



Team **Gold**

Treating Hydrocephalus

A wireless, non-invasive intracranial pressure (**nICP**) monitor for at-home and hospital use to quantitatively support medical intervention decisions

Total Number of Interviews Conducted:

38

Events Attended:

4

of Email Interactions:

94

Team **Gold**



Anubhav Shankar
Bioengineering



Elizabeth Wang
(and Hershey)
Bioengineering, EECS



Mariam
Ayrapetyan
Bioengineering



Mitchell Wong
Bioengineering



Vicky Cui
Bioengineering, EECS

Mentors

Dr. Sunghoon Kim | MD, UCSF (**Clinical Client**)

Prof. Amy E. Herr | Professor, Bioengineering

Dr. Susan Jenkins | Managing Director, Innovative Genomics Institute

Darren Cooke and Rhonda Shrader | NSF iCORPS

Size of Opportunity

CSF Management Market

- **\$1.35 bn** in 2017 (global)
- estimated \$1.75 bn in 2023
- **\$615 mn** in United States in 2023

... By Region

- U.S. -- 36%
- Europe -- 32%
- Asia Pacific -- 24%
- Middle East & Africa -- 8%

... By Treatment

- Shunt Insertion -- 59%
- Ventriculostomy -- 22%
- Medication -- 12%
- Others -- 7%

Shunt:

Medtronic
Johnson and Johnson
Integra LifeSciences
SOPHYSA
B.BRAUN

Key Manufacturers

Rhaeos (Flow sensor)
ShuntCheck (Flow Sensor)
Brain4Care (nICP)

Others:

MVP Timeline

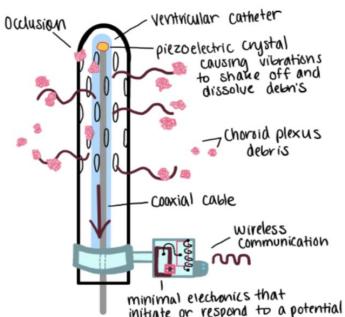
Ultrasonic Cavitation

BioE 192 prototype

Eliminate occlusions of the shunt proximal catheter through ultrasonic waves



Week 0



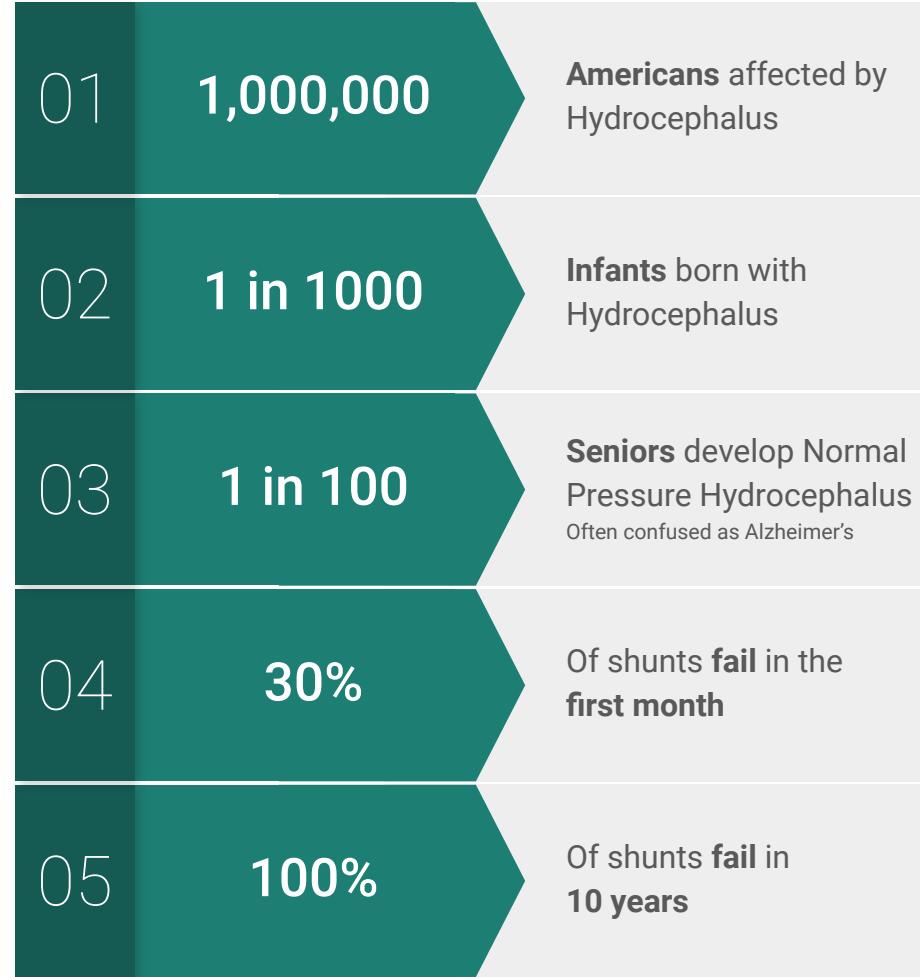
Week 0

Original Hypothesis: Ultrasonic Cavitation is a necessary treatment tool to reduce shunt malfunctions

21 individuals were emailed,

No interviews were scheduled,

Changed who we contacted and how we emailed them

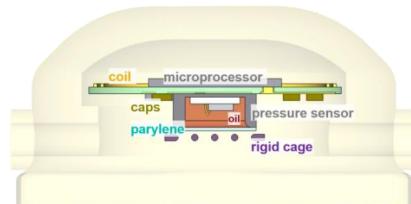


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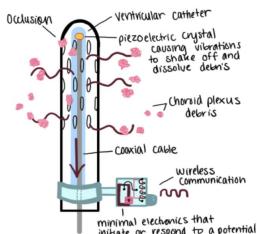
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Week 1

Week 0



Wireless, Invasive Pressure Monitor

Dr. Kim's Idea

- implantable sensor module with wireless read-out of pressure data
- different from existing wired catheter pressure sensors
- requires invasive implant procedure

Week 1

Business Model Canvas

The Business Model Canvas

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Hydrocephalus - Intracranial Pressure Sensor
Dr. Sunghoon Kim, UCSF

Designed by: Team Gold
Anubhav Shankar, Mitchell Wong,
Elizabeth Wang, Mariam Ayrapetyan,
Vicky Cui

On: 06/03/2020
Iteration # 2

Key Partners	Key Activities	Value Propositions	Customer Relationships	Customer Segments
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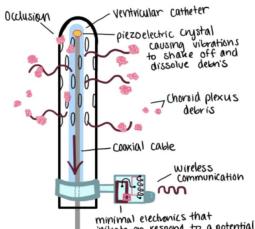
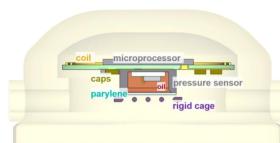
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Potential PIVOT

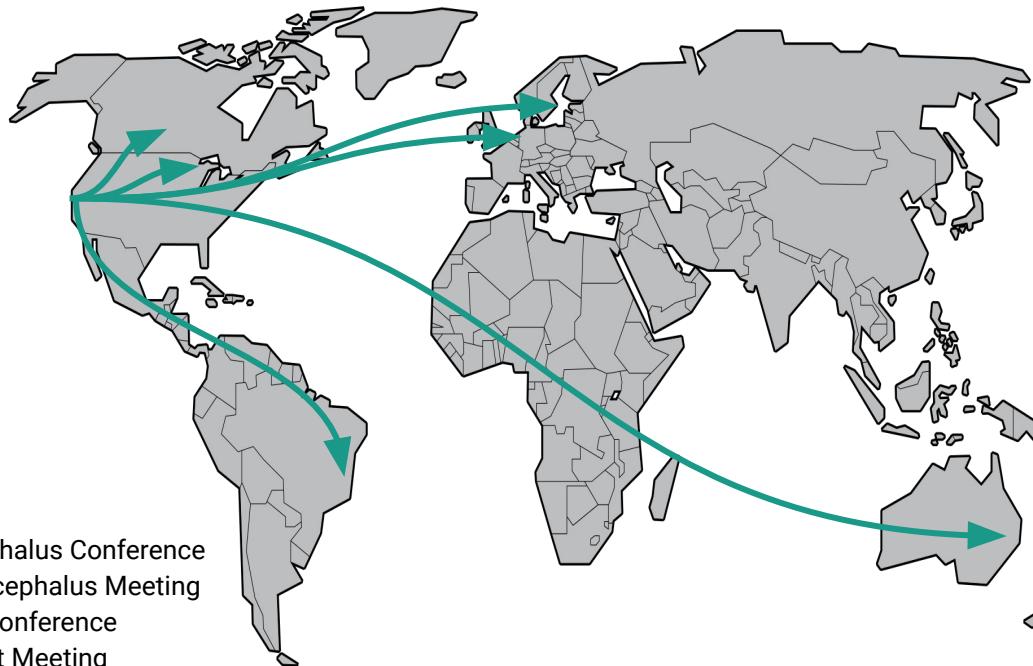
Interview Findings

- Improvements on shunts
- ICP sensors (invasive vs. noninvasive)
- Flow sensor
- Other home-monitoring devices

Customer Discovery

14 Physicians

Neurosurgeons (Pediatric and Adult), Neurologists, Neuroscientists



4 Events

HA Seizure + Hydrocephalus Conference
HA Young Adult Hydrocephalus Meeting
HA Connect National Conference
UCI Value Management Meeting

6 Organizations

Alumni, Capstone Team
Hydrocephalus Association
Pediatric Hydrocephalus Foundation
Rhaeos (competitor)
H-Cubed (competitor)
Brain4care (competitor)

15 Patients

Pediatric hydrocephalus,
Adult hydrocephalus,
Congenital and acquired
hydrocephalus

What our customers said

A-HA!

"The HOLY GRAIL --
noninvasive measurement
of (intracranial) pressure"
- Dr. Clark
Texas Children's Hospital

"Because flow thru shunt is
not constant, need to
monitor **for hours**"
-- Dr. Whitehead
Texas Children's Hospital

"You are good until you
are not... A device to
**monitor intracranial
pressure** would be great
to **notify patients** of
shunt failure" -- D. H.

"There's **no visibility** into
the functioning of the
shunt! I'm worried about
not knowing the
mechanism of the shunt
function in his head." --
A.B

Customer Ecosystem

Money \$\$

Influence

Product

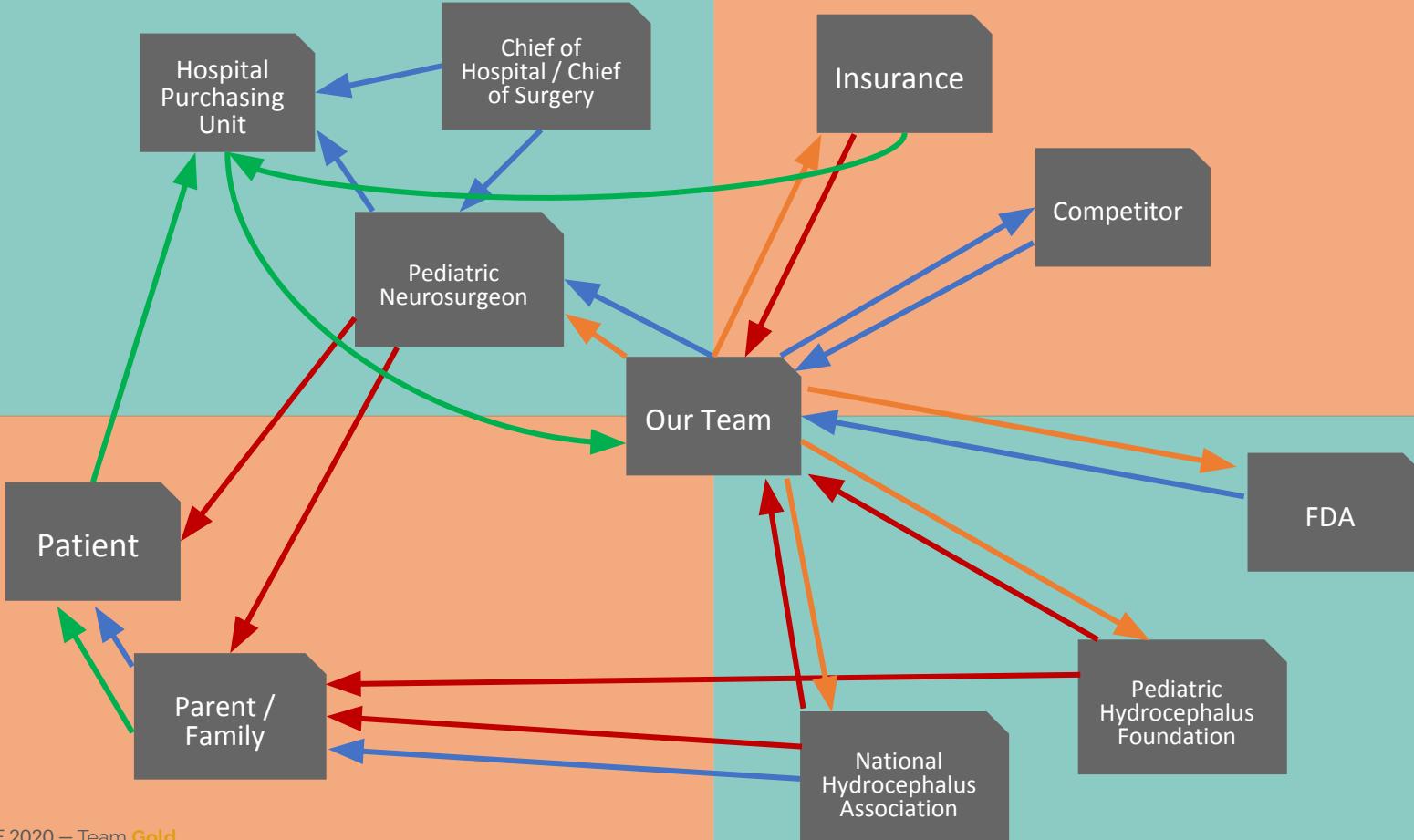
Information

HOSPITAL

OTHER

INDIVIDUALS

ORGANIZATIONS



Customer Archetypes

Meet our customers ...



