2008

Quality Assurance Based Healthcare Information System Design

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ABSTRACT

Despite decades of research, health information systems have been characterised by cost over-runs, poor specifications and lack of user uptake. We propose an alternative approach to their design.

By viewing health care as a process and quality as continuously seeking iterative improvements to processes, an object-oriented analysis reveals a class model, which supports quality assurance (QA). At the heart of the model is the ability to store actions for comparison with intentions. Measurement of the proportion of planned tasks that are executed provides a basis for identifying when to alter a process. We show that the model is able to represent medical and administrative procedures and argue that it forms an electronic record suitable for health care organisations.

Were this record to become a standard, software could be developed close to the point of use, in harmony with the needs of stakeholders, so avoiding many criticisms of health information systems.

Keywords

Quality assurance, health information system, object-oriented design, feedback.

INTRODUCTION

An overview of medical informatics research (Jaspers, Knaup, & Schmidt, 2006) suggested that: *"The computerised patient record is playing a growing part in medical informatics research and evaluation studies, but the goal of establishing a comprehensive lifelong electronic health record [EHR] is still a long way off."* This view is supported by the Health Committee of the British House of Commons (House of Commons Health Committee, 2007).

We propose a novel approach to the development of an electronic record for health care providers, which starts by asking the question: "Why should a health care provider invest in computer hardware and software?" Among the reasons should be the desire to improve productivity by avoiding re-work, mistakes, delays, snags as well as through better use of man-hours and machine-time. These objectives can be met by applying the quality assurance (QA) ideas of W. Edwards Deming (Deming, 1990a).

In this concept paper, we develop an object-oriented model of an electronic record for health care, derived from an analysis of Deming's QA approach. We show that the resulting model permits the storage of health data, the storage of descriptions of clinical procedures as well as supporting the iterative improvement of those processes. The same model can also be used for the many non-medical tasks that facilitate the delivery of health care. We suggest that software systems specifically aimed at supporting QA have the potential to offer health care organisations a return on their investment and open the door to a lifelong electronic record of health care.

In a second stage, this paper reviews the ideas developed on the basis of QA, from a critical perspective, leading to an entirely different perception of the aim and outcomes of our model. From this viewpoint, QA can be interpreted as a standardised ongoing conversation about the important characteristics of healthcare processes. We argue that despite the criticisms, the model remains useful and relevant as a means of supporting and guiding discourses between health care provider staff and software implementers.

QUALITY ASSURANCE

According to Deming, quality is not an entity; it is a process. An organisation delivers quality by seeking continuously and forever, iteratively to improve their processes and product. Health care may be viewed as a process that may be broken down into a sequence of sub-processes. This invites an infinite regress but a halt is called at the point where an operational definition exists to demonstrate satisfactory completion of a step. A minimum requirement for the latter is a specific test of the process and a criterion from which it is possible to decide whether a process has passed or failed (Deming, 1990b).

Failures to meet operational definitions will vary over time. In general there are two reasons: special causes or systematic causes. Special causes usually represent rare or exceptional circumstances and should be remedied on a case by case basis because the variation is likely associated with a machine, worker or group of workers. Systematic causes, such as such as failure to cope with a patient's complicating condition, require the development of a better system (Deming, 1990b).

Incremental improvements should be sought in the component steps of a process and its operational definitions. Meaningful feedback should be sought systematically from the patient as well as those delivering the service. The patients' interaction with the process and the short and long term effects should be examined systematically as should the requirements on staff and resources. The procedure suggested by Shewhart and popularised by Deming offers a useful methodology: plan, implement, observe and review (Deming, 1990c).

The planning phase involves answering questions about what defines the process; what changes are desirable; and what is known and what needs to be known. If there is evidence that a change is needed then the modification is put into practice. If more data are needed, a plan is made to gather it. The implementation executes the altered process or gathers the required data on as small a scale as can be demonstrated to provide meaningful results. The observation phase monitors the effects. The review phase analyses the data, and answers questions about what was learnt and about what can be predicted regarding future operations. This is not a "one-off" cycle but should be continuously repeated.

