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Exploring medical device design and use through layers of Distributed Cognition: How a glucometer is coupled with its context

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ABSTRACT

Medical devices are becoming more interconnected and complex, and are increasingly supported by fragmented organizational systems, e.g. through different processes, committees, supporting staff and training regimes. Distributed Cognition has been proposed as a framework for understanding the design and use of medical devices. However, it is not clear that it has the analytic apparatus to support the investigation of such complexities. This paper proposes a framework that introduces concentric layers to DiCoT, a method that facilitates the application of Distributed Cognition theory. We use this to explore how an inpatient blood glucose meter is coupled with its context. The analysis is based on an observational study of clinicians using a newly introduced glucometer on an oncology ward over approximately 150 h (11 days and 4 nights). Using the framework we describe the basic mechanics of the system, incremental design considerations, and larger design considerations. The DiCoT concentric layers (DiCoT-CL) framework shows promise for analyzing the design and use of medical devices, and how they are coupled with their context.

1. Introduction

Medical and biomedical informatics concerns the processing of information within software and technology (e.g. [1,2]), and within broader sociotechnical systems involving clinicians, patients, artifacts, etc. (e.g. [3,4]). Medical device designs, which stretch across this remit, are becoming more complex through increasing functionality and more complex controls. Furthermore, the systems through which they are procured, managed and used are also becoming more complex and fragmented e.g. through different committees, managers, trainers and users with different roles and responsibilities. There is a need for more studies that reflect on findings at broader sociotechnical and policy levels [5]. Misattributing medical device issues to the wrong part of the sociotechnical system can hinder corrective action: for example, on one ward staff believed that frequent device alarms were an issue for the manufacturer to address, when actually this was a device configuration choice under the control of hospital management [6]. Trends for technology in other domains suggest an outward movement through layers of problems. The problems considered about a system are initially hardware ones, but over time as the technology matures, software issues become relevant, then user interface ones, and then on to more collaborative, workplace and organizational issues. One way to think of this is that the technology 'reaches out' from its traditional interface [7].

A critical challenge for research and development is to develop appropriate analytic tools to keep abreast of modern device design and use issues (e.g. see [5]). Distributed Cognition (DCog) has promised much as a framework for analysis [8]. However, some believe that the absence of an off-the-shelf methodology and appropriate analytical support has hindered it reaching its potential [9]. This paper introduces a multi-layer framework by augmenting DiCoT, which is a method that facilitates DCog analyzes. The framework, DiCoT-CL, has the user–device interaction at its core with concentric layers of system around this interaction. It provides analytic support so that different themes in the informatics environment around a device can be investigated at different levels. In particular, we use the approach to investigate the design and use of a modern inpatient glucometer, and how it is coupled with its context. The glucometer is an important and ubiquitous device in clinical contexts that has received little attention from researchers interested in sociotechnical systems.

2. Background

To set the context for this work, we look at four areas. First, we describe how the increasing complexity of medical devices engages

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with issues at different layers of the sociotechnical system and how we need methods to keep abreast of these developments. Secondly, we outline the theoretical and methodological advances in Distributed Cognition and highlight the potential for a layered approach to sociotechnical analysis. Thirdly, we describe current multi-level approaches to sociotechnical analyzes to contextualize our contribution to Distributed Cognition and medical device design and use. Finally, we motivate our case study area, given that relatively little attention has been paid to blood glucose meter evaluations despite their clinical importance.

2.1. Layers of the sociotechnical system

As devices develop and increase in complexity they engage with new problems at different layers of the sociotechnical system. Grudin [7] introduces the concept of 'reaching out', in which he observes an outward trend in technological advancement. He suggests that the principal focus of activity in computer development has moved from hardware, to software, to user interface issues, to more advanced interactions between user and computer, to the computer integrating with groups of users in the work setting. As a layer is mastered, more resources can be dedicated to the next most pressing issue. This does not mean that new layers are superior, or that previous layers should be neglected: only that new challenges are faced by designers of the technology.

'Reaching out' can be seen in medical device development. For example, Sims et al. [10] describe historical developments of infusion pumps and highlight how 'stand-alone pumps' have developed into 'intelligent infusion devices'. The infusion pump has reached out from hardware issues, to software and interface issues, to broader and more complex systems, including data mining and quality control mechanisms that stretch well beyond its original interface. Blood glucose meters, or glucometers, can also be understood as reaching out: in Clarke and Foster's [11] history of blood glucose meters we see hardware developments (e.g. from testing urine to testing blood for glucose), to software related developments (e.g., meters handling more data and providing computer-assisted analyzes); interface and interaction developments followed (e.g., moving to operator-independent steps to reduce variances in calibration, maintenance and reading techniques), followed by further developments in managing blood glucose monitoring (e.g., data management and more connectivity with information technology systems). As medical devices increase in complexity, methods for research and development need to advance to stay abreast of the new challenges that are faced.

2.2. Distributed Cognition and DiCoT

Distributed Cognition (DCog) is an approach that was developed in reaction to classical forms of cognitive science that focus on what goes on in the head of the individual. DCog focuses on describing a 'cognitive system' that typically includes interactions between people, the artifacts they use and the environment they work in [12]. It focuses on how information processing is coordinated in sociotechnical systems. Its attention to how artifacts and external systems are structured makes it applicable to system design. DCog has been used in many contexts. Analytic tools have also been developed to facilitate its application [13–16].

The origins of DCog emerge from a question: how do we best characterize how humans process information and interact with the world? Furthermore, do we emphasize information processing in the head, or information processing in the world? Rogers [12] proposes that there has been a shift from classic theory that has an 'in the head' focus to more modern theory that has an 'in the world' focus. The classical theories of the early 1980s focus largely on the cognition of an individual; here, the world is seen as data, the body as an input device, and, once this data has been transferred to the mind, calculations can be made on how best to act. Card et al.'s [17] Model Human Processor is an archetypal framework from this era, which focuses on how an individual processes data from the world. This classical perspective influenced fields such as psychology, philosophy and AI: e.g. Newell and Simon's [18] Physical Symbol System Hypothesis stated that a system that could take symbols, combine them into structures and process them to create new expressions has the necessary and sufficient means for general intelligence. Rogers [12] summarizes modern theories that reacted against the focus on the human as an isolated symbol manipulator. These more modern theories include notions of the extended mind [19], situated action [20], embodied cognition [21], and DCog [22]. All of these emphasize how the world and body play an active role in thinking and acting, i.e., it cannot be reduced to symbols and data to be processed solely within the skull. So, how we characterize the way humans process information needs to account for the active role of the world in cognition and action.

Hutchins and colleagues developed DCog in the late 1980s. Hutchins [22] argued that by looking at cognition 'in the wild' we see how cognition is distributed across representations, artifacts, time and people in teams. Exemplars include teams navigating large vessels from the bridge of a ship [22] and coordinating representations in the cockpit of a plane [23]. He argued that no one individual could be regarded as navigating the ship or controlling the plane. The full account of how information processing is coordinated in these systems includes interactions between individuals, the artifacts they use and the environment they work within. Furthermore, Hutchins [22] emphasized how cultural heritage impacted the coordination of information in systems, i.e. how modern systems are built on and evolve from previous tools, artifacts, ways of thinking and ways of working from generations past.

Flor and Hutchins [24] proposed a 'complex cognitive system' as the unit of analysis. It is complex because it involves people, tools, artifacts and representations; it is cognitive because it is grounded in how information is processed; and it is a system because it has different dependencies and interacting parts. Hollan et al. [8] state that there are two defining features of DCog: (1) that it expands the unit of cognitive analysis from the skin and skull to complex sociotechnical systems (e.g., control rooms); and (2) that it expands the mechanisms that are presumed to participate in cognition from internal thoughts to physical and digital tools, team members, and multiple modalities (e.g., gestures).

Hollan et al. [8] have proposed an ambitious framework for DCog and argued that it is well suited 'to understanding the complex networked world of information and computer-mediated interactions and for informing the design of digital work materials and collaborative work places' [12]. Essentially, it is well suited to investigating the coordination of work, particularly where work involves interactions between different people, representations and artifacts. The case for its relevance for medical informatics, to study human performance and the design of technology, has been argued previously [25]. Studies in this area include the following.

- Hazlehurst et al. [26] used DCog to analyze verbal exchanges between surgeons and perfusionists in cardiac surgery. They identified six types of verbal exchanges that help coordinate work and achieve successful performance.
- Cohen et al. [27] analyzed instances of perceived violations and miscommunication from audio recordings of morning rounds and handovers in a psychiatric emergency department. Using a DCog perspective, they gained insights into how potential errors are identified and handled across artifacts, space, time and people.

- Tariq et al. [28] used DCog to identify gaps in information exchanges that could contribute to medication errors in residential aged care facilities. They found that DCog helped move from attributing error to individual care providers to looking at weaknesses and vulnerabilities in the information flow more broadly, e.g. medication artifacts, procedures and communication channels.
- Ancker and Kaufman [29] used DCog to argue that the quality of health numeracy relies not only on individual numeracy skills but also on a broader system that includes communication skills and well-designed documents and artifacts to support cognition.
- Rajkomar and Blandford [30] used DCog to understand the infusion administration practice in an Intensive Care Unit (ICU). They found that there is a significant distribution of cognition socially, physically and through technological artifacts. They identified potential improvements that could increase safety and efficiency based on their analysis.

Collectively these studies highlight a focus beyond the individual to the structure of systems, the coordination of resources, the design of representations and artifacts, and the analysis of communication exchanges in healthcare.

Hazlehurst et al. [25] argue that different approaches can be identified within studies that privilege different phenomena in the DCog system. For example, Horsky et al. [31] assess the user interface of a computer-assisted provider order entry system, which privileges individual behavior. They use a combination of analytical and empirical techniques that included a cognitive task analysis, usability testing, and a cognitive walkthrough to evaluate the technology. Nemeth et al. [32] privilege artifacts as they propose a cognitive artifact analysis. Here researchers look at the structure of the artifacts in practice and supplement this with interviews and observations as a way of finding out how work is organized. Hazlehurst et al. [25] privilege action in an activity system. They and other researchers use a combination of recordings, interviews and observations to explore how activities within a system are structured and coordinated [26–28].

Despite DCog's broad use some argue that it has not realized its full potential because there is no 'off-the-shelf' methodology for using it [9]. Rogers [12] reflects on the challenges of using DCog, e.g., there is no set of features to attend to, there is no checklist or recipe to follow, and it requires a high level of skill to move between different levels of analysis, and dovetail the detail and the abstract. This has led some to develop more structured approaches to gathering and analyzing data from a DCog perspective. These include two general approaches in the Distributed Resources (DR) Model [13] and DiCoT [15,16], and an approach designed to analyze adverse events in clinical environments in Determining Information flow Breakdown (DIB) [14].

The Distributed Resources (DR) Model [13] was developed to provide a detailed focus on the coordination of information resources in DCog systems. A simple everyday example is that someone might use a plan-following strategy as they collect items on their shopping list one by one, in order, and cross off the completed items on that list with a pen. This coordinates different information resources, i.e. a plan of future goals, the current state in the task and a history of completed goals. The DR model has been applied to more complex systems in healthcare. For example, Horsky et al. [31] used it to study a computer-assisted provider order entry system. The DR model helped reveal that it placed unnecessarily high cognitive demand on the user, which particularly affected those users who did not have a good mental model of the system.

DIB (Determining Information flow Breakdown) [14] was designed to analyze what led to, or could potentially lead to, an adverse clinical event. Its focus is on breakdowns in information flow in the broader system, but there is emphasis on the chain of events that could lead to an adverse event. There are three stages to the method: data gathering, modeling the DCog system, and using a checklist to help analyze information flow failure.

DiCoT (Distributed Cognition for Teamwork) was developed to provide a semi-structured approach to analyzing sociotechnical systems whilst being informed by theoretical principles from the DCog literature [15,16]. It combines the structure and methodological advice of Contextual Design modeling [33] and DCog theory (e.g. [22]). Like the DCog approaches described above, in practice DiCoT typically involves observations and interviews. A point of differentiation is that it focuses on developing five interdependent models with different foci: artifacts, physical, information flow, social and evolutionary. Echoing Hazlehurst et al. [25], who talk about different DCog approaches privileging different aspects of the DCog system, DiCoT's models each privilege a different aspect of the system. An overall understanding of the system is gained by combining them. They have 18 associated principles that help the analyst bring DCog concepts and concerns to the investigation [15]. Rajkomar et al. [35] have recently identified the need for and added principles to do with time to the methodology. DiCoT has been applied to a variety of complex systems in healthcare: ambulance control room dispatch [16]; mobile healthcare work [35]; medical equipment library design [36]; infusion pump use in intensive care [30]; and home hemodialysis [34].

