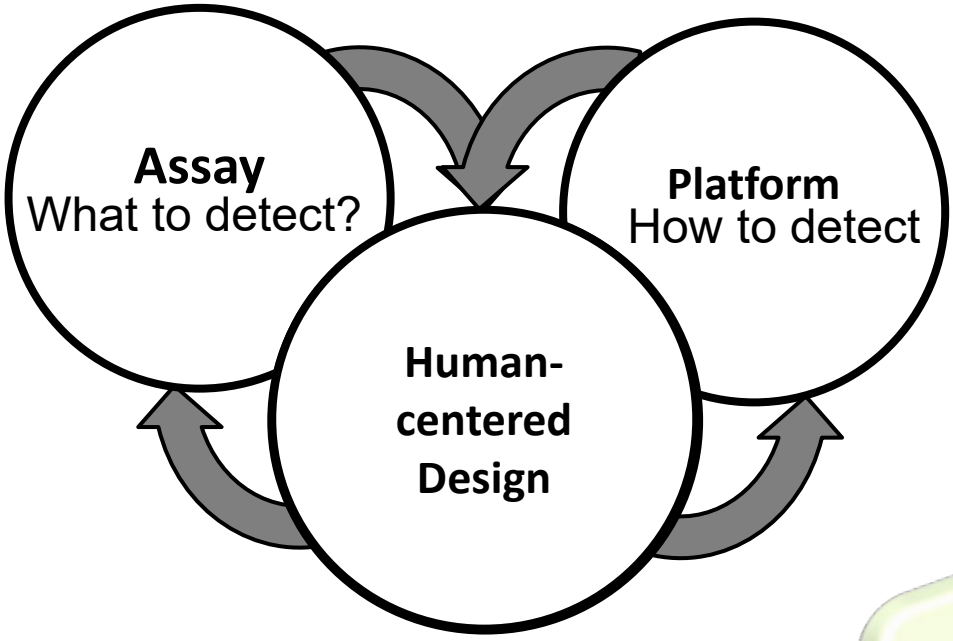
HUMAN-CENTERED DESIGN IN GLOBAL HEALTH DIAGNOSTICS

ENGINEERING POINT-OF-CARE DIAGNOSTIC TECHNOLOGIES



Will anyone use it (correctly)?

Framework from:

Incorporating The Needs Of Users Into The Development Of Diagnostics For Global Health: A Framework And Two Case Studies.

Jacqueline C. Linnes, Elizabeth Johansen, And Ashok A. Kumar. In Diagnostic Devices With Microfluidics. CRC Press, 2017

and previous joint presentations with Elizabeth and Ashok

Why Engage Users

Fishburne, T., in: Constable, G., *Talking to Humans*, Edited by Rimalovski, F., 2014.

When to Engage Users

Early & iteratively in order to increase certainty around critical assumptions.

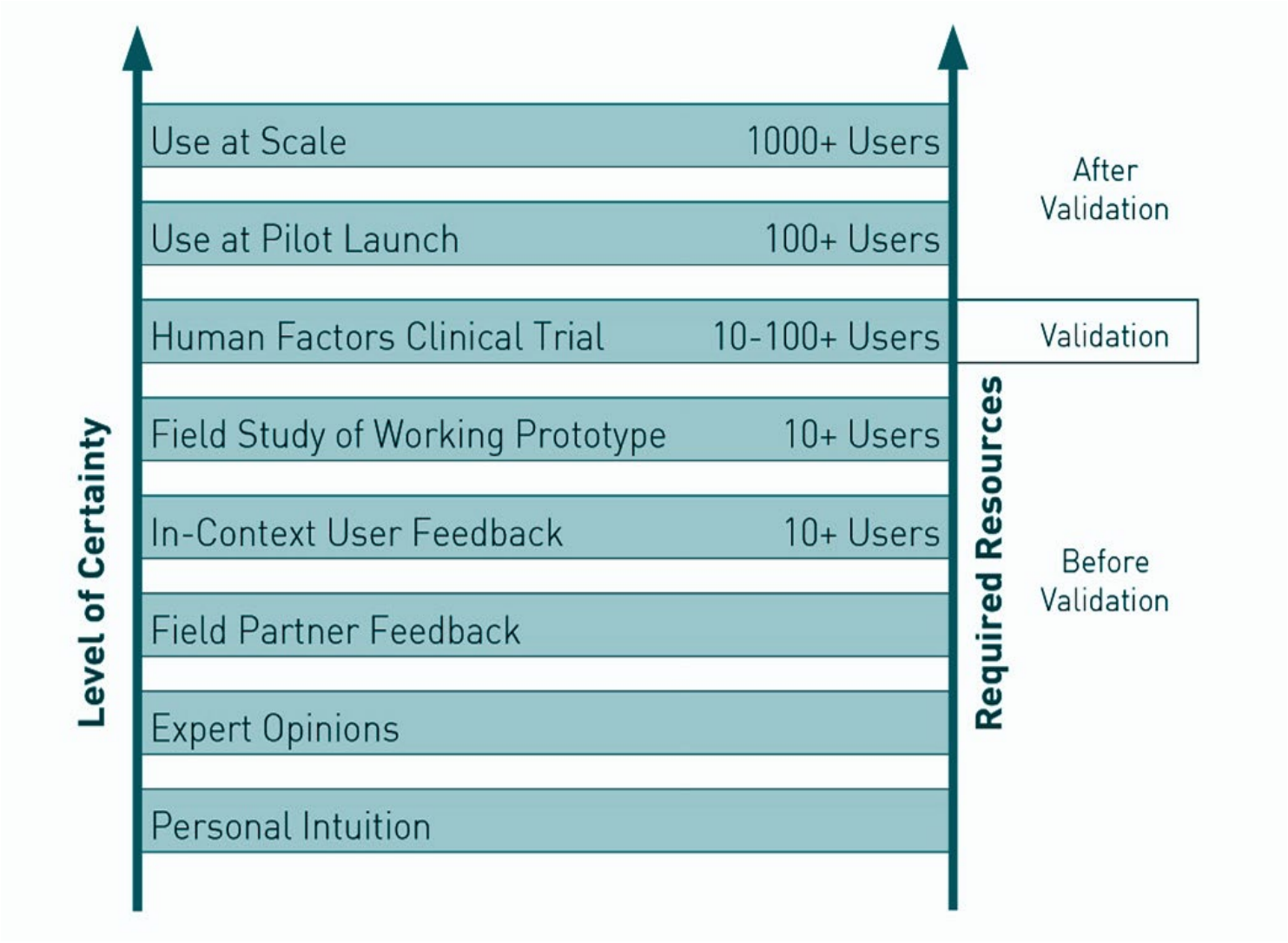
Defining the problem:

- The correct users have been identified
- The correct need has been identified
- The correct context has been identified
- The correct barriers have been identified

Defining the solution:

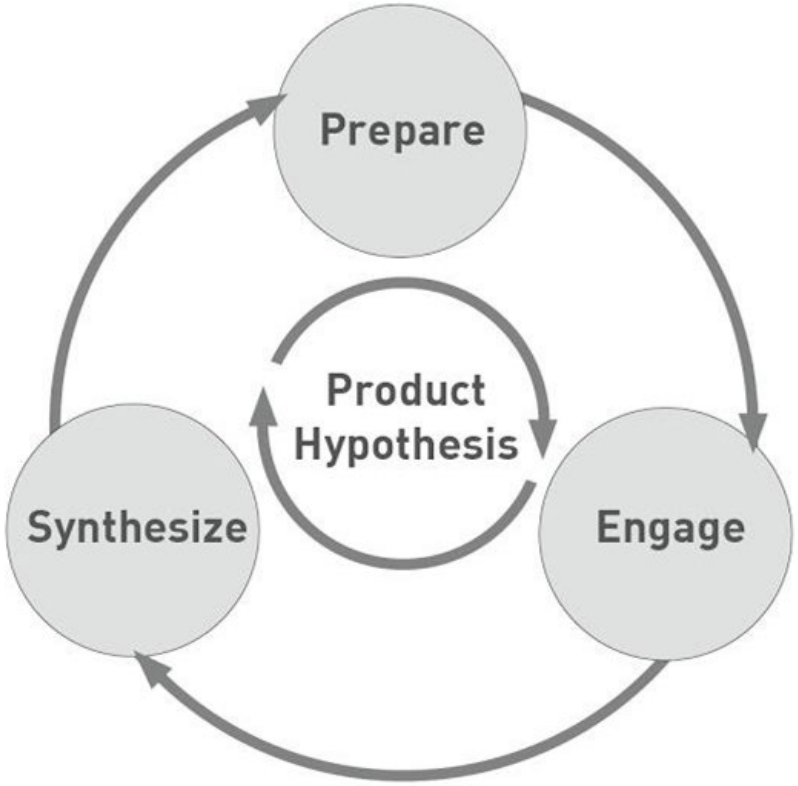
- The target users will be able to use the solution effectively
- The solution is desirable to the target users
- The solution will be adopted by the target users

When to Engage Users



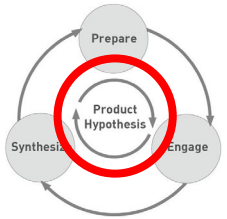
Linnes, J. et al in: *Diagnostic Devices with Microfluidics*, Edited by Piraino & Selimovic, 2017.

How to Engage Users



Linnes, J. et al in: *Diagnostic Devices with Microfluidics*, Edited by Piraino & Selimovic, 2017.

Critical Assumptions



The Need

- What needs to be solved

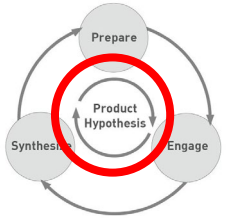
The Users

- Who will interact with the solution
- What training does the user have

The Context

- Where is the implementation
- What are the current constraints (available resources, time, cost considerations)

Product Hypothesis



Includes the need, the user, and the context.

A particular group(s) of users

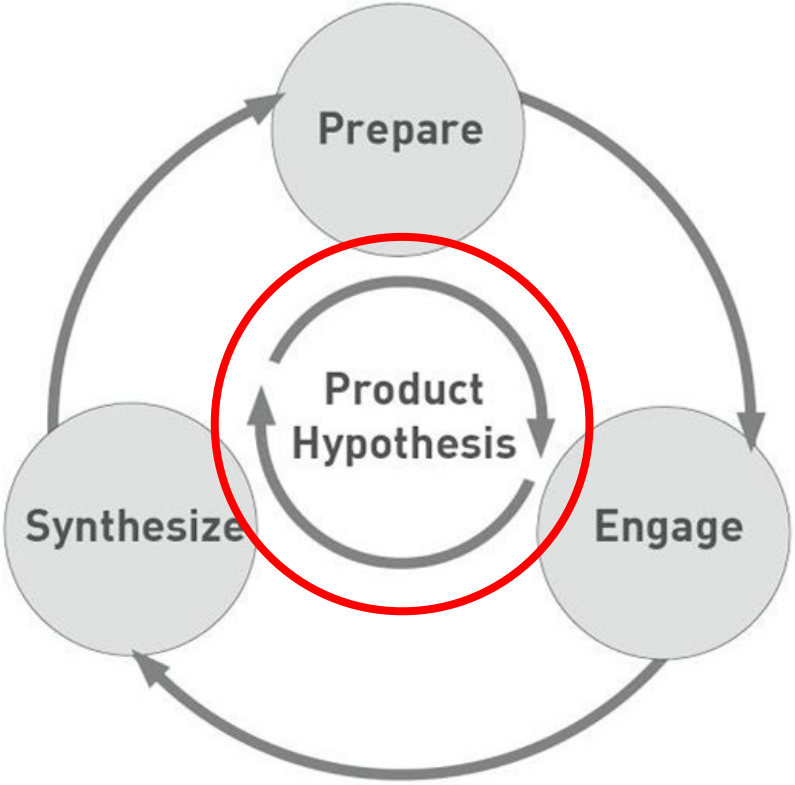
\- NEED -

A solution to their specific problem within the context of important identified constraints.

Steps to Engage Users

Create a Product Hypothesis including:

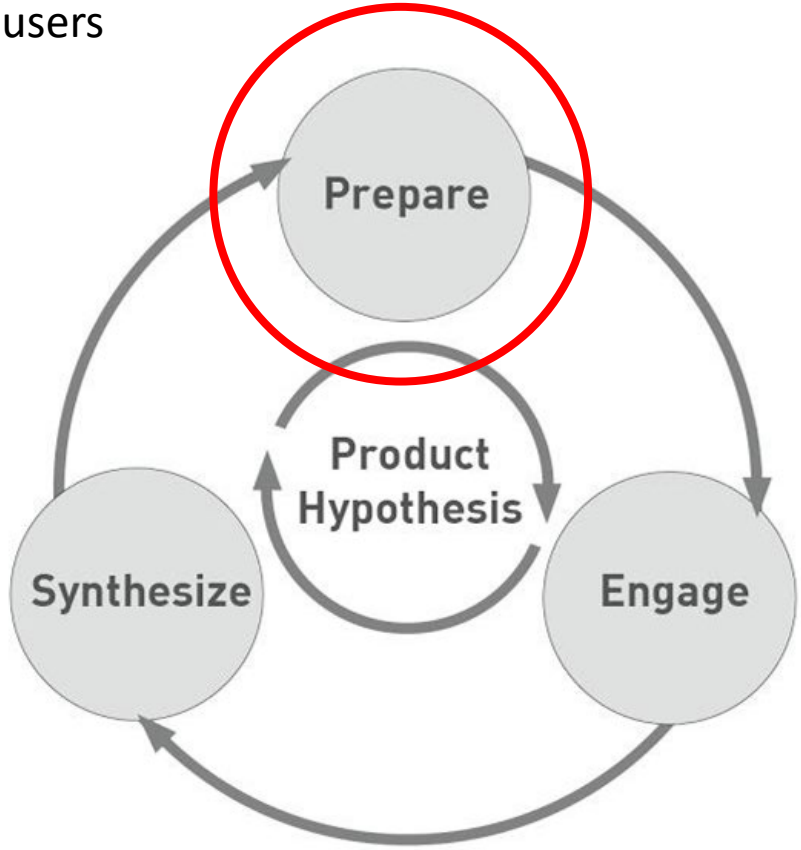
- The user
- The context(s)
- The need



Linnes, J. et al in: *Diagnostic Devices with Microfluidics*, Edited by Piraino & Selimovic, 2017.