OBJECT-ORIENTED DESIGN

Analysis

In this section an object-oriented analysis of the description of quality assurance is conducted looking for the types of data required to store records to support QA (Booch, 1994). In doing so, ideas from models of goal-based business processes are employed (Kueng & Kwalek, 1997).

Each process may be regarded as a series of actions. Useful associations for the latter might be: who took part, when, employing which skills, using what equipment, and working in which locations. The functions of equipment and the capabilities of locations may also be of value.

An action that performs a test results in an observation. We distinguish two types of observation: 'humanoid' and 'mechanoid'. The former is defined as an observation where no data about what the sensor detected are available; only a person's interpretation of what was present. The latter is defined as an observation where a machine will provide the same account of what its sensors detected to multiple independent observers. In principle, the data loss due to the processing of a mechanoid observation is explicit and available for all to examine and verify. In the case of the humanoid observation, there are no such guarantees. The advantage of mechanoid observations is that there is less likelihood of the reviewer appearing to criticise an individual's actions and findings, which may induce fear of feedback (Adshead, White, & Stephenson, 2006).

The next step is to analyse the observations and formulate explanatory hypotheses. Arguably a hypothesis is a 'higher level' observation. Hypotheses prompt plans of action, which identify tasks that ought to take place. The process of selecting tasks is the action of planning. Tasks may have a justification, based on current knowledge. A proposed mechanism for recording these data is the 'indication'. Each task should be realised by an action. A task may not be carried out for various reasons, resulting in failure of an operational definition. There should be a mechanism to gather data about the reasons for such problems, at the time of the event. This is another form of indication; this time with the attribute of being against (or contra to) a task.

We assert that ordinarily no one acts in isolation; everyone lives and works in a physical and a social environment and inherits a genetic legacy. Every person has relationships with other people. This might be a genetic relationship, marriage or friendship. There is a need to be able to record the types of person to person relationship.

A person may have a role within an organisation. Organisations may be viewed as being composed of a number of sub-organisations. These may have a location in space. Each location may be composed of sub-locations. For QA, organisations must have the ability to store plans about how various situations might be managed. This is achieved by the "remembers" link from Actor to Plan. Using plans, changes to the set tasks, resulting from a Shewhart cycle, can be recorded. This part of the model provides a memory of why a process exists in a particular form.

Class model

The links in figure 1 are to be read from left-to-right and from top-to-bottom. The QA feedback loop is shown by the links between Action, Observation, Analysis, Hypothesis, Planning and Task.

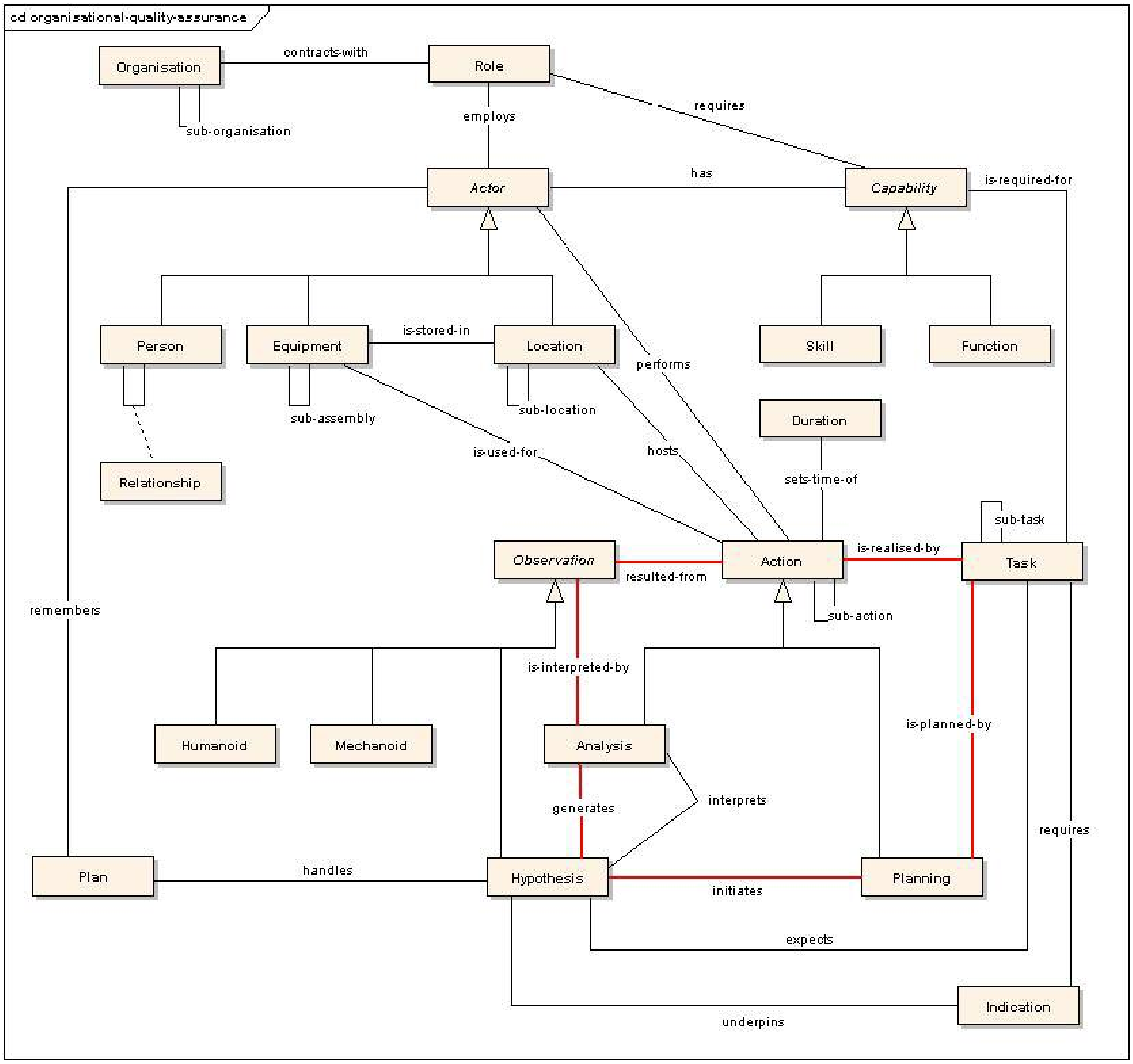

Figure 1: Class model derived from analysis of the QA process.

Whereas the health care practitioner performs actions on a person and gains feedback from observation of that individual, QA performs actions on plans and gains feedback from observation of the extent to which the plans are successfully carried out.

Statistical process control can be achieved by continuous measurement of the proportion of tasks in a plan that were correctly realised, plotted against time. When the proportion falls outside pre defined, acceptable variation, steps should be taken to identify and resolve the special cause. Otherwise the objective of QA should be to reduce the variation associated with the process by designing a better system.

Representation of Clinical Care

Useful concepts in the management of patients in the healthcare setting can be modelled by the data types and relationships shown in figure 1. What follows is not intended as proof of validity of the model but rather as illustrations of its utility in representing medical and administrative processes.

A requirement for representing health data is that diagnosis is appropriately handled. A diagnosis is a statement of the form: "given the information available up to now, in the opinion of the assessor, it is probable that disease X, caused by pathology Y is present". Inherent in the concept is uncertainty and the likelihood of change as a result of new data. Review of health care processes requires that cases be identified not only by the clinician's diagnosis (which would be tautologous) but also by criteria based on observations, whether humanoid or mechanoid. This goal is achieved by recording separately Action (the method of testing), Observation (the results), Analysis (the inferences derived from the observations) and Hypothesis (the diagnosis).

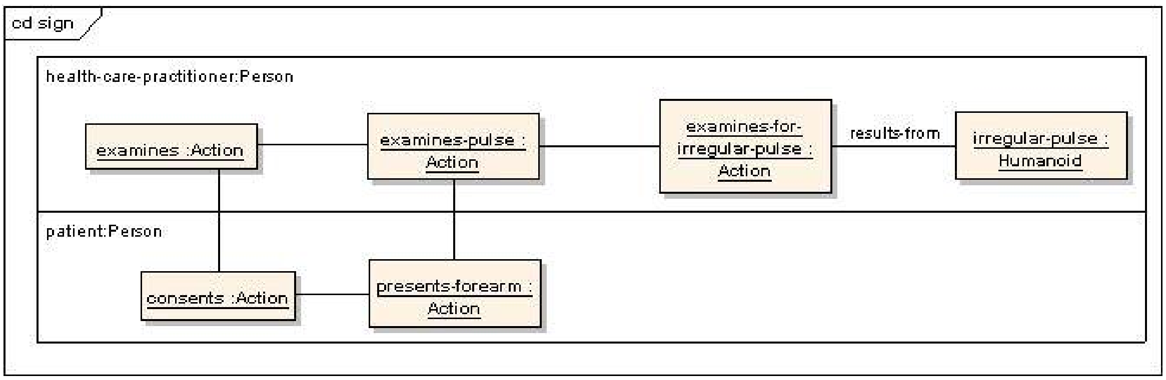

Figure 2: Representation of an observation

In figure 2, were the irregular-pulse Humanoid Observation missing, in the presence of the other actions, it would be reasonable for an analyst to deduce that the clinician examined for an irregular pulse and found none. If the 'examines-for-irregular-pulse' Action were absent, no such deduction could be made. In this way, the class model handles a very useful concept in medical diagnosis: the relevant negative, which serves to help reduce the list of possible hypotheses as to the cause of a patient's problems.

An example plan is provided for part of the management of ovarian cancer (Shaw, Wolfe, Devaja, & Raju, 2003). In figure 3, the task of sampling peritoneal fluid or washings begins by asking the surgeon to examine for peritoneal fluid. Two possible outcomes are expected: either there is or there is no fluid in the abdominal cavity. If fluid is present, a sample is taken. If no fluid is present, peritoneal lavage is performed and a sample of the lavage fluid (washings) taken. We see here a demonstration of the model's ability to store decision support information.

The cost of health care processes has been difficult to determine. The model provides a mechanism by which this might be achieved. Each Role could be associated with a cost per unit time. Since an Actor's Role is known as well as the Duration of an Action, it is possible to calculate the total cost of any process by summing the costs of each Action and sub-Action.

Evolutionary system

Darwin defined evolution as "descent with modification", in "The Origin of Species". It is an iterative process whereby the frequency of alternative forms of a gene (allele) changes as a result of the differential reproduction (natural selection) of classes of organisms that differ from one another in one or more alleles. Analogous characteristics can be seen in the QA model. Each iteration of the QA process is similar to the reproductive process driving evolution. The remembering of plans performs an analogous role to alleles. The counterpart of natural selection is the process of changing plans systematically (the Shewhart cycle), based on data recorded about practice and on research.

For the model to be most effective, comprehensive data collection must be undertaken not only about clinical activities but also about the various non-clinical processes that support the delivery of health care. Not only should practitioners be involved in data collection but all ancillary staff and management as well.

Use of the class model to represent processes needs to be standardised through the systematic exploration of use-cases and through iteration in the light of actual use. In particular processes, operational definitions and observations should be standardised not only in terms of the objects used to represent them but also in relation to terminology. It may be useful to standardise names for diagnoses, but it is not necessary since the analyst can define the tests and observations that confirm the presence of a disease as part of the process of identifying cases.

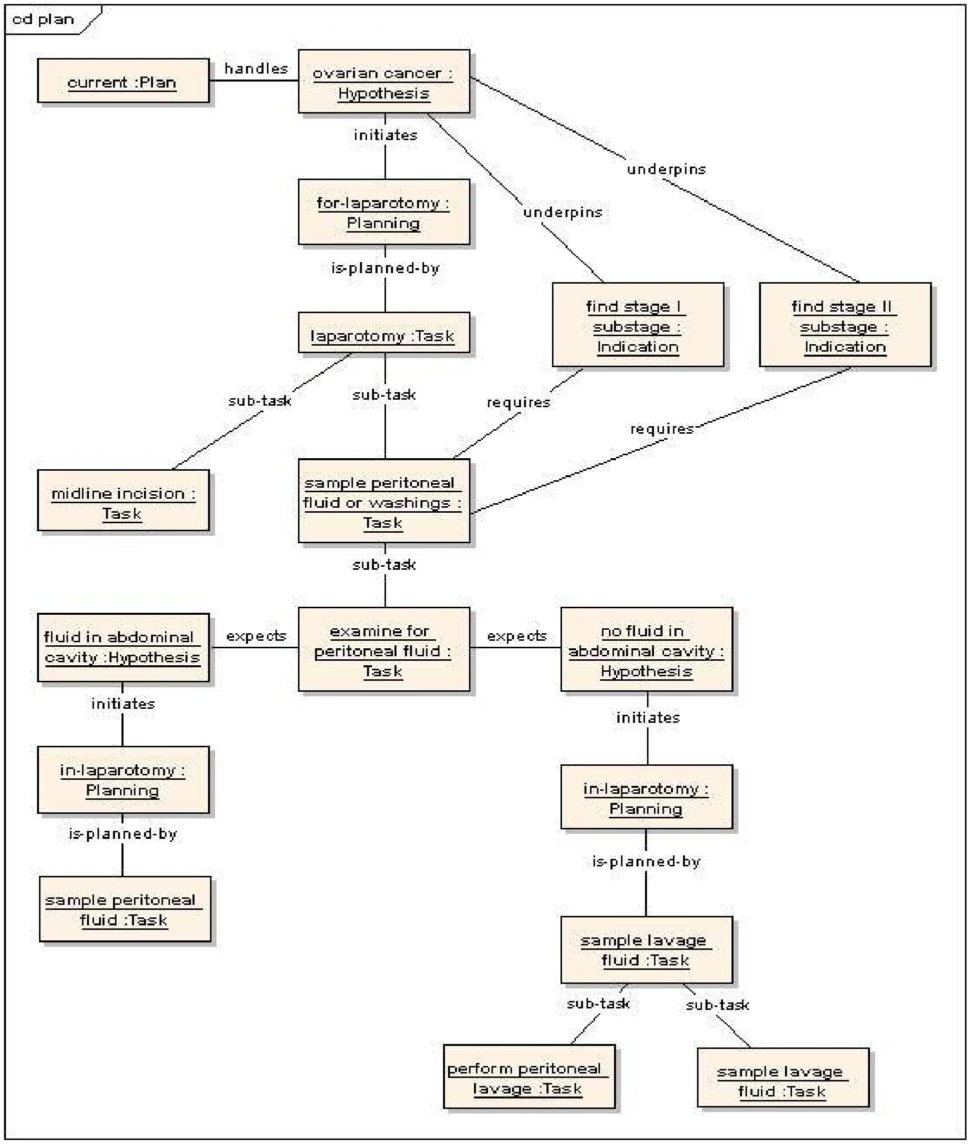

Figure 3: Plan for the early stages of a laparotomy for ovarian cancer

CRITIQUE OF THE QA MODEL

The QA model of healthcare information systems is based on assumptions that may be familiar with medical as well as ICT professionals. It implicitly assumes that reality can be described in a relatively straightforward manner. Patients as well as medical professionals are viewed as rational individuals who seek to communicate in order to achieve a mutually beneficial outcome. The technology required to underpin the QA system has not been considered in any detail and is presumed to be unproblematic. Use of technology follows functional requirements. Briefly, the model we have developed follows the positivist mainstream model of information systems research and practice. This approach has the advantage of being familiar to many of the relevant stakeholders of healthcare information systems. At the same time it may cause problems. A primary indicator of the shortcomings of the mainstream understanding of information systems is the persistently high failure rate. Despite decades of research on information systems, the majority of systems can still be considered failures due to price overruns, poor specifications, lack of user uptake etc. Wilson & Howcroft have pointed out that the concept of failure is problematic per se (Wilson & Howcroft, 2002). It is probably unproblematic to state that the history of Information and Communications Technology (ICT) projects in the British National Health Service (NHS) is a history of failures.

The Critical View

Developing a new approach, such as the QA approach we are suggesting here, should thus consider early on whether there are factors that are likely to cause systems to fail despite sound conceptual underpinnings. We will use this section to sketch a possible counterargument to our QA approach in order to then propose how the model could be used to address these.

For this purpose we will briefly look at the position of Critical Research in Information Systems (CRIS) (Howcroft, Trauth, & NetLibrary, 2005) and explore which issues this may raise for our model. CRIS is an approach to Information Systems (IS) that draws from critical theories in the social sciences and attempts to discover angles typically overlooked by traditional research. A main aim of CRIS is to promote emancipation understood as the ability of individuals to live a self-determined life. CRIS is a useful choice of approach to our QA model because it emphasises aspects of social reality that our model so far neglects, such as organisational and national politics, gender, class, conceptualisation of technology and others. Moreover, CRIS, because of its emphasis on emancipation, has an ethical underpinning (Stahl, 2008), which maps well onto the implied ethical dimension of healthcare. The purpose of healthcare provision in general can be seen as emancipatory.

CRIS draws on a range of theoretical roots and it is impossible to undertake a comprehensive analysis of our model from a CRIS point of view. We will therefore draw on the CRIS literature that explicitly refers to healthcare IS in order to identify dominant issues that our approach so far has not covered.

Rationality

A good point to start a critique of mainstream IS that might be applied to our model is the concept of rationality. Like most complex concepts this one is difficult to grasp and define. Its clearest example may be the autonomous individual on whom neoclassical economic theory is built. Such an individual is rational because she has a complete set of preferences and acts in order to maximise her utility according to these preferences. Translated into a healthcare setting, this means that individuals, be they patients, doctors, or any other stakeholders, act in a way to maximise the overall utility. It is easy to see that this will break down at the point where preferences are not identical. The patient may want a maximum of healthcare, whereas the doctor may view this as medically unwarranted and the manager as too expensive. In addition, patients are often described as irrational when their actions do not contribute to their health, or doctors are seen as irrational when they do not follow organisational goals.

The concept of rationality has been critiqued for a variety of reasons. It may simply not be possible for humans to be rational in the sense described above. Our individual preferences are not complete and often contradictory. In addition we lack the knowledge and cognitive capacities to make optimal decisions. A system based on the idea that people are and will be have rationally is thus likely to face problems. An additional problem arises when technical systems are introduced to increase the rationality of healthcare provision. Empirical evidence suggests that the 'irrational' nature of human interaction does not change by the introduction of information systems. In fact the introduction of such systems often introduces new irrationalities (Berg, 1999).

A further problem of rationality arises due to competing demands. We have already indicated that healthcare IS are often seen as ways of saving money. This is a legitimate aim. However, one should see that it will in many cases conflict with the similarly legitimate aims of other stakeholders (Adams & Fitch, 2006). The use of information systems to promote a financial perspective on rationality can thus be seen as an attempt to promote a particular agenda.

