

SYSTEMS ENGINEERING AND POINT OF CARE TESTING: REPORT FROM THE NIBIB POCTRN SYSTEMS ENGINEERING WORKSHOP

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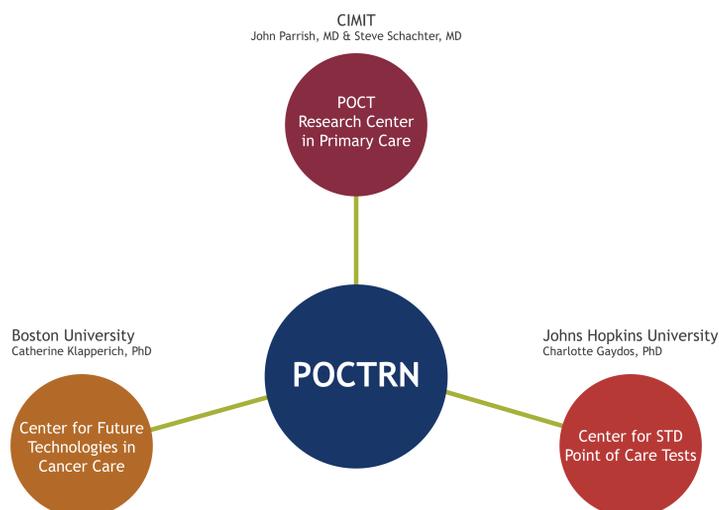


ABSTRACT

Systems engineering is an interdisciplinary field that seeks to better understand and manage changes in complex systems and projects as whole. Systems are sets of interconnected elements which interact with each other, are dynamic, change over time and are subject to complex behaviors. This poster presentation will report on the results of an NIBIB/POCT workshop exploring the future of point of care testing and technologies and the recognition that these new technologies do not exist in isolation but within of other technologies and systems that influence their likelihood of success or failure and their effectiveness.

INTRODUCTION

The US healthcare delivery systems is undergoing significant change. To address emerging challenges and unmet needs, NIBIB created the Point-of-Care Technologies Research Network (POCTRN) whose purpose is to drive the development of appropriate point-of-care technologies (POCT) merging scientific and technological capabilities with clinical need. www.poctrn.org



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Technologies do not exist in isolation but rather within systems of other technologies and which in turn influence their effectiveness and likelihood of success or failure. The Institute of Medicine and National Academy of Engineers called for the introduction of systems engineering tools into healthcare to help solve this and other problems. POCT is potentially disruptive, changing where, when and how we deliver care. The POCTRN adopted the policy of encouraging a systems engineering approach to the design, development and evaluation of POCT.

POCTRN SYSTEMS ENGINEERING WORKSHOP

In this workshop, a diverse group of individuals from around the country, from disciplines ranging from clinical care, engineering, regulation affairs and many others to members of the three major NIH funded efforts in the area the Centers for POCT for sexually transmitted disease, POCT for the future of Cancer Care, POCT primary care research network, gathered together for a modified deep dive workshop exploring the current state of the art and mapping probable future directions and developing longer term goals.

The invitees were broken up into 4 thematic groups: Home, Outpatient, Public/shared space and Rural/global. Each group proceeded to explore the problem and solution space for point of care tests and technology within their theme. While each thematic area had specific challenges, many commonalities also emerged. This effort thus helped create a conceptual framework for POCT as well as identifying many of the challenges for POCT going forward.