Steps to Engage Users

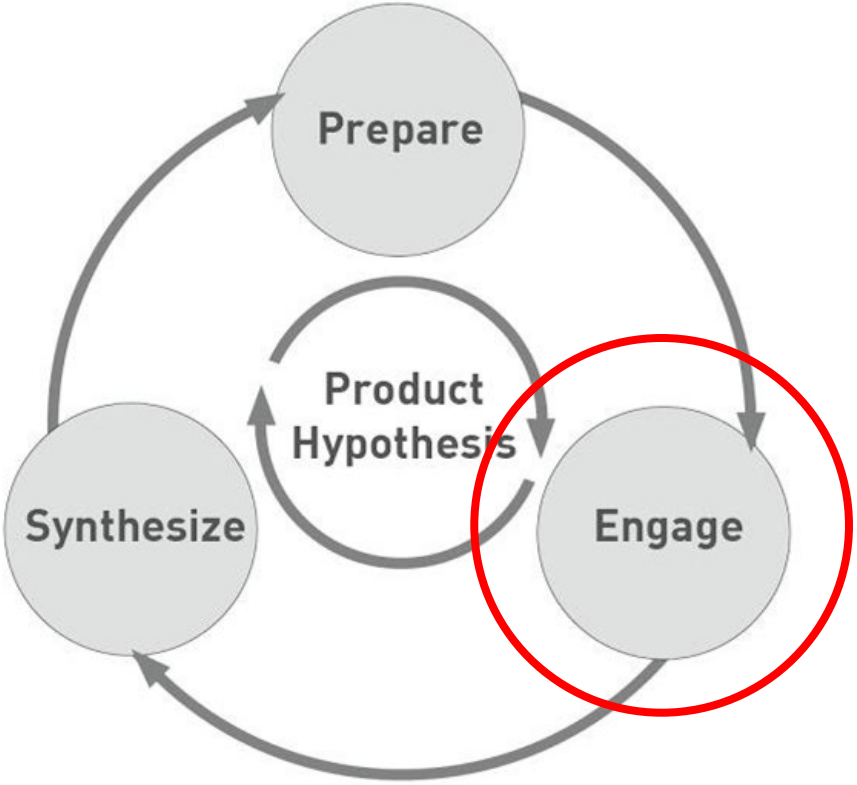
Prepare to engage users



Linnes, J. et al in: *Diagnostic Devices with Microfluidics*, Edited by Piraino & Selimovic, 2017.

Steps to Engage Users

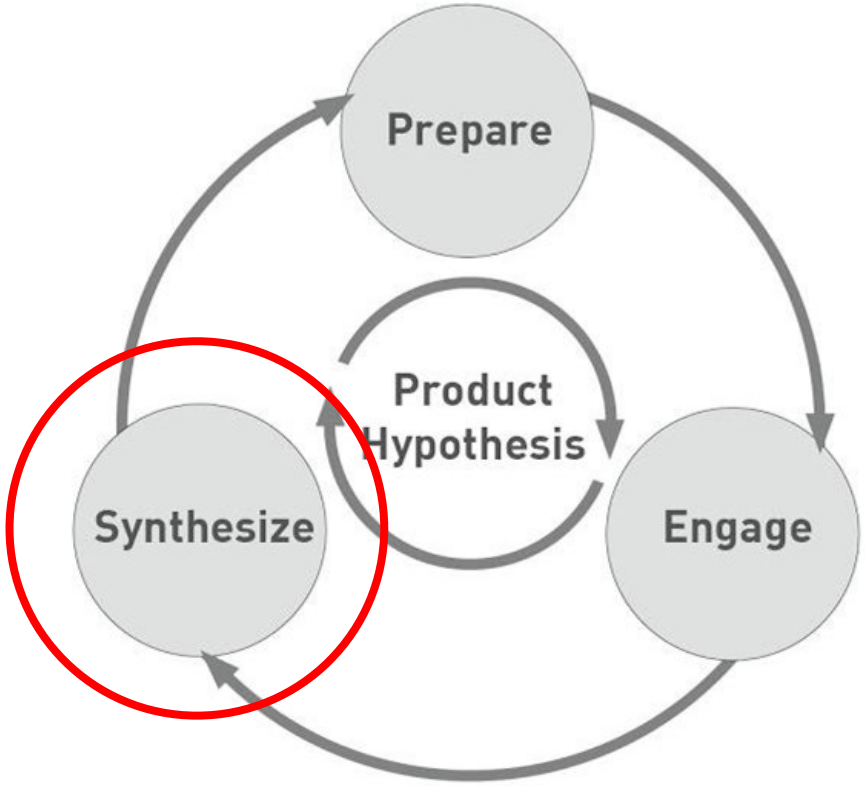
Engage users



Linnes, J. et al in: *Diagnostic Devices with Microfluidics*, Edited by Piraino & Selimovic, 2017.

Steps to Engage Users

Synthesize findings

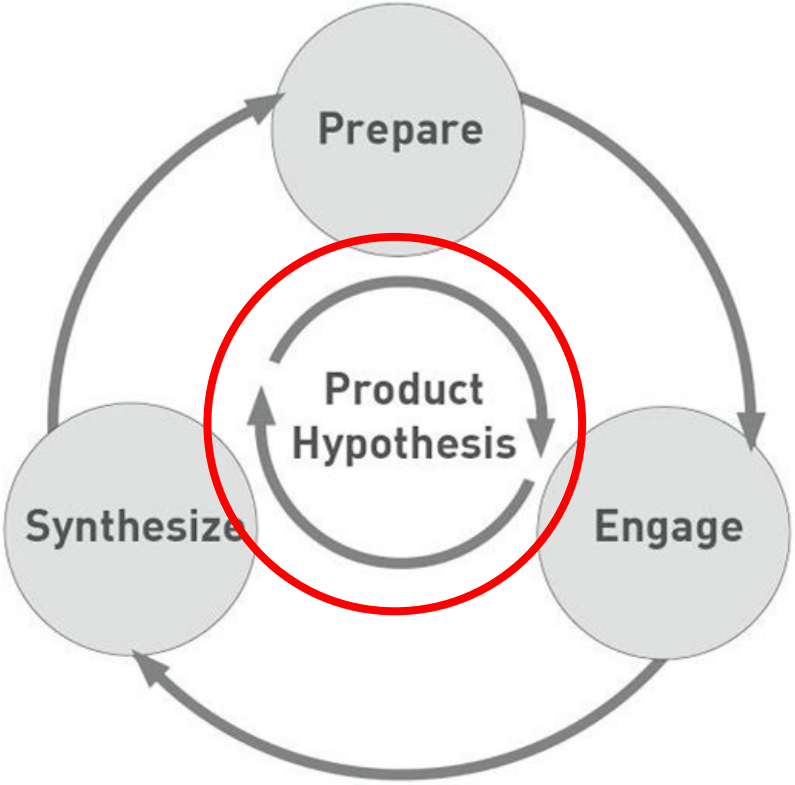


Linnes, J. et al in: *Diagnostic Devices with Microfluidics*, Edited by Piraino & Selimovic, 2017.

Steps to Engage Users

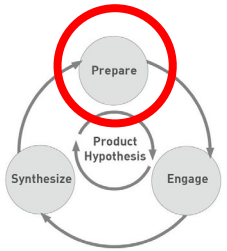
Update Product Hypothesis including:

- The user
- The context(s)
- The need



Linnes, J. et al in: *Diagnostic Devices with Microfluidics*, Edited by Piraino & Selimovic, 2017.

Prepare



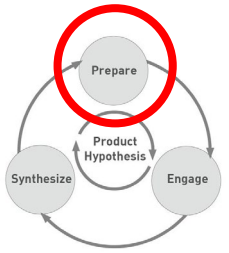
Preparations for a field visit.

- Identify appropriate sites and participants
- Define the type of information to be collected
- Pilot interviews and demonstrations before going to the field

WHO, WHAT, WHERE, WHEN, WHY, AND HOW OF ENGAGING USERS

Method	Description
Who to visit	*Extreme users and extreme contexts*: Visit a small number of users and contexts that represent a wide variety of needs and uses. 3-20 extreme users will inform future directions
What to ask	write down a list of potential questions and activities. Questions should include basic background information, information about daily life and personal goals, and feedback about existing devices or representations of the new technology.
How to protect participants	Consider Institutional Review Board (IRB), Institutional Animal Care and Use Committee (IACUC), or FDA approvals
How to choose team roles	Having at least two core team members enables more thorough documentation, brings multiple viewpoints to bear, and increases Safety
Obtaining user permission	Document with Notes and Photos. Ask permission first! Take as many photos as possible during user interactions. Include portrait shots of all users, existing devices and prototypes in use, and indoor and outdoor surroundings
Access users via a field partner	which features of existing technologies or simulated devices they would combine to make their ideal
Preparing your translator for HCD	*Big picture and specifics*: *Don't filter*: Give the literal translation *Save advice and training to the end*:

Engage



Preparations for a field visit.

- In-context interviews
- Usability evaluations
- Observations
- Other techniques to supplement in-field visits

The goal is to move beyond what a user simply says, to understand what they think, feel, and actually do.

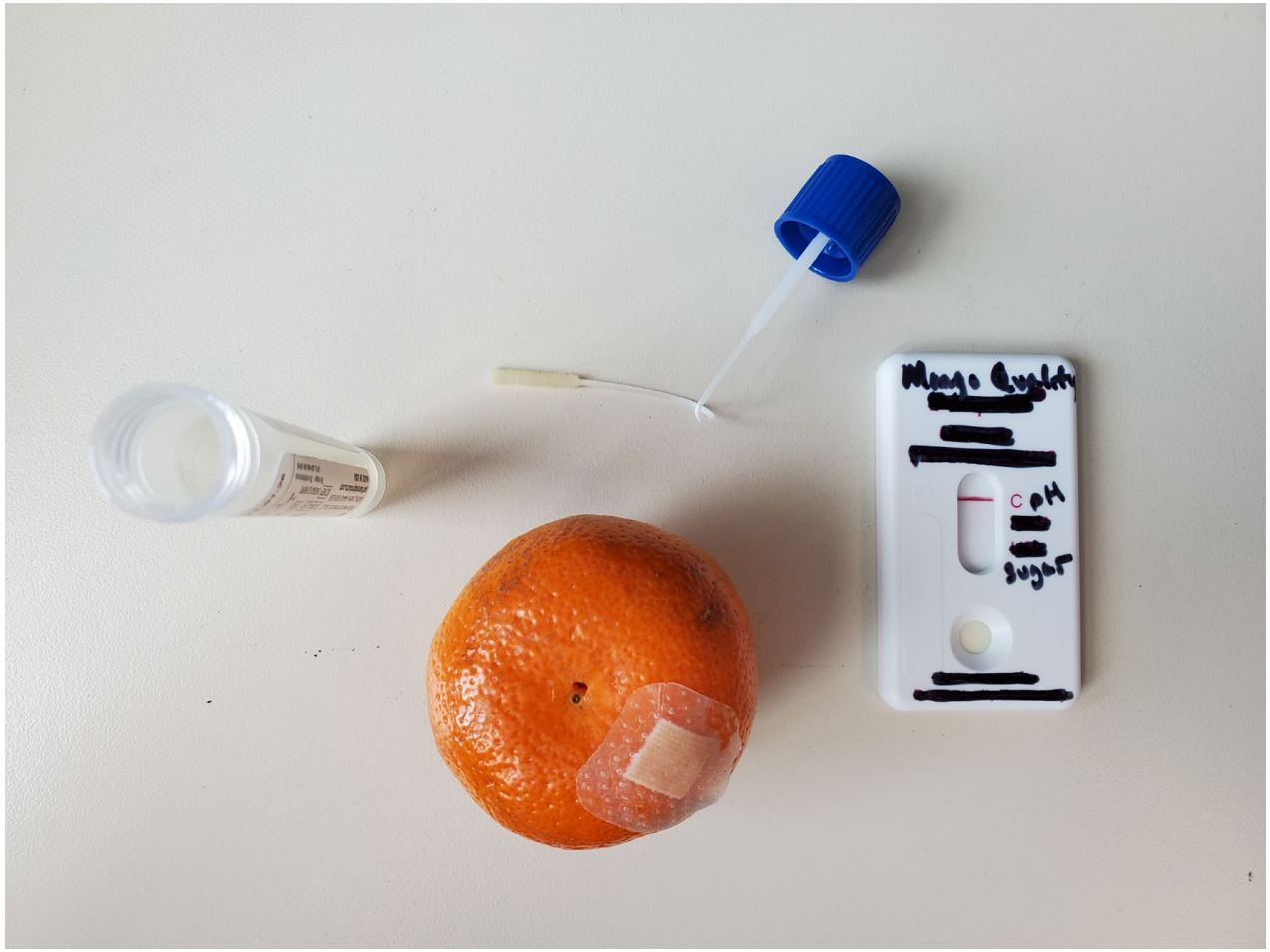
Linnes, J. et al in: *Diagnostic Devices with Microfluidics*, Edited by Piraino & Selimovic, 2017.

ENGAGEMENT TECHNIQUES:

Method	Description
Open-ended questions	Questions that require more than just a “yes” or “no” answer encourage storytelling
5 Whys	Up to 5 follow-up questions to clarify motivations
Show and Tell	Follow a patient journey from registration to departure See existing technologies in use
Simulated Use	how the user interacts with current Technology. Narrate what they are doing and ask questions during the process
Feature comparison	With existing commercialized technology, prototypes, simulated devices, and sketches as prompts, ask the user to list the most important qualities
Design the ideal	which features of existing technologies or simulated devices they would combine to make their ideal
User-made prototypes	Ask the user to make a sketch or prototype showing how one or more aspects of the diagnostic experience could be improved.
Usability Evaluation	Simulate

SIMULATED EXPERIENCE

- **Walkthrough of how the device might work:** Mock up the experience even in the earliest stages of development before the technical components are completed. A combination of off-the-shelf and custom components can be used to simulate all or part of a user experience in the earliest stages.

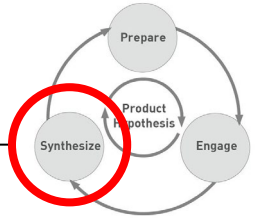


EVALUATION TECHNIQUES:

Method	Description
In-context evaluation	Ask target users to operate one or more simulation devices in the context of where they would anticipate using it.
Hallway evaluations	Recruit a small number of users who are unfamiliar with the device by walking down a hallway in your own lab or office. Hallway evaluations are limited to highlighting aspects of the diagnostic experience that are clearly *not* easy to use.
Follow-up questions	At the end of each test run, ask the user: • What are your favorite and least favorite features? • Which step is easiest and which is most difficult? • What would you never do or use?
Product qualities ranking and Comparison	compare multiple simulated devices to each other and to other existing technology

Linnes, J. et al in: *Diagnostic Devices with Microfluidics*, Edited by Piraino & Selimovic, 2017.

