

COLLOQUIUM ANNOUNCEMENT

**ANTICIPATING THE HUMAN FACTORS OF
NEXT GENERATION INFUSION DEVICES**

47th Annual Meeting of the Human Factors and Ergonomics Society, Denver, CO

Thursday, October 16, 2003, 08:30 to 12:00

Co-leaders: Richard Cook, Cognitive technologies Laboratory, University of Chicago
Jay Crowley, Center for Devices and Radiological Health, FDA

Plan for the Colloquium:

It is clear that producing high quality human factors in the next generation of infusion devices will require reaching out past current approaches. To anticipate the research and demonstrations needed to support future design decisions, this colloquium will bring together experts from several disciplines in a small group for discussion of aspects of the experience with devices to date, the implications of findings from research on automation in healthcare and other domains, and the possible and desirable future pathways for infusion device development and integration. Colloquia attendees will be those actively engaged in design of devices, research on devices and related issues, and the use of advanced medical technology in healthcare. The discussion will focus on possible futures for infusion devices and the issues that are likely to arise.

The goal of the colloquium is to outline and characterize unanswered questions and fruitful areas of investigation that might inform the design decisions that will be made in the next half decade. Using the topics and issues raised in discussion, the leaders will compile a draft whitepaper that sketches the anticipated future challenges and opportunities. The whitepaper will be circulated for comments and a final version will be prepared within 6 months. A listserver for participants will be established to aid in the process of review and revision. The whitepaper will be distributed free of charge via the leaders' websites. If the session is productive, tracks on this topic will be proposed for future HFES meetings.

Background:

Infusion of medication and fluid is a primary mode of therapy for many illnesses. There are many different infusion devices. They incorporate a variety of microprocessor controls and displays and are user programmable. The applications and underlying technologies of infusion devices are changing rapidly. Infusions are used no longer used only in

hospitals but also in outpatient clinics and at home. Some devices may be patient controlled, e.g. patient controlled analgesia pumps, and many now incorporate computational aids-to-programming, e.g. dose conversion schemes. Distributed information technology offers the prospect of integrating infusion device operation into hospital clinical information system networks, permitting more complicated infusion regimens, control and monitoring from remote locations, and the application of various decision aids at different stages of the medication administration process. Future infusion device operation will involve human and machine operator agents working in tandem. This, in turn, places a premium anticipating the human factors of these devices, in particular the cognitive ergonomics of automation.

Poor coordination between human and computer is a potent source of accidents. Incident report collections, including the FDA's MAUDE database, suggest that problems with programming, operating, and troubleshooting infusion devices are common. The sources of these difficulties are not well understood but the variety of applications, complexity of infusion regimens, and the physics of infusion therapy (e.g. inability to observe directly slow infusions) all contribute.

Integrating devices into clinical information systems offers an attractive pathway for reducing problems in operation and aiding in device fault troubleshooting. Drug identification aids, e.g. bar coding, and parameter downloading through the medical information bus (MIB) are on the near horizon. Devices with wireless control allowing central station detection and monitoring of device programming and operations are not far off. The introduction of such new technology has its own risks. The history of such developments in other high hazard domains shows that integration and distribution of control generates new forms of failure, requires new knowledge and expertise among operators, and poses new challenges for those

seeking to understand the genesis of failures and accidents involving infusion devices.

Until recently, attention has focused mainly on mechanical issues related to infusion devices, e.g. free-flow hazards in tubing setups or flow continuity problems at low flow rates. These issues are now well understood. The problems with future devices, in contrast, are more likely to be related to *information technology* rather than mechanical device features. To incorporate human factors in these new designs requires that designers and manufacturers anticipate the consequences of the shift to this new technology. A host of questions arise, e.g.:

- What should be the content of training when discrete devices become integrated into clinical information systems?
- What are the consequences of mixing together old and new devices? How should new drug regimens be incorporated into these complex systems?
- How can these systems be tested and validated and who should be responsible for doing so?
- What is the role of the operator in these systems?
- How are authority and responsibility to be divided between operators and the distribute information technology?
- How should the tradeoff between more device features and more complexity be managed?
- What consequences will arise as heavily regulated devices become controlled by unregulated clinical information systems?

Accumulated painful experience with clumsy automation and its consequences in the 1980's and 90's led to calls for "user centered" automation and spurred investigation of user cognitive models and work requirements as prerequisites to development of new information technology. Taken together, this experience suggests that *the future of infusion device technology combines both threat and opportunity*.

The *threat* is that new infusion device technology will repeat the pattern of other domains, generating technology centered automation that is, as Woods has put it, strong, silent, and hard to direct, and that creates new workload and generates new forms of failure. The *opportunity* is that anticipating the human factors of these devices will lead to designs that embody cooperative automation that functions as an effective "team player" in the work setting, enhances the resilience and robustness of healthcare delivery, and serves as a model for progress on the human factors of other medical devices.

Participation:

Colloquium attendance is by invitation only and attendance will be limited to facilitate interactions among the group. Preference will be given to those with relevant expertise and involvement in infusion device design, evaluation, or use and researchers, managers, or public policy analysts with specific interest in infusion devices. Although not required, participants will be invited to submit position papers for distribution prior to the session. Additional background material for the meeting will be distributed by e-mail over the summer.

Membership in the HFES is not required to participate in the colloquium although participants will need to register for the annual meeting.

Interested parties are invited to contact the colloquium leaders for details and a proposed schedule for the session:

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