The notion of different levels of granularity within a system seems a natural partner to DCog approaches. For example, this comes through in the discussion of more structured approaches above: whereas the DR model is more suited to analyzing detailed interaction with information resources at the individual level, DiCoT is more suited to analyzing the coordination of information at the team level. Also, more generally, within a DCog analysis we have choices of how to bound our unit of analysis, e.g. it could include the worker and a tool, the worker at their desk, or the whole room with multiple workers. This again implies multiple levels. The idea of multiple levels within DCog raises further questions: how far do these distributed systems spread; in what ways do they branch out; and where are their limits? However, this has not been discussed in relation to DCog previously. Answers to these questions could provide needed guidance for people interested in medical device design and use. This is particularly so as devices become more complex and 'reach out' [7]. Furthermore, supporting systems that impact the quality and safety of devices (e.g., in procurement, management and use) are becoming increasingly complex and fragmented, and arguably need to be included in assessments of how devices perform in practice.

2.3. Multi-level approaches for sociotechnical analyzes

Approaches to DCog fit within a broader literature of sociotechnical system analysis. Sociotechnical approaches focus on the complex interplay between people, artifacts, and technology to include teamwork and organizational influences. Kaplan [37] argues for methodological pluralism in this area and reviews literature that proposes to broaden evaluations to include: cognitive approaches [38,39]; sociological approaches [40–42]; action research approaches [43]; and social interactionism [44,45]. These approaches consider the sociotechnical system holistically but are distinguished by privileging different factors within the larger system and use different methods for engaging with these issues. Many approaches that argue for a more holistic sociotechnical approach to medical informatics contrast themselves with a reductionist view. This leads to a dichotomy: approaches that focus on a detached technical system and approaches that focus on a system as embedded in context.

Few studies in medical informatics offer a way of seeing the dichotomy between detached and embedded technical systems as a graduated spectrum. Such studies include the work of Saleem et al. [3], Sittig and Singh [46] and Coiera [47].

- Saleem et al. [3] refer to an expanding unit of analysis from interface issues, to workflow issues, to organizational issues in their discussion of computerized clinical reminders. They use this to recognize a broad array of barriers that prevent nurses using computerized clinical reminders optimally.
- Sittig and Singh [46] illustrate the complex interrelationships between different dimensions of sociotechnical systems in a space that includes hardware, software, user interface, personnel and organizational issues. They stress that components in their framework have to be looked at collectively, because they form more than the sum of their parts.
- Coiera [47] refers to four levels of information system design, i.e. algorithms, computer programs, human–computer interaction and socio-technical systems. He argues that we need a descriptive logic that traverses these different levels.

The focus of this paper is testing whether and how these types of multi-level frameworks could inform analytic support for applying DCog to studies of medical device design and use. Just as DiCoT provided scaffolding for analysts to apply themes and principles from DCog, without changing or contributing to the underlying theory per se, the framework proposed in this paper offers the addition of concentric layers to facilitate analysis. This has the potential to contribute to Coiera's [47] suggestion of a cross-level descriptive logic, i.e. a framework of concepts and relationships which can provide an explanation of phenomena that cross different levels in the sociotechnical system.

The idea of having systems nested within systems, and multiple levels of influence, for sociotechnical analysis has its roots outside informatics. One of the most cited examples is Rasmussen's [48] work in the field of safety. To explain what affects risk management, Rasmussen [48] outlines six levels (i.e. work, staff, management, company, regulators and associations, and government) and describes what disciplines study these different levels and what stressors they are under. Multi-level and multi-component frameworks have also been developed to address human factors and patient safety issues. Henriksen et al. [49] show a five-tier model with active and latent conditions that contribute to adverse events in healthcare. Vicente et al. [50] introduce a broad framework for analyzing risk and safety in healthcare. Carayon et al. [51] introduce SEIPS (Systems Engineering Initiative for Patient Safety), which is a broad framework that includes work system components, processes and outcomes. These frameworks are not specifically designed for studies of device design and use, and the technological component within them is not their focus. Also, these broad frameworks aim to cover the potential for many contributing factors to risk and safety; they are less applicable for dealing with the fine-grained details of interaction. Halverson [52] observes that the fine-grained descriptions associated with DCog approaches can facilitate moving from description to design because it describes systems at the right level to impact the design of representations and processes.

Karsh et al. [53] review other multi-level models in human factors and ergonomics. They define an area of meso-ergonomics, which focuses on the causal relationships between at least two different levels in a sociotechnical system. This contrasts with macro-ergonomics that looks at factors at a high level, e.g. organizational; and micro-ergonomics that looks at factors at lower levels, e.g. physical and cognitive. They state that there are few studies that look at the relationships between levels. They offer a framework to identify and test hypotheses between levels, and it is clear from their review that more research, theory and models are needed to advance this area. Our focus in this paper is on a multi-layer approach to DCog.

2.4. Evaluating blood glucose meters

As described above, as devices 'reach out', studies to support their design and use should diversify to include not only hardware and software issues, but also interface, workflow and organizational issues. A hospital blood glucose meter was selected as the focus for this study. To date, there has been relatively little research on the broader levels of inpatient glucometer informatics compared to studies looking at their clinical accuracy. Studies that look at glucometer usability have identified problems. For example, Rogers et al. [54] carried out a usability test of home use glucometers. They report that they are not simple, typically involving over 50 procedural steps to take a reading. They provide recommendations for their improvement. Price [55] describes the repeated hospitalization of a patient who had sporadic low glucose readings and hyperglycemia complicating her dosing decisions. Only after extensive investigation was it revealed to be an issue with her use of her glucometer rather than peculiarities with her condition. McDonald [56] reports a patient who nearly received a fatal dose of insulin because he was given another patient's identification wristband by mistake. Perry and Wears [57] highlight that at least some of the resilience in inpatient diabetes management systems is maintained because clinicians treat device readings with caution, and cross-check readings with other devices where they suspect inaccuracies. These cases suggest that inpatient glucometer systems are an important area for further study.

