~~You are~~ Not a failed version of normal.

A co-design exploration of systems and difference
in the North American medical device development space.

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1 Copyright Notice.

2 Abstract.

The scene is set through building a reflexive, design-centred collaboration space. Within this space, we co-designers follow a systems and foresight methodology to explore questions of equity in medical device development. The researcher's extensive experience in medical device development is leveraged, and the collaboration space is arranged to mimic the power dynamic between expert and users, so central to the task of fitting a medical device to the market. Collaboratively, we explore origins of system behaviours and dynamics, by tracing real-life tragedies, and opportunities for equity imagined through outlier success stories. This paper examines the changes and challenges in outcome that are brought about when "designing the designing" is prioritized as well as critically examining how these findings might apply to the system of medical device development as a whole.

A collaboration-building branch of this project provides a case study in which co-design theory is moved into practice. A branch dedicated to systemic exploration of medical device development reflects critically and creatively on the researcher's practice, with specific interest in the Flourishing Business Model Canvas as well as risk/benefit analyses essential to achieving safety and effectiveness. Findings from each branch are proposed as the nexus of departure from which an individual may press for increased awareness of systemic inequity in environments into which products will be launched.

This research makes the case that the choice to prioritize "designing the designing" is necessary but not sufficient. Without a wholesale change of values in these ecosystems, this may be a small step toward increasing awareness. Values must undergo transformation at the business strategy level or above, for equity practices to become embedded in the system.

Keywords: power, reflexivity, intersectionality, social determinants of health, equity, futures, participatory foresight, co-design, systems thinking, design thinking, values, medical device development, flourishing business model canvas, ecosystems.

3 Acknowledgements.

Thank you to my primary advisor, Greg Van Alstyne, for our generative discussions and your detailed focus, especially on the collaboration-building parts of this work.

Thank you to Lorraine Randell, for helping guide my focus, and reminding me of the impact of one better.

Thank you to my Son, Partner, Parents, Brother, Family, and Friends for supporting me with love through this degree.

Thank you to my Strategic Foresight & Innovation (SFI) and Inclusive Design professors and classmates, and my friends for agreeing to co-design this beast of a project with me.

Thank you to my mentor for your suggestion to explore the actions of Second Sight.

Thank you to OCADU for awarding me with the President's Scholarship to attend this program.

Figure 1: Have you been helped?
From: (Pyle, 2022). ©2022 by Nathan Pyle.

I hope this is a block I will build on as I launch into the future.

Thank you for helping me get to this line in the sand.

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4 Positionality.

4.1 Me.

I am a descendant of settlers with ancestors from the Netherlands and Great Britain, who settled initially in Alberta, Manitoba, and Nova Scotia between two and four generations ago. I grew up mostly in Southeastern Ontario and lived abroad for a few years during my youth as my family moved to Sweden and France.

I am a queer and genderqueer, white, and a parent.

I have been predominantly educated in the Canadian education system through public school and university where I studied mechanical engineering. I have been employed in the field of medical device development for over 15 years, focused mostly on developing imaging devices.

4.2 My Method.

Figure 2: A caddis fly larva covered in gold and precious stones.
From: (Cowen, 2013).

The way that I like to think about my method in this paper is based on this bug called the caddis fly.

In this analogy, I am that bug and that bug metamorphizes, but while it is in its underwater larva form it covers its abdomen with parts of its environment around it. Normally it lives in a wetland or marsh and covers itself in little sticks and pebbles, but in this image, Hubert Duprat put gold and semi-precious stones in a tank and the resulting houses they created were from these materials.

I am trying to make sense of the world for my next big change by borrowing ideas from other people in the environments I put myself in, building their valuable inputs of gold into a shell of understanding to help launch me into the next thing.

4.3 Tone of the Report.

This report is a documentation of learning while applying a dynamic (and messy) design process. I value of inclusion of "behind the scenes" views, so I have intentionally included some of the messiness and backstage views to show the steps that I took on this path of inquiry. This report documents my process of learning something new and trying to move the foundations of my practice from one mindset to another. To borrow the words of Tyson Yunkaporta in *Sand Talk*:

> What I say will still be subjective and fragmentary, of course, and five minutes after it is written it will already be out-of-date – a problem common to all printed texts. The real knowledge will keep moving […], and I'll move on with it. You'll move on too. Already you might take away [something], add your own shades of meaning, share it, and grow something from that pattern that could never be imagined on a page (Yunkaporta, 2020, p. 17).

5 Land Acknowledgements.

I want to share the three land acknowledgements we co-designers used to start three of our co-design sessions exploring the current world, a future world, and a transition world of the medical device development space together.

Land Acknowledgement for the current world.

OCADU exists on the ancestral and traditional territories of the Mississaugas of the Credit, the Haudenosaunee, the Anishinaabe, and the Huron-Wendat, who are the original custodians of the land on which the University operates.

Bringing attention to the land and to the struggles for Indigenous and Black liberation is vital to frame the collective work towards sustainability and our collective thriving future.

We are gathering remotely, and I invite you to take a moment to breathe, experience, and think about both the place that you are in now and the place we are creating by being here together online.

Land Acknowledgement for a future world.

Please read the poem, *A Digital Land Acknowledgement*, by Dierdre Lee (2020).

Land Acknowledgement for the transition.

This is a land acknowledgement I am working on.

Please take a moment to get comfortable where you are and let's take a few combined breaths together. (In and out). (In and out). (In and out).

Before we start our learning journey together today, I would like each of us to consider where on the planet you are today and the path we have taken to get to where you are physically and to the space we are creating together on this call.

For me, this started with who I am, from my identity, my family, my chosen family and my friends and kinship network. To the things that I do and how I go about doing them in the world. It is how I affect the people, the animals, the plants, the water, the land, and the air that I interact with.

Who has been where you are before you?

How do their paths intermingle and co-exist with yours?

I believe are all in Canada today and I invite you to consider the other people past and present who have layers of history and future on the same land on which you live.

I would like to acknowledge the land I am living and working on is the traditional territory of many nations including the Mississaugas of the credit, the Anishnabeg, the Chippewa, the Haudenosaunee, and the Huron Wendat peoples, and it remains the home to many diverse First Nations, Inuit and Metis and will continue to be in the future.

I live and work on treaty land and recognize that we here in tkoronto are all treaty people. The original agreements to share this land were made under the “dish with one spoon” covenant where the “dish” represents the land that is to be shared peacefully and the “spoon” represents the individuals living on and using the resources of the land. This covenant recognizes the connectedness of our actions and asks that we consider what we do in relation to the effects of our actions on others, including future generations.

To me, as a descendant of immigrants, this means I have inherited these responsibilities and that I need to ensure that my actions align with this agreement. How might your actions today help you be a good ancestor?

While giving space to learn, be imperfect, and move through the situations, remembering the quote “Sometimes, being brave means trying again tomorrow.”

Thank you.

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9 Statement of Contributions.

One of the key values this paper seeks to embrace, and question is how one comes to know or experience something.

I had the pleasure of working with many co-designers on this project. It is my pleasure as well to list them here to acknowledge the work we did together over discussions and Miro board jamming in five, 90-minute sessions. The insights and experiences we share, and their reactions to my work, coloured, changed, and influenced the final product as you see it here. These conversations will continue to influence my lessons learned and the swirls of emergent ah-ha's that come out of this work for me.

I have permission from my consenting co-designers to share their names as covered in OCADU REB Number: 2022-49.

Thank you to those co-designers who wish to remain anonymous.

Thank you to the following co-designers, in reverse alphabetical order:

Zemina, Julia Forrester, Shreya Chopra, and Chelsea Bell Eady.

10 Aim.

This paper is my response to seeing the transdisciplinary social justice work of others and wondering how I might morph my practice of medical device development to be more aligned with these values.

This is not a how-to guide, nor is this a paper that outlines the causes of systemic inequities. The paper *does* point to the works of others who have inspired me to better see these inequitable systems and work to transform them. A core tenet of this paper is that there are some folks whom the world was not designed for, essentially because of their "demographics." I am convinced that the world can be re-designed in a way that is more inclusive and that would better serve and benefit these human beings. But I am also aware that to do this, we must not forget Einstein's observation "We cannot solve our problems with the same thinking we used when we created them" (Bonchek, 2016).

This paper is trying to design meetings that convene those with needs, and those with specialized expertise, while intentionally working to disrupt power and expertise hierarchies, enabling all to better hear those who are embedded in the complexities systems where the solutions are needed.

In my journey, at first, I found a theory of how to do this – through co-design – but documented examples of respectful, ethical translations of this theory to practice were more difficult to locate. It seems that story is not as widely shared. So, this is my attempt to add to that niche. This project offers a case study of my foresight-centred co-design exploration of the medical device development space. In it, I work with my co-designers to practice some of the requirements to try and understand the nestedness of the systems that a design is operating in, change the power dynamics of design and understand the effects of the design on the ecosystem into which it is meant to be released.

Some limitations of this project are important to share here. This was a practice-run, limited in time and scope. The co-designers with whom I engaged were fellow Master of Design students who were not a vulnerable population, nor were they representative of any population completely embedded in the problem space. We came together around the shared purpose and values of democratizing the design process. This project tried to stay true to the co-design. We tried not to "parachute in" with solutions, in the manner of professional consultants. Nor did we attempt to impart a new skillset by simply leaving a report for the researched population to implement. The point, ultimately, was to be reflexive and to look for areas where the power of the medical device development system could start to question power practices, in keeping with the values of co-design. The tools and recommendations this report makes are directed at medical device developers, and I am a member of this group. I feel that my choice to centre this critical work on my own profession was a kind of compromise. My intention was to leverage my own professional knowledge in a practice-run to minimize any potential harm and explore how a group of values-aligned co-designers could practice listening and working together in foresight and futures work. I hope that lessons learned from this scenario may be used later in a more community embedded design processes.

11 Background: The Journey to This Project.

The propensity to believe that everything, even very complex problems, can be solved through the application of a simple technology fix, is known as *solutionism* (Selinger, 2023). Without context, the complexity of a problem is difficult to see, let alone define and improve. Current applications of human-centred design thinking promise that they will help find and unravel the complexity of any problem. However, when design thinking is implemented within the structures of capitalism and colonialism as well as the biases in Western medicine, the voices that could actually explain the complexities of the system, of those who are inline to use the solution every day, are now reduced to mere sound bites. This is effectively what is seen with designers from outside the community who may well be unreflexively going through the design thinking playbook. Every design is influenced by the ecosystems within which it is designed (Vink et al., 2017). This means that the power given to different voices in the conversations can be modulated by the way we "design the designing." And this in turn changes the possibilities for the designs that are designed.

11.1 Design Solutionism is great at making one-note solutions.

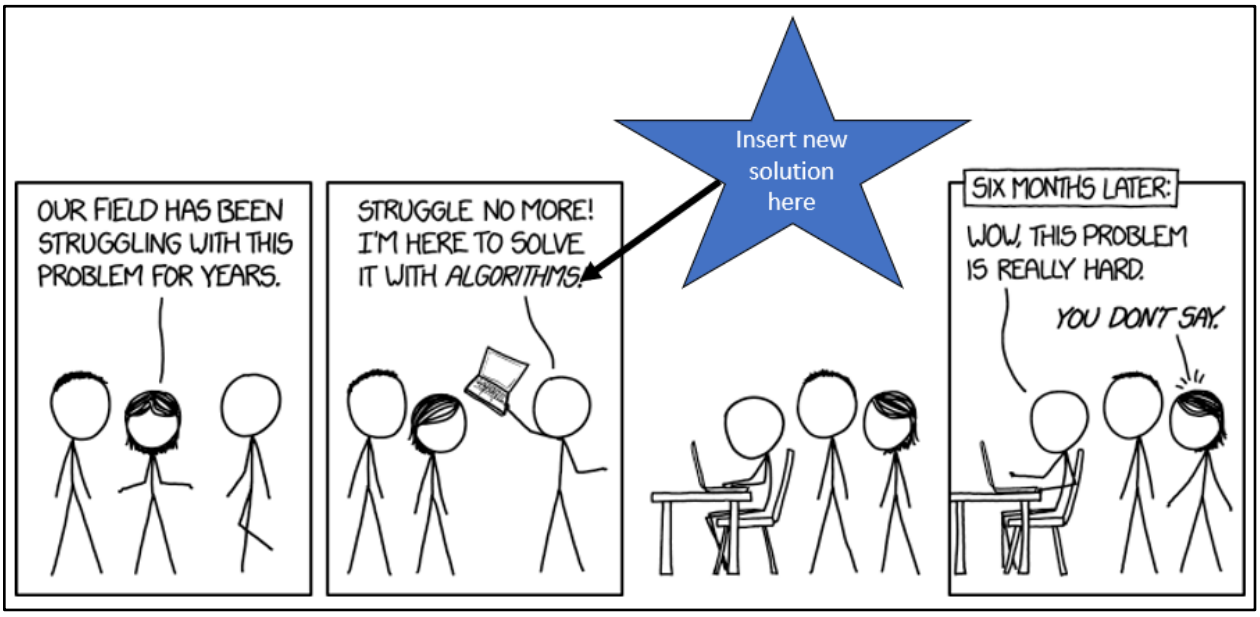

Figure 3: Here to Help.
Adapted from: (Munro, 2017).

Design solutionism is great at making one-note, partial, or band-aid solutions, but these solutions seldom take in all the complexity of the situations into which they are launched.

In my experience as a medical device development engineer, teams are very focused on solutions and are drawn to complex problems. If we jump in without understanding the problem and try to draw scalable truths to solve, sometimes we only provide this quick or partial fix or don't solve the problem the user really wants or needs solving. This is because the designer reflects their assumptions on the users' needs, and this can lead to a discrepancy in priorities between the designer and the user.

Design in medical device development is a specialized field that requires the attainment of education that is not accessible to everyone. Concerningly, this power to design is sometimes mistaken for the power to determine what needs to be built for someone else. Or it is mistaken for evidence that the designer knows best. To empathize in this context takes user experiences, and views these through the lens of the designer rather than the lens of the user. In this system, the user is marginalized and ultimately does not have a choice in what is made.

How might we make things that are what people really want and need?

11.2 Design Thinking?

Initially, I was enthralled by the promise of Design Thinking.

The excitement of learning about an issue through user interviews and feedback, empathizing, and applying engineering and designer expertise through brainstorming, and prototyping to create an elegant solution that would match the stated and discovered needs (IDEO, n.d.). This was the process I learned about in undergraduate engineering and applied extensively in the corporate world. We interviewed and observed leading experts or Key Opinion Leaders in the field to help find new niches and possibilities for products that would help revolutionize health care. We went deep into the subject, looking at connecting processes and personnel to ensure a good fit in safety and effectiveness, and market attainability, by asking such formal questions as:

- What does the device need to do?
- Who does this device help?
- How might it be used?
- Who is going to set it up?
- How the device might be stored between uses? Is it going to be cleaned?
- How the images from it will be transferred and used for the surgery in a month's time?
- How long does the device need to last?
- Who has the buying power within the clinic to approve the purchase?
- Who must assess that this device is the right fit for the hospital's workflow?
- How big is the market?

No illness or problem seemed beyond reach. If anyone were to get sick, through Design Thinking we could consult with the experts, and by simply combining their deep knowledge with our very thorough assessment of the situation as experts in human-centred design, we would make some brilliant devices to help make you better again!

11.3 Capitalism is not compatible with making complex, equitable solutions.

Notwithstanding the disruptive and 'think-outside-the-box' solutions that Design Thinking is capable of developing, we can point to strong critiques of its "short-term focus on novel and naïve ideas [resulting] in unrealistic and ungrounded recommendations" (Ackermann, 2023, p. 4). This comes as no surprise when we note that all this design is being practiced within the current system of Western capitalism, captured in Mark Zuckerberg's early aughts Facebook motto, "Move fast and break things" (Baer, 2014)). Under this business strategy, designers are faced with cost pressures to reduce the scope, resources, and time spent on design projects while at the same time hunting for repeatable patterns that can be productized and scaled for maximum profit.

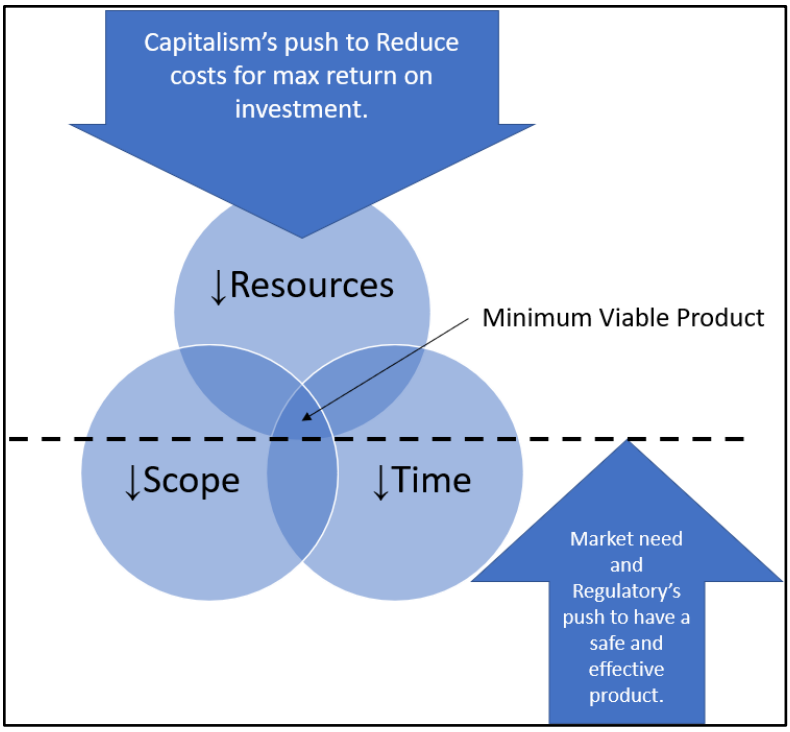

Figure 4: Pressure on product creation due to capitalism and market need.

This means that the design thinking approach sometimes turns into a box-checking exercise, with the designer asking the user formal questions and then synthesizing. This inevitably over-filters the findings through the designer's biases and lived experience, replacing the chance to empathize with a single drive to determine the minimum viable product (Figure 4) that fits this list of requirements. Most famously, this was summarized by Steve Jobs as:

> Some people say, "Give the customers what they want." But that's not my approach. Our job is to figure out what they're going to want before they do. I think Henry Ford once said, "If I'd asked customers what they wanted, they would have told me, 'A faster horse!'" People don't know what they want until you show it to them. That's why I never rely on market research. Our task is to read things that are not yet on the page. (Isaacson, 2015)

This quote only acknowledges the product development strategy of the system. At the business strategy level, the drive to make money is alignment with the core competencies of the business through the values of the company (Porter, 1996). These values cascade down to the product level. If a business is working within capitalism, the reductive forces are driving for a product that works for the lowest cost and maximum returns, which are the values that in turn channel where funds are allocated and form the metrics that bound the creativity of the designers. The designers thus must find ways to design within this framework, aligning their choices on how they get to the requirements for a design.

11.4 Filtered Empathy can lead to a discrepancy in priorities between the designer and the user.

The problem with this type of empathy is that it diminishes the opinion of those who will use the design and removes their autonomy. For instance, rolling around campus in a wheelchair will not make you understand what it is like to use a wheelchair and the needs of a person who uses a wheelchair, even if

it may allow you to see more of the access problems that a wheelchair user faces. At the end of the day, you can stand up, so knowing their top priorities is not something you discover through this empathy-building exercise. Even asking the users or Key Opinion Leaders formal questions about what they need will not necessarily get to the root of these priorities as these individuals are also steeped in the cultural norms and biases of the systems we operate in. The productization force of design thinking is to create a product or service to help improve immediate issues, so these cultural norms and biases are on a level above the inquiry and empathy that designers explore by applying design thinking (Hochachka, 2009).

> "In order to empathize with someone's experience you must be willing to believe them as they see it and not how you imagine their experience to be" – Brené Brown (Brown, 2012)

Because of this propensity to explore and improve within the system of cultural norms and biases, the mantra of "nothing about us, without us" is central to disability and other vulnerable population activism (Lebrecht & Newnham, 2020). Further underscoring this, is the name given to design efforts that violate this mantra, resulting from "parachuted-in" design: a disability dongle. Coined by disability advocate and design strategist Liz Jackson, a disability dongle is: "an elegant and well-intended, but ultimately useless solution to a problem people with disabilities never knew they had (Young, 2019). Perversely, our publicity-driven system is quick to celebrate 'dongle creators' for their good deed of helping but rarely notices that these solutions do not address the holistic or even the most urgent needs of the users. In most cases, what is wanted and needed by the user is access to co-directing the design, not being portrayed as the grateful-for-anything recipient of the design (Jackson et al., 2022).

A solution created without all the complexity of the context of where and by whom it is going to be used puts the user in a position to critique it, but this ability to critique is lost in the power differential and lack of awareness of the different lived experience of the user (Jackson et al., 2022).

> To be oppressed means to be deprived of your ability to choose. – bell hooks (hooks, 1984, p. 5)

11.5 Choice can be found in dialogue. But the person critiquing must be heard.

In my Innovative Research Methods class (Tunstall, 2020), Dr. Tunstall asked us to read and consider the ethics of design as a dialogue with the example of the crowbar (Schwab, 2017). This article suggested that initially when the crowbar was launched it was for construction demolition, but quickly became a tool associated with break-in-enter. As a result, the industry has again followed up with more secure designs for windows and doors and alarms, to which someone intent on break-in-enter responds with a new solution, and so on. The article concludes that just because a tool can be abused does not mean it should not be created, and points to customers and demand-driven forces of the market to guide creative adjustments to products to improve them. After warning against designing solely for this, the author quotes Marvel's Stan Lee, reminding designers that "with great power comes great responsibility" (Schwab, 2017).

An example of a designer-led medical device product is a stair-climbing wheelchair (Jackson et al., 2022). Some wheelchair users find this device beneficial to safely bring them up a set of stairs. But if you talk to the majority of wheelchair users, widespread, dignified, accessible architecture and ramps would give them the access they want, and this would have access benefits beyond just the individuals with access to resources to purchase the chair and renovate their spaces to fit them (Lebrecht & Newnham, 2020; Young, 2019). This user-critique-driving-device-change dialogue outlined in the article by Schwab (2017) is not present when the users do not have the power or resources to press for modifying a solution.

Thus, when the user's voice is relegated to just a consultant and a one-note solution is made, the user's choice is extinguished, and they must use this misfitting solution or continue without access.

Why was this stair-climbing wheelchair made? And more broadly, who gets to be the designer of medical devices and determine what devices are made and who gets to be those they are designed for?

11.6 Expert Designers and Solutionism in Medical Device Development.

The regulations that govern the medical device development space stipulate that designers must have educational proof of competence in the skills they are applying to the design and in the standards of Medical Device Quality and Risk that regulate the industry (ISO 13485:2016 and ISO 14971:2019). So, if you can't access this education, or you are outside the part of the medical system that is being explored to be productized, then you can't occupy the role of a designer. Even more difficult in this situation is, simply making your voice heard as a user.

When following these regulations (ISO 14971, 2019), the people who weigh the risks and benefits and decide the device options for the users are a "diverse" group of individuals. However, in general practice, this means a group of individuals with different roles who are nevertheless drawn solely from within the same medical device development company. These people take the "empathy" that they have developed for different parts of the user's experience through design thinking and proceed to use their expertise to interpret it and weigh the risks and benefits of the device to the user. Nor is simply adding a few token users to the team sufficient, because assuming that a few users' views can represent a diverse community will not account for the diversity within a community (Creative Reaction Lab, 2020).

Similarly, those considered by the system to have the "right" expertise or educational skills to develop medical devices, have the value of their judgement raised up. This grants them sole power to translate "patient voice" into "user needs," and to weigh the risk and benefits to assure that what is built is "safe and effective." The system does recursively ask for validation that the device satisfies the user's needs, but this still does not question whether the device is being made because of a broader bias in society or ask for reflection if this solution is a short-term individual fix in the context of the need for a broader shift in society.

There is a need for short-term fixes, especially with the slow speed of change to undo biases at the broader societal level. This is what provides choice to the users. However, a short-term fix without the context of the broader biases celebrates the designers and silences the users' power to ask for broader systemic change.

11.7 Benefits of Large Systems, but...

Hans Rosling, a Swedish physician and statistician, has argued that capitalism and Western medicine have been two of the most significant forces behind global progress in human health and prosperity. Capitalism has enabled the growth of markets, the creation of wealth, and the spread of technology and innovation, which in turn have helped to lift people out of poverty and improve their quality of life. In his book "Factfulness," Rosling provides many examples of how the forces of capitalism have led to increased prosperity and health outcomes around the world (Rosling et al., 2018).

One of the most significant benefits of capitalism is its capacity to create economic growth and development, which in turn leads to increased access to healthcare and better health outcomes. As

countries become wealthier, they are better able to invest in healthcare infrastructure, research and development, and disease prevention programs. Capitalism has also led to the development of new medical technologies and treatments, which have helped to improve health outcomes for people around the world.

Western medicine, which is based on scientific evidence and research, has also played a crucial role in improving global health outcomes. By categorizing illnesses and symptoms, and training medical professionals to provide effective treatments for a wide range of diseases and conditions, Western medicine has helped to increase life expectancy and reduce mortality rates. Hans Rosling argues that the widespread adoption of Western medicine has been one of the most significant drivers of progress in global health in recent decades (Rosling, 2009).

Rosling's argument is that in general things are getting better because the averages of all human experiences are getting better. However, this is an aggregate picture that does not show the massive disparity in outcomes experienced by those on opposing sides of the matrix of domination (Pauly Morgan, 1996). Within healthcare, some of these factors are called the social determinants of health.

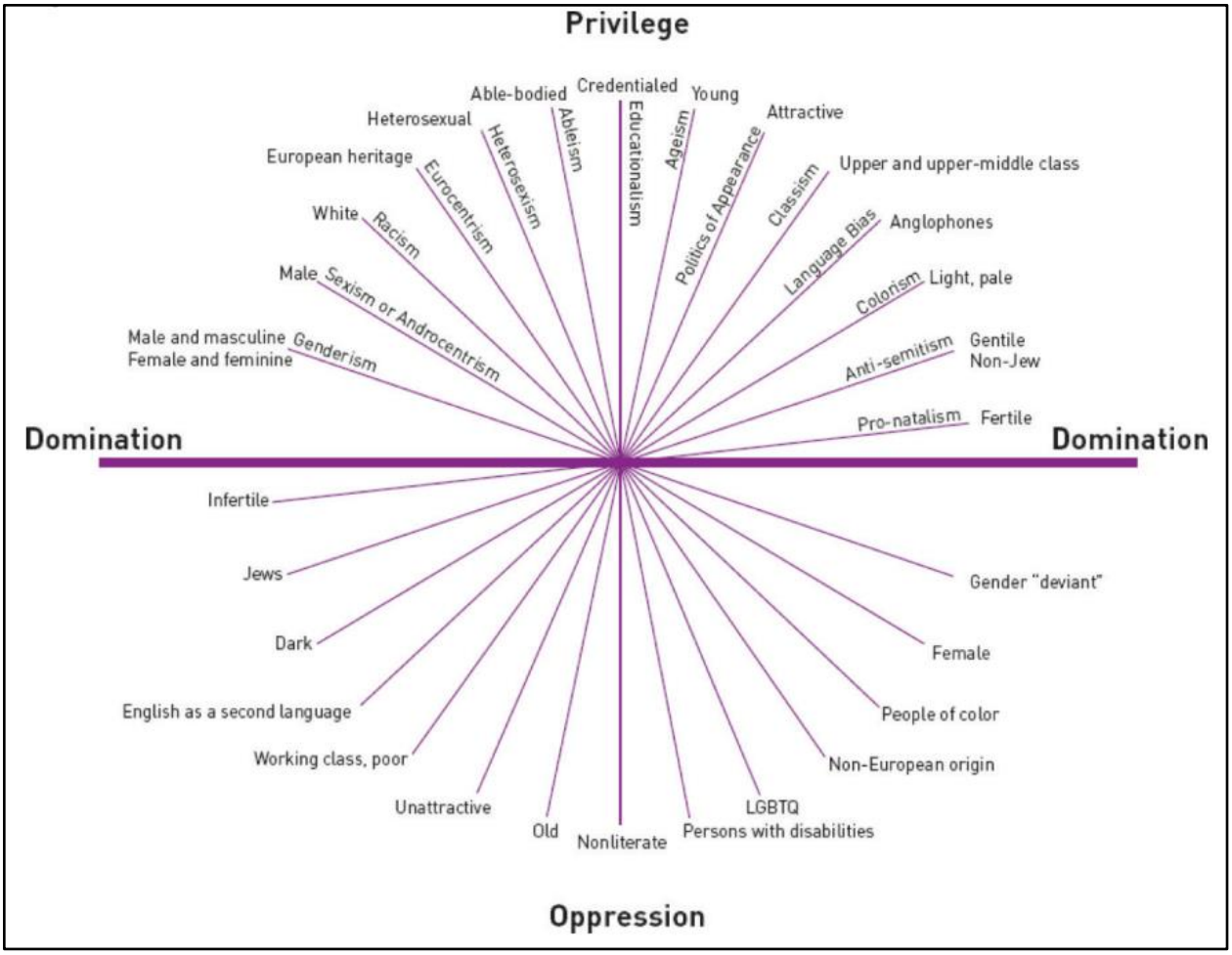

Figure 5: Matrix of Domination.
Adapted by AWIS from: (Pauly Morgan, 1996).

Social determinants of health are things that can impact a person's health that are outside of their control, like the conditions in which they live, learn, work, and play (Canada, 2001). Current and historical biases also play a role in social determinants of health. For example, experiences of discrimination because of race, ethnicity, gender, orientation, ability, size, or other factors can affect the opportunities of an individual and populations as a whole and make them less healthy by limiting access to education, job opportunities, safe places to live, and healthcare (Government of Ontario, 2012).

We can do better.

11.8 Those who can use what is made, and those who can't.

The human population can be modeled like a "starburst" (Treviranus, 2019) with most of the points near the centre. Outliers spread randomly around the core, which when flattened into two dimensions becomes a bell curve, with 80% of the population falling within the middle 20% of the curve (Treviranus & Nicoll, 2021b).

This distribution pattern was noted by those who applied the mathematical tool of average to the human body and behaviours, and by economists, both of whom assigned value to these measurements based on their proximity to the average, making the faulty corollary that all individual human is a deviation from a single perfect human. This approximation of humans to average was noted by businesses as an economically viable way to design things for the biggest market (Treviranus & Nicoll, 2021b, 2021a), or those who are closest to normal. For twentieth-century mechanized industry and mass culture, it was necessary and profitable to target "the normal," as this is where the market resides. For twenty-first-century practice, considering outliers, those for whom large, centralized, hierarchical systems do not work, is where innovation comes from (Treviranus, 2019).

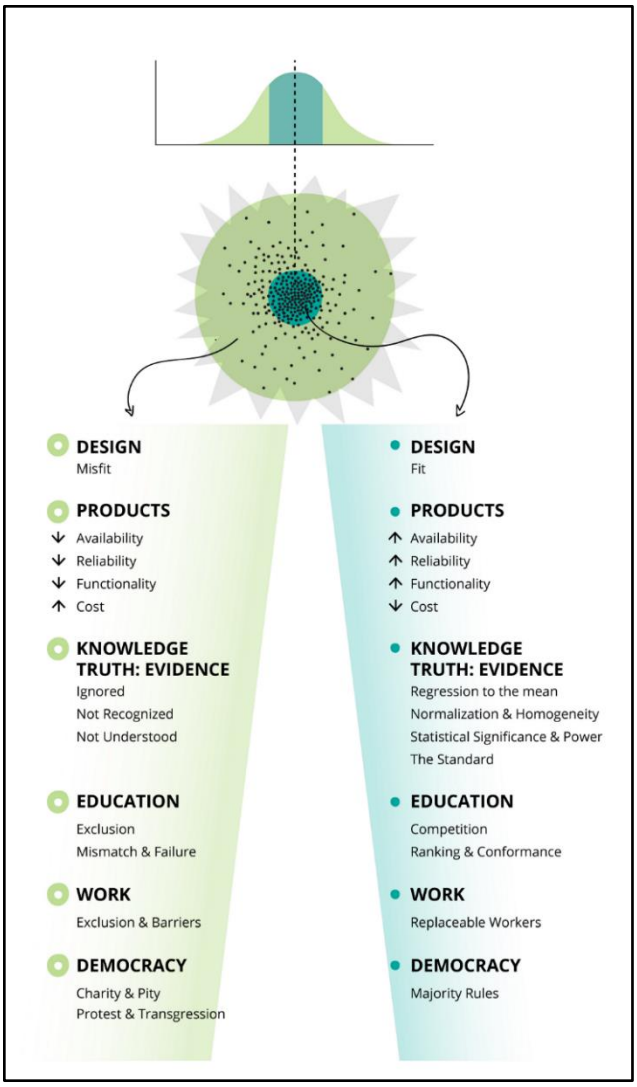

Figure 6: Impact pf the bell curve of human diversity on the fit of design.
From: (Treviranus, 2019).

11.9 Undoing Race Correction Inspiration.

I learned in depth about race inequities through the work of Dr. LLana James. In her work, she methodically catalogues the proof that biological race does not exist and is just a socially defined construct of the system that has impacts on morbidity and mortality in the Black population (James, 2020). This racism has been coded into the medical system and one of the places it comes up is as multipliers in medical devices that are applied based on visual assessments of a patient from clinicians, making non-white people score as less sick despite the same presentation of an illness (Braun, 2005, 2021). The historical journal articles and papers that these multipliers are pulled from are based in the racism of the authors and the effects of the social determinants of health on marginalized people and wrongly equating this to a biological racial basis for poorer test scores and greater illness (End Race Correction, 2023). Unfortunately, these have been coded unquestioned into the medical and medical device development systems. Dr. James has co-created a coalition to end the practice of race correction in medicine, tackling this systemic problem with a multi-faceted approach, led by the people who are

most affected (End Race Correction, 2023). This work targets the retraction of historic literature that is racist, stopping the current practices with legal action and redress to those affected, education with increase representation and diversity of example, and overall, a requirement to stop teaching race-based medicine and making centring whiteness the default neutral example (Deyrup & Graves, 2022; End Race Correction, 2023).

To learn more about other supporting roles I could play in this space, I went to literature by Dr. James's Ph.D. supervisor, Dr. Stephanie Nixon, and her work on privilege and critical allyship (Nixon, 2019). Nixon draws on scholars in anti-oppression including Kathryn Pauly Morgan (1996), and acknowledges that her position of privilege allows her paper to reach a different set of eyes within healthcare (Nixon, 2019).

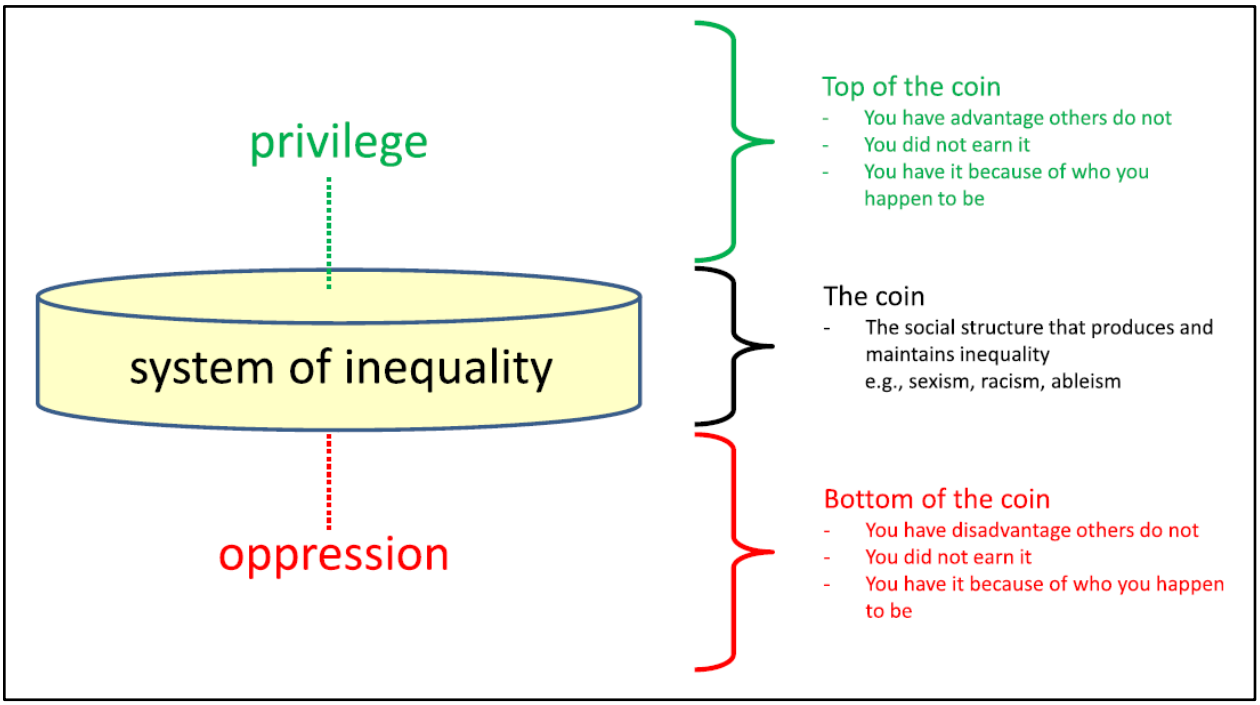

Figure 7: The coin model of privilege.
Adapted by (Nixon, 2019) from: (Pauly Morgan, 1996).

The coin model imagines the inequitable system as a coin (Figure 7). The side of the coin you fall on depends on your intersectionalities (Crenshaw, 2016), not something you have done to earn this position. Those on top of the coin do not have to consider its workings during their day-to-day lives and therefore this coin may be frequently invisible to them. Whereas those on the bottom of the coin have to navigate through its systemic barriers and can therefore see its workings, although these barriers mean they incur disadvantages from this system more readily (Nixon, 2019).

If inequities are to be dismantled while minimizing the harms of the chaos of changing systems, those on the top of the coin must first, become aware that there is a coin, and then use their power to help dismantle the system. But this is not a solo process. This model cautions that dismantling the workings of the system and its tendril-like impacts must include everyone. Furthermore, this dismantling must be led by the disadvantaged, through redress, and rebuilding more equitable processes and systems (End Race Correction, 2023; Nixon, 2019).

The coin model allows me to see the different roles within the process of designing while dismantling inequities, and I recognized a version of it appearing in the Equity Centred Community Design model (Figure 8) by Creative Reaction Labs (Creative Reaction Lab, 2020). Specifically, this process groups those who participate in designing into two categories: Equity Designers with lived experience in the system of oppression, and Allied Designers who will leverage their power, access, and any special skills in service of the Equity Designers' goals. This model goes further to say that the designing needs to be embedded in the problem space and start with an exploration and acknowledgement of the history and context of the problem space before embarking on any solutions.

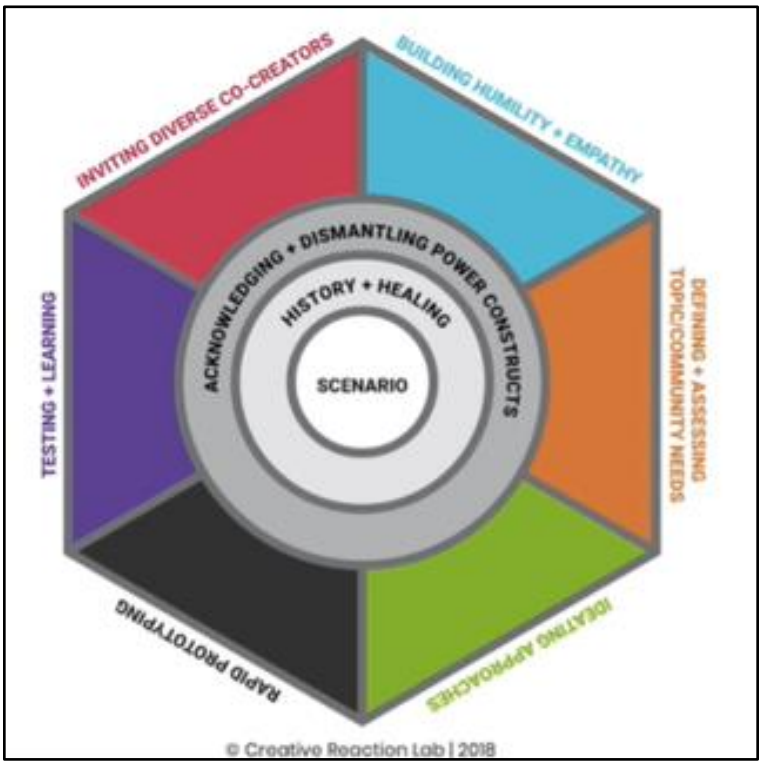

Figure 8: The Equity-Centered Community Design Model.
From: (Fast Company, 2018). ©2018 Creative Reaction Lab.

How do I move from theory to action? How do I shift focus from evaluating these frameworks and new ways and tools for seeing the system, to making concrete changes in my practice?

12 The Power of Community Design.

I came to SFI and embarked on this project because I saw that despite the good that was done within medical device development, and the benefits that were rendered, there were larger inequities that were not addressed based on who was considered a designer and who was considered the user. I wanted to know if there was a way for my profession to do better.

- Are there some things that should not be allowed to exist?
- How do you weigh the potential long-term harms and benefits of making a thing?

These are big questions. How do I do something and not just get frozen in "analysis paralysis" because I don't know where to start? To be able to apply this to my work, I felt I had to try something (Figure 9).

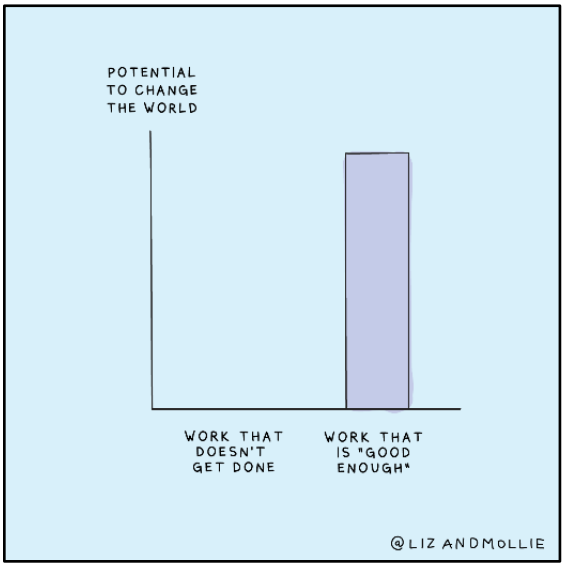

Figure 9: Cartoon graph of work that can potentially change the world.
From: (@lizandmollie, 2020). ©2020 @LIZANDMOLLIE.

As I was exploring different methodologies to further incorporate equity into my design process, I was inspired by the process of participatory design and co-design from my Health Equity (Moscou, 2021) and Inclusive Design courses (Treviranus & Nicoll, 2021a, 2021b), and from a Health and System Equity panel that spoke about using co-design in underserved Toronto communities in the middle waves of the COVID-19 pandemic (Ikura et al., 2022).

In this last inspiration, Sophia Ikura of Health Commons Solutions Labs spoke of the fundamental mismatch of solutions to demographic needs in underserved communities during the first few waves of the pandemic. Ikura described "solutions" such as drive-thru COVID-19 testing stations deployed in parts of Toronto with a low prevalence of car ownership and use. Such gaffs show a misunderstanding on the part of governments and policymakers of the order of concerns of communities (Ikura et al., 2022). She concluded that communities have a real desire to keep themselves and their members safe. However, as we can learn from the social determinants of health (Canada, 2001), there are many levels of safety. For instance, consider hypothetically that you are a service industry worker in a low-paying, precarious job with no sick days. When you can't eat or pay rent without working, the prospect of going

to get tested for COVID-19, knowing that a positive result will require you to stay home means that you need to avoid COVID testing to survive (Ikura et al., 2022). If the services that are provided by policies and government as health care do not match the needs of the community, they are a burden to the community, not a gift or a helpful service.

These “solutions” are too often implemented without due regard to the context of the situation into which they are inserted. We do harm if we do not consider that different communities have different needs and community members have skills of their own already in place to keep each other safe. To activate and add to these informal infrastructures successfully you need to be able to build trust and develop a relationship with the community members, not just parachute in, provide a solution, and exit (Ikura et al., 2022; Moll et al., 2020). It is unfortunate, that the “parachute-in” approach has historically been employed in too many underserved communities by too many large institutions. The result has been a destruction of trust. But all is not lost. Ms. Ikura concluded that communities have rich networks that could be the base of complex solutions, and to protect these, they are looking for long-term commitments to change through processes such as co-design, not just a parachuted in one-time or one-noted solution (Ikura et al., 2022; James, 2020).

This care of long-term impact is the feeling I wanted to put into my designing.

13 Method.

With this inspiration pointing me at the problem, why did I not jump right into dismantling inequitable systems?

For many reasons, with one of the main ones being that despite being an engineer with medical device development experience, co-design is a fundamentally different method from what is currently used in my field. I wanted to practice and learn a bit more about using this method of working together to see what other changes might make it easier for a co-design method to be adopted, as well as where it might be helpful within medical device development process.

Thus, for my MRP project I set out to:

- Employ the method of co-design, specifically looking at questions of care for co-designers.
- Together use systems and foresight tools to explore the medical device development space.

To do this, I created a case study to explore how I might change the way I design. As part of establishing an appropriate scale and diversity of knowledge in the project, I recruited my cohort classmates from across design Master of Degree programs within OCAD University.

In the next portion of this report, I record what happened, and reflect on the lessons I learned.

13.1 Structure of the Method and Research Questions.

To explore this case study, I used a double-diamond approach (Ball, 2019). First, discovering the theory of collaborating, and then defining the ritual we created together. We used this ritual as we expanded our discussion to look at systems and foresight in the medical device development space, converging to deliver insights into collaboration and the systems and foresight work.

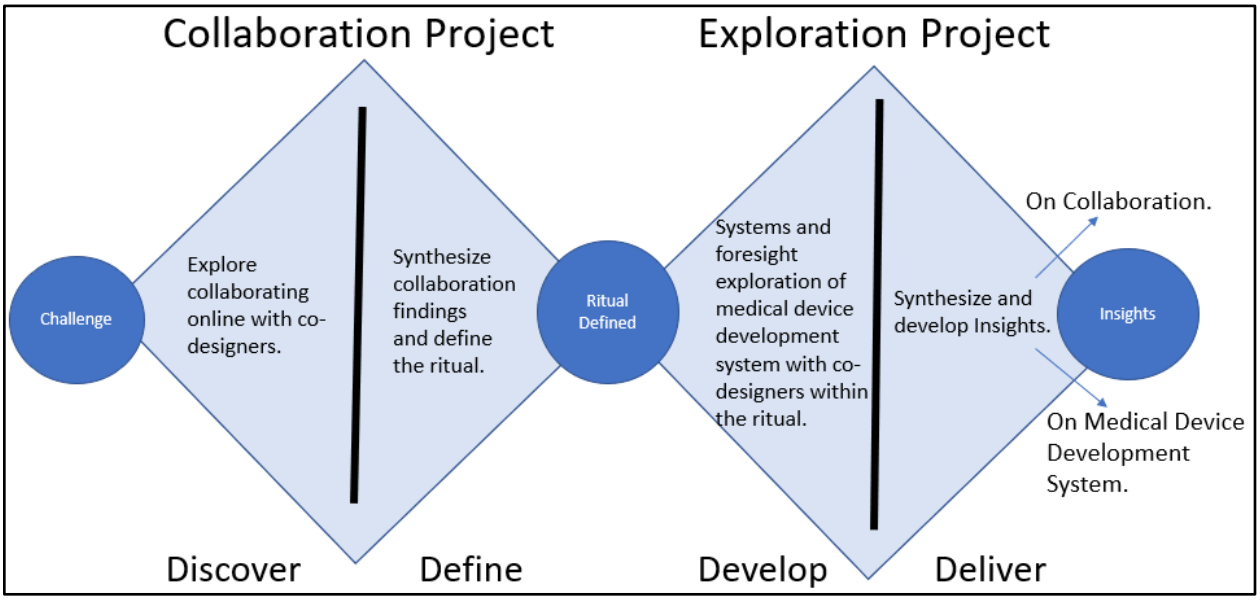

Figure 10: Double Diamond methodology superimposed with stages of the project.

The project fell into two sections with the following research questions:

1. Determining how we were going to co-design together and designing the ritual for our work (the Collaboration Project).
    a. How can we meet to build trust and community in a design-centred collaborative format?
    b. What is the ritual of meeting that we develop?
2. Testing the ritual by bringing a systems and foresight methodology to questions of equity in the medical device development space (the Exploration Project).
    a. How do the boundaries of the problem we are solving change because of these different inputs?
    b. What are some factors that could influence moving the current medical device development space to a more equitable design methodology future?

14 The Collaboration Project.

In this collaboration, I was trying to replicate some of the dynamics that happen during the product development cycle in the medical device development process. To do this I applied the tenet of co-design reflexively: questioning and upsetting power structures on three levels of designing the designing, the system, relational, and self (Mitchell, 2021). Additionally, this was a master's project and a practice-run project, so we had to consider some additional constraints, namely in embeddedness, expertise/role, and timeline. In this portion of the paper, I will talk about the constraints of the project and then outline the theory and practice that we drew on to provide a loose structure to initiate our group work together and create our meeting ritual.

14.1 Constraints of the collaboration.

There were three main constraints to this project compared to trying to apply co-design in a real medical device development setting:

1. Co-designer non-embeddedness,
2. Co-designer expertise/roles, and
3. Project timeline.

First, **the project was not embedded in the system we were trying to understand**. We co-designers were not designing a medical device and we tried to address this by looking at the system rather than the use case of a device. The reason that embeddedness is important in co-design is that this allows the development of specific complex solutions through the unique view of the interconnections to their specific system that the co-designers have. We reasoned that looking at the systems and questioning the biases and assumptions of this was something that we co-designers had expertise in and could be considered embedded enough to explore together through co-design.

Second, the **difference in the expertise that exists between medical device developers and users was not replicated exactly** in this project as the people who I asked to join me in this exploration were other design master's students at OCADU. Instead, we took on different roles in the project. I took on the role of expert, sharing my 15 years of medical device development experience in the system of medical device development. The co-designers took on the role of the users, with context from reading about a recent medical tragedy, the company Second Sight, and its sudden cessation of all support of their ocular implant. These were the power structures we were reflexive about, and trying to upset to ensure that the work we did was democratic.

Finally, **the timeline of the project was limited** by the scope of a master's major research project. This meant that I converged some of the ideas that we came up with toward this goal. To this end, we employed reflexive hypothetical questions at the end of each design session about who was missing from the conversations that we had had, and about the power we had explored in the systems. The answers to these questions were used to steer the topics of subsequent sessions, or alternatively, when their scope did not match the size of the project, they were cited as potential areas for future work.

Additionally, because of this time constraint, rather than speeding through all aspects of the design project we **added some principles of Open Space Technology**, or unconference design, to try and further centre the process being democratically led by co-designers (Owen, 2008). I explained this to my

co-designers with the words of adrienne maree brown, in Emergent Strategy: “There is a conversation in the room that only these people at this moment can have. [Let’s] Find it.” (brown, 2017).

With these constraints named, the report can delve into the theory woven into the collaboration.

14.2 Combining Theories to practice co-design and unconference.

Combining co-design and Open Space Technology (OST) was straightforward because these are both participatory design processes. Co-design focuses on reflexiveness (Mitchell, 2021), and unconference focuses on co-designer-led exploration (Owen, 2008). In this section, I am additionally sharing some of the theories I used to understand the self, relational, and system levels of co-design where reflexiveness was required.

Co-design is a participatory design framework and a reflexive process that, when applied appropriately, can reduce unlevel power structures within a group, thereby democratizing design. It has been developed on the premise that:

> Everything we design takes shape in a complex ecosystem of people, objects, practices, and infrastructures that all act on and are influenced by one another. (Qazi, 2018, p. 7)

The framework by Qazi has questions that can be posed throughout that help forefront critical thinking about the power structures within these complex interactions by looking at the system, relational, and self levels. In contrast, the unconference approach, is a participatory meeting that focuses participants on self-organizing and creating their own agenda based on the topics and issues they are most interested in discussing (Budd et al., 2015). Together these powerful tools can empower co-designers to discover loci for system-level innovation based on the expertise of the people in the room.

14.2.1 Self Level.

At the level of self, the objective of combining co-design and unconference practices calls on co-designers to show up with a great deal of self-awareness. According to Brené Brown, "vulnerability is the birthplace of innovation, creativity, and change" (Brown, 2010). To engage in innovation and outside-the-box thinking, individuals must let go of the need for certainty, perfectionism, and external expectations by leaning into self-acceptance. Furthermore, individuals need to feel valued, understand their contribution to the project, and be able to operate within their personal boundaries while pushing toward the shared agenda (Brown, 2012)). Brown's work, like that of Nedra Glover Tawwab's, emphasizes the importance of cultivating qualities that develop one’s agency, empowerment, and willingness to share (Brown, 2012; Glover Tawwab, 2021).

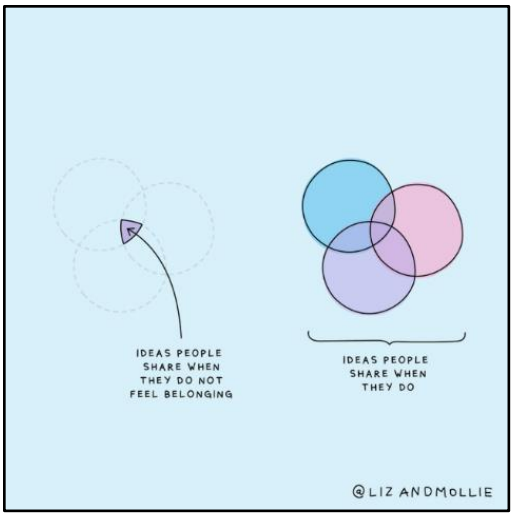

Figure 11: Belonging.
From: (@lizandmollie, 2021b). ©2021 @LIZANDMOLLIE.

14.2.2 Relational Level.

The individual co-designers combine to become a community that has relational needs. This is a network of collaborators who all see themselves (temporarily at least) as allied with design aims and feel community among each other in the process. At the relationship level, combining co-design and unconference practices can help groups develop a greater sense of trust and collaboration. Co-design emphasizes the importance of listening and valuing different perspectives and skills, which can help build stronger relationships between individuals (Moll et al., 2020). While unconference practices encourage participants to share their knowledge and expertise and can foster a culture of collaboration and knowledge sharing (Budd et al., 2015). By combining these two practices, groups can create a more inclusive and collaborative environment and belonging.

Belonging to a community is important for individuals to share and innovate (Kahane, 2017). In the book *Collective Genius* (2014), Dr. Hill et al. found that having a Shared Purpose and Shared Values is not enough for constructive teamwork. The team must also establish norms for how people interact and think within the group. This includes mutual trust, respect, and influence in interactions, questioning assumptions, prioritizing data, and considering the entire problem, and takes time (Hill et al., 2014). Specifically, the group needs to create a brave space, where members understand their respective roles, value each other, and share a language and methodology for approaching the problem (Verduzco-Baker, 2018). This fosters respect, trust, and psychological safety within the team and creates a sense of community (Figure 11).

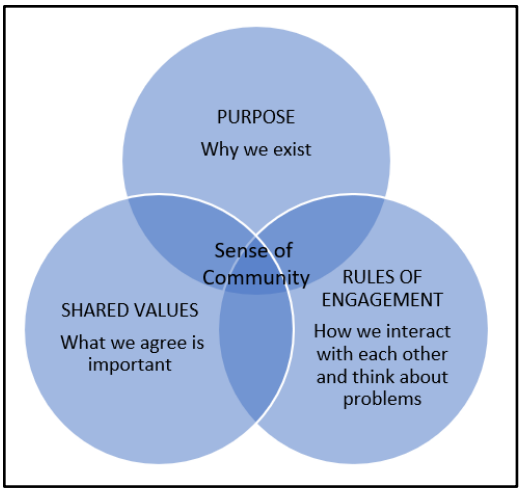

Figure 12: Framework to set up for groups to innovate.
From: (Hill et al., 2014, p. 192). ©2014 Hill et al.

14.2.3 System Level.

Finally, at the system level, combining co-design and unconference practices can help groups develop a greater understanding of complex systems and how they work. Co-design emphasizes the importance of systems thinking and understanding how different parts of a system interact with each other (Mitchell, 2021). Unconference practices, which allow participants to explore and discuss different topics and ideas, can help groups develop a more nuanced and holistic understanding of parts of complex systems (Owen, 2008). By combining these two practices, groups can develop solutions that consider the complexity and interconnectivity into which the solutions will be launched.

14.2.4 Facilitator Role.

Setting up this value system of coupled co-design and unconference is initially the role of the facilitator through setting up the project, positioning participants for success, and responding to their inputs transparently (Edmondson, 2019; Kahane, 2017). Similarly to Hill, Kahane suggests that the facilitator should lead in establishing group goals and rules of engagement for communication. In addition, the facilitator must understand and listen to the reactions of the group, modulating communication to maintain engagement and assertiveness, all while helping the group be reflexive of its power structures at each of the self, relational, and system levels (Edmondson, 2019). Some suggestions about how this might be done come from Zaki's work empowering participants through pre-reading prompting articles to level the power differential within a group (Zaki, 2019). Without enforcing strict procedures, how can this be done?

14.3 "Just enough structure" to realized strategy.

While this theory of co-design and unconferences gave a lot of structure for the ritual, I quickly found that a challenge is that many aspects of co-design can't be mandated. Specifically, you can know that co-design requires trust and vulnerability from the co-designers (Moll et al., 2020), but this is not a feature that can be forced, it is something that needs to be developed or is emergent. So, what were some things that we could try to help us become closer as a group and set up "just enough structure" (Mitchell, 2021) to be able to move towards the goal of the meeting while also leaving room for dialogue and uncertainty that opens the doors for changing it all?

I imagine co-design as trying to change who is in the driver's seat of Mintzberg's intended versus realized strategies (Mintzberg, 1994). In Figure 13, the conventional design thinking process does not account for, or try to counter, the culture in which the design is being made. The users are being consulted, so the design that is produced is very much along the lines of the plan or constraints the designer had in mind, to begin with. In Figure 14, designing the design process through a power-reflexive process such as co-design is the first step in the strategy, puts the user (in this case the Equity Designers) in the driver's seat for the intended design and allows them to realize their design with the aide of the designers (Allied Designers) (Creative Reaction Lab, 2020).

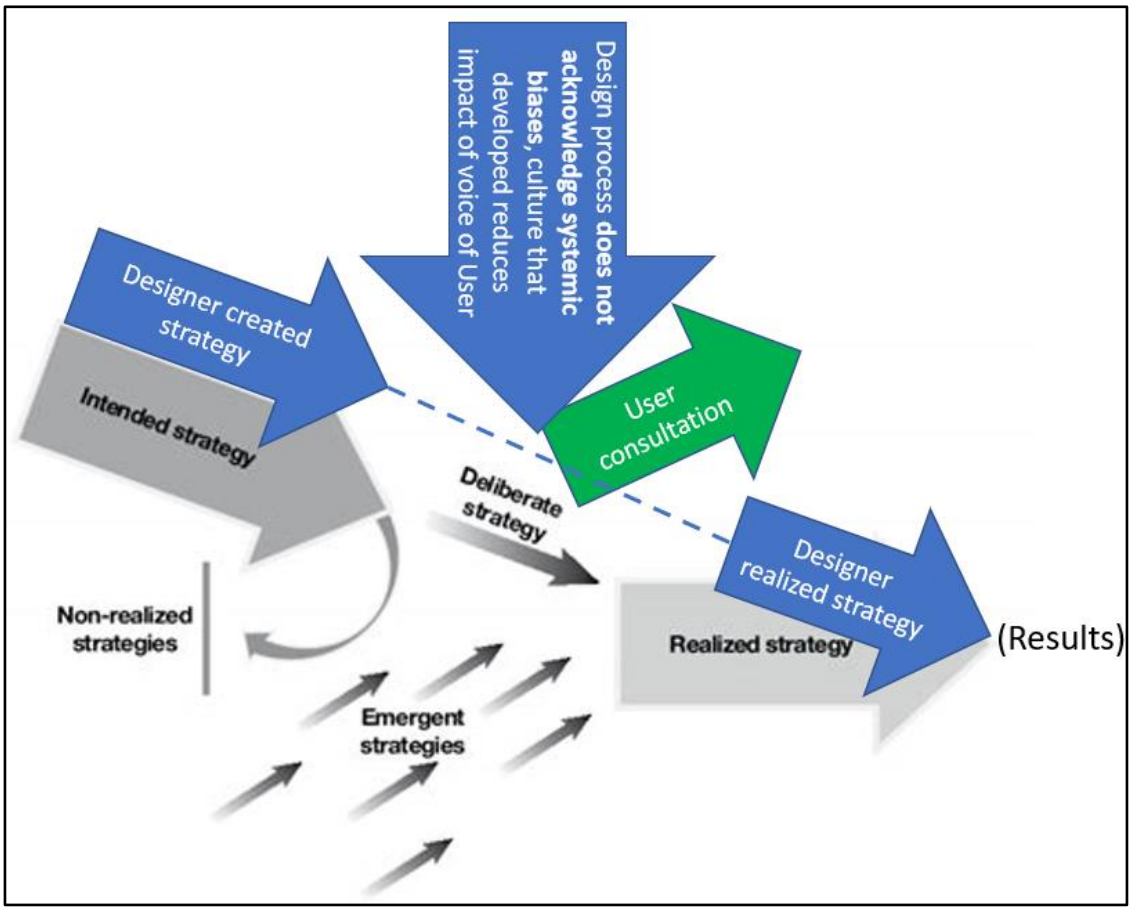

Figure 13: Comparison of the conventional design thinking process (blue and green arrows) with Mintzberg's Intended Versus Realized Strategies (grey arrows).
Adapted from: (Nel, 2016).

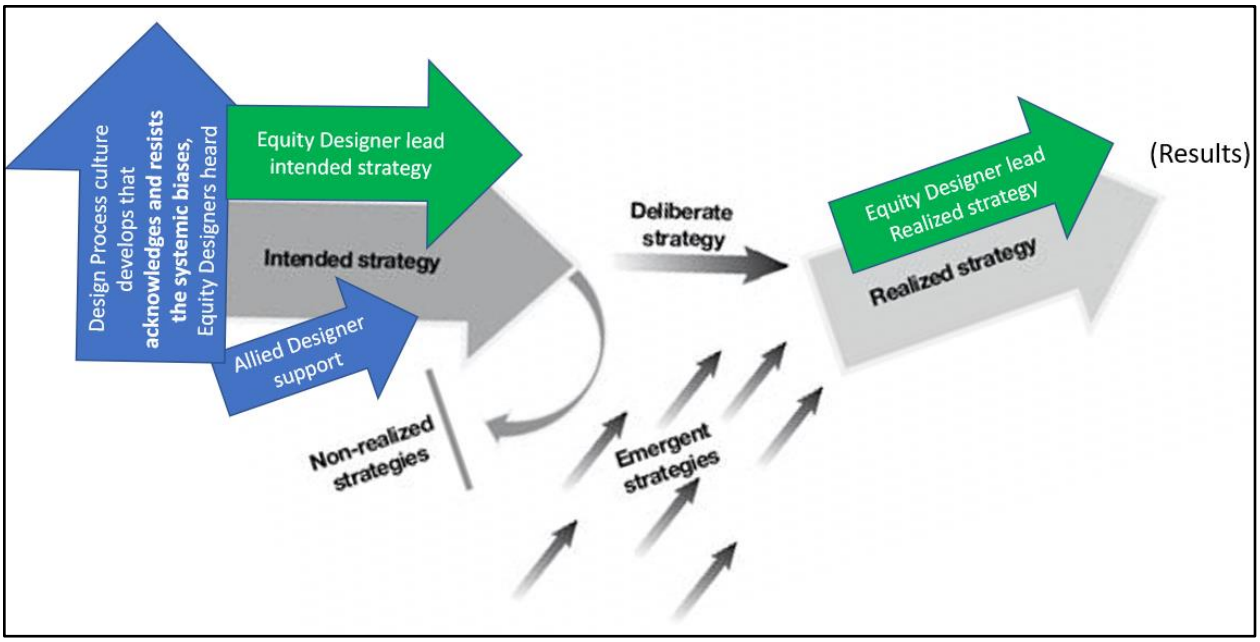

Figure 14: Comparison of the co-design process (blue and green arrows) with Mintzberg's Intended Versus Realized Strategies (grey arrows).
Adapted from: (Nel, 2016).

It is a bit meta, but in co-design (Figure 14), in order to achieve the first upward arrow, acknowledging the biases of the systems in which the designing will be happening in, the values that allow more democratic listening to your co-designers need to be imbued into the design process (this value transfer happens in non-co-design processes as well, as outlined in section 11.3, but it is not widely acknowledged). The way we make this happen is a two-staged process following the memorable quotation attributed to Peter Drucker regarding the interplay between strategy and culture: "Culture eats strategy for breakfast" (Fletcher, 2021). As a facilitator, I have to create the guiding path and react to the driving path that my co-designers create as we work together.

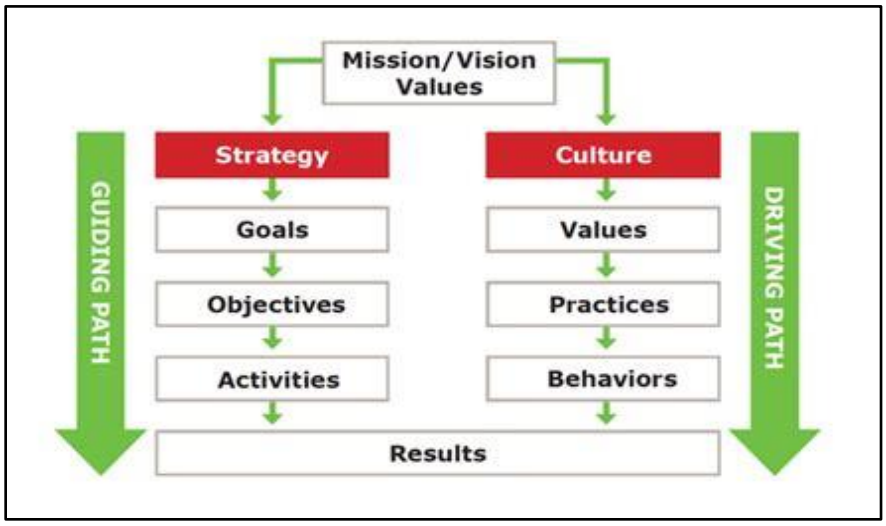

Figure 15: Interplay between strategy and culture.
Adapted by (Rick, 2015) from: (Wook Shin et al., 2017).

As the facilitator my "just enough structure," was my guiding path. Stating and showing my values through the alignment of words and actions in the proposed goals, objectives, and activities. This is what I seeded the co-design ritual design sessions with and together we developed the culture of behaviours and practices that showed our values and created the ritual for the exploration project.

14.4 Seeding the co-design.

I seeded the initial sessions of co-design with the information outline shown in Table 1. We reviewed it as visuals outlined on a shared Miro board that I narrated, and we discussed.

Table 1: Facilitating Guiding Path.

Guiding Path Steps	Actions
Mission/Vision/Values	Share a synopsis of the journey to this project.
Strategy	Share a request to help design the session seeded with some of the theories of co-design and unconference structure.
Goals	Share the following initial goals of the sessions: ● Medical device development best practices and regulations have been implemented reactively in response to tragedy. How might we look at recent medical scandals and industry trends to anticipate changes that could happen next, and imagine the potential futures that could occur as well as the leverage points to improve the equity of the system? ● What are some connection-building rituals that help facilitate sharing and collaboration in peer networks working on systems and foresight problems?
Objectives	In initial meetings, Designing the Designing to set up a reflexive practice. Becoming more aware of the power structures we are working with and within, and whether those who are going to be affected by the design have a voice in this process (Treviranus, 2019). In preparation for collaborative foresight work through the Systemic Tool Kit.
Activities	Provide suggestions of connection-building rituals we could try: ● **Sharing food together.** Dr. Weston found during her arts-based collaborative explorations that getting groups to eat together led to more unstructured conversations and more fruitful discussions later due to sharing this time (Weston et al., 2020). ● **Short unstructured time together to talk about things not related to the project.** Dr. Treviranus tried to replicate the feeling of chatting while sitting next to someone on a short bus trip by putting people together in breakout rooms for short periods to expressly engage in random discussion (Treviranus & Nicoll, 2021b). I found this to be a good practice to get to know people better online and tried to help ease those who were worried about small-talk by providing a list of ice-breaking questions to start with. Delve into questions together: What is required in a great collaboration?

14.5 Sessions 1 and 2.

The collaboration ritual creation was covered in the first two sessions. To document the work that we did together I created a dashboard from the activities developed together in Miro. It documents what the co-designers chose to share about the things we discussed during the sessions. Within this report, in addition to being labeled as the work from the sessions, some details of what was covered in the sessions and some of the raw Miro board work is shared within pages with a black border.

At the beginning of each session as a check-in, the co-designers did an arrival quiz and claimed a post-it colour to be used for the duration of the session. The option of using a yellow Post-it Note to keep comments anonymous was also always available. The themes or insights that I garnered from reviewing the work outside these sessions are shown in circular tags rather than rectangular Post-its. The other ingredients of the session are also shared on these spreads such as answers to the anonymous check-in and check-out questions.

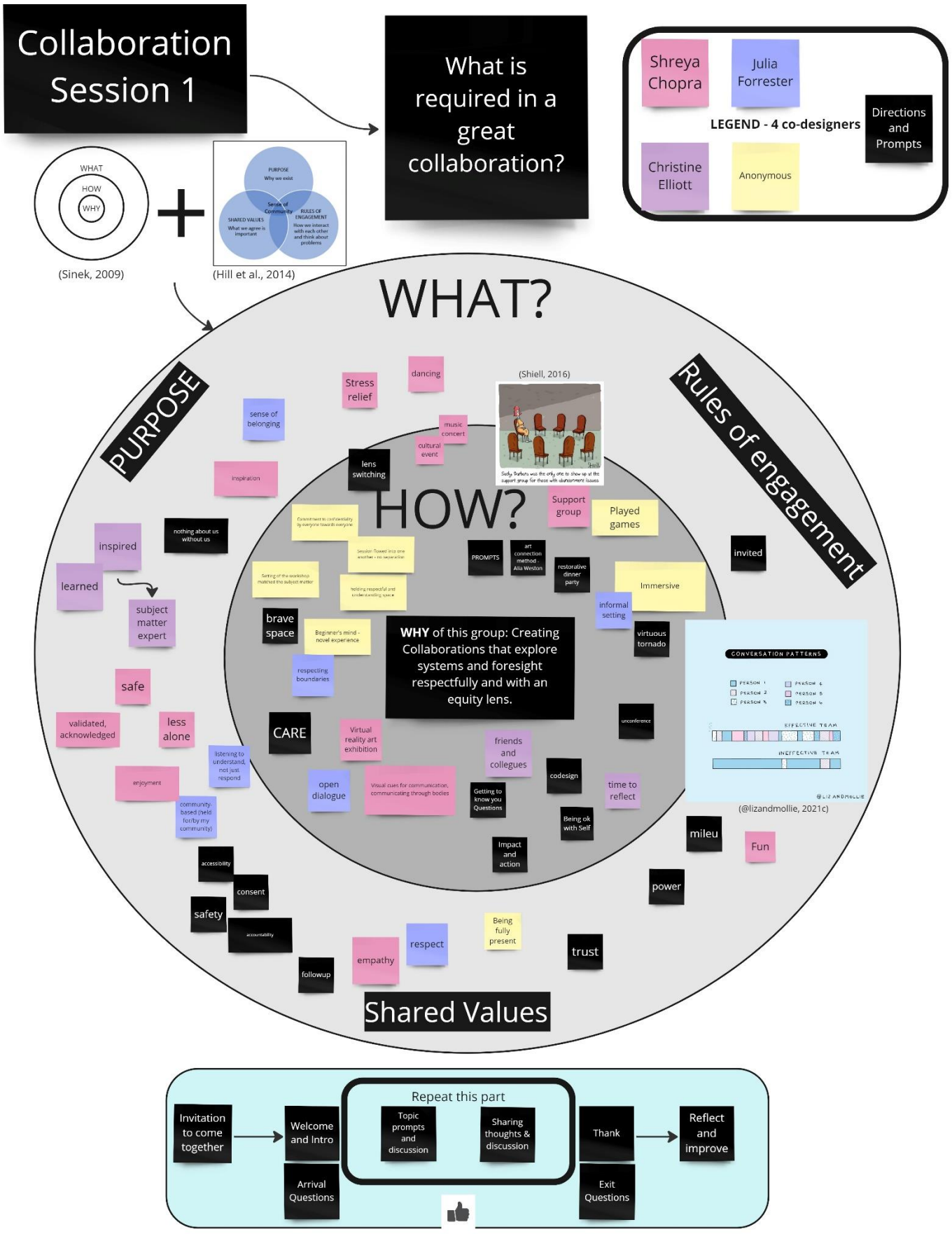

Figure 16: Collaboration Session 1, Collage page 1.
Sources: (Hill et al., 2014; @lizandmollie, 2021c; Shiell, 2016; Sinek, 2009)

In the first sessions, after working through the guiding path steps outlined in Table 1, we explored the why of our work. Simon Sinek suggests that starting by asking the question WHY is a good way to galvanize a group towards a purpose (Sinek, 2009). I provided framework for the discussion as an overlay of the three aspects a group need to innovate: Shared values, purpose and rules of engagement by Hill et al. (2014) and asked the group to deconstruct the WHAT and HOW of making excellent collaborations together.

From this discussion I presented examples of group guidelines from Scholar's Strike and an OCADU art therapy brave space and together we developed our own group guidelines that would help us be supportive co-designers over the next sessions.

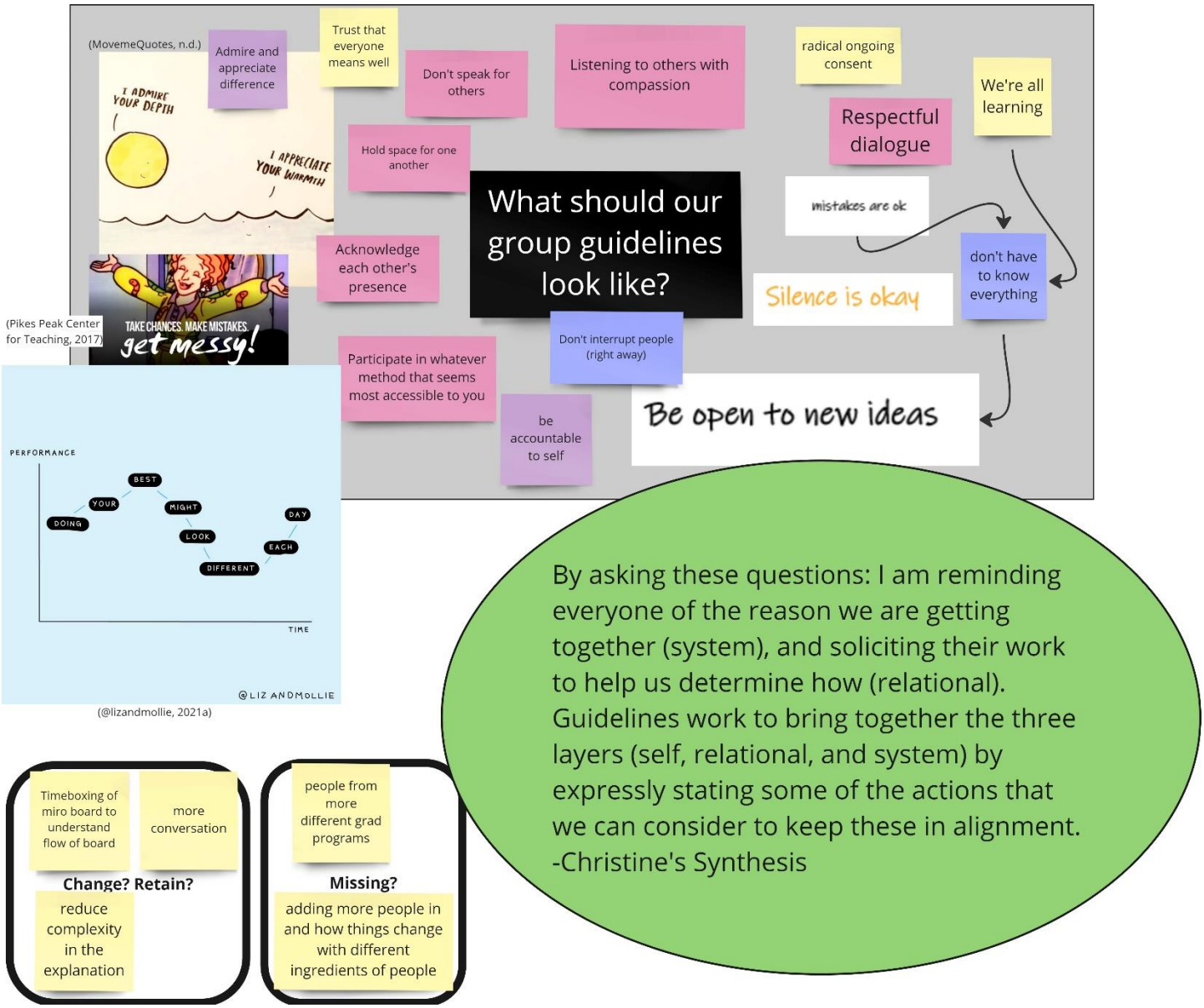

Figure 17: Collaboration Session 1, Collage page 2.
Sources: (@lizandmollie, 2021a; MovemeQuotes, n.d.; Pikes Peak Center for Teaching, 2017)

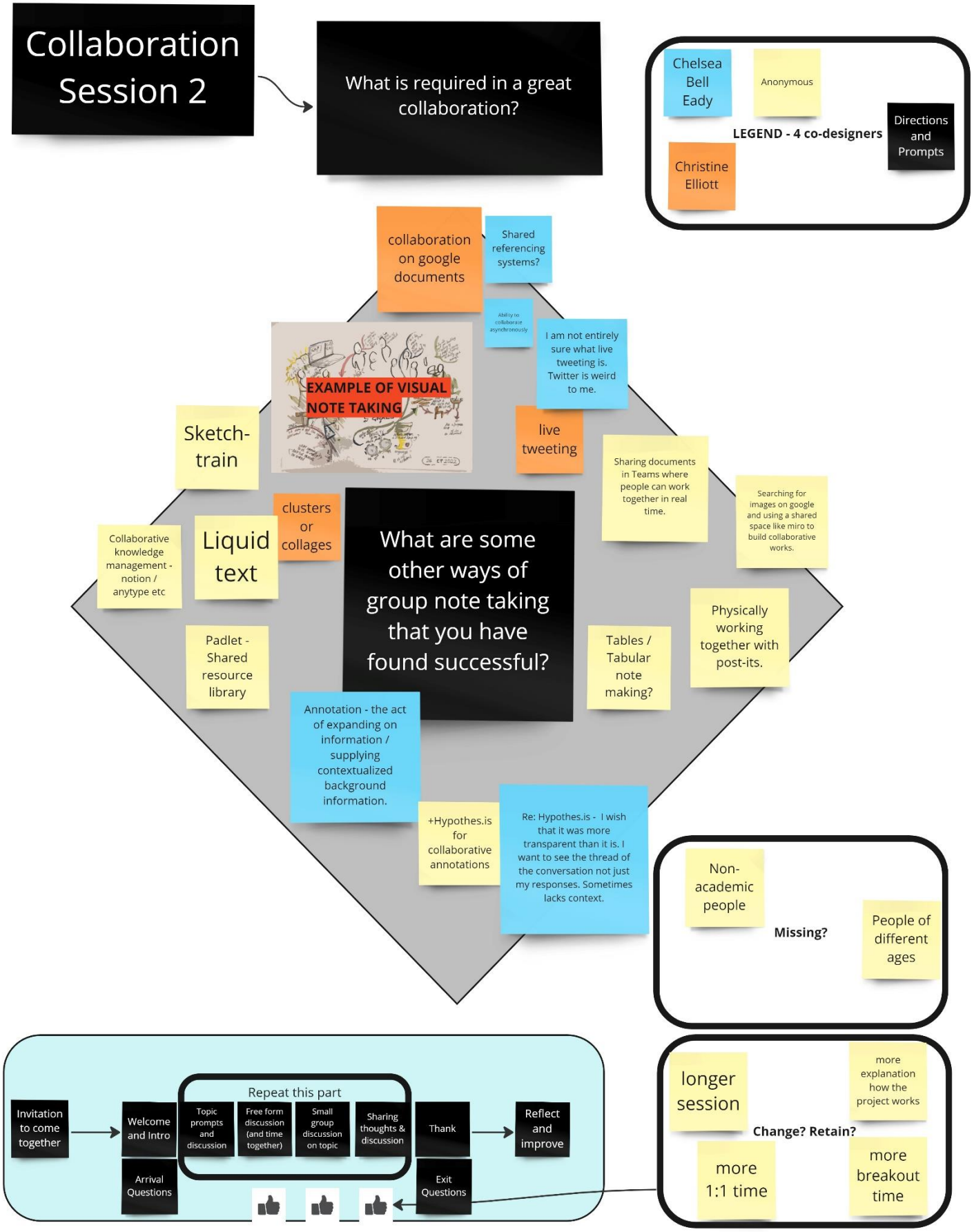

Figure 18: Collaboration Session 2, Collage page 1.

In session 2, I focused on explaining the journey of getting to the topic of the exploration project to show the work-in-progress nature of the project. This focus was also to get participants to think about the process and take to heart the co-design aspect, trying to give them permission to break rules and direct the flow of the sessions.

This was the first session where the one-on-ones in breakout rooms were tried. We found it very successful and universally enjoyed by the co-designers

Figure 19: Collaboration Session 2, Collage page 2.

14.6 Collaboration: Lessons learned.

Some of the broad lessons learned from the initial collaboration sessions were as follows:

There is a tension between the willingness to embrace uncertainty required by co-design and the requirements to have a predetermined project: Co-design is often used as an umbrella term for participatory, co-creation, and open design processes (Qazi, 2018). I wanted to try exploring the medical device development space by focusing both on designing the process we used to explore together, as well as on the exploration project. I thought that a meeting developed in tandem with the group that came to the table to participate would be a better forum for sharing and getting at the root of our thoughts on the system we were exploring.

This need for open-endedness was at odds with the MRP process where an outline of the plan and delineation of risk and benefit needs to be assessed before permission is given to proceed. I, therefore, outlined the projected and suggested tools that we were going to use to satisfy this requirement. However, within this methodology, I explained the updates about the project that the co-designers would receive, the ongoing consent that would be requested of co-designers at each new juncture, and the ability of the co-designers to stop collaborating at any time to try to make room for uncertainty and change. We did explore new topics and discussions together, but I believe if we had come up with less structure, we could have created the methodology and structure together as well and this might have led to further unearthing of unexpected/non-predetermined findings.

Scheduling is hard. After having accrued above my minimum number of co-designers I tried to schedule the date of the first 3-hour session and found that at most I could get one or two people out of eleven to agree on a time. As a result, I lengthened the promised breaks and ran sessions two 90-minutes sessions a week apart, and my co-designers were able to attend.

Busy participants. My co-designers were fellow master's students and recent graduates and were all very busy. One of my sessions was scheduled during spring break, which was not attainable for any co-designers.

Time is precious and prompts were not universally done. Despite a friendly reminder email with links to the articles and an example, reading of the prompts was not something that many co-designers were able to do ahead of time. I think the amount of time the reading and responding required was more than the co-designers had available for this project and the benefits were not as visible or well explained. I probably did not explain this portion of the project enough for it to be valuable to the co-designers.

Planned more in preparation for the sessions than we got to do. Across all sessions, I overestimated the amount of material we were going to be able to get through together. Time for one-on-one breakout conversation and well as discussion on the topics seemed to be highlights and co-designers wanted more of this in the review surveys.

Collaboration over meals not tried. As we were doing this work there were some secondary waves of COVID. We, therefore, did not gather in person or hybrid form but were all online. Exploring documentation on how to care for communities during COVID (Win, 2022), we decided to simply share warm beverages while we sat together on our video meetings, rather than sharing a meal together as suggested to build community ties by Weston (Weston et al., 2020).

14.7 The Ritual.

To embody the understanding, we brought to the project and built together we generated the following ritual (Figure 20). There are three main parts: Before, Meeting, and Reflection. Within the Meeting portion, there is a welcome and a thank you bookending the session, and then a repeated portion in the middle where the topic of discussion is presented, co-designers separate and socialize with each other expressly avoiding the topics of the session and then continue in this small group to discuss the topic. The last part of this repeated portion is the co-designers come together to share with the group again. The middle part can be repeated if there is adequate time and we included breaks as necessary.

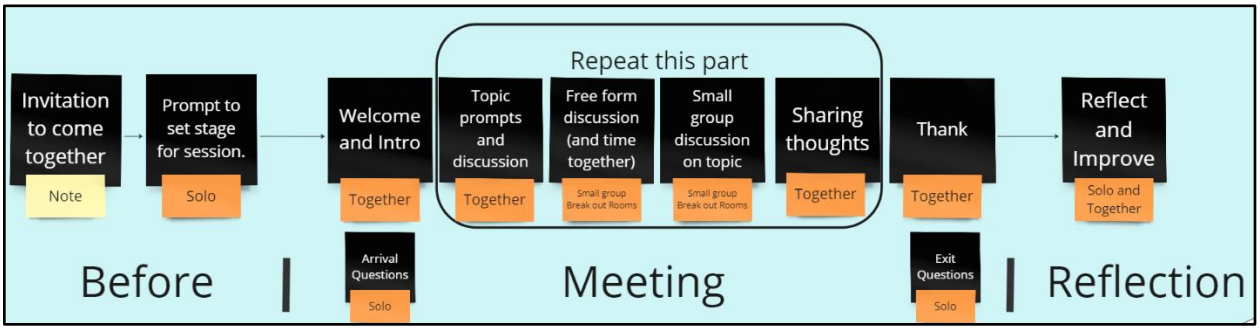

Figure 20: Ritual Structure.

The ritual we developed was not elaborate (Figure 21), but it was intentional and loose to provide some structure but not be constraining. The reflexive parts of the co-design showed up in a verbal reminder at the start of the meetings, and anonymous questionnaires at the start and end of the meeting to allow critique of the sessions, who the co-designers thought we might be missing from our conversations (Treviranus, 2019), and to help determine possible next or future steps for the project.

Figure 21: Rituals don't have to be too elaborate.
From: (Thompson, 2013). ©2013 Richard Thompson.

15 The Medical Device Development System Exploration Project.

This part of the report summarizes the work that we co-designers did together exploring the North American medical device development space. The focus of this exploration was looking at how the structure of the system influences the way it works, exploring ways that the system currently reduces possible harms, and looking for avenues to increase equity in the system by speculatively generating a possible future world.

It was a challenge to determine how to present this work as the process was very generative and non-linear, by design. Forcing this into the streamlined systems tool kit required that I follow a path through the work built only on a subset of bricks we built together. In keeping with the group-centred commitments to show the work and the tenet of attributing where the work came from, I will be sharing some of the raw Miro screenshots of our work together, the stories we shared that positioned us within the generative worlds, and the notes arising in my secondary syntheses presented in the report.

The synthesis is aligned with the original goal of this paper, trying to see the workings of the system and possible alignments with equity work. It is not a commentary on the relative importance of the work that was chosen to be synthesized, compared to what was left in raw form. There were many deep discussions, but in the spirit of co-design discussions, and the solo design of the synthesis, I felt like I could only apply the work to modifications of my own roles within this system.

The work covered in the co-design sessions is shown within sections of the text within boxed pages to facilitate the choice of a more concise read of the system and foresight project.

15.1 System exploration project methodology and tools.

To delve into the systems and foresight of the medical device development space we used a set of tools and steps (Figure 22), from the Systemic Design Toolkit (Namahn, 2020). The initial stages of the system exploration leaned heavily on my experience in medical device development to determine the players and power structures within the system. The dynamics of the system were uncovered through studies of three past medical tragedies, and a recent tragedy, Second Sight. We then pulled this information together by developing a foresight scenario using Causal Layered Analysis at the ends of a three horizons framework, to explore the forces that might push the current world towards a more equitable preferred future. Finally, I reflected our work back on the tools that I have access to as a medical device developer to think about what modifications could be made to help move towards this preferrable future.

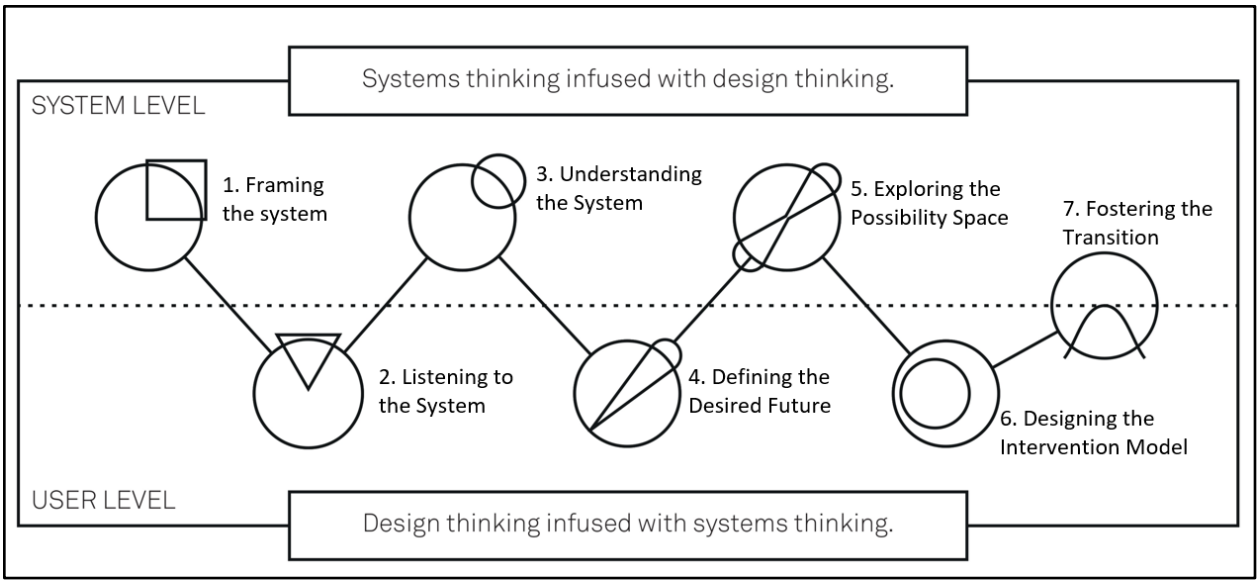

Figure 22: Flow chart of the Systemic Design Tool kit.
Adapted from: (Namahn, 2020).

The three horizons framework is a tool developed by Bill Sharp that can be used to imagine ways to change a system (Roworth, 2018). In this context, three overlapping, but offset across a time axis, peaked curves are imagined. The first is the current state of the system, the second represents a transition time with emerging challenges and opportunities, and the third horizon represents a longer-term, transformative vision for the future or the preferred future. The framework can help designers identify the key forces and tensions that could be leveraged to help move toward the preferred future (Roworth, 2018). By exploring all horizons of the three horizons framework together, designers can explore the complexities of moving towards this vision of the future.

The Causal Layered Analysis (CLA) is a framework developed by Dr. Inayatullah (2008). It is a sensemaking tool that we chose because it can help designers explore complex issues and events by analyzing them at four different layers: the litany, systemic, worldview, and myth layers.

These defined layers facilitate delving deeper into a phenomenon or the why's of a world, getting past the surface-level issues (the litany layer), into the underlying systemic structures and processes (the systemic layer), the cultural and social values that underpin those structures (the worldview layer), and the deeper, often unconscious beliefs and stories that shape our perceptions and actions (the mythic layer) (Inayatullah, 2013; Ramos, 2016). This type of exploration can help gain a more comprehensive understanding of the issue and identify potential points of intervention or change, as well as points to measure to help with a pivot between two worlds.

15.2 Report layout of the Exploration Project.

Each section of this framework is laid out in order and explored with the following questions following a concatenated Objective, Reflective, Interpretive, Decisional (ORID) format, for its strength at focusing a conversation towards a useful result (Stanfield, 2006):

- The questions that were asked in this stage.
- What happened in this stage?

- Reflections and changes.

15.3 How did I choose when to involve my co-designers?

I wanted to co-design both systems and foresight with this group and was limited with the amount of work I could ask of them as volunteers on my project. I thought that the group work would be most useful in a generative format, opening the possibility space of the solutions and helping me find some of my blind spots and biases.

16 Applying the Systemic Design Tool Kit to the Exploration Project.

At a high level, Table 2 shows the stages that we co-designers followed to explore this topic together. Although they are outlined at the start of the journey in the report, the method was only loosely planned before the exploration started.

Table 2: Systemic Exploration Toolkit and exploration's corresponding actions.

	Stage of Systemic Design Tool Kit (Namahn, 2020)	Actions Performed (Greyed cells indicate collaborative work)	
1	Framing: Who are the players and where is the boundary of the system?	Preparation	Created the Actors' Map.
2	Listening: How might the system change?	Preparation	Created an Influence Map to track different interactions within the system layers and actors.
		Review of Prompt	Co-designers read and responded to a prompt reading and questions about Second Sight in preparation for Session 3.
3	Understanding: Where do emergent behaviours happen?	Preparation	Mapped points on the Influence Map that cause system changes because of some famous medical tragedies.
		Session 3	Outlined three medical device tragedies and how they changed the landscape of medical device development. Co-designers created a CLA summary of this world after a PESTEL analysis of trends and themes.
		Synthesis	Revisited influence maps and looked at the differences the co-designers brought into play. Created a causal loop related to the Second Sight tragedy. Summarized the CLA.
4	Defining: What is a desired future state?	Preparation	Outlined two texts that were the basis of the desired future: *The End of Average* (Rose, 2016) and *What Can the Body Do?* (Hendren, 2020).
		Review of Prompt	Co-designers read and responded to a choice of prompt on average and marginalized populations in preparation for Session 4.
		Session 4	Explored how the current definition of average came to be and pockets of innovation in disability space based on *The End of Average* and *What Can the Body Do*? Co-designers created a CLA summary of this world.
		Synthesis	Summarized the CLA.
5	Exploring: moving between current and preferred worlds.	Preparation	Prepared for further work on CLA and 3 horizons based on the CLA's created in sessions 3 and 4.
		Session 5	Revisited CLA's from sessions 3 and 4 as the worlds at either end of a three horizons framework. Looked at changes that could help morph the system towards the preferred future.
		Synthesis	Completed three horizons framework.
6	Creating: What can I do?	Synthesis	Investigated medical device developer tools that could be used in this system to push toward the preferred future.

	Stage of Systemic Design Tool Kit (Namahn, 2020)	Actions Performed (Greyed cells indicate collaborative work)	
7	Fostering: Next Steps and Future Work.	Synthesis	Some suggestions of avenues to present this work.

16.1 Stage 1 – Framing: Who are the players and where is the boundary of the system?

To frame the system, you need to explore the boundaries of and the actors in the system (Namahn, 2020).

16.1.1 What questions were asked in the Framing stage?

- Who is involved in the system of medical device development in Canada and the USA?

16.1.2 How were the system players discovered?

The first frames that I brought to this problem were from my experience developing medical devices. Specifically, my experiences teaching colleagues about how to work in this regulated environment in my role as a Quality and Regulatory Engineer. I shared cautionary tales of mistakes made by other companies to convince my colleagues of the value of the regulation, explaining the edge cases and how now the standards we were required to follow are updated to mitigate these issues in the system. It was an attempt to share system understanding and turn the why into a motivating factor to help us work through the "boring" paperwork. The boundaries in this system were the players and entities that I interacted with while working in medical device development. To showcase these, I mapped out them on the actors map below (Figure 23).

16.1.3 The players involved in this system.

The actors map showed the different stake-holding entities that are involved in the system. It is a visual representation of who knows the most about the problem space and the amount of power each entity has to change it. The different annuluses within the diagram show approximately the levels of the system, society, ecosystem, organization, and individual.

As I was mapping, I was struck by the question "What kind of knowledge?" Because although there is frequently little medical knowledge residing with the patient, ultimately, they are the only one who can know how they are doing and what they are experiencing. To differentiate between these two types of knowledge, I denoted medical knowledge in green and the individual patient's knowledge of self in yellow. Another interesting finding was the size of the Media bubble. It hit all parts of the knowledge axis as it has both information and misinformation components.

Figure 23: Actors Map of Medical Device Development System.

16.2 Stage 2 – Listening: How might the system change?

To listen to the system, you need to look at the interactions within the system (Namahn, 2020).

16.2.1 What questions were asked in the Listening stage?

- What signals, trends, and forces are important in this exploration of medical device development?

16.2.2 How might the system change due to tragedy?

I asked the co-designers to prepare for our first exploration session together by reading and responding to an article about the recent medical tragedy of a company called Second Sight (a choice of articles of various lengths and media was provided to account for different accessibility and time requirement needs). The prompt primed the discussion by allowing the co-designers to understand the scope of the upcoming session, reflect on their own boundaries and what they might want to share and have some notes prepared to help ease into the discussion.

16.2.3 Some locations of change in the system due to the tragedy of Second Sight.

The following box-framed page is the summary of the Second Sight tragedy and some emergent themes and connections the co-designers shared in response to this prompt.

16.2.3.1 The story of Second Sight.

Second Sight developed the Argus II, an ocular implant, that replaces damaged photoreceptors in the retina (Fleiss, 2022). The device works by converting video captured by a camera in a pair of glasses into a 60-pixel array that stimulates the optic nerve through the implant. Although it doesn't provide regular vision, users can learn to navigate and read large print with training and rehabilitation. However, the implant and rehabilitation cost nearly $500,000 per user and were only approved for a small population with end-stage retinitis pigmentosa (Strickland & Harris, 2022a). Despite the heavy selection criteria, over 350 people had the device installed by the end of 2019 (Dankosky, 2022).

In 2019, Second Sight announced its plan to pivot exclusively towards brain-implanted products but promised to continue supporting all Argus implants (The Current, 2022). However, in early 2020, the company ran out of money, laying off most employees without warning to users. This caused issues for users with problems or questions about their devices, and some lost function of the device or resorted to DIY fixes. After a few months, Nano Precision Medical purchased Second Sight, but the patient response has been mixed, with some wanting the device removed and others wanting to continue using it despite the company's change of management and priorities (Dankosky, 2022).

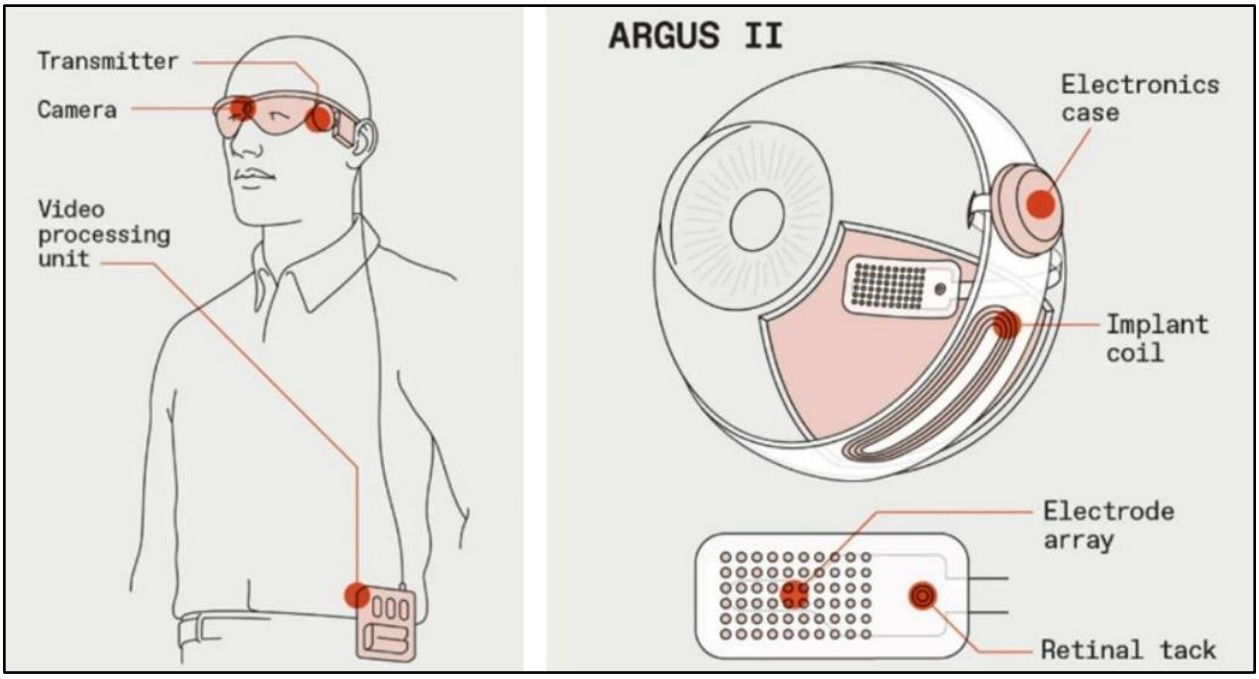

Figure 24: A drawing of the different components of the Second Sight device.
From: (Strickland & Harris, 2022a), ©2022 James Provost.

16.2.3.2 Places of potential system change found during the Second Sight exploration.

I was excited to see some of the co-designers foreshadow our session 3 discussion by sharing about other medical catastrophes like Theranos and the Sackler's. Additionally, they reminded me of an outlying early adopter of computer-brain interfaces, a cyborg named Neil Harbison. There were additional themes of the value of a human's experience and feeling like Second Sight had treated its users as disposable. Finally, there was a lot of discussion about the role of those in power to ensure that the risks are understood in clinical trials by those overseeing and those who agree to participate.

16.3 Stage 3 – Understanding: Where do emergent behaviours happen?

To understand the system, you need to see the variables and how these drive emergent behaviours (Namahn, 2020).

16.3.1 What questions were asked in the Understanding stage?

- What are the main interactions between the different Actors and Entities in the medical device development space in Canada and the USA?
- What behaviours emerge from our understanding of the medical device development space?
- What does a CLA of this world look like?

16.3.2 How did we discover the emergent behaviours of the system?

In this stage, we explored the stories of three medical device tragedies and their effect on the Influence Map of medical device development. In breakout rooms, the co-designers combined this with their feedback from the prompt by discussing different trends and signals in medical device development over the PESTLE framework. The PESTLE framework is a list of categories, (Politics, Economy, Society, Technology, Law, and Environment) that can be used to help pull ideation around a question broad (PESTLEANALYSIS CONTRIBUTOR, 2022).

We came back together as a group, sharing highlights of our discussions and then delved into this world in depth through a side-by-side exploration of the CLA. Following this, I synthesized the notes from this meeting into a summarized CLA for this world.

16.3.3 The emergent behaviours of the system.

16.3.3.1 Emergent behaviours shown in the influence maps.

Two emergent behaviours were observed during our discussion of the three tragedies: *accountability* and *learning*. Additionally, we were able to overlay areas where the system might be affected by tragedies and show a causal loop that demonstrates some inequities in the system through the effect of agreeing to try a one-note solution such as the Argus II system by Second Sight.

The accountability behaviour of the system happens at two levels: relationally and systemically. It can be observed relationally between the medical device company and users through actions of development when the company proposes products and asks for feedback on requirements and prototypes, and once the device is launched, through service and support (Figure 25). At the system level, formal accountability is visible at two moments: once when the medical device company is requesting clearance to sell, and again if an adverse event occurs with the device due to use or misuse. In both cases, these events trigger administrative interaction between the device maker and national regulatory bodies (Figure 26). The device maker's request to sell triggers a regulatory check to ensure that the company is following regulations. An adverse event triggers a set of investigative and corrective actions, from stop-use orders to forcing recalls, with the intent to prevent a device from causing more harm and ensure that sufficient protections are implemented and tested before device use restarts. If criminal intent is determined through these investigations the government has given the national regulatory bodies the power to also engage the judicial system.

The learning behaviour of the system mostly happens on the higher level as it requires more players and time to implement rules at a national or international scale (Figure 26). It does, however, happen relationally too. At the systemic level, the learning that happens is how to create a specific kind of safe

device. Initially, experts convene and determine what the standard should entail, and they iterate through this with feedback from many sources. When a standard is launched, it is studied and adopted in whole or part by the national regulatory bodies. The learning happens because as the standard is used and medical device companies make new innovative devices that push the boundaries of the standard, the accountability behaviour gets to the root of why the unsafe situation occurred and can trigger modification of the standard. At a relational level (Figure 25), there is a bit of learning between the medical device company and the user in a supply-demand manner. Relationships building with users can give the medical device company special insight into what needs to be made in return for greater access to the market.

Equity-based laws that are embedded within the standards and regulations could potentially be enforceable by the accountability and learning behaviours of the system. But unfortunately, racism and ableism are encoded into some of the standards as well (Braun, 2005; End Race Correction, 2023; Villines, 2021). Although there are mechanisms to report issues, or "adverse events" caused by medical devices, between the user and the national regulatory body, this path is normally followed by the clinicians, not the patients. So, complaints normally fall within the biases of Western medicine. With enough of a collective, patients can petition the government or report issues through the media. However, this action is difficult as it requires a lot of time and resources to coordinate this voice. Additionally, users can provide feedback to a clinician, but fear this might result in a different level of care (CareQualityCommission, 2013). As a result, there is no straightforward mechanism to remove instances of oppression from this system. Society-level, or accountability to the biases in Western medicine, further becomes mired by the threat clinicians feel of potential malpractice suits and the size of the problem, making them more prone to following the standards than addressing the systemic issues that the individual patient presents. Therefore, the system's emergent behaviours also reinforce the disadvantages of society.

The influence maps (Figure 25 and Figure 26), show the specific locations where the tragedies we explored impacted the influence maps, their tags touching the relevant actors and processes.

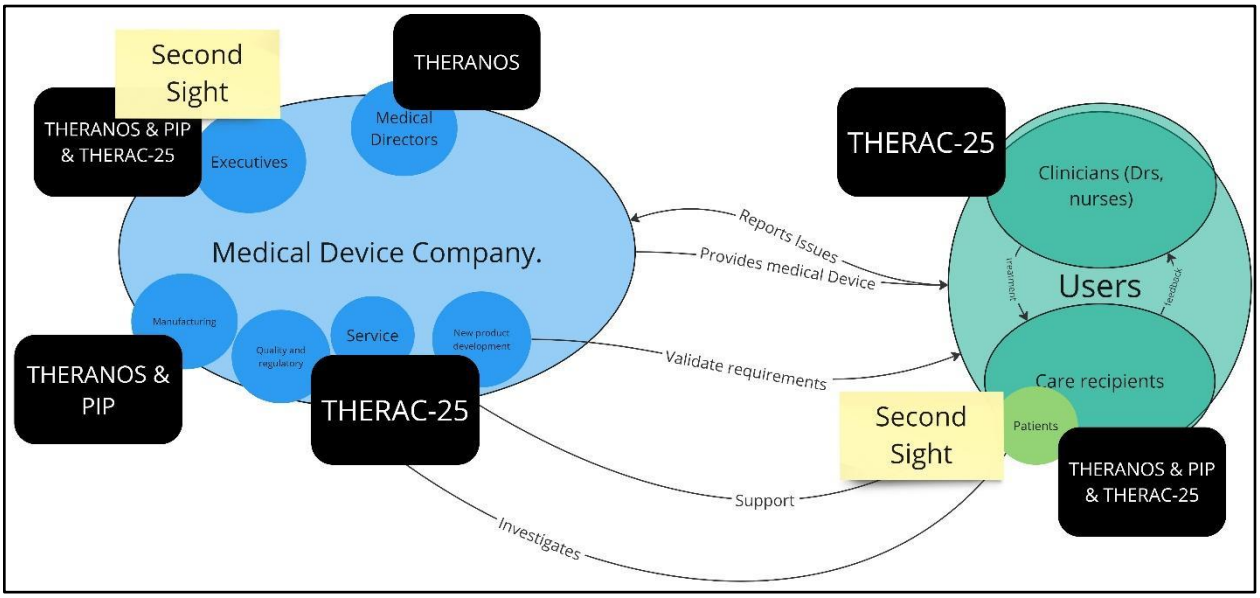

Figure 25: Influence map for Medical Device Company: User – Medical Device relational interactions.

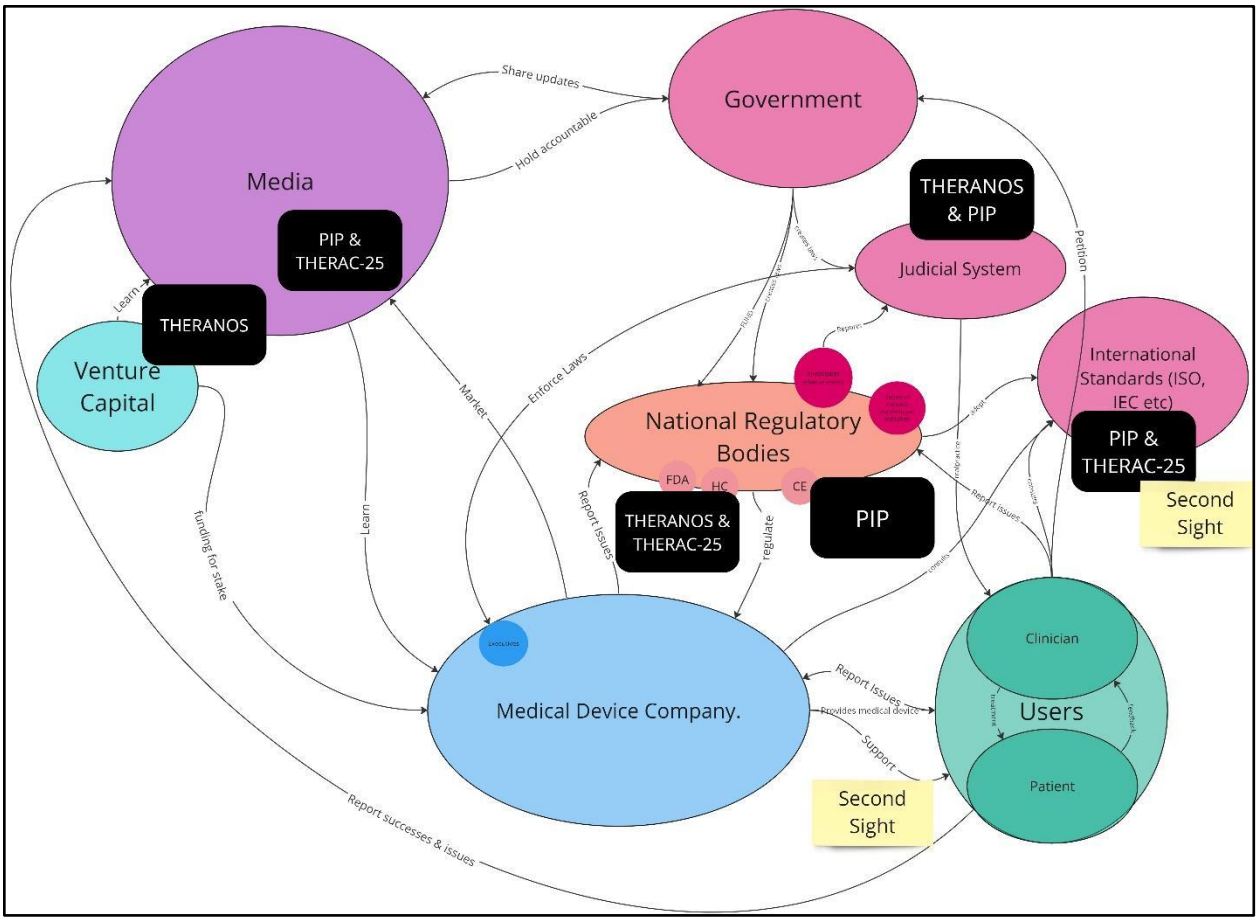

Figure 26: Influence map for Medical Device Development space highlighting systemic Regulatory interactions.

16.3.3.2 Inequity Shown in a Causal Loop.

To showcase the pressures and challenges a user might experience when they chose a one-noted compared to a systemic solution, I created a causal loop from the Second Sight example.

In the Second Sight example, we see a "shifting the burden" causal loop (Namahn, 2020), with the top loop as the option for the user to agree to be a test subject when a society-level system is not built for them (i.e., trying to modify self to navigate a world that is built for those who can see). If a medical solution is not the right solution or is only a temporary solution, there are side effects that can develop such as reliance on the solution. Then, if the solution is removed, or stops working without a backup, the user is back to a place where they are dealing with the same environmental conditions, but this time potentially in a worse state than they were before without having tried the device as they now have a dependence on the solution.

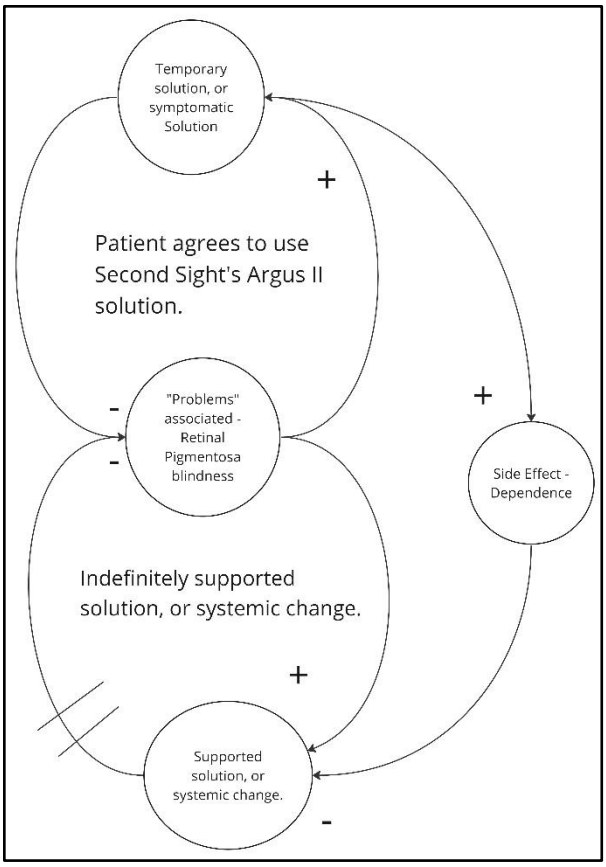

Figure 27: "Shifting the burden" Causal Loop of the Individual choice to use the Second Sight Argus II system. Adapted from: (Namahn, 2020).

The lower loop in Figure 27 shows what it would look like if instead of creating the temporary solution, the environment is changed (albeit a slower change), thus reducing the "problems" (trying to restore a manner of sight is not the only way to navigate and read), but in a way that is supported and not prone to failure in the same way. This solution could have fewer side effects on the user, but it involves societal change, which is currently a hard to sell to those who do not experience the problem and who benefit from the profit of users being "fixed" by the one-note solution.

16.3.3.3 Session 3: Stories of medical device tragedy and system change.

This section tells the stories and shows the work we co-designers covered together during session 3 to provide the hindsight and examples to build our CLA of this current state. We looked at three medical device tragedies and began with a Canadian tragedy, the Therac-25.

Figure 28: A drawing of a Therac-25.
From: (Fabio, 2015).

The Therac-25 was a linear accelerator, a device used in focused radiation treatments for cancer, by providing a beam of electrons that precisely targeted cancerous lesions. The precision meant higher doses could be used while reducing the damage to surrounding healthy tissue. But this also meant that a mistake could result in a large radiation overdose.

Atomic Energy of Canada Limited (AECL) wanted their device to be leading edge, so they made it a very software-based system. In fact, they removed some hardware protection locks that worked in previous versions of the device in favour of software-only controls. This move was supported by their users because these hardware interlocks were physically very difficult to move. Despite these changes, the new device was able to breeze through regulatory requirements based on similarities to the previous model and AECL was selling in Canada and the USA in the early 1980s (Leveson & Turner, 1993).

Shortly after launch, they started to get some questions about radiation overdoses. AECL dismissed these as impossible. When additional reports came in AECL looked and found a faulty microswitch. They designed a fix, installed the updated parts, and instructed the site to continue use. However, soon three more overdose failures were reported, where the patient experienced 100x more dose than the device reported having given (Leveson, 1995). By this point, the sites were finally able to recreate two problems. First, by typing quickly, a technician could toggle to a high-powered beam and cause the software to start shooting higher doses of radiation than planned. Second, the beam sometimes turned on when the patient positioning light was pressed. These failures had hardware redundancy in previous versions of the Therac devices (Porrello, n.d.; *What Happened?*, 2017).

The FDA and Health Canada ordered that all uses of the Therac-25 cease, and AECL had to design, test and install hardware interlocks on all the devices before they went back into service again. But in the

wake of this tragedy, six people were severely overdosed and 4 people died (Fabio, 2015; “Therac-25,” n.d.).

AECL made some big mistakes when they designed the Therac-25, including:

- Assuming that they could run the same tests for a hardware-based and software-based system.

As a result of the investigation, there were changes to the standards and the best practices as enforced by the FDA and Health Canada, the regulatory bodies (Medley, 2008):

- A software testing standard, ISO 62304, was updated and made a different manner of testing required for software that controlled safety-critical actions. Further, within this standard, software that is critical to patient safety needs a mechanical fail-safe.
- There was also an increased understanding that real user feedback was needed to ensure that the product that was being designed matched the way the users worked.

Figure 29: A silicone breast implant.
From: (FDA, 2023).

The second tragedy was centred on a company based in France, Poly Implant Prothese (PIP) (Kirsh, 2017). This company became a worldwide supplier of silicone breast implants. After achieving a place of prominence in the global market, the CEO decided to cut costs and changed the grade of silicone that was being put into the breast implants from medical grade to an in-house variety that is considered industrial grade.

As a result, the implants failed at a rate twice that of medical-grade implants and when they failed, they caused scaring and pain. As these adverse events were reported to regulatory bodies, it was recommended that people who have them, get them removed or replaced, requiring additional surgery and recovery not universally covered by insurance (Medley, 2008).

The executives at PIP made big mistakes in their choice to change the silicone grade, including:

- Taking advantage of the lack of material controls monitoring cosmetics devices for corporate greed.

As a result of the investigation there were changes to standards and best practices (Medley, 2008):

- A new version of best practices was released by the European regulatory body that specifically included implantable cosmetic devices as medical devices, strengthened material controls, and more training for auditors.
- Further, worldwide, the risk management standard was updated to stipulate that cost could not be an excuse for not performing safety mitigation against a risk.
- Additionally, even with the older rules, the CEO was charged criminally for his disregard for human suffering in his single-minded pursuit of wealth.

Figure 30: Elizabeth Holmes, former CEO and founder of Theranos, staring at a small vial of blood. From: (Sherberg, 2018).

This final company we explored is from the USA. Theranos was a company that had a meteoric rise in value before it released its first product and became valued at 9 billion dollars because it appeared it would revolutionize haematology (Hall, 2019). It was headed by a charismatic young woman, Elizabeth Holmes (Figure 30), who claimed to have developed a device that could do a full suite of blood tests from a single drop of blood.

Theranos marketed their device widely before they received clearance to sell (something that is not supposed to happen until the FDA has reviewed results proving a company's claims) and quickly had contracts with Walgreens and CSV for in-store blood testing programs (Sherberg, 2018). But as they launched pilot programs, there were device issues, with delayed results, and unanswered questions about quality. Finally, a whistleblower revealed that Theranos's device could only do a blood test for herpes and the testing had been done by buying competitors' devices and running the samples through them (O'Brien, 2022).

Additionally, during the FDA's investigations, it was found that Theranos had no people in positions of power on their board of directors who had experience in medicine or specifically, haematology (Roff, 2023).

The executives at Theranos made big mistakes marketing a device that they could not prove worked, including:

- Deceiving regulatory agencies and the public about the abilities of the product.
- Not having relevant medical experience among the directors of the company.

As a result of the investigation, there were changes in:

- Availability of venture capital due to increased skepticism.
- Reinforced requirements for transparency to regulatory bodies and conclusive testing before mass marketing.
- Additionally, even with the older rules, the CEO and president were charged criminally for their disregard for the standards and misleading the regulatory bodies and the public.

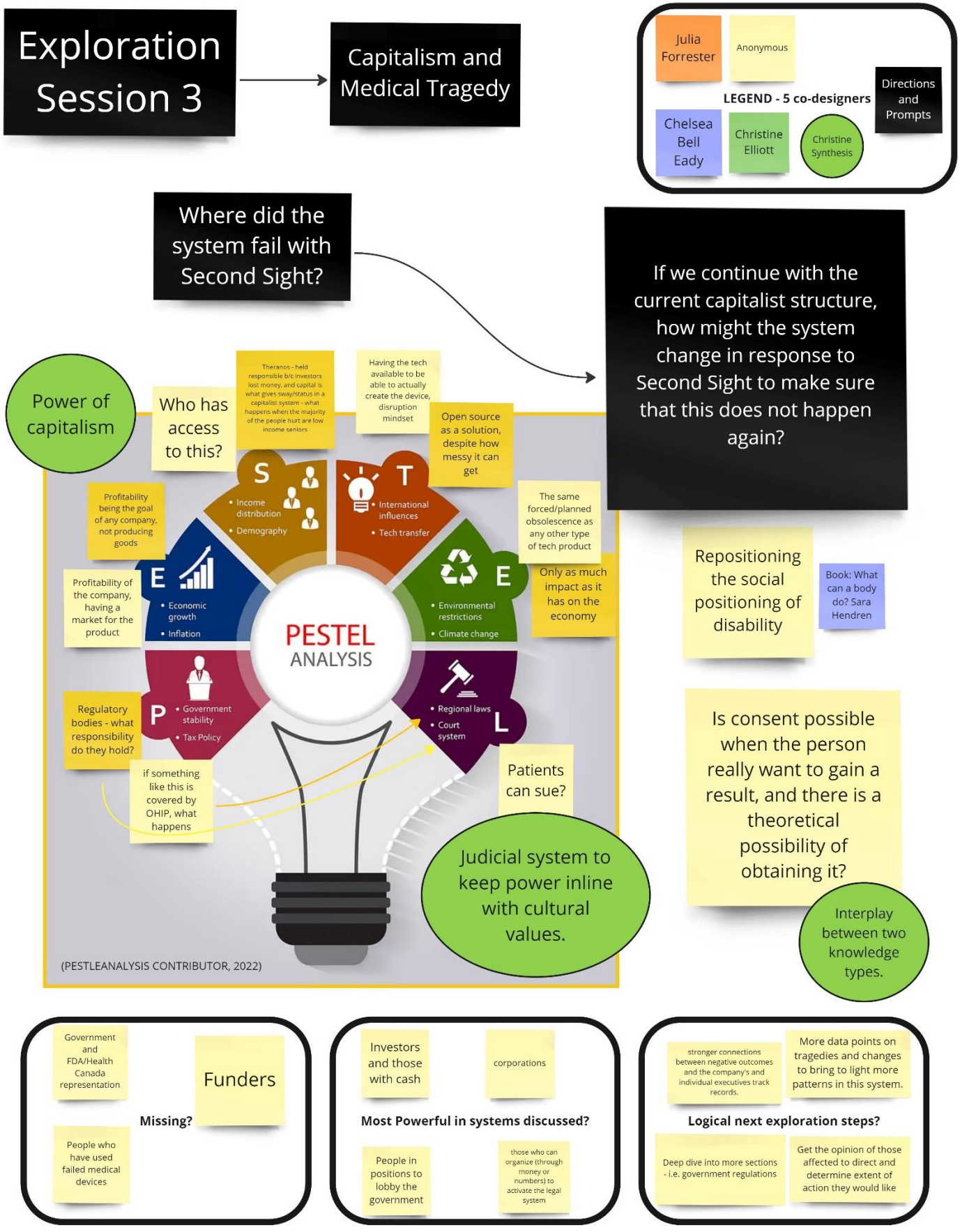

Figure 31: Exploration Session 3, Collage page 1.
Source: (PESTLEANALYSIS CONTRIBUTOR, 2022)

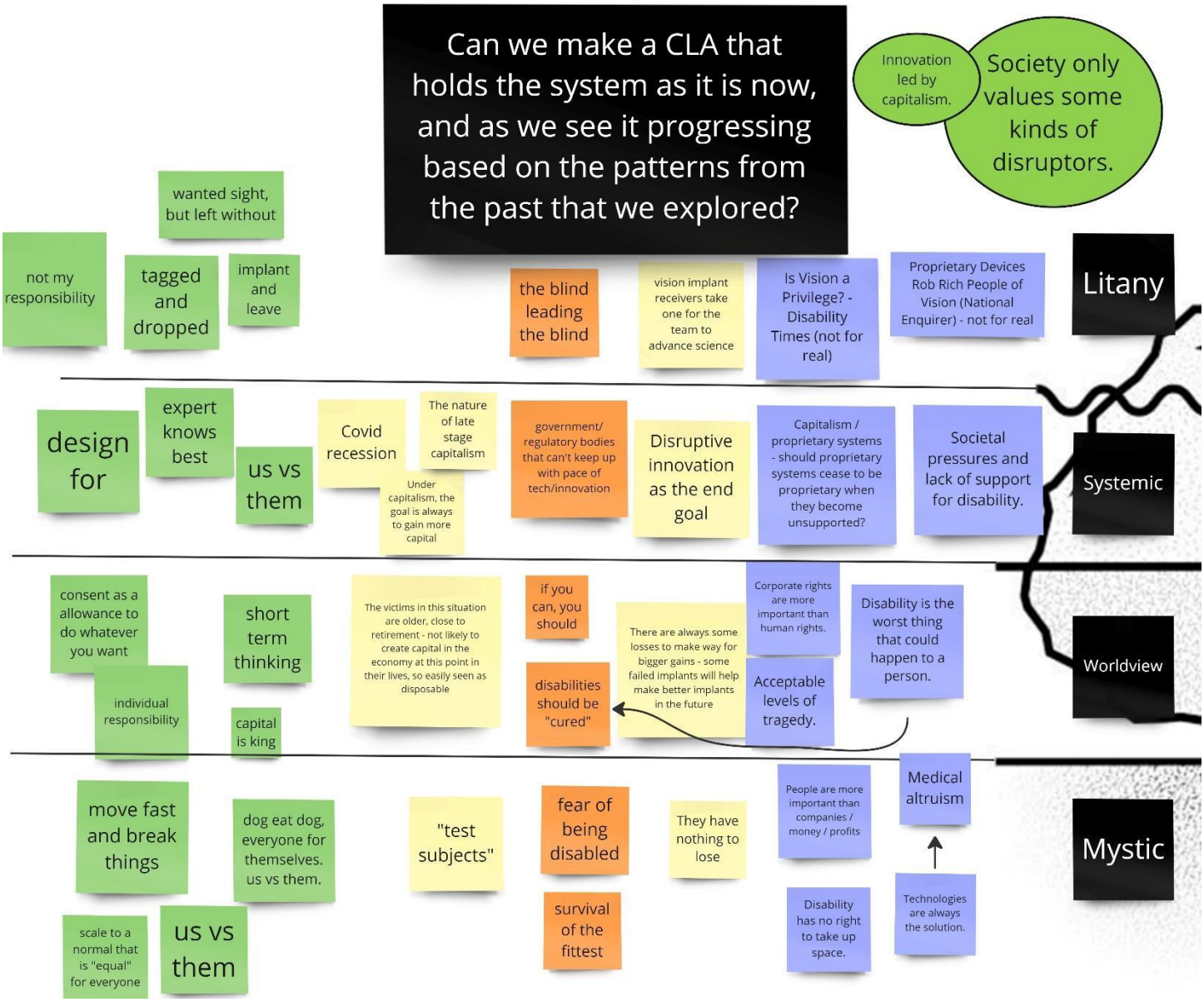

Figure 32: Exploration Session 3, Collage page 2.

16.3.4 Current World of medical device development Causal Layered Analysis.

To pull our work together into a single CLA, I synthesized our discussions from session 3 in the text beside Figure 33. I also found a comic (Figure 34) that held for me many of the topics we discussed during the session. This comic, I imagine, represents the invisibility of the difficulties that an individual might experience to those who don't experience those same conditions. The precarious set of blocks needing a lot of balance to maintain the same level as standing on a single block shows the discrepancy of privilege and perspective between designers in the current system.

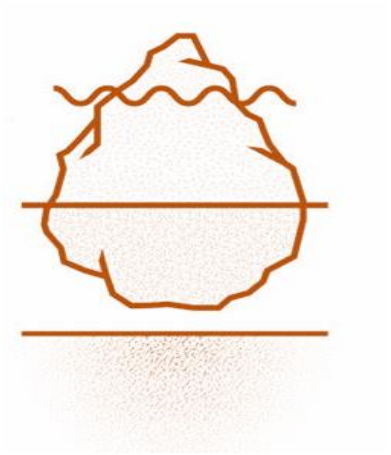

Figure 33: Causal Layered Analysis Iceberg.

Litany – Trial and error without consideration of long-term consequences for all.

Systemic Causes – "Experts" push to fix things and "deviations" are corrected.

Power is gained from normalcy and accomplishments.

Worldview – Capital is king.

Find what can be scaled to the most profit.

Myth & Metaphor – Move fast and break things, until you are forced to be accountable.

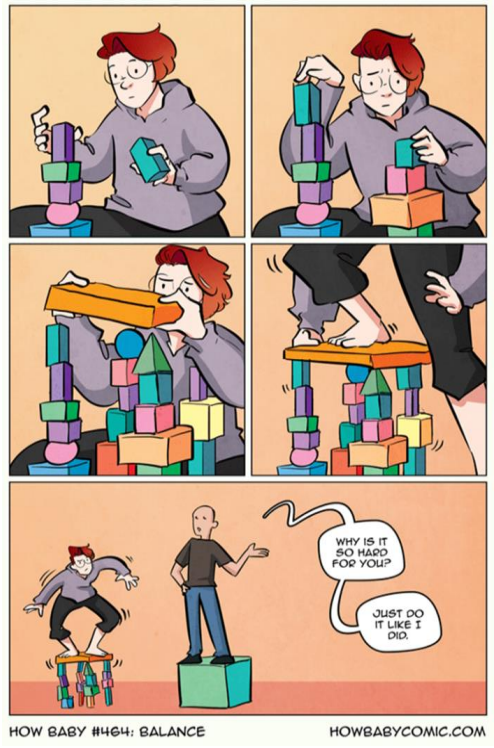

Figure 34: Balance as a metaphor for the invisibility of the effects of systemic disadvantages. From: (Lindsay, 2020). ©2020 Lindsay.

16.4 Stage 4 – Defining: What is a desired future state?

To define the desired future, explore (Namahn, 2020).

16.4.1 What questions were asked in the Defining stage?

- What is a preferred future for medical device development where a tragedy like Second Sight would be less likely to occur?

16.4.2 How did we discover our preferred future?

In this stage, co-designers were asked to read and respond to a prompt about bias in technology in preparation for exploring a possible future (Curry & Hodgson, 2008). The future we explored was based on some of the material I learned from two courses in OCADU's Master of Inclusive Design program, Unlearning and Questioning INCD-6001 (Treviranus & Nicoll, 2021b) and the Inclusive Design Foundations INCD-6002 (Treviranus & Nicoll, 2021a). To do this, we looked at two books. First, key topics within the book *The End of Average* by Todd Rose such as how the use of the mathematical function of average has become so ubiquitous (Rose, 2016). And second, from the book *What Can the Body Do?* By Sara Hendren, stories of the inventions that came from communities where the needs of those normally thought of as outliers were prioritized (Hendren, 2020). We discussed these examples in breakout rooms and finished by exploring the CLA for this world. Following this, I synthesized the notes from this meeting into a summarized CLA for this preferred future world.

16.4.2.1 Session 4: Stories from The End of Average and What Can the Body Do?

I asked the co-designers to prepare for our second exploration session together by reading and responding to an article about the effects of biases in technology today (Centre for Ethics, 2019; Harrison, 2023; Simonite, 2020). The prompt primed the discussion by allowing the co-designers to understand the scope of the session, reflect on their own boundaries and what they might want to share, and have some notes prepared to help ease into the discussion.

To start this session, I wanted to mimic the opacity of different levels of a system by providing an example of a convention whose history is not commonly remembered and not noticed (Figure 35). So, from the Inclusive Design courses and *The End of Average*, we followed the history of how the average became such a universal measurement of human behaviour and characteristics.

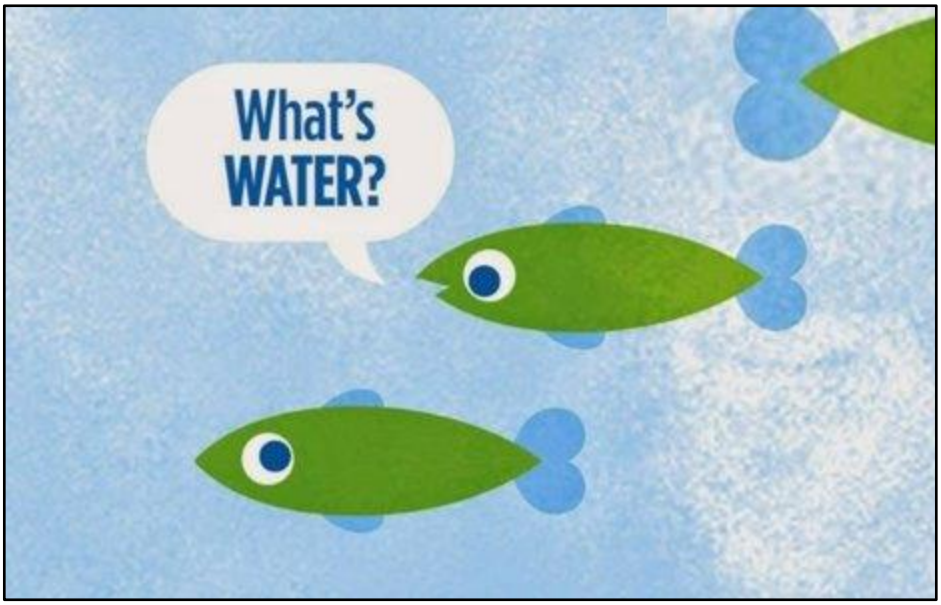

Figure 35: What's Water? A commentary on the invisibility of the systems you are swimming in. Adapted from: (treehouseletter, 2016).

The idea of the average has had a profound impact on the way we think about ourselves and others. It has been used to classify, measure, and predict human behavior, from physical characteristics to life milestones, and even career success. The use of the average, or "averagarianism," morphed through the work of Lambert Adolphe Jacques Quetelet, Francis Galton, Frederic Taylor, and Edward Thorndike (Rose, 2016; Treviranus & Nicoll, 2021a), Figure 36.

Quetelet was the first to apply the concept of the average to humans in the mid-1800s. He initially planned to make a name for himself in astronomy but was unable to access the observatory due to a war. This led him to think about the unpredictability of humans and whether science could be used to make them more predictable (Rose, 2016). He applied the method for measuring planetary speed, which involves taking multiple measurements and calculating their average, to human physical characteristics and later to behaviors and life milestones. He believed that there was an "Average Man," and that all humans deviated from this standard by varying degrees (Treviranus & Nicoll, 2021b).

Galton, a contemporary of Quetelet, took the concept of the average a step further. He believed that there was directionality to each characteristic and that the upper class was better because they had

succeeded at many things. He grouped people into categories ranging from eminent to imbecile, with the royalty of England being the height of eminence and peasants at the opposite end, as imbeciles. This is also where the belief originated that above average is good and below average is bad (Rose, 2016).

Taylor further developed the concept of averagarianism in the early 1900s. He believed that by taking away the individuality of humans and making them into interchangeable units, standard processes for work could be created that would be more efficient (Rose, 2016). He believed that there was one best way to do a task and that managers should optimize the use of standard humans to the process to be as efficient as possible. This idea was later codified by Edward Thorndike and integrated into the education system to create a flow of workers needed for these systems (Treviranus & Nicoll, 2021a).

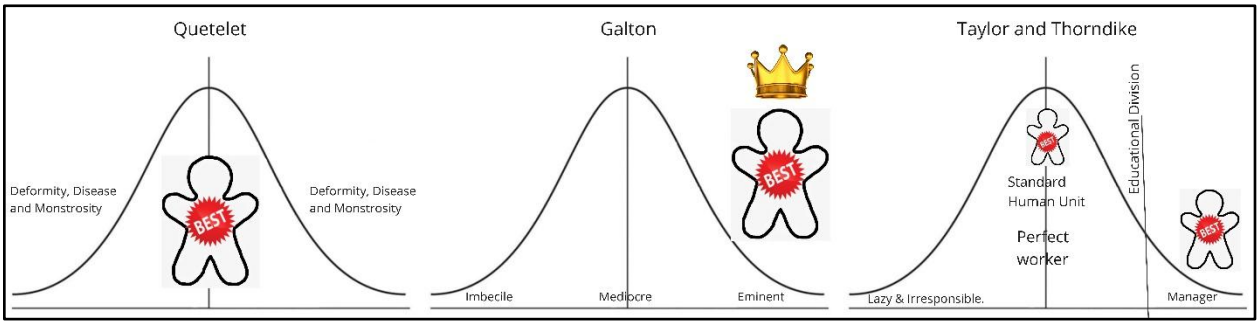

Figure 36: The change in cultural understanding of the average human over time from Quetelet to Galton to Taylor and Thorndike.

The use of the average has been beneficial in many ways. It has been used to increase efficiency, create standard processes, and lift many people out of poverty (Treviranus & Nicoll, 2021a). However, it has also been used as the basis for many harmful practices, such as determining criminality through cranial measurements and eugenics, and the claim of lifting people out of poverty has been questioned recently (Sullivan & Hickel, 2023). When the average becomes the "neutral" goal, and the history of its origin and what was measured is lost, it can contribute to othering people and separating them along lines of intersectionalities such as race or ability. The average is based on what is measured, and this frequently matches the beliefs of those in power and this can become the “single story,” or stereotype (Adichie, 2009; Ruttenberg, 2018), Figure 37. Those who do not conform have higher barriers to entry into the system, if they can enter at all, and do not share the benefits.

Figure 37: Two quotes highlighting the need for difference.
Left image adapted by (A-Z Quotes, n.d.) from: (Adichie, 2009). Right image from: (Ruttenberg, 2018).

The use of the average has had a profound impact on the way we think about ourselves and others. While it has been beneficial in many ways, it has also been used as a tool for harm. We must be mindful of the limitations of the average and not assume that all characteristics we associate with a group of people are inevitably true for an individual.

The End of Average suggests three approaches to centering individuals while still utilizing the advantages of average measurements (Rose, 2016). First, "jaggedness" recognizes that averages can obscure the complexity of individual traits, for example variations in different components of intelligence. Second, "context matters" acknowledges that human behavior can vary based on the situation, even if an individual's behavior is consistent within a specific context. Third, "unique pathways" emphasizes that there is no one set path to achieving a milestone, and individuals may have their own authentic strengths and weaknesses. Finally, after accounting for individual differences, it is important to examine aggregate data to see what insights can be gained (Rose, 2016).

With this in mind, in our first discussion (Figure 39) we co-designers considered how to separate the average from the morals it has become entwined with, and what we could centre instead weighing the medical and social models of disability (2020), Table 3.

Table 3: Definitions of the medical and social models of disability.

Medical model of Disability:	Social Model of Disability:
Body is the location of impairment – individual holds responsibility for coping.	The interactions between the body and the shape of the world make disability in lived experience, and therefore responsibility lies in society and individuals to address.

In our second discussion (Figure 40), we delved further into alternatives to one-note solutions created to address the “average” need. Remembering our equity causal loop (Figure 27), we found areas were centring of difference has been built for rather than one-note solutions that push an individual to fit within what is thought of as “normal” within a society. The examples we went through included different solutions for cosmetics for breast cancer survivors, Deaf Space architectural designs at Gallaudet University where American Sign Language is the primary language (Hendren, 2020), and curb cuts (Young, 2019). In this report we will cover just the discussion of curb cuts.

Curb cuts are a technology that was hard fought for in the USA and only mandated in 1990 with the passing of the Disabilities Act. Before this they were frequently requested but only sometimes built, primarily for areas with disabled veterans (Young, 2019). In the decades before the Act was passed disabilities activists performed guerrilla modifications to their communities, putting wooden ramps over stairs, and in some cases smashing curbs away to create rough ramps to showcase the future that they wanted (Lebrecht & Newnham, 2020). Frequently they came across the legislator perspective of:

> Curb cuts, why do you need curb cuts? We never see people with disabilities out on the street. Who is going to use them? (Hendren, 2020, p. 147).

Highlighting the medical model of disability in the built environment at this time. After activism pushed for passing access legislation more inline with the social model of disability, and curb cuts have become more common, the widespread benefits are very clear. Access is a bit easier for those with mobility devices such as wheelchairs and walkers, but also for those with strollers, bikes, and travelers with rolly-bags.

Figure 38: Examples of a curb cut and ramps to provide access to stores. Left image from: (Grainer, 2017). Right image from: (Patis, 2015).

In Toronto we have a company calling on this "hacker" or tactical urbanism heritage called StopGap that advocates for more accessible architecture practices by making bespoke brightly coloured ramps (STOPGAP, 2023). This makes shops more accessible while also calling attention to the inaccessibility of the built environment.

Through these examples, *What Can the Body Do?* identified key elements of the design process, including respectful design, which prioritizes user needs and involvement in product development, as well as interrogative design, which creates designs that appeal to a broader audience beyond a specific niche. Additionally, the book highlighted the importance of tactical urbanism, which involves creating prototypes in the actual environment where the product will be used to better understand its practicality and effectiveness (Lebrecht & Newnham, 2020; Young, 2019). These principles encourage designers to move away from hierarchical design approaches and instead prioritize empathy, inclusivity, and collaboration throughout the design process (Hendren, 2020).

With these examples, we imagined a preferred future and created the litany level of this world together Figure 40.

Figure 39: Exploration Session 4, Collage page 1.
Source: (Brand, 1999)

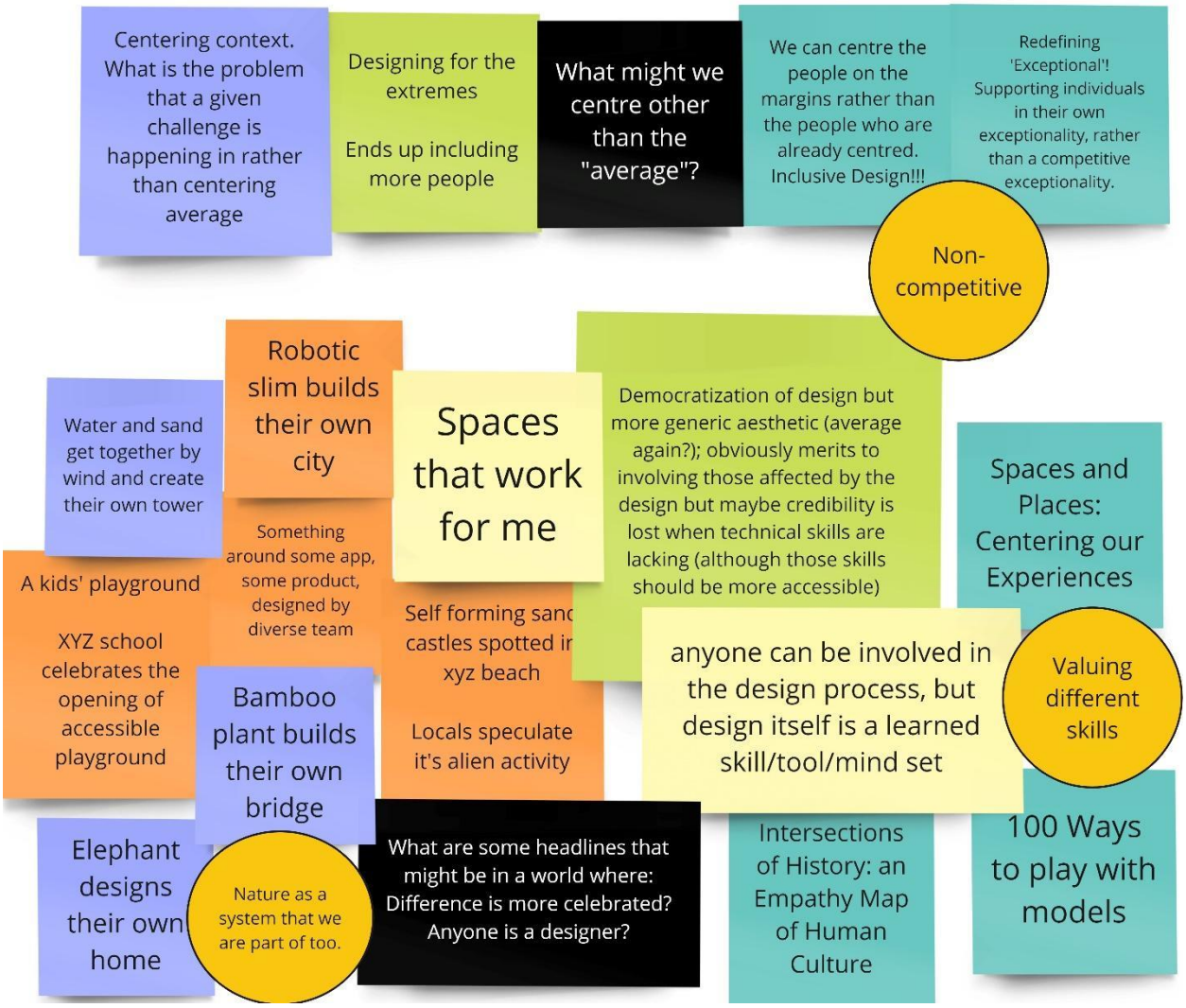

Figure 40: Exploration Session 4, Collage page 2.

16.4.3 Preferred Future world of medical device development Causal Layered Analysis.

To pull our work together into a single CLA, I synthesized our discussions from session 4, which are shown in the text beside Figure 41. I also found a comic (Figure 42) that held for me many of the topics we discussed during the session. This comic, I imagine represents taking the time to sit down and listen to the needs of the person being designed for. Setting up the parameters of the design by outlining their hands. And using that outline, and the window it creates to hear the world through their eyes and move forward together based on that understanding.

Figure 41: Causal Layered Analysis Iceberg.

Litany – This is what I can do. Does this work for you?

Systemic Causes – There is time to learn what works for you, curiosity and value to discover the individual fit, and abundant resources to achieve and communicate.

Worldview – If you share something new you have tried that works for you this might make my experience better.

Myth & Metaphor – "Because we've Always Done It This Way" is a dangerous precedent.

Centring, and learning from difference increases opportunity.

Figure 42: Poem analogy for the preferred future. From: (Gregory, 2003). ©2003 Danny Gregory.

On the street with my boy and he said, "Dad, you could draw

my hands if you want to"

and, of course, I did.

We sat down

on a bench on

6th ave and

he sat very, very

still while I traced his hands.

then he held them up and we looked through his window.

16.5 Stage 5 – Exploring: Moving between the current and preferred worlds.

To explore the possibility space imagine different ways the preferable future could occur (Namahn, 2020).

16.5.1 What questions were asked in the Exploring stage?

- What is valuable about the current world that we would want to retain in the preferred world?
- What seeds of this preferred future world are visible in the present?
- What are some tensions and forces that could move us toward our preferred future?

16.5.2 How did we explore the factors that could affect the future?

In this stage, we co-designers revisited the two worlds and immersed ourselves in them. Through breakout room discussion we looked at what in the present would be helpful to retain, and what seeds of the future are visible in the present. After sharing our findings, we explored some of the factors that might help push the transition between the current and preferred futures through the questions of: what was helpful to retain? What are some pockets of the future in the present? and what other forces might help move from one to another? (Roworth, 2018). Following this, I explored our results against the levers of system change (Meadows, 1999).

16.5.3 What can help us push toward the preferred future?

A lot of the examples discussed during the co-design sessions and in this paper have been about activism led by those directly affected by oppression. Centring the voice and needs of Equity Designers is always important and these are the forces that should be pulling us towards our preferred future. In this section, the examples I share are specifically focused on actions of developers that can help shift between the current and preferred future worlds, first by looking at the #techwontbuildit movement as a suggestion of a movement type that should be retained as we head towards the future, and second, by exploring the way companies that make cochlear implants are acting in the interests of their users while regulations are not yet ratified.

16.5.3.1 Helpful to retain going into the future.

There is a role for those who are part of the design process, but don't have executive powers, to act in alignment with equity goals and hold executives accountable when they see inequity in the systems they are designing. Frequently designers or developers need the paycheques that their employers supply and this sometimes dampens questioning of the values of the company they work for. Acting in line with values is imperative for change to occur, and it is more powerful to do in the collective. In this section, I will outline an example of a developer lead movement, #techwontbuildit, that managed to have an impact on the contracts that their executives chose to pursue (Costanza-Chock, 2020). This is presented as something that is present in the current world that would be helpful to retain in the transition and future worlds.

The #techwontbuildit movement emerged in response to growing concerns about the role of technology in enabling harmful policies and practices, particularly those related to immigration and surveillance (Lahoti, 2019). The movement began in 2018, when employees of major tech companies, including Google and Microsoft, began speaking out against contracts with government agencies such as Immigration and Customs Enforcement (ICE) and Customs and Border Protection (CBP). The employees argued that their companies should not be providing technology that could be used to facilitate human rights abuses or violate people's privacy (Costanza-Chock, 2020).

The movement gained momentum as more tech employees and activists joined the cause, staging protests and circulating petitions. Some employees even resigned from their jobs in protest. As a result of the pressure from the #techwontbuildit movement, several major tech companies, including Microsoft and Amazon, announced that they would not renew their contracts with ICE and CBP. Other companies, such as Salesforce, faced pressure from their employees to reconsider their relationships with government agencies that were perceived as problematic (Lahoti, 2019).

The #techwontbuildit movement had a significant impact on the contracts that big tech companies took, forcing them to consider the ethical implications of their business decisions. It also highlighted the power that employees can wield when they organize and speak out against injustice within their companies. However, some critics argue that the movement was not as effective as it could have been, as some companies continued to work with government agencies that were implicated in human rights abuses. Overall, the movement helped to raise awareness about the role of technology in facilitating oppression and the responsibility of tech companies to act ethically (Lahoti, 2019).

Developers can work together and gain a collective power to keep the company accountable to equity values, and this is helpful to retain while moving toward the preferred future.

16.5.3.2 Pockets of the Future in the Present.

Outside of the national regulatory body's required rules for a device, companies can decide to mobilize together to act in the interests of their users while regulations are not yet ratified.

One of the prompts from session 3, (Strickland & Harris, 2022b), compared the loss of support for the ocular implant by Second Sight with how the cochlear implant market has developed. I see this as a pocket of the future in the present where companies work together outside of the standards development and judicial arm of the medical device development regulations to ensure that they support their user even if the user may not always choose their model of a device over a competitor's.

Cochlear implants are a polarizing technology because of the push towards the normalcy of hearing and the difficulties some people have in adjusting to the device (Goodwin, 2023). However, placing cochlear implants in juxtaposition to the Second Sight ocular implants, comparisons can be made on similar technologies where companies have made different decisions of how to support their users (The Current, 2022). There have been many iterations to cochlear implants and there is a strong push between the companies who make the devices to have body internal components standardized and interchangeable with competitors' devices and iterations of the device be backward compatible (Strickland & Harris, 2022b). The companies additionally have warranties on their products which puts more responsibility on the design teams to make sure that the robustness of the components is up to the task of long-term function.

> No regulations or voluntary standards exist for how long a piece of hardware or software should be supported, but [..] the company starts by offering a 10-year warranty on its implants and a 3-year warranty on its sound processors. As the company develops each next-gen sound processor, its engineers work to ensure that the new technology works with all of the old implants, which are often technologies "from a different era." - Scott Housley, VP Marketing Cochlear (Strickland & Harris, 2022b).

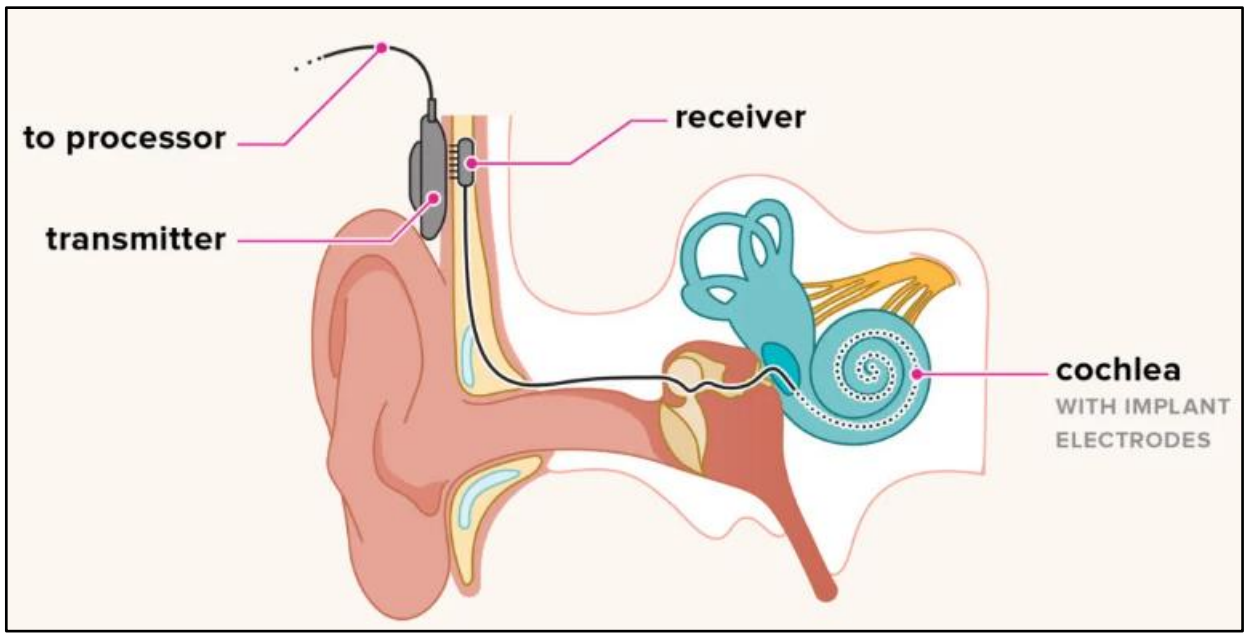

Figure 43: Cochlear implant.
From: (Goodwin, 2023).

Cochlear implants are a larger and more developed market than that for the Second Sight ocular implants and 5-10 years is a start for length of life for components (Cochlear, 2023; Cochlearimplanthelp, 2015), even if it is not the length of use of the product, which can be the length of a human life. Another suggestion this industry has tried is involving ethicists in the design process (Strickland & Harris, 2022b). Further future looking suggestions include adding requirements to make the technology compatible with open sourcing, or working with patient advocates to ensure a serviceable back end of the technology is available to patients so they might be better able to get support for their implanted devices even if the company dissolves (Strickland & Harris, 2022b). These latter two are sometimes hacked by patient support, but currently it is a fairly regulated path because of the medical device manufacturer's regulated responsibility to cyber security concerns (IEC 62304:2006, 2015).

Collectives at the level of competing companies could share the costs and the benefits of ensuring that the devices that they produce are a good fit for their users by developing best practices within their industry. This might be a pocket of the future in the present.

16.5.3.3 Tensions and forces between worlds.

Donella Meadows was a prominent environmental scientist and author who developed a framework for understanding how complex systems can be changed. She identified 12 "levers" of system change that could be used to create change in a wide range of systems, from environmental ecosystems to social and economic systems (Meadows, 1999). These levers include things like changing the rules of the system, altering the power dynamics within the system, and shifting the mindset or paradigm that underlies the system. Meadows emphasized that no single lever is sufficient on its own and that different levers may be more or less effective depending on the specific system in question (Meadows, 1999). Her framework has been influential in a variety of fields and is often used as a starting point for discussions about how to create meaningful change in complex systems.

Based on our co-design work together, I positioned some of the topics we delved into in a sketch of the leverage points of system change by Donnella Meadows (Meadows, 1999). I utilized the four-category approximation of the leverage points presented by the United Nations Development Program (Bovarnick & Cooper, 2021):

Physical Events: Constraints, parameters and numbers, buffer sizes, materials stocks and flows.

Informational/Patterns of Behaviour: Relative delays, negative and positive feedback loops, and information flows.

Social/System Structure: Rules of the system, structure of the system, goals of the system.

Conscious/Mental Models: Mindset/paradigm, Power to see the paradigm as such.

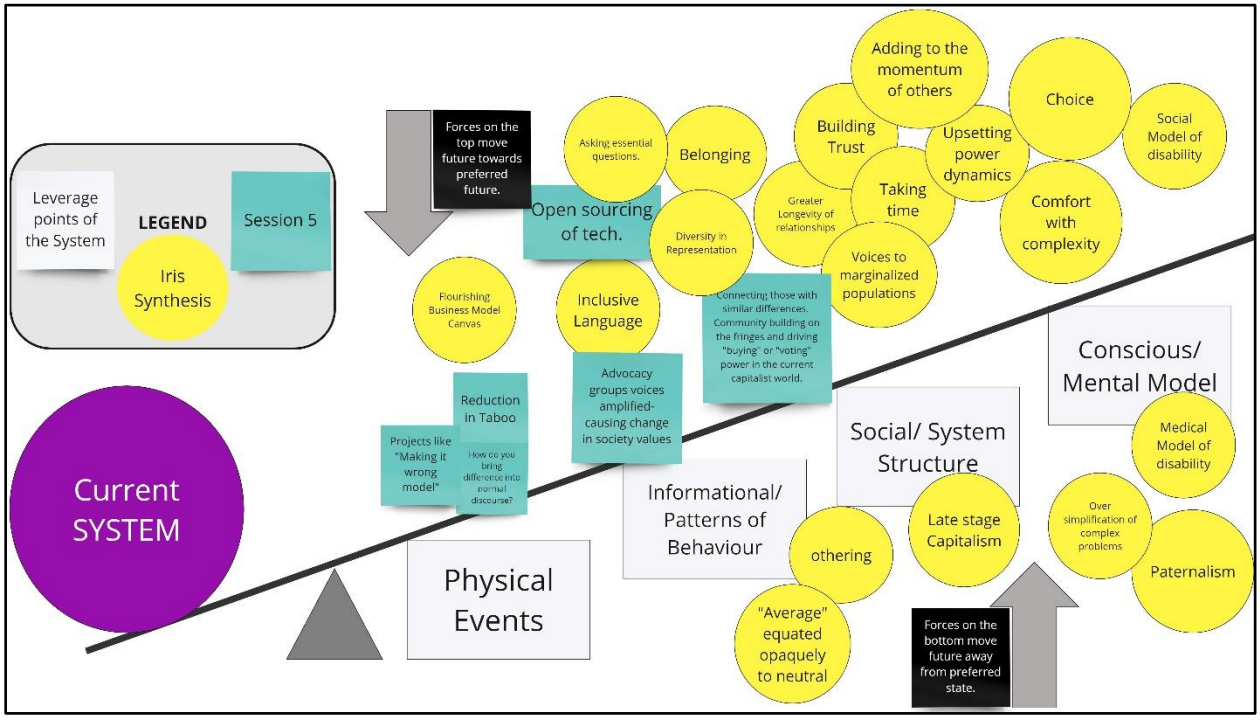

Figure 44: System levers to help and hinder moving between the current and preferred worlds.

The worlds that we discussed in our co-design sessions together focused strongly on the highest themes on this diagram: Choice versus Paternalism and the Medical and Social Models of Disability. However, as Donnella Meadows emphasized, many levers will be used in order to move from the system in its current configuration to the future (Meadows, 1999).

16.6 Stage 6 – Creating: What can I do?

To create interventions for change: Where are parts in the system where change can help move from the present towards the desired future (Namahn, 2020)?

16.6.1 What questions were asked in the Creating stage?

- What parts of the system can I make suggestions for on my own?
- From my experience in business, and quality and regulatory roles within medical device development, how might the tools of these trades become more aligned with the equity goals of this work?
- Are there additional places to explore to help push the system toward the preferred future?

16.6.2 What happened in the Creating stage of the Exploration Project?

This is the solution suggesting part of the Exploration Project. This is where continuing as a co-design group to develop long-term, complex, and integrated solutions is most important if the solutions are to be put back into our shared community. However, this co-design process was a practice-run, and the group of people who I convened do not plan to continue with this project. So, to apply my findings to the future of medical device development space, in this section I critique the tools of this profession, to which I belong.

For me, this part of the work marks a shift from looking at possible changes in the system to looking at the tools of my trade and how these interface with this system. I feel comfortable exploring possible avenues of development without co-designers because of this shift.

16.6.3 How might we change medical device development documentation tools?

Medical device developers, rather than users, are in the position of power to decide what they develop within the medical device development space. According to the coin model of critical allyship, increasing awareness of the inequities in the systems in which they are developing is a first step that could help achieve more equity in this system (Nixon, 2019).

In this work, it emerged that power and responsibility are concentrated in the executives of the company making the medical devices as we developed the actors map Figure 23 and the influence maps Figure 25 and Figure 26. Within a medical device development company, executives are responsible both for attaining the business goals of minimizing costs and maximizing profits and for the safety and effectiveness of the device by presenting a product for sale within the regulated medical device environment (ISO 13485, 2016; ISO 14971, 2019).

The flourishing business model canvas (Figure 45) is a tool that could address this dual need, as it is well supported in literature to aid with business resilience and sustainability (Upward, 2016; Upward & Jones, 2016), and therefore could be a draw for executives to help their businesses succeed. To do this, the flourishing business model canvas has three additional sections outside of the rectangles representing the business, showing the environment, the social conditions, and the economic conditions the company is working in or planning to work in (Upward, 2016). These sections are showing higher levels of the system than what is commonly explicitly considered in many businesses including in medical device development (Osterwalder & Pigneur, 2010). Starting to use this flourishing business model canvas to create a device, could lead to opportunities for increased awareness of the real complexities of the environment and increased device resilience which is a real, long-term benefit for any business (Upward, 2016).

Additionally, the central value section is different on the flourishing business model canvas compared to the version originally proposed by Osterwalder (Osterwalder & Pigneur, 2010). In the flourishing version, values are subdivided into values that are created and values that are destroyed for each of the stakeholders (Flourishing Business Canvas, 2023). This is an important difference because it could be used to put front and centre the impacts on users of choosing to use the device (e.g., changed dependency levels on a device compared to support that had been accessed through other parts of the community (16.3.3.2)). Additionally, this section in conjunction with the society section could be used to determine the alignment of the proposed device to larger equity goals. From a business perspective, this increases the avenues for possible innovations, and from an equity perspective, this awareness could help open an area for dialogue and possible societal changes.

This tool is not going to force awareness to happen or force a company to act more equitably. But this tool has proven business value and opens the door for different conversations about why and how a device is going to be created based on the biases and inequities of the system the product will be launched into.

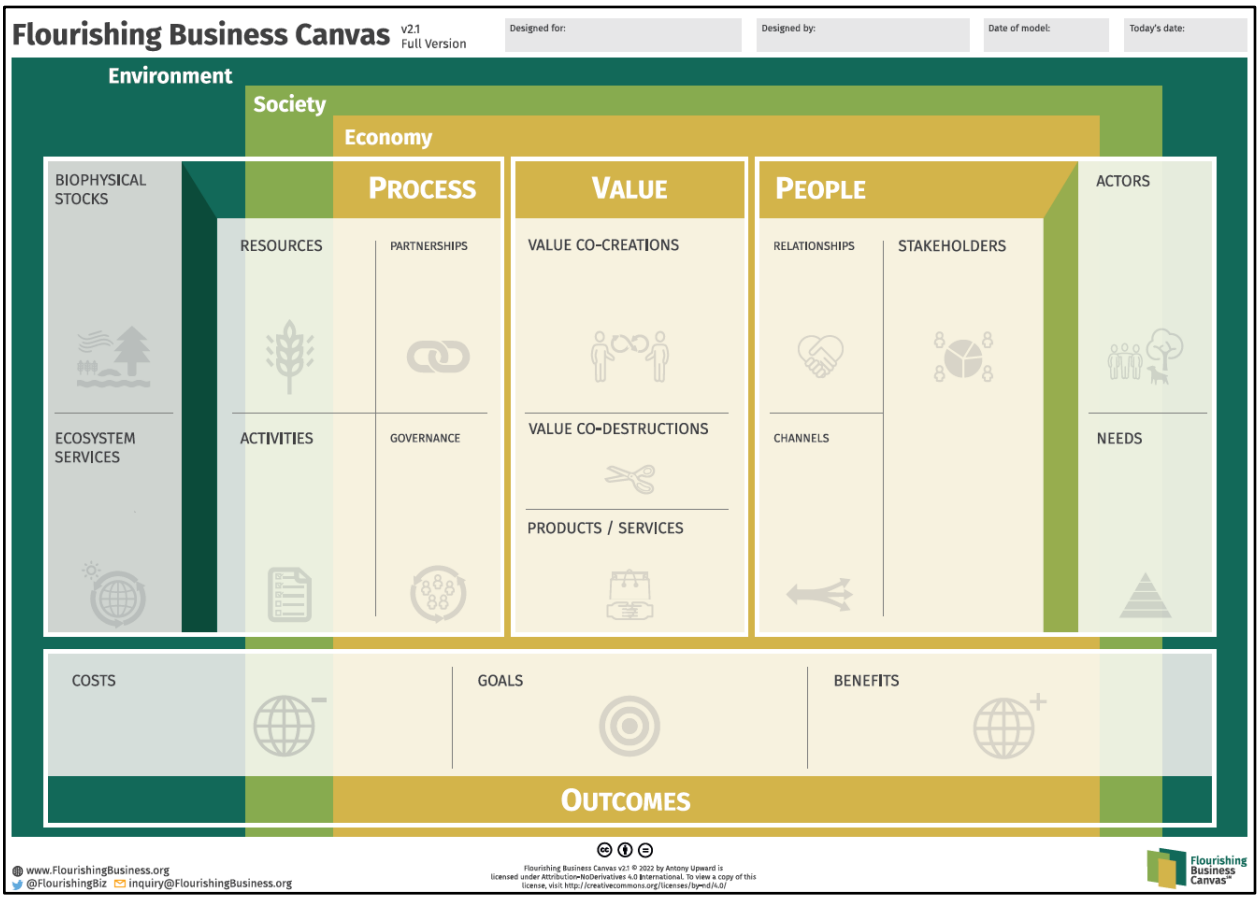

Figure 45: Flourishing Business Model Canvas.
From: (Flourishing Business Canvas, 2022). ©2022 Antony Upward.

Use of the flourishing business model canvas could have downstream effects on the quality and regulatory assessment of the device. It could allow broader environmental scanning to be embedded within the risk management assessments.

A common tool that is part of the risk assessment within medical device development is the Failure Modes and Effects Analysis framework, or FMEA (Quasar, 2022). This tool looks at many manners of a proposed product's potential to fail. For each potential failure that is conceived, a cross-department team explores reasons why this failure might occur (through both normal use and misuse), the likelihood of it occurring, and the impact of it occurring. The team then creates a plan to mitigate both the likelihood and severity of it happening through documented design changes.

A universally understood drawback of the FMEA tool is its single-source methodology of analyzing risk and failure (Lyons, 2016; QualityMedDev, 2021). The structured approach to using this tool generally looks at the anticipated workflow of the product under-design, its manufacturing and transport, and potential intentional and non-intentional misuses. However, there is no view of the larger systems that the device is used in. The need to fill in the society, environmental, and economic sections of the flourishing business model canvas could open this area for exploration within the FMEA or other failure discovery risk assessment methods. Adding questions about the consequence of launching the device into the world, such as those from the reflexive stage of participatory design might broaden the view of the complexity of the system the medical device product is going to be launched into.

- "Who will be the most impacted by this design? [..]
- Will this intervention create dependency of the community on the designers?
- Which skills are created, [and] which are erased? Whose abilities am I enabling?
- How might we modify the design to mitigate the disruptive qualities?" (Qazi, 2018, p. 45)

Creating more awareness about equity issues on the chance that different questions are asked, and processes and products are changed slightly is a very small step.

16.6.4 Collectives and mindset change.

In their article on co-design, Qazi notes, "how practitioners understand design and participation shapes how they engage in the process of participatory design" (Qazi, 2018, p. 20), and thus can be used to both perpetuate current inequities or to democratize design. Similarly, what we additionally found from the example above of aligning the cascading tools towards equity and inclusive designs is that within capitalism, both the business strategy and the product development approaches must be aligned to this goal for real changes in outputs to occur. If this equity alignment occurs at or above the business strategy level, these values allow facilitated investment of time and resources to create competencies in exploring the broader systems and may ultimately create more equitable designs.

Taking more time to create a product in a capitalist environment, when a smaller minimum viable product is possible is a harder business case to make, but not impossible.

From examples in session 4 (16.4.2.1), demonstrations of good solutions by users through guerrilla hacking, tactical urbanism, or pockets of the future, can be used to help show the value and extensive use of more equitable, or social-model-of-disability-focused proposals. This is the start of an in-situ dialogue that (Schwab, 2017) outlined for the crowbar and might be enough to interest executives and create an enticing business case. However, if the current expert-user power differential remains within the system and the power to design remains focused in the medical device developers, these suggestions will likely be taken by the development companies, interpreted through their lenses, and sold back to the user. This perpetuates the power dynamic and again does not create an embedded, complex, or equitable solution.

From session 5 (16.5.3.1), a manner that can help move towards the preferred future is that workers can act as collectives and demand that executives follow more equitable solutions and spend on making the design process more inclusive and holistic. This might be difficult if a worker is relying on the company for salary, but there is a lot of precedent from union activism and social justice movements to showcase the power that collectives can wield. This type of action can push for change, but the end result of these changes needs to be codified into regulation or changes in cultural values for businesses not to just revert to previous behaviour if the collective becomes less effective at holding them accountable. Collectives should quickly engage with those they are in solidarity with to ensure that they are pushing in alignment with the goals of equity seekers (Nixon, 2019).

We do see from the influence maps and from the stories of the tragedies from session 3 (16.3.3.3), that the national regulatory bodies can change what is made by medical device companies, by introducing standards and by the threat of referral to the judicial system when non-compliance or adverse events occur. In the absence of equity alignment at the business level, standards could be co-designed and enacted, but these require a lot of time and resources and therefore prolonged support from the government levels to make sure that this is done authentically.

At the end of the day, many of these ideas are asking permission for equity. This is not right.

There are a lot of places in the world right now where there are inequities. There are real immediate problems that can cause all manner of harm to those who are oppressed. These urgent issues need to be addressed without having to take the time to convince the unaffected that they are important. Unfortunately, equity seekers are not in power, so how can we change the way that we make barriers in a way that protects groups that have thus far been othered by those in power? One component of this may be returning to an awareness step so powerful collectives can be formed to demand action on addressing real needs, while working together to realign power with these values.

16.7 Stage 7 – Fostering: Next Steps and Future Work.

To foster transition: Share how you envision putting the changes that you outlined into the world and how this might enact behaviour change in the system (Namahn, 2020).

16.7.1 What questions were asked in the Framing stage?

- How can the learnings from this project be shared?
- What are some of the next steps for this project?

16.7.2 Sharing Lessons Learned.

Two sections of learning can be shared from this project: 1) a better understanding of co-design in practice, and 2) how different tools within the medical device developers tool kit might become more reflexive of the systems in which they are used.

To foster a better understanding of co-design among SFI masters students: Although I learned about participatory design through SFI, the intricacies and implications of the process were not covered. **There are courses with this practical co-design focus offered in the Inclusive Design Master of Design program** that could be suggested for those interested in learning more. Additionally, **reviewing some of the power-reflexive questions posed by co-design** (Qazi, 2018) within SFI courses could lead to a greater understanding of the impacts of choosing co-design as a process.

To share this work with medical device designers: As outlined in this work, medical device development tends to focus on designing within the niche where a problem has been found, rather than asking what other systems might be causing the issue to occur. Developing a course or **workshop for quality and regulatory professionals could help them to better understand the system and examine and modify the tools they use** in alignment with seeing the systems surrounding medical device development.

16.7.3 Next Steps.

I plan to take the lessons I learned together with the reflexive practices I developed and applying them to my own design practice. In addition to implementing the sharing suggestions, some other next steps could be taken to further the work in this project:

If I continue this work, the co-designers suggested including groups who were missing from each of the discussions we shared, following the Virtuous Tornado methodology (Treviranus, 2019). These proposed groups were both more powerful and more related to the problem spaces that we were exploring and could hypothetically be asked to join us to **expand on the scope of the current work and create more complex or system-embedded solutions**.

In order to help with the adoption of moving from a regular to a flourishing business model canvas, Equity and Allied Designers could co-author **white papers on how viewing the system in the medical device through the flourishing business model canvas context can be beneficial to business executive needs**. Placing examples of these in general circulation could aid in their adoption.

If medical device co-design is tried in an embedded project with vulnerable groups, **investigating the use of different tools for systems and foresight exploration** from the community could help produce futures that are more resonant for them. The system exploration and foresight tools this project used were developed to help strategy in war (Jones & Bowes, 2021), and building from a different base might have a structure that more resonance within the community that the design will ultimately reside.

Another avenue to explore applications of this work is artificial intelligence (AI). Similar to the discussion on the obscured use of average, AI amasses human data and applies probabilities to it to give the "best" answer, while operating within many systems and with opacity on the path of origin of the "why" of the recommendation. Specific standards are being developed to control its use in medical device development (CIFAR, 2021; FDA, 2022), and many "experts" talking about how best to apply them. However, **applying the democratizing aspect of co-design in looking at the futures of AI space and generating a speculative or experiential future could be used to question the equity of having just experts creating standards with such potential for far reaching ramifications.**

Finally, this project was deeply reflective on the self, relational and system levels, but this was all within a human context. Another level to add, that would help to offset the Western biases of this work, would be to **further consider the way we are talking about the resources that we are designing with and the closed, interconnected system of the planet we live on**.

17 Conclusions from Collaboration and Exploration Projects.

17.1 The Collaboration Project.

In an article on co-design, Jess Mitchell states that you can really only determine if you did co-design in retrospect (Mitchell, 2021). My retrospective analysis of this project is that we did *not* do co-design, although we *did* manage to imbue many of its tenets within the group work that we did together. Two aspects of the project worked at cross purposes to co-design and instead led to more of a conventionally prepared facilitated meeting: 1) the structure of the project, and 2) the stakes of the participants.

17.1.1 Structure and stake, compared to conventionally prepared facilitating.

Compared to conventionally prepared facilitating, this co-design practice-run was more time and labour intensive than my experiences of design under more prescriptive facilitation. Even taking into account additional work that resided with me to document the research project, the two sessions at the start co-designing how we would be designing also added time and work when viewed through the conventional facilitating lens of productivity towards the systems exploration goals. However, especially in the online environment, a tension exists among goals that seemed at odds with one another: showing respect for participants' time by coming prepared with a firm agenda, and showing respect by building uncertainty into the meeting, and sharing unstructured time to build trust.

I believe some of the pre-defined structure of the project made co-design difficult. The promise in the initial consent of the project, to explore systems and foresight tools together, was enough to pre-determine many of the required deliverables and made it difficult to do a lot of deviation within the finite time allotted. Two ways to get closer to co-designing, which stem from the review of this project are to make the consent at the beginning of the project broader and while designing the ritual with the group, co-designing the exploration path.

The co-designers' stake in this practice-run project was very different from an embedded co-design project. This impacted our ability to actually do co-design. The group of co-designers I worked with were all students at various stages of Master of Design Education at OCADU. There is a final project or thesis that we all must do to complete this degree, and they all knew that the sessions we were doing together were mine. While I tried to encourage interrupting and suggesting changes to the format, they knew the scope of an MRP and the impact of change from personal experience. Because of this, I think there was some hesitancy to push against the frameworks that I proposed to explore the medical device development space. I also had the most invested in this particular framing of the topic, and we were all fairly new to using these tools, so there was strong interest in going through the tutorial steps of what was proposed, as opposed to proposing a different tactic to delve into this topic further. These differing goals and stakes in the solution had a very strong impact on who directed the path we followed, and thus the co-design.

Pre-defined structures and differing stakes among co-designers can limit the ability to deviate from the established path and truly engage in co-design. However, it may be possible to overcome these challenges and achieve a more collaborative and participatory approach if the initial consent was broadened and the exploration path was co-designed with the group. Ultimately, co-design requires a delicate balance between structure and flexibility and an understanding of the co-designers' motivations and goals.

17.1.2 Did we build trust and community in a design-centred collaborative format?

I think that we came together as co-designers with a high level of trust for the type of activity we were pursuing and framing the work as a "practice-run" made the stakes of the outcome relatively low. Given this starting point, I don't think I had the right precision tools in place to measure changing levels of trust and community within this group. However, I think we did enjoy our time together, especially in the non-critical path actions of talking to each other socially, and we definitely influenced each other's thinking about the problem space. These suggest the method succeeded in developing deeper community.

17.1.3 What is the ritual of meeting that we develop?

The ritual we developed is shown in Figure 20. This ended up being less useful than I thought it would be at the beginning of the project because it is something that needs to be reflexively built for the group that comes together to participate in the design.

17.2 The Exploration Project.

This project helped us co-designers to frame the medical device development space as a system with emergent, dynamic behaviours and see it as part of a ecosystem. This allowed me to think about ways the tools my profession of medical device development use might be shifted into greater alignment with more equitable futures.

17.2.1 How did the boundaries of the problem space we explored change because of this co-design approach?

The boundaries of the co-design project seemed more porous than a conventional facilitation project. This report minimized this difference to bring the work into focus around my original goal of finding equity alignments within my work. The collaged and post-it-ed images of the work we did in our sessions together attempt to highlight the contributions of the co-designers and show some of the additional different ideas we explored together.

Very specifically, I feel the future that we developed together was greatly influenced by the co-designers' discussions and their different educational backgrounds as a mix of Strategic Foresight & Innovation and Inclusive Design students. One of the biggest changes was a co-designer's suggestion to include work from the book *What Can the Body Do?* by Sara Hendren in the exploration of the preferred future. This really galvanized the different core beliefs in the current and preferred worlds between the medical and social models of disability. Additionally, this text provided examples of pockets of the future in the present that drove discussions about the forces to move from the current world to the preferred.

17.2.2 What factors could influence moving the current medical device development space to a more equitable design methodology future?

Moving toward equity requires more than token actions, and the power to move the system depends on what leverage point it is implemented at.

Adapting some of the current tools used within medical device development may be able to increase awareness of the different systems the device and the users are steeped in, and this might even change some of the questions that the individuals using these tools start asking. On its own, however, adapting current tools is unlikely to bring about large changes or equitable solutions. The process of co-design

could be brought into current practices as well, but, if the inclusion of co-design techniques is done within the current reductive values of capitalism, co-design will not actually be created. Like running through a "playbook" of design thinking, the same extractive, expert filtering-user experience dynamic will remain to maximize profit while creating a minimum viable product.

The change needs to come at the level of the executives in the medical device companies, or at the level of the standards and national regulatory bodies within the medical device development system (Figure 26). This is the worldview and myth levels within the CLA and the social/system structure to conscious/mental model stages within Donella Meadow's leverage points (Figure 46).

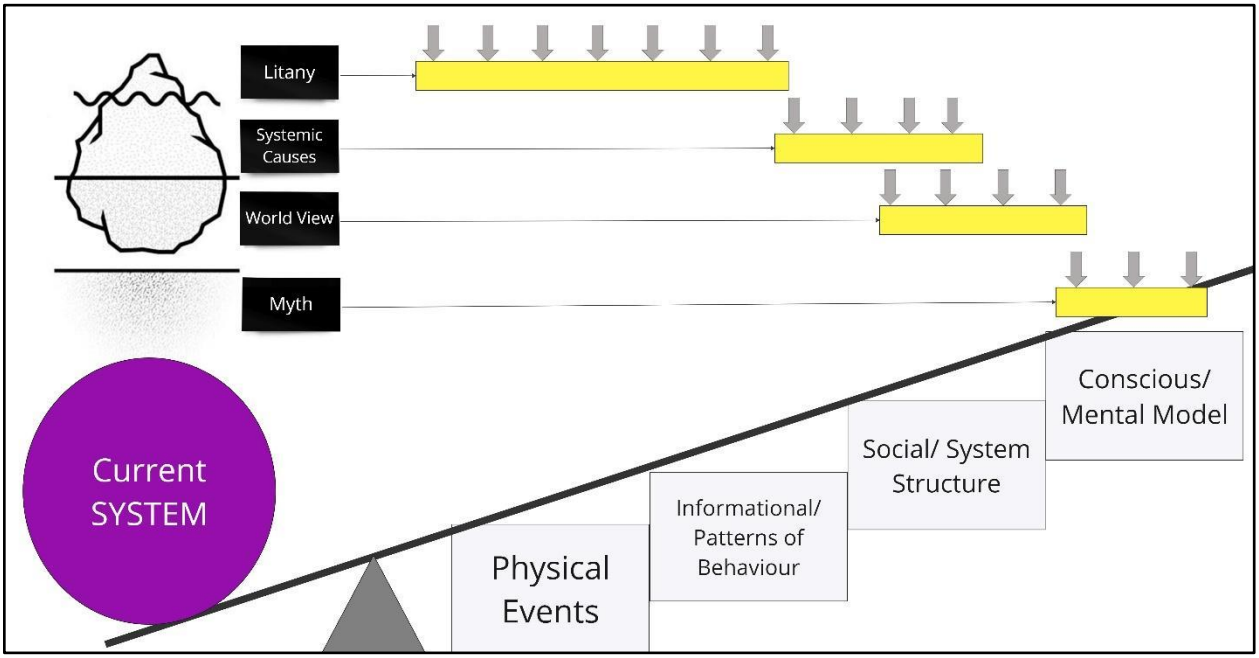

Figure 46: Lining up the Causal Layered Analysis with Donella Meadow's Leverage Points of a System.

Looking at the leverage points, it is clear that small changes do help to change systems, but the impact is small. A larger change could be a role for collectives to help change the minds of the executive and standards developers. Movements like #techwontbuildit show that collective pressures can help to hold accountability, and change cultures. But unless the social/system structure or conscious/mental model, or the myth and worldview of the system is changed by these actions, these movements will have to continue to organize and morph to keep the pressure to change on those power.

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