Synthesize



Turn learnings into action.

- Summarize in a way that gives other team members and partners a feel for who was visited and what was learned.

- Give the extended team access to raw information such as photos and user quotes

- Onboard new team members, partners, or contractors in future phases of the project.

Linnes, J. et al in: *Diagnostic Devices with Microfluidics*, Edited by Piraino & Selimovic, 2017.

Incorporating the Needs of Users into Point-of-Care Diagnostics

Elizabeth Johansen, Spark Health Design

MicroTAS, October 22, 2017

CASE STUDY: BOVINE PROGESTERONE TEST

COURTESY OF ELIZABETH JOHANSEN, SPARK HEALTH DESIGN


IDEO
Long-Acting
Cough
8 Hours
Multi-Sym
Cold
Spark
Health
Design
Photos Courtesy: IDEO
© Elizabeth Johansen


design that matters
INNOVATION FOR SOCIAL ENTERPRISE
JAUNDICE TREATMENT


JanaCare
DIAGNOSTICS FOR CHRONIC DISEASE

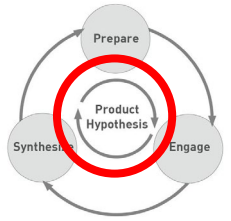

design that matters
INNOVATION FOR SOCIAL ENTERPRISE
+
AFFORDABLE DESIGN
AND ENTREPRENEURSHIP
HYPOTHERMIA PREVENTION
Photos Courtesy: Deisgn that Matters, Jana Care, and Diagnostics For All
@ Elizabeth Johansen


DIAGNOSTICS FOR ALL
DIAGNOSTICS FOR DAIRY FARMING
Spark
Health
Design

The Need

Increase smallholder dairy farmer income through better heat detection.

Product Hypothesis



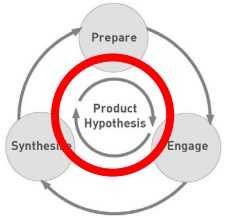
Includes the need, the user, and the context.

A particular group(s) of users

\- NEED -

A solution to their specific problem within the context of important identified constraints.

Product Hypothesis



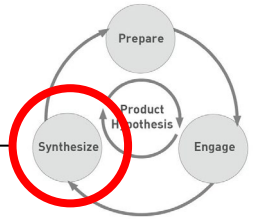
Before the field visit.

Dairy farmers in Kenya and East Africa with fewer than 5 cows

\- NEED -

A < US$0.50 progesterone test kit that is easy for farmers to use on the farm to identify cows ready for artificial insemination, decreasing dry time, and ultimately increasing farmer income.

Synthesize: Critical Assumptions

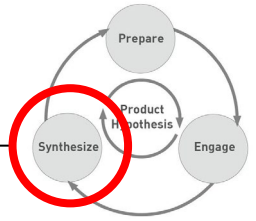


The Need.

Before the Field Visit

- With current methods of heat detection, dairy cows are not operating at optimal milk production
- More efficient heat detection in cows could lead to greater milk productivity and more income.
- The test must be sold for less than US$.050 per kit to affordable and lead to significant increased income.

Synthesize: Critical Assumptions Cont.

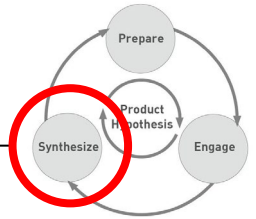


The User.

Before the Field Visit

- The test will be performed by a farmer drawing blood from the cow by lancing the ear.
- A farmer will be able to correctly interpret the results of a lateral flow test on the farm and have the confidence to decide whether to call for an AI tech.

Synthesize: Critical Assumptions Cont.

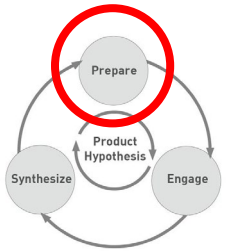


The Context.

Before the Field Visit

- The test will be performed on a farm in East Africa.
- There will be a safe place on the farm to put the test while waiting for the results to develop.
- Test kits will be sold at local agricultural and veterinarian supply and service shops (Agro-Vets).
- Strips will be packaged in vials of 10-20 to reduce costs.

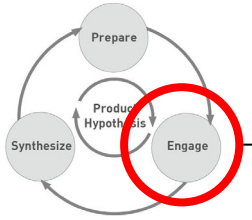
Prepare



Preparations for a field visit to Kenya.

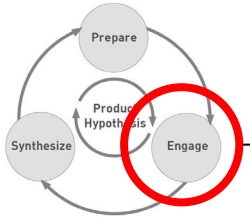
- Recruiting Plan:
  - visit 5 smallholder dairy farmers, 3 AI technicians, some veterinarians, some Agro-Vets.
  - Visit extremes in location & size of farm, level of experience, level of success
- Field Partner: Sidai Africa, Ltd.
- Protocol
- Assets including prototypes & instructions
- Didn’t require IRB or IACUC a this point

Engage: Open-Ended & 5 Whys



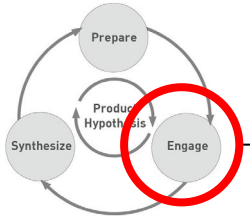
Will farmers feel comfortable drawing blood from their cows?

Engage: Simulated Use Test



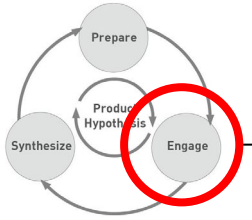
Is it easy for farmers to use on a farm?

Engage: Simulated Use Test



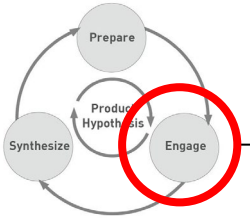
Is it easy for a farmer to interpret the test results?

Engage: Open-Ended Questions



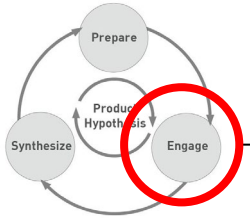
What price would a farmer pay? How much can they afford?

Engage: Shadow



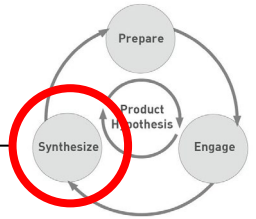
Is it easy for AI techs to use on a farm?

Engage: Create Prototype



Is there a safe place to put the test on the farm while waiting?

Synthesize: Critical Assumptions



The Need.

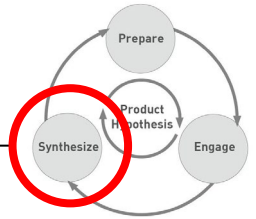
Before the Field Visit

- With current methods of heat detection, dairy cows are not operating at optimal milk production.
- More efficient heat detection in cows could lead to greater milk productivity and more income.
- The test must be sold for less than ~~US$0.50 per kit~~ to affordable and lead to significant increased income.

After the Field Visit

- With current methods of heat detection, dairy cows are not operating at optimal milk production.
- More efficient heat detection in cows could lead to greater milk productivity and more income.
- The test must be sold for less than US$3 per kit to affordable and lead to significant increased income.

Synthesize: Critical Assumptions Cont.



The User.

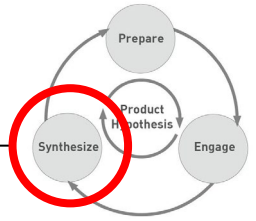
Before the Field Visit

- The test will be ~~performed by a farmer drawing blood from the cow by lancing the ear.~~
- ~~A farmer will be able to correctly interpret the results of a lateral flow test on the farm and have the confidence to decide whether to call for an AI tech.~~

After the Field Visit

- The test will primarily be performed by AI techs who are trained to perform venous blood draw.
- AI techs will have sufficient vision to correctly interpret the test results on the farm and confidence to decide whether to administer AI.

Synthesize: Critical Assumptions Cont.



The Context.

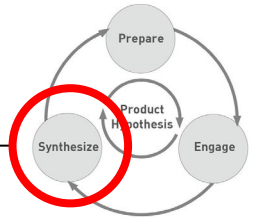
Before the Field Visit

- The test will be performed on a farm in East Africa.
- ~~There will be a safe place on the farm to put the test~~ while waiting.
- Test kits will be sold at local agricultural and veterinarian supply and service shops (Agro-Vets).
- ~~Strips will be packaged in vials of 10-20 to reduce costs.~~

After the Field Visit

- The test will be performed on a farm in East Africa.
- The kit will include component(s) to keep the strip safe while waiting.
- Test kits will be sold at local agricultural and veterinarian supply and service shops (Agro-Vets).
- Each strip will be sealed in a foil pouch with desiccant to increase affordability and right-sizing for portability.

Synthesize: Product Requirements



After the Visit.

Test Strip

- Sample - whole blood venous blood draw into vacutainer
- Time to result - shorten as much as possible

Supplies

- Include a component to protect it while running it and remind person to check back in when result is ready.
- Kit cost must include all necessary supplies such as vacutainer to avoid interfering substances.

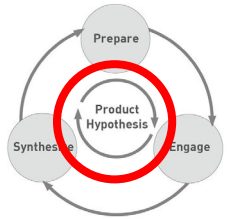
Instructions & Read Guide

- Include a warning to read the test in good lighting.

Packaging

- Primary strip packaging would be sealed foil pouch with desiccant.
- Secondary kit packaging will be a plastic bag that fits well in AI tech's backpack.

Product Hypothesis



After the field visit.

Dairy farmers in Kenya and East Africa with fewer than 5 cows

\- NEED -

A ~~< US$0.50~~ < US$3 progesterone test kit that is ~~easy for farmers~~ easy for AI techs to use on the farm to help identify cows ready for artificial insemination, decreasing dry time, and ultimately increasing farmer income.

CASE STUDY: NEONATAL THERMAL REGULATION IN LOW AND MIDDLE INCOME COUNTRIES

The Problem

+

→

Hospitals face acute shortage of incubators

By | February 26th 2009

https://www.standardmedia.co.ke/business/article/1144007581/hospitals-face-acute-shortage-of-incubators

WHO Warns of Severe Global Shortage of Nurses

https://www.voanews.com/science-health/coronavirus-outbreak/who-warns-severe-global-shortage-nurses

By Lisa Schlein
April 07, 2020 10:11 AM

Slide: Sherri Bucher

80-90%

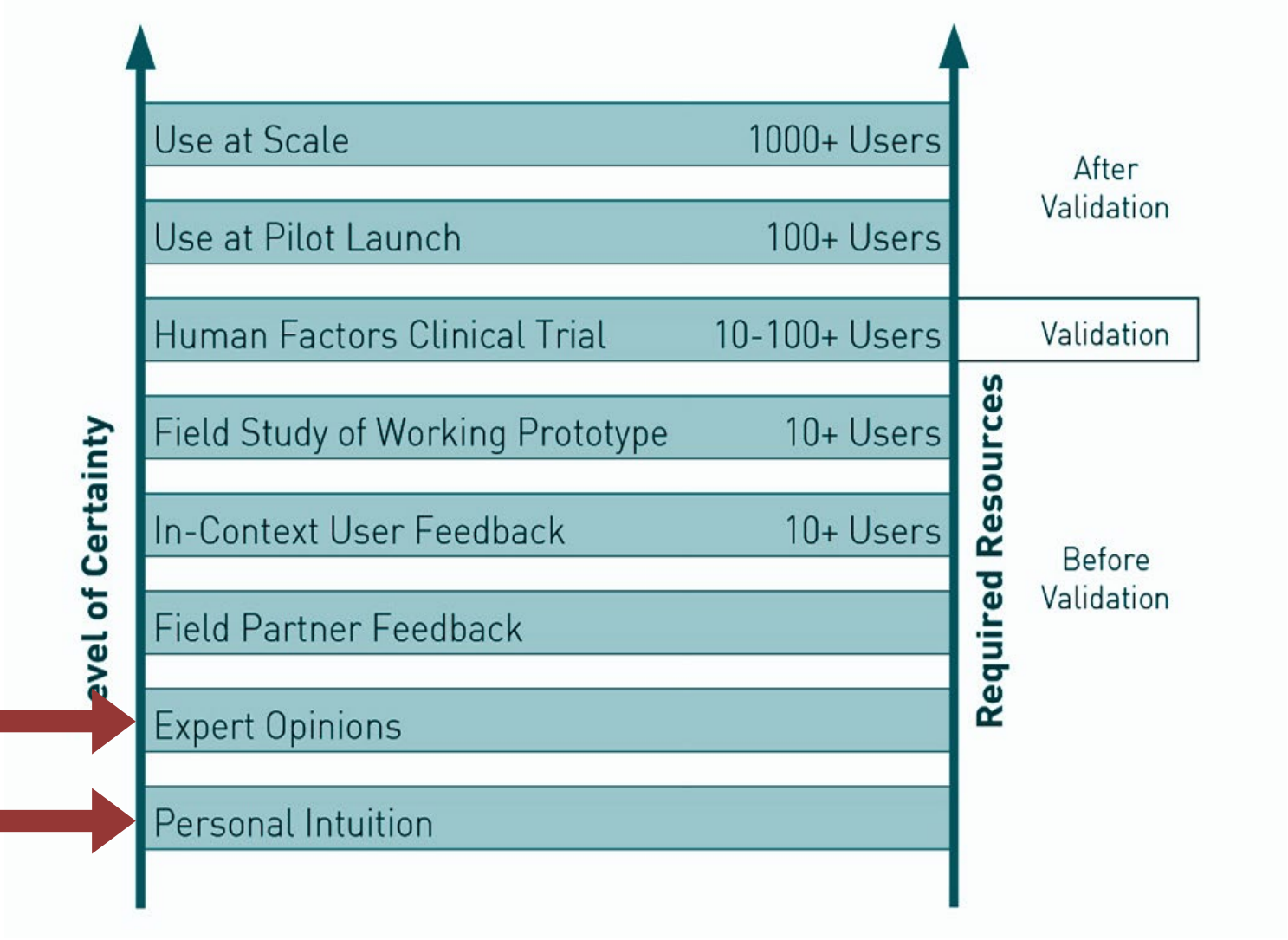
of all medical technology in the developing world is hand-me-down equipment.

40%

is out of service at any given time

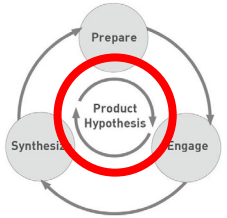
NEONATAL INCUBATOR IN HAITI

Level of certainty



Linnes, J. et al in: *Diagnostic Devices with Microfluidics*, Edited by Piraino & Selimovic, 2017.

Critical Assumptions



The Need

- Premature neonates born in low-resource settings require thermal regulation

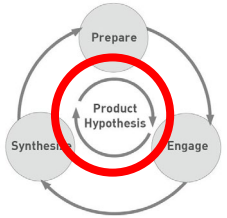
The Users

- The nurse or doctor will operate equipment

The Context

- Incubators provide the best thermoregulation and safety for developing baby
- Existing technologies fail because of the inability to fix broken parts due to expense, lack of training, and/or lack of component availability

Product Hypothesis



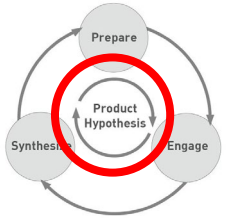
Includes the need, the user, and the context.

A particular group(s) of users

\- NEED –

A solution to their specific problem within the context of important identified constraints.

Product Hypothesis



Includes the need, the user, and the context.

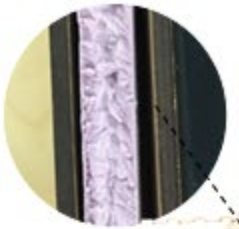
Doctors and nurses in low-resource hospitals

\- NEED –

a neonatal incubator that automatically and accurately provides thermoregulation of premature infants and is low cost, insulated, and easy to operate and repair

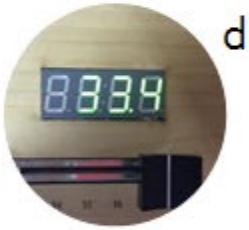
Rice 360 – flat-pack incubator

Double-walled wood and acrylic box



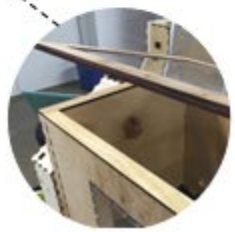
Heating pads in back wall and beneath floor

Infant temp is constantly displayed



Probe reads temp of infant constantly

Alarms alert to power loss or overheating



Hinged lid and viewing ports

DESIGN THAT MATTERS - NEONURTURE

COZYTHERM - HOT COT

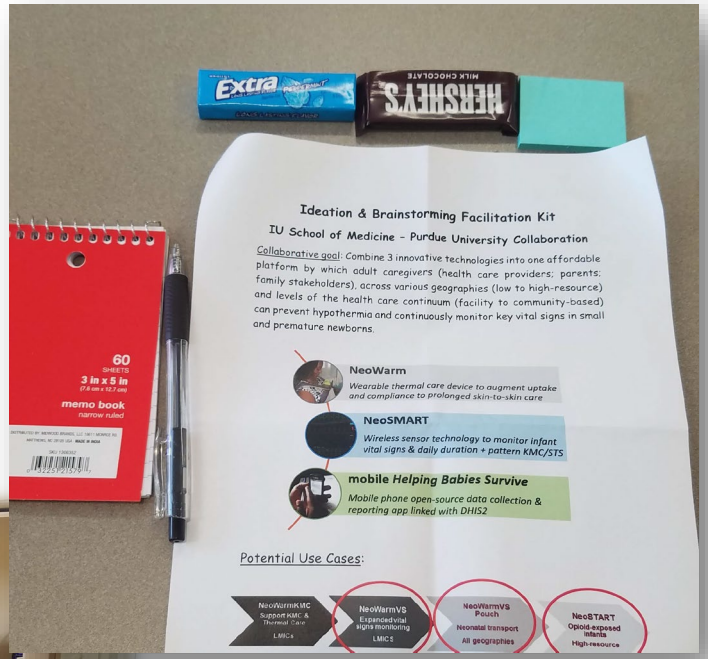
LINNES LAB LAB USER ENGAGEMENTS

- Doctors and Nurses at a hospital in Haiti
  - Hosted by Kay McKesson clinic and Dr. Julia von Oettingen (McGill University)
- Neonatologists at Riley Children's Hospital
  - Hosted by Dr. Sherri Bucher (IU)

IN CONTEXT: HAITI

A CLOSER LOOK

STATE OF THE ART SOLUTIONS



Photos: Jacqueline Linnes, Riley Children's Hospital

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PURDUE UNIVERSITY

Riley Children's Health
Indiana University Health

EXISTING ALTERNATIVE SOLUTIONS

Kangaroo Care

https://parentinghub.co.za/2017/12/kangaroo-mother-care/

KANGAROO CARE FOR FATHERS

Skin-to-skin contact:

- Provides thermoregulation
- Supports brain growth
- Reduces infection
- Stabilizes heart rate
- Improves maternal lactation
- Reduces hospital costs

http://unicef.tumblr.com/tagged/Kangaroo-Care

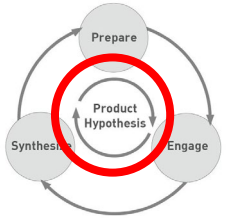
Initial Product Hypothesis

Doctors and nurses in low-resource hospitals

\- NEED –

a **neonatal incubator** that automatically and accurately provides thermoregulation of premature infants and is low cost, insulated, and easy to operate and repair

Redefined Product Hypothesis

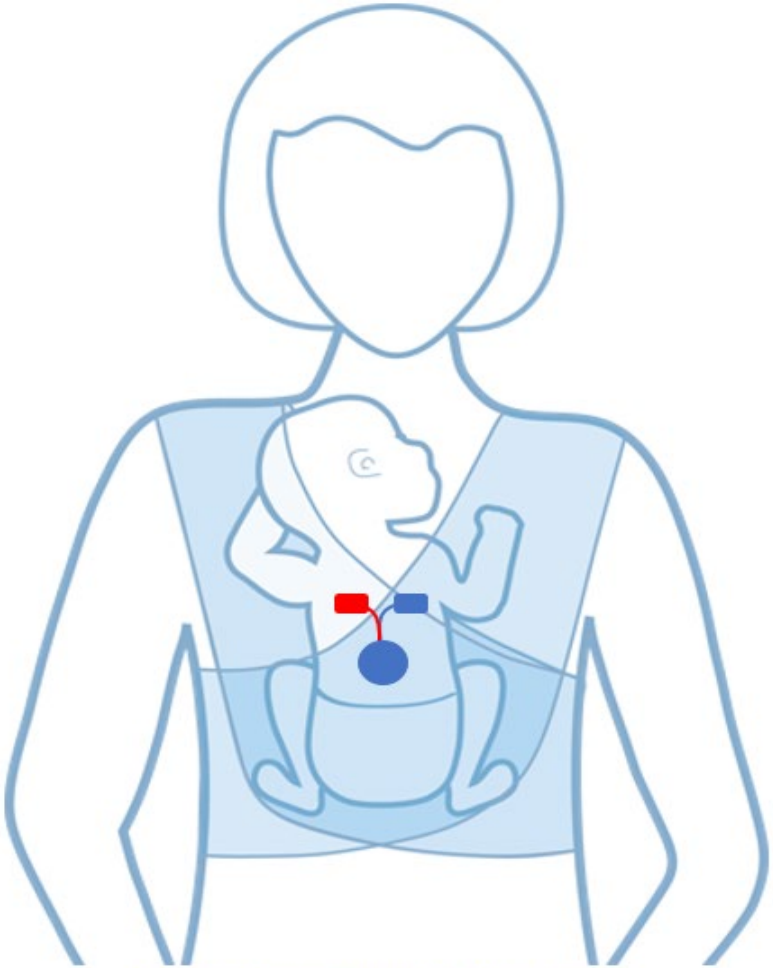


New mothers and fathers in low-resource **settings**

\- NEED –

a system to automatically, accurately, and **conveniently** provide thermoregulation of **their newborns** that is low cost, insulated, and easy to perform

IU & PURDUE NEOWARM COLLABORATION



Adapted from www.babyktan.com

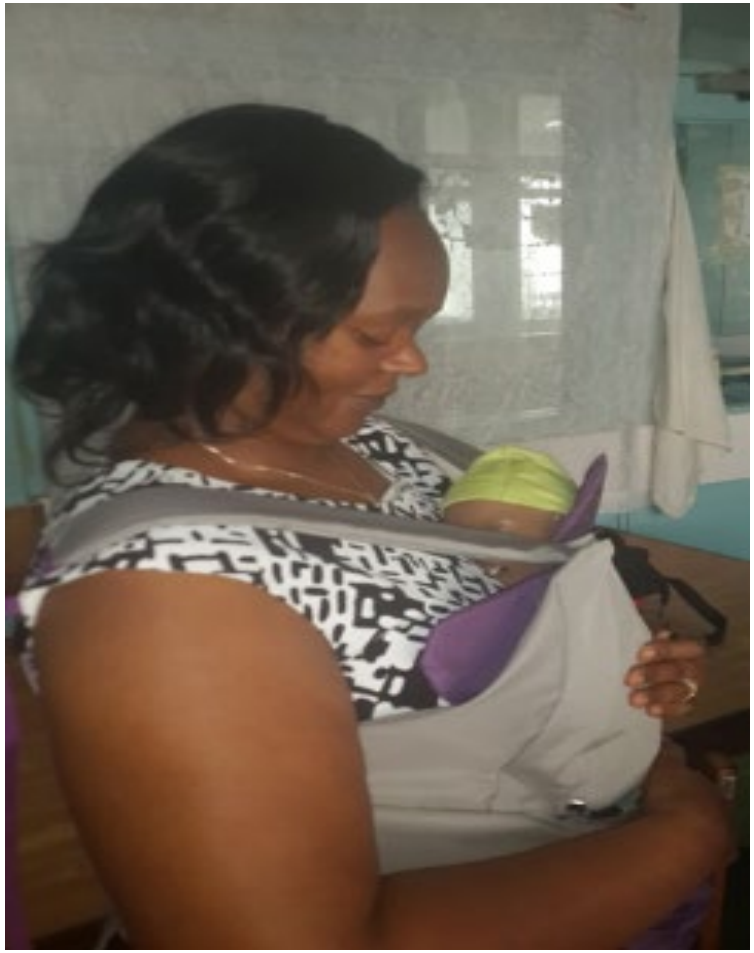


Photo credit: Sherri Bucher

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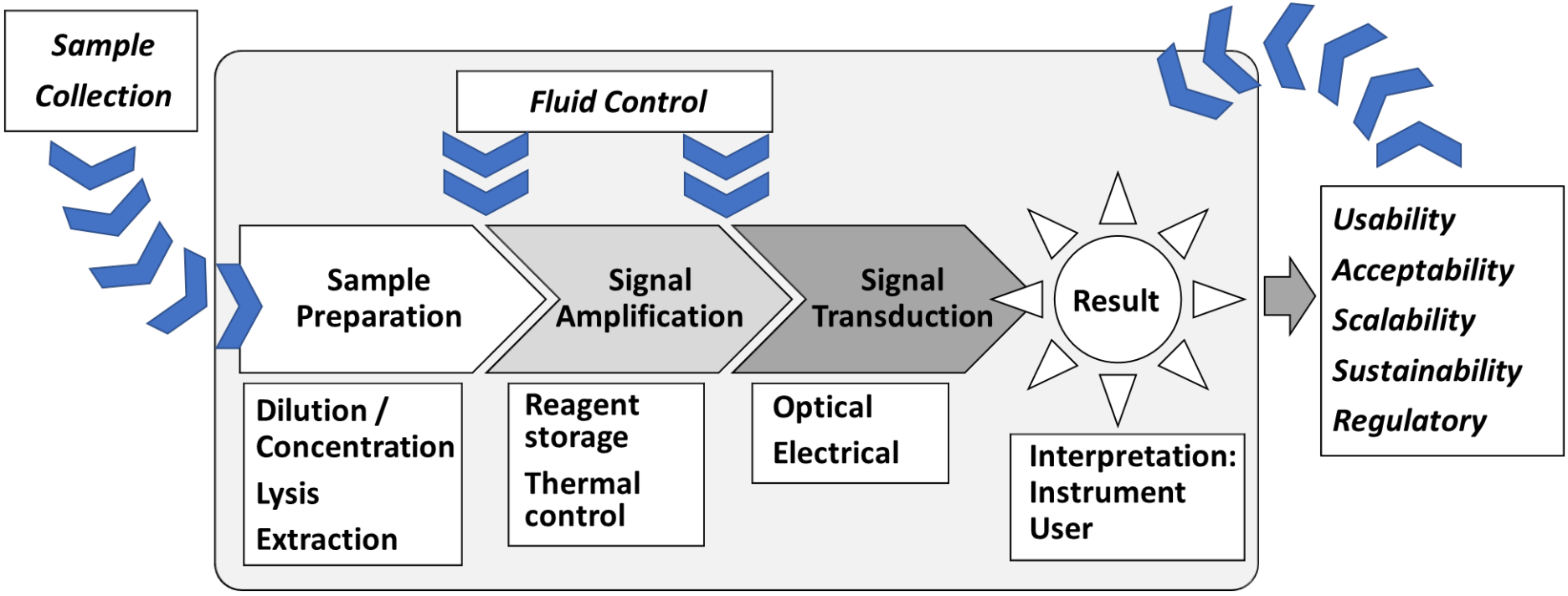
PURDUE UNIVERSITY

