BRAVE NEW WORLD: MEDICAL DEVICES, CLINICAL INFORMATION SYSTEMS, NETWORKS, AND PATIENT SAFETY

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Improvement of patient safety is one of the main justifications for proposals to expand the role of information technology (IT) in healthcare. Many proponents now envision future hospitals as seamless IT networks that integrate diagnostic and therapeutic clinical computing with work process and business management. The potential for this pervasive computing environment to improve work processes and increase efficiency is clear. It is far less clear, though, what sorts of human factors issues are likely to arise as the role of IT systems in healthcare increases. This paper poses questions about the influence of IT on sharp (operator) end performance, including: What are the effects of dissolving the boundaries among discrete devices, clinical information systems, and the business processes of healthcare? How will responsibility and authority be distributed and managed in such a networked environment? Will clinicians become the agents of the machines, as some would like? At what point will accountability be assigned? How can designers avoid creating technology-centered automation? The answers have significant implications for the future of clinical care and patient safety.

INTRODUCTION

In contrast with other sectors such as the military and aviation, little attention has been paid to the systemic aspects of healthcare. The research that is necessary to obtain that understanding is performed infrequently. This is because research into healthcare cognition is difficult, for a number of reasons. Information is dense at the sharp (operator) end. Practitioners devote more attention to their own science than they do to support issues. Clinical practice changes often and there are many points of view as to how it should be performed. Views on what constitutes the preferred approach to clinical care are subjects of debate. (Nemeth, *et. al, in press*) For these reasons, sharp end research takes significant sustained effort.

Healthcare provides a useful ground to explore the development and implications of IT at multiple levels. The desire to create systems that are human-centered (Billings, 1997) is worthwhile, yet is far more difficult than many appreciate. This is what David Woods (1994) meant by noting that "the road to technology centered systems is paved with user-centered intentions." IT development that is intended to be user-centered but does not succeed leaves us with results that are molded solely by technological considerations. As the complexity of clinical care grows, information technology (IT) support spans multiple applications that include medical devices, clinical information systems, as well as work management, accounting, and documentation. This paper poses questions about the influence of IT on clinician performance across equipment, systems, networks, and work processes that have significant implications for healthcare and patient safety.

EQUIPMENT ISSUES

Most infusions of powerful, fast-acting medications are now administered by microprocessor-controlled pumps that must be programmed by clinicians. (Hunt-Smith, *et.al.,* 1999) The current generation of infusion devices incorporates multiple modes of operation, involves substantial operator programming, and contains layered, nested menus with complex branching. Interface designs provide little useful feedback about the state of program entry, the history of operation, or the past or present states of infusion devices. Research in our lab (Nunnally, *et.al.*, 2004) shows that practitioners have to perform additional work in order to coordinate and program these devices. This frequently causes experienced device operators become lost while programming, have difficulty tracking device states, and misinterpret device function. For example, infusion pumps are set-up to administer drugs using parameters that do not match the way the clinicians think about infusions. We have found that operators first figure infusions in terms of flow rate (*ml/min*), then need to convert to other parameters (*mg/kg/min, mcg/kg/hr*) in order to program the infusion.

As a further example, representations of current pump state and the programming paths that are available to reach goal states are often ambiguous. This forces the practitioner to develop coping strategies that are effective when used to program an infusion device in specific circumstances, yet are vulnerable to failure in actual use.

While some patients receive one infusion such as a maintenance fluid or parenteral nutrition, many others receive multiple infusions. Because neraly every infusion is controlled by a pump, multiple infusions require multiple pumps. Patients can be seen receiving infusions from as many as ten pumps at a time. If programming one pump is confusing for clinicians, programming and maintaining this many complicates their work further. The circumstance becomes even more difficult when infusions need to be set up rapidly.

Forecasts for the provision of intravenous medications predict that infusion devices will be connected to a series of other networks (Cook, 2003) including computerized physician order entry (CPOE), pharmacy information system (PIS), bar code medication administration (BCMA), and electronic medical record (EMR).

SYSTEMS ISSUES

The smooth operation of a suite of operating rooms requires a particular kind of expertise, which makes coordination among all team members essential. Nemeth, *et. al.* (2004) describes how both anesthesia coordinators and acute care team members in an operating room (OR) suite at a major urban teaching hospital look at the current state of procedures, what has happened, and what they anticipate will happen in order to manage resources throughout each day of procedures. This occurs constantly through the day. The day's intentions and assignments are embodied in a master schedule that is developed the day before, and implemented on, the day that scheduled proceedures are performed. Hard copies of this artifact currently portrays procedures according to operating rooms and the cases that are assigned to each room, by time of day.

OpAssign, the recently-installed computer-supported version of the master schedule, was designed to mimic the hard copy. In the transition between hard copy and-automated versions, unforeseen complications developed. Using the OpAssign system, case status information is frequently posted late by a half hour or more, forcing team members to do extra cognitive work as they make in-person trips and phone calls to verify case status. The roster on the electronic display shifts each time a case is deleted, causing the reader to search the display every time in order to locate a particular case. The computer interface requires practitioners to drill down as a far as four menu levels to find information that was previously available in one glance using the paper version. Computer-supported displays go "down," preventing team members from seeing or entering information. The electronic displays offer only a static or a narrow, limited "keyhole" view of the day, requiring clinicians to perform extra cognitive work to foresee overlaps, bottlenecks, or gaps in resources. This prevents practitioners from making connections that are a necessary part of their cognitive work. Displays allow only truncated descriptions of procedures, that creates misleading representations of what should be prepared in advance. This has caused departments to plan for the wrong procedure, which wastes staff and equipment preparation and results in postponed procedures. Displays do not allow for informal and subtle adjustments to the ways that team members communicate. All of these cause great difficulty as clinicians try to make the moment-by-moment decisions that are necessary for resource allocation. (Nemeth and Cook, 2004)

CLINICAL WORK MANAGEMENT

IT has been proposed as a solution to reduce what has been termed "human error" in the provision of healthcare. The notion behind this initiative is that if humans "make errors," then the removal of humans will remove errors as well. The problem is not "human error." If it exists, error is a consequence of interaction with IT systems rather than a cause of adverse outcomes.(Reason, 1990:173) It is the human practitioner who ensures success. On the surface, healthcare work seems to flow smoothly. That is because the clinicians who provide healthcare service make it so. Just beneath the apparently smooth-running operations is a complex, poorly-bounded, conflicted, highly variable, uncertain, high tempo work domain. The *technical work* (Cook Woods, and Miller, 1998) that clinicians perform resolves these complex and conflicting elements into a productive work domain. (Nemeth and Cook, *in press*). The challenge is to foresee how IT can aid, not replace, the cognitive work that is performed in healthcare.

In its current state, misperceptions about IT have substantial consequences for clinical work management. Husch, *et.al.* (2005) contend that dose-related error reduction relies on interfacing infusion devices with other systems dealing with the use of medications such as the electronic medical record, computerized physician order entry, bar code medication administration and pharmacy information system. Such systems may be beneficial, but they can also suffer from difficulties such as being unable to handle marginal conditions that are a regular part of patient care. For example, computerized physician order entry relies on a centralized computer system to track and manage the provision of medication. CPOE is intended to create a continuous connection from physician, to pharmacist, to nurse. The approach is intended to reduce causes of medication error by improving the reliability and accuracy of health care system performance. While IT can improve on some difficulties, it can also introduce others. Indeed, Koppel, *et.al.* (2005) report that clinicians at one major acute care facility perceive their CPOE system to have problems related to data entry, and lack confidence in this clinical IT system's reliability.