3. Method

3.1. Study design

Ethical clearance was granted by an NHS REC (National Health Service Research Ethics Committee) to perform an investigation into medical device design and use on the Oncology Ward of a busy London Teaching Hospital. Oncology is representative of a specialty not specializing in diabetes whilst managing several patients with diabetes, e.g. due to the age of their patient population. After a broad examination of the different devices used, the glucometer was selected as a focus because it had just been introduced onto the ward. Therefore there was potential to examine issues with its adoption and implementation – and also how the sociotechnical system adjusted itself to accommodate the technology [47].

DiCoT [15,16] was used as a method to facilitate the application of DCog. As noted above, this focuses on constructing five interdependent models (information flow, artifact, physical, social and evolutionary) and applying associated principles. These models and DCog theory influenced data gathering and analysis; however, we included and were sensitive to other related research areas that did not strictly fall within DiCoT's remit, e.g., how the medical device impacted on patient care and experience. These models guided rather than dictated, and their boundaries and scope were not treated rigidly.

3.2. Setting

The oncology ward has 24 beds; 16 are in 4-bed bays and the remaining 8 are single side-rooms. Most patients are being treated for cancer, e.g. receiving chemotherapy or radiotherapy, or are receiving palliative care. Regular blood glucose readings need to be taken from patients who have diabetes or who are receiving treatment that requires close monitoring of their blood glucose levels. The daytime nursing staff includes one nurse manager, four nurses and two healthcare assistants, but staffing levels vary and may include student nurses and temporary staff who are unfamiliar with working on the ward.

Glucometers play a vital role in inpatient diabetes management, enabling bedside reading of patients' glucose levels in a matter of minutes. A new glucometer had just been introduced onto the ward at the start of the study. It differed from its predecessor in two important regards: the first was that it had barcode scanning capability, so staff and patients needed their ID scanned; the second is that its readings were uploaded to a central database, so diabetes specialist nurses and biochemists could monitor the data for clinical and quality control purposes. The remaining description of the device and its use was developed from our data, rather than from an instruction manual or other formal publication, so it is reported as part of our results.

3.3. Data gathering

Observations and interviews were conducted over 11 days and 4 nights over a 5-month period, totaling about 150 h of fieldwork. 26 episodes of blood glucose monitoring were directly observed over 6 days, i.e., where the researcher accompanied the user of the glucometer. Not every observation day resulted in glucometer observations because staff were too busy to notify the field researcher, or other activities conflicted with these observations. Extensive field notes were kept of the context, observations and interviews.

Data points for the qualitative study included:

(1) Observations of specific blood glucose meter readings.
(2) Interviewing users between readings.
(3) Observing the general ebb and flow of ward life.
(4) Talking to users during downtime in their work.

Additional data points were sought towards the end of the study to supplement our findings on the ward:

(5) Interviewing a diabetes specialist nurse who interacted with the system's centralized database.
(6) Interviewing a biochemist who also interacted with the database.

The second author familiarized himself with the device's manual so that those details could be compared to what was found in the empirical study.

3.4. Analysis

Part of the analysis and results for this evaluation are reported elsewhere [58]. The analysis here focuses on exploring the application of DiCoT-CL to the data. Following [59] our aims were to gain deeper conceptual insight into the system, to describe the mechanics of the system, and to consider incremental and more substantial design ideas.

The analysis was shared between the first and second authors. The first author acted as the researcher in the field and the main analyst; the second author supported the analysis by creating formal models that complemented the DiCoT analysis [60]. Together we discussed data and analyzes, generated new questions to direct further data gathering, and identified issues.

Initial analysis involved repeated reading and coding of data, where observations in field notes were organized loosely under the five different DiCoT models. These notes contributed to further analysis: information flow diagrams were drawn to show steps in key tasks in the information flow model, diagrams were drawn of different physical areas, schematics of artifacts were drawn noting their functions and how they are used, different roles and responsibilities were detailed, and notes were made on historical factors where appropriate like details of the previous model. These emerging details, shaped by DiCoT, were interrogated so gaps could be found and further data gathered to fill these gaps. Gaps that needed data beyond the ward emphasized the expanding analysis, e.g. needing to talk to the diabetes specialist nurse. More locally, partial hierarchies began to emerge, including: healthcare assistants and nurses in the social model; the bed-side and the ward in the physical model; the glucometer, the case, the trolley in the artifact model. The unit of analysis stretched and flexed to incorporate meaningful data. These often implicit analytic moves, which happen in the ebb and flow of qualitative research, would have gone unremarked if the fifth author had not drawn attention to them. Factors that were close and far from the device were sketched as concentric layers of systems. The first author explored this idea further by building on previous analyzes and returning to field notes. The partial hierarchies that began to emerge were completed in a more top–down manner to satisfy the representation we were developing. We considered concentric layers of systems in terms of each of DiCoT's five models.

Fig. 1 shows this nested system view with the user–device interaction at the center of the system. The concentric layers represent the layers of focus that apply to the different models. These layers represent choices about where to focus and bound the unit of analysis. Typically, as we move towards outer layers, we find that one layer subsumes another, and so in this sense they become nested views of the system, one layer on top of another.

This analytic framework lends itself to understanding the couplings and dependencies that influence the performance of medical device use at different layers of the sociotechnical system. For example, staff regarded 'nuisance' infusion pump alarms as a design issue for the manufacturer but in fact this was a configuration decision made by hospital management [6]. Similarly, in this study, the glucometer had lockout features that staff blamed on the design of the device when these were intentionally configured

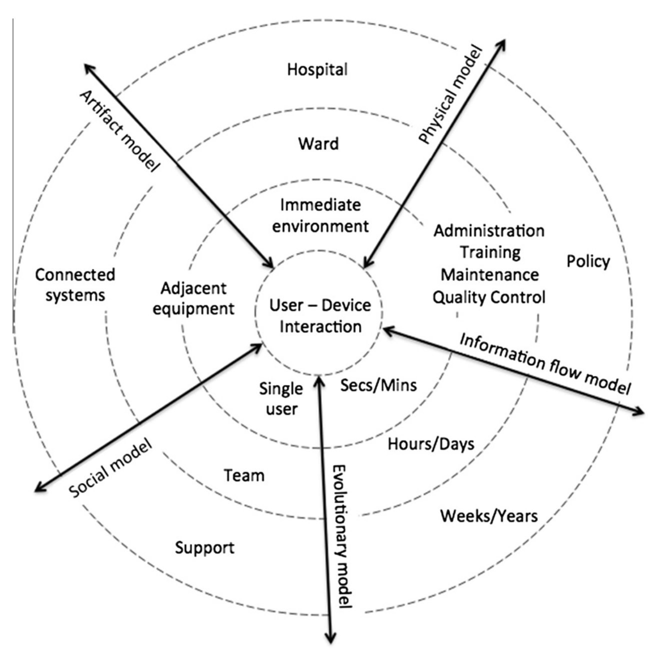

Fig. 1. The DiCoT concentric layers (DiCoT-CL) framework puts the user–device interaction at the center of the analysis. Each concentric layer represents a broadening out of the sociotechnical system around this interaction. Each layer is divided into five areas to reflect the themes of the different DiCoT models, i.e. information flow, artifact, physical, social and evolutionary models.

