their qualifications as trainers, FT and PT trainers differed in their levels of experience, and did not share equivalent status. Thus the lack of uniformity has led trainers to stratify their experience on the basis of time served within a hierarchy where dedicated full-time trainers occupy the top position, irrespective of their training qualifications or pedagogic rationality.

Consequently, the basis on which trainers are recognised in the Forum provides a springboard for developing deliberative enquiry (based on appreciating differences in pedagogic rationality, expressed in EFsD, instead of enquiring about functional status). In effect, this

constitutes a recommendation for expansive learning and development in order to re-direct attention to professionalism.

*RQ2d: How are trainers working within the Trainers Forum to establish shared understandings about practice/training issues?*

A secondary contradiction (L2RU-OB, illustrated in Chapter 9, Figure 9-11) presenting through a rule that the object of sharing and discussing practice in the TF was not about training the trainer highlighted how an opportunity to address members' needs and to reach a common understanding of the goals of the Forum has been forestalled. Consequently, upholding this rule hinders its development as a CoP.

Furthermore, analysis of practice in the TF from three different CoP perspectives (core, active and peripheral) - that may also be appreciated as social positions in a horizontal division of labour – has established its conceptualisation from two different operational levels of professionalism (conscience/compliance), each of which has a different rationality and focus. That is, CoP members who operate from a culture of conscience have demonstrated concern with organisational learning, where training is an expansive process of co-constructing meaning mediated through a deliberative pedagogy. By contrast, CoP members who operate from a culture of compliance remain concerned with the functional task of delivering training by means of a transmissive pedagogy. Meanwhile, the social mechanisms underscoring community outcomes are summarised in Table 10-1 as the cultural conflict underscoring the spectrum of professionalism in the TF.

Therefore, as this study has revealed, the Forum's potential lies in appreciating the *use* value of adopting an enquiry-led pedagogy, which hinges on the deliberative capability of trainers:-

- to take the strategic training focus necessary to develop professionalism and,
- to appreciate the role and need for consistency of idiom, methods and culture in the pedagogy of organisational learning.



Thus, the journey in the Trainers' Forum towards becoming a community of practice reflects its struggle as an emergent profession to develop its specialist knowledge and tools in order to establish autonomy of standards.

**10.2.3 Research Question 3: How can the Trainers' Forum realise its potential as a CoP to provide guidance about training standards generally, and evaluation practices in particular, in order to transform training culture from one of compliance to one of conscience?**

Challenging “tick-box” mentality both inside and outside the Forum provides a springboard to resolve the dominance of transmissive pedagogy. In particular, adopting an enquiry-led approach in the Forum helps trainers develop their professionalism through questioning of the value of expedient delivery in the workplace, with its associated object of minimising training costs. By this means, we might appreciate that the *use* value of enquiry-led training to organisations lies in developing the deliberative capability of trainees - to reduce instances of GCP non-compliance - thereby increasing the cost-effectiveness of clinical development programmes. More crucially, in *exchange*, the requirements of regulators are satisfied if not exceeded.

Frequent use of the phrase “tick-box exercise” expressed the tension between the *use and exchange values* of expediently delivered training. Its use also illustrated the primary contradiction in tools used in the Forum; namely, in the cultural elements of pedagogy operating as standards: compliance versus conscience (L1TO2d: Culture). Consequently, as discussed in Chapter 8, developing the highest standards of training practice in the Forum (and in turn, GCP in the workplace), through the exercise of conscience, remains challenging while employers' way of doing things predominate (transmissive monologue in a culture of compliance) within this community. For example, as revealed in Chapter 8, section 8.3.1, transformation of the workplace object of expediency into a rule inhibited dialogic interactions and fruitful discussion, particularly where it fulfilled an expansive purpose.

If, as expansive learning theory suggests, the TF, as a community of practice, represents a boundary-spanning structure then small changes in this activity system have the potential to

transform activity within each of the inter-related activity systems and vice versa. However, a demonstration of the effect of small changes was limited in this study to empirical-analysis of activity in the TF. Nevertheless, identifying the links between these systems through highlighting contradictions that impinge upon TF activity is the first step in making change possible.

Hence, to reach shared understanding and agreement about ‘good’ training practice within the TF, the process probably begins with the inclusive setting of the meeting agenda. But, who decides which issues are topical? And, if the constituents of best practice are not explicitly mentioned or discussed how can best practice be recognised? Therefore, if the agenda serves as the expression of the TF’s goals - to share best practice and discuss topical training issues - then perhaps more trainers should voice the need for more discussion about the nature of practice, starting with its definition. Moreover, as the research revealed, there is a need to appreciate that giving precedence to employers’ interests in terms of *what* may be discussed, and *how* it may be discussed conflicts with the purpose of the Forum, as a vehicle for CPD.

Such small changes, especially in the organisational approach towards setting and agreeing agenda topics, irrespective of members’ status as core, active or peripheral may enable more trainers in the TF to fulfil their training needs through consciously developing competence about whatever aspects of practice are of concern, such as the process of evaluation. In this way, as a whole, the CoP may shift its sense of *conscious incompetence* about evaluation to the next level, that of *conscious competence*<sup>223</sup>, by sharing experiences and thereby developing or helping to construct knowledge. Shifting towards a more transparent or inclusive approach towards all members - peripheral and active/core – may increase members’ ‘buy-in’ or involvement, which in turn may increase the likelihood that the CoP will continue to develop and sustain members’ interest and passions.

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<sup>223</sup> Howell (1982:29-33) describes the four stages as: unconscious incompetence; conscious incompetence; conscious competence and unconscious competence.

In effect, these observations constitute opportunities and recommendations for expansive learning in the TF, identified through analyses of contradictions within and between its elements and its neighbouring systems.

#### **10.2.4 Reflecting on thesis propositions**

The hypotheses proposed in Chapter 1 concerning the system of activity within a professional community of practice were that:-

- If trainers feel divided in their commitments (between their profession, and their employer), then they may speak a language (of process pedagogy) to satisfy their professional peers, but feel forced to deliver cost-constrained training that will satisfy their executive employers
- If the activities of communicative action (dialogue, and giving and taking of reasons to develop dialectical understanding of training) are emphasized within the forum, then trainers may be more likely to become a community of practice reaching shared understanding about an enquiry-led pedagogy and a culture of conscience in relation to training and ultimately, regulation.

These propositions were examined on the basis of rigorous analyses, at each of the three stages of a CHAT methodology in order to address research questions posed in this thesis. Accordingly, a conceptual-analytical framework, substantiated by empirical evidence, was proposed to describe and analyse the concept of practice that embodied the object of activity. This framework succeeded, when applied during actual-empirical analysis as an evaluative tool in two main aspects:-

1. Allowing declarative and procedural models of practice (i.e. expressed and modelled within contrasting pedagogies and associated training idioms) to be evaluated against defined categories of the concept of practice, theoretically derived from the literature, and

2. Linking elements of pedagogy (approach, methods, culture and idiom) to epistemological stance or *frames of discourse* categorised as discourse combinations (*saying-writing-doing-being-valuing-believing*).

Consequently, examining these propositions established the factors hindering or helping the development of the Trainers' Forum as a Community of Practice. In particular, a link was established between the concept of practice (expressed within a dominant transmissive pedagogy and its associated idiom) in the Trainers' Forum and the larger socio-cultural context (compliance culture rooted in the system of regulatory governance), which explained "why we do what we do". Nevertheless, trainers also had insight into their needs (to develop competence regarding evaluation; to develop a facilitative model of training).

In conclusion, the springboards to expansive learning highlighted in this thesis offer the opportunity for future developmental research in the Trainers' Forum, since the challenge remains to push participants into "formulating qualitatively new models as genuine keys for resolving the double bind" (Engeström, 1987, (5):7).

### **10.3 Implications of using AT for this study: contribution to knowledge; strengths, limitations and future recommendations**

As discussed in Chapter 4, section 4.2, as a "theoretical investigation moving on the level of categories", an AT-based methodology is challenging, especially when considering "...how to bring the categories developed into fruitful contact with practice" (Engeström, 1999b:22).

Yet, as discussed in Chapter 2 (section 2.5), because AT can be operationalised it passes the test of being an applied theory. That is, as shown in Chapter 3, the basic AT model and the subsequent framework developed during the conceptual development phase is focused, specific, and contains unique measurable/observable and understandable elements, which Storberg-Walker (op.cit.:567) offers as the definition of an applied theory.

Nevertheless, because AT can be applied in varied ways to differing contexts, its flexibility as a methodology poses several concerns or weaknesses (Mwanza, 2002 (4): 22; Blin, 2002) involving:-

- A lack of stipulated methodology for its application
- A lack of standardised approach or replicable method for its operationalisation, leading to difficulty in “... replicating, comparing and criticising the approaches taken to operationalise Activity Theory.” (Mwunda op.cit.(4):92)
- A need for expansion of AT (e.g. “to include a language of description that would allow identification and investigation of: the circumstances in which particular discourses are produced; modalities of their cultural production; and, their implications in shaping learning and development” (Daniels, 2004).

These concerns are addressed in turn.

Engeström comprehensively illustrates expansive research methodology, providing the stages and steps that formulate analytical strategy, as illustrated in Chapter 3, section 3.4. Even so, this is necessarily non-prescriptive since third generation activity theory produces a need to develop conceptual tools to understand dialogue, multiple perspectives and voices, and networks of interacting activity systems. Inevitably, the development of these tools reflects the unique features of the activity system revealed through theoretical and empirical investigation. Nevertheless, as demonstrated through Engeström’s CHAT, expanding the basic model to include at least two interacting activity systems contextualises and thus, reveals the cultural and historical dimensions of the activity system under investigation.

Hence, revealing the “modalities of cultural production” depends on the conceptual tools that emerge from, and are grounded in, the unique system under examination. Accordingly, any attempt to standardise the application of AT through conceptual tools must account for the unique conditions, motives or goals giving rise to the operations, actions or collective activity within a particular system of human activity, given its complexity. This attempt has involved

identifying the objective regularities of a practice through its cognitive and cooperative tasks, which constituted the routinised actions within a system of activity. In turn, these objective regularities are revealed in the declarative conceptions, procedural models and patterns of interaction/social discourses within the activity system.

Moreover, as shown in Figure 2-2 (Chapter 2), 3<sup>rd</sup> generation AT or CHAT gives us a definitive triangular model to systematically operationalise six elements that serve as a unit of analysis in an applied theory of social learning. Furthermore, these six elements **are** standardised (subject, object, tools, rules, community and DoL). However, the task of identifying these activity system elements and the unique reasons for contradiction within and between them is problematic. It depends on creatively, yet systematically discerning layers of social reality, and delineating each in turn as separate but inter-related systems of activity. Even so, this six-point unit of analysis still provides the methodology to proceed systematically on three levels: that of routine operation, individual action and collective activity through the medium of *object-historical*, *theory-historical* and *actual-empirical* analyses of the activity system of interest and its rich layers of context. Therefore, in general terms, the contribution of this study has been to show how AT can be applied as an approach and method with theoretically formulated and empirically tested evaluative tools, to reveal the richness of human experience and the complexity of human activity in terms of its cognitive and cooperative social elements.

Moreover, in specific terms through this research, it has been demonstrated that in taking a practical turn (via phenomenological examination during the first stage of *object-historical* analysis) an activity system methodology offers the following:-

- a way to determine the nature of the relationship between the predominant *transmission* pedagogy observed at the TF, as a particular standard of training practice, and the compliance regime that pervades the larger “system” of quality standards in the context of clinical research conduct

- a means to examine this relationship in terms that move beyond basic classificatory explanations, to demonstrate how community outcomes and underlying social mechanisms are linked.

For example, characterising the features of so-called traditional transmission pedagogues or progressive enquiry pedagogues within the TF into distinct sociological groupings to see **who** they were as individuals - might, or might not, have revealed why particular groupings collectively leaned more towards a compliance culture or strove to develop a culture of conscience. The more pertinent questions perhaps were **how** these groupings formed and **why** particular tendencies prevailed, as a consequence of particular conditions.

Thus, in the second stage of *theory-historical* analyses, a concept of practice was identified through observing the patterns of activity and action in the Forum. That is, the concepts and models partly constructed within the central activity, and partly imported into it as cultural artefacts were analysed. Finally, the latter stage of analysis culminated in actual-empirical-analysis of "...the internalized (conceptions of practice) and invented models (what practice looks like at the TF) professed and actually used or upheld by the participants of the activity" (Engeström, op.cit.: 6). In this way, the categories developed through theoretical investigation were brought into "fruitful contact with practice" (Engeström, ibid.: 22).

Hence, in this study, activity theory provided a systematic methodology to simultaneously examine, describe and analyse, on the one hand, how the concept of training practice manifested within a particular community of practice – the TF, and on the other, how this concept of practice was influenced by the wider contextual framework and its socio-cultural underpinnings. Moreover, the history of the Trainers' Forum as an activity system was embedded not only in its internal structure and organisation, but also in the global history of the tools, procedures, concepts and principles that became mediators of its activity.

In addition, as a metatheory, activity theory also provides the means to "...develop analytic categories for theoretical frameworks in epistemology" (Scribner, 1997). Consequently, in this study, the EFD was identified as a mediating tool in the activities of sharing and learning.

Thus, in the final actual-empirical stage of analysis the complex nature of activity in the CoP, in terms of the socio-cultural underpinning of its cognitive and co-operative elements, was further distinguished using the contrasting EFsD observed within the CoP (i.e. in terms of *saying-writing-doing* and *being-valuing-believing* discourse combinations that indicated knowing was embodied as received or constructed).