Riley Children's Health
Indiana University Health

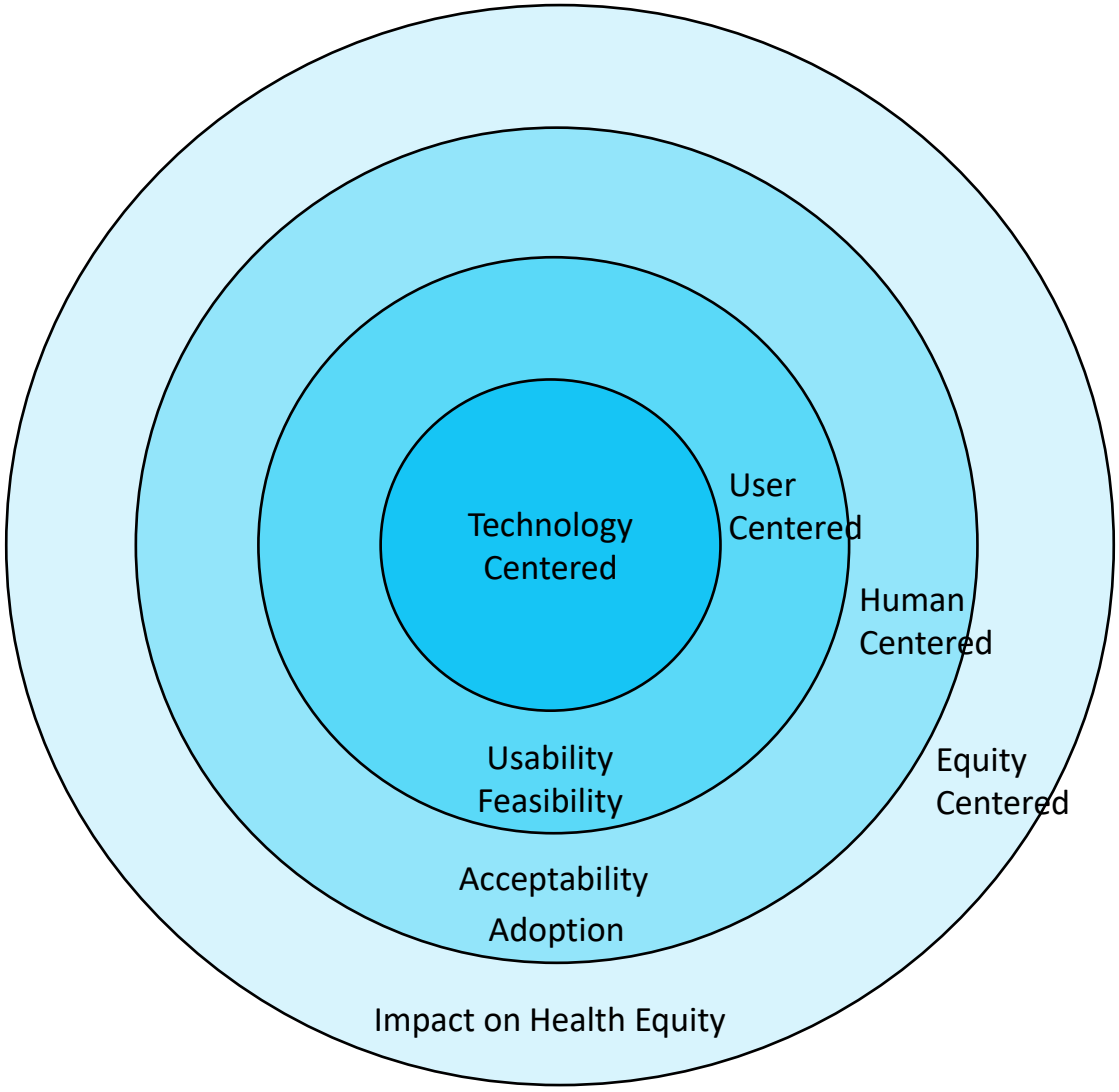
ADDITIONAL WORK EDUCATING THE DIAGNOSTICS COMMUNITY (AND MYSELF!)



Sritong et al. *Lab on a Chip*, 2023, 23, 888-912

EQUITY-CENTERED DESIGN THAT I AM LEARNING EVEN NOW

(THANKS TO NATALIA RODRIGUEZ, GRACE BURLESON AND KATHLEEN SIENKO!



Rodriguez, Burleson, Linnes, Sienko. *(2023)*
Annual Review of Biomedical Engineering

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THANK YOU!

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10

Incorporating the Needs of Users into the Development of Diagnostics for Global Health: A Framework and Two Case Studies

Jacqueline C. Linnes, Elizabeth Johansen, and Ashok A. Kumar

CONTENTS

10.1 Introduction

Technologies created with users in mind are more innovative, require fewer resources to develop, and have better chance of making an impact (Griffin and Hauser 1993; Maidique and Zirger 2013). A canonical example of the

importance of design is the Apple iPod; few consumer companies are as synonymous with the word "design" as Apple. The size, click wheel control, and LCD screen all enabled a user experience that ensured the iPod became the dominant player in the market despite not having a "first mover" advantage in the space of portable MP3 players. Moreover, competitors' designs took cues from the iPod, leading to a convergence in design (Peng and Sanderson 2014). Similarly in diagnostic technology, adoption and implementation improve with thoughtful design; it impacts both initial uptake as well as continued use (Langhan et al. 2015). No matter how sensitive or specific a diagnostic is, if users are frustrated by the device (e.g., the results of a colorimetric test are too subtle to interpret) or the device is difficult to fit into the clinical workflow (e.g., the time for the test is significantly longer than the average provider visit), it will have trouble achieving widespread use and competing devices with poorer technical performance but better user-design may be adopted instead.

Increasingly, designing with end-user needs in mind is not only important for adoption but also for patient safety and for regulatory approval. The U.S. Food and Drug Agency (FDA) provides examples of medical emergencies caused by devices developed for the wrong patient populations (e.g., critically ill hospital patients receiving the wrong insulin doses because blood glucose monitors were designed and tested for patients in-home, not in hospital intensive care units) (FDA 2014). Accordingly, the FDA now provides specific guidance for human-factors studies for medical devices (FDA 2016). Similarly, the European CE Mark requires compliance with ISO/EN 62366, which includes usability testing. The FDA provides additional recommendations and instructions for diagnostic tests designed for point-of-care use according to the 1988 Clinical Laboratory Improvement Amendments (CLIA) to ensure that the tests are suitable for the lay user (FDA 2008; Kingsley and Backinger 1993). Although regulatory approval requirements vary from country to country, U.S. FDA approval or CE Marking can often assist with speedy approval in other countries.

Engineers and scientists are perfectly placed to address both the technical requirements and the needs of device users to develop new global health technologies. In fact, the Accreditation Board for Engineering and Technology (ABET), the body responsible for accrediting engineering training programs around the world, recognizes the integral role that design plays in technology development (ABET 2015). In their criteria for student outcomes in all areas (engineering programs, computing programs, engineering technology programs, and applied science programs), ABET student outcomes include "an ability to design a system, component, or process to meet desired needs within realistic constraints such as economic, environmental, social, political, ethical, health and safety, manufacturability, and sustainability."

This chapter focuses on understanding and designing for the needs of the patients and caregivers who will actually use diagnostic technologies.

Using the framework of human-centered design (HCD), we lay out techniques for applying this framework to diagnostic design and follow these methods with two case studies in which these methods are used in the field. Finally, we address some of the most common myths and misconceptions preventing test developers from using HCD.

10.1.1 General Embodiments and Framework of HCD

The scene in the comic in the figure below is all too familiar. As scientists and engineers, we are comfortable solving a technical problem and spend a long time perfecting a potential solution before sharing it with the world. However, the solution suffers because it has not benefited from the feedback of real end-users and stakeholders in the problem.

Failing to incorporate end users into a design. (From Fishburne, T., in: Constable, G., *Talking to Humans*, Edited by Rimalovski, F., 2014.)

HCD is a framework for developing in-depth understanding and addressing the needs of all stakeholders taking part in a product, service, or experience. In terms of diagnostic development, device users, their use environment, and their motivations and expectations are taken into account during development. HCD includes a mix of empathic design, user-centered design, and participatory design techniques (Seshadri et al., 2014). The HCD process encourages a team to develop empathy by understanding the big picture of a user's life including hopes, dreams, and emotions. This empathy fuels inspiring ideas that lead to a well-received, holistic product experience. HCD incorporates user-centered design by emphasizing iterative user

feedback with prototypes. Finally, HCD contains participatory design elements that invite users themselves to design and prototype aspects of the product, service, or experience. In HCD many team members, not just a specialized designer, should understand and represent the user's point of view (Peace Corps 2007; Sanders 2002; UX Mastery Community 2016).

In diagnostic development, user needs are one of the most difficult aspects to integrate during the long, often laboratory-based, creation process. We seek to lay out benefits and example methods for closely integrating user needs into the technical diagnostics development process yielding better health outcomes for fewer dollars spent. This integration is especially valuable in global health, where funding can be scarce and health impact is paramount. Several excellent examples of point-of-care diagnostic development integrating user needs in different countries have been described in other articles (Derda et al. 2015; Kumar et al. 2015; Laksanasopin et al. 2015; Oden et al. 2010). Here, we provide an introduction to the HCD framework, step-by-step techniques, and case studies to further illustrate how these techniques improve diagnostic devices.

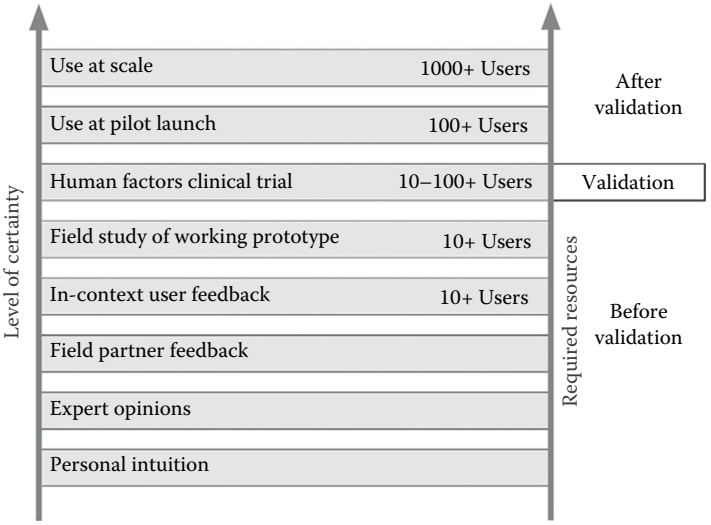
10.1.2 HCD Can Be Incorporated throughout the R&D Process

A typical diagnostic development process takes 2–5 years depending on technical novelty. This process is described in the 2004 United States FDA/Industry In Vitro Diagnostic (IVD) Roundtable as consisting of seven phases: (1) viability/feasibility, (2) planning, (3) development, integration, and verification, (4) internal validation, (5) external study validation, (6) launch readiness and release, and (7) sustaining engineering (Phillips et al. 2006).

By engaging with users through activities during the feasibility, planning, and development phases, test developers can increase certainty around their assumptions that

- The correct target users have been identified.
- The target users will be able to use the diagnostic correctly and effectively.
- The diagnostic will be well adopted by the target users.

As seen in the following figure, there are numerous opportunities to increase certainty about the user needs surrounding a diagnostic, or other medical technology, throughout a device's development. Those in the middle of the ladder of certainty (field partner feedback, in-context user feedback, and working prototype field demonstrations) are often overlooked ways to learn about the target usage despite being economical alternatives to waiting until a resource-intensive human factor trials for validation, when the cost of failure is much higher.

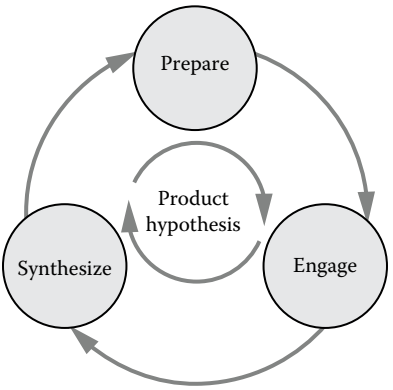


Ladder of certainty. Activities to increase knowledge of a medical technology's fit for the user.

10.2 Techniques

This section describes techniques to include HCD in the development of diagnostics. The techniques listed here are by no means exhaustive. For additional ideas, consider referencing materials from design consultancies IDEO and IDEO.org, Design that Matters, and the Stanford D. School (IDEO.org 2015; Plattner 2011; Prestero 2010; Stout 2003).

The following figure shows a process loop for learning about the target user. It is used throughout the chapter and can be adapted to any stage of product development. Activities are centered around developing and iterating on a product hypothesis—a description of the relationship between the user, context, and diagnostic need. A cycle of three activities continually improves the product hypothesis. First, *prepare* to engage with stakeholders by defining with whom to meet, planning the type of information you wish to gather and how it will be acquired, as well as obtaining required approvals. Then *engage* with your users to develop empathy for their experiences and understand the context in which your potential solutions will be applied. Finally, *synthesize* what was learned to refine ideas for potential solutions, embody these ideas in a way that users can respond to, and then put the simulated devices and kits in front of users to empathize once again. An R&D team might iterate through this HCD loop dozens of times during the normal multiyear diagnostic development process.



Cycle of human-centered design learning.

10.2.1 Initial Product Hypothesis

A product hypothesis is the embodiment of the most important assumptions surrounding the users, the context of use, and need that a product will solve. To develop an initial product hypothesis, create a list of assumptions surrounding the product. This list should detail all of the users who will come in direct contact with a diagnostic device, the important qualities of the contexts where the device will be operated, and the needs being satisfied. The list may also include specific needs, users, and contexts that will not be satisfied by this product. After the list of assumptions is created, summarize this in a single statement of the most important assumptions including the users, context, and need

A particular group(s) of users

—NEED—

A solution to their specific problem within the context of important identified constraints

Below is an example of a product hypothesis from Design that Matters' Firefly Phototherapy project to treat newborn jaundice. The resulting medical device is now treating newborns with jaundice in 22 developing countries.

Low-resource hospitals providing overnight care that wish to improve treatment outcomes and reduce newborn referrals

—NEED—

A cost-effective, durable tool that is intuitive for nurses and that can be placed in the mother's room to provide individual infant phototherapy to otherwise healthy newborns with mild to severe jaundice while allowing infant warming.

Here, the need is to improve treatment outcomes for newborns with jaundice and reduce newborn referrals to higher level hospitals. Satisfying this need will reduce newborn mortality through successful treatment of more newborns and reduce the burden on higher-level hospitals so they can focus on more complex newborn conditions. The users include the specific patients (otherwise healthy newborns with jaundice) and the operators (nurses and potentially mothers). The context is low-resource hospitals providing overnight care.

Additional examples can be found in the case studies within this chapter, as well as from author E. Johansen's workshop at the 2016 Unite for Sight Conference (Johansen 2016).

10.2.2 Prepare

Address the who, what, where, when, why, and how of engaging users before you begin in order to get the best results. Many teams working in global health will find themselves interacting with end users who do not speak the same language and are from different cultures. In addition, users may have different professional experience from the team. Planning to visit users early and often can ensure proper time is taken to overcome these potential barriers. The following table provides tips to help teams prepare to engage users in a global health setting.

Method	Description
Who to visit	• *Extreme users and extreme contexts*: Visit a small number of users and contexts that represent a wide variety of needs and uses (the extremes). If the diagnostic technology satisfies these extreme users, then it will probably work well for those in the middle of the bell curve. • *Number of users*: Depending on the technique used, 3–20 extreme users will give enough information to inspire the design direction.
What to ask	Before engaging any users, write down a list of potential questions and activities. This kind of document is often called a protocol in HCD, but it will only be a starting point, not a rigid script the way that a protocol is designed for in-lab verification test or a clinical trial. Questions should include basic background information, information about daily life and personal goals, and feedback about existing devices or representations of the new technology.
How to protect participants	Organizational approvals may be required before engaging users to protect study participants from risks to privacy or mental, physical, or emotional health. It is important when the information will be disseminated, published, or used for regulatory approval processes. Consider Institutional Review Board (IRB), Institutional Animal Care and Use Committee (IACUC), or FDA approvals based on the policies of your organization, as well as funders, and field partners (Varricchione 2016).

