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### **Delivering Clinical Decision Support Services: There is Nothing so Practical as a Good Theory**

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## Commentary

Delivering clinical decision support services: There is nothing as practical as a good theory<sup>☆</sup>John Fox<sup>a,c,\*</sup>, David Glasspool<sup>b</sup>, Vivek Patkar<sup>d</sup>, Mark Austin<sup>a</sup>, Liz Black<sup>a</sup>, Matthew South<sup>a</sup>, Dave Robertson<sup>b</sup>, Charles Vincent<sup>c</sup><sup>a</sup> Department of Engineering Science, University of Oxford, Parks Road, Oxford OX2 3PJ, United Kingdom<sup>b</sup> School of Informatics, Informatics Forum, 10 Crichton Street, Edinburgh EH8 9AB, United Kingdom<sup>c</sup> Imperial CPSSQ, Imperial College London Medical School Building, St Mary's Campus, Norfolk Place, London W2 1PG, United Kingdom<sup>d</sup> Department of Academic Oncology, Royal Free Hospital, Roland Hill Street, London NW3 2PF, United Kingdom

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## 1. Introduction

In “Grand challenges for decision support” Sittig et al. [51] set out 10 critical problems for “designing, developing, presenting, implementing, evaluating, and maintaining all types of clinical decision support capabilities for clinicians, patients and consumers”. Sittig et al.’s identification and prioritization of obstacles to the successful development and deployment of clinical decision support (CDS) technology drew on the experience of the authors and a number of consultants who are recognised leaders in the field. Their top 10 challenges include many that others in the field would strongly agree with; indeed they were identified and prioritized on the basis of empirical experience and with the expectation that overcoming these challenges will depend heavily on practical problem solving and finding out “what works” in clinical use. They published their discussion in order to “inspire stakeholders in a position to advance the state of CDS technology and practice”.

As active participants in this field we take the position that an empirical approach to design must be accompanied by sound theoretical principles and safe engineering methods. We illustrate this with an approach to CDS design that starts with a formal model of knowledge-based decision-making, clinical processes and distributed care services, identifying four key pillars of theory, and relationships between them. Sittig et al.’s challenges are reviewed to consider how such a framework can facilitate application design and implementation, clinical use, service interoperability etc. We do not claim a formal approach to design is an alternative to empirical evolution of clinical services but is a foundation on which practical experience can be understood, shared and built upon.

The background to this discussion of course is that we are currently seeing rapid growth of policy, and national development programs, in the area of eHealth (for example, see [42] and the [www.OpenClinical.org](http://www.OpenClinical.org) website). There is also considerable growth of applications and services for medical knowledge management and clinical decision support in the commercial sector (the OpenClinical portal currently lists 280 suppliers worldwide<sup>1</sup> and this is certainly incomplete). However, Sittig et al. observe that “There are few CDS implementations to date in routine clinical use that have substantially delivered on the promise to improve healthcare processes and outcomes, though there have been an array of successes at specific sites in individual domains”.

The fragmentation and slower take-up of CDS technology than many of us expected are a consequence of many factors [27]. Key challenges for large-scale take-up of CDS technology include the need for integration with standards (e.g. [54]) and the creation of mechanisms for capturing medical knowledge with good properties of verifiability, scalability, reusability, interoperability etc.

While published evidence supports the view that clinical successes are still limited and the field is fragmented Sittig et al. seem to us to be taking an overly pessimistic position. Technologies based on the PROforma decision-modelling and workflow-design language [53], for example, have been used to build many applications which have been successfully trialed [19,20].<sup>2</sup> Nevertheless we endorse many of Sittig et al.’s observations from a UK perspective and we wish to add to their analysis by offering a complementary view that, as in other fields of engineering, the empirical identification of practical issues and evolution of pragmatic solutions needs to be accompanied

<sup>1</sup> <http://www.openclinical.org/suppliers.html>.<sup>2</sup> A commercial platform, Arezzo<sup>®</sup> is available and has been used to deliver a number of proprietary applications including a national roll-out of decision support applications which is under way in New Zealand and a decision support service for patients, NHS Direct, in the UK (see [www.infermed.com](http://www.infermed.com)).<sup>☆</sup> A response to Sittig et al. Journal of Biomedical Informatics 41 (2008) 387–392.\* Corresponding author. Address: University of Oxford, Oxford, United Kingdom.  
E-mail addresses: [john.fox@eng.ox.ac.uk](mailto:john.fox@eng.ox.ac.uk), [johnfox@robots.ox.ac.uk](mailto:johnfox@robots.ox.ac.uk) (J. Fox).

by principled approaches to design and implementation. A combination of good design theory and learning from practical experience is the way forward for successful delivery of CDS technologies.

The many technical, pragmatic, social and political challenges have frequently led to *ad hoc* design and delivery of decision support services. We believe this is in part an inevitable consequence of the research community being early in the learning curve, but that this is changing. As we will try to show in this discussion a formal approach to design can help in analysing practical problems, suggest possible solutions, and inform the design and implementation of the chosen solution.

## 2. Goals and approach

We have been pursuing a particular theoretical direction in our own research for many years, and we believe that this has proved to be more productive than might be anticipated from Sittig et al.'s analysis. We attribute *PROforma*'s successes in large part to the power of taking a *formal* and *declarative* approach to modelling the logical and procedural aspects of clinical decision-making, and the availability of tools and a development lifecycle which support this approach. Declarative modelling techniques have guided language design; logic programming has been extensively used in application engineering, and mathematical logics of various flavours provide the formal foundations for the work. Our approach to modelling clinical expertise also draws heavily on work in cognitive science, AI and knowledge engineering.

We have chosen to discuss Sittig et al.'s paper around this particular approach because it is the one we know best and because our aim is to illustrate in concrete terms one theory-based approach to design. We wish to acknowledge at the outset, however, that other approaches might have been taken, and that others may prefer to take, such as those based on statistical approaches to decision-making, operations research and organisation theory, and rigorous software engineering methodologies will play a key role in delivering the kinds of informatics services we discuss. We have no doubt that readers with a different bent could argue that such methods also provide the basis of a principled approach to the design of clinical decision support services, and that this might well yield different or even greater benefits. However, we would reiterate Sittig et al.'s invitation for all to participate in the discussion of grand challenge problems in the field, and the benefits of other approaches to achieving our shared objectives.

The discussion that follows is grounded in four key dimensions, covering decision-making and decision theory, process modelling and workflow, knowledge representation, and organisational theory. Each of the dimensions is also a major research area in its own right. However, we do not provide a review of the relevant research literature here. We are not setting out to review the field any more than was the original essay that we were responding to. Like Sittig et al., we wish to use our discussion as a vehicle to make methodological and strategic observations and to contribute to the debate they initiated.

Lastly, discussions with our colleagues frequently reveal “grand challenge problems” that do not appear in Sittig et al.'s list of 10, nor in our list. It is not our aim to propose a complete view of the key challenges facing the field (nor was it Sittig et al.'s) but only to use some of the widely acknowledged research challenges to motivate the development of an engineering framework which will inform the sound design and safe deployment of CDS applications.

## 3. The scope of “clinical decision support

We start by revisiting the question of what CDS is, since this determines the scope of any design theory that will be fit for pur-

pose. Sittig et al. define a CDS system as “providing clinicians or patients with computer-generated clinical knowledge and patient-related information, intelligently filtered or presented at appropriate times to enhance patient care”. In a recent systematic review of clinical decision support Garg et al. [22] reviewed 100 different published trials. A classification of these systems is given in Table 1. This is consistent with Sittig et al.'s definition: the majority of CDSs published to date offer relatively simple functions such as alerts and reminders, and information search, retrieval and filtering services.

