

# Developing Clinical Decision Support: Traversing the Institutional Landscape

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# Precision Medicine

## Premise

not everybody given the same medicine at the same dose will have the same response

## Promise

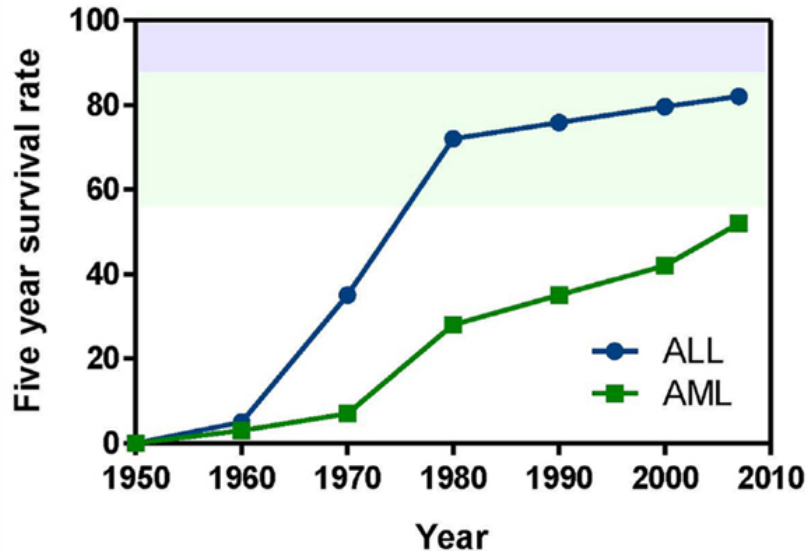
leverage individual information from genes, environment, lifestyle. etc...to accurately treat disease

## Challenge

knowledge and skills to implement differ from clinician to clinician



# Success with Optimal Utilization



# Busulfan in Bone Marrow Transplantation

- part of conditioning regimen
- large inter-individual variability
- narrow therapeutic index
- FDA product label addresses individualization



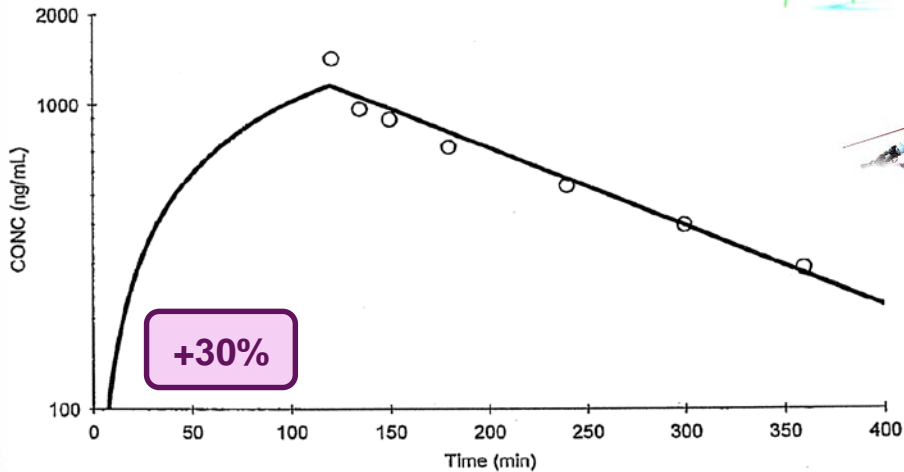
failure to  
engraft

severe liver  
toxicity

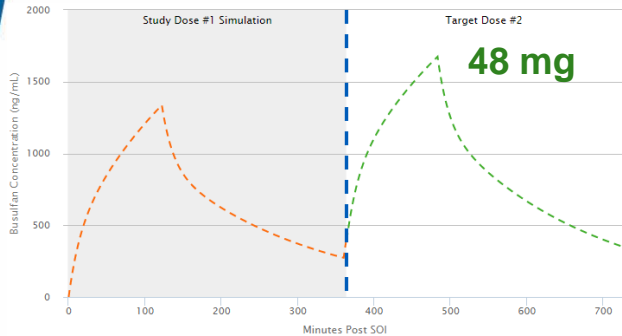
# Busulfan Individualization: Original Process