Therefore, it is the contention of this thesis that CHAT does not lack rigour, through weaknesses in its methodology, due to a lack of standardisation. However, its application inevitably depends on the critical skill of the developmental researcher to discern *what's going on around here* using all the available tools provided by CHAT. Far from lacking tools or standardised methodology, AT provides a plethora of tools that perhaps are seldom used fully. This research has endeavoured to use these tools to their fullest extent. Rather than claiming to expand AT, its application has been demonstrated at the level of declarative conceptions (concept of practice), procedural models (methods), and social discourses/interactions (experience of practice) to explain the intimate and intricate relationship between object-oriented actions and cultural means in a community of practice.

This approach of exploring the concept, method and experience of practice has served to illustrate how the conceptual tools that are necessary for *actual-empirical* analysis may be constructed based on *object-* and *theory-historical* analyses of the activity system under investigation. That is, through the language and behaviour observed at the TF, an evaluative instrument (as shown in Table 9-2 and Table 9-3 derived from *object-historical* and *theory-historical* was tested via *actual-empirical* analysis to illuminate the objective regularities of practice observed in the activity system of trainers. Moreover, through this instrument, elements of pedagogy (approach, methods and idiom) were linked to trainers' epistemological stance (knowledge: constructed or received) or EFsD (*saying-writing-doing* and *being-valuing-believing*).

Nevertheless, CHAT is not without its challenges. In particular, adopting an interlocutory position presented the real time challenge of how to present and discuss findings. Thus,



negotiating this middle ground meant maintaining a balance between needs and influence as a participant, and research instincts. At times, this endeavour was confusing, overwhelming and frustrating. In practice, it involved knowing when to seize the moment, which might make a difference to the unfolding activity, to ask questions or to challenge assumptions. Moreover, such interactions were more often spur of the moment than planned, but which nevertheless were guided by a desire to understand and communicate others thoughts, feelings and experiences about common needs, and how these might be satisfied within the TF.

AT provides the tools to unravel the complexity inherent in the relationships between subjects and tools, which mediate the object of activity according to the rules of the system under investigation and its division of labour. Its strength lies in the interlocutory approach, which focuses attention on the object of activity in the system under investigation and its context rather than the reflective researcher's position, relative to the object of study (i.e. subjective/objective or insider/outsider).

Therefore, in contrast to other studies, focus was on a community of practice spanning a field of practice (clinical research training) and based within a professional institution, rather than any individual organisation and its geographical distribution. Studies have shown that communities of practice can make a difference to business outcomes via the development of social capital. However, "there has been relatively little systematic study of the link between community outcomes and the underlying social mechanisms at work" (Lesser and Storck, op.cit.:833). This developmental study has endeavoured to address this gap, focussing attention primarily on opportunities to extend professionalism thereby moving towards a culture of conscience, such that regulatory requirements may be exceeded rather than merely fulfilled.

It remains to be seen whether "the conflict between internal and external resources", which trainers appreciate, may be resolved. However, if it holds that "...because communities of practice are not confined by institutional affiliation, their potential value extends beyond the boundaries of any single organisation" (Wenger *et al* (op.cit.: 4) then members of the

Trainers' Forum have an opportunity to transform the status quo. As such, the outcome could affect not only the system of activity inside the TF, but could change the ethos and moral order of corporate power elite within their organisations. Accordingly, the springboards to expansive learning highlighted in this thesis offer the opportunity for future developmental research.

However, the hypotheses of this thesis established that both internal and external factors have hindered the development of the Trainers' Forum as a Community of Practice, which leads to the conclusion that transforming a *culture of compliance* into a *culture of conscience* in the field of clinical research represents a challenge for at least two reasons: -

- First, globally - because the regulatory agenda dominates the drive to uphold standards in the field of clinical research, rather than a desire to excel.
- Second, locally - because contrasting pedagogies competing within training discourses have implications for the development of standards about training in general, and for evaluation practices in particular.

Nevertheless, as found in this study, a need exists for trainers to realise their potential as practitioners through discussing the nature of what constitutes best practice, in order to grasp their experience and turn it into knowledge, since

*"...Learning is the process whereby knowledge is created through the transformation of experience. Knowledge results from the combination of grasping experience and transforming it" (Kolb, 1984).*

Otherwise, training standards may continue to be dominated by regulatory purposes, reinforcing a culture of compliance, which paradoxically may limit the expansive development of practice. Accordingly, the Trainers Forum provides the means for further specific developmental research, which offers a three-fold opportunity:-

1. On the basis of the springboards identified in the Forum, to push participants into "formulating qualitatively new models as genuine keys for resolving the double bind".

2. To participate in the ongoing activity of sharing practice by means of demonstrating dialogic, dialectic practice.
3. To further validate the conceptual framework developed in this study as an evaluative tool.

In terms of the recommendations for future general developmental research, because propositions in this thesis were theoretically derived and empirically tested within a specific context, whether *what happens around here* can be generalised in conceptual terms to other settings, and their objects, depends on finding similarities in patterns between their features, conditions and circumstances, as discussed in Chapter 4.

On this basis, since CoPs are considered as social structures where “learning is an integral and inseparable aspect of social practice” (Lave and Wenger, 2002:57), it is feasible to replicate CHAT methodology, as demonstrated in this thesis, in other communities of practice.

However, each system under investigation contains its own unique features and objective regularities, according to its constituent cognitive and cooperative elements of practice.

Therefore, the reliability of the conceptual-analytical framework proposed in this thesis depends on whether generalised elements of practice, theoretically derived, can be validated in different contexts through identifying their objective regularities, as illustrated in Tables 3-2 and 3-3.

In conclusion, therefore, the evaluative tool yielded from object-historical and theory-historical analysis, and tested or validated in actual-empirical analysis, is unique to the activity system under investigation, necessarily reflecting its emergent features and objective regularities. Anticipating otherwise risks misunderstanding or misrepresenting the complexity of the human activity being investigated.

**Table 10-1: Cultural conflict underscoring the spectrum of professionalism in the TF**

	Organisational grouping	Emergent profession	Individual trainer
Professionalism (Quality or standards of practice)	Functional tool	Culture of conscience	Culture of compliance
Pedagogy		Constructive	Transmissive
Focus		Strategic: organisational learning (T/cycle)	Operational: functional task (delivery)
Rationality		Expansive expressive function	Restricted technical function
Epistemology		Knowledge is co-constructed through deliberation	Knowledge is transmitted through delivering information

## References

## REFERENCES

Abraham J. (2007). *Building on Sociological Understandings of the Pharmaceutical Industry or Reinventing the Wheel? Response to Joan Busfield's 'Pills, Power, People.'* *Sociology*, 41: 727-736. Available at <http://soc.sagepub.com>. Accessed 23<sup>rd</sup> June 2008.

Alexander R. (2005). *Culture, dialogue and learning: notes on an emerging pedagogy. Education, Culture and Cognition: intervening for growth.* International Association for Cognitive Education and Psychology (IACEP) 10th International Conference, University of Durham, UK, 10-14 July 2005. Available at [http://www.robinalexander.org.uk/docs/IACEP\\_paper\\_050612.pdf](http://www.robinalexander.org.uk/docs/IACEP_paper_050612.pdf). Accessed 24th August 2008.

Altrichter H., Posch P. & Somekh B. (1993). *Teachers investigate their work: an introduction to the methods of action research.* London, Routledge.

Anderson LW. & Krathwohl DR. (Eds.). (2001). *A taxonomy for learning, teaching and assessing: A revision of Bloom's Taxonomy of educational objectives.* Complete edition, New York: Longman.

Argyris C. & Schön D. (1996). *Organizational Learning II: Theory, Method, and Practice.* San Francisco: Addison- Wesley.

Argyris C. & Schön D. (1978). *Organisational learning: a theory of action perspective.* New York: McGraw-Hill.

Armstrong PW. & Kaul P. (2004). *Charting the course of clinical research: from an inspired past to a promising future.* *Am heart Journal*, 148:190-192.

Aungst J., Haas A., Ommaya A. & Green LW. (Eds). (2003). *Exploring Challenges, Progress, And New Models for Engaging the Public in the Clinical Research Enterprise.* Clinical Research Roundtable Workshop Summary. Available at <http://www.nap.edu/catalog/10757.html>. Accessed 29th July 2008.

- Bacon W., Groundwater-Smith S., Nash C. & Sachs J. (2000). *Legitimizing Professionalism?* Paper presented at the British Educational Research Association Conference, Cardiff University, 7-10 September 2000.
- Bailey V., Bemrose G., Goddard S., Impey R., Joslyn E. & Mackness J. (1995). *Essential Research Skills*. Hammersmith, London: Collins Educational.
- Ballantine C. (1981). *Taste of raspberries, taste of death. The 1937 elixir sulfanilamide incident*. FDA Consumer Magazine. June 1981 issue. Available at <http://www.fda.gov/oc/history/elixer.html>. Accessed 7th December 2005.
- Bakhtin MN. (1981). *The dialogic imagination*. Austin: University of Texas Press.
- Bakhtin MN. (1986). *Speech genres and other late essays*. Austin: University of Texas Press.
- Barab SA., Barnett M., Squire K. (2002). *Developing an empirical account of a community of practice: characterizing the essential tensions*. The Journal of the Learning Sciences, 11(4): 489-542.
- Barley SR. (1988). *On Technology, Time and Social Order: Technically Induced Changes in the Temporal Organization of Radiological Work*. In Dubinkas FA. (ed.). *Making Time: Ethnographies of High-Technology Organizations*. Philadelphia: Temple University Press, pp. 123-169.
- Barton D. & Tusting K. (Eds.). (2005). *Beyond communities of practice: Language, power and social context*. New York: Cambridge University Press.
- Bassey M. (1999). *Case Study Research In an Educational Setting*. Buckingham: Open University Press.
- Bates I. (2002). *The competence and outcomes movement: the landscape of research, 1986-1996*. School of Education, University of Leeds. Education-Line. Available at <http://www.leeds.ac.uk/educol/documents/00002216.htm>. Accessed 12th March 2004.

- Belenky MF., Clinchy BM., Goldberger NR & Tarule JM. (1986). *Women's ways of knowing: The development of self; voice and mind*. New York: Basic Books.
- Bellman L. (2001). *Courage, Faith and Chocolate Cake: requisites for exploring professionalism in action*. *Educational Action Research*, 9(2): 225-241.
- Berman J., McCombs H & Boruch RF. (1977). *Notes on the contamination method: Two small experiments in assuring confidentiality of response*. *Sociological Methods and Research*, 6: 45–63.
- Blin F. (2005). *CALL and the development of learner autonomy - an activity theoretical study*. Unpublished doctoral thesis, Institute of Educational Technology, The Open University, UK. Available at <http://www.dcu.ie/~blinf/thesis.htm>. Accessed 10th November 2008.
- Blomberg J., Giacomi J., Mosher A & Swenton-Wall, P. (1993). *Ethnographic Field Methods and their Relation to Design*. In D. Schuler and A. Namioka (eds.). *Participatory Design: Principles and Practices*. Hillsdale, NJ: Lawrence Erlbaum, pp. 123-155.
- Bloom BS. (Ed.), Engelhart MD., Furst EJ., Hill WH. & Krathwohl DR. (1956). *Taxonomy of educational objectives: The classification of educational goals*. Handbook 1: Cognitive domain. New York: David McKay.
- Bohman J. (2008). *Critical Theory as Practical Knowledge: Participants, Observers, and Critics*. In *The Blackwell Guide to the Philosophy of the Social Sciences*. Eds Turner S & Roth PA (pp 89-109). [Online]. Blackwell Publishing Ltd. Available at <http://www3.interscience.wiley.com/cgi-bin/bookhome/117886345>. Accessed 19th July 2008.
- Boreham N. & Morgan C. (2004). *A sociocultural analysis of organisational learning*. *Oxford Review of Education*, 30(3): 307-325.
- Bourdieu P. (1977). *Outline of a theory of practice*. Translated by Richard Nice. Cambridge, UK: University Press.



- Bourdieu P. (1990). *The logic of practice*. Translated by Richard Nice. Cambridge, UK: University Press.
- Bourdieu P. (1991). *Language and symbolic power*. Thompson J. (Ed). Translated by Gino Raymond & Matthew Adamson. Polity Press.
- Bourdieu, P. (1998). *Practical Reason: On the Theory of Action*. London: Polity Press.
- Bourdieu P. & Wacquant LJD. (1992). *An Invitation to Reflexive Sociology*. University of Chicago Press, Chicago.
- Boyt TE, Lusch RF & Naylor G. (2001). *The role of professionalism in determining job satisfaction in professional services: a study of marketing researchers*. Journal of Service Research, 3 (4): 321–330.
- Bringslimark V. (2004). *If training is so easy, why isn't everyone in compliance?* BIOPHARM International. January 2004.
- British Educational Research Association. (2004). *Revised Ethical Guidelines for Educational Research*. Available at <http://www.bera.ac.uk/files/2008/09/ethica1.pdf>. Accessed 6th June 2004.
- Brown JS. & Duguid P. (1991). *Organizational Learning and Communities-of-Practice: Toward a Unified View of Working, Learning and Innovation*. Organization Science, 2(1): 40-57.
- Buckland S. (2005). INVOLVing the public in clinical research. Clinical Research Focus, 16(5):25-26.
- Busfield J. (2006). *Sociological Understandings of the Pharmaceutical Industry: Sociology*, 40: 297-314. Available at <http://soc.sagepub.com/cgi/content/abstract/40/2/297>. Accessed 23rd June 2008.

- Busfield J. (2007). *Sociological Understandings of the Pharmaceutical Industry: A response to John Abraham*. *Sociology*, 41: 737-739. Available at <http://soc.sagepub.com>. Accessed 23rd June 2008.
- Campbell A. (2002). *'I think I'll do some research today': issues around teacher research and professional development*. Paper presented at the Annual Conference of the British Educational Research Association, University of Exeter, England, 12-14 September 2002. Available at <http://www.leeds.ac.uk/educol/documents/00002296.htm>. Accessed 19th march 2009.
- Campbell DT. & Fiske DW. (1959). *Convergent and Discriminant Validation by the Multitrait-Multimethod Matrix*. *Psychological Bulletin*, 56 (2): 81-105.
- Carbonara P. (1996). *Hire for attitude, train for skill*. *Fast Company*, (4):73. Available at <http://www.fastcompany.com/magazine/04/hiring.html>. Accessed 25th March 2009.
- Carlsen WS. (1997). *Never ask a question if you don't know the answer: The tension in teaching between modeling and scientific argument and maintaining law and order*. *Journal of Classroom Interaction*, 32(2), 14-23.
- Carspecken P. (1996). *Critical ethnography in educational research: A theoretical and practical guide*. New York: Routledge.
- Carr W & Kemmis S. (1986). *Becoming critical*. Lewes: Falmer Press
- Catto G. (2005). *Professionalism pompous, pretentious and outmoded?* *Journal of Interprofessional Care*, 19(4): 313 – 314.
- Cazden C. (1988). *Classroom discourse: The language of teaching and learning*. Portsmouth, NH: Heinemann.
- Chambers N. & Chambers O. (2001). *Chambers Compact Dictionary*. Chambers N & Chambers O. (Eds). Larousse Kingfisher Chambers: London.

- Charmaz K. & Olesen V. (1997). *Ethnographic research in medical sociology – its foci and distinctive contributions*. *Sociological Methods and Research*, 25: 452–494.
- Chief Scientist Office (2005). *AstraZeneca’s experience of a Medicines and Health Care Product Regulatory Agency (MHRA) Inspection*. *Research Matters*. Newsletter of the Chief Scientist Office. Issue 29 (Summer): 3-5. Available at <http://www.sehd.scot.nhs.uk/cso/Publications/rm29/rm29.pdf>. Accessed 1st August 2005.
- Cochrane-Smith M. & Lytle S. (1993). *Inside/outside: Teacher research and knowledge*. New York: Teachers College Press.
- Cohen L. & Manion L. (1994). *Research methods in education* (4th Ed). London, UK: Routledge.
- Cole M. (1996). *Cultural Psychology: a once and future discipline*. Cambridge, MA: Harvard University Press.
- Cole M. & Engeström Y. (1993). *A cultural-historical approach to distributed cognition*. In G. Salomon (Ed.), *Distributed cognitions: Psychological and educational considerations* (pp. 1-46). New York: Cambridge University Press.
- Collier JH. & Toomey DM. (1997). *Chapter 3: Writing Scientific and Technical Texts: Part 3: Cognitive and social constraints*. In *Scientific and Technical Communication: Theory, Practice, and Policy*. Digital Edition. Available at <http://www.faculty.english.vt.edu/Collier/stc/index.htm>. Accessed 9th August 2009.
- Crawford K. & Hasan H. (2006). *Demonstrations of the Activity Theory framework for research in information systems*. *Australasian Journal of Information Systems*. 13(2). May.
- Critten P. (1999). *Coming out of the closet – we’re all professional now*. *Continuing Professional Development Journal*, Issue 1. [online]. Available at <http://www.openhouse.org.uk/virtual-university-press/cpdl>. Accessed on 25th Nov 2004.

- Daniels H. (2004). *Activity theory, discourse and Bernstein*. Educational review, 56(2): 121-132.
- Daniels H. (2007). *Discourse and Identity in Cultural-Historical Activity Theory: A response*. International Journal of Educational Research, 46:94-99.
- Daniels H. & Warmington P. (2007). *Analysing third generation activity systems: labour-power, subject position and personal transformation*. Journal of Workplace Learning, 19 (6): 377-391.
- Dave, RH. (1970). *Psychomotor levels*. In RJ. Armstrong (Ed.) *Developing and writing educational objectives* (pp. 33-34). Tucson AZ: Educational Innovators Press.
- Davenport TH., Jarvenpaa SL. & Beers M. (1996). *Improving Knowledge Work Processes*. Sloan Management Review (Summer), pp. 53-65.
- Davis DA, Taylor-Vaisey AL. (1997). *Translating guidelines into practice: a systematic review of theoretic concepts, practical experience and research evidence in the adoption of clinical practice guidelines*. CMAJ.; 157:408-416.
- Davis P. (2005). *A sociocultural approach to theorising classroom practice*. From *Understanding and developing inclusive practice in schools. A collaborative action research network*. Economic and Social Research Council Teaching and Learning Research Programme Phase I Network. Available at [http://orgs.man.ac.uk/projects/include/experiment/pauline\\_davis.pdf](http://orgs.man.ac.uk/projects/include/experiment/pauline_davis.pdf). Accessed 28th October 2008.
- Deal TE. (1985). *The symbolism of effective schools*. Elementary School Journal, 85 (5): 601-620. Reprinted in Westoby, A. (Ed.) (1985). *Culture and Power in Educational Organisations*. Buckingham, Open University Press.
- Dennis A. (2005). *The European Directive on Clinical Trials: is harmony always a happy state?* ECP. Legal & Regulatory (Spring issue): 30-33. Available at [samedanltd.com](http://samedanltd.com). Accessed 29 July 2005.

- Di Giovanni & Hayes, G. (2001). *Introduction*. In *Principles of Clinical Research* Eds. Di Giovanna I and Hayes G. Hampshire: Wrightson Biomedical Publishing Ltd.
- Doyal (2002). *Good Clinical Practice and informed consent are inseparable*. *Heart*, 87:103-106. Available at [www.heartjnl.com](http://www.heartjnl.com). Accessed 18<sup>th</sup> October 2006.
- Engeström Y. (1987). *Learning by expanding. An activity-theoretical approach to developmental research*. Helsinki, Finland: Orienta-konsultit.
- Engestrom Y. (1990). *Learning, working, imagining: Twelve studies in activity theory*. Helsinki: Orienta-Konsultit.
- Engeström Y. (1993). *Developmental studies of work as a testbench of activity theory: The case of primary care medical practice*. In S. Chaiklin & J. Lave (Eds.), *Understanding practice: Perspectives on activity and context* (pp. 64–103). Cambridge, MA: Cambridge University Press.
- Engeström Y. (1999a). *Activity theory and individual and social transformation*. In Engeström Y, Miettinen R, & Punamaki P (Eds.). *Perspectives on activity theory* (pp. 19–38). Cambridge, MA: Cambridge University Press.
- Engeström Y. (1999b). *Learning by expanding: ten years after*. Introduction to the German edition of *Learning by Expanding*, published in 1999 under the title *Lernen durch Expansion* (Marburg: BdWi-Verlag; translated by Falk Seeger)
- <http://lchc.ucsd.edu/MCA/Paper/Engestrom/expanding/intro.htm>. Accessed 14<sup>th</sup> September 2008.
- Engeström Y. *The Activity System*. Available at <http://www.edu.helsinki.fi/activity/pages/chatanddwr/activitysystem>. Accessed 24<sup>th</sup> October 2007.
- Eraut M. (1994). *Developing Professional Knowledge and Competence*. London: Falmer Press.

- Evans L. (2008). *Professionalism, professionalism, and the development of education professionals*. *British Journal of Educational Studies*, 56 (1): 20–38.
- Evetts J. (2003). *The Sociological Analysis of Professionalism: occupational change in the modern world*. *International Sociology*, 18 (2): 395-415.
- Fairclough N. (1992). *Discourse and social change*. London: Longman.
- Fisher JA. (2005). *Pharmaceutical paternalism and the privatisation of clinical trials*. PhD thesis. UMI Microform 3183626. ProQuest Information and Learning Company, Ann Arbor, MI, USA.
- Fitzpatrick S. (2008). *Evolving CPD: ICR's Revised Scheme for Points-Based Continuing Professional Development*. *Clinical Research Focus* , 19(8): 16-20.
- Fontaine N. & Rosengren B. (2001). *Directive 2001/20/EC of the European Parliament of the Council on the approximation of the laws, Regulations and administrative provisions of the Member States relating to implementation of good clinical practice in the conduct of clinical trials on medicinal products for human use*. Official Journal of the European Communities. L121: 34. Available at <http://www.eortc.be/Services/Doc/clinical-EU-directive-04-April-01.pdf>
- Frey JH. (1986). *An experiment with a confidentiality reminder in a telephone survey*. *Public Opinion Quarterly*, 50: 276–79.
- Friedson E. (1994) *Professionalism Reborn: Theory, Prophecy and Policy*. London: Policy Press.
- GAO May. (1992). *Quantitative Data Analysis: An Introduction*, GAO/PEMD-10.1.11, June 1992. Available at <http://www.gao.gov/special.pubs/pe10111.pdf>. Accessed 23rd June 2006.
- Gee JP. (1996). *Social linguistics and literacies: Ideology in discourses*. (2nd ed). London: Falmer.

- Geertz C. (1973). *Thick description: Toward an interpretive theory of culture*. In Clifford Geertz, *Interpretation of Cultures*: 3-32. New York: Basic.
- Giddens A. (1976). *New rules for the sociological method*. London: Hutchison.
- Giddens A. (1984). *The constitution of Society. Outline of the Theory of Structuration*. Cambridge: Polity Press.
- Gilleard J. (1996). *Self-development of peripheral trainers: deciphering the dichotomies*. *Journal of European Industrial Training*, 20 (7): 17–23.
- Gleeson D., Davies J. & Wheeler E. (2005). *On the making and taking of professionalism in the further education workplace*. *British Journal of Sociology of Education*, 26, (4): 445 – 460.
- Gold R. (1997). *The ethnographic method in sociology*. *Qualitative Enquiry*, 3(4): 387-402.
- Goldfarb N. (2007). *Greg Koski on Human Subjects Protection*. *Journal of Clinical Research Best Practices* 3(9). Available at [www.firstclinical.com](http://www.firstclinical.com). Accessed 3<sup>rd</sup> November 2007.
- Gongla P & Rizzuto CR. (2001). *Evolving communities of practice: IBM Global Services experience*. *IBM Systems Journal*, 40(4), 842-862.
- Gonzalez-Rey FLS. (2002). *L.S. Vygotsky and the question of personality in the cultural-historical approach*. In Robbins D. & Stetsenko A. (Eds). *Voices within Vygotsky's Non-Classical Psychology: Past, Present, Future*. New York, NY: Nova Science.
- Goode WJ. (1957). *Community within a community*. *American Sociological Review*, 22:194-200.
- Grace G. (1995). *School leadership: beyond educational management: an essay in policy scholarship*. (London, Falmer).
- Grigg M, Endacott R, Hermann H, Harvey C. (2004). An ethnographic study of three mental health triage programs. *International Journal of Mental Health Nursing*, 13: 146-151.

- Grossman PL. (1991). *Overcoming the apprenticeship of observation in teacher education coursework*. *Teaching and Teacher Education*, 7 (4), 345-357.
- Hall R. (2001). *Schedules of practical work for the analysis of case studies of learning and development*. *Journal of the Learning Sciences*. Special issue on *Methodologies for capturing learner practices occurring as part of dynamic learning environments* S. Barab and D. Kirshner (Eds.).
- Halliday J. (2008). *MacIntyre and Practice: Implications for Workplace learning*. Paper presented at the European Conference on Educational Research (From Teaching to Learning?). Available at [http://www.eera-ecer.eu/publication-database/conference/2008/contribution/macintyre\\_and\\_practice\\_implications\\_for\\_workplace\\_learning/](http://www.eera-ecer.eu/publication-database/conference/2008/contribution/macintyre_and_practice_implications_for_workplace_learning/). Accessed 24<sup>th</sup> May 2009.
- Halliday MAK. (1993). *Towards a language-based theory of learning*. *Linguistics and Education*, 5:93-116.
- Halverson R. (2003). *Systems of practice: How leaders use artifacts to create professional community in schools*. *Education Policy Analysis Archives*, 11(37). Available at <http://epaa.asu.edu/epaa/v11n37/>. Accessed 16<sup>th</sup> October 2007.
- Hammersley M & Atkinson P. (1995). *Ethnography: Principles in Practice*. London, Routledge (first published 1983).
- Hasu M & Engeström Y. (2000). *Measurement in Action: An Activity-Theoretical Perspective on Producer-User Interaction*. *International Journal of Human Computer Studies*, 53: 61-89.
- Hayes G. (2004a). *Formulating training strategies*. *Clinical Research Focus*, 15 (6): 22-26.
- Hayes G. (2004b). *Training needs analysis & evaluation*. *Clinical Research Focus* 15 (9):18-23.
- Hayes G (2008). *Unity in diversity. A message from the Vice-Chair*. *Clinical Research Focus* , 19 (10): 5.



- Henderson L. (2001). *The choice for more training*. Centerwatch. March issue: 8(3).
- Hepworth-Jones B. (2004). *The inaugural meeting of the ICR Trainers' Forum*. Clinical Research Focus, 15(1): 34-35.
- Hepworth-Jones B. (2005). *MHRA Expectations & Inspections* Clinical Research Focus, 16(5): 39-43.
- Hofer BK. & Pintrich PR. (1997). *The development of epistemological theories: beliefs about knowledge and knowing and their relation to learning*. Review of Educational Research, 67(1): 88-140.
- Holzkamp K. 1983. *Grundlegung der Psychologie*. Frankfurt am Main/New York: Campus.
- Hooper J. (2005). *Challenges and trends in clinical research*. ECP. Clinical Trials (Spring issue): 34-38. Available at samedanltd.com. Accessed 29 July 2005.
- Houle CO., Cyphert R. & Boggs, D. (1987). *Education for the professions. Theory into Practice*. Interprofessional Education, 26(2): 87-93.
- Howell WS. (1982). *The empathic communicator*. Belmont, CA: Wadsworth Publishing Company.
- Hoyle E. (1975). *Professionalism, professionalism and control in teaching*. In V.Houghton et al. (Eds) *Management in Education: the Management of Organisations and Individuals* (London: Ward Lock Educational in association with Open University Press).
- International Conference on Harmonisation of Technical requirement of Pharmaceuticals for Human Use (ICH). (1996). *Topic E6 Note for Guidance on Good Clinical Practice: Consolidated Guideline*. London: European Agency for the Evaluation of Medicinal Products.
- Jenkins R. (2002). *Pierre Bourdieu*. Revised Edition. London: Routledge.
- Johnston P, Woodside-Jiron H & Day J. (2001). *Teaching and learning literate epistemologies*. Journal of Educational Psychology, 93(1):223-233.

- Jones C. (2003). *As if business ethics were possible, 'within such limits'*. *Organisation*, 10(2):223-248.
- Jost JT. & Hardin CD. (1996). *The Practical Turn in Psychology: Marx and Wittgenstein as Social Materialists*. *Theory Psychology*, 6: 385-393. Available at <http://tap.sagepub.com/cgi/content/abstract/6/3/385>. Accessed October 18<sup>th</sup> 2008.
- Kardash CM., & Scholes RJ. (1996). *Effects of pre-existing beliefs, epistemological beliefs, and need for cognition on interpretation of controversial issues*. *Journal of Educational Psychology*, 88(2): 260-271.
- King A. (1993): *From sage on the stage to guide on the side*. *College Teaching*, 41(1): 30-35.
- Kirkpatrick DL. (1975). *Techniques for Evaluating Programs. Parts 1, 2, 3 and 4. Evaluating Training Programs*. ASTD.
- Knights D. & Wilmott H. (1999). *Management lives. Power and identity in work organizations*. (London, Sage).
- Kolb DA. (1984). *Experiential Learning: experience as the source of learning and development*. New Jersey: Prentice-Hall.
- Koski G. (2000, December 4). *Letter to OHRP Staff re: Compliance Oversight Procedures*. Available: <http://ohrp.osophs.dhhs.gov/references/ohrpcomp.pdf> . Accessed March 11, 2004.
- Koski G. (2001a). *Biomedical Research Progress: In Whose Interest?* Presentation at the Institute of Medicine Southern California Regional Meeting, University of Southern California Keck School of Medicine. Los Angeles: Institute of Medicine. Quoted in: Oliwenstein L. (2002). *Media, public scrutinize clinical trials*. *HSC Weekly* 8(13):1.
- Koski G. (2001b). *Protection of Human Research Subjects: From Compliance to Conscience*. Article based on remarks delivered at the 26th Annual AAAS Colloquium on Science and Technology Policy, held May 3–4 in Washington, DC. Available at [www.aaas.org/spp/yearbook/2002/ch20.pdf](http://www.aaas.org/spp/yearbook/2002/ch20.pdf). Accessed 29 July 2008.

- Koski G. (2002). Letter to Honorable Tommy Thompson Secretary, United States Department of Health and Human Services, October 9. Available: <http://irb.mc.duke.edu/PDF/koskiLetter.pdf> [accessed March 11, 2004].
- Krathwohl DR., Bloom BS., & Masia BB. (1964). *Taxonomy of educational objectives: The classification of educational goals. Handbook II: The affective domain*. New York: David McKay.
- Kuutti K. (1996). *Activity Theory as a potential framework for Human-Computer Interaction research*. In B. Nardi (ed.). *Context and consciousness: Activity Theory and Human-Computer Interaction*. Cambridge, MA: The MIT Press, pp. 17-44.
- Lave J. (1996). *Teaching, as Learning, in practice*. *Mind, Culture, and Activity*. 3(3):149-164.
- Lave J. & Wenger E. (1991). *Situated learning: Legitimate peripheral participation*. New York: Cambridge University Press.
- Lave J. & Wenger E. (2002). *Legitimate peripheral participation in communities of practice*. In: Lea, M.R. & Nicoll, K.: *Distributed learning. Social and cultural approaches to practice*. RoutledgeFalmer.
- Lee RM. (1993). *Doing Research on Sensitive Topics*. London: Sage.
- Lemke JL. (2001). *The long and the short of it: Comments on multiple timescale studies of human activity*. *The Journal of the Learning Sciences*, 10(1&2):17-26.
- Leontiev AN. (1978). *Activity, Consciousness, and Personality*. Hillsdale: Prentice-Hall.
- Leontiev AN. (1981). *An outline of the evolution of the psyche*. (pp. 156-326). In *Problems of the Development of the Mind*. (Trans. M. Kopylova) Moscow: Progress Publishers.
- Lesser E.L. & Storck J. (2001). *Communities of practice and organizational performance*. *IBM Systems Journal*, 40 (4): 831-841.

- Lester S. (1995). *Assessing the self-managing learner: a contradiction in terms?* Adapted from a Paper for the Higher Education for Capability Conference beyond Competence to Capability and the Learning Society (Nov 21 1995). Education-Line. Available at <http://www.leeds.ac.uk/educol>. Accessed Sept 28th 1999.
- Levinas E. (1999). *Alterity and Transcendence*. Trans. M. Smith. New York: Columbia University Press.
- Levinson BA. (1998). *The Social Commitment of the Educational Ethnographer: Notes on Fieldwork in Mexico and the Field of Work in the United States*. In *Being reflexive in critical educational and social research* (pp83-91). Eds Shacklock G and Smyth J. London: Falmer press.
- Lewin K. (1951). *Field theory in social science; selected theoretical papers*. D. Cartwright (ed.). New York: Harper & Row.
- Liikanen E. (2003). *Commission Recommendation of 6 May 2003 concerning the definition of micro, small and medium-sized enterprises* (notified under document number C(2003) 1422). (2003/361/EC). Official Journal of the European Union. L124: 36.
- Lim CP. & Hang D. (2003). *An activity theory approach to research of ICT integration in Singapore schools*. *Computers and Education*, 41: 49-63.
- Loecher U. (2000). *Small and medium-sized enterprises – delimitation and the European definition in the area of industrial business*. *European Business Review*, 12 (5): 261-264.
- Lomax P. (1986). *Action Researchers' action research: a symposium*. *British Journal of In-Service Education*, 13 (1).
- Lorriman J. (1997) *Continuing professional development: a practical approach*. London, UK: The Institution of Electrical Engineers.
- Lotman YM. (1988). *Text within a text*. *Soviet Psychology*, 26(3), 32-51.

- Lyons N. (1990). *Dilemmas of knowing: Ethical and epistemological dimensions of teachers' work and development*. Harvard Educational Review, 60: 159-180.
- MacIntyre A. (1985). *After Virtue. A study in moral theory*. 2<sup>nd</sup> Edition. London: Duckworth.
- Macnaghten P. & Myers G. 2004. *Focus Groups: The Moderator's View and the Analyst's View*. In *Qualitative Research Practice*. Gobo, G., Gubrium, J., Seale, C. & Silverman, D. (Eds). London: Sage.
- Madden CA. & Mitchell VA. (1993). *Professions, standards and competence: a survey of continuing education for the professions*. University of Bristol, Department for Continuing Education.
- Mann H. & John-Steiner V. (2002). *The gift of confidence: a Vygotskian view of emotions*. In Wells G and Claxton, G (Eds). *Learning for Life in the 21<sup>st</sup> century. Sociocultural perspectives on the future of education*. London: Blackwell publishing.
- Martin B. (1999). *Suppression of Dissent in Science Research*. In *Social Problems and Public Policy*, 7:105-135. (Eds Freudenburg WR. & Young TIK.). Stamford, CT: JAI Press.  
Available at: <http://www.uow.edu.au/arts/sts/bmartin/pubs/99rsppp.html> 28jan01. Accessed 12<sup>th</sup> June 2006.
- Marx K. (1973). *Grundrisse: Foundations of the critique of political economy* (rough draft). Harmondsworth: Penguin Books.
- Massey A. (1998). *The way we do things around here: the culture of Ethnography*. Paper presented at the Ethnography and Education Conference, Oxford University Department of Educational Studies (OUDES), 7-8 September. Available at: [www.geocities.com/Tokyo/2961/waywedo.htm](http://www.geocities.com/Tokyo/2961/waywedo.htm). Accessed 15th Feb 2008.
- Mayo E. (1933). *The human problems of an industrial civilisation*. New York: MacMillan.
- McAteer E. (1999). *Evaluation Cookbook. Learning Technology Dissemination Initiative*. Available from <http://www.icbl.hw.ac.uk/ltidi/cookbook/>. Accessed 12<sup>th</sup> December 2007.

- Mellor R. & Mann R. (2001). *Effective training – it's the thought that counts*. Industrial and Commercial Training. 33(1): 12-15.
- McNiff J., Lomax P. & Whitehead J. (2003). *You and your action research project*. 2<sup>nd</sup> Edition. London: RoutledgeFalmer.
- McNiff J. & Whitehead J. (2006). *All You Need to Know about Action Research*. London: Sage.
- Meyers EM. (2007). *From activity to learning: using cultural historical activity theory to model school library programmes and practices*. Information Research. 12(3) paper 313. Available at <http://InformationR.net/ir/12-3/paper313.html>. Accessed 14th September 2008.
- Mezirow J. (1991). *Transformative Dimensions of Adult Learning*. San Francisco: Jossey-Bass.
- Miller FJ. (2002). *I = 0 (Information has no intrinsic meaning)*. Information Research, 8(1), paper no. 140, pp1-9. ISSN 1368-1613. Available at <http://informationr.net/ir/8-1/paper140.html>. Accessed 3rd April 2007.
- Millerson G. (1973). *Education in the professions*. In *Education and the Professions, History of Education Society*, Methuen, London.
- Minton D. (2005). *Teaching skills in further and adult education*. London: Thompson Learning.
- Monaghan C. (2006). *Communities of Practice: Learning Opportunities in the Adult Higher Education Classroom*. Proceedings 26<sup>th</sup> Annual AHEA Conference. October 11<sup>th</sup>-14<sup>th</sup>, Dallas, Texas. Available at [www.ahea.org/conference/proceedings/2006.pdf](http://www.ahea.org/conference/proceedings/2006.pdf). Accessed 26th August 2008.
- Montgomery D. (2004). *Learning: E-volution or Revolution?* Clinical Research Focus, 15 (2): 25-27.

- Mulhall A. (2003). *Methodological issues in nursing research. In the field: notes on observation in qualitative research*. Journal of Advanced Nursing, 41(3): 306–313.
- Murray L. & Lawrence B. (2000). *Practitioner-based enquiry: principles for postgraduate research*. London: Falmer.
- Mwanza D. (2001). *Where theory meets practice: a case for an Activity Theory based methodology to guide computer system design*. KMI Technical Reports, KMI-TR-104, Knowledge Media Institute. Milton Keynes, UK: The Open University. Available from <http://kmi.open.ac.uk/publications/pdf/kmi-01-7.pdf>. Accessed 14th May 2009.
- Mwanza D. (2002a). *Conceptualising work activity for CAL systems design*. Journal of Computer Assisted Learning, 18: 84-92.
- Mwanza D. (2002b). *Towards an Activity-Oriented Design Method for HCI Research and Practice*. PhD Thesis - The Open University, United Kingdom. Available from <http://kmi.open.ac.uk/people/mwanza/Phd.htm>. Accessed 8th May 2009.
- Mwanza D. & Engeström Y. (2005). *Managing content in e-learning environments*. British Journal of Educational Technology, 36(3):453-463.
- Nardi BA. (Ed.). (1996). *Context and consciousness: Activity theory and human-computer interaction*. Cambridge, MA: The MIT Press.
- Nathanael D. & Marmaras N. (2005). *Historical analysis as a means to uncover the dynamics of evolving practices*. ACM International Conference Proceeding Series; 132: 65-70.
- Nicholls G. (2001). *Professional development in higher education: new dimensions & directions*. London: Kogan Page.
- Nixon J. (1996). *Professional identity and the restructuring of higher education*. Studies in higher education, 21: 5-16.

- Nixon J., Martin J., McKeown P. & Ranson S. (1997). *Towards a Learning Profession: changing codes of occupational practice within the new management of education*. British Journal of Sociology of Education, 18 (1):5-28.
- Noble, M. (2008). *ICR members helping each other*. Clinical Research Focus, 19(10): 37-39.
- Nystrand M., Gamoran A., Kachur R. & Prendergast C. (1997). *Opening dialogue: Understanding the dynamics of language and learning in the English classroom*. New York: Teachers College Press.
- Ozga J. (2000). *Policy research in educational settings: contested terrain*. Buckinghamshire: Open University Press
- Parrott A. (2005). *Letter to the editor*. Clinical Research Focus, 16(4): 27-28.
- Parry T. (2007). *ICR Trainers' Forum - Summary of Meetings in the Second Half of 2006*. Clinical Research Focus, 18 (5): 26-31.
- Paterson AS. (1997). *A humanistic framework for interviewer skills*. Paper presented at the British Education Research Association Annual Conference (Sept 11-14 1997: University of York). Education-Line. Available from <http://www.leeds.ac.uk/educol/documents/000000325.doc>. Accessed 21st February 2008.
- Perry WG. (1970). *Forms of intellectual and ethical development in college years*. New York: Holt, Rinehart, Winston.
- Phillips M. & Friedman A. (2001). *CPD: individual professional learning in practice. Research summary. A study of the barriers and drivers to participation in Continuing Professional Development*. Bristol: PARN.
- Pinder S. (2005). *The EU Clinical Trial Directive: Effects for CROs Operating in Europe*. EPC. Legal & Regulatory. (Summer issue). Available at [www.samedanltd.com](http://www.samedanltd.com). Accessed 1<sup>st</sup> December 2005.
- Polanyi M. (1967). *The Tacit Dimension*. New York: Anchor Books.



- Popkewitz TS. (1998). *Knowledge, power, and curriculum: Revisiting a TRSE argument*. *Theory and Research in Social Education*, 26(1): 83-101.
- Popper K. (1959). *The Logic of Scientific Discovery*, 1934 (as *Logik der Forschung*, English translation). Mohr Siebeck. ISBN 3-16-148410-X.
- Powell L. & Holt G. (2008). *If You Raise the Water Level, Everybody's Boat Floats! Increasing the Talent Pool Resourcing Clinical Trials*. *Clinical Research Focus*, 19(11): 39-40.
- Pring R. (2000) *Philosophy of Educational Research*. London: Continuum
- Putnam RT & Borko H. (2000). *What do new views of knowledge and thinking have to say about research on teacher learning?* *Educational Researcher*, 29(1): 4–15.
- Ranson S. (2003). *Public accountability in the age of neo-liberal governance*. *J. Education Policy*, 18(5): 459-480.
- Reamer FG. (1979). *Protecting research subjects and unintended consequences: The effect of guarantees of confidentiality*. *Public Opinion Quarterly*, 43, 497–506.
- Reichenbach R. (1998). *The postmodern self and the problem of developing a democratic mind*. *Theory and Research in Social Education*, 26 (2): 226-237.
- Rogers C. (1983). *Freedom to Learn for the 80's*. Ohio: Merrill.
- Rogoff B. (1998). *Cognition as a collaborative process*. In W. Damon, D. Kuhn, & R. S. Siegler (Eds.). *Handbook of child psychology: Vol. 2. Cognition, perception, and language* (pp. 679-744). Wiley: New York.
- Schultze U, Boland RJ Jr, Harvey L & Karsten H. (1998). *Four perspectives for understanding work practices: Giddens, Bourdieu, Foucault and narrative*. Proceedings of the international conference on Information systems. International Conference on Information Systems archive, Helsinki, Finland. ACM: Association for Computing Machinery. Available at <http://delivery.acm.org/10.1145/360000/353110/p407->

schultze.pdf?key1=353110&key2=4042861611&coll=&dl=ACM&CFID=15151515&CFTOKEN=6184618. Accessed 23<sup>rd</sup> October 2006.

Scott G., Fitzpatrick S. & George A. (2000). *A partnership between ACRPI and Liverpool John Moores University*. Qual Assur J., 4: 83-89.

Scribner S. (1997). *A sociocultural approach to the study of mind*. In E. Toback, R. J. Flamagne, M. B. Parlee, L. M. W. Martin, & A. S. Kapelman (Eds.). *Mind and social practice: Selected writings of Sylvia Scribner* (pp. 266-280). Cambridge University Press: New York.

Shirley JL. & Padgett SM. (2004). *Professionalism and Discourse: But Wait, There's More!* American Journal of Bioethics.,4 (2): 36-38.

Sierhuis M. (1996). *Selective ethnographic analysis. Qualitative Modelling For Work Place Ethnography. Collaboration and Practice: Work Anthropology in Corporate Settings*. Available at <http://www.agentisolutions.com/documentation/papers/Aaa.pdf>. Accessed 2<sup>nd</sup> January 2008.

Singer E. (1978). *Informed Consent: Consequences for Response Rate and Response Quality in Social Surveys*. American Sociological Review, 43(2):144 - 162.

Singer E. (2004). *Risk, benefit, and informed consent in survey research*. Survey Research, 35(2-3): 1-6. Available at <http://www.srl.uic.edu/Publist/Newsletter/2004/04v35n2-3.pdf>. Accessed 27<sup>th</sup> February 2008.

Singer E., Hippler HJ. & Schwarz N. (1992). *Confidentiality assurances in surveys: Reassurance or threat*. International Journal of Public Opinion Research, 4: 256–68.

Singer E., Van Hoewyk J. & Neugebauer RJ. (2003). *Attitudes and Behavior: The Impact of Privacy and Confidentiality Concerns on Participation in the 2000 Census*. Public Opinion Quarterly 67, 368-384.

- Singer E., Von Thurn D. & Miller R. (1995). *Confidentiality assurances and survey response: A review of the experimental literature*. *Public Opinion Quarterly*, 59: 266–77.
- Social Research Association. (2003). *Ethical Guidelines*. Available at <http://www.the-sra.org.uk/documents/pdfs/ethics03.pdf>. Accessed June 23<sup>rd</sup> 2007.
- Spradley JP. (1979). *The Ethnographic Interview*. New York: Holt, Rinehart and Winston.
- Spradley JP. (1980). *Participant Observation*. New York: Holt, Rinehart and Winston.
- Stenhouse L. (1975). *An Introduction to Curriculum Research and Development*. London, Heinemann.
- Storberg-Walker J. (2008). *Wenger's Communities of Practice Revisited: A (Failed?) Exercise in Applied Communities of Practice Theory-Building Research*. *Advances in Developing Human Resources* 2008; 10; 555. Available at <http://adh.sagepub.com/cgi/content/abstract/10/4/555>. Accessed 6<sup>th</sup> November 2008.
- Strauss AL. & Corbin JM. (1990). *Basics of qualitative research: Grounded theory procedures and techniques*. Newbury Park, CA: Sage.
- Svennson LG. (2006). *New professionalism, trust and competence: some conceptual remarks and empirical data*. *Current Sociology*, 54 (4): 579–593.
- Sweetman J. (2003). *Good clinical practice: a nuisance, a help or a necessity for clinical pharmacology?* *Br J Clin Pharmacol*, 55: 1-5.
- TESOL 1996-2007. *Qualitative Research: (Critical) Ethnography Guidelines*. Available at: [http://www.tesol.org/s\\_tesol/sec\\_document.asp?CID=476&DID=2157](http://www.tesol.org/s_tesol/sec_document.asp?CID=476&DID=2157). Accessed 29<sup>th</sup> Jan2008.
- The National Academy of Sciences (2003). *Exploring Challenges, Progress, and New Models for Engaging the Public in the Clinical Research Enterprise*. Clinical Research Roundtable Workshop Summary. <http://www.nap.edu/catalog/10757.html>. Accessed 24 July 2008.

- The Nuremberg Code. (1949). *Trials of War Criminals before the Nuremberg Military Tribunals under Control Council Law No. 10, 2:181-182*. Washington, D.C.: U.S. Government Printing Office.
- Trochim WM (2006). *The Research Methods Knowledge Base*. 2nd Edition. Available <http://www.socialresearchmethods.net/kb/constval.php> (1 of 2). (Version current as of 20 October 2006). Accessed 9<sup>th</sup> July 2008.
- Turner S. (1994). *The social theory of practices: Tradition, tacit knowledge and presuppositions*. Chicago: University of Chicago Press.
- Turner SP. (2008). *Cause, the Persistence of Teleology, and the Origins of the Philosophy of Social Science*. In *The Blackwell Guide to the Philosophy of the Social Sciences*. Eds Turner S & Roth PA (pp 19-41). [Online]. Blackwell Publishing Ltd. Available at <http://www3.interscience.wiley.com/cgi-bin/bookhome/117886345>. Accessed 19th July 2008.
- Vanderstraeten R. (2007). *Professions in organizations, professional work in education*. *British Journal of Sociology of Education*, 28(5): 621-635.
- Van Dongen AJ. (2001). *Good Clinical Practice, a transparent way of life. A review*. *Computerized Medical Imaging and Graphics*, 25: 213-216.
- Vasilyuk F. (1991). *The Psychology of Experiencing: The Resolution of Life's Critical Situation*. Hemel Hempstead: Harvester.
- Vella J. (2002). *Learning to Listen. Learning to Teach. The power of dialogue in educating adults*. Revised Edition. San Francisco: Jossey-Bass.
- Verma GK & Mallick K. (1999). *Researching Education: Perspectives and Techniques*. London: Falmer press.
- Vesper J. (2001). *Performance: The goal of training or why training is not always the answer*. *BioPharm*. (February issue): 44-46.

- Vinson NG & Singer J. (2004). *Consent issues raised by observational research in organisations*. NCEHR Communiqué, 12 (2): 35-36. NRC 46561. Available at <http://cogprints.org/3722/1/NRC-46561.pdf>. Accessed 27th February 2008.
- Vygotsky LS. (1978). *Interaction between Learning and Development* (pp. 79-91). In *Mind in Society*. (Trans. M. Cole). Cambridge, MA: Harvard University Press.
- Vygotsky LS. (1987). *Thinking and speech*. In R W. Rieber & A. S. Carton (Eds.). *The collected works of I. S. Vygotsky, Volume 1: Problems of general psychology* (pp. 39-285). New York: Plenum.
- Vygotsky, LS. (1994). *The problem of the environment*. In Van der Veer, R. and Valsiner, J. (Eds). (pp. 338-354). *The Vygotsky Reader*. Cambridge, MA: Blackwell,
- Wainwright D. (1997). *Can Sociological Research Be Qualitative, Critical and Valid?* The Qualitative Report, 3, (2). Available at <http://www.nova.edu/ssss/QR/QR3-2/wain.html>. Accessed 24th January 2008.
- Webb J., Schirato T. & Danaher G. (2002). *Understanding Bourdieu*. London: Sage Publications.
- Wells G. (1999). *Dialogic Inquiry: Towards a Sociocultural Practice and Theory of Education*. Cambridge, UK: Cambridge University Press.
- Wells G. (2000). *Dialogic inquiry in education: Building on the legacy of Vygotsky*. In C. D. Lee and P. Smagorinsky (Eds.), *Vygotskian perspectives on literacy research*. New York: Cambridge University Press, (pp. 51-85). Available at [http://people.ucsc.edu/~gwells/Files/Papers\\_Folder/Index%20Papers.html](http://people.ucsc.edu/~gwells/Files/Papers_Folder/Index%20Papers.html). Accessed 21<sup>st</sup> March 2008.
- Wells G. (2001). *Action, Talk and Text: Learning and Teaching through Inquiry*. Teachers College Press.

- Wells G. (2002). *Dialogue in Activity Theory*. *Mind, Culture and Activity*, 9(1): 43-66.
- Available at  
[http://people.ucsc.edu/~gwells/Files/Papers\\_Folder/Dialogue%20and%20AT.pdf](http://people.ucsc.edu/~gwells/Files/Papers_Folder/Dialogue%20and%20AT.pdf). Accessed 23<sup>rd</sup> March 2008.
- Wells G. (2007). *Who we become depends on the company we keep and on what we do and say together*. *International Journal of Educational Research*, 46: 100–103.
- Wells G. & Claxton G. (2002). *Learning for Life in the 21<sup>st</sup> century. Sociological perspectives of the future*. London: Blackwell Publishing.
- Wenger E. (1998). *Communities of Practice: Learning, Meaning, and Identity*. Cambridge, UK: Cambridge University Press.
- Wenger E., McDermott R., Synder W. (2002). *Cultivating Communities of Practice*. Boston: Harvard Business School Press.
- Wertsch JV., Del Rio P. & Alvarez A. (1995). *Sociocultural studies: History, action, and mediation*. In Wertsch JV, Del Rio P, & Alvarez A (Eds). *Sociocultural studies of mind* (pp. 1-34). New York: Cambridge University Press.
- Whalen MD. & Khin-Maung-Gyi F.A. (2003). *Human Research Protections and Good Clinical Practice (GCP): The relationship among GCP, the auditing process and institutional review boards*. *Journal of GXP Compliance*, 7(2): 44-48.
- Whitehead J. (1989). *Creating a living educational theory from questions of the kind, 'how do I improve my practice?'* *Cambridge Journal of Education*, 19(1): 41-52. Available at  
<http://people.bath.ac.uk/edsajw/writings/livtheory.html>. Accessed 2nd Oct 2002; 31 Aug 2008.
- Whitehead J. & McNiff J. (2006) *Action Research: Living Theory*. London, Sage.

- Williams J., Davis P. & Black L. (2007). *Sociocultural and Cultural–Historical Activity Theory perspectives on subjectivities and learning in schools and other educational contexts*. *International Journal of Educational Research*, 46: 1–7.
- Williams JS., Wake GD. & Boreham NC. (2001). *College mathematics and workplace practice: an activity theory perspective*. *Research in Mathematics Education*, (3): 69-83.
- Wilsher C. (2002). *A qualitative examination of FDA warning letters – what can we learn from GCP inspections?* *Qual Assur J*; 6: 143-157.
- Wilson J. (2003). *How are research and clinical trials governed?* *Clinical Trials*, ECP (Autumn). Available at [samedanltd.com](http://samedanltd.com). Accessed 29 July 2005.
- Wolcott HF. (1987). *On ethnographic intent*. In Spindler G. & L (Eds). *Interpretative ethnography of education: at home and abroad*. Hillsdale, NJ: Erlbaum.
- World Medical Association. (1964). *Declaration of Helsinki*. Available at <http://www.wma.net/e/policy/b3.htm>. Accessed 16th Dec 2006 and 16<sup>th</sup> March 2009.
- Worthen H. (2000). *Studying the workplace: considering the usefulness of activity theory*. Available at <http://lche.vesd.edu/MCA/Paper/worthen/helena.html>. Accessed 24th July 2007.
- Yamagata-Lynch (2003). *Using Activity Theory as an Analytical Lens for Examining Technology Professional Development in Schools*. *Mind, Culture and Activity*, 10(2): 100-119. Available at <http://www.niu.edu/~lynch/publications.html>. Accessed 15th April 2008.
- Young S & Mitchell J. (2003). *Putting more practice into communities of practice*. Paper presented to the sixth Australian VET Research Association Conference “The Changing Face of VET”, 911 April (2003). Australian Technology Park, Garden Street, Eveleigh NSW, Sydney. Available at [http://www.avetra.org.au/abstracts\\_and\\_papers\\_2003/refereed/Young.pdf](http://www.avetra.org.au/abstracts_and_papers_2003/refereed/Young.pdf). Accessed 22nd June 2007.

- Zimmerman JF. (2000a). *Something is missing from GCP training*. SoCRA Source. (Feb). Society of Clinical Research Associates. Available at [www.impactcg.com](http://www.impactcg.com). Accessed 10<sup>th</sup> Oct 2005.
- Zimmerman JF. (2000b). *T2K – Training 2000*. Applied Clinical Trials, (June). Available at [www.impactcg.com](http://www.impactcg.com). Accessed 10<sup>th</sup> Oct 2005.
- Zimmerman JF. (2000c). *GCP Training for clinical investigators: the top priority for a new era*. The Monitor Summer 2000. Association of Clinical Research Professionals. Available at [www.impactcg.com](http://www.impactcg.com). Accessed 10<sup>th</sup> Oct 2005.
- Zimmerman JF. (2000d). *Get ready for compulsory clinical investigator training*. The Monitor Fall 2000. Association of Clinical Research Professionals. Available at [www.impactcg.com](http://www.impactcg.com). Accessed 10<sup>th</sup> Oct 2005.
- Zimmerman JF. (2000e). *Welcome to T2K! Time to break old habits*. The Monitor (Spring). Association of Clinical Research Professionals. Available at [www.impactcg.com](http://www.impactcg.com). Accessed 10<sup>th</sup> Oct 2005.



## **Bibliography**

**BIBLIOGRAPHY**

Bower M. (1966). *The will to manage: Corporate success through programmed management*. New York: McGraw-Hill.

Bruner J. (1990). *Acts of Meaning*. Cambridge, MA: Harvard University Press.

Bulmer M. (1982). *When is disguise justified? Alternatives to covert participant observation*. *Qualitative Sociology*, 5(4): 251-264.

Dewey J. (1916). *Democracy and Education* [online]. Available at <http://www.gutenberg.net/etext97/dmedu10.txt>. Accessed on 18<sup>th</sup> May 2003; 10<sup>th</sup> June 2006.

Engeström Y. (1991). *Developmental work research: reconstructing expertise through expansive learning*. In Nurminen M & Weir G. (Eds.). *Human jobs and computer interfaces* (pp. 265-290). New York, NY: North-Holland.

Engeström Y. (2000). *Activity theory as a framework for analysing and redesigning work*. *ERGONOMICS*, 43 (7): 960-974.

Engeström Y. (2001). *Expansive Learning at Work: toward an activity theoretical Reconceptualization*. *Journal of Education and Work*, 14(1): 133-156.

Engeström Y. (2004). *New forms of learning in co-configuration work*. *Journal of Workplace Learning*, 16, (1-2):11-21.

Engeström, Y. (2007). *Enriching the theory of expansive learning: lessons from journeys toward co-configuration*. *Mind, Culture, and Activity*, 14 (1-2): 23-39.

Engeström Y, Virkkunen J, Helle M, Pihlaja J & Poikela R. (1996). *The Change laboratory as a tool for transforming work*. *Lifelong Learning in Europe*, 1(2): 10-17.

Fernandes J. (1993). *Review: A guide to the perplexed ethnographer in an age of sound bites*. *American Ethnologist*. 20(1): 179-184.

Freire P. (2003). *Pedagogy of the oppressed*. New York: The Continuum International Publishing Group Inc.

- Freire P., & Macedo D. (1987). *Literacy: Reading the word and the world*. Westport, CT: Bergin & Garvey.
- Gajic A., Herrman R. & Salzberg M. (2004). *The international quality requirements for the conduct of clinical studies and the challenges for study centers to implement them*. Editorial. *Annals of Oncology*, 15: 1305-1309.
- Gallimore R. & Tharp R. (1990). *Teaching mind in society: Teaching schooling, and literate discourse*. In L. C. Moll (Ed.), *Vygotsky and education: Instructional implications and applications of sociohistorical psychology* (pp. 175-205). New York: Cambridge University Press.
- Gibbs J. (2005). *What You Don't Know about AIP Can Hurt You*. Medical Device & Diagnostic Industry Magazine, November 2005. Available at [www.devicelink.com/mddi/archive/05/11/012.html](http://www.devicelink.com/mddi/archive/05/11/012.html). Accessed 30<sup>th</sup> November 2005.
- Glaze JE. (2001). *Reflection as a transforming process: student advanced nurse practitioners' experiences of developing reflective skills as part of an MSc programme*. *Journal of Advanced Nursing*, 34(5):639-647.
- Golby M. (2009). *Resourcing in crises? ICR Resourcing Forum*. *Clinical Research Focus*, 20(1): 21-23.
- Goldfarb N. (2006). *Clinical Research Milestones 1986 whistleblowers protected through Amended False Claims Act 1863*. *Journal of Clinical Research Practices*, 2 (6).
- Hall J. (2001). *The drug development process*. In *Principles of Clinical Research* Eds. Di Giovanna I and Hayes G. Hampshire: Wrightson Biomedical Publishing Ltd.
- Johnson DW. & Johnson RT. (1991). *Learning Together and Alone: Co-operative, Competitive and Individualistic Learning (3<sup>rd</sup> Ed.)*. Englewood Cliffs, N.J: Prentice Hall.
- Lester S. (1999). *Professional bodies, CPD and informal learning: the case of conservation*. *Continuing Professional Development Journal*, (2)4:110-121. Available at <http://www.openhouse.org.uk/virtual-university-press>.

Long LN. (1999). *ROI: Capturing the big picture*. Technical Training, (November/December issue): 31-33.

Lytle SL. & Cochran-Smith M. (1992). *Teacher research as a way of knowing*. Harvard Educational Review, 62: 447-474.

MacIntosh DR. (2003). *Clinical Monitoring. Answers to questions about Good Clinical Practice*. Applied Clinical Trials (July issue). 27-29.

Mezirow J. (1981). *A critical theory of adult learning and education*. Adult Education, 32:3-24.

National Commission for the Protection of Human Subjects of Biomedical and Behavioral Research (1974-1978). *Ethical Principles and Guidelines for the Protection of Human Subjects of Research (Belmont Report)*. (1979). Available at <http://www.hhs.gov/ohrp/humansubjects/guidance/belmont.htm>. Accessed 29 August 2008.

Petty G. (2004). *Teaching Today: a practical guide*. 3rd Ed. Cheltenham: NelsonThornes.

Salzberg M. 2003. *Quality requirements in clinical studies: a necessary burden?* Swiss Med Wkly, 133:429-432. Available at [www.smw.ch](http://www.smw.ch). Accessed 1<sup>st</sup> March 2004.

Schön, D. (1987). *Educating the Reflective Practitioner*. San Francisco, CA: Jossey-Bass.

Singer E. (1993). *Informed consent and survey response: a summary of the empirical literature*. Journal of Official Statistics, 9: 361–375.

Singer E. (2003). *Exploring the meaning of consent: Participation in research and beliefs about risks and benefits*. Journal of Official Statistics, 19, 273–286.

Singer E., Mathiowetz N. & Couper M. (1993). *The Impact of Privacy and Confidentiality Concerns on Survey Participation: The Case of the 1990 U.S. Census*. Public Opinion Quarterly 57, 465-482.

Sotto E. (1994). *When teaching becomes learning: A Theory and Practice of Teaching*. London: (Cassell Education). 1st Edition. Continuum International Publishing Group Ltd.

Stern D. (2003). *The practical turn*. In *The Blackwell Guidebook to the Philosophy of the Social Sciences*. Eds Turner S & Roth PA (pp. 185-206). Blackwell.

University of Oxford. *The Learning Needs Analysis Toolkit*. (2008). Available at <http://tall.conted.ox.ac.uk/lnat/benchmarking.php>. Accessed 16 June 2008.

U.S. Public Health Service Syphilis Study at Tuskegee. (2008). *The Tuskegee Timeline*. Dept of Health and Human Services. Centres for Disease Control and Prevention. 25<sup>th</sup> June. Available at <http://www.cdc.gov/tuskegee/timeline.htm>. Accessed 31st August 2008.

Vygotsky LS. (1981). *The genesis of higher mental functions*. In V. Wertsch (Ed.). *The concept of activity in soviet psychology* (pp. 144-188). Armonk, NY: Sharpe.

## Appendices

**Appendix A: Trainers' Forum mission statement**

*“...The steering group decided that the aims of the Forum will be to facilitate (in relation to training):*

- *Sharing of best practice*
- *Discussions of new technologies*
- *Discussions surrounding topical issues*

*To “Train the Trainer” will not be an aim of the Forum. The Forum will be open to any Institute member involved in training on a day-today or ad hoc basis who has training as part of their responsibilities or job description, whether employed by a pharmaceutical company/public sector or freelance consultant. We plan to hold meetings in May, September and December each year.”*

## Appendix B: Questionnaire

*This questionnaire is designed to gather information about trainers and their organisations, as part of a PhD research study in Education. By completing this questionnaire, you consent to responses being used for research purposes as part of a PhD thesis by Marie McKenzie Mills, Institute of Education, University of Warwick.*

*The questionnaire is anonymous, and totally confidential, so please be honest with your responses to give a fair and accurate representation of your situation. Please try to answer each item in this questionnaire as it best applies to you.*

### Section 1: Thinking about your current role & responsibilities

*Please circle the number for each response that most closely corresponds to your view.*

Section 1(a): Course design, delivery & evaluation

	Strongly agree	Tend to agree	Tend to disagree	Strongly disagree
--	----------------	---------------	------------------	-------------------

#### I can decide:-

1. Learning objectives	4	3	2	1
2. Content	4	3	2	1
3. Materials (course manuals, handouts, slides, exercises)	4	3	2	1

#### I can choose:-

4. Methods (classroom, e-learning etc.)	4	3	2	1
5. Strategies (lectures, exercises incl. Q&A, role plays, assessment tests etc.)	4	3	2	1

#### I have access to tools that:-

6. Check trainees' reactions to the course content, delivery methods etc. i.e. 'happy sheets'	4	3	2	1
7. Check knowledge or skill levels before, during or immediately after a training event	4	3	2	1
8. Assess changes in trainees' behaviour or attitudes on-the-job (O-T-J) after a training intervention	4	3	2	1
9. Assess whether training helped trainees achieve their performance-related goals	4	3	2	1
10. Measure the impact of training on business goals	4	3	2	1

### Section 1(b): Organisational tendencies

	Strongly agree	Tend to agree	Tend to disagree	Strongly disagree
--	----------------	---------------	------------------	-------------------

#### In my organisation: -

11. Training is performed on a reactive* basis	4	3	2	1
12. Training is performed on a pro-active* basis	4	3	2	1

*\*Please can you explain or give an example of what it means to be pro-active and/or reactive in your organisation?* \_\_\_\_\_

\_\_\_\_\_

\_\_\_\_\_

\_\_\_\_\_



<b>Continued</b>	<b>Strongly agree</b>	<b>Tend to agree</b>	<b>Tend to disagree</b>	<b>Strongly disagree</b>
<b>Section 1(b) Organisational tendencies</b>				
13. Trainees performance O-T-J is routinely assessed by trainers	4	3	2	1
14. Trainees performance O-T-J is routinely assessed by others* e.g. line managers	4	3	2	1
<i>*Please give details:</i>				
15. Training needs are identified from audit reports	4	3	2	1
16. Training needs are identified routinely using various O-T-J resources* e.g. monitoring visit reports	4	3	2	1
<i>*Please give details:</i>				
17. Training records contain evidence that shows trainees understand how GCP applies to clinical research	4	3	2	1
18. The methods used to train personnel about our processes and procedures are documented* e.g. in training manuals, SOPs, course curricula	4	3	2	1
<i>*Please give details:</i>				
19. Most internal training courses have been validated by a formal evaluation program	4	3	2	1
20. Training records contain evidence that demonstrates what trainees learned from a training session or course	4	3	2	1
21. An SOP for training documentation is available	4	3	2	1

## **Section 2: Demographics**

### **Trainer characteristics**

22. What is your current job title? \_\_\_\_\_

*Please answer all the questions by circling the response that most closely corresponds to your view in the 'Yes' or 'No' column.*

	<b>Yes</b>	<b>No</b>
I am male	2	1
23. I am female	2	1
24. I am a science graduate	2	1
25. I am a post-graduate*	2	1

\* Please provide details \_\_\_\_\_

<b>Continued</b>		
<b>Trainer characteristics</b>	<b>Yes</b>	<b>No</b>
26. I have a training qualification*	2	1
<b>* Please provide details<sup>224</sup></b>		
27. I am a member of more than one professional institution	2	1
28. Have you been in a training role in other organisations?	2	1
29. From your total work experience (inside & outside the pharmaceutical industry) approximately how long have you trained others?	Years	Months
30. When did you join the pharmaceutical industry?	Month	Year
31. When did you join your present company?	Month	Year
32. How long have you been in your current role?	Month	Year

*Please answer all the questions by circling the response that most closely corresponds to your view in the 'Yes' or 'No' column.*

<b>Organisational characteristics</b>		
	<b>Yes</b>	<b>No</b>
33. My present employer is a pharmaceutical company	2	1
34. My present employer is a clinical research organisation	2	1
35. My present employer is a biotechnology company	2	1
36. I am self-employed*	2	1

*\*If your employer type is not described in Q34 – Q37, please describe here :*

*Please place a tick in the box for the response that applies most closely to you.*

37. In my organisation globally there is between		
1 and 10 employees		
11 and 50 employees		
51 and 250 employees		
251 and 1000 employees		
1001 and 5000 employees		
Over 5000 employees		
Don't know		
Other *		

*\*Please give details:*

*Thank you for your participation. Please return to M. McKenzie Mills [Address details supplied]*

<sup>224</sup> Omitted in Questionnaire #1

## Appendix C: Research Project Information Sheet-1

Dear Colleague,

With your help and permission during today's Training Forum, I hope to gather research data for my PhD in Education at the University of Warwick. My working title is *A study of training practices in the field of pharmaceutical clinical research: concepts, methodology and experience.*

I need your help to gather data for my study, which is mainly about the effects of regulations on training practices. My primary aim is to explore the impact of regulations on different social and cultural traditions in organisations affecting training practices. The main objective is to examine relationships between characteristics of training practitioners, practice settings (i.e. organisational characteristics, support frameworks and constraining factors) and evaluation practices, especially in relation to GCP training.

My secondary aim is to explore perceptions about the practice of evaluation and evidence used to demonstrate outcomes in training records. My intention is to identify the differences trainers make as practitioners to training process, compared to subject matter experts. Eventually, I hope to share the results through publication.

Attached is a questionnaire. As the questionnaire is anonymous, and totally confidential, I hope you will feel free to respond as honestly as possible.

I will need to carry out some follow up interviews, either by telephone or in person. These will probably take no more than one hour. So, if you would be willing to take part in these, again in total confidence, to discuss issues relating to GCP, standards and training practices in your organisation, then please provide your name and contact details on the separate consent form. All information that I collect during and after the Forum will be treated in the strictest confidence and will not be used to reveal your identity in any way.

Your agreement to take part in my research means that you are willing for me to use data gathered today at the Forum, such as your responses to my questionnaire and any other information or observations that I may gather during the workshop for the purposes of my research.

Even if you do not wish to take further part in my research, if you complete the questionnaire, then please sign the consent form, then give both documents back to me.

Finally, regardless of whether you wish to be a participant, if you would like further information about my research in due course, then please do not hesitate to ask, call or e-mail me.

Kind regards,



Marie McKenzie Mills

Clinical Scientist and Trainer BSc (Hons), MA, MEd, C.Biol., MICR Tel/Fax/Mobile: [Details provided]

**Appendix D: Research Project Consent Form-1**

*A study of training practices in the field of pharmaceutical clinical research: concepts, methodology and experience.*

I give my permission for Marie McKenzie Mills to use data gathered for the purposes of her doctoral research. I understand that my participation is confidential, and that data will be anonymised.

Print name:

Signature

Date:

---

My contact details are provided below solely to allow interview arrangements to be made for the purposes of research.

E-mail address:

Telephone number:

Best time to call

Day \_\_\_\_\_

Time \_\_\_\_\_ a.m. / p.m.

**Return address:** Marie McKenzie Mills [*address details supplied*]

**Thank you for your help.**

**Appendix E: Research Project Information Sheet-2, 3 & 4**

Dear Colleague,

I need your help to gather data for my PhD at the University of Warwick. My working title is:

*[A study of training practices in the field of pharmaceutical clinical research: concepts, methodology and experience<sup>225</sup>.]*

*[Developing a community of practice for Trainers: towards a culture of conscience in clinical research<sup>226</sup>]*

One of my objectives is to consider the effects of regulations on training practices. You will be helping me to examine evaluation practices generally, and in relation to GCP training. Eventually, I hope to share the results through publication.

Attached is a questionnaire. As the questionnaire is anonymous, and your participation is confidential, I hope you will feel free to respond as honestly as possible. Data will be used solely for the purposes of research. No matter how little or how much you are involved in training others, your participation helps me to gather data for my study.

I would like to carry out a follow up interview, either by telephone or in person. This will probably take around 30 minutes to less than an hour. Another interview may be needed sometime after that, but not necessarily. In taking part in either of these interviews, you agree that I can use information gathered for the purposes of my research.

If you are able to help further with taking part in an interview, again in total confidence, then please provide your name and contact details either by e-mail or through completing and returning the consent form to the address at the bottom of the form. All information that I collect will not be used to reveal your identity in any way.

Even if you don't wish to take part in an interview, please return the questionnaire to me, at the address below, as soon as you can, preferably before [26<sup>th</sup> March 2007; 30<sup>th</sup> June 2007; 30<sup>th</sup> April 2008].

Finally, regardless of whether you wish to be a participant, if you'd like further information about my research in due course, then please don't hesitate to call or e-mail me.

Kind regards,



Marie McKenzie Mills BSc (Hons), MA, MI.Biol., C.Biol., MICR

Clinical Scientist and Trainer

Mobile: [details supplied] Address: [details supplied]

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<sup>225</sup> RPIS-2 & 3 [Circulated February 2007; May 2007]

<sup>226</sup> RPIS-4 [Circulated March 2008]

**Appendix F: Research Project Consent Form-2, 3 & 4**

*A study of training practices in the field of pharmaceutical clinical research: concepts, methodology and experience*<sup>227</sup>.

Developing a community of practice for Trainers: towards a culture of conscience in clinical research<sup>228</sup>

I am willing to be interviewed and for Marie McKenzie Mills to use data for the purposes of her doctoral research. I understand that my participation is confidential, and that data will be anonymised.

Print name:

Signature

Date:

My contact details are provided below solely to allow interview arrangements to be made for the purposes of research.

E-mail address:

Telephone number:

Best time to call

Day \_\_\_\_\_

Time \_\_\_\_\_ a.m. / p.m.

**Return address:** Marie McKenzie Mills [*address details supplied*]

<sup>227</sup> IC\_2 & 3 [Circulated February 2007; May 2007]

<sup>228</sup> IC\_4 [Circulated March 2008]

**Appendix G: Interview Schedule-1**

## Employer details

Type: CRO/ITP/Pharma?

Size: S/M/L

**Background**

Can you tell me a bit about your role in training?

Is it your main role?

How long have you been involved in training?

How or why did you get involved in training?

Do you consider yourself a trainer?

What did you do before you were involved in training?

What do you like / dislike most about the role?

**Qualifications**

Do you have a qualification in training? Y/N

Y – please give details

No – do you see yourself obtaining some kind of qualification in the future? Y/N

About your qualification in training:-

Can you tell me more about the story behind your obtaining it:-

Why did you go for it?

How did you do it?

Was it straightforward for you? Did your employer support you?

Y – please give details:  
tell me about the  
qualification you plan to  
get and why?N – any particular  
reason why no plans?

Do you agree / disagree with the statement that there's "...a shortage of trainers who have both subject matter expertise combined with training skills"?

**Training**

What are your aims with training?

For you, what does the process involve?

How do you like to be trained?

Why?

**Methods**

How do you go about achieving your aims?

How do you decide which methods to use?

What methods do you prefer to use at the TF? *OR*

Which methods would you prefer session leaders used at the TF?

Which methods do you think tend to be used most at the TF and why?

**Approach**

In your approach to training – is it mostly about:-

Discussing “issues” using whatever tools you decide help with the task OR

Giving / presenting information in whatever format is determined in your organisation, dealing with Q&A at the end?

Which approach do you think is most often used in CR training?

When it comes to GCP training: do you agree or disagree with the statement that "there are only so many things we can say about GCP and only so many ways we can say it"?

Would you be prepared to make a case that **quality** is more important than **quantity**, for example with an inspector, if they suggested that everyone needs GCP training at least twice a year?

*Why Y or N?* If Yes - How would you do that?

Can the TF help with this issue of quality vs. quantity (or any other issue re training standards)?

If so, how? If not, why?

*Review with interviewee which meetings have been attended as per list<sup>229</sup>*

Why have you attended some meetings and not others?

What did you want from the TF?

Were your aims / expectations fulfilled?

What did you do to fulfil your aims, if anything?

How would you describe your participation?

Did anything affect you, or stay with you from a particular Forum lecture or discussion?

How did this affect you?

---

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Date of Trainers Forum meeting	Agenda Title
Dec 2003:	Inaugural meeting
May 2004:	Formulating your training strategy (eval methods/TNA)
Dec 2004:	Innovative training techniques
May 2005:	A day in the life of...a trainer in the pharmaceutical industry
Sept 2005:	Preparing for Regulatory inspections
Sept 2006:	Managing learning
Dec 2006:	Are you fit for purpose? Developing the trainer
May 2007:	Regulatory inspections. The role of the trainer.
Sep 2007:	Making learning the priority



## Appendix H: Interview Schedule-2

### TF participation / relationships

How did you become aware / get involved with the TF?

How did the TF come about?

What difference did/does attendance make to you e.g. is it about meeting new people, earning CPD points for attending or something else? Why?

What do you have in common with other trainers who participate in / attend the TF? How does this affect you?

### TF organisation & processes – how does the TF work?

#### TF: common interests

What are your thoughts on TF's aims stated in mission statement: "...to share best practice; discuss topical issues and issues related to new technology; but that "the purpose of the Forum will not be to *Train the Trainer*".

What is your feeling about these as shared aims?

What's meant by BP? How is it shared?

From your point of view – what happens/happened at the TF?

Why do you see it this way - did something happen to shape your view at the TF / elsewhere?

Why is the TF not about training the trainer?

#### Dominant interests

What do you see as the purpose of the TF?

Who has responsibility for leading and/or organising the TF? Why?

How do you see the TF working? Who decides the agenda – issues/topics for discussion?

How are learning activities organised?

What about SGMs? What are they meant to do?

Why be a SGM?

Should SGM be made known to everyone?

What diff, if any, would that make to the TF?

What do you think can be achieved in working within the TF?

For example, can we agree "what's adequate training in GCP" with regard to inspection of training records?

How does the TF compare to other groups / societies you belong to, or meetings you attend?

Should attendees have **more** or **less** input into meetings as participants / organisers?

What difference might such changes make to the TF?

At what point would you consider changing your level of participation i.e. step up / down your involvement?

What would that mean for you i.e. what would you do to get more or less involved?

Is there a reason why you haven't done this yet?

What needs to change, or happen before you'd do this?

Support: Should materials from the TF be available generally on the ICR website?

What wider issues might be / are involved – e.g. practical difficulties with organising/running etc?

Any other aspect of the TF that's an issue for you that I haven't mentioned?

## Appendix I: Data coding conventions (in footnotes)

Source	Source identifier	Source data type	Source data identifier	Unique identifier
Trainers' Forum meeting	TF	Digital recording	DR	TF_DR_meeting id_meeting date
		Field Note	FN	TF_FN_meeting id_meeting date
Trainers' Forum session	TFS	Digital recording	DR	TF_DR_meeting id_meeting date-session#
		Field Note	FN	TF_FN_meeting id_meeting date_session#
Report of TF meeting	Rep	ICR journal (Clinical Research focus)	CRf	TF_rep_mtg id_mtg date_CRf issue_date
Steering Group	SG	Minutes	mins	SG_mins_mtg id_mtg date
Private communications among Steering Group	SG	e-mail	e-mail	SG_e-mail_date_topic title
		Meeting Feedback	Feedbk	SG_Fdbck_meeting id_meeting date
		Conference call	FN/DR_TC	Pre-meeting_meeting id_meeting date
				Post-meeting_mtg id_meeting date
Public communication from SG to TF members	TF_pu	Field note	FN	Meeting id_date
		e-mail	e-mail	TF-pu_e-mail_date_topic title
Personal communication	PC	Field Note	FN	PC_FN_TF member or interviewee #_participation status_EFD_date
		e-mail	e-mail	PC_e-mail_TF member or interviewee #_participation status_EFD_date
Interview transcript	Interviewee	Core, active or peripheral member	Core; act; peri	Interviewee#_participation status_EFD constructed or received

## Appendix J: Excerpt from a dialogical, enquiry session

Transcribed from Session 1, 6<sup>th</sup> December 2004, Trainers' Forum

Ref	Thick description	Coding
S1	The session leader, John (TFS-B), briefly introduces himself and his background, <u>writing a single word</u> "innovation" <u>on the white board</u> . He then <u>stands in silence, smiles, looking around</u> at participants. He then <u>invites participants to define</u> this word.	[Enq-Mdol-c] [Dial-Exp-c] [U-Mdol-c]
S2	<u>Participants offer several definitions</u> including: "...continuous change and improvement" "...doing better things or doing things better" "...something new" "...a new way of doing something".	[Par-Mdol-c] [Enq-Exp-c] [Dial-Exp-c]
S3	John then <u>leads discussion</u> about how innovation might also be <u>understood</u> not just as the introduction of something new or novel, but as "appropriate novelty" if it is to be useful or effective (which he also writes on the board).	[Enq-Mdol-c] [Fac-Mdol-c]
S4	He then <u>asks</u> : "...what culture do we need to encourage learning?" or "which is more appropriate, training needs analysis or learning needs analysis?"	[Open-Exp-c] [Ref-Mdol-c] [Incl-Mdol-c]
S5	After approximately <u>ten minutes discussion</u> , John says "... <u>me talking about innovation in this session is inappropriate, so...</u> ". He then <u>assigns</u> different parts of <u>an activity</u> to each group at four different tables.	[Par-Exp-c]; [Consc-Mdol-c]; [Org-Exp-c] [U-Exp-c]; [Ref-Mdol-c]
S6	<u>John ends the activity, asking each group to share understanding</u> about their part of the activity, after which John explains it's designed to identify and match specific learning skills with particular training methods through which they might be elicited.	[Par-Exp-c] [U-Mdol-c] [Org-Exp-c]
S7	Concluding, John poses further questions for reflection: "...which training methods promoted which skills of learning and which training methods help learning most?"	[Qual-Mdol-c]; [Ref-Mdol-c]; [Enq-Mdol-c]; [Think-Mdol-c]
S8	Discussion then ensues about why trainers have developed an over reliance on using PowerPoint slides:-	[Quant-Mdol-r]
S9	Participant 1: "...admittedly, using PowerPoint is easy, but it gets the message across quickly."	[Quant-Mdol-r]; [Trans-Mdol-r]
S10	Participant 2: "...yeah. But with standard operating procedures – how do we make them interesting? Sometimes there's just <u>too much to go through</u> . And <u>it's got to be done</u> . Running <u>an exercise is maybe ideal</u> ... but which bits do you focus on?"	[Quant-Mdol-r] [Comp-Mdol-r] [Qual-Mdol-c]
S11	<i>[Other participants nod their heads in agreement with this comment, and look to TFS-B for his feedback.]</i>	[Ortho-Exp-r]