this way by hospital management. Both of these examples are latent conditions that can play an active role in the use and performance of the device. Latent conditions would be represented at the outer layers of Fig. 1.

Fig. 1 depicts how the performance of medical devices is coupled with different individuals and groups, to adjacent equipment, to training, to configuration and policy decisions and to different tasks. These dependencies are essential to the quality and safety of device use. This framework is used to describe the mechanics of the sociotechnical system and to gain incremental and more substantial design insights.

In our analysis potential issues and insights came from different sources. These sources often interact in implicit and complex ways meaning that ideas become untraceable. However, we have tried to give examples of the different sources that have contributed to the insights in our analysis:

- People self-reported problems in context, e.g. users of the new glucometer reported their concerns about needing to use the device in an emergency situation where they did not have a hospital number (e.g., for a visitor to the hospital).
- Issues were observed in context; e.g. a device user was observed to put blood on the test strip before the device was ready to receive it which voided the interaction.
- Modeling the system using DiCoT highlighted issues; e.g. this drew our attention to the arrangement of equipment and how artifacts supported or hindered cognition, such as differentiation between the two quality control fluid vials which had different colored lids.
- Issues were highlighted by modeling the system using DiCoT-CL, e.g. this emphasized not only the task of a single blood glucose reading but also the task of doing a blood glucose round because we were encouraged to look at a higher order of task as we moved out to additional layers.
- Formal modeling of the system revealed issues by identifying gaps in the analysis; e.g. this required further detail from the fieldwork such as not only the need for the device to have a hospital number entered but how long the number was, whether it was always the same length, and whether it was presented as a continuous number or chunked in some way. These details would often surface between the first and second author before any modeling had been done.
- Issues were found by comparing actual practice with the device's manual, e.g. we found that a feature to allow clinicians to override the need for a quality control check in an emergency situation had not been enabled. We would have no knowledge of this unless we looked at the manual.

4. Results

Here we focus on the analyzing the system in terms of the layered framework. A full list of the 19 issues we identified with the device's design and use, and more general themes for guiding situated ergonomic assessments of medical devices, can be found in [58].

Following DiCoT's concentric layer (DiCoT-CL) framework in Fig. 1 we identify different layers within the sociotechnical system that surrounds the glucometer. This shows how cognition is distributed, and how sociotechnical dependencies and couplings reveal themselves in the basic mechanics of the system, through the coordination of different artifacts, people, tasks, physical spaces and periods of time.

4.1. Concentric layers within the artifact model

During observations each artifact that was used with the glucometer was noted and analyzed to see how they mediated cognition. Later, these artifacts were organized according to the DiCoT-CL framework where it became apparent that those closer to the glucometer's use on the ward played a larger role in our analysis.

The obvious artifact at the center of the analysis is the glucometer itself. We first came across it being used with adjacent equipment: the device in its docking station; taking a blood glucose reading also involved the use of paraphernalia in its accompanying case, and this was often used with other equipment on a trolley. Fig. 2 illustrates these three different layers of adjacent equipment used alongside the device: this was not a standalone device.

At the first layer we see the device in its docking station. The device has a black and white touch screen interface, a power button, a slot for inserting the test strips that will receive the blood, and a scanner to scan barcodes to identify patients, staff, batches of test strips and fluids. The device plays a critical role in information transformation in the system, turning blood glucose levels into numerical figures, and turning physical barcodes into digital readings. The docking station charges the device and allows it to upload and download data to a central database. This plays a critical role in information movement, making locally recorded information available hospital wide.

At the second layer we see the case that comes with the device. It contains essential artifacts for taking blood glucose readings. This includes two vials containing test strips for readings, lances used to prick patients' fingers, swabs to absorb excess blood after the reading, and fluids that are required for quality control checks. The case itself is designed to carry the glucometer and its equipment. This facilitates portability but there is also real value in having this essential paraphernalia organized and in one place for taking readings: the arrangement of equipment facilitates the physical and cognitive task of using the device.

When we accompanied healthcare assistants on their blood glucose rounds a third layer of connections became apparent; this involved setting up a trolley that could be wheeled around to the different patients needing a reading. The trolley contains essential equipment for a successful blood glucose meter reading that goes beyond the case and the device. This includes a box of gloves for infection control purposes, a sharps bin so that lances can be disposed of by the bedside, and a cardboard tray so that other non-sharp material can be collected and disposed of later, e.g., test strips and swabs. The organization of artifacts facilitates the cognitive activity of performing tasks because they are available when required. This can be designed into the system (e.g. the case above) or users can reconfigure the system to suit their needs (e.g. the set-up of the trolley).

Issues related to the fine-grained details interaction, which impacted the coordination of information, could be observed towards the inner layers of the framework. For example, a healthcare assistant was observed to use three testing strips for one reading. On further enquiry it was revealed that he should have waited for the device to display a small icon before applying blood to the test strip. His usual routine was disturbed because he was preparing for the reading outside a single side-room rather than doing the reading on an open ward. The lack of salience of the small icon on the display contributed to the error.

Artifacts that were important for device use but outside the scope of our analysis included the PC-based supporting software and central database, the printer that prints the patient ID labels showing their barcodes, and the paper based blood glucose monitoring charts that are filled out when a reading is taken. These are represented as connected systems in the outer layers of Fig. 1.

4.2. Concentric layers within the social model

As our observations proceeded different user groups were encountered in the fieldwork reflecting how cognitive activities

Fig. 2. Three consecutive levels of the artifact model are shown from left to right.

are socially distributed in the system. Their interaction with the device was observed and we interviewed people where appropriate to find out their role, expertise and issues with the system. We identified where these roles were at different layers in the social model.

