# NIHR Child Prosthetics Research Collaboration; Starworks 2018/19 update

## 1. Executive summary

Since its inception, The Starworks Network has applied an inclusive and responsive approach to engaging the stakeholder community (including academics, clinicians, industry experts and, crucially, children and families), ensuring their voices shape the project direction as well as the research priorities it supports. This is evident in the project journey so far (where collaborative 'Sandpit' event themes were informed by an initial, multi-stakeholder needs assessment) and is also reflected in the diversity of Proof of Concept (PoC) projects that it has funded through an open application process. The projects cover a range of topics, including comfort, customisation, information needs and efficiency of electric limbs, and were approved by a multidisciplinary panel of judges, including representatives of related charities.

There has been good progress to date across all of the Starworks funded PoC projects, as detailed in section 2 below. Many projects explore issues that were raised earlier in the Starworks project, for example the challenge of children's rate of growth, and the need for them to visit limb centres regularly for refitting (causing children and parents to miss time in school and work) as limbs cannot currently be adjusted at home. The PoC projects have addressed this from different angles, for example developing sensor arrays to better understand where/when pressure exceeds comfortable levels (Project 001), developing socket liners that can be more customised or adapt to changing volumes of the stump (Projects 016 and 014) and challenging current methods of housing electrode sensors on electric limbs (Project 018). This highlights the importance of the Starworks Network in facilitating in-depth exploration of such complex challenges.

The Starworks Network continues to apply an inclusive and responsive approach to supporting the PoC projects. Whilst some projects have operated more independently that others, careful monitoring via progress reports and regular contact by email has anticipated potential issues in advance, with support offered on a case by case basis. This support has included guidance on ethical review, questionnaire design, regulatory frameworks and signposting to further resources. This, and further detail on Added Value activities are detailed in section 4.

The Starworks team have attended several kick-off meetings for the PoC projects either in person (whenever possible) or via teleconference (including Projects 001, 006, 010, 018, 006). We have also facilitated opportunities for PoC project teams to meet and learn from each other, encouraging a collaborative approach to the network and supporting future sustainability (see section 3).

## 2. Interim progress reports

The PoC projects were contacted close to an approximate halfway point for the projects and asked to provide an interim report on progress using the template provided. The template (available in appendix 1) aimed to generate comparable data across the projects quickly, with simple questions regarding progress, challenges, next steps and feasibility of completion (on time and within budget). Projects were also given guidance on invoicing and a visual overview of the process (see appendices 2 and 3). All of the PoC teams submitted their reports within the 1 month deadline, with the exception of one project (due to delayed responses from their internal finance department).

As outlined in the executive summary, most PoC projects are progressing well, on time and within budget. Further details are available on request, with a summary of each project as follows:

- 001 aims to develop a first-of its kind Socket Interface and fit Monitoring System (SIMS) for children with lower limb absence, which will use a system of sensors in the socket and a smartphone App to help identify the appropriate time for socket adjustments. They have engaged over 15 children with limb losses and their families as well as 8 clinicians to identify the key design criteria. Subsequently, an initial proof-of-concept was implemented incorporating Southampton's novel interface sensors and a parent App, with positive initial feedback. Their next steps are to conduct a preliminary study with children and families, leading to the evaluation, development and optimisation of a SIMS prototype to fulfil the design requirements identified following the initial consultation with stakeholders.
    - *Key take away message:* A new socket fit monitoring tool to help alert children, their parents and clinicians for timely socket adjustments.

- 002 delivered a reliable clip-on Lego platform (Play Attachment) to sit on top of a children's split hook hand prosthesis, aimed at making it more playful and fun. The project investigated different fabrication techniques including 3-D printing to ensure ease of use, ensuring unaffected prosthetic function and a quality fit to Lego parts. The project redesigned an early prototype (developed in previous clinical practice), producing CAD designs and 20 milled usable left- and right-handed platforms compatible with Lego pieces, as well as a high-quality 3-D printed demonstrator play attachment. The milled parts are available and possible next steps could be to apply for ethical approval to permit a small study to evaluate the impact of the play attachments for young split hook users.
    - *Key take away message*: Transforming functional hand prostheses to be more acceptable to children, and toward a more 'toyful' aesthetic.

- 004 aims to develop 'Limbformation' - a website for families and children with limb loss or limb difference and educators working with these families. The purpose is to empower, support, and educate through factual information and personal stories. Progress so far includes conducting extensive surveys across all stakeholder groups and running two Family focus groups to establish website content. The team has also agreed a contract with a website builder as well as submitted and approved a wireframe, style, logo and front end of the website. The next step will be for full website to be submitted for feedback and approval, followed by a full day of tutoring on CMS and website management. The team will then upload text, images (including infographics responding to child and parent priorities) and information.
    - *Key take away message:* Limbformation will be a 'one stop shop' for all families including a child with limb difference.

- 006 aims to teach children how to control multifunctional prosthetic hands through computer gaming. They have created a prototype game which trains the player how to use their muscles for interacting with a prosthesis. Their next steps are to gain feedback from children.
    - *Key take away message:* We want all child who get prosthetic hands to be able to control them properly so that we can show that these hands can make a difference.

- 009 aims to develop 3D printable prosthetics for infants with upper limb differences. The project has developed the first iteration and designs that are now ready to be assessed for suitability within the medical team. The next step will be to iterate the designs a final time with the intention to improving the end products. A group of families in associations with Reach will then provide feedback to an independent panel assessment on the positive and negative aspect of the designs. This evidence will be co-lateral to help secure second phase funding.

- *Key take away message:* The 3D printed prosthetics are developed to engage and inspire infants to help improve adoption comparable to the current NHS offering.

- 010 aims to develop a new prosthetic knee for children which uses the natural properties of specialist materials to more closely mimic a natural leg rather than relying on pistons, electronics and robotics typically employed in adult legs to compensate for their weaknesses. The team have produced a prototype knee which is lightweight, easily maintained, waterproof, and bends to 135 degrees thus providing extra flexibility for children in play. Some aspects of this design are currently being prepared for a patent application. The next stage is to optimise the design and produce pre-production samples which can be tested by volunteers.
    - *Key take away message:* The key feature of the knee is that it is designed to enable children with an above knee amputation to take part in play and other activities alongside other children.

- 014 aims to address the age-old challenge of developing a robust prosthetic socket that is also comfortable and adaptable to growth, by designing and making socket and liner components from advanced composite materials via digital manufacturing methods. Progress includes developing an understanding of auxetic structures for the comfort and adaptable liner, the development of fully-parametrized Computer-Aