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#### Agenda

Review: Maker Hypothesis, Objectives

Objectives of Process Documentation

Review Maker Theory of Change

Methods and Analysis

Findings

Reflections

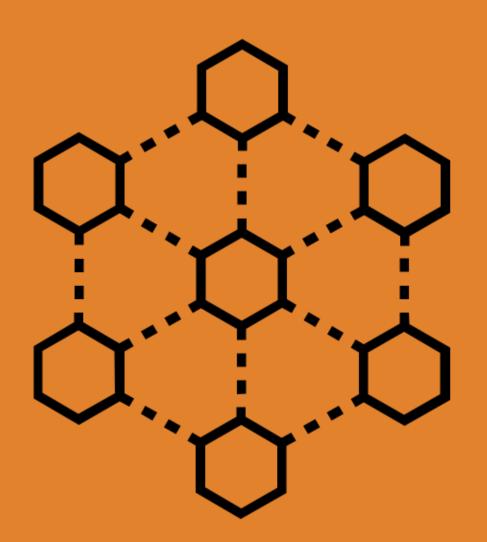
### What was Maker about?

**locally design** low-cost, highquality, alternatives to essential MNCH equipment and spare parts

Inkages between Makers and
MNCH health professionals



## **Maker Hypotheses**



THE HUB

# can locally design and build select equipment and spare parts for labor and delivery and newborn care is a viable model

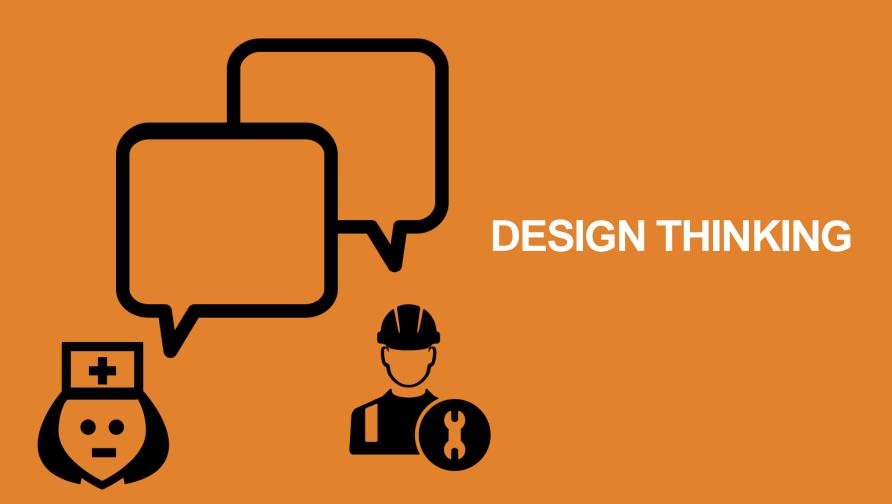
Components of viability as defined by the Maker team

Establishment of governance structures

Processes for management and decision making

Diversified funding

**Business operations** 





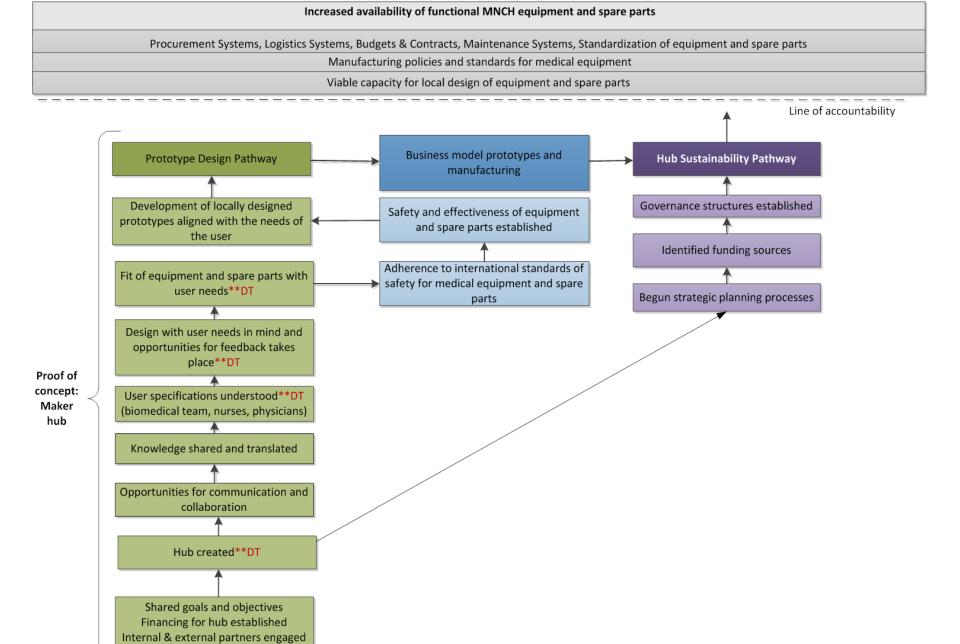
**EMPATHY** 

FIT

**BUY-IN/OWNERSHIP** 

For Maker, the case study of DTSI is drawn from the process documentation since all DTSI activities apart from the ideation pertain to the approach taken to develop equipment prototypes

## **Maker Theory of Change**



#### Foundational enabling environment

Management structures in place

Implementation Strategy · Relevant research undertaken / Health care challenges understood

## **Objectives**

#### **OBJECTIVES OF PD ROUND 1**

Hub creation

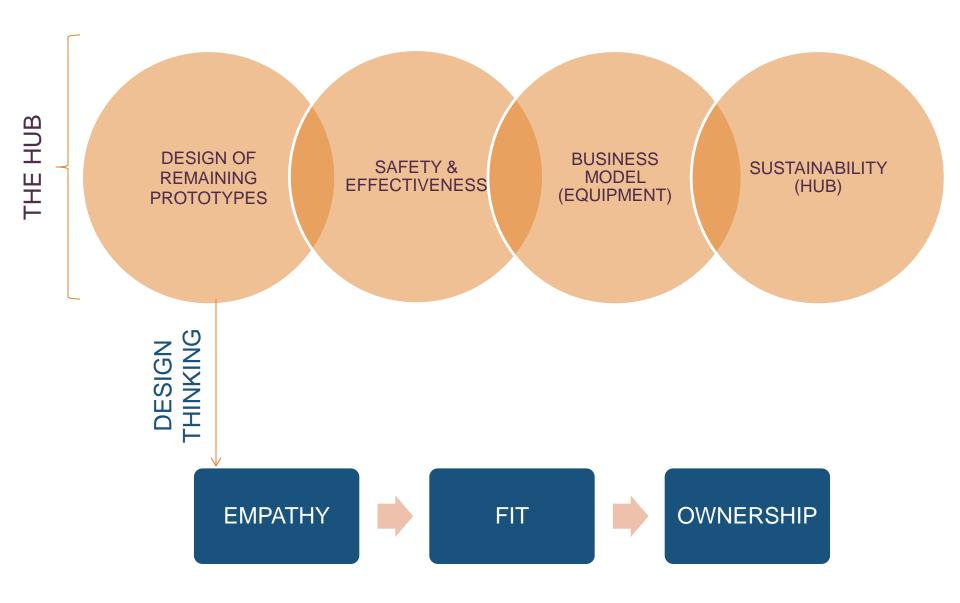
Hub operations

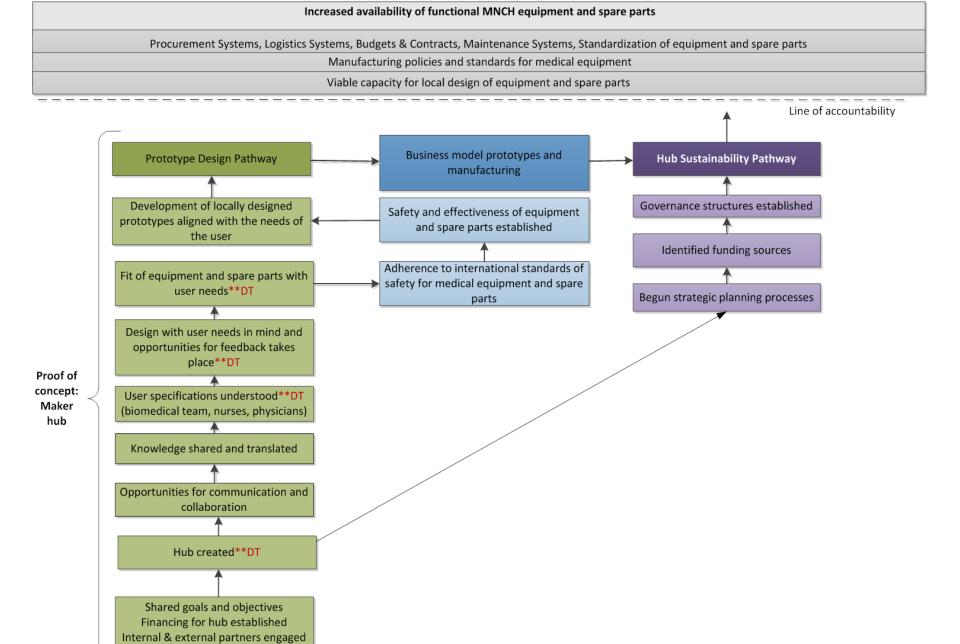
Hub understanding of Maker goals and objectives

Design of first prototype

DESIGN
THINKING

#### **OBJECTIVES OF PD ROUND 2**





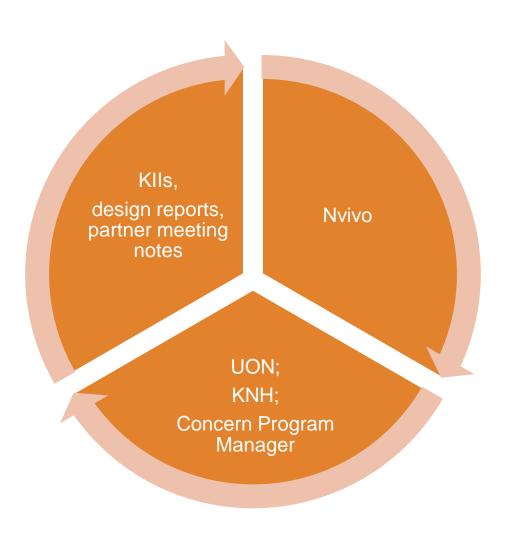
#### Foundational enabling environment

Management structures in place

Implementation Strategy · Relevant research undertaken / Health care challenges understood

## **Methods & Analysis**

#### **METHODS & ANALYSIS**



QUALITATIVE THEMATIC CODING ITERATIVE REVIEW

## Findings

#### **EQUIPMENT DEVELOPMENT TIMELINE**

Resuscitaire

Incubator

**Patient monitor** 

Oxygen blender

**Delivery Bed** 

**Vacuum Extractor** 

**Phototherapy Unit** 

**Exam Light** 

#### **Suction Machine**

| Needs<br>Assessment | 9 pieces<br>prioritized | UoN<br>visits<br>to<br>KNH | Prelim<br>designs | 4 pieces<br>prioritized | Model<br>finalized            | Prototype<br>built &<br>finalized                            | KEBS<br>review &<br>approval | Clinical<br>Testing |
|---------------------|-------------------------|----------------------------|-------------------|-------------------------|-------------------------------|--|------------------------------|---------------------|
| Jan '14             | Mar '14                 | Apr-<br>May<br>'14         | May-<br>Aug '14   | June '14                | betwe<br>clinicians,<br>UoN e | Mar-Oct '15  age visits een KNH biomeds & agineers L-Dec '15 | Dec '15 -<br>TBD             | TBD                 |

# Design and fabrication of Prototypes

Mechanisms for design and fabrication

# Frequent exchange visits

Monthly partners meetings

Project status and decisions

Identifying sources of local material

Identifying equipment needed to fabricate





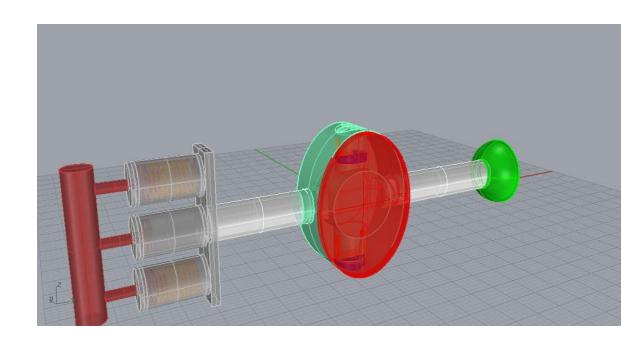
Undergoing KEBS review
Clinical trial protocol approved

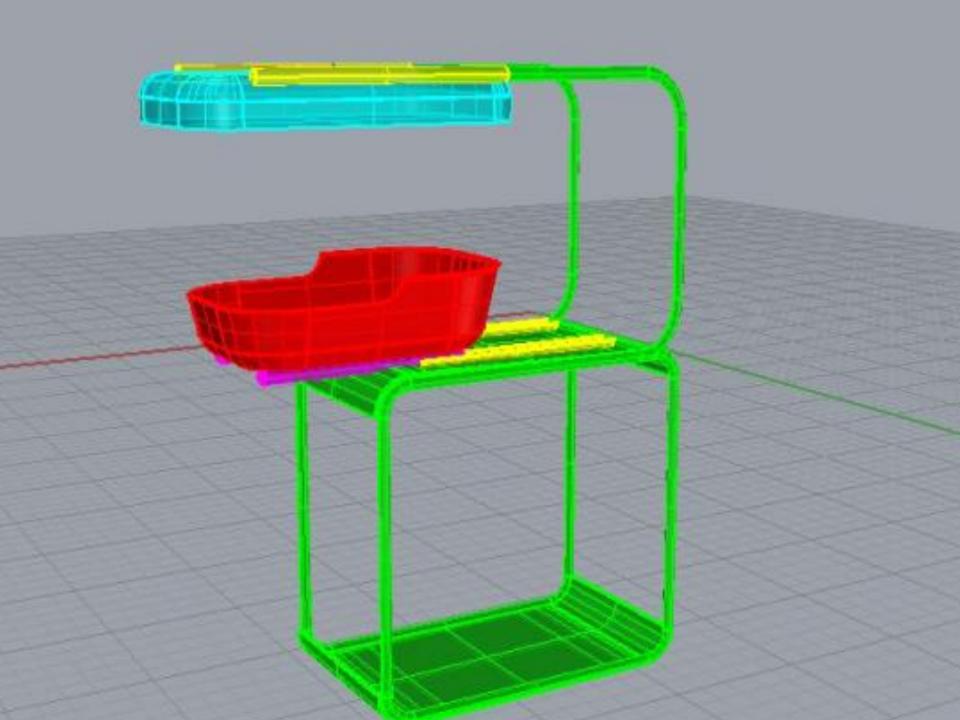
**SUCTION MACHINE** 

## Designs developed for 3 other pieces of equipment w/clinician input

- Exam light
- Vacuum extractor
- Phototherapy machine







## Findings | design thinking

#### **Design Thinking Hypothesis**

Application of design thinking methods within Maker will:

Create UON Fab Lab **EMPATHY** for KNH clinicians & biomedical team

Result in **FIT** of equipment prototypes with the desires and needs of KNH clinicians and biomedical team

Result in **BUY-IN/OWNERSHIP** of equipment by KNH clinicians and biomedical team

#### EMPATHY | FIT | BUY IN/OWNERSHIP

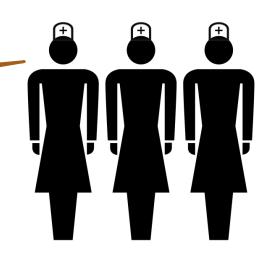
Nurses felt heard

UON Fab Lab reported spending time with nurses in KNH to understand their context

Multiple, frequent meetings

On the examination light:

"There was a lot of cooperation. They would listen and try to modify according to our specifications. They did almost exactly what we anticipated or wanted"



#### User requirements | on suction machine

- COLOR
- FILTER
- MOVABLE CASTORS
- MATERIAL FOR BOTTLES
- HEIGHT OF THE HANDLE
- BOTTLE HOLDERS
- GAUGE
- SIZE



## **UON Fab Lab perspective on engaging users** (clinicians)

"The nurses have been cooperating. They have looked at our designs, made suggest ions to improve."

"The success of the first equipment we made was the suction machine was highly dependent on their input."



"When you are making these designs, getting input from the hospital was quite important, because we in engineering don't use medical stuff, so we could design something that doesn't work well in a hospital environment."

#### EMPATHY | FIT | BUY IN/OWNERSHIP

Challenge to ascertain fit and ownership because the suction machine has not been used at KNH

The RME plan was to do a usability test during clinical testing to ascertain fit.

Ownership was considered an important by product of empathy and fit and therefore could not be tested as well

The other pieces of equipment are in the design stage.

Nurses expressed excitement at the suction machine, as well as some disappointed that more prototypes have not been completed as yet.

## Safety & Effectiveness

KEBS engaged

Clinical testing protocol approved

Clinical testing unable to get underway because project ran out of time



## **Business Model**

#### For Equipment

- · Goal: Get it to market
- Hired consultant in 2014, gaps in methodology

"But another aspect that has not been considered, is how these pieces of equipment will get to the market." – UON Fab Lab engineer

#### For the Hub

- Goal: understand what it took to run a hub like Maker
- Concern Fellow brought on in 2015 to work on this model
- Analysis Underway
- No business model analysis on the hub itself as yet.

Financial viability analysis is incomplete at this time.

# Sustainability

- What does sustainability mean for the hub?
- What are the core components?
- Progress along the sustainability pathway as described in the TOC
- Interviewees were not sure about next steps on Maker but expressed interest in remaining engaged going forward
- An analysis on sustainability could not be We cannot conclude on the sustainability of the hub at this time

## **Unintended Effects**

# Improved working relationship between clinicians and biomedical team

"Most of the time we interact with fellow staff and equipment, but here, creating a forum in the hospital where clinicians are talking to biomeds on developing equipment – it was the first of its kind".

#### **UNANTICIPATED ACTIVITIES PER THE TOC**

KNH Calibration Center KNH biomedical team capacity building

UON student capacity building
UON Maker space
UON equipment to create prototypes



Consumed project resources



#### Quotes from project staff

"Also I think another achievement was overall capacity building for KNH through Maker which

# was able to take our staff to the U.S. which was also linked to calibration center. It broadened their scope and capacity and thinking to see wider aspects of how things are done out there. But most specifically of course, that was for the calibration center, but that capacity building was huge."

- KNH staff

"We must really be thankful to the Maker project for initiating and supporting Kenyatta to build the

#### calibration center...

The calibration center is helping KNH do other things and Maker really contributed to purchasing some of the equipment that made the center running. So that is one thing I can say has been a real benefit to KNH from the Maker project."

- KNH staff

"The Maker Space has expanded the ability of the **Science Park** to take ideas to the next level of usability."

- UON staff

### Context



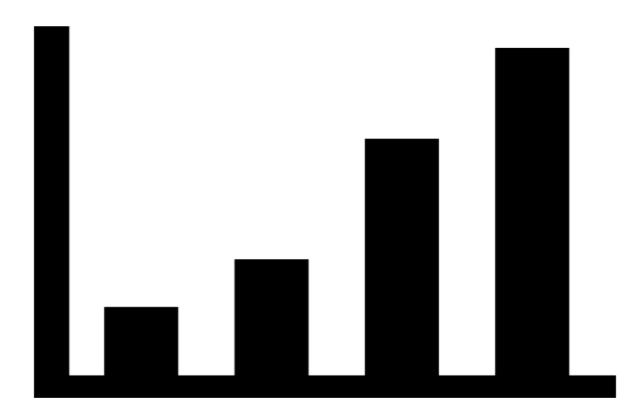
"Another challenge is building medical devices in an environment without national policies and guidelines on research and development of medical devices".

- Maker hub member

"...been able to talk, advocate and show an implication to external stakeholders led by the government that Kenya can build our own medical devices. This has been done through conferences and meetings. We have been able to share progress with a national task force. We have been able to share through briefings and have briefed the first lady. We briefed the ministry of health and the ministry of education, science and technology on this project and then have been able to talk about work externally. This has attracted a lot of interest.."

# PD ROUND 1 FINDINGS – OVERLAP AND DIFFERENCES

Overlap between PD round 1 and 2 findings How do PD findings differ? How were findings from PD round 1 used?



#### What worked well | Results reported in round 1:

- Suction machine almost complete
- Concern management recognized
- KNH and UON Leadership recognized
- Strong mechanisms for communication and collaboration during prototype design: partners meetings and exchange visits

- Students and clinicians learning from each other
- Student experience real world application
- Capacity building of biomedical team

#### What worked well | Results reported in round 2:

- Working suction machine produced\*
- Designs for three pieces complete
- Clinical trial protocol approved
- Concern management recognized\*
- KNH and UON leadership recognized\*
- Strong mechanisms for communication and collaboration during prototype design: partners

- meetings and exchange visits\*
- Students and clinicians learning from each other\*
- Student experience real world application\*
- Capacity building of biomedical team\*
- Calibration Center
- Maker space at science park

#### Challenges reported in round 1

- Portal use
- Scheduling of partner meetings
- Keeping nurses informed about progress on equipment
- Concern about the end goal
- Different expectations from hub members
- Timelines
- Limited hub engagement on sustainability as defined at the beginning of the project
- Procurement and university bureaucracy
- Student turn over