- S12 John: "...So, picking up on that point (directing his gaze towards one group)...how then do we help learners to apply 'the message'?" [Qual-Mdol-c & Het-Exp-c]
- S13 Participant 1: "...well, often we've no time really...that's the problem...we just have to be able to show we've done it...slide handouts can go in the training file..." [Comp-Mdol-r]
- S14 Participant 3 interrupts: "... It's all very well talking about 'death by PowerPoint' but the reality is this is dry stuff and half the time you're under pressure to keep up...never mind anything else..." [Comp-Mdol] [Ortho-Exp-r]  
[*more knowing nods and cross-talking among the group*].
- S15 Discussion continues between six or so members, about the struggle to keep up with the quantity of curriculum content while attempting to maintain the quality of delivery, depending on the time/budget available. [Qual-Mdol-c] [Mod-Exp-c] [FJU-Exp-c]
- S16 John concludes discussion by asking participants: "... What has happened during the session? What was its purpose?" [Fac-Mdol-c]; [Mod-Exp-c]
- S17 Participants agree that there's a range of possible methods of teaching & learning to suit their purposes, but disagree that it's difficult deciding what method to use and when, while John responds: "...Learners must always be pushed to develop their analytic and evaluative skills to reach common agreement about what is understood". [Dial-Exp-c] [FJU-Exp-c] [Mod-Exp-c]
- S18 Finally, John explains that he demonstrated teaching and learning is possible without using PowerPoint. [U-Mdol-c; FJU-Exp-c] [TC-Mdol-c; TC-Exp-c]
- S19 Concluding, he then suggests to participants that they develop their training and learning skills further through seeking a qualification, details of which he then circulates<sup>230</sup>. [Consc-Exp-c]
- S20 During the break, I ask 11 participants what they thought of the session: four say they enjoyed it and found it inspirational; four others say it's confusing because although it was fun, they can't really see how such a methodology can be applied to their situation; three others consider it a waste of time and irrelevant to the serious business of clinical research since "...it's merely a chance for John to flog his wares" (Fred). [TC-Mdol-c/TC-Exp-c] [CSM-Mdol-r vs. TC-Exp-c] [CSM-Mdol-r]

- Session ends -

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230 City & Guilds The Introduction to Delivering Learning (7302); Jan 2003

### Appendix K: Excerpt from a monological, transmissive session

Excerpt from Session 4, 8<sup>th</sup> October 2008 Trainers' Forum, Part 4: Examples of a popular approach to investigator training (duration 03:22). Available at [http://www.pharmaed.net/media\\_gallery/video\\_gallery.asp](http://www.pharmaed.net/media_gallery/video_gallery.asp).

Ref	Thick description	Coding
S1	Following on from her previous monologue, Linda continues... "The <u>answer really does lie in face-to-face and virtual options, because of the cost of events, which is one big issue, particularly in this climate. Currently, however, the practical logistics - having whole departments - to get people together in one place, at one time, is not a sensible approach.</u> It's a pretty <u>luddite</u> approach.	[Qual-Mdol-c] [Quant-Mdol-r] ( <i>contradiction</i> ) [Ortho-Exp-r]
	[0.39sec].	
S2	[ <i>Silent audience with a few people shuffling in their seats</i> ]	[PresLi-Mdol-r]; [Info-Mdol-r]
S3	But, if you have a "live" investigator meeting, it means that you have a date by which you create all of the <u>material</u> . You have a date where you have people on their hindlegs <u>presenting that material</u> . And you have people who can listen to that - in an audience [ <i>points at audience present</i> ].	[Peda-T-Meth-r] [Trans-Mdol-r]
S4	And that's useful. [ <i>Tilts head to one side while shrugging shoulders</i> ] Some people really like that.	[Ortho-Exp-r]
S5	But if you have that live investigator meeting, you can <u>capture it in some format</u> - whether it's with a Powerpoint; with a transcription; or with an audio-recording; transcribing and translation; film it; stream it.	[Trans-Mdol-r] [Trans-Exp-r]
S6	[ <i>Gesticulates with hands for emphasis on certain words, and alternates between turning body to address the slide screen and the audience</i> ]	[PresLi-Mdol-r] [Info-Mdol-r] [Comm-Mdol-r]
S7	You can also then evaluate the live event. Because, of course, you capture it while it's happening. So, you have some feedback loop as to the quality of the <u>offering</u> .	[Trans-Mdol-r] (i.e. delivering a product not conducting a process)
S8	Then you can provide it "virtually", and track the uptake on the web. Then, <u>you will know who, at what</u> centre, has been in, <u>how long they've spent in</u> [ <i>the virtual environment</i> ]...	[Comp-Mdol-r]
S9	And in the test section - <u>who has answered which questions correctly or incorrectly?</u>	[Comp-Mdol-r]
S10	And you can <u>sort the data in a number of diff ways</u> : <ul style="list-style-type: none"> <li>• according to the investigator centre;</li> <li>• according to the line manager; role; country;</li> </ul> So, it's a very powerful management tool.	[Quant-Mdol-r]
S11	[ <i>Untranscribed section concerning <u>technical aspects</u> of learning management systems</i> ]	[2.07min] [Info-Mdol-r]; [Mono-Exp-r]
S12	The one very important thing to add on - I know there are	[2.28]

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	lots of people here, very experienced freelance trainers working in this area - <u>I don't, for one moment, think that's [referring to the virtual learning method described as a 'powerful management tool' in the previous segment] going to make any of you redundant.</u>		[Trans-Id-r]; [Excl-Mdol-r]
S13	[A few audience members appear distracted, and look away from the slide screen]	[2.11-3.17mins]	[Mono-Exp-r]
S14	Because, of course, there may well be a live event; but <u>part of the very useful approach, I feel, is interactive workshops after the event, particularly in relation to GCP,</u> which can be regionalised, so that they can be done in local language, even down to the centre level.		[Peda-L-meth-c] (contradiction)
S15	And that reduces the cost significantly. Because, you have people who know what they're doing. They've <u>been through the training materials</u> - be that on line, or disc versions, and then can explore the issues that still arise regionally.		[Cov-Mdol-r]
S16	And, that then makes a very <u>cost-effective implementation</u> of studies.	[3.21]"	[Comp-Mdol-r] [Quant-Mdol-r]

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### Appendix L: Interview extract, Line 160, Donald (interviewee #8)

I think the training cycle has been ... ever since I started training in '95 ... I think the training side is largely ignored. We don't quantify the gap. The training that we design is not always necessarily the correct training to fill that gap ... and then the gap is not evaluated later to find out if it's been closed. I think it's a box-ticking exercise in ... in most cases. People like to see that it's been done.

When people talk about an individual's training record, so again when we go back to procedural documents ... they'll say: um ... What percentage of people are (sic) compliant in SOPs, things like that? And I always ask the question: well, what do you mean by compliant? And, they say: well, what percentage of people have actually taken the training? My response is: well taking the training is not compliance ... and people have a ... I think they have a misunderstanding of what ... they ... or what we mean by compliance.

The fact that they've done the training doesn't mean that they understand how to implement that process, or how to comply with the process. I think that there's a joint responsibility...and I also think trainers don't do enough to push back to the senior managers. They don't do enough to actually explain the position and rather than push back and say: no, we're not doing that, because...etc.

If they're asked to develop some training, either by immediate reaction or by some perceived need, trainers immediately start to think about how they can develop the training. What they don't do - and I think this is another sort of area that's missing - is they don't try and quantify the gap ... they don't try and identify exactly what the problem is. Because sometimes - and this goes back to the training cycle - the problem does not require training solutions. It's something else. It is a non-training need, rather than a training need and what we try and do is fix non-training problems with training ... and the cycle goes on

And this is known. Everything I'm saying - you go to the Trainers' Forum, they all say this.

## Appendix M: Extract from handout distributed by a facilitative trainer

(5<sup>th</sup> March 2008 TF)

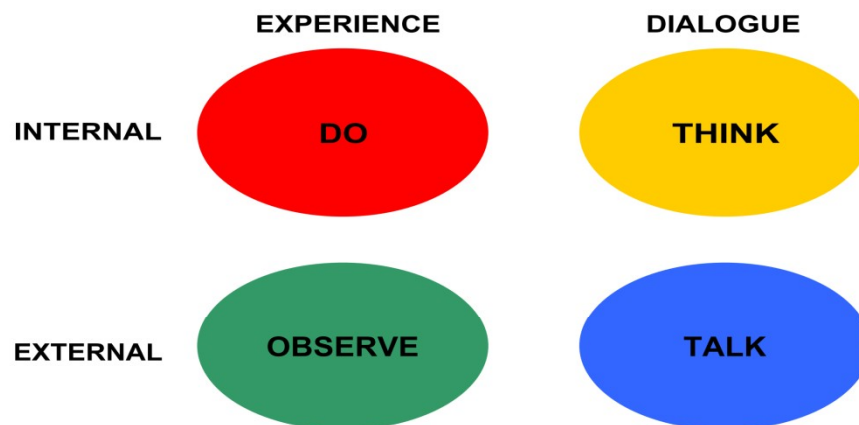


### ACTIVE LEARNING

Many educationalists today want to move past passive learning to active learning, to find better ways of engaging participants in the learning process. But many trainers feel a need for help in imagining what to do, in or out of the classroom, which would constitute a meaningful set of active learning activities.

The model below offers a way of conceptualising the learning process and choices that can be made.

#### A Model of Active Learning



3

Dee Fink, University of Oklahoma Instructional Development Program.

Available at <http://www.ou.edu/pii/tips/ideas/model.html>



Appendix N: Personal Communication (with James, 31<sup>st</sup> October 2008)

Ref	Segment	Analyses
S1	I would have needed to be made of asbestos to have survived the criticism repeatedly levelled at me for daring to suggest that, to quote a well-known American book, " <u>telling ain't the same as training</u> ".	[U-Mdol-c]
S2	The <u>near religious pursuit of training to achieve compliance prevents all rational discussion about how training should be approached, delivered, evaluated and accredited.</u>	[Consc-Exp-c] [Stds-Perf-Proc-c]
S3	Indeed, <u>why all the interest in training - what about learning?</u> Nearly <u>everything focuses on content delivered and recorded.</u>	[CU-cons-c]; [Conc-Mdol-c]
S4	The MHRA does not have sufficient resources to look into the <u>competence of trainers</u> and until they do I doubt that industry will concern itself with moving beyond their overweening dependence on the <u>weapons of mass instruction such as PowerPoint.</u>	[Stds-Comp-frmwk] [Think-Mdol-c]
S5	It is perverse that so much effort is directed towards achieving meaningful objectives for clinical trials which are themselves subject to peer review and external scrutiny yet <u>the concept of learning objectives gets little more than lip service.</u>	[Qual-Mdol-c]; [Excl-Mdol-r]
S6	<u>And as for all this about blended learning -- any Trainer and/or teacher worth their salt will know that a range of methods (blend?) is of critical importance in helping your learners achieve their goals.</u>	[Fac-Mdol-c]
S7	The second reincarnation of the Trainers Forum has seen it progress to a stage where <u>participation is perceived as the key to the future and evidence of progress beyond didactic methods.</u>	[U-Exp-c]; [Think-Mdol-c]
S8	As I have said earlier, participation for its sake alone is not sufficient and <u>illustrates a lack of understanding about the need to define learning objectives and then design/select appropriate methods to help accomplish these.</u>	[Consc-Exp-c]
S9	Moreover, it is important to remember that 95% all <u>learning takes place informally</u> when deciding how far learning objectives will be achieved during an individual training session.	[Dial-Exp-c]

## List of Abbreviations

### List of Abbreviations

AS	Activity System
AT	Activity Theory
BP	Best Practice
BERA	British Educational Research Association
Biotech	Biotechnology
CHAT	Cultural Historical Activity Theory
CIPD	Chartered Institute of Personnel and Development
Clin Ops	Clinical Operations
CPD	Continuing Professional Development
CoP	Community of Practice
CR	Clinical research
CRA	Clinical Research Associate
CRf	Clinical Research Focus (magazine title)
CRM	Clinical Research Manager
CRO	Clinical/contract research organisation
CSM	Curriculum subject matter
3-D	Three dimensional
DHHS	US Department of Health and Human Services
DoL	Division of Labour
DWR	Developmental work research
EC	European Community
EDR	Expansive developmental research
EFD/ EFDc/ EFDr	Epistemological Frame of Discourse indicating constructed or received knowing
EFsD	Epistemological Frames of Discourse
eLearning	Electronic Learning
EU	European Union
Eval/eval'n	Evaluation
F2F / F-to-f	Face-to-face
FT	Full-time
FDA	Food & Drug Administration
GCP	Good Clinical Practice
GLP	Good Laboratory Practice
GMP	Good Manufacturing Practice
HCI	Human-Computer Interaction
ICF	Informed Consent Form
ICR	Institute of Clinical Research
Investmt	Investment
ITP	Independent training provider

KB	Knowledge based
KBT(s)	Knowledge based trainer(s)
KM	Knowledge management
L1 -5	Kirkpatrick's levels of evaluation
MHRA	Medicines and Healthcare Products Regulatory Agency
n=	Number equals
NHS	National Health Service
PGCE	Post-Graduate Certificate in Education
Pharma	Pharmaceutical industry
PMs	Project Managers
Prep	Preparation
pTs	Professional Trainers
PT	Part-time
OHRP	Office for Human Research Protections
ORoP	Objective Regularities of Practice
OTJ	On-the-job
Q & A	Question and Answer
SG	Steering Group
SGm	Steering Group member
SIG	Special Interest Group
SME	Subject Matter Expert
SOP	Standard Operating Procedures
S. Quo	Status Quo
SRA	Social Research Association
SWOT	Strengths, weaknesses, opportunities, threats
RIS	Research Information Sheet
ROI	Return on investment
T/cycle (S1-4)	Training cycle (stages 1,2,3 &4)
TF	Trainers Forum
TFm	Trainers' Forum member
T & L	Teaching & Learning
TN	Training needs
TNA	Training Needs analysis
USA	United States of America
vs.	Versus