In 2003, 2.9% of reported errors were attributed to a long-suspected cause of medication adverse events: illegible handwriting. However, in that same year, computer entry accounted for 13% of reported errors. Nearly 20% of hospital and health system medication errors that were reported in 2003 involved computerization and automation. (USP, 2004) One reason, among many, is that systems vary widely among organizations. One clinician found the Department of Veterans Affairs' EMR "vastly better" than the EMR at a large urban teaching hospital which he found "exceedingly painful to use." (Anesthesiologist M. O'Connor, Personal Communication, 16 November 04)

Efforts are underway to develop facility-wide centralized systems to manage all medications including infusions. The integration of multiple departments and systems that would be involved in such an arrangement poses similar potential difficulties with unforeseen consequences.

NEW CAPABILITIES, AND PROBLEMS

IT systems that have been developed wiothout an appreciation for the work they are intended to support are experiments, rather than operational systems. (Nemeth and Cook, *in press*) Their combination into series of other similar systems should be a cause of concern for those who presume that IT will improve work productivity and reliability. The notion that a system can be fixed after it is installed does not necessarily apply. Improvement to one portion of the system to provide care may not yield a benefit if the remainder of a system is dysfunctional (Edwards, 2005)

As the use of IT grows, the distinctions blur between products and systems, and systems and networks. For example, depending on the way that a problem with an infusion device is described it can be seen as an issue for pharmacy, bio-medical engineering, purchasing, IT, education, or unit manager. This lack of distinction fragments and decentralizes responsibility for a single medical device, as well as the reporting and resolution of problems that are associated with it. As the trend continues, it can be expected to blur the responsibility for the safe introduction and use of a single device. The blending of systems and subsequent blurring of their boundaries has implications for a number of issues, including.

Role of operators

- Will clinicians become the agents of the machines, as some would like?

Troubleshooting

- How will systems be identified when problems occur?
- How will problems be traced if their original source is not known?

Accountability

- Where does responsibility for a system begin and end?
- At what point will accountability be assigned?
- How will responsibility and authority be distributed and managed in such a networked environment?
- How will responsibility be assigned when systems fail to perform?

Ripple effects

- How will information propagate across the systems?
- In what ways will changes to one system (including outage or degradations) affect others?

Barriers

- What are the effects of dissolving the boundaries among discrete devices, clinical information systems, and the business processes of healthcare?
- What means will be available to stop the progress of processes that are undesirable once they begin?

Verification

- At what point(s) will it be possible to verify the accuracy, recency, appropriateness of information?

Development

- How can designers ensure that they create IT systems that are human-centered, not technology-centered?

HEALTHCARE IT AS A TEAM PLAYER

Equipment and systems that are intended for use by clinicians must necessarily reflect actual clinical practice in order to be suited for use at the (operator) sharp end. The efforts that are required to accomplish this are not simple, as this is the most complex and varied work setting that IT has tried to support. (Rasmussen, 2000)

Support for sharp end cognitive work requires attention to the subtleties and complexities of the real world of clinical care that are unforgiving in their consequences. This insight comes from research into sharp end healthcare practice using methods from the social sciences and engineering that reveal the deeper, durable aspects of the healthcare work domain. (Nemeth, Cook, and Woods, 2004) The lessons from such research can be used as a foundation to meet the challenges that are inherent in making IT a team player in healthcare. Klein, *et.al.* (2004) propose ten traits for automation to participate in *joint activity*—extended actions that are carried out by an ensemble of people who are coordinating with each other:

1-Fulfill the requirements of a Basic Compact to engage in common-grounding activities

2-Able to adequately model other participants' actions vis-à-vis the joint activity's state and evolution

3-Be mutually predictable

4-Be directable

5-Able to make pertinent aspects of their status and intentions obvious to their teammates

6-Able to observe and interpret signals of status and intentions

7-Able to engage in negotiation

8-Enable a collaborative approach

9-Able to participate in managing attention

10-Help to control the costs of coordinated activity

CONCLUSION

The challenge for human factors professionals is to anticipate the changing landscape that these issues present, to appreciate the actual nature of complex work domains through substantive research, and to foresee opportunities to shape clinical IT systems before they are installed and made operational.

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