Dr. Stewart

Pediatric Neurosurgeon at Seattle Grace Hospital

- Sees **10+** hydrocephalus patients a week
- **40%** of his surgical volume is shunt placements or revision surgeries

- **nICP** monitor helps confidently check shunts and diagnose shunt failure



Amanda

A 20 year old **Hydrocephalus patient**

- had **23** hydrocephalus-related **surgeries**
- has occasional headaches and is worried about whether they originate from shunt failure

- **nICP** monitor reduces her anxiety
- Shows real time data on her phone about how her shunt is doing and if it's failing



Sarah

Committee Member of Seattle Grace **Purchasing Unit**

- attends committee meeting once a month with all attending surgeons to discuss supplies and device purchasing
- negotiates pricing and deals with vendor companies

- Wants **nICP** monitor at her hospital because of low cost and high success rate

Week 3

Business Model Canvas

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Week 3

Business Model Canvas

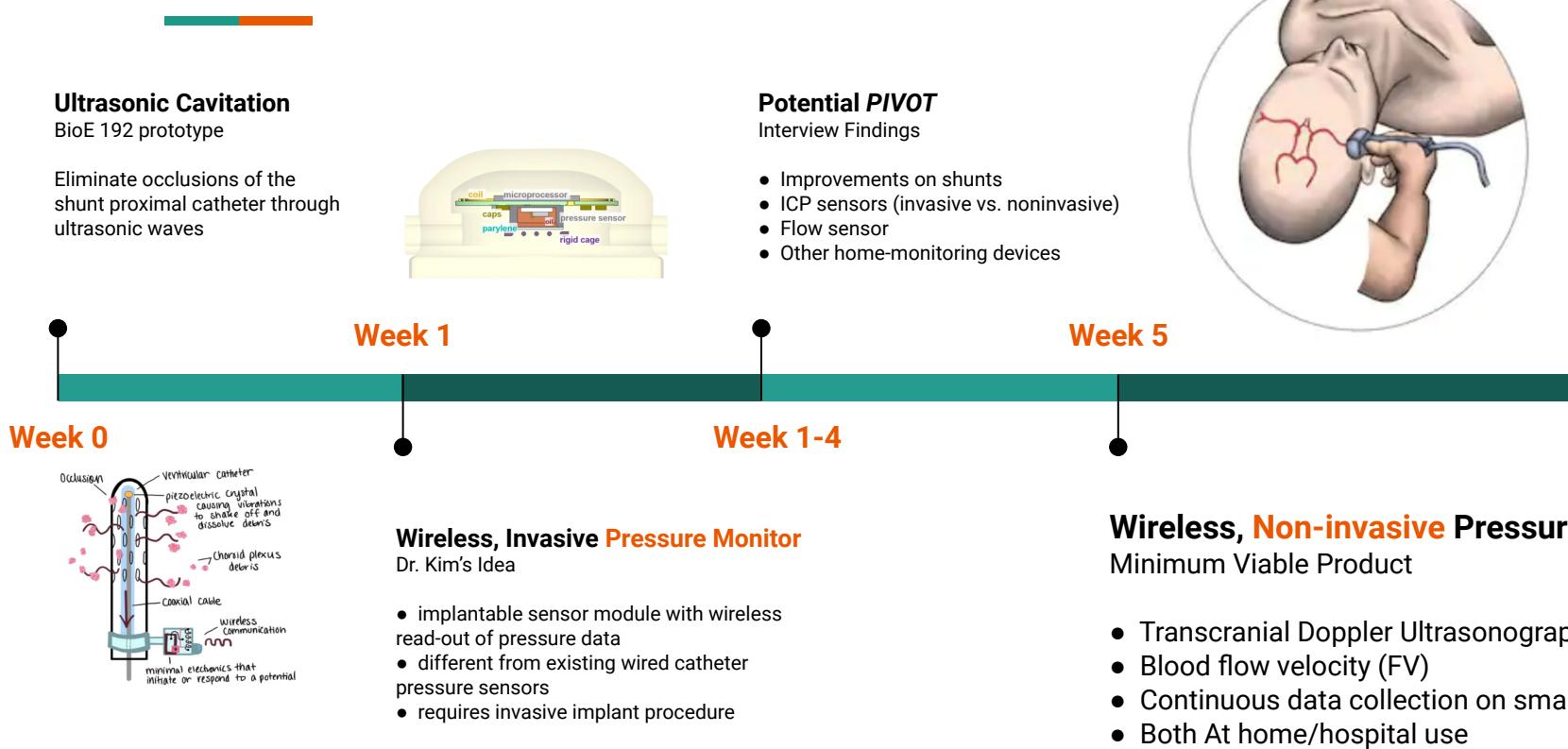
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MVP Timeline



Final Business Model Canvas

The Business Model Canvas

Designed for:

Treating Hydrocephalus

Clinical Client Dr. Sungsoon Kim, UCSF

Designed by: Team Gold

Anubhav Shankar, Mitchell Wong,
Elizabeth Wang, Mariam Ayrapetyan,
Vicky Cui

On: 07/08/2020

Iteration # 6

Key Partners

Advertisement:

- Non-profit orgs (HA, PHF)
- AANS, CNS, ISPN conferences
- Google Web Ads

Manufacturing:

- Manufacturing/production companies
- companies that sell biocompatible materials and parts for the device (MEMs)

Distribution:

- Contracts with distributors (delivery trucks, storage facilities) -- provide timely delivery: overnighted, 2-day, ground delivery
- Amazon

Development:

- consult pediatric neurosurgeons to ensure medical safety and efficacy, and usefulness
- partner with university researchers for R&D, and to keep up with relevant cutting-edge research

Key Activities

Development:

- Research & Development (animal trials, safety and quality)
- peer-reviewed scientific pubs.

Approval:

- filing a patent
 - FDA approval & Health Tech Assessment
 - Acquiring insurance CPT code
 - Meet with hospital purchasing parties to answer their questions and negotiate prices and packages
- Commercialization:**
- attending conferences
 - manufacturing, distribution.
 - advertising & pitches to hospital

Key Resources

For Development:

- research lab space and materials for device fabrication
- engineers and medical experts

For Distribution:

- Patient platforms (Facebook, Reddit)
- product website for info, and patient purchases
- sales team pitching to hospitals

For Relationships:

- medical domain experts (doctors)
- funding for patent and FDA
- grant funding (PHF, HA, government)

Cost Structure

Employee Salaries (engineers, consultants, technical support) •
 Manufacturing costs •
 Marketing and sales •
 Research & Development costs •
 costs of clinical trials and FDA Approval Process •
 Distribution/Delivery costs •
 Cost of attending and presenting at conferences •

Value Propositions

MVP: wireless, non-invasive intracranial pressure (**nICP**) monitor for at-home/hospital use (potentially via transcranial doppler (TCD) methods)

Customer 1: Patient

- monitoring condition and shunt function at-home
- easy-to-use, more data at fingertips, smartphone compatible
- greater confidence in medical decision making
- reduced anxiety and fear for patient and parents of shunt failure

Customer 2: Physicians

- easy-to-use, fast, and accurate assessment of shunt function in hospital setting
- quantitative support for medical intervention
- safe (reduced chance of infection), noninvasive for patient
- replace old technologies

Customer 3: Insurance

- less billing by hospital (saves money) for shunt revision surgeries and brain scan procedures

Customer 4: Purchasing Party

- reimbursable -- CPT code
- increases cash/patient flow and reduced OR time for hospital

Customer Relationships

Customer 1: Patient

- Get: Web/TV advertisements,
- Keep: troubleshooting hotline/YouTube videos

- Grow: user-turned-evangelists in hydrocephalus support groups, testimonial videos and blogs

Customer 2: Physicians

- Get: HA conferences, surgery/neuro conferences (AANS, CNS, ISPN), sales person
- Keep: technical/troubleshoot advisor
- Grow: user-turned-evangelists

Customer 3: Purchasing Party

- price negotiations & safety trial -- contract/bulk pricing or discounts

Channels

Customer 1: Patient

- Online direct sales
- Amazon/web seller

Customer 2: Physicians

- sales person meet with neurosurgeons and neurologists

Customer 4: Purchasing Party

- sales person meet with purchasing party

Customer Segments

Customer 1: Patient

- pediatric patients
- communicating or non-communicating Hydro.
- congenital or acquired
- with a shunt, at risk of shunt failure

- adult patients
- congenital transitioning Hydro patients
- late acquired Hydro. (TBI or hemorrhage, meningitis)
- with a shunt, at risk of shunt failure
- maybe normal pressure hydro (NPH)

- Family and caretakers
- parents of young patients

Customer 2: Physicians

- pediatric neurosurgeons
- concerned with shunt function during emergency
- neurologists
- assessing shunt function
- ER doctors
- assessing shunt function in ER among differential diagnoses

Customer 3: Insurance

- assigning CPT codes

Customer 4: Purchasing Party

- purchasing hospital devices

Revenue Streams

Customer 1: Patient
 Direct Sales -- Per unit, fixed pricing -- approx. \$1500-2000 for device •
 Purchase hardware, free Smartphone compatible app •
 Comes with manufacturer's warranty •

Customer 2: Physicians

- Direct Sales -- Per unit, fixed pricing •

- Contract -- Bulk sales, discounted •

- Cost of device proportional to potential CPT insurance reimbursement •

Value Proposition Canvas

Beneficiary:

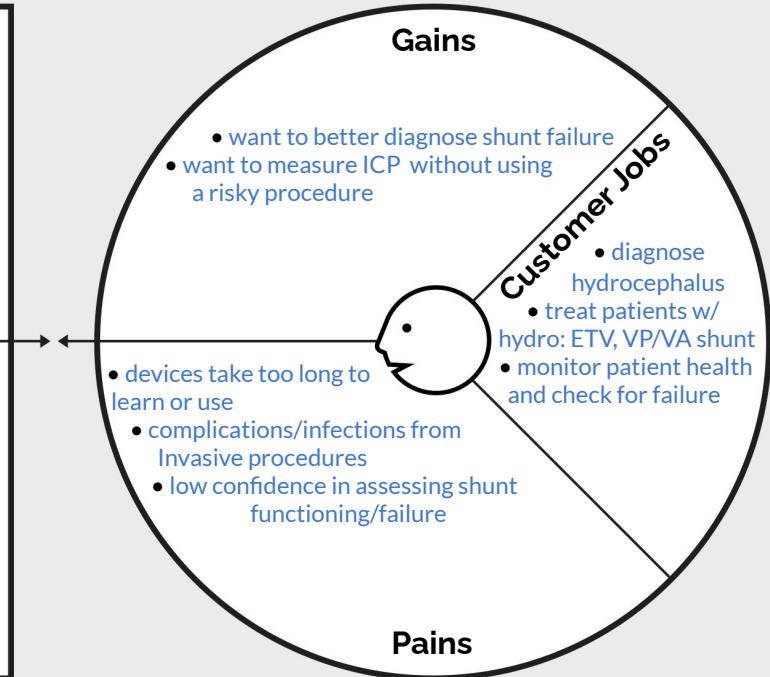
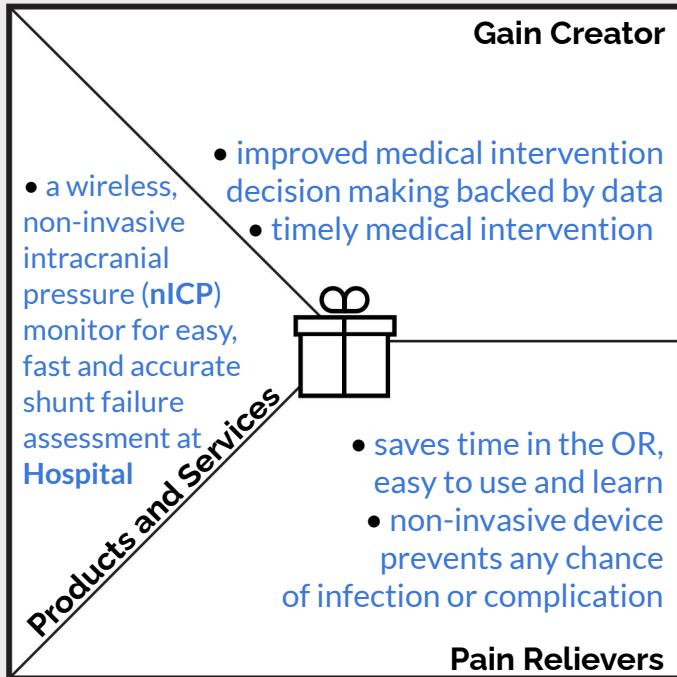
Neurosurgeons &
Neurologists

The Value Proposition Canvas

Value Proposition Easy-to-use, fast, accurate, noninvasive shunt assessment in hospital

Customer Segment

Neurosurgeons / Neurologists



Value Proposition Canvas

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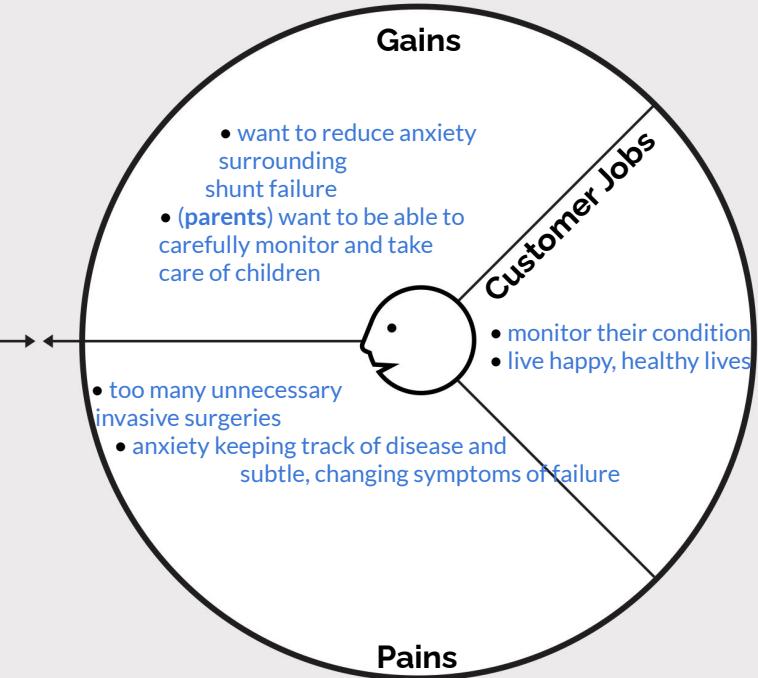
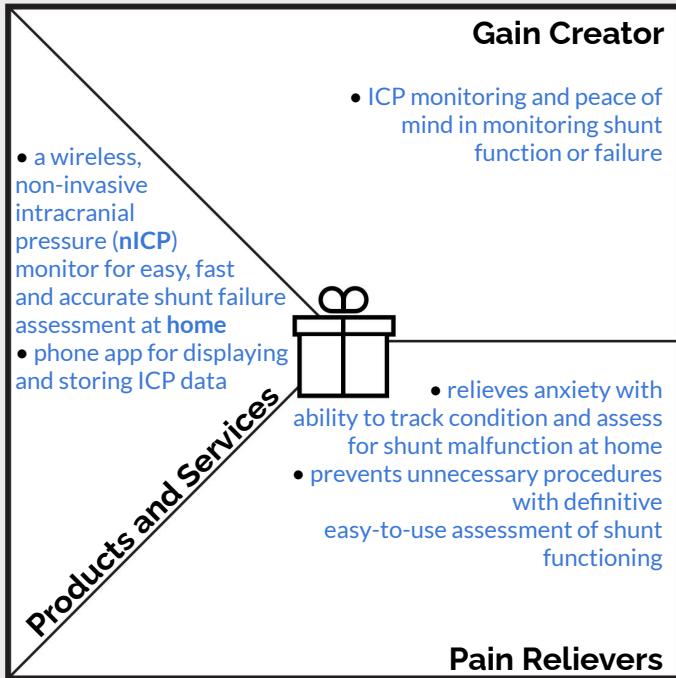
Hydrocephalus
Patients

The Value Proposition Canvas

Value Proposition Reduced time, money and anxiety on assessing shunt

Customer Segment

Patients -- both pediatric and adult



Value Proposition Canvas

Beneficiary:

Purchasing Unit
(Hospital)

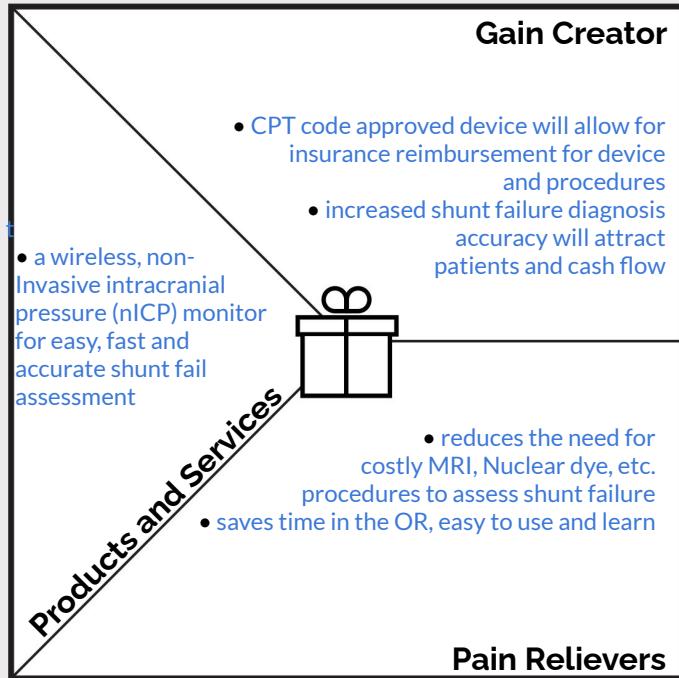
The Value Proposition Canvas

Value Proposition

Increased cash/patient flow and decreased OR Time

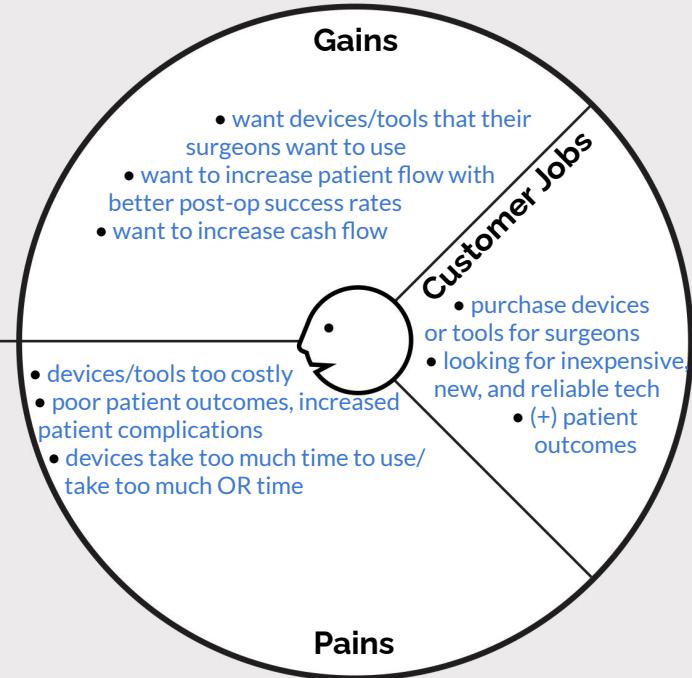
Customer Segment

Hospital -- Purchasing Unit



Customer Segment

Hospital -- Purchasing Unit

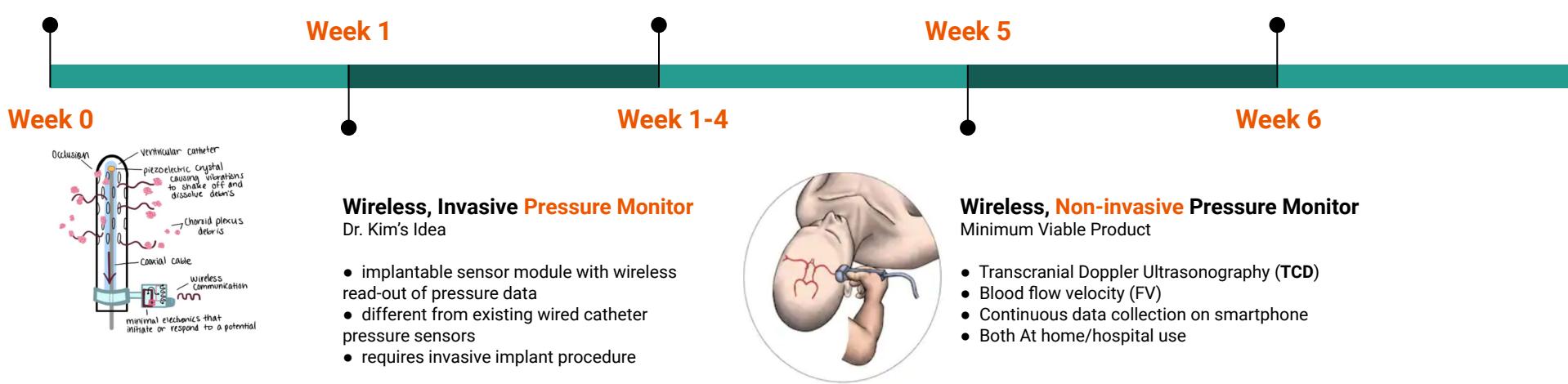
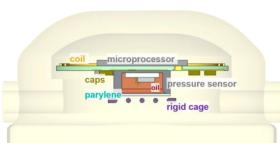


MVP Timeline

Ultrasonic Cavitation

BioE 192 prototype

Eliminate occlusions of the shunt proximal catheter through ultrasonic waves



"The HOLY GRAIL --
noninvasive measurement of
(intracranial pressure)"

- Dr. Clark

Texas Children's Hospital

"Noninvasive pressure monitoring has been
disappointing . . . someone needs to find a new signal
source . . . and it's going to be very difficult"

- Dr. Eide

Oslo University Hospital

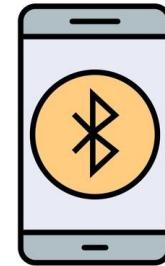
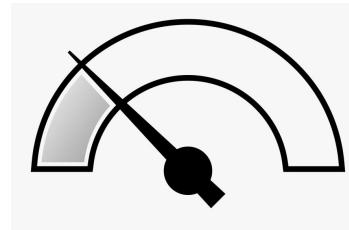
Lessons Learned

- Don't be afraid to reach out to stakeholders
 - Make use of connections
 - Learn from people with experiences
- Be open-minded and unafraid to listen to the data
 - Pivot if necessary
- Keep large amounts of interview data organized
 - Put new insights into accessible and interpretable form.



Final Minimal Viable Product

- Wireless
- Noninvasive
- Easy to use
- Smartphone compatible
- "Reimbursable" with insurance code
- Measure intracranial pressure accurately and precisely



To accomplish this, perhaps take advantage of optic nerve compression measurements

Next Steps



White paper

To share what we learned and contribute to the resources for Hydrocephalus, we want to formally publish our research



Share Materials

For all the physicians who said *“let me know what you find,”* we plan to share our research with them



Awareness

Hydrocephalus isn't well known. We need to take responsibility to raise awareness.



More Research

Continue to read more and track the progress of research teams around the world

Acknowledgements

A sincere thank you to all the support and guidance from ...

Professor Amy Herr & Dr. Susan Jenkins

Darren Cooke & Rhonda Shrader

Dr. Sunghoon Kim

All the physicians we interviewed.

All companies and organizations we interviewed.

All the hydrocephalus patients we interviewed.