(*Continued*)

Method	Description
How to choose team roles	Having at least two core team members enables more thorough documentation, brings multiple viewpoints to bear, and increases safety in any context in the team's home country or abroad. However, bringing more than 3 or 4 people can be overwhelming when speaking with an individual. Assign the roles of moderator, note-taker, photographer, prototype handler, and observer to each team member.
How to document	• *Notes*: Include user quotes written verbatim, layout sketches of important rooms/locations, narratives of user actions during a usability evaluation, and/or potential error modes. • *Photos*: Take as many photos as possible during user interactions. Include portrait shots of all users, existing devices and prototypes in use, and indoor and outdoor surroundings. Do not worry about a camera being conspicuous; user evaluations are already a spectacle.
Obtaining user permission	In all cases, it is important to obtain permission to gather feedback from and take photos of users. Funders, organizations, and field partner hosts may already have guidelines to follow. Here are some guidelines to consider: • Ask for permission to take photos and notes. Do not take photos or ask questions until permission is granted. Take photos that depict people with dignity. • If the team takes photos with a variety of different permission levels (for publication, for internal use only, etc.), a photo management system, such as a set of folders that helps keep track of different levels of permission, should be used. • More examples of photo permission policies as well as methods for informed consent can be found in Corti et al. (2000) and Gardner (2015).
Access users via a field partner	• *Field partner*: To provide feedback before, during, and after travel, hosts in-country travel, and potential future partner for clinical studies and implementation. • *Qualities of a great field partner*: Ability to grant access to users in context and obtain any government or institutional permissions. See Kumar et al. (2015) for more suggestions on forging field partnerships.
Qualities of a great translator	Experience translating in a conversational setting and knowledge of relevant medical terms.
Preparing the translator for HCD	• *Big picture and specifics*: The team is looking to learn about users' lives broadly, as well as get specific feedback about ideas. • *Don't filter*: Give the literal translation of what a user says when possible. Paraphrasing or interpreting while taking notes can lose the original information and miss critical insights that are not apparent until later. • *Save advice and training to the end*: The translator may be a professional whose job is to educate users. It is, however, important for the team to understand the user's perspective, especially if this information is incomplete or incorrect.

10.2.3 Engage

Once preparation is complete, the team is ready to engage users. There are many ways to efficiently learn from users. Four basic techniques are highlighted in this text: in-context interviews, usability evaluations, observations, and techniques to supplement in-field visits. Within each technique is a list of methods that have been used specifically to gain insights for diagnostic technology development. In some cases, not all techniques may be appropriate for use depending on the cultural context or other barriers. Maintaining flexibility to adjust for new information about context or culture is important in all the techniques described in the following text.

10.2.3.1 In-Context Interview

During an in-context interview, the team spends 1–2 h interacting with users in the context where they will eventually operate the diagnostic device. Environments could be as diverse as a clinic exam room, a pop-up tent, an intensive care unit, an emergency room, a mobile or stationary lab, or a home. The goal is to move beyond what a user simply says, to understand what they think, feel, and actually do. The below table provides helpful methods to use during in-context interviews.

Method	Description
Open-ended questions	Questions that require more than just a "yes" or "no" answer. They encourage storytelling to reveal the motivations, desires, and feelings of users.
The five whys	Following an open-ended question with up to five follow-up questions to clarify motivations.
Tour	A great way to start an interview, whether in a home or clinic setting. Follow a patient journey from registration to departure, or a diagnostic from storage to disposal. Meet potential interview subjects and collect existing technology for product comparison activities.
Show and tell	This method is helpful for learning how the user interacts with current technology. Example activities include operating the user's diagnostic equipment, packing a bag with diagnostic technology or samples for transport, or storing equipment or samples. Ask the user to narrate what they are doing and ask questions during the process.
Usability evaluation	A usability evaluation can take place in the latter half of an interview and is described further in the next section.
Product qualities ranking and comparison	With existing commercialized technology, prototypes, simulated devices, and sketches as prompts, ask the user to list the most important qualities of the diagnostic. Example qualities include accurate, rapid, easy to use, few parts, shelf stable, and professional looking. Have the user sort the qualities from most important to least important and then sort each technology from best to worst fit for each quality.

(*Continued*)

Method	Description
Design the ideal diagnostic	Ask the user which features of existing technologies or simulated devices they would combine to make their ideal diagnostic experience.
User-made prototype	Ask the user to make a sketch or prototype showing how one or more aspects of the diagnostic experience could be improved. This could mean modifying an existing prototype, or making something new in order to gain further insight into user pain points and possible experience improvements. Consider sample collection, consumables, fluid handling, electronics, instructions, and packaging.

10.2.3.2 User Observation

One of the best ways to understand how the diagnostic technology will fit into the context is to see the target users performing daily routines using existing diagnostic technology as well as other tools of the trade. Observations can be punctuated with questions to understand why a target user is completing the current actions. The following table describes three methods for user observations that can be used.

Method	Description
Fly on the wall	Spend from 30 min to several hours observing the activities taking place and technology being used in a single room in a context such as a clinic or diagnostic test lab.
Shadow	Follow a target user such as a healthcare worker as they go about their daily routine.
Benchmark observation	Spend a day at a hospital, clinic, or diagnostic lab close to where the team works, even if the context is very different. Observe any challenges in how state-of-the-art diagnostic technologies are being used in well-resourced contexts. Many of the features that are hard to use in this environment will be even more difficult to use in a lower-resource environment.

10.2.3.3 Usability Evaluation

Usability evaluations help to pinpoint specific aspects of the diagnostic that can lead to user error or are undesirable to users. During a usability test, a user operates one or more diagnostic tools while the team observes and documents the interaction. The tools could be a combination of simulation devices, working prototypes, off-the-shelf components, or devices currently on the market. If the test cannot be performed in the actual use environment, the team simulates aspects of the actual use environment as closely as possible, including but not limited to the location, environmental conditions,

sense of urgency, lighting, and training. The user is asked to narrate aloud what they are doing while they do it. The team might ask questions while the user performs the task only as long as they pertain to the step currently being completed and do not detract from or contribute to the correct use of the test.

It is valuable to mock up the diagnostic experience even in the earliest stages of development before the assay is completed. A combination of off-the-shelf and custom components can be used to simulate all or part of a diagnostic use experience in the earliest stages. The below table includes ideas for prototyping diagnostic experiences.

Component	Method for Simulation
Sample collection	
Sample matrix	The viscosity and color are the most important features of a sample matrix in a usability simulation. For example, blood can be simulated by mixing water, red food coloring, and cornstarch.
Fingerstick	Various lancing devices can be compared by using them on a piece of fruit. A drop of simulated blood can be placed on a finger protected by a glove, and then touched directly to a sample pad or a capillary device.
Device	
Lateral flow and dipstick	Existing off-the-shelf test strips such as a $1 pregnancy test can stand-in for a future test by still performing the functions of absorbing the fluid and developing while the user waits. Alternately, build a device with multiple control lines to simulate the presence of one or more lines as a result.
Colorimetric and novel paper devices	A simulation device that performs basic functions of absorbing the fluid and having similar graphics and colors as the potential final design. Urinalysis dipstick pads or water quality pads can be used to simulate results.
Instrument-based or digital reader	Simulate the experience by creating a set of models mocking up each user interaction with the consumables and the instrument or reader. The outer form of the instrument might be 3D printed or cardboard. Buttons and display can be mocked up with a cell phone embedded in the housing. Existing programs like InVision App, Origami, or Pixate can take a set of images and turn them into clickable screens that take a user through the device states ultimately displaying results. A commercialized digital reader or existing instrument can be used to run simulated tests, even if the end results display reads an error. Explain why the reading returned an error and tell the user the typical range of results.

(*Continued*)

Component	Method for Simulation
Liquid reagents and handling	
Reagents and wash	Simulate viscosity and color using water, food coloring, and corn starch or surfactant as needed.
Handling	Off-the-shelf containers and dispensers such as dropper bottles, microcentrifuge tubes, and disposable transfer pipettes are a great start. Some custom items can be prototyped using 3D printing, or by modifying off-the-shelf parts.
Packaging	
Primary packaging	Determining the most user-appropriate primary packaging early helps stability testing in the long term. Off-the-shelf vials with desiccant lids and heat-sealable foil pouches are readily available, affordable, and invaluable in user tests. Foil pouches can be used to package test strips, consumables, and even vials of reagent.
Secondary packaging	Secondary packaging such as boxes and bags holds kit supplies together and custom labels add to the user experience.
Instructions and read guide	
Print	If the final design is likely to be laminated to increase durability, consider printing on a glossy business flier paper or using a laminator.
Digital	For digital instructions, software packages can enable teams to create app or web prototypes from a series of images.

Below is an example introduction to a usability evaluation with a simulated whole blood diagnostic device that authors A. Kumar and E. Johansen have used in the company Jana Care. This method of introduction was also used by Diagnostics For All in the case study described in Section 10.3.

> We have a simulation of the test we are developing. We would love for you to try it and give us some feedback. Can you please lead us to the location where you would most likely use this test if you had purchased it? (walk to area) We don't have a final product yet, so we made these simulation devices you can use with water instead of blood to see what it might be like to use this test. We are not going to show you how to use it, rather we want to see if the instructions and materials we have provided would be enough to tell you how to do it. This is a test for us—not for you—a test of how well we have designed this diagnostic to ensure you can use it easily. Now is the time when we can still make changes, so we look forward to your feedback.

The following table outlines some of the available methods for performing a usability evaluation. Additional material can be found in introductory anthropology textbooks and qualitative research design resources, such as *Introduction to Qualitative Research Methods: A Guidebook and Resource* by Taylor, Bogdan, and Devalt (Taylor et al. 2015).

Method	Description
In-context evaluations	Ask target users to operate one or more simulation diagnostic devices that provide the experience of using a finished device. Ask them to perform the evaluation in the context where they would anticipate using the test. Between users, change which option is tried first to decrease the effect of order on the feedback. The goal is to give the user very little instructions on how to use the test to highlight any difficulties in following the instructions.
Hallway evaluations	Chances to interact directly with actual users are infrequent, yet it is important to iterate rapidly toward a user-friendly solution. Hallway evaluations are an affordable way to test usability in between field visits. Recruit a small number of users who are unfamiliar with the diagnostic by walking down a hallway in the lab or office. Find some users with characteristics similar to your target user such as nontechnical background, eyesight, medical training, literacy level, and even culture and language. Perform usability evaluations with these users. Hallway evaluations highlight aspects of the diagnostic experience that are clearly *not* easy to use. However, if the diagnostic is easy to use for hallway test subjects, it still may not be easy enough to use for the target user. The ultimate proof will be testing with the target users in their context of use.
Follow-up questions	At the end of each test run, ask the user • What are your favorite and least favorite features? • Which step is easiest and which is most difficult? • What would you never do or use?
Product qualities ranking and comparison	Follow the product qualities ranking and comparison described in the in-context interview section to compare multiple simulated devices to each other and to other existing technology.

If there is no time to create simulated devices and the diagnostic is still in its earliest stages, having other tangible items will help the conversation. Possibilities include samples or photos of competitor devices, or diagnostics from different domains that may deliver a very similar user experience. The user may also have devices in their context that can be used to react and give feedback. Devices already owned by the user, such as old glucose monitors at a diabetic's home, can be brought together for conversation and comparison.

10.2.3.4 Techniques to Supplement In-Field Visits

Especially for global health projects, it can be difficult to travel to the actual sites of expected device use. The team can gain an initial understanding of the context and target use environment by interviewing global health experts who have experience serving the target users. However, these experts can supplement but not replace an in-context experience. A phone or video conference can also be a good way to check in with key users before and between field visits to the target context of use. Video has the advantage of being able to assess the user's reactions. Techniques for phone interviews include

asking open-ended questions, the five whys, showing digital images of competitor products and new technology concepts, and product quality ranking.

10.2.4 Synthesize

The purpose of synthesis is to turn learnings into action. The team must summarize in a way that gives other team members and partners a feel for who was visited and what was learned. It is important to also give the extended team access to raw information such as photos and user quotes so they may bring their own insights to bear. Providing summary information in combination with raw data also enables the team to more easily ramp on new team members, partners, or contractors in future phases of the project.

Summarizing information during synthesis can involve a wide variety of techniques (see the below table). More details about the techniques listed here appear in the case studies.

Method	Description
Techniques to use after every engagement	
Critical assumptions	A list of critical assumptions about the user, context, and need being addressed.
Product hypothesis	A one-sentence summary of the product's user, context, and the need being addressed.
Product requirements	A living document listing all requirements for the diagnostic kit to be successful (Mallette 2016). These include • Features and functions supporting user needs and intended use • Performance requirements and characteristics • Physical characteristics and exterior design • Product configurations and external interfaces • Packaging and shipping • Service and installation • Labeling and product documentation
Photo bank	Create a folder in the team's project workspace to collect all photos. At the end of each day, transfer all photos taken into a new sub-folder with date and title. As a bonus, copy the best photos of the day into a best-of sub-folder for easier future reference.
Quotes and notes	Create a folder in the team's project workspace to collect direct quotes and notes. Create one file for each in-context interview, phone interview, observation, or usability evaluation. Scan in hand-written notes. As a bonus, pull together quotes and organize them by theme.
Optional additional techniques for synthesis	
Use cases	Describes each use case for the diagnostic technology including target user, value proposition, and other stakeholders involved.
User journey maps	A step-by-step map for each important use case. Consider steps like awareness, selection, purchase, use, disposal, and repeat purchase.
Pugh chart	A chart that enables a team to weigh the importance of different features to resolve conflicting requirements (e.g., of models and quality of inputs)

10.3 Case Studies

In this section, we share two case studies to illustrate different ways to incorporate some of the techniques described in the previous section in the context of developing two specific diagnostic tests: (1) a progesterone test for cows—work that author E. Johansen was involved in while working at Diagnostics For All, and (2) a diagnostic test for sickle cell disease—work that author A. A. Kumar led while at Harvard University.