A further problem of rationality is that there are different types of rationality that determine our social reality. Information systems tend to represent an abstract rationality, which is arguably often not compatible with the practical rationality of healthcare practitioners. Hanlon et al give an example of the NHS direct system, a nurse-based 24 hour health advice system, whose technical base represents a rationality that is not compatible with the rationality of the nurses operating it (Hanlon et al., 2005). A different example of problems of competing rationality is developed by Klecun & Cornford who show that a traditional view of rationality when used for evaluating healthcare systems fails to pick up relevant issues (Klecun & Cornford, 2005).

Concepts of Technology

A central question in critical discourses revolves around the conceptualisation of technology. Critical scholars often draw on other discourses such as the social construction of technology but also on traditional critical theory to develop an account of how the very concept of technology affects social outcomes (Feenberg, 1991; Feenberg & NetLibrary, 1999). The point here is that technology is not a neutral tool that can be used to whatever purpose the user decides to employ it. Instead, technology is seen as endowed with certain values and affordances that favour certain uses over others.

This point is linked with questions of technical determinism. Much mainstream work on ICT seems to assume that technologies have certain uses that they are built for and that users will make use of the options of technology in the way they were planned for. On the other hand there are numerous examples of technology either not being used or being used for purposes different from those envisaged. This has to do with what has been termed the "interpretive flexibility" of technology (Doherty, Coombs, & Loan-Clarke, 2006) (or interpretative flexibility (Cadili & Whitley, 2005)).

An important aspect of the concept of technology is the capacity of ICT to capture reality. In our model this issue is highlighted by the distinction between humanoid and mechanoid observations. Technologies are much better at capturing some aspects of reality than humans and vice versa. Healthcare information systems are likely to favour mechanoid observations because they are easier to integrate in technical contexts. This is likely to lead to reductionist perspectives on healthcare which can blend out the immeasurable, which arguably is often an important aspect of medical practice (Hanlon et al., 2005).

The main point here is that a naïve reliance on an intuitive understanding of technology is not likely lead to the success of a new approach. If the QA model is to be successful, then design and implementation should be aware of competing demands on technology but also different users' conception of technology.

Politics and Hidden Agendas

One reason why the above two points are of relevance to our approach is that technology is often used for political purposes. Such purposes can stem from organisational politics as well as national politics. The primary example of this is the growing influence of financial considerations. One main benefit of healthcare IS is that they tend to allow a more detailed breakdown of costs of treatments and a clearer allocation of these costs to different stakeholders. At the same time this leads to a strengthening of cost considerations when compared with others.

The UK government has promoted new ICTs in the NHS partly on the grounds of facilitating more choice for patients. This can be seen as a positive aim as few would dispute that the ability to choose one's doctor is bad. However, one needs to understand that this rhetoric of choice can also lead to a fundamental restructuring of healthcare provision and change the balance between market and state allocation of resources (Mol, 1999).

A different example is the distribution of power in organisations. Traditionally, healthcare in western countries tends to be very much centred on doctors. They hold the knowledge, they make decisions and they allocate the resources. Doctors' autonomy is a highly valued tradition. However, in complex modern healthcare organisations, power is increasingly taken away from doctors and moved towards managers. Such power struggles are normal and can be found in most sectors and organisations. What is important for us to note is that technology can be used as a tool in such struggles. This can lead to the acceptance or rejection of a technology

Social Consequences of Technology

A final point worth mentioning here has to do with the social consequences of technology. The wide availability of healthcare information via the internet has already started to impact on doctor-patient relationships. Patients are better informed and often have specific demands on doctors. Doctors, on the other hand, often resist this change of role which threatens their traditional position of authority.