At the innermost layer were the patient and the healthcare assistant, the latter being the main clinical user of the device. There were normally two healthcare assistants who each had responsibility for doing the blood glucose meter rounds on one half of the ward. The healthcare assistants would often tell the patients their readings because they were interested and could monitor their own health. This contributed to the situation awareness of the patient.

At the second layer, nurses are responsible for the diabetes management of their patients. When healthcare assistants are delayed or too busy, nurses may take the blood glucose reading; this illustrates how the system can be socially reconfigured to accomplish shared goals. Also, if a reading is outside tightly controlled parameters, the healthcare assistant should notify the nurse responsible for that patient immediately. These were the two main user groups involved in the use of the device on the ward.

At the third layer we move away from the team on the ward to include diabetes specialist nurses and biochemists. These individuals monitor the data that is uploaded to a central database for clinical reasons, e.g., so that diabetes specialist nurses can intervene or provide additional support for some patients, and for quality control purposes, e.g., so that faulty devices can be replaced and staff training can be targeted at those who need it. The device affords the raising of situation awareness amongst staff with oversight responsibilities. It also became apparent in talking to these individuals that they had responsibility for choosing how to configure the device, administer training and influence policy that has a direct impact on device practice on the ward. For example, they chose not to enable a feature to allow clinicians to override the need for a quality control check in an emergency situation. This is an example of a higher-level factor, in the outer layers of the framework, which impacts the coordination of the system. These are captured as supporting roles in Fig. 1.

4.3. Concentric layers within the information flow model

Activities were observed during observations that contributed to the completion of tasks. These tasks make up the main subject of interest of the information flow model, with the accompanying communication with people, interaction with artifacts, and mediations through different representations.

Using the DiCoT-CL framework we took the task of blood glucose reading as the core activity that we were interested in. We moved out to consecutive layers as we considered tasks and functions further away from its primary purpose of doing a blood glucose reading. For example, such tasks and functions are represented as administration, training, maintenance, quality control and policy in Fig. 1.

The core activity of blood glucose reading included the staff scanning their own ID, scanning the patient's ID, inserting the test strip, retrieving a sample of blood, and recording the figure. This core activity is remarkable in the manner in which it orchestrates different mediating artifacts to identify specific staff and patients, allow access to use the device, and how it transforms blood glucose levels from a droplet of blood into a numerical value, which it associates with a particular patient. In another sense it is unremarkable and accepted as normal by staff and patients. Other activities were included at this first layer that were critical to the use of the device. For example, quality control checks are needed every 24 h to check the device is reading accurately. If they are not performed then it locks out the user.

Staff also complained about another feature of the device that could prevent its use in an emergency, i.e. the design of the device does not allow for blood glucose tests on people without a patient ID number. This was a concern because a visitor could collapse and need testing but they would not have a patient ID to access the device. The diabetes specialist nurse and biochemist reported that the nurses should know that they can enter 2222 or 9999 as a substitute for a real ID. They said medical staff in Accident and Emergency used this frequently, because people would be treated before they had received a patient ID. Since this workaround is used infrequently on the oncology ward, many staff were unaware of it. These two contexts in the same hospital have different behaviors and requirements.

At the second layer it became apparent that blood glucose 'rounds' were important in practice; these go beyond a single reading. Healthcare assistants note down all the beds they need to visit at the beginning of the round and then approach them in order, thereby organizing their round. There is currently little support from the device in terms of doing a blood glucose round as opposed to a single reading.

At the third layer we noted information flows that have an impact on the device's practice and related functionality but seem distant from its primary purpose in terms of location and timescale. These include training, policy and configuration decisions, and tasks related to monitoring the centralized database.

4.4. Concentric layers within the physical model

During observations, sketches, photos and notes were taken of the arrangement of equipment, room layouts, and other physical features of the environment. Attention was paid to how the use of space impacted cognition, and how it helped or hindered information flow. The DiCoT-CL framework provided a convenient structure to consider the bed, the ward and the hospital.

The first layer of the physical model was the immediate environment for device use: by the bedside. 'By the bedside' was different in different contexts. For example, in four bed bays the trolley was placed quite close to the patient and the device was prepared there. In patient side-rooms it was left outside and the device was prepared there before entering the room, mainly for infection control reasons. These physical constraints play a role in task performance as the example of the healthcare assistant missing the small icon above demonstrates.

At the second layer that included the ward, we noted different issues. Part of the healthcare assistant's procedure was to notify the nurse immediately if a reading was outside the controlled parameters; however, on a busy ward with multiple rooms it was not always easy to find the correct nurse and this could delay the round. There was a breakdown in information flow.

The third layer was beyond the ward to the hospital layer (see Fig. 1). The diabetes specialist nurse and the biochemist monitored data across the hospital on the centralized database. This was a new capability that came with this system. This introduces a new level of informatics that includes different professionals interacting in new ways across multiple hospital locations.

4.5. Concentric layers within the evolutionary model

The evolutionary model did not play a significant independent role in guiding the empirical observations. However, for completeness we include it. DiCoT-CL encourages the analyst observe how the device and its practice reach out across different periods of time (see Fig. 1). At the first layer we include those interactions that happen across seconds and minutes, e.g., a blood glucose meter reading. At the second layer we include those interactions and activities that stretch across hours and days, e.g., a blood glucose round and training. At the third layer we include those interactions that stretch across weeks, months and years, e.g., policy and purchasing decisions. Across broader conceptions of time are also the evolutionary developments of products, technology and services whose history and trajectory affect what is happening at the present. These much broader timescales relate to the cultural heritage described by Hutchins [22].

5. Design considerations

Based on these findings, and the different levels of analysis, there are design considerations that emerge both locally around the device and more broadly within and across layers. The former are typically incremental while the latter may represent more radical re-design possibilities.

