Innovation Procurement and High Complexity

3D Prosthetics with Sunnybrook and Nia

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3D Printing for Prosthetic Sockets

"The thickness of a t-shirt." That is the precision that a prosthetist aims for when they are producing a socket for a person missing a lower limb. The socket is the critical interface between the human body and a mechanical device. Within this precision tolerance, a fitting is comfortable and functional. Too tight or too loose the socket becomes uncomfortable and can cause skin breakdown. Traditionally, prosthetists make sockets by creating a mold from a plaster cast and then melting a sheet of thermoplastic around the mold. The fitting involves many patient interactions and adjustments to the socket; there is an artisanal quality to the work.

"If we could turn around and make a new socket as needed every three weeks, every month, instead of every three or six months, and the cost was the same to us as making a socket every three to six months, then that would be a fantastic improvement in patient outcomes, in my mind."

A Prosthetist on the St. John's Rehab Prosthetic Team

Over time, the shape of a socket will need to change as a patient's swelling decreases and muscles atrophy following their amputation. The size and shape of a residual limb can change significantly over the first year, and then continue to change more slowly throughout the rest of an amputee's life. Prosthetic patients start on a temporary, or prep, device, and a new amputee generally goes through a series of temporary sockets in the first year or two following their amputation. This can be costly (Ontario has a 25 % co-pay on prosthetics), and replacement of the device is sometimes prohibitive to people living on low incomes. The ideal is for amputees to have a new socket when they need it, rather than when they're able to afford it or when their old one is so poor-fitting that they're starting to have issues.

Thermoplastic sheets cost between one and two hundred dollars, and the production of each socket uses one of these sheets, as well as plaster and cement for the casting. Sometimes fitting adjustments or mistakes in fabrication require materials to be discarded and the process to start over. With increasing labour costs, and as constraints in the health system keep getting tighter and tighter, there is growing interest to find solutions that increase the efficiency and effectiveness of prosthetics, while offering a more cost effective and less invasive fitting process for patients. An emerging solution is 3D printing for the fabrication of prosthetic sockets. This involves a digital scan of a limb that is then rendered as a 3D print out of a socket, completely replacing the casting process. Plaster casting is uncomfortable and messy for patients, and the materials needed to 3D print a socket cost about a quarter of the material needed for a socket made with traditional casting, plus less labour is required.

The current plaster casting process usually ruins the cast in the process. This means that a replacement socket requires starting over with re-casting. With a digital model, a replacement socket simply means, "press print." Casting is messy and uncomfortable for patients. What 3D printing offers is moving from an artistic representation of a limb to a completely objective one, and in doing so, can reduce the cost and improve the patient experience. With 3D printing, modifications become much more cost effective, and the scanning of the limb - done with a tablet with a scanning attachment - is cleaner and less painful. Prosthetists can adjust a test socket and refine the fit, then record these changes in a computer and print a brand-new unmodified socket that incorporates all the changes. Further to that, there is a digital record that retains all the changes and tricks to fit that person for next time. While that might not always apply if the patient's limb has changed significantly, this historical perspective is not something available using a traditional casting method.

The Nia-Sunnybrook Partnership

The Prosthetic team at St. John's Rehab includes three physicians, eight prosthetists, one or two prosthetic interns and three orthotists. The primary workspace is a 10,000 square foot prosthetics lab at Sunnybrook. St. John's Rehab has a much smaller prosthetist workspace. The two campuses are 12km apart. Prosthetics generate approximately $500,000 annually for the hospital.

St. John's Rehab has seen their prosthetics volume increase dramatically in the past five years, a function of their merger with Sunnybrook in 2012. Sunnybrook is now the sole provider of prosthetics for St. John's Rehab, where prior to the merger there were multiple community prosthetic providers. As well, they are seeing an increased number of diabetic amputations and an increased number of patients referred from other hospitals because of population density increases and over occupancy issues. The requirement for prosthetics is increasing, while at the same time there is a limited supply of new prosthetists. A small number can be trained each year, and the demand for them is high. This results in a lot of pressure in the hospital to find efficiencies and improve patient outcomes for prosthetic patients.

