Understanding User Needs in Low-Resource Settings for Diagnostics Development

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Roger B Peck
Technical Officer
Diagnostic Solutions
rpeck@path.org
We Don’t Speak the Same Language

1. How the customer explained it
2. How the project leader understood it
3. How the analyst designed it
4. How the programmer wrote it
5. What the beta testers received
6. How the business consultant described it
7. How the project was documented
8. What operations installed
9. How the customer was billed
10. How it was supported
11. What marketing advertised
12. What the customer really needed

(iSwing)
Low-resource settings are many and varied

- Laboratory infrastructure
- Transport logistics
- Population
- Disease endemicity
- GDP and healthcare expenditures
- Urban vs. rural
- Policy/political will
Understanding the Gap

- User Needs Assessments
- User Centric Design
- Use-case Scenarios
What Do We Mean By “Needs Assessment”? 

1) Identify Challenges – Technology, People & Process

2) Inform Product Development – Requirements and Specifications

3) Direct Product Introduction – Identify Stakeholders and Get Buy-In
Various types of Needs Assessments

<table>
<thead>
<tr>
<th>Concept</th>
<th>Planning</th>
<th>R&amp;D</th>
<th>Pilot</th>
<th>Transfer</th>
<th>Sustain</th>
</tr>
</thead>
<tbody>
<tr>
<td>Needs ID &amp; Assessment</td>
<td>Discovery &amp; Feasibility</td>
<td>Development &amp; Prototyping</td>
<td>Pilot &amp; Evaluation</td>
<td>Introduction &amp; Deployment</td>
<td>Integration &amp; Sustainability</td>
</tr>
</tbody>
</table>

**Problem Characterization**
- Landscape Analysis
- User Needs Assessments
- Product Specification Assessments
- Stakeholder Assessments

**Market Sustainability**
- Segmentation and Market Size Assessment
- Stakeholder Assessments
- Competitive Analysis
- Due Diligence
- Willingness-to-pay

**Economic Rationale**
- Cost Analysis
- Cost-effectiveness Analysis
- Scenario and Sensitivity Analysis

**Policy Environment**
- Stakeholder Assessment
- Feasibility Assessment
- Acceptability Assessment
Target Population

- Who are the buyers, the users and the end beneficiaries?
- What are their drivers and motivators?
- Lower socio-economic and vulnerable groups
  - What diseases affect them most?
  - What is their level of access to health services?
  - Where and when do they access health care?
  - What are their health seeking behaviors?
Disease epidemiology

- Incidence and prevalence
- Regional distribution
- Morbidity, mortality, and DALYs
- Populations most affected
- Symptomatic presentation
- Disease control targets
Clinical action

• How does a diagnostic test impact clinical decision making?
• Is an effective treatment available?
  • Cost
  • Drug resistance
  • Complexity or length of treatment
  • Side effects
• How important is turnaround time?
• Understand where your product will be used
Know your Audience

Introducing

CAPABLE: Sensitive and flexible for every need
INTUITIVE: Imagery of every cell
AFFORDABLE: Designed and priced for every lab

is a compact 12-channel flow cytometer that provides high-end performance and images every cell. It can accommodate four lasers, an AutoSampler, and a Quantitative Imaging upgrade to suit beginners and experts alike. Despite its incredible features, it starts at only $79,000!
Where will it be used?
Where will it be used?
Where will it be used?
How will it be used?
What other resources are available?
Local supply chains may be variable
What resources are available?
Who will use it?
How does it fit with competing priorities?
Status quo diagnostic practices and capacity

• Current diagnostic practices
• Distribution of health facilities and labs
• Profiles of health care facilities
• Workflow for specimen collection, processing, and testing
• Procurement processes
• Decision making processes for use of diagnostic tests
Diagnostic products and market environment

- Diagnostic products currently available and in use
- Benefits and drawbacks of existing products
- Key market players
- Margin, pricing, and promotion practices
- Product distribution channels
- Regulatory requirements
- Endorsement by international agencies
Attributes desired in a new product

- Throughput
- Turn around time
- Required performance
  - Sensitivity
  - Specificity
  - Positive predictive value
  - Negative predictive value
  - Results read-out
  - Qualitative vs. quantitative results
  - Reactions to product concept
User Centric Design

• A philosophy, process, and toolkit designed to develop products that are suited their users and their environment.

• Every product is influenced by what somebody thinks is user centric design, so why does it go wrong so often? Because “they” don’t use a coherent process and “they” violate simple rules about data creation and consumption...
Some Simple Rules

• Match the system to the real world
  • Users’ language vs. system-oriented terms
  • Real-world conventions
  • Natural and logical order
Some Simple Rules

• Make things hard to misuse
  • Rather than possible to use correctly
Some Simple Rules

• Make it easy to recover from errors
Some Simple Rules

• Support undo and redo
  • Should not cause catastrophes
  • “Reset” path
Some Simple Rules

- Use standards
Some Simple Rules

• Foster recognition, don’t require recall
Some Simple Rules

• Aesthetic and minimal design
User Centric Design – Getting Started

• Start with a premise or a question
  • Make it scalable
  • Can start from exploratory research
  • Improvements or cost reductions

• Develop the “front end”
  • Exploration – ethnographic interviews, product placement, participatory design....

• Hone in on salient points to determine Who, What, Where, When and How
  • Needs
  • Scenarios (User and Market Requirements Document)
  • Product Requirements (Product Requirements Document)
  • Specifications (Functional Specifications Document)
I need a test that works better than what I am using now.

I need something that is less invasive than current tests.

I need something that healthcare workers can use in the field.

I need something that tells me current vs. past infections.
I need a test that works better than what I am using now.

I can test for re-emergence of infection.

I can test for the test for monitoring prevalence of infection.

I can test for exposure and/or potential transmission.

Works before symptoms are visible.

Fast turn around time.

Easy to use.

Minimally invasive.

Thermostable.

Nucleic acid based test.

Time to results 20 minutes.

3 steps at most.

Finger prick.

Whole blood.

45 C for 3 months.
Conclusion

• We need elegantly simple solutions to complex problems
• The solution must be appropriate
• Good is not the enemy of the best
• Do the right thing
Thank You

Together we are making a difference