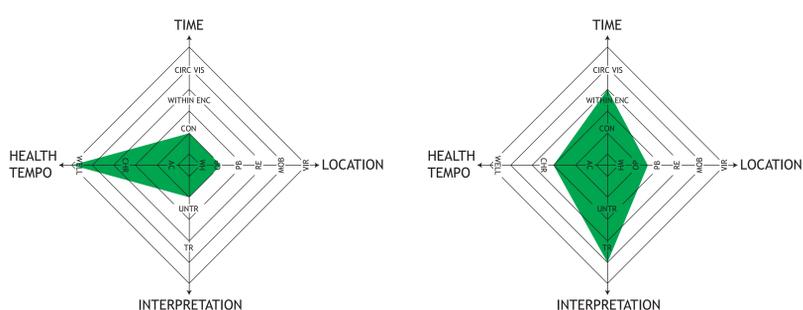
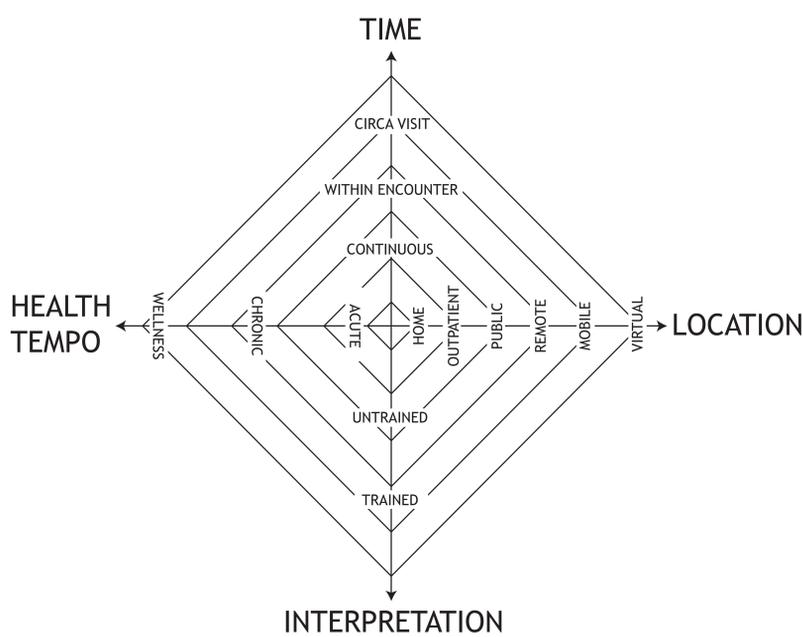
As illustrated in the figure on the right, four main dimensions were identified as defining the functional space for both point of care testing and treatment, these are:

- TIME**
 The interval between test performance and receipt of information by end-user
 Continuous—e.g. pulse oximeter or a pedometer
 Within Encounter—less than 15-20 minutes
 Circa Visit Turnaround—interval of 1-2 working days

- LOCATION**
 Where the test is performed and/or where information received
 Home
 Outpatient medical facility (non-hospital)
 Public or shared space
 Remote
 Mobile
 Virtual

- INTERPRETATION**
 Requirements needed to translate POCT information into a usable form
 Trained
 Untrained

- TEMPO**
 The tempo of a disease or illness refers to the pace and urgency of the individuals health issue
 Acute
 Chronic
 Well



CHALLENGES

There were several current and future challenges, specifically:

CHALLENGE AREAS
Design
Patient driven demand and technology
Information Characteristics and Presentation
Health Information Systems
Connectivity
Workflow and implementation
Maintenance/Cost
Quality Control

To address these challenges, it is recommended that the POCT community consider the following actions:

- Address the technologies' usability, ergonomics, and the behavioral and cultural effects on the individual and society early on in the development process
- Increase the focus on privacy and confidentiality concerns that these technologies raise in parallel to their development
- Survey the landscape of end-users and their needs on a regular basis and providing a mechanism for engaging community driven technology
- Set interoperability standards and standards of reliability and accuracy
- Develop communication and educational standards for clinicians and patient end-users
- Evaluate new systems in the context in which they are implemented—before, during and after implementation
- Include the functions of maintenance and repair as integral to the implementation plan
- Encourage regulatory bodies to develop multiple tracks to examine and regulate new POCT technologies based on a risk assessment and stratification of the technologies
- Encourage regulatory bodies to develop surveillance and outreach programs to help facilitate and guide quality controls for new and developing technologies

CONCLUSION

POCT has the potential to profoundly shape future healthcare delivery. These technologies, however, have the potential to radically alter where, when and how care is delivered and therefore they need to be understood from a systems perspective to best allow their and the system's success.

REFERENCES

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