The ideal for Sunnybrook is a one-site solution where scanning, printing and fitting are all done at the same site. A multi-site solution slows down and complicates the process. There are many vendors in the market working on 3D solutions for prosthetics, but there is not yet a viable single site solution. Sunnybrook had previously trialed one other 3D printing solutions. However, these solutions were deemed unviable because the final socket printing was done offsite. As a result, the efficiencies and cost savings were negated with shipping delays and customs fees.

Nia has developed technology for 3D printing of prosthetics that is in use in Uganda, Cambodia and Tanzania. In Africa, approximately 1% of all people who need some type of a prosthetic device actually get it, mainly because there aren't enough prosthetists. There is a need for innovative solutions that link practice and technology. Nia has a lot of experience and learning from their work in resource-poor countries. They have working technology that is functional at four sites internationally. They had completed user trials, touch point maps, journey maps and conducted a 130 patient clinical trial in Africa. Nia was interested to develop their solution for the North American market.

St. John's Rehab and Nia have been discussing the potential of exploring 3D printing for amputee patients at Sunnybrook for a couple years. Nia understood that there would be an application for their technology in higher-income countries. They saw this partnership as a great opportunity to test out that proposition with a preeminent hospital and rehab centre.

Nia Technologies (Nia) is a Canadian, not-for-profit, social enterprise, created in 2015 out of a partnership with Christian Blind Mission Canada (cbm), an international development charity and the University of Toronto. Nia researches, develops, and deploys innovative technologies in resource-poor countries.

Sunnybrook is an academic health sciences centre located in Toronto, Ontario. It is the largest trauma centre in Canada and is one of two major trauma centres in Toronto. Sunnybrook has over 10,000 staff. St. John's Rehab Hospital is part of Sunnybrook Health Sciences Centre and is dedicated to specialized rehabilitation. St. John's Rehab has 174 beds and cares for about 2,500 inpatients and supports 50,000 outpatient visits annually.

The IPPCD Program

Dr. Amanda Mayo, a Physiatrist at St. John's Rehab had previously sought funding from various sources to support a partnership to explore 3D printing for prosthetics, but was unsuccessful. Sunnybrook applied

to the IPPCD program and, following the structured process for selecting a vendor, Nia was the best fit for their challenge.

One of the main objectives of the IPPCD program is to create solutions that are a better fit with real- world healthcare contexts by involving end users and all stakeholders in shaping them. The process starts with a challenge brief written by the healthcare provider. In the brief, the healthcare provider describes its challenge, the outcomes it seeks and the criteria it will use in selecting a vendor. Interested vendors respond with innovator briefs describing their proposed approach to overcoming the challenge. Healthcare providers review the submissions to determine a short list of vendors and then invite them to pitch their innovative approaches to tackling the challenge and discuss potential solution possibilities.

The selected vendors and healthcare providers apply user-centred design principles and other rapid prototyping methods to identify and deal with the risks of introducing innovation in a complex healthcare setting. The teams are supported with hands-on co-design workshops at MaRS and regular review sessions with the MaRS team. This phase is iterative and can have many design cycles. Based on the insights gained from previous iterations, the provider and vendor team scopes a minimum viable product to evaluate outcomes and a viable business model for procuring the solution. The team uses the results to make a final decision on whether to move forward with procurement.

With IPPCD, MaRS engaged healthcare procurement experts, care delivery organizations and the technology venture community to create a process for new forms of collaborative value creation by:

- providing a structured process that is compliant with the Broader Public Sector Procurement Directive, but still allows for flexible application of the process for different types of projects;
- facilitating innovation partnership formation through broad yet targeted networks and dialogue processes;
- providing guidance and accountability through workshops, bi-weekly check-ins and resource materials; and
- designing and administering grant incentives for participants to help cover the cost of procurement using a novel approach.

The IPPCD program provided a catalyst and platform for Nia and Sunnybrook to more deliberately engage in this partnership. The program helped give the idea some profile and legitimacy at Sunnybrook, and the grants were critical to securing the time of prosthetists to participate in testing and development of solutions.

Challenges in Developing the Solution

The IPPCD program culminates in a final pitch where participating healthcare provider-vendor partnerships vie for up to $25,000 in additional grant money to help with the implementation of the solution. Sunnybrook and Nia chose not to put their solution forward for Solutions Day (July 2018). The development of a solution for Nia and Sunnybrook moved at a different pace than the IPPCD program timelines because of various challenges, including the complexity of the program, the time commitment of the partners, and the need for more project management. These, and other, challenges are explored in depth below.

Nia and Sunnybrook had made some progress with their work together, but because of these various challenges, the hardware and software was not yet ready, and as a result the necessary testing had not yet been completed at Solutions Day.

This project was out of sync with the stages and milestones prescribed in the program. On one hand, this isn't a major disruption for these partners; they are continuing to work together in a partnership with the intent to develop the 3D printing solution for Sunnybrook. The delays have prompted Sunnybrook to explore other solutions for procurement, although they continue to work with Nia on software iterations.

The experience of Nia-Sunnybrook offers some insights into factors that affect the development timeline. Some of these are manageable issues that are hopefully instructive to other partnerships that may want to move faster through a co-design. At the

same time, this initiative is addressing a highly complex challenge, and demonstrates that different timelines and supports are needed in higher complexity challenges.

1. Complexity of the problem being addressed

The problem being solved in this situation is one of the more complex challenges in the IPPCD program. It involves innovations in hardware, software, and the patient care pathway. 3D printing for prosthetics is potentially quite disruptive to the prosthetics field. Added to this, Nia is a not-for-profit who had, up to this point, operated overseas in a very different healthcare context. Integrating feedback usually involved changes to both hardware and software, and as a smaller not-for-profit, Nia did not have the capacity for rapid turn-around. It wasn't until towards the end of the IPPCD program (summer 2018) that Nia had integrated enough of the feedback to be ready to test and verify adaptations to the hardware and software. The stages of IPPCD were skipping ahead of where Nia and Sunnybrook were at in their development. Longer periods between co-design sessions, and a greater number of co-design sessions, would have helped them to integrate sufficient learning into the hardware and software to be ready for the next phase.

2. Commitment of time from the partners

Sunnybrook and Nia each faced time constraints that made it difficult to fully put in the time needed to support the development process. Sunnybrook is currently short one prosthetist, which has placed additional demand on the clinical workload of their prosthetics team. As a result, their time to trial the solution, provide feedback and problem solve some of the issues has been limited. The engagement of prosthetists is critical to the development of the solution. There are many nuances to a prosthetists work, and their time experimenting and providing feedback is critical to help translate what prosthetists do into a digital toolset.

At the same time, Nia's work overseas takes them out of the country and for the most part, out of communication, for long periods of time – sometimes a month or more. The international work is, of course, a priority for Nia . They have received significant grants for their work in resource-poor countries (The last thing Sunnybrook would want to do is take away from Nia's work in getting kids prosthetics and orthotics in the developing world.) The result of these constraints is that the development effort has been episodic, slowing the overall pace of the project.

"It's probably less risky to do the 3D printing process, but as it involves patient care and feedback with a new technology, a new care process, it was prudent to get ethics, to ensure a safe trial and allow dissemination of results to other centres through academic journals and research conferences ." Dr. Amanda Mayo

3. Size of Sunnybrook and project management

There is approximately 10,000 staff at Sunnybrook. It is an organization the size of a town, and navigating its various systems and structures added time and complexity to the co-design process. The biggest challenge was that there was no single point of contact or natural interface for the project with Sunnybrook. There is a lot of institutional support for the concept, and lead physician Amanda Mayo has been successful in communicating about the general idea to people at different levels within the organization. The project lead's focus and expertise are research and development. In the context of a large institution, there was a great need for project management, a missing piece. As a result, the coordination between Nia and Sunnybrook was inefficient.

4. Comprehensive legal process

The initiative went through multiple revisions to the legal contracts and intellectual property agreements. Sunnybrook is very aggressive in asserting their intellectual property interests, and at the same time, the partners in this initiative wanted to ensure that Nia's ideas from its not-for-profit work were protected. This whole process took several months and involved multiple Sunnybrook attorneys. This was – in part – a function of the challenges noted above, and also the result of numerous back-and-forth with the Sunnybrook and Nia stakeholders.