A further social consequence of the introduction of ICT into healthcare is that it will inevitably lead to changes in procedures. The mere fact that data is to be recorded changes the way doctors interact with patients. This is of course usually intended and thus not to be lamented. However, the changes will often go beyond what was envisaged. If, for example, a system captures the number of patient a doctor sees, then this is likely to affect management's view of the doctor. As a consequence the doctor is likely to pay attention to the number of patients seen and may make choices on which patients to see. An unintended consequence may be that easier cases will find it easier to be treated than difficult ones because they take less time and improve the doctor's performance record. This is what Zuboff described as “informating”, a property of ICT that not only captures but also produces information, which then changes the original processes (Zuboff, 1988).

While the nature of interaction between stakeholders can change, the very practice of medicine can also be changed. Again, this is intended, and our QA model explicitly aims to improve healthcare provision by allowing doctors to better understand the consequences of their decisions. On the other hand, there is a danger that it will lead to increased bureaucracy and medicine by algorithm. The danger of “cookbook medicine” based on standards and protocols developed on the basis of collected data (Berg, 1997) is not to be underestimated.

The QA Model Response

The above critique of the QA model does not claim to be complete. Its purpose is to show that there are aspects of healthcare IS that our model does not capture but that still have the potential to affect its success.

We believe that all of the points are valid and relevant but do not have to lead to the downfall of the QA model. The important point to avoid these issues is to start the QA process with a suitable interpretation of what QA is about. QA is an iterative process that allows continuous interaction with the aim of improving outcomes. This means that it must be open to changes in focus and criteria of quality as well as a shifting view of relevant data and ways of collecting it. Understood this way, QA can be seen as a standardised ongoing conversation about important characteristic of a process.

Such an open understanding of QA would pre-empt much of the critique discussed earlier. It would not make assumptions about appropriate standards of reality and allow for a questioning of implied standards via the QA process. It would be open to different concepts of technology including the resulting means of collecting, formatting, and storing information. These larger contextual issues, including political and social consequences of technology, may be impossible to include in the technical model that we have started to develop. However, the QA process as a whole will have to be sensitive to them, given that they are arguably important not only for user acceptance of technology but for the entire QA process in healthcare.

One could argue that this will require something like a 2nd order QA process. We need to think about some way of continually ensuring that the QA process is of high quality. Again, there is a question whether this can be technically implemented and in what way it will require organisational changes.

A final issue has to do with development and implementation of a QA system. While we have tried to make a sound statement on some of the conceptual basics, the critique has shown that context sensitivity will be required. It is unlikely that the same implementation of the same system in different contexts will lead to comparable results. This is where the socio-technical approach to systems design and development (Mumford, 2003) is likely to be able to address many of the challenges by allowing for participation of a range of stakeholders, most importantly of end users.

CONCLUSIONS

We conclude that software systems should be able continuously to change to meet local quality assurance requirements, in a way that is also sensitive to context.

This has implications for the dilemma of whether to impose large software systems or allow individual health providers to develop their own. We suggest that the problem largely disappears if there is a standard electronic record for health care. We propose that by combining QA and the observation that health care may be modelled as a set of processes, it is possible to define an electronic record capable of recording health care and the supporting non-clinical activities. In effect, we define a basis for a standard electronic record for health information systems.

Quality is better viewed as the outcome of quality assurance, which in turn may be described as a continuous conversation about the important characteristics of a process (Barry, 2007). Our model has the ability to track changes in procedures and to measure the resulting outcomes. Use of our electronic record could support the evolution of health care processes toward an optimum that minimises unnecessary re-work and makes best use of resources, so providing a return on investment. Were it to be used extensively, the focus of external health reform might alter to ensure that the conditions necessary to support quality assurance exist, by removing fear of feedback.

The next step of our research will be to examine the effect of the model on clinical processes. We plan to build a prototype and undertake a quantitative and qualitative evaluation in an environment where a comparison can be made with the effects of alternate software systems.

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