Aspect	Limitation
<ul style="list-style-type: none"><li>Reference lab contacted &gt;48 hr in advance</li></ul>	inconvenient
<ul style="list-style-type: none"><li>Admission restricted Mon-Thur</li></ul>	
<ul style="list-style-type: none"><li>Samples manually logged</li></ul>	inefficient
<ul style="list-style-type: none"><li>Recommendation via call(s) coordinated b/w lab and team Mon-Fri 9-5 (PST)</li></ul>	
<ul style="list-style-type: none"><li>Dose #7 modified</li></ul>	excessive
<ul style="list-style-type: none"><li>Questionable PK modeling</li></ul>	inaccurate

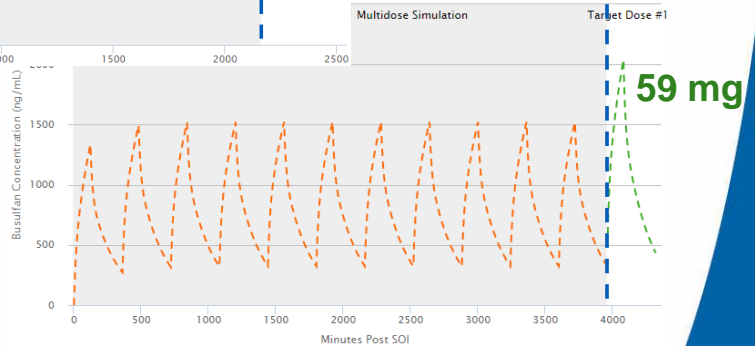
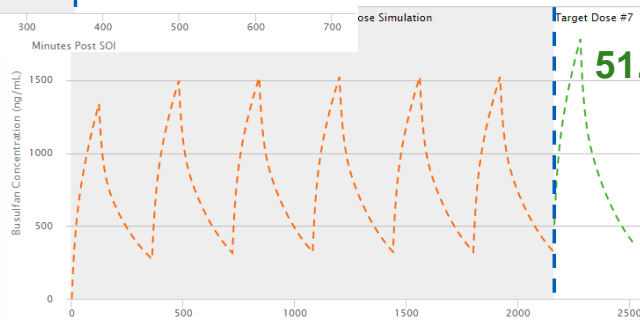
# Reference Lab #1



# Reference Lab #2



$$\frac{\text{Exp}_{\text{observed}}}{\text{Dose}_{\text{original}}} = \frac{\text{Exp}_{\text{desired}}}{\text{Dose}_{\text{new}}}$$



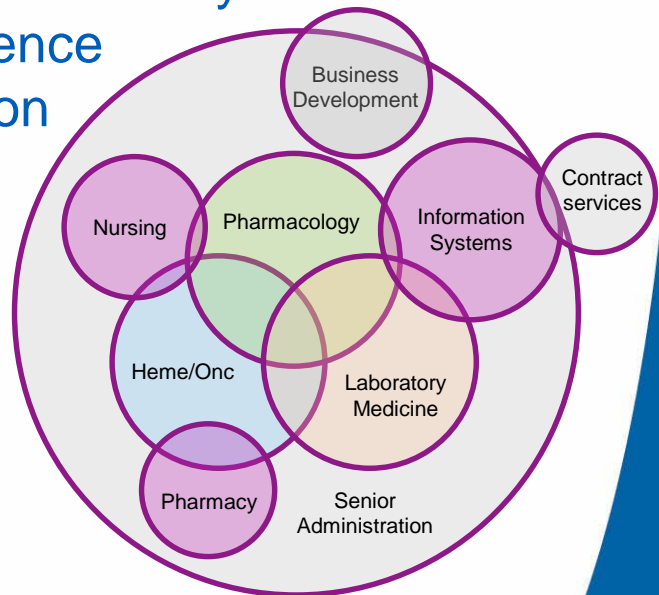
# Solutions Considered for Children's Mercy

1. bring plasma assay online
  2. perform modeling & simulation in house
    - a. formal pharmacokinetic consult
    - b. access to external PK software
      - rarely designed for physician user
      - can be unnecessarily complex
    - c. clinician-driven decision support tool
- } interrupt the flow of care



# Successful DSTs...

1. developed with local users
2. available at time/location of decision making
3. integrate within the charting/order entry system
4. do not require additional data entry
5. justify decision with evidence
6. provide a recommendation



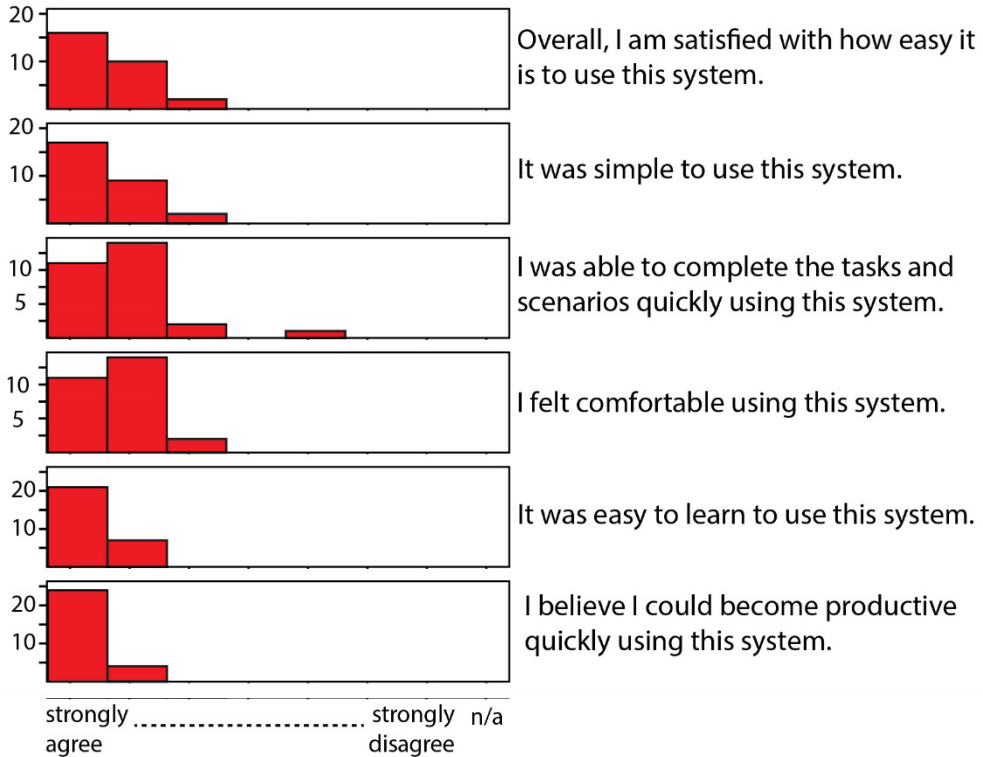
AHRQ Publication 12-E001-EF. April 2012

# DST Development Activities

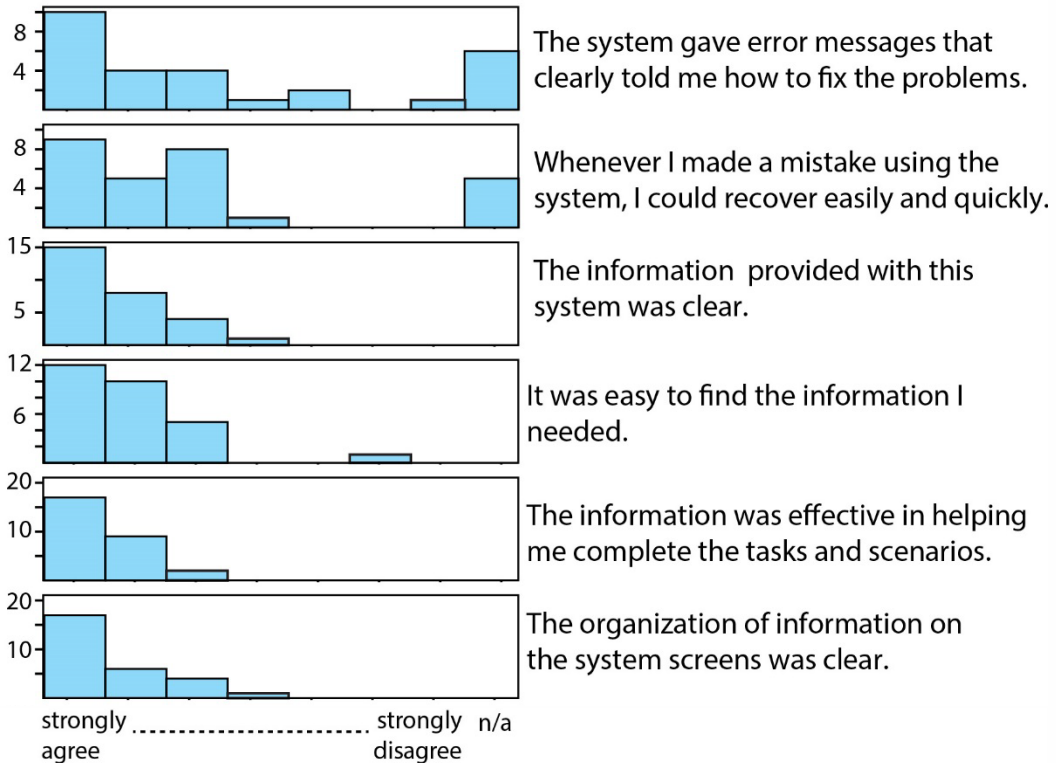
1. Requirements Analysis
  2. Prototype and Design
  3. Unit and Integration Testing
  4. Functional Testing
    - Structured Cognitive Walkthroughs
    - Usability Testing
- 