10.3.1 Case Study 1: User Feedback on a Bovine Progesterone Diagnostic Test in Kenya

The context: In Kenya, the majority of dairy cattle are owned by smallholder farmers on farms of less than 2 ha, with an average herd size of 2–4 cows (Thorpe et al. 2000). Selling milk is often the only source of income for these families. Optimal milk production requires a cow to be pregnant once every 15 months. Currently, a farmer observes behavioral changes in the cow that indicate ovulation and then calls for artificial insemination (AI) services. Depending on behavioral observations alone, cows in Kenya are dry (not producing milk) approximately 40% of the time (Odima et al. 1994; Waithaka et al. 2002). By better predicting heat in cows, U.S. dairy farms are able to minimize dry time to 15% on average.

With support from the Bill & Melinda Gates Foundation, Diagnostics For All (DFA) has been developing a bovine progesterone rapid diagnostic test to help identifying cows in heat. DFA is a 501c3 nonprofit developing point of care diagnostics to benefit low-resource communities in the developing world. The test is a whole blood progesterone lateral flow dipstick test. High or low progesterone is indicated by the presence of one or two lines. When low progesterone is accompanied by behavioral signs of heat, the cow is likely to be ready for insemination. A progesterone test has the potential to help farmers avoid costly unsuccessful insemination attempts, reducing unprofitable dry time, and increasing farmer income by as much as $50/year/cow.

This case study illustrates some of the HCD techniques used during and insights derived from a 7-day field evaluation in Kenya. This field evaluation took place mid-way through the feasibility phase for the progesterone diagnostic. The project team during this visit included Director of Product Design Elizabeth Johansen, Senior Scientist Dr. William Matthew Dickerson, and Research Associate Kendall Milkey.

Using HCD techniques to engage users directly, the team discovered the primary target users would be artificial insemination technicians instead of farmers, the sample collection method would be venous draw instead of ear stick, the strips should be packaged in foil pouches instead of vials, and the total cost for the kit could potentially be $3 instead of $0.50 leaving more room for innovation. The product hypothesis and assumptions from before and after the visit to Kenya are summarized in the following table.

Before the Visit	After the Visit
Product hypothesis	
Dairy farmers in Kenya and East Africa with fewer than 5 cows. —NEED— A <$0.50 progesterone test kit that is easy for farmers to use on the farm to identify cows ready for artificial insemination, decreasing dry time, and ultimately increasing farmer income.	Dairy farmers in Kenya and East Africa with fewer than 5 cows. —NEED— *A <$3 progesterone test kit that is easy for AI techs* to use on the farm to *help* identify cows ready for artificial insemination, decreasing dry time, and ultimately increasing farmer income.
Critical assumptions	
The need	
With current methods of heat detection, dairy cows are not operating at optimal milk production.	No change.
More efficient heat detection in cows could lead to greater milk productivity and more income.	No change.
The test must be sold for less than US$0.50 per kit to be affordable and lead to significant increased income.	The test must be sold for less than *US$3* per kit to be affordable and lead to significant increased income.
The user	
The test will be performed by a farmer drawing blood from the cow by lancing the ear.	The test will *primarily* be performed by *AI techs who are trained to perform venous blood draw*.
A farmer will be able to correctly interpret the results of a lateral flow test on the farm and have the confidence to decide whether to call for an AI tech.	*AI techs will have sufficient vision to correctly interpret the test results on the farm and confidence to decide whether to administer AI*.
The context	
The test will be performed on a farm in East Africa, with a particular focus on Kenya.	No change.
There will be a safe place on the farm to put the test while waiting for the results to develop.	*The kit will include component(s) to keep the strip safe* while waiting for results to develop.
Test kits will be sold at local agricultural and veterinarian supply and service shops (Agro-Vets).	No change.
Strips will be packaged in vials of 10–20 to reduce costs.	*Each strip will be sealed in a foil pouch with desiccant to increase affordability and right-sizing for portability*.

Prepare: To prepare for the Kenya field visit, the DFA team began by generating a list of critical assumptions using the methods (literature, expert phone interviews, etc.) described in Section 10.2. These assumptions were summarized in a product hypothesis shown in the above table. The team also developed a recruiting plan, which included a request to visit at least

five smallholder dairy farmers, at least three AI technicians, as well as veterinarians and others who handle cows. The team also specified extremes including location and size of farm, level of experience, and level of success in farming.

In order to test these assumptions, the DFA team engaged Sidai Africa Ltd., a field partner from prior project visits. Sidai is a social enterprise revolutionizing livestock and veterinary services through a network of franchised and branded Livestock Service Centres in Kenya. The team set up a series of calls with Sidai executives and coordinated closely with Sidai's Technical Director, Dr. Odede Ochieng, to discuss the recruiting plan and field visit plan. Dr. Odede Ochieng also became the team's host and translator during the visit. As a veterinarian, his role included forming relationships with farmers and Agro-Vet shops across Kenya.

Engage: During this visit to Kenya, the team performed in-context interviews of potential users, usability evaluations embedded in the interviews, and observations. Highlights of the visit that led to important insights are detailed in the following text.

The team wanted to test the assumption that farmers would be comfortable drawing blood from their own cows. The use of open-ended questions followed by the five whys helped generate an important learning during an interview with one smallholder farmer.

Moderator: Have you ever drawn blood from your cows for any reason? (yes/no question)

Farmer: Yes we have.

Moderator: Could you tell a story of a time you took blood? (open-ended question)

Farmer: One time the vet came and took blood from the jugular vein of one cow, then she made a smear and took it to the lab to diagnose tick-born infection. I asked how to take blood myself in the future in case the vet was unavailable in the future.

Moderator: Why did you ask to do the blood draw yourself? (first why)

Farmer: Well, I have never personally taken blood, but I had one of my farm hands learn how. I wanted him to know how to take blood in case the vet was unavailable in the future.

Moderator: Why didn't you do the blood draw yourself? Why did you ask a farm hand? (second why)

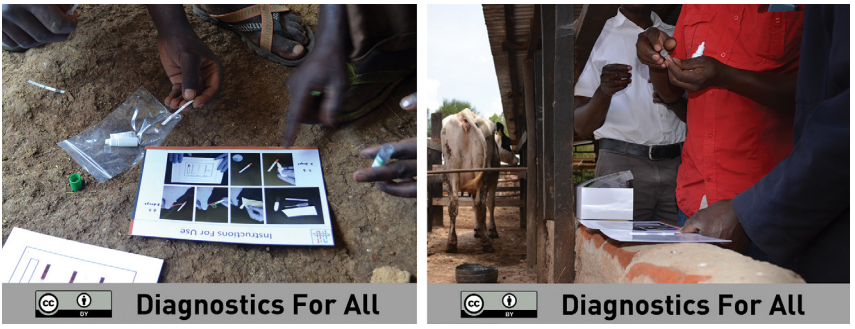
Farmer: I am not comfortable treating my animals on my own because of the sympathy and pain I have for them. That's why I get other people to care for them.

Without asking why several times, the team would not have realized the farmer had never drawn blood from his own cows and did not wish to. The team might have left this interview feeling validated in their approach to

have farmers run the diagnostic test on their own cows. Receiving similar answers from other farm visits, as well as expert opinions from veterinarians and Agro-Vet shop owners led the team to consider artificial insemination service providers as the primary users for this test.

Asking users to try a simulation diagnostic test kit helped test assumptions about whether users can correctly interpret the results, how test strips should be packaged, and the cost of the test kit. The progesterone test was still in the feasibility phase at the time of this visit, so the team had to come up with a way to mimic the potential use experience. Dr. William Matthew Dickerson and Kendall Milkey conceived of and created simulation lateral flow strips that would show one or two control lines with application of water.

During the second half of each in-context interview, the team gave farmers, AI techs, and other stakeholders an opportunity to try two different simulation test kits reflecting a variety of packaging, procedure, and results. Each user was given a basic introduction to the purpose of the test without any verbal instructions on how to conduct the test. They were asked to perform the test in the most likely context they would use it on the farm (see figure below).

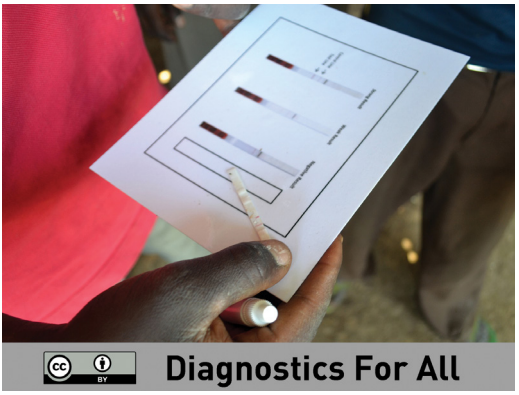


Users from two different farms try the simulated progesterone test kit in the context where they would eventually use it. (Courtesy of Diagnostics For All, Salem, MA.)

Through observations of use of the simulated kits, the team quickly learned that a single strip in a foil pouch is preferred over strips packaged in vials. While using a simulated diagnostic kit, a manager at a large farm opened a vial of 10 test strips; three fell onto the dirt floor. He indicated he much preferred the individually pouched strips he saw in the second simulation kit as he was less likely to waste extra test strips. In addition, after trying the simulation kits, a smallholder farmer noted he may never have enough money to buy 10 tests all at once. He preferred individually pouched strips for affordability because he could purchase one at a time.

Asking users to interpret the simulation tests highlighted the difficulty of reading the strip in a shady farm building. In addition, the team discovered that many farmers will not be able to correctly read the strips due to

uncorrected vision impairments. On a visit to one smallholder farm, three herdsboys tried the simulated diagnostic kits. When it came time to read the results in the shade of the barn, one herdsboy said, "I can see two lines on the strong results strip, and one line on the negative results. The middle strip looks plain to me." In fact the middle strip had two lines, including a control line and a light test line (see figure below). He was still unable to see a line even in the sun. This same issue of readability occurred on other farms as well. Reading was not as difficult for AI techs who already had to see small markings and labels to perform artificial insemination.



Laminated read guide showing images of what a strip looks like with a positive, negative, or invalid result. (Courtesy of Diagnostics For All, Salem, MA.)

Enabling the farmers to experience a simulation kit also opened a doorway to discuss pricing. After observing his son try two simulation kits, one smallholder farmer said, "How accurate is the kit? It must be very certain to be worth it. I would pay $5 USD if the kit was certain." This feedback along with similar feedback from other farmers and AI techs gave the team preliminary evidence that a $5 diagnostic service including $3 test kit may be affordable for farmers and still yield reasonable service fees for AI techs. Note that pricing feedback from a handful of people is difficult to depend on; the team could increase certainty by following up with a market study of price sensitivity performed with partner Sidai Africa Ltd.

The team had the opportunity to shadow two different artificial insemination providers to several service calls from farmers. The team asked for the AI techs to try fitting a range of potential diagnostic packaging into their equipment backpacks and comment on which would be the preference. Packing options included strips in a vial, strips in individual foil pouches, kits in plastic Ziploc bags, and kits in paperboard boxes. One AI provider summed it up the best: "I like the tests in individual packs instead of getting many tests in a box. The box won't fit in my backpack that carries the liquid nitrogen canister. The foil pouch saves us space. I would carry it in the front

pocket of my bag. Carrying up to ten would be manageable, but it would also allow me to carry fewer if that's all I need."

One user-created prototype highlighted the need to find a good, safe place on the farm for the test to stay while waiting for results. After trying a simulation kit, the team asked one AI tech to use nearby materials to make something to keep the test strip safe on the farm. The AI tech found a piece of wood on the ground and said, "When you're on the farm, animals are moving around. I think a heavy stand like this wood block would be better and would allow an AI provider to help the farmer while waiting for the results." See figure below.

User supplying their own prototype to support the device in the field. (Courtesy of Diagnostics For All, Salem, MA.)

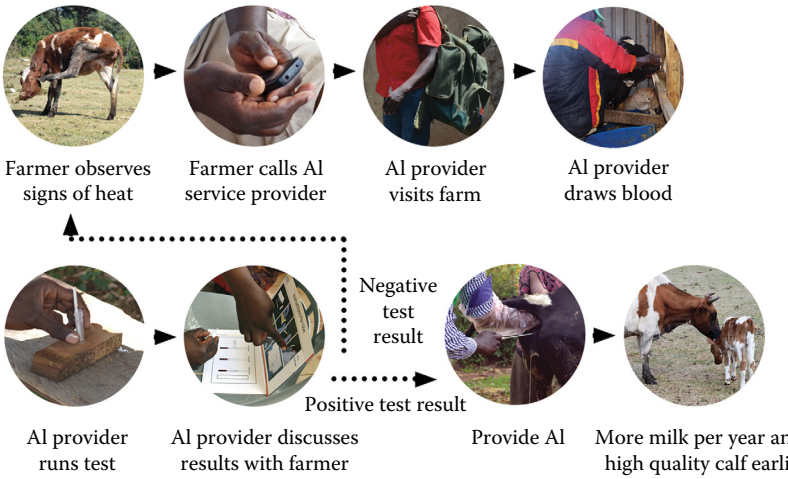
Synthesize: The first step upon returning from Kenya was to generate a revised product hypothesis and set of critical assumptions seen in the previous table. Findings from the trip also provided guidance on how to modify the diagnostic kit components going forward. Updated product requirements are shown in the following table.

Component	Requirement
Test strip	Sample collection method will be venous blood draw into a vacationer instead of ear prick. Development will not require any ear stick samples.
	Preferred strip packaging is individually sealed foil pouches. Stability trials should be performed in this packaging.
	Waiting for results is a challenge; time to result should be limited.
Supplies	The test needs one or more component(s) to protect it while it runs and keep in a conspicuous place so users remember to come back and read the result at the right time.
	The cost of the kit must include sample collection supplies to avoid accidental introduction of an interfering substance such as an anticoagulant in a locally sourced supply.

(*Continued*)

Component	Requirement
Instructions and read guide	Include a warning to read the test in good lighting.
Packaging	Test strips will be individually packaged in foil pouches with desiccant.
	All supplies and instructions required to run one test will be contained in a plastic bag to minimize kit size and enable sales of individual kits.

The team also mapped out a step-by-step user journey map to help gauge the potential effect of changes to the kit (see the following figure). This journey map also helped partners envision how the strip would be used in the market.



Bovine progesterone test user journey map: confirming signs of heat. (Courtesy of Diagnostics For All, Salem, MA.)

Armed with the new learnings about the target user, sample collection method, user-preferred packaging, keeping the strip safe during wait time, and affordable kit cost, the team returned to complete the feasibility phase of development.

