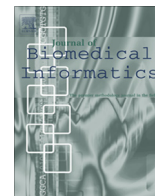




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Exploring medical device design and use through layers of Distributed Cognition: How a glucometer is coupled with its context

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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.

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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.

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