However, the definition contrasts somewhat with Greenes' [27] observation that the purposes of decision support systems are diverse, leading to a need for a variety of capabilities including answering questions, actively making decisions and monitoring and optimising processes and workflow (p87). Only a small number of the service types in Table 1 offer help in identifying options, weighing evidence for the options and making recommendations based on evidence. Furthermore, none of the applications reviewed by Garg et al. appear to be aimed at supporting extended clinical workflows or management of information and decision-making in plans that unfold over time (e.g. chronic disease management and multi-disciplinary care pathways).

While the provision of patient-specific and timely reminders and filtered information to decision-makers is important our view is that the aspiration of CDS developers should be to support as many elements of the clinical decision process as possible, and that decision-making, workflow management and care planning and monitoring are important aspects of clinicians' work that can clearly benefit from computer support. Guideline modelling languages such as Asbru [49], GLIF [41], and *PROforma* [18,53] have in contrast set out to provide formalisms for specifying decisions in the context of clinical workflow and care plans. The data in Table 1 are telling as they suggest not only that it is more difficult to deliver the more sophisticated forms of CDS but also that the chances of success, shown in the final column, fall with increased complexity.

This inevitably invites pessimism about the potential clinical value of more complex services and hence an emphasis on “challenges”. Our own interpretation is more optimistic: we are still learning how to develop and deliver CDS technologies of all kinds, and at this point it is not surprising that it is easier to build simple rather than sophisticated applications. However, we should not limit the scope of our discussion to applications with simple technical solutions since our technical capabilities will no doubt progress.

Different developers have different priorities for decision support R&D. Greenes, for example, [27] sees workflow support as complex and relatively low priority. Tu et al. [54] limit their objectives in developing the SAGE guideline platform to “workflow aware” decision support. However, we argue that the research community needs to understand how decision-making fits into

**Table 1**

A selective classification of different types of clinical decision support systems reviewed by [22]. The third column shows the number of each type and column 4 the number of these which demonstrated significant clinical benefits.

Capabilities	Example techniques	Instances	
Monitoring, alerts and reminders	Algorithmic and rule based methods	41	30
Modelling and prediction	Calculators, Statistical modelling	35	24
Focusing and information retrieval	Search engines, navigation, InfoButtons	11	6
Framing and making decisions	Decision analysis, logical decision models	7	2
Support for complex and multi-disciplinary care	Workflow	0	0

the larger procedural and organisational context of care in order to ensure that current technologies are realistic and safe, and to open up options for more sophisticated CDS services in the future.

#### 4. Foundations for CDS design

We conceive of clinical decision support technology as based on four theoretical “pillars”: decision theory, theories of knowledge representation, process design, and organisational modelling. As remarked above we do not regard this particular choice as complete or unique; however, we do believe it is important to have a consistent and sufficiently broad theoretical framework, whatever it may be, as a basis for rigorous work on CDS technologies.

##### 4.1. Decision theory: Descriptive and normative approaches

A precondition for a well conceived approach to CDS design is surely an understanding of the nature, strengths and limitations of human decision-making in the clinic. There is a well established research literature on human judgment (covering reasoning, problem solving and decision-making, see e.g. [8,25] and how this research illuminates the nature of clinical judgment including the causes and prevention of medical errors (e.g. [13,47]). Errors arise from everyday mistakes, such as forgetting or not being aware of key information, but also from not-so-simple judgmental biases of which we are generally unaware [55]. Cognitive biases and other sources of error have long been recognised in clinical settings (e.g. [14]) as has the potential for their mitigation with decision support technologies.

There is an even larger research tradition in “rational” reasoning and decision-making. These subjects have been investigated formally in many disciplines, including applied mathematics, statistics, and computer science and applied to medicine, economics and in many other fields. Orthodox theories of rational medical decision-making usually adopt a quantitative approach, such as decision models based on multi-attribute and expected-utility theory (see e.g. [52]). These can be contrasted with proposals in computer science and AI where symbolic frameworks and logic languages for formalising medical knowledge have been more prominent.<sup>3</sup>

Our own approach to decision-making in the clinical context is based on a cognitive view of rational decision-making which subsumes a number of distinct types of logical inference [17]. By “inference” we mean any process that derives conclusions from data, and by “rational” we mean inference that is consistent with defensible norms. The main kinds of inference within this framework are: (1) inferring clinical goals; (2) generating decision options or candidates which will satisfy a goal; (3) identifying relevant evidence and constructing arguments for each candidate based on the evidence; (4) assessing and comparing the overall merit of the candidates; and (5) making commitments based on relative merit and other criteria, such as safety criteria. As remarked earlier our purpose is not to justify this particular framework here but only to use it to demonstrate the feasibility and utility of one theory-grounded approach to the design of decision support systems.

##### 4.2. Process theory: Formal representation of processes and plans

A second important foundation for CDS design is an understanding of clinical processes. CDS research has in the main focused on

individual points of care rather than processes of care. Whether we consider aids like clinical alerts and reminders or more sophisticated data interpretation and decision-making, CDS developers tend to focus on individual tasks rather than care plans or pathways which are extended in time and are structurally more complex. A striking feature of Table 1 is that the majority of evaluations to date deal with clinical systems which are limited to a single point in time where data need to be recorded, alerts flagged or decisions made and orders issued. There have been relatively few studies of how to integrate CDS systems into care planning or clinical workflow.

In contrast, research on business process modelling has developed formal notations for automating workflows but there has been little work on situation interpretation or decision-making. However, with the growing success of CDS technologies the research community is turning its attention to more ambitious goals. The clinical guidelines community has recently developed computational models which combine decision-making with clinical process modelling. These can be used to specify clinical pathways, guidelines and protocols, care plans and other processes in an executable form, dubbed *Task Network Models* (TNMs) by Peleg et al. [43]. TNM languages such as Asbru, GLIF, and PROforma (op cit) are designed to capture clinical processes in a way that formalises tasks and execution constraints as clinicians perceive them.

There is also growing interest in comparing and combining TNM concepts with Petri Net formalisms which are popular in business process modelling [26,39] and this may provide a firmer basis for formal analysis of clinical workflow. The *1st International Workshop on Process-oriented Information Systems in Healthcare* took place in Brisbane, Australia in 2007, where central themes of the meeting were the use of clinical guidelines and decision support in the context of business process and workflow models.

##### 4.3. Knowledge theory: Formal representations of knowledge

A third foundation is the need for a sound theory of knowledge representation. Clinical decision-making and process planning apply medical knowledge in interpreting data and achieving clinical goals. Knowledge is formalised in AI and knowledge engineering using semantically rich representations of medical concepts and tasks. In the 1980s expert systems appeared as an alternative to quantitative decision-theoretic frameworks, in which decisions and processes were modelled using semantic networks; *if...then... rules*; task agendas; and so on. While showing promise these methods were criticised for lack of theoretical principles but have since evolved into very powerful and principled techniques. In our own work we have found first-order logic and associated logic programming techniques (e.g. [2]) to be highly expressive for representing medical knowledge and applying it in clinical process modelling and application development. These subsume a range of knowledge representation formalisms with well understood computational properties and efficient software interpreters.

Given continuing developments in medical knowledge representation it would be premature to insist on any particular formal framework for knowledge representation. However, our expectation is that all medical data and knowledge will in due course be modelled using semantically rich models, such as formal ontologies of medical concepts<sup>4</sup> based on first-order representation techniques such as description logics.

##### 4.4. Organisation theory: “Agents” and shared care

A final foundation for CDS design is a principled approach to understanding organisations, particularly distributed ones. Histor-

<sup>3</sup> Despite the scale and quality of the research, quantitative techniques for modeling clinical reasoning and decision-making under uncertainty have had modest influence on clinical practice. The dependence on hard-to-acquire objective data (such as statistical and cost-benefit data) and difficulties, shared by clinicians and patients, in understanding and acting appropriately on quantitatively framed decision models has limited adoption.

<sup>4</sup> <http://www.openclinical.org/ontologies.html>.



ically the responsibility for the detection and diagnosis of a patient condition and subsequent treatment and follow-up were localised, in that the knowledge, actions, and responsibilities required for these duties were centered upon a specialist team of professionals working in a particular physical place. However, clinical practice is increasingly complex, distributed and service oriented. Actions are performed at numerous specialist sites between which responsibilities for care are distributed (and patients move between them to access services). Tasks may still be localised but responsibilities are often distributed and/or shared between individuals who have limited knowledge of each other's expertise.

The pressures driving clinical practice in this direction seem irresistible because they derive from increasing demand for health-care provision. This might, at first sight, seem to spell trouble given Sittig et al.'s observation that clinical decision support systems have been effective only when narrowly applied. It is now possible, however, to formally specify specialist services such as decision support and workflow management, and we know how to confederate such systems without unduly compromising the autonomy of each local service.

Fig. 1 illustrates this with a model of a multi-disciplinary organisation that we developed for scoping decision support services for women with (or at risk of) breast cancer. The theoretical framework underlying our approach to organisational modelling assumes that clinical processes and their component tasks are carried out by autonomous specialist agents (human or software) that can provide decision-making, care plan management and other knowledge-based services when requested to by other agents. Each block in Fig. 1 consists of a nested set of services formalised in PROforma, where each service may provide support for clinical data capture, alerts, order entry, decision-making, local workflow management, communication and coordination, and so on. The service model includes over 220 local services and subsumes more than 65 different points in the pathway where clinical decisions need to be taken and which, if not taken correctly or properly coordinated, have the potential for patient harm (see video at [http://acl.icnet.uk/credoweb/videos/credo\\_short\\_hq.asx](http://acl.icnet.uk/credoweb/videos/credo_short_hq.asx)).

Each service or collection of services in this model is viewed as an independent agent that communicates information and requests for service to other agents in the organisation. Specialist agents can send messages to each other, seek advice and explanations for advice, manage workflows and care pathways, and identify other agents to take responsibility for particular aspects of a patient's care. We argue later that organisational and cultural aspects of deployment also often need to be considered in CDS design but theoretical foundations are weakest in this area and we see this as a key area for research. The use of multi-agent technology for

healthcare applications is a rapidly growing area of research, see e.g. Nealon and Moreno [40].

## 5. From theories to challenges

Each of these four theoretical pillars is a substantial field of study. However, our experience has been that many of the practical challenges for CDS lie at the *intersections* between these fields. This is useful as it allows us to conveniently organise our discussion of practical challenges within the six pair-wise intersections between the pillars A–D, although we do not attach any theoretical weight to this organisation. These six crossover areas are:

Decisions and plans:

- E: Knowledge representation for decision-making (A + C).
- F: Framing and making decisions within plans (A + B).
- G: Knowledge of and reasoning about processes and plans (B + C).

Sharing decisions and plans:

- H: Joint and distributed decision-making where responsibility is shared (A + D).
- I: Shared and distributed execution of plans in organisations (B + D).
- J: Managing distributed knowledge and data within and across organisations (C + D).

These topics seem relevant whatever theoretical point of view is adopted with respect to the design of decision support services. In the remainder of this section we briefly outline how each offers a distinct challenge to CDS research and development.

### 5.1. Knowledge requirements of decision-making

What information is important in making a particular decision? This question underpins concerns about filtering and summarisation of information, and the efficient design of human–computer interfaces, which are both challenges identified by Sittig et al. It lies at the intersection between theories of decision-making and knowledge representation (pillars A and C). There are many ways to approach this challenge depending on which theoretical platforms one chooses to adopt for decision-making and knowledge representation.

Logic is an expressive, versatile and intuitive language in which to formalise knowledge for decision-making. Fig. 2 shows an exam-

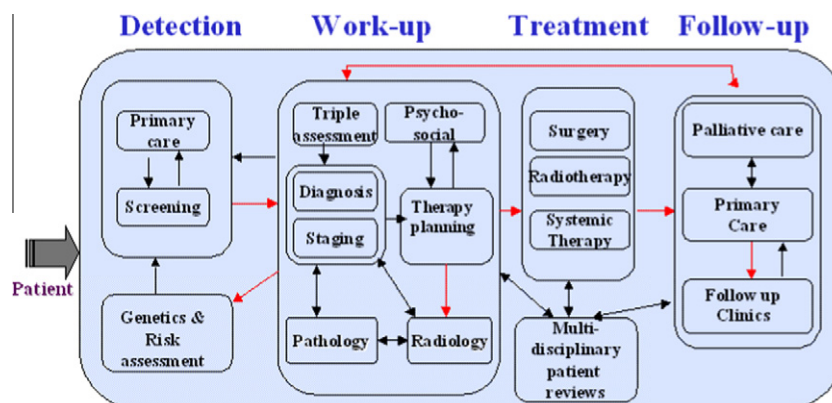


Fig. 1. Process model of a multi-disciplinary care pathway for patients with suspected breast cancer: the pathway should overall be read left to right (control flows through detection, work-up, treatment and follow-up phases) but many of the services within each box can run sequentially or concurrently depending on specific data flows shown by the arrows.

**Pathway information**

**Clinical tasks**

- Patient view
- Clinician view
- Edit baseline other risks for this patient
- adjuvantOnline tool for baseline risks
- Edit baseline cancer risks for this patient
- Edit evidencebase

**Additional services**

- View protocol summary
- View data summary
- Refresh page

**Advanced features**

- View PROforma plan
- View PROforma tree

Clinician view

**Best available evidence is presented in the form of pros and cons related to alternative possible interventions.**

**Considered interventions**

- Combined chemotherapy plus tamoxifen** ⓘ ⓘ
  - Improves overall survival by 50% compared to tamoxifen alone. ⓘ
  - Improves disease free survival by 50% compared to tamoxifen alone. ⓘ
  - May cause excess 20% risk of alopecia compared to tamoxifen alone. ⓘ
  - May cause excess 3% thromboembolic episodes compared to tamoxifen alone. ⓘ
- Adjuvant aromatase inhibitors** ⓘ ⓘ
- Adjuvant tamoxifen** ⓘ ⓘ
- Adjuvant combination chemotherapy** ⓘ ⓘ
- Ovarian ablation** ⓘ ⓘ
- No treatment** ⓘ ⓘ

**Pathway information**

**Clinical tasks**

- Patient view
- Clinician view
- Edit evidencebase
- Edit baseline cancer risks for this patient
- Edit baseline other risks for this patient
- adjuvantOnline tool for baseline risks
- Preference data

**Additional services**

- View protocol summary
- View data summary
- Refresh page

**Advanced features**

- View PROforma plan
- View PROforma tree

Patient view

**Weighing up the risks and benefits**

**Available options**

- Combined chemotherapy and tamoxifen** ⓘ ⓘ
 

You may have treatment with anti-cancer drugs (to kill any cancer cells that remain after surgery) and tamoxifen (a drug that blocks the action of oestrogen in the body).
- Aromatase inhibitors** ⓘ ⓘ
 

These are a newer type of drug that stop the body making oestrogen, a hormone that can encourage some breast cancers to grow. Aromatase inhibitors include anastrozole (brand name Arimidex), exemestane (brand name Aromasin) and letrozole (brand name Femara)
- Tamoxifen** ⓘ ⓘ
- Chemotherapy** ⓘ ⓘ
- Ovarian ablation** ⓘ ⓘ
- No additional treatment** ⓘ ⓘ

Fig. 2. CDS for breast cancer therapy based on the argumentation framework (see text).

ple of a decision support system which applies specialist domain knowledge of breast cancer in framing and making a decision about treatment. Here the user sees candidate therapies in order of relative overall preference, based on logical *pros* and *cons*, with *acceptable* candidates checked. The format can also be naturally extended to provide an evidence-based rationale for recommendations [21,24]. The underlying logical form of the arguments also facilitates presentation of information in other ways, as shown in the patient-oriented version at the bottom of Fig. 2.

However, there are significant research questions here, including:

- How can a logical model handle conflicting evidence and values? For example, a recommendation by a CDS for the management of a specific condition may be inappropriate for some patients but not others (e.g. one cancer patient values increased survival over poor quality of life due to an aggressive treatment, while another has the opposite valuation).
- Analogous issues arise whether one adopts an orthodox (e.g. expected utility) theory of decision-making or a more qualitative perspective on the underlying medical logic expressed as an argument net. A key question concerns the relationship between the clinically familiar and semantically intuitive concepts of “benefits” and “harms” versus the abstract quantitative notion of mathematical utility in decision theory.
- Is it possible to combine the naturalness and expressive power of logic with the benefits of quantitative decision models? This raises difficult technical challenges (see [32]).

## 5.2. Framing and making decisions within plans

Most CDSs are developed with one, relatively isolated decision in view (for example, what drug to prescribe, or whether to refer a patient to a specialist). However, in clinical practice decisions frequently cannot be viewed in isolation, because they may depend upon the results of previous ones or influence future decision points in a plan that have not yet been reached. The challenge is to apply theories of decision-making in the context of a framework for understanding processes and plans – the intersection between areas A and B.

Much of clinical practice can be understood in terms of creating, modifying or interpreting plans which are extended in time (treatment plans, trial protocols, care pathways etc.) and subsume many decision points that potentially interact to reduce treatment effectiveness, clinical efficiency or patient safety. This point is well illustrated by the work of Peter Hammond ([17], chapter 8) who carried out a detailed review of more than 50 cancer treatment protocols in order to identify potential interactions between treatment actions that had possible safety implications, and developed formal rules that would guide the management of these interactions. An example of a Hammond rule concerns the need to avoid action side effects that could diminish the benefits of treatment or exacerbate known hazards, and ensure that actions are scheduled in the safest way. These principles were captured as programmable rules expressed in first-order logic. For example:

*If* Action1 has been decided as a part of Plan and  
Action2 has been decided as a part of Plan and

Action1 followed by Action2 causes Effect and  
Effect is hazardous

Then Action1 should be performed after Action2 in  
Plan

Despite the importance of plans and planning in clinical practice there appears to be little scientific research into how clinicians actually plan care. Planning is demanding in terms of cognitive resources [23] and time. This creates pressure to minimise individualisation of care, despite wide agreement on the need for increased personalisation. As with experts in other domains [35] clinicians reduce the need to generate plans from scratch by learning large numbers of simple, stereotyped plans during their training and practice, which they may adapt to different situations.

The management of a patient over time can be viewed as the traversal of clinical “scenarios” and associated actions and further decision points along a single path rather than constructing detailed individual care plans *ab initio*. Johnson et al. [29] draw on this idea in their proposal for a care planning model in which simple *rule-in* and *rule-out* conditions are associated with each clinical scenario to determine the next course of action. However, we are not aware of any systematic efforts to formally model decision-making within care planning. As remarked earlier most work on CDSs has focused on individual decision points; extensions of clinical decision models into the temporal and process domains seem overdue.

### 5.3. Reasoning about tasks and plans

As clinical informatics moves beyond simple risk calculators and treatment choices and towards supporting complex treatment pathways extended over time, the demands on the formal theory underpinning the systems become correspondingly greater. For example, we would like formal strategies for analysing whether a computerised guideline really is a faithful representation of the authors’ intentions, or to check for issues like ambiguity, incompleteness, inconsistency, violation of regulations or operational constraints. Unless there are defensible principles for checking and updating plans there will be implications for patient safety.

Plans can be described formally in a number of notations, including workflow modelling notations such as BPMN [58], planning languages developed in AI (see e.g. [6]), graph formalisms such as Petri nets [44], and languages for modelling clinical guidelines and pathways, such as task network languages [43]. Whatever one’s choice of process modelling style there are a number of potential benefits of using a formal process representation.

- The model can be directly translated into an executable form, so that decision support can be delivered as part of a workflow management service.
- Automated verification techniques can be used to check that a care pathway or patient plan is consistent, complete and satisfies critical constraints, such as timing, resource or safety constraints.
- Use of time and clinical resources can be optimised.

Relatively little work has been done to date on the formal analysis of temporal processes in medicine. However, the use of Petri Nets (PNs) and their higher level variants (Coloured PNs, time PNs, and hierarchical PNs) are being increasingly studied for their potential use for the integration of decision support and executable clinical workflow models and guidelines [26,39]. However, this modest body of work only scratches the surface of what we believe to be a key problem; how to formalise decisions in a context-sensitive way within extended care plans and workflows.

### 5.4. Joint and distributed decision-making for shared care

In modern healthcare systems treatment decisions are often made jointly by clinicians with different expertise who share responsibility for care (and the patient is increasingly involved as well). A comprehensive breast cancer service, for example, involves many individual professionals from half a dozen disciplines, and a number of key decision points in the treatment process require input from multiple clinicians. One mechanism for managing this is the “multi-disciplinary meeting” (MDM) in the management of cancer, in which the whole clinical team comes together to review a list of current patients and the therapeutic and other clinical decisions.

Shared responsibility for decision-making is likely to become increasingly common throughout medicine as the explosion of new knowledge forces greater specialisation, yet individual specialists only see part of the clinical picture – with consequent risks for reduced quality of care and patient safety. CDS systems will be expected to support such joint decision-making, for which we believe new collaborative decision models and technologies will be needed.

There is considerable research relevant to understanding group decision-making in, for example, the social psychology literature (see e.g. [12,16]). We have found it useful to view the challenges of joint decision-making as lying at the intersection between decision theory and organisation theory (pillars A and D). Issues within these areas that impinge on this challenge centre around communication and coordination of the information needed to make good decisions between participants [11]. Frameworks grounded in quantitative decision models, formalised medical logics, computational frameworks for multi-agent systems, or combinations of these and other approaches, are all potential candidates for providing the required theory.

### 5.5. Joint and distributed execution of plans within organisations

It is common today for doctors, specialist nurses and technical staff to take responsibility for different steps in a patient’s care plan. A care pathway may include many planned services, as illustrated in Fig. 1, each being the responsibility of a different specialist team, and each service subsuming multiple workflows and sub-plans. In multi-disciplinary cancer care each of these services, sub-plans, workflows etc. can be modelled as sets of interlocking guidelines and specialist decisions that should be enacted in a coordinated fashion. These include ordering investigations and specialist technical services such as imaging, capturing clinical data and recording adverse events, identifying clinical trials for which the patient may be eligible, and so forth.

Clinical computing and communication researchers have not extensively considered the theoretical issues of maintaining the integrity of complex, flexible processes that span groups of interacting people and systems, although some attention has been given to this problem by researchers viewing the organisational care pathways of clinical institutions in terms of large-scale flow of clinical work and information [45].

Applications have polarised somewhat into those which are highly centralised (coordinating all services and interactions through a server) versus more experimental work on distributed and multi-agent systems (e.g. [28,37,59]; Han, 2008). Multi-agent systems technology does not as yet have proven benefits for healthcare applications, and indeed raises significant issues for security, safety etc, but there are strong arguments that a wholly centralised approach to decision support and process management will not be viable in the medium term [3]. Issues of scalability and the desire for openness in accessing and using medical, scientific and other kinds of knowledge are key drivers for the need to

develop a more distributed perspective as we discuss in the Section 3.2.6.