5.1. Incremental design considerations

Incremental design considerations can reveal themselves through the course of analyzing the basic mechanics of the system. Due to the sociotechnical focus of the analysis, these design considerations go beyond the device to the broader system. They include adaptations of the context to fit the device and adaptations for the device to fit its context. Design considerations from issues reported in Furniss et al. [58] which impact the transformation and propagation of information include the following:

- Staff could be better informed about how data was downloaded and uploaded to the device, and informed of what happened to that data. This could facilitate better problem solving when breakdowns occur.
- Staff could be better informed about the codes (e.g. 2222 or 9999) needed to by-pass entering a patient ID number if it is not known in an emergency, or an emergency button could be implemented so that staff do not need to recall arbitrary codes that are rarely used on inpatient wards. A helpline could assist staff when breakdowns occur.
- Functionality to acknowledge the sharing of staff barcodes could be designed into the system, e.g., to record when a senior nurse allows a student nurse to use the glucometer. This could improve knowledge about the prevalence of this practice rather than it being hidden.
- The continual manual entry of staff ID, rather than scanning their barcode, could raise an alert with staff who monitor the central database because this may indicate that the member of staff needs a new barcode sticker. Automatic monitoring could trigger an alert for this practice.
- Patient hospital numbers could be chunked, e.g., into groups of 4 digits with spaces between instead of a single string of digits, to allow for easier data entry and error checking. For example, 975324680192 is arguably harder to read and check than 9753 2468 0192. This fine-grained detail of interaction could impact the cognitive task.
- The HI and LO fluid containers required for the quality control checks are differentiated by color (i.e. grey and white lids). However, it is not clear which is which. A 'H' or 'L' on the lids could help offload cognitive effort.
- A small drip icon indicates that the glucometer is ready to receive blood but this is not perceptually salient. This appears to be a legacy icon from previous versions of the device that do not take advantage of the display technology now incorporated. The device could display a large countdown from 3, to 2, to 1, rather than a small drip, to indicate when the device is ready for the next step.
- Healthcare assistants could be supported if they cannot find the patient's nurse to warn them of a high or low reading, e.g. a delayed reminder could allow the round to progress and the nurse to be notified later (this buffers the critical information until later in the process), or a paging system could notify the nurse remotely (this facilitates information flow).

5.2. Non-incremental design considerations

Substantial (non-incremental) design considerations can be inspired from different sources, e.g. by analyzing the basic mechanics of the system or self-reported from people in context. However, due to their innovative nature they require more support to see the system in new ways. Using the concentric layers framework encouraged us to think creatively about: (1) different layers that affect device practice; and (2) new forms of interaction between these layers.

An example of thinking creatively about different layers is moving from seeing the glucometer as a single-use device that measures one patient at a time, to thinking about how it can support healthcare professionals performing a blood glucose meter round. This insight came from thinking about what higher layers meant for the device in the information flow model. In particular, we related this to observations of users scribbling down the identity numbers of patient beds they needed to visit. This is a novel frame of thinking about the device: i.e., the suggestion that the device could support healthcare professionals on their round breaks the normal mode of thinking about the glucometer as a single-use device.

An example of considering novel forms of interaction between layers arises from thinking about extending the notes facility. At the moment this is a facility to record extra information about a blood glucose meter reading (at layers 1 and 2), which is monitored by diabetes specialist nurses and biochemists (layer 3) but staff (at layers 1 and 2) underutilize it. Information is only moving up the hierarchy. Following this line of thought highlights the potential for information to move back down the hierarchy, i.e., two-way interaction between the healthcare professionals and diabetes specialist nurses and/or biochemists. Development of the notes facility could facilitate dialogue about a patient or issues with the device. This is a novel frame of thinking about the device: i.e., the suggestion that the device could be used as a two-way communication channel rather than information only going one way. Further support could be given in the form of a help line whereby staff are made aware of the number on the glucometer or docking station. Such a help line could also address issues such as what to do in case a hospital number is not known or unavailable.

6. Discussion

Researchers applying sociotechnical approaches to medical informatics have long argued for holistic approaches to device design and evaluation. For example, devices should be seen as being embedded in context (e.g., [37]), and reciprocally coupled to context (i.e., the device influences practice, and practice influences the device) (see e.g., [61]). However, less attention has been given to thinking about different layers of sociotechnical systems for studies of device design and use.

We have proposed and applied an approach based on concentric layers of Distributed Cognition. We have argued that such developments in methods are necessary to meet the challenges of devices that are 'reaching out', becoming more complex, and are more commonly procured, managed and used by a fragmented organizational system. We have offered a framework for describing a system along DiCoT's five themes at different concentric layers, DiCoT-CL.

DCog has a rich history that covers different contexts, foci and methodological developments. We have focused on DiCoT, which builds on our previous work in healthcare [16,36] and analyzing medical devices more specifically [30]. What DiCoT emphasizes, which previous methods do not, is analytic support to facilitate a DCog analysis through models and their associated principles. Our previous studies using DiCoT have looked at different levels in the sociotechnical system. For example, when analyzing the London Ambulance Service control room we looked at the individual workstation level, desk level with multiple operators and room level with many desks in the physical model [16]. What we found whilst conducting this analysis was that different levels can be attended to across the other models too. This paper modifies DiCoT by proposing concentric layers of Distributed Cognition around a medical device.

The clear focus on the informatics within and around the user–device interaction, at different levels, from a DCog perspective, distinguishes our approach from broader sociotechnical approaches for studies of medical device design and use. Broader approaches to human factors and patient safety [e.g. 49–51] have not been developed to specifically focus on the design and use of devices. These broad approaches could be repurposed to focus more on the role of a device in a sociotechnical system; however, they would still lack the emphasis on the device's design and use that we propose in our framework. DiCoT-CL puts the user–device interaction at the analytic core of the framework, which lends itself to device design and evaluation studies that include the sociotechnical system, rather than studies of sociotechnical systems that include a device. Furthermore, these broad approaches are typically used for identifying latent and active conditions in the system that might lead to an adverse event, and weaknesses in the system that might erode patient safety. None provides a detailed DCog description or model of the system. In our results we have examples of higher-level factors (e.g. management choosing to not enable a feature on the device that allows users to bypass quality control checks, even in emergency situations) and fine-grained details of interaction (e.g. confusing the HI and LO fluids, chunking hospital numbers, and missing the small icon to indicate that the device is ready to receive blood), which impacts the coordination of information in the system. Halverson [52] observes that building such a description of the system facilitates design insight. In other words, a DCog description or model acts as a representation to scaffold moves from analysis to design. For example, noticing the healthcare assistant missed the small icon, identifying that the salience of the icon contributed to the error, and then proposing a redesign of the interface to improve the salience of the interaction shows how we move from data, to theory, to considering redesigns.