10.3.2 Case Study 2: End-User Feedback on a Diagnostic Test for Sickle Cell Disease in Rural Zambia

The context: Sickle cell disease is a genetic blood disorder affecting roughly 300,000 children born each year (Piel et al. 2013; Serjeant 2010). The vast majority of children born with sickle cell disease are in sub-Saharan Africa and India. Untreated, sickle cell disease leads to increased risk for bacterial

infection, body pain, and potentially stroke. Although many of these risks can be mitigated by simple interventions—prophylactic penicillin or pneumococcal vaccine, hydration, and parental education—a lack of early diagnosis is an important contributor to the estimated 50%–90% mortality rate for children under 5 born with sickle cell disease in sub-Saharan Africa (Emond et al. 1985; Hankins and Ware 2009).

A team of scientists under the direction of Prof. George M. Whitesides at Harvard University developed a low-cost diagnostic to screen for sickle cell disease in point-of-care settings using the density of red blood cells to distinguish between normal, healthy blood, and blood with sickle cell disease that is characteristically accompanied with high density red blood cells (Bartolucci et al. 2012; Fabry et al. 1984). The technology uses a small capillary with liquid polymers and a simple centrifuge to perform the density-based separation. The team previously described the technology (Kumar et al. 2014b), clinical trials (Kumar et al. 2014a), and the process of developing the technology (Kumar et al. 2015) in detail. For the purposes of this discussion on HCD, we will focus on the user evaluation done by the team in rural Zambia. Before beginning field work, the team had developed a first iteration of a product hypothesis drawing on the previous experience of A. A. Kumar who had served as a Peace Corps Volunteer in rural South Africa, had attended a winter school in India on technology in rural areas, and had visited health facilities in Kenya to assess diagnostic needs. The team also relied on the knowledge of Dr. Thomas P. Stossel, a hematologist who had spent over a decade doing work with a nonprofit in rural Zambia and initiated programs to treat sickle cell disease in Zambia. These personal experiences complemented the literature to create a set of assumptions about the need for a diagnostic test for sickle cell disease (which would later be modified after the field study) (see the following table).

Before the Visit	**After the Visit**
Product hypothesis	
Rural health centers in Zambia —NEED— A <$1 diagnostic test for sickle cell disease to screen newborns, identify common genotypes, and takes less than 20 min to perform.	Rural health centers in Zambia —NEED— A <$1 diagnostic test for sickle cell disease to screen *young children at the time of routine vaccinations* (*6–12 months*), *which is simple to interpret* and takes less than 20 min to perform.
Critical assumptions	
The need	
There is a high prevalence of undiagnosed sickle cell disease in rural Zambia.	There is a high prevalence of undiagnosed sickle cell disease in rural *and urban* Zambia.
Simple interventions to treat sickle cell disease are available at rural health centers.	No change.

(*Continued*)

Before the Visit	After the Visit
The test must be sold for less than US$1 per test.	No change.
The user	
The test will be performed by a nurse or a community health worker or paramedical staff.	The test will *primarily* be performed by a community health worker or paramedical staff.
Health staff are comfortable performing fingersticks.	No change.
The context	
The test will be performed in rural health centers in Zambia and reference labs are available in urban centers.	The test will be performed in rural *and urban areas* in Zambia, and *reference labs are generally unavailable* (*only identified two in the whole country at the time of the study*).
Power is generally unavailable in rural Zambia.	*Limited power is generally available in rural Zambia through car batteries charged with solar panels*.
Diagnostic tests must provide results in under 20 min to fit into the workflow of rural clinics and to ensure follow up.	Diagnostic tests must provide results *in 20–30 min to* fit into the workflow of rural clinics and to ensure follow up.

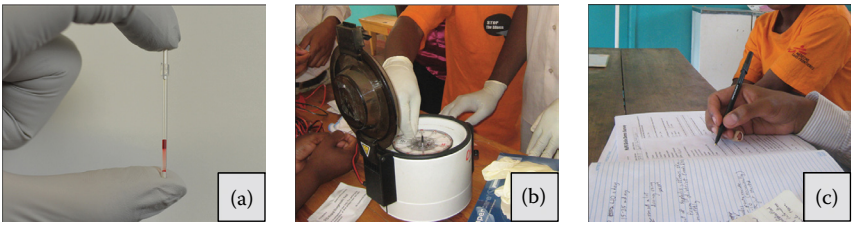
Prepare: Through Dr. Stossel's previous work in Zambia, the Harvard team connected with a team of clinicians, led by Dr. Catherine Chunda-Liyoka, at the University Teaching Hospital (UTH) in Lusaka, Zambia. Working together, the expanded team crafted a grant proposal to develop the rapid test for sickle cell disease that was funded by the Harvard Office of Technology Development. This grant included support for fieldwork to test the performance of a density-based assay to detect sickle cell in patients in Zambia. One of the justifications for a field trial fairly early in the research process was that there was a much higher frequency of sickle cell patients in Zambia. In addition to the plans to test the performance of the device, the team also made plans to test the usability of the device in rural health centers in Zambia. An additional grant from the Harvard Global Health Institute enabled the team to spend time and resources on human factors work that leveraged the networks built in Zambia for the clinical study.

To take advantage of this funding, the team carried out three steps in preparation of doing a rural survey: (1) worked with experts and local stakeholders to identify appropriate participants, (2) defined the types of information to be collected, and (3) practiced demonstrations before going to the field. Specifically, the team identified the Northern Province of Zambia as a geography with a potentially high concentration of sickle cell disease by talking with local experts at the University Teaching Hospital in Zambia, including Dr. Chifumbe Chintu and Dr. Chunda-Liyoka. The team then connected with the local Peace Corps office in Zambia to identify rural health centers with volunteers who would be amenable to hosting researchers.

Working with the Peace Corps, we prepared sites in advance of our visit in order to have a large attendance of community health workers. Peace Corps Volunteers and their counterparts at each site assisted in translating and getting stakeholder buy-in during the evaluations.

Ahead of the trip to the rural site, the team worked with our Zambian counterparts at the University Teaching Hospital (UTH) in Lusaka to create surveys to assess knowledge about sickle cell disease, familiarity with rapid diagnostic tests, and feedback on our prototype of a rapid test for sickle cell disease. Along with the team member from Harvard, a nurse from UTH planned to travel to the rural sites. The team also took all the equipment thought necessary to run the test in rural areas, including a small hematocrit centrifuge and a car battery for power.

Engage: The materials developed were used at two separate rural health centers to perform in-context interviews that consisted of a general education session about sickle cell disease, a presentation and demonstration of our prototype diagnostic (see a and b in the figure below), a tour of health facilities, and a survey of health workers that later evolved into interviews with individual health workers (see c in the figure below). During the tour of each facility, we took pictures of anything that could be of relevance: hand washing stations, solar refrigerators for vaccines, storage rooms, and patient waiting areas. During demonstrations, we had volunteers come and try the test procedure to see how easy or difficult it was and we observed and noted the results (see a and b in the figure below).



A team of scientists from Harvard and health workers from the University Teaching Hospital in Zambia did usability testing of a density-based rapid test for sickle cell disease (a). Community health workers and nurses tried using the diagnostic procedures (b). In-context, individual interviews captured insights into clinical workflow and design constraints for repid tests (c).

We also practiced observations and shadowing by embedding the nurse from our team into the clinical work at each rural health center for a day. This allowed our team to better understand the workflow at the rural sites and the challenges they faced. It also enhanced stakeholder acceptance as the clinic staff saw that we were not just taking information from them but also providing assistance while we were there. Observations of patients coming to the clinic helped us to understand that the main doctor or nurse generally only gets to spend 20–30 min to see patients and that patients often sit in a line outside the clinic for 20–30 min. Afterwards, patients would generally return home (sometimes traveling many kilometers on foot).

At the first health center, written questionnaires were given to health workers to fill out (see c in the figure on the previous page). We soon realized that they saw it more as an assessment of their understanding rather than a feedback tool; many of them showed stress trying to provide the "right" answer and we had to assure them that we wanted whatever answer they gave and there was no right or wrong answer. To remedy this situation at the second health center, we used the surveys to perform individual interviews. This format allowed the investigator to clarify answers and push for more thorough responses by adding open-ended questions and asking "why" certain responses were given.

Synthesize: After the study at the two sites, we were able to tally responses from surveys and interviews, review photographs and notes, and discuss observations. This time spent digesting the information yielded several insights.

Time requirement: During observations and in-context interviews, we created an informal map of the typical flow of patients (i.e., creating a journey map): (1) check in and wait (and get rapid tests done), (2) see a nurse or a clinical officer for consultation, and (3) go to the dispensary to collect any medications or receive shots. In order to maximize the workflow at the clinics, the staff members ran rapid tests for malaria on most febrile patients that were waiting to be seen. The time waiting before seeing a nurse or doctor is a useful time to perform rapid tests as the information from the tests can be used to inform clinical decisions, such as what medications to give the patient. To fit into the workflow at the clinics we visited, the longest time a test can take is roughly 20–30 min.

Power requirements: In the United States, there is much speculation that a manual centrifuge is better than a battery-powered centrifuge in low-resource settings (Brown et al. 2011; Saad Bhamla et al. 2016; Wong et al. 2008). The reasoning put forward is that electrical power is unreliable and batteries are not easily available, so power-free options are required. Some of these assumptions require significant caveats. Manually pedaling a bicycle, spinning a salad spinner, or cranking an eggbeater may be effective methods to achieve centrifugation, but one would be hard pressed to find the volunteer or health care provider in a rural clinic who can afford to spend 10 min in manual labor for every sample to be processed. In interviews, health worker after health worker described their ideal test as one you set, maybe press a button, and leave until it is time to read it. A battery-powered centrifuge meets this requirement but a manual centrifuge does not. If one considers batteries, the type of battery is important. In rural Zambia, AA and AAA batteries required a trip to the main town. The Hemocue Hemoglobin Analyzer at one clinic we visited was not being used, partly because the batteries were dead. In both villages, however, there were cars and, thus, car batteries. Moreover, car batteries connected to solar panels were often found in enterprising households to charge cell phones (sometimes for a small fee). When we ran our centrifuge from a car battery, it was not out of the ordinary.

Level of differentiation required: Two versions of the sickle cell test were developed. One test was simple and only differentiated between sickle cell disease (of any genotype) and non-sickle cell disease (normal hemoglobin or sickle cell trait). The other test additionally provided differentiation between the two main genotypes of sickle cell disease, but the reagent was slightly more complex. Based on observations and interviews at the rural health centers, we concluded that basic care and simple, yet important, interventions (i.e., folate, hydration, parental education, pneumococcal vaccine for children, prophylactic penicillin) could be given for patients with sickle cell disease. Differentiated care for subtypes of sickle cell disease would be difficult to implement and is not even common practice in well-resourced settings. Strategically, we decided to focus further development on the simpler test that did not differentiate subtypes.

Perception of the problem: Sometimes, the information we received was contradictory. When asked about whether health workers believed sickle cell disease was a major issue in their area, some were certain that it was while others were adamant that no sickle cell disease was present in their community. With our counterpart Zambian nurse spending a day in clinic, meeting patients and speaking with locals, we identified a potentially significant burden of sickle cell disease based on symptomatic patients. We concluded that the conflicting information we received from health workers was potentially a perception and education issue. Any new diagnostic in these areas would, thus, need to be accompanied by education programs to help improve understanding of the disease and its treatment.

Following the field study in Zambia, the lessons learned from the field study were combined with the scientific knowledge gained from clinical trials to develop a next generation diagnostic test for sickle cell disease.

10.4 Top 5 Misconceptions about HCD in Diagnostic Development

Bringing Human-Centered Design (HCD) into the practice of diagnostic development is extremely rewarding, but it also has its challenges. The following list includes some of the common misconceptions surrounding creating a diagnostic device that will be easy to use and adopted by users.

1. *If my device passes a human factors usability trial at the end of my development process, it will be well adopted by users.*

   If the team has not explored diagnostic use in the market with end users before the validation phase, it is possible for the diagnostic to fail the human factors trial. Even worse, it is possible to set up such a trial that does not test the diagnostic in a way it will actually be used

in the market. In fact, even the U.S. FDA recognized that most study evaluations occur in idealized conditions (FDA 2014). The diagnostic might pass with flying colors only to enter the market and fail through user error or lack of demand.

2. *Doing a user evaluation with a small number of users won't yield actionable information; the sample size is just too small*.

   Engaging small numbers of users iteratively with HCD before a product hits the market dramatically increases the chance of user acceptance and correct use. However, the information gained through HCD techniques will be qualitative, not quantitative. Users may give conflicting information. No diagnostic device will satisfy everyone and no device will ever be perfect. The benefit of HCD is to dramatically increase the chance of user acceptance and correct use before it hits the market. Ultimately, the team must make the call about how to interpret the learnings. Some information will lead to new solutions, and other information is okay to ignore. Learning and applying HCD takes time, patience, and bravery.

3. *The technology is too constrained, we are already in the middle of R&D: there isn't any leeway for user-driven changes*.

   It is never too early and never too late to get value from HCD. Some teams will not engage users for fear they will learn something to which the diagnostic cannot respond. Please trust that the team is more creative and resourceful than imagined! There is a solution to most user challenges, but the team must be brave enough to look the challenges in the eye in order to generate a solution. Remember, responding to a user challenge does not always require changing the core technology; there are many challenges that can be mitigated by better user instructions, packaging, training, or selecting a better off-the-shelf fluid dispenser.

4. *I can't show a simulated device to users or field partners because it would be misconstruing that we have a working device*.

   Depends on the audience and the simulated device. It is possible to explain, even across languages and cultures, that the diagnostic is just at the idea phase. Thank the user or partner for being part of the earliest development stages and help them understand the feedback they give will help bring shape to the product, which will in turn bring positive impact to many people. In this way, the team builds a cohort of cheerleaders who want the product to come to market and are happy to give ongoing feedback and even partner for activities such as clinical trials, distribution, or manufacturing.

5. *HCD is about using personal intuition to create a better product*.

   A key tenet of HCD is that the team's intuition, free from interaction with users, is insufficient. In global health diagnostic development, team members may be very different from the target user along

dimensions of culture, lifestyle, socioeconomics, education, profession, and more. The methods and techniques listed here have been honed as efficient ways of yielding relevant user information with a small investment of time and resources. In particular, the HCD techniques and methods listed here have shown preliminary usefulness in diagnostics development. For further learning, the Acumen Fund and IDEO.org provide a free online course called Design Kit, which teaches HCD methods (http://plusacumen.org/).

10.5 Conclusions

HCD is a process and set of methods for getting a nuanced, in-depth understanding of the needs of users and other relevant stakeholders. The HCD framework and accompanying case studies provide detailed examples of critical insights into diagnostic users and other relevant stakeholders that cannot be gained through any amount of test development in the lab. These insights are crucial to designing a diagnostic test that meets the needs of users in order to prevent test failures, misdiagnoses, or lack of test adoption.

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