### 5.6. Managing distributed knowledge and data within and between organisations

While agreeing with Sittig et al.'s view that impact of CDSs is most easily achieved by building systems that are focused on specific tasks and domains this view is not consistent with the aspiration to provide support for joined-up and multi-disciplinary healthcare. Our final challenge therefore lies at the intersection between knowledge representation and organisational modelling (pillars C and D) and concerns the management and maintenance of healthcare information that is distributed across organisations rather than held centrally. Addressing this will require a step change in the way medical information is managed, not simply connecting up many conventional computer systems.

In clinical institutions each component service of the overall system relies for its effectiveness on being focused and modular. However, decisions and plans must be carried out by specialist professionals working together in a coordinated way even though the medical knowledge and clinical data they need to work effectively are increasingly distributed over a wide variety of sources: a vast and growing medical literature; patient records and notes; databases local to different clinical services; and countless medical systems and devices with their own specialised data management functions. This specialisation, and the particular local needs and circumstances of each clinical unit, make it increasingly unlikely that large-scale centralisation of information systems will be helpful or practical. We will need more agile styles of integration.

The intersection of internet technology with knowledge engineering is producing such methods. New *formats* for standardising of the representation of knowledge passed between agents are emerging [36]; new *infrastructures*, such as peer to peer and grid environments (see e.g. [50]) can support flexible interaction and offer acceptable guarantees of anonymity and availability. New *languages* offer formal ways to specify interactions between agents (e.g. [7,46]). The fact that such facilities can now be delivered on the internet means that it is becoming possible to pull together evidence and data that lie largely outside the frontiers of any one healthcare provider, even one on the scale of the UK National Health Service. Instead of viewing openness as something to be suppressed, which is unachievable, technologies and methods are now emerging that can make it work in our favour and give us better decisions as the global knowledge base increases.

Having set out the main areas where we see key challenges to the development of theory and practice of decision support systems we can now revisit the 10 specific challenges identified by Sittig et al. in the light of this framework. Our approach is complementary to theirs; while they concentrated on issues that obstruct the adoption of current types of decision support we are discussing broad technical and scientific areas which introduce research challenges which, if not solved, will severely restrict the capabilities of CDSs into the future. We do not claim that our approach is uniquely correct, but we do insist that there should be *some* sufficiently versatile and demonstrably sound framework to underpin design in any field where safety issues are pervasive.

### 5.7. What should CDS applications provide?

#### 5.7.1. Summarise patient-level information

"No one can retain and process the entire content of a complicated patient's data". This remark by Sittig et al. refers to one of the major causes of human error and motivates the high priority they give to the problem of summarising patient information. In their short essay they do not consider what this might imply in de-

tail, nor what principles distinguish good and relevant summarisations from bad ones, but it is certainly a key problem.

There are many different ways of summarising patient data, ranging from disease-based or intervention-focused summaries to episodic and time-based overviews. For a practical example take the multi-disciplinary cancer meeting (MDM) referred to above. This mechanism is widely used as a coordinating and decision-making mechanism in the management of solid tumours in the UK. An MDM typically includes 20+ patients whose treatment is to be decided or reviewed in an hour or so, so there is a premium on brevity and relevance to the decision context. Fig. 3 gives two examples of summarisation screens from *MDT Suite* which has been developed for this setting<sup>5</sup> in the management of colon cancer at the John Radcliffe Hospital in Oxford, England.

Fig. 3a is an overview screen which is designed to give a fast reminder of each case before discussing the specific therapy decision. This summarisation mechanism uses a domain ontology describing cancer and related conditions and formalised in OWL, covering symptoms, signs and test results, and a "patient history" class. Each concept in the ontology knows how to summarise itself based on its property values and so a summary of the patient is generated recursively by asking the patient instance to summarise itself. The argumentation approach to decision-making creates further summarisation opportunities, such as considering arguments "which could be true" if certain data were known, leading to a missing data summary at the top right of Fig. 3b. The summariser identifies any arguments for each candidate for the decision for which a data value for one or more premises are missing, and then forms a comment describing how that argument could affect the decision regardless of what value it might be. These summaries are generated in a succinct form by including only items at the most general conceptual level determined by the colon cancer domain ontology [1].

A role of theory here is to guide the summarisation of data in a form that is natural for clinical users and relevant to their perceived task and responsibilities. As we see in *MDT Suite* various kinds of summarisation fall out of a logic-oriented decision theory in a straightforward way (area A above). However, the summarisation challenge also touches on area E (formal knowledge requirements for sound decisions); H (joint and distributed decision-making); and J (distributed representation of knowledge and data within organisations).

#### 5.7.2. Prioritize and filter recommendations to the user

Sittig et al. call for a robust, reliable, evidence-based CDS model which can automatically prioritize recommendations according to a "multi-attribute utility" model. Our own approach to this is based on the argumentation framework that lends itself well to the use of multi-attribute decision criteria, and the prioritization and presentation of the options with the associated evidence-based rationale (area E, knowledge representation for effective decision-making). Fig. 4 illustrates this for a decision about the choice of imaging modality in the initial assessment of women with suspected breast cancer [56]. In this particular example argumentation logic is used in a straightforward way. If arguments can be constructed that a candidate action is appropriate to the clinical situation, that candidate is presented to the user (filtering). Prioritization can be simply on the basis of the number of relevant arguments that can be constructed for and against each candidate action. In practice this simple approach is often highly effective though it can be enhanced with more precise quantitative techniques where required.

<sup>5</sup> Taken from *MDT Suite*, a decision support technology developed by Mark Austin and Matthew Kelly using a variant of the argumentation framework described earlier [1].



**John SMITH 68 Male**    **T2 N0 M0**    **Downsized**  
 Investigations | History | Images | Decision  
**Summary**  
 Presented with **Rectal Bleeding** and **Change in Bowel Habits**  
 WHO performance status **0** .  
**Downsized T2 N0 M0**  
**5 cm Low (0-5cm) tumour in Rectum** with **0 mm CRM**  
 Biopsy shows **G2 - Moderately differentiated Adenocarcinoma**  
**No metastatic disease**  
 Imaging studies: **MRI (colorectum), Colonoscopy** and **CT**  
 New biopsies show small focus of residual adenocarcinoma

**John SMITH 68 Male**    **T3 N0 M0**    **Pre-Op**  
 Investigations | History | Images | Decision  
**Select Candidate**  
 **Pre-Op Chemoradiotherapy**  
   Anterior rectal tumour [k]  
   CRM less than 1mm [k]  
   Low rectal tumour [k]  
   Stage II rectal cancer [nci/nccn]  
 **Pre-Op Long Course Radiotherapy**  
   CRM less than 1mm [k]  
   Patient can tolerate chemotherapy (consider chemoradiation) [acp...]  
   Stage II rectal cancer [nci]  
 **Surgery**  
   CRM less than 1mm [k]  
   Stage II rectal cancer (surgical resection) [nci/nccn]  
**Pre-Op Chemotherapy**  
**Chemotherapy for advanced disease**  
**Symptomatic Care**  
**Refer to Other Specialist**

Missing Data  
 Obstructing Primary  
 Tumour Mobility  
**Tethered rectal cancer would support Pre-Op Chemoradiotherapy**  
 Add Missing Data

**Fig. 3.** Screen shots from *MDT Suite* (see text). (a) Top: summary screen to assist MDM members to recall patient case (many team members) will have seen the patient before but with so many other patients a name or ID may not cue the appropriate context. (b) Bottom: treatment options summary with logical argumentation and reminders of missing data and possible relevance.

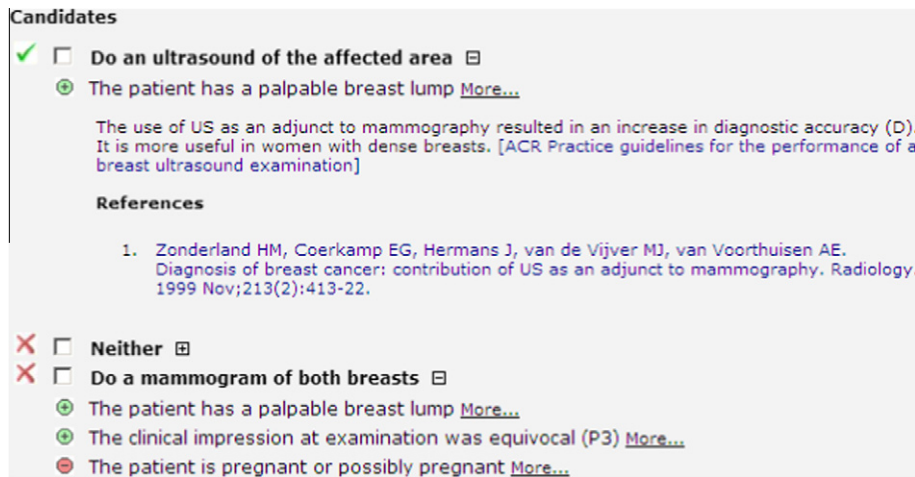
In terms of the framework outlined above we view this research challenge as firmly within area E but, as observed earlier, this observation is neutral about the specific decision procedure to be adopted, which may include logical, quantitative or hybrid methods.

### 5.7.3. Improve the human–computer interface

Kawamoto et al. [34] observe that the ability to support a clinician's decision-making at the point of care is one of the major success criteria for CDS systems. A common and well justified complaint, however, concerns the poor standard of user interfaces in many CDS applications (indeed in medical software generally). Sittig et al. list a variety of areas for attention, ranging from clearer displays to reduced intrusiveness (“proportional to the importance of the information”). Unfortunately the many different weaknesses

they identify are unlikely to be abolished by a couple of neat design ideas. Here we would again urge the benefits of an approach to design based on general principles as well as a pragmatic assessment of what has worked in the past.

An understanding of the nature of clinical decision-making is important for a successful CDS interface. In particular we see areas A (decision theory) and E (knowledge representation for effective decision-making) as providing the most relevant theoretical underpinnings. Two pieces of evidence for this claim come from the domain of clinical genetics. The RAGs system for taking family history and carrying out risk assessment for breast and ovarian cancer [15], and the REACT system for planning the care of women with a genetic predisposition to these diseases [23] both exploit argumentation in making and explaining clinical recommendations: 96% of GPs who used RAGs preferred the argument-based re-



**Fig. 4.** An example of a PROforma decision support service for advising on selection of imaging modality, ultrasound and/or mammography. The arguments for the option are listed under each candidate – arguments *for* are in green and marked with a plus, with arguments *against* in red (minus). The user can pull up the evidence that justifies any argument (e.g. clinical guideline, published trial) where required. All arguments are given equal weight in this example but where there is information to quantify the strength of arguments this can be displayed and incorporated into the recommendations. (For interpretation of references to color in this figure legend, the reader is referred to see the web version of this article.)

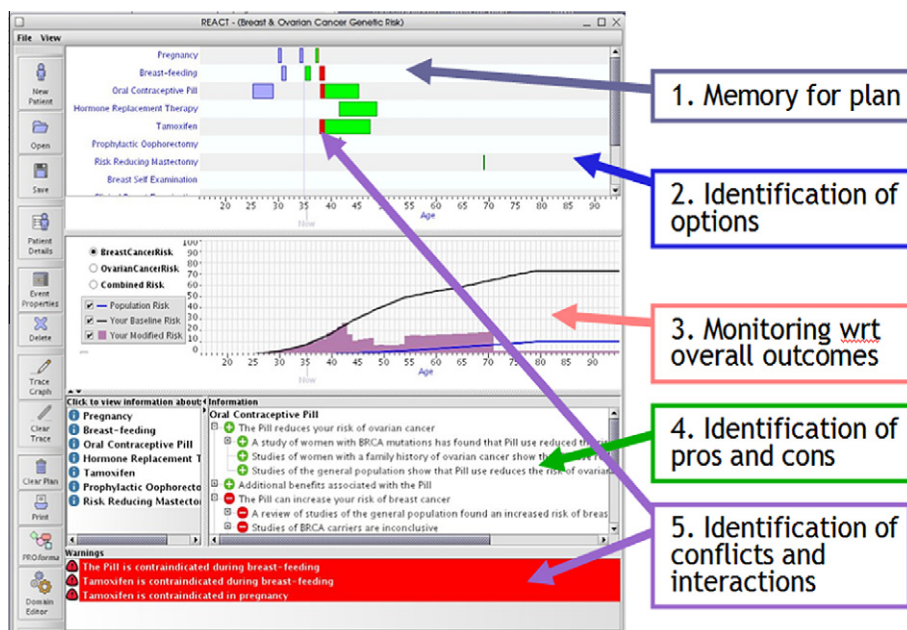
port to a statistical display of genetic risk [30,31]; 7/8 initially sceptical genetic counsellors found REACT's user interface to be clear and effective as a basis for working with patients during counselling (see Fig. 5). The combination of quantitative risk displays and argument-based explanations in REACT appears to provide effective mitigation of some of the cognitive demands created by the complex task of interpreting risk information and developing care plans [23].

In short, to improve usability of clinical user interfaces we advocate basing design around a firm theoretical understanding of the clinician's perspective on the medical logic in a decision, the qualitative as well as quantitative aspects of the decision, and providing an evidence-based rationale for all recommendations offered by a CDS.

#### 5.7.4. Combine recommendations for patients with co-morbidities

"The challenge" according to Sittig et al. "is to create mechanisms to identify and eliminate redundant, contraindicated, potentially discordant or mutually exclusive guideline-based recommendations for patients presenting with co-morbid conditions or multiple medications. "... Addressing this challenge may require new combinatorial, logical, or semantic approaches to combining and cross-checking recommendations from two or more guidelines".

Combining two plans logically is a non-trivial problem, and we see a particular challenge in providing sufficiently rich representations of process, rationale, and consequences of planned actions to allow this to be done in practice. Such a process may, for example, require knowledge not just of the particular steps in a clinical pro-



**Fig. 5.** The REACT system for planning under risk. The system has four main panels. Panel 1 shows a timeline and the set of events and actions on this time line (the user manipulates this directly). Panel 2 shows how risk changes over time during the proposed plan. Panel 3 shows the arguments for and against any selected action in the plan. Panel 4 highlights conflicts or other alerts. Risk, argumentation and conflicts are updated in real time if the user modifies or changes the timing of planned interventions.

cess but of the clinical goals those steps are intended to achieve (because these goals may be compromised in the combined plan even if the individual steps in the processes are correctly carried out). Another type of knowledge that is required is the expected result of combinations of clinical actions, for example, the action of drug A (required by treatment plan 1) in the presence of drug B (in treatment plan 2). In many cases this knowledge is available; contra-indications and interactions are well known for many classes of interventions, although they may not be familiar to the clinicians involved. However, in other cases predicting the combined effect of two medications may require a deep understanding of the domain, for example, in the form of a detailed physiological and pharmo-kinetic model.

Critical issues to be addressed within area I include how to combine plans specified in some formal language(s), identify interactions between concurrent treatment plans and identify inconsistent constraints and the knowledge required for their resolution.

Aspects of this challenge also fall within area E – formal knowledge requirements for sound decisions – because we need to determine the minimum amount of information that needs to be passed between clinicians in different specialities in order for them to make sound decisions, area H – joint and distributed decision-making – because we need to support negotiation between users when plans conflict, and area J – distributed representation of knowledge and data within organisations – because we need to understand how to make the right connections between distributed sources of information to ensure that all interactions between care plans are identified.