Researchers with deep expertise in DCog may not need the analytic support that DiCoT and DiCoT-CL provide. However, DiCoT responds to the criticism that DCog lacks analytic support: DiCoT gives structure to the application of DCog. DiCoT-CL extends this support for medical device design and use to include:

- Putting the medical device at the heart of the analysis.
- Encouraging reflection on gaps in the analysis, e.g., to check that all DiCoT's models have been explored at the different layers that are included in the analysis.
- Encouraging reflection on issues that relate within and between layers (see the section on non-incremental design considerations).
- Providing a bridge for analysts who are comfortable focusing on the device but who want to take a systematic approach to including the broader sociotechnical system.
- Encouraging analysts to reflect on the scope of their analysis.

DiCoT-CL helps scope sociotechnical DCog studies and evaluations of medical devices: rather than assuming some arbitrary boundary of a system, we are reminded of the multiple layers to choose from and analyze. More broadly, analysts should explicitly consider what layers their study includes, what is on the periphery, and what is excluded. Engagement with different layers can be adjusted within a study as the analyst gets a better idea of what is and is not important as they engage with data: flexibility exists with DiCoT-CL.

DCog systems can potentially be distributed across a broad area in terms of time and space. In our analysis of the glucometer we present three layers: from the individual to the ward to the hospital (see Fig. 1); but these layers could be adjusted to be finer grained, there could be more layers, and they could stretch further to include multiple hospitals (e.g., data could be monitored at an inter- rather than intra- hospital layer) or even as far as international markets, regulation and government. All of these layers have the potential to impact device design and use. Which layers are addressed depends on the purpose and resourcing of a study. As Reason [62] notes, research costs for investigating the impact of more remote levels increase and the ability to make effective system changes decreases.

Any framework that guides analysis highlights some areas and de-emphasizes others. DiCoT-CL encouraged us to look at the glucometer differently, and so led to more substantial design considerations. One insight came from pondering what higher layers of the information flow model might mean for this device. This led to thinking about the device as supporting a blood glucose round rather than just as a single reading device. A second insight came from pondering how the notes facility of the glucometer was currently only a one-way channel between layers, and perhaps could be used as a two-way channel in further iterations of the device. It is possible that these insights could be gained without support from DiCoT-CL. However, the structure of this framework facilitated these insights.

6.1. Limitations and future work

Structure in a framework can add analytical value in terms of providing guidance and raising model-driven questions and ideas that might not have otherwise have occurred to the analyst. For example in Section 5.2 we highlight two design considerations that were influenced by the structure and parts of the framework. However, the structure of a framework can mask relationships and phenomena that the framework does not include. Essentially it emphasizes some things and de-emphasizes others, and so readers should be mindful of what DiCoT-CL attends to and what it could distract from.

Frameworks can be applied in rigid and loose ways. We view DiCoT-CL as a guiding framework that leans towards a looser use. The analysis should be grounded in the data, meaning that the framework's boundaries could bend and blur in practice. Novice users of DiCoT may be more concerned about applying the method correctly, trying to fit data to the five models quite rigidly, whereas more experienced users see it as a means to an end with the end being to understand and gain insight into the system [63]. Applying the framework in an overly rigid way could stifle insights and results.

Putting the user–device interaction at the center of the analytic framework biases towards human–computer interaction issues rather than human–human issues. This has consequences for its focus and the issues that it engages with. The value of putting the device at the center is that it focuses analysis on its design and use, and how it is coupled to the context. Human–human issues still might be revealed at higher levels of the social model, but these should still contribute to a story about how the informatics environment influences, and is impacted by, the device.

One of the implications of this approach is that an understanding of the device's performance is heavily coupled to a context. This decreases claims to generalizability of an analysis but provides a deeper understanding of what affects a device's performance in a particular setting. Sittig and Singh [46] highlight the importance of analyzing systems holistically such that what is said of a device in one context might not hold for the same device in a different context, because the complex adaptive system cannot easily be reduced to its components. Successive analyzes of the same device in different settings should allow one to recognize general patterns across contexts. This will not be a surprise to those familiar with ethnographic research techniques that essentially share the same issue. We have achieved this by observing the glucometers use by different users, on different patients, in different parts of the oncology ward.

The proposed framework has been heavily influenced by the characteristics of our case study, which has been based on the detail of a single ward. An example that DiCoT-CL would find challenging would be the analysis of a medical device that moved across multiple wards or contexts. For example, consider a defibrillator used by an ambulance crew or infusion pumps used by community nurses. The challenge is incorporating common abstract patterns between contexts, whilst accounting for the nuanced details between contexts. An example that emerged in our study was whether staff know to enter 2222 or 9999 if they do not have a valid patient ID available – they do not know on the oncology ward but they do know in accident and emergency. It is not the case that the ward level for one context translates to ward level of a different context, i.e. these levels are hierarchical and lateral movements should be made with caution. Potential could lie in comparing different DiCoT-CL diagrams of the same device, which would have a common core but different outer layers to account for different contexts. However, outer layers can impact lower layers as in the 2222/9999 example. So a common core cannot be assumed. These examples across contexts are beyond the scope of the current paper.

Hospital systems are becoming more interconnected and technology is observed to 'reach out', and so we believe that DiCoT-CL is applicable to other medical devices. However, this framework should be tested in further studies, to see how it can inform and guide from the beginning of an analysis. In addition, this study is largely descriptive to introduce the framework. Future studies should build on this by focusing on new incremental and substantial insights within and between layers in different contexts.

7. Conclusions

Medical devices are becoming more interconnected, complex and supported by fragmented organizational systems. We need to develop analytic tools that can describe and capture these issues, with a particular focus on the informatics within and around medical devices. We have proposed a novel framework: the DiCoT concentric layers (DiCoT-CL) framework, which aims to provide such support. This framework advances analytical support for DCog studies that aim to evaluate the design and use of medical devices in practice. It achieves this by building on DiCoT, which is a method that constructs five interdependent models (i.e., information flow, artifact, physical, social and evolutionary) to describe and analyze systems. DiCoT-CL organizes the models into concentric layers of Distributed Cognition with the medical device as the central focus. For researchers interested in medical device assessment and development this encourages reflection on the device's coupling to different layers of the system, reflection within and between levels, and reflection on the scope and coverage of the analysis.

Competing interests

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