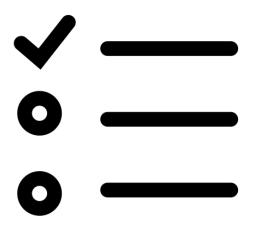
#### Challenges reported in round 2

- Portal use\*
- Scheduling of partner meetings due to multiple schedules\*
- Keeping nurses informed about progress on equipment\*
- Concern about the end goal\*
- Different expectations from hub members\*
- Limited hub engagement on sustainability as defined at the beginning of the project\*
- Procurement and university bureaucracy\*
- Student turn over and junior students\*
- Fewer partner meetings and exchange visits in the last quarter

#### How was data from PD 1 used?

# Summary

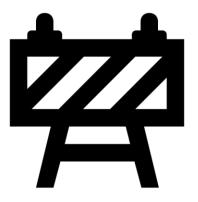
#### DRIVERS OF MAKER PROGRESS



- Concern Program Management
- Leadership by KNH & UON PIs
- Engaged and motivated teams
- Communication between clinicians and engineers

#### BARRIERS TO ACHIEVING INTENDED OUTCOMES

- Lack of a consistent, skilled engineering workforce
- Lack of local, high quality material and equipment for fabrication
- Leadership and personnel transitions
- Procurement related challenges
- Finances & Reporting
- Ambitious timelines
- Contextual factors like lack of policies
- Lack of infrastructure
- Management and administrative capacity



# HUB REFLECTIONS | If you could do this again what would you change?

Team composition, expertise, skills

Team retention

Procurement and finance

Industrial innovation space

Engage medical device corporations

Expand diversity of users: bring in health care workers from other facilities

**Timelines** 

Take context into account (policies)

"How to engage innovators and leverage their ideas and enthusiasm? Institutional organogram versus ground up innovation".

#### **RECAP**

Revisit the Maker hypotheses: The Hub

Kenya based physicians, nurses and biomedical engineers from KNH in collaboration with University of Nairobi Fab Lab engineers (i.e., the Maker Hub) can **design and build** select equipment and spare parts for labor and delivery and newborn care **locally**.

The Maker Hub model is **a viable model** that can address challenges in the social sector through creative collaboration, leadership and governance, processes for management and funding and mechanisms for problem solving to ensure its long term sustainability

#### **RECAP**

#### **Design Thinking Hypothesis**

Application of design thinking methods within Maker will:

Create UON Fab Lab **EMPATHY** for KNH clinicians & biomedical team

Result in **FIT** of equipment prototypes with the desires and needs of KNH clinicians and biomedical team

Result in **BUY-IN/OWNERSHIP** of equipment by KNH clinicians and biomedical team

#### **Revisit the TOC**

- Did the project achieve what it set out to achieve in this time frame?
- Is this the right pathway for a project like Maker?



Increased availability of functional MNCH equipment and spare parts Procurement Systems, Logistics Systems, Budgets & Contracts, Maintenance Systems, Standardization of equipment and spare parts Manufacturing policies and standards for medical equipment Viable capacity for local design of equipment and spare parts Line of accountability Business model prototypes and **Hub Sustainability Pathway** Prototype Design Pathway manufacturing Development of locally designed Governance structures established Safety and effectiveness of equipment prototypes aligned with the needs of and spare parts established the user Identified funding sources Adherence to international standards of Fit of equipment and spare parts with safety for medical equipment and spare user needs\*\*DT Begun strategic planning processes parts Design with user needs in mind and opportunities for feedback takes place\*\*DT Proof of concept: User specifications understood\*\*DT Maker (biomedical team, nurses, physicians) hub Knowledge shared and translated **Maker Space Renovation** Opportunities for communication and collaboration Where do Calibration equipment for these **KNH** activities fit? Hub created\*\*DT Biomed calibration training Shared goals and objectives Financing for hub established Internal & external partners engaged Management structures in place

#### **SUMMARY FINDINGS & DISCUSSION**

Hub created and functioned as envisioned

The idea of engaging clinicians and engineers to design prototypes has been **successfully demonstrated** 

#### HOWEVER,

Maker designed one prototype | expected 9

None have been clinically tested

Hub viability and sustainability inconclusive at this time

Fit and ownership of equipment by users inconclusive on current timeline

#### **CREDITS**

#### **Noun Project Images:**

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