5. Unclear business model

There is some uncertainty with both of the partners on the business model for the Nia solution. Nia's work in low-income countries is supported by philanthropic grants and in that context, is not displacing an existing practice or technology in the same way as the introduction of 3D printing in a North America. Developing the solution in North America includes sorting out a pricing and service model, which Nia has not yet developed. Both partners understand that the solution is more than simply the sale of hardware and software, however, at this time there is some confusion between Nia and Sunnybrook about options for how to structure the business model. Each is looking to the other for ideas and options about how to construct a sustainable deal.

The business model is a critical piece for procurement. The co-design between Nia and Sunnybrook focused on the clinical benefits and the technology of the solution, with some initial development of the business model as part of IPPCD. However, the complexity of the 3D printing challenge (changing a sector), as well as the added layer of having a not-for-profit looking to transition into a dual market strategy, more focus and support for business model development would have been helpful to this team. This challenge underscores the need for more development cycles, and with more development cycles it can be expected that the business model will advance.

Nia and Sunnybrook are continuing to work together to address these challenges and move the project forward. The clinical trial which is now underway – and explained in more depth below - will be a crucial next step.

Unique Partnership Features

The Sunnybrook-Nia case has two unique characteristics in comparison to the other initiatives that were part of IPPCD: the inclusion of a clinical trial alongside the co-design process, and a vendor that is a not-for-profit organization.

Formal Ethics and Co-design

This project directly involves patients, and even though the risks are low, it was determined that formal ethics approval was the appropriate step to obtain patient feedback on the new process and technology. The Research Ethics Board (REB) granted approval in [October 2018] and in November 2018, the first patients consented to participate. They will begin with the trial once the printer and software is fully functional. The objective is to have 20 patients complete both a traditional and 3D printing of a socket by the spring of 2019.

Traditionally, a project like this may have been a fully funded research study. The advantage of this is that a prosthetist could be dedicated entirely to the initiative. In this situation, there are no clinical responsibilities for the prosthetist and they can focus on testing and experimentation with iterations of the solution. The challenge is that the funding required for this scenario is higher.

The REB was deliberately designed to not be too onerous. The wording of the ethics submission allows for updates and adaptations to the Nia software, and is based on a pragmatic approach of getting information and perspective on patient outcomes, cost savings, and what worked and didn't work from a prosthetists' perspective. The trial will study the benefits of adopting a single site 3D printing solution, which will be useful for making the business case within Sunnybrook.

Although Nia had already conducted a clinical trial in Africa, having a trial done in North America is understood to be a critical step. Even though their trial in Africa involved 130 children over multiple years and in multiple countries, that work is considered less

legitimate by the developed world prosthetists because it's a developing world clinical trial.

The trial is helpful in this example for several reasons. This trial will provide evidence to the clinicians. The Sunnybrook prosthetists are keen on the concept of 3D printing; however, within the field there is both enthusiasm and reluctance towards the shift to 3D printing. There is a sense that in order to shift the prosthetics field, clear and compelling evidence is needed. Furthermore, as a research hospital, the ability to publish is important for the institution, and both Amanda and Matt have research and teaching roles with the University of Toronto. A trial is in the professional interests of the lead individuals from each organization, and for Sunnybrook, a clinical trial on innovative technologies contributes to the organization's leading edge reputation.

Not-for-profit Vendor

Another unique feature of this case example is Nia is a not-for-profit vendor. All of the other vendors that participated in IPPCD were for-profit companies. As Nia looks to develop a North American market for their solution, they are exploring the possibility of creating a separate for-profit enterprise. Nia is carefully considering how to create the for-profit enterprise in such a way that they do not reduce their capacity to develop and deliver systems that provide prosthetics for people in the developing world.