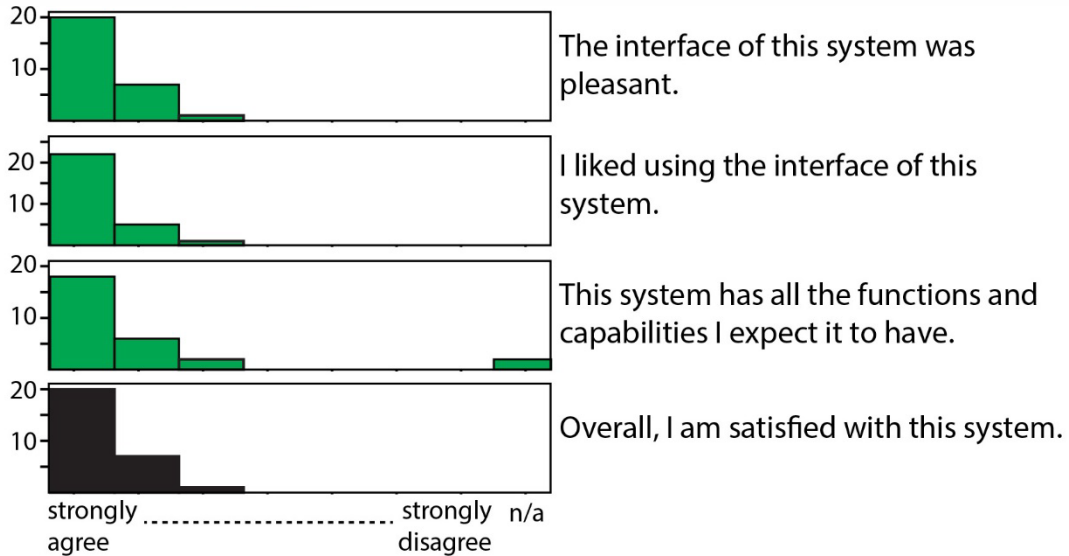
# System Quality



# Information Quality



# Interface Quality & Overall



# Busulfan Individualization: Revised Process

Original Limitation	Solution
<ul style="list-style-type: none"><li>Reference lab contacted &gt;48 hr in advance</li></ul>	<ul style="list-style-type: none"><li>Reference lab contacted same day</li></ul>
<ul style="list-style-type: none"><li>Admission restricted Mon-Thur</li></ul>	<ul style="list-style-type: none"><li>Admission Sun-Sat</li></ul>
<ul style="list-style-type: none"><li>Samples manually logged</li></ul>	<ul style="list-style-type: none"><li>EHR PowerForm</li></ul>
<ul style="list-style-type: none"><li>Recommendation via call(s) coordinated b/w lab and team Mon-Fri 9-5 (PST)</li></ul>	<ul style="list-style-type: none"><li>Performed when convenient 24/7</li></ul>
<ul style="list-style-type: none"><li>Dose #7 modified</li></ul>	<ul style="list-style-type: none"><li>Dose #2-3 modified</li></ul>
<ul style="list-style-type: none"><li>Questionable PK modeling</li></ul>	<ul style="list-style-type: none"><li>Accurate PK modeling</li></ul>

# DST Development Activities

1. Requirements Analysis
2. Prototype and Design
3. Unit and Integration Testing
4. Functional Testing
  - Structured Cognitive Walkthroughs
  - Usability Testing

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5. Regression Testing (CQA)
6. Refactoring



# Primary Challenge



## IT Innovation Stream

ideal  
compliant  
streamlined  
predefined roadmap  
dedicated personnel

## Traditional IT

compliant  
inefficient (dual hats)  
iterative decision making  
communication gaps  
resource costs

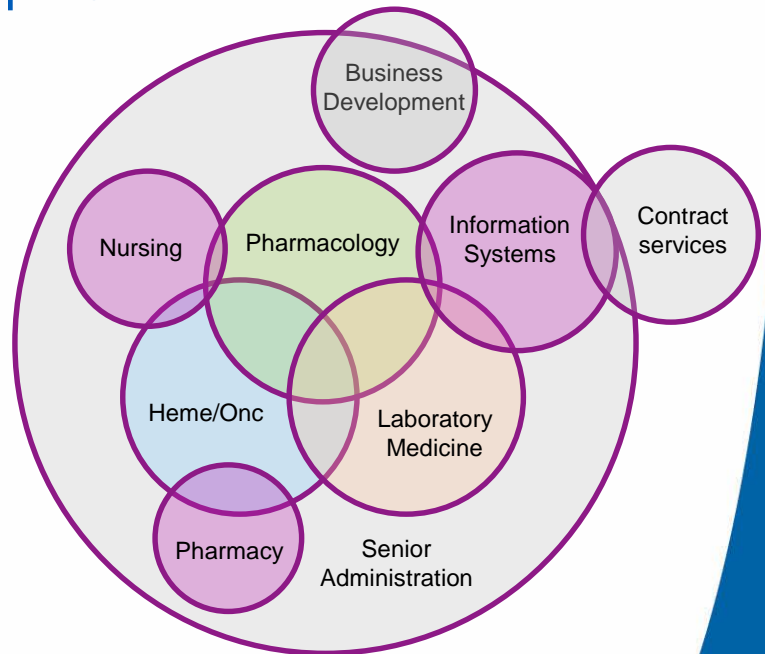
## Shadow IT

efficient  
impractical  
non-compliant



# Secondary Challenges

- long-term management
- business plan development
- accessibility
- sustainability
- regulatory clearance



# Design and Testing of an EHR-Integrated, Busulfan Pharmacokinetic Decision Support Tool for the Point-of-Care Clinician

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