## 5.8. How to deliver CDS services better

### 5.8.1. Disseminate best practice in CDS design, development, and implementation

Sittig et al. view “best practice” largely in terms of the features that have made clinical decision support systems successful in the past. A conclusion of their commentary is that a challenge for the future is “primarily a matter of identification, communication, and education” to ensure that CDS designers are aware of what has been done and what they need to do to have a successful system. We share their concerns about the need for a community memory to avoid reinventing the wheel; our own contribution to addressing this problem is the OpenClinical information service and web portal ([www.openclinical.org](http://www.openclinical.org)). This aims to promulgate awareness of past and ongoing research, the state of the art in design and engineering of clinical decision support and knowledge management services, as well as practical successes in clinical research and in the commercial sectors.

This challenge is of course at a rather different level to previous ones. Dissemination of new practices in any technical field has to confront sociological, political and business obstacles (particularly where the research and development community is international) and these are distinct from the scientific and technical problems of identifying best practice. Consequently the purely technical framework we are discussing here is not directly relevant to this challenge. However, we would note some technical aspects of “best practice in CDS design” which would be mitigated by an explicit and rigorous engineering approach.

We would suggest, firstly, the importance of a sound professional knowledge of the four pillars of the field: decision theory, formal knowledge representation, process modelling and organisation modelling. Secondly, we would insist on the need for and use of good software engineering practices in CDS design and implementation – this is after all a field which is intimately bound up with human safety. Thirdly, it is critical to *support norms of best clinical practice* so the design, development and delivery of CDS applications should be accompanied by evidence or other form of

rationale for all recommendations. Lastly, designers and engineers need a broad appreciation of non-technical factors which will determine which CDS proposals are likely to be useful and which not and should not depend solely on technological expertise as a foundation for design.

### 5.8.2. Create an architecture for sharing CDS modules and services

This challenge concerns the modularisation of CDSs in order to simplify fabrication and delivery of new services. As Sittig et al. put it “The goal is to create standards based interfaces to externally maintained CDS services that any EHR could subscribe to in such a way that healthcare organisations and practices can implement new [CDS interventions] with little or no extra effort”.

The SAGE decision support infrastructure [54] emphasises a related need for standard formats which are integrated into the guideline model (e.g. SNOMED CT and LOINC for terminology, HL7 Reference Information Model or the GELLO expression language). To this list we might add standards for decision-modelling and for process modelling and workflow (including guideline interchange formats). In fact, as Fig. 6 shows, there are many potentially relevant standards covering a wide range of medical services, with new standards constantly emerging to extend or replace older ones. For example, any of the potential standards for modelling clinical guidelines (Asbru, GLIF, PROforma, SAGE etc.) may need to interoperate with CDS components formalised in a number of inference-related standards, including the HL7 standard GELLO, the Argument Interchange Format AIF developed in the EU funded ASPIC project [9] or Microsoft’s XML standard for Bayesian networks XBN.

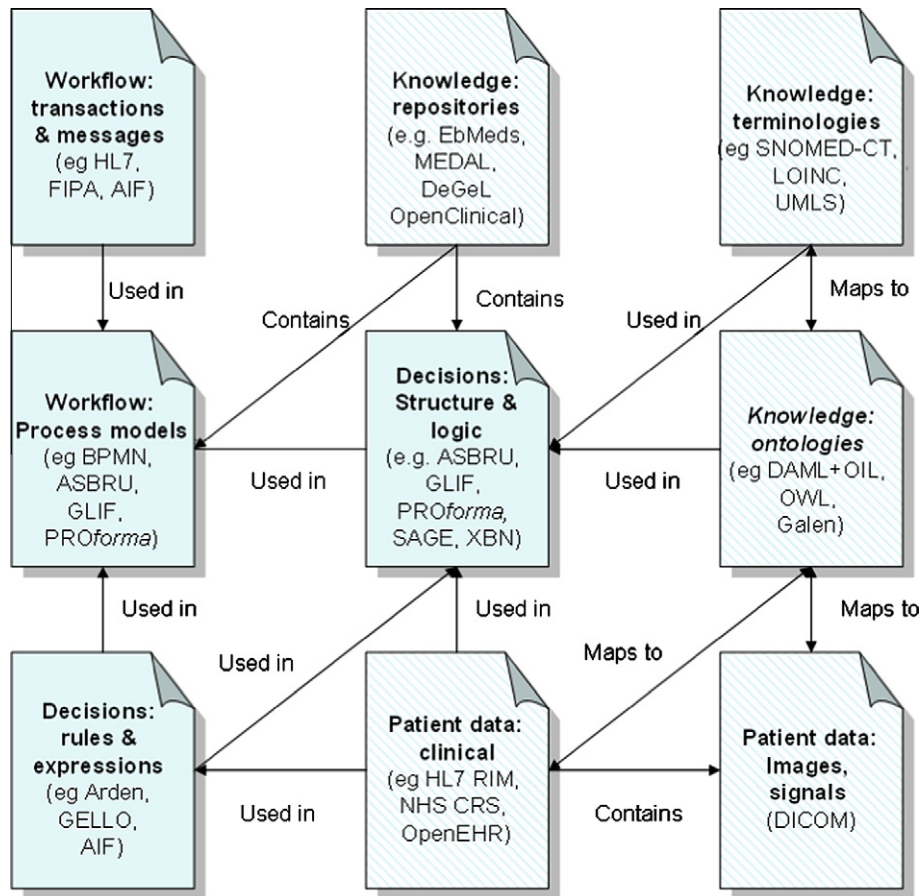
Sittig et al. consider the issues of standards and interoperability from the perspective of rapid deployment of services. Focusing on existing standards seems to be a sensible direction to take if one intends to build a CDS for the here and now, but adoption of specific standards is always a trade-off between the benefits that standardisation brings and the inflexibility and restrictions entailed in standards as circumstances change. In our view attention needs to be given to developing a more flexible framework that begins with the assumption that nothing is set in concrete: new standards *will* appear and *must* evolve as technological capabilities advance. We believe that a standards “meta-model” is needed to facilitate change, accommodating new decision support concepts and other service possibilities and formalisms as they appear.

A possible approach to take here lies squarely in research area B, in which the community would seek to agree a meta-standard, using a sufficiently expressive formal framework, such as ontological modelling in a description-logic with sufficient expressive power. On this model a standard and its component parts are seen as instances or sub-classes of a *generic standard* model. For example, all standards might be required to specify a controlled terminology (technical and/or medical); a syntax or grammar for defining predicate and function terms and expressions; mapping rules between ontological concepts and expressions in different standards etc. Intermediate nodes (sub-classes) in the meta-standard ontology would inherit these attributes.

We may also require that any CDS or guideline modelling standard makes reference to concepts like decisions, workflows, and communications. All proposals for decision support standards could be required to provide a syntax and semantics for representing options, evidence rules, and commitment rules; all proposed standards for modelling plans, care pathways or workflows might be expected to make explicit the steps of the plan, safety rules/abort conditions, and co-morbidity constraints.

The feasibility of a meta-ontology that would cover a range of decision support, process models, and related standards is speculative. Among the benefits of such a model, however, would be that it would guide definition of new standards, encourage discussion





**Fig. 6.** Some of the areas in which informatics standards exist that are likely to impact on the development and maintenance of CDS services (centre). Boxes which are hatched refer to data representation standards; others refer to standards for implementing clinical services. The particular set of “standards” are intended for illustration only; the maturity and level of acceptance is variable and the specific selection included are likely to date rapidly as new standards emerge.

between standards groups and help to ensure interoperability at a standard-to-standard level. Experience using an ontological approach to defining a meta-framework for modelling argumentation systems [9] suggests that these benefits are real though the evidence is scanty. Our primary objective, however, is to draw attention to the need for some kind of unified approach to standards without which, we believe, the current slow pace of adoption could well get worse as the number of legacy standards increases and begins to make interoperability of systems and components harder rather than easier.

### 5.9. Content development, use and reuse

The successful introduction of CDS systems is not just a matter of developing sound technologies and successful applications; the creation of bodies of knowledge (content) will also be critical for building clinical credibility and the business cases that industry will require if it is to invest in the field. Greenes [27] argues that the deployment of CDS technology will continue to progress at a slow pace until we have put a number of critical “lifecycles” in place that address challenges of supply, curation, and deployment of knowledge in an appropriate, scalable and safe way.

#### 5.9.1. Create internet-accessible CDS repositories

Although there are many public repositories of text clinical guidelines these documents have limited effect in changing clinical practice (e.g. [10]). We need to find ways of building on the huge global effort on guideline compilation in a way that does influence

practice. Greenes [27] and Sittig et al. summarise the challenge as building “one or more internet-accessible repositories of high quality, evidence-based, tested, clinical decision support knowledge modules ... which can be easily downloaded, maintained, locally modified, installed and used” ... “with appropriate business models to ensure sustainability”.

We agree that the move to internet-based guideline repositories, and especially the development of sustainable business models and ecosystems around them, are key. A number of repositories broadly of this type are already in development (e.g. EBMeDS in Finland,<sup>6</sup> DeGeL in Israel [48], the MEDAL medical algorithms project in development in the US [33] and OpenClinical.net.<sup>7</sup>

To achieve scalability and interoperability on a large-scale, we believe this effort will need to draw upon a deep understanding of the nature of clinical decisions and other tasks as well as the formalisation of knowledge. However, a move to internet-based guideline repositories is inevitable given the volume of guidelines currently in circulation and the increasing computer literacy of medical practitioners. We see many of the challenges in this area as practical rather than technical but hard technical challenges also remain of course – for example, Greenes [27] identifies the need for a systematic approach to knowledge authoring and curation, which is realistic about the sources of knowledge (in clinical research), quality of content (rigorous development, testing, and maintenance lifecycles) and the wide adoption of standards which facili-

<sup>6</sup> [http://www.kaypahoito.fi/kotisivut/sivut.koti?p\\_sivusto=1434](http://www.kaypahoito.fi/kotisivut/sivut.koti?p_sivusto=1434).

<sup>7</sup> <http://www.openclinical.net>.



tate reusability of content and interoperability or applications as discussed earlier. Here it seems that we will face theoretical as well as practical challenges in knowledge representation (area B), modelling clinical decisions (A) and processes (C).

#### 5.9.2. Prioritise CDS content development and implementation

Given the current state of the art Sittig et al. believe that the development of content on a convincing scale will take many years, and that we will need to prioritise this development to maximise value on the shortest possible timescale. For example, we may choose to prioritise chronic care applications over acute care, or patient demands over clinical value. This seems to be a political challenge more than one of informatics, concerning the policy opportunities and choices created by technical developments rather than the technical problems themselves. In fact we wonder whether this is a “challenge” that the research community can address at all. Priorities can be set in a centralised way but large healthcare organisations and national programmes, such as the NHS or the National Institute for Clinical Excellence in the UK struggle to retain control as patients vote with their feet and clinicians with their clinical judgement. We do not take a strong position on this but we note that many observers feel that national and other priorities will be set by the beneficiaries – including commercial content providers and patient lobbies as well as healthcare organisations – not by the R&D community.

What we as researchers in the technical aspects of CDS are perhaps able to contribute is ways of making the process of developing CDS content easier and quicker. One way in which we believe this will happen is through the gradual creation of internet-based communities of practice (see challenge 7), which, if appropriate infrastructure is available, can establish a “virtuous cycle” in which more and more people and organisations can participate in the development, review, use and refinement of guideline content. This could lead to progressive increases in the efficiency of the content development processes, validation and deployment processes.

#### 5.9.3. Mine large clinical databases to create new CDSs

As part of the scalability agenda Sittig et al. identify the need to develop “new algorithms . . . to mine large clinical data repositories to expand the global fund of clinical knowledge, which . . . underpins CDS interventions [and] improved outcomes”. This point is orthogonal to, though not independent of, CDS R&D because it centres on generating new knowledge rather than applying the knowledge. Their key point is that we need automated machine learning as well as manual data mining techniques.

There is abundant evidence that the huge amount of medical information that we already have – generic knowledge and personalised data – has insufficient influence on clinical decision-making. Increasing the store of knowledge, while clearly an improvement, does not address the specific challenges of providing effective CDS services (in fact it makes the situation more challenging). We would therefore prefer to separate the issues of information generation and information use in order to focus more clearly on the immediate problems of making effective use of the knowledge we already have, so that we can do justice to the acquisition of new knowledge which advances in machine learning and data mining will undoubtedly bring.

#### 5.9.4. Use free text information to drive clinical decision support

“We need methods of extracting the clinical information contained in the free text portions of our electronic health record systems into a form that would allow clinical decision support systems to access and utilise this information”. Unlike challenge 9 this challenge is not so much about acquisition of new knowledge as about the conversion of data in one form (written, informal) into another form (machine encoded, formal).

This is certainly a fascinating and an important problem, but we see the challenge involved in accurate, automatic extraction of information from free text as currently intractable. The issue here is that it is far from clear that semantic interpretation of free text will be developed in the visible future to the point where clinical decision-making could safely rely on it – bearing in mind that the whole issue could also become irrelevant with the gradual phasing in of fully computer-interpretable electronic health records using controlled vocabularies/ontologies and other standardised coding schemes. Despite our own enthusiasm for natural language techniques for decision support interfaces (e.g. see [5] in this journal) we suspect that restrictions on artificial languages for describing clinical data will provide a far more secure basis for CDS design, and pragmatic pressures towards standardisation and interoperability are likely to continue to drive policy in this direction.

## 6. Closing remarks

Having argued that there is nothing as practical as a good theory we must also acknowledge that there is nothing as disastrous as a bad theory. Most medical informaticians think that clinical medicine is more complex, busier, more diverse and has more traps for the unwary than, say, most business domains. Imposing neat theoretical ideas from basic computer or cognitive sciences is naive if we do not understand the complexities of everyday clinical practice, and is a recipe for failure at best and the disdain of one’s clinician colleagues at worst.

A notable danger lies in assuming that elegant theoretical ideas, such as abstract notions of rationality and scientific theories of medical thinking and clinical decision-making, can be directly applied to clinical practice. Modern medicine is scientifically grounded but even in the contemporary period of evidence-based practice many practitioners maintain that clinical work is an “art not a science”, in that it must combine scientific perspectives with an understanding of individual human values and emotions. Right or wrong, technologies based on “rational theories”, however, powerful, will not get their vote.

However, the scale and complexity of modern healthcare systems is increasing relentlessly. The sheer quantity of medical information, even within a single specialty, is already beyond the power of one person to comprehend [4,17]. Evidence is accumulating that failing to provide standard treatment is a problem of epidemic proportions [38]. Over 10% of patients admitted to NHS hospitals experienced an adverse event; around half of these events were judged preventable with ordinary standards of care. A third of adverse events led to moderate disability or death [57].<sup>8</sup> Like Sittig et al. and many others we believe that decision support technologies offer a new option for preventing and mitigating medical errors and organisational failures, but we also believe that the scale of the problem, and the key issue of safety management, mean that an empirical approach to CDS design and application deployment by itself is not to be trusted. In our view it demands a systematic approach which is grounded in clear engineering principles. These principles can draw from theories of clinical judgement and the causes of medical error; rational theories of decision-making; formal and verifiable representations of medical knowledge, and appropriate combinations of these and other traditions.

What is also critical, though, is that design principles are sufficiently well articulated that they shed useful light on the reasons why particular technologies or applications succeed or fail in clinical practice and, if they do not succeed we can see how the theories are being used inappropriately or if they are just plain wrong.

<sup>8</sup> These results have been extensively cited and discussed, see <http://www.bmj.com/cgi/content/abstract/322/7285/517>.

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