Nia sees public health benefits to improving how prosthetics are done in the developed world, but these pale in comparison to the public health benefits in the developing world. If successful, this scenario could create a "Robin-Hood" situation where the sales in high-income countries benefit the development of technology and the implementation of solutions in low-income countries. If they move ahead with this strategy, it will require technical legal and accounting expertise to navigate the implications of assigning the IP from a not-for-profit to a for-profit enterprise. As partners, Sunnybrook and Nia have lots of agreement about the potential of the proposed solutions, and interest in moving them forward. It is not entirely clear where the ownership and agency rests for ultimately solving the problem. The unique dynamic of a healthcare institution that has research and development interests, and a not-for-profit whose primary focus has been international development work, leaves us with a question of who should lead? In the other IPPCD projects, the dynamic between the procurer and developer was more clear-cut. This situation adds some challenges, but also opportunities for thinking differently. What would a Sunnybrook led model for scaling look like where Nia receives royalties? And would that be viable and desirable to a vendor like Nia?

"We want our systems to recognize them as experts, help them be experts and help them communicate their expertise to other people. I actually think of that as the more important design goal ... in order to have good patient outcomes you need prosthetists to be fully actualized."

Matt Ratto, Chief Science Officer, Nia

Future Potential

It is not a question of if there will be 3D printing for prosthetic sockets; rather, it is a question of how soon and in what way. The field is moving in this direction and eventually 3D printing will be part of a prosthetist's toolkit. Even though the pace of progress has been slow with the Sunnybrook-Nia partnership, it has advanced the idea and surfaced some thinking about what the future potential could be. The clinical trial will help with dissemination of these ideas within the profession.

- New roles for prosthetic technicians. Less time in the modification of casts could open up role with other new technologies that are emerging (e.g. maintenance of advanced myoelectric prostheses and microprocessor knee units)

- 3D printing benefiting other areas of rehab, such as masks for burn patients, braces for other limbs, or the printing of orthotics
- A more objective measure of limb change, which can help patients make the case with their insurance provider for the need for a new prosthetic, and potentially changing the insurance funding model for prosthetics
- Practitioners sharing digital scans to support collaborative practice and learning
- Access to the techniques and practices of world-class clinicians for the education of new prosthetic clinicians, and help support more clinicians to be trained
- Digital scanning in rural and remote sites that simplify the patient experience (travel burden and costs) of fitting a prosthetic socket

Conclusion: More development cycles for more complex challenges

Sunnybrook and Nia got a lot of value from the IPPCD program. It provided a catalyst for a deeper engagement in their partnership. The work site observation, planning and process mapping was helpful. Both Sunnybrook and Nia resisted some of the project documentation that was part of IPPCD, and would likely have benefitted from some adaptations to IPPCD that are more suited to their stage of development.

The Nia-Sunnybrook case raises the question of what is the appropriate timeline for innovation procurement when working on more complex challenges. Project management would help somewhat, but many of the challenges outlined in this case will likely resolve in time. The higher complexity of the challenge, and the added layer of institutional complexity, simply needs more time to work through.

Complex challenges within institutions with complexity on the scale of Sunnybrook should be well suited to innovation partnerships, but there is more to figure out in how innovation partnerships – and the programs that support their development - are constructed to more optimally support these situations. The case highlights the need to think about, and support, multi-cycle development processes. The challenge for healthcare is what is the scalable funding model for R&D processes like innovation partnerships.

The experience of Nia-Sunnybrook challenges the idea that a successful version of one round of an IPPCD project ends with procurement within the cycle of the program. That was not possible for this initiative. However, the need for the solution is compelling, and the partners continue to work together and make progress towards a possible solution. One version of procurement could be a renewed commitment to continue to develop and explore a solution together. While it added time to get set up, the clinical trial provides a practical and focused next step for the project. Twenty patients is a manageable scope and will provide useful evaluation data that will help guide procurement decisions at Sunnybrook.

The ideal procurement pathway for this challenge and these partners is a longer-term development cycle. The end of IPPCD should bring people to a place of asking some key questions: What have we learned? Do we need to learn more and need another cycle of exploration and development? Have we learned enough and we have a viable solution that is ready for procurement? Have we learned enough to say with confidence that we need to completely get rid of the idea we are working on and start from a completely different place? Procurement for further testing is what the Sunnybrook-Nia project turned into. This happened in an emergent way, and it would have been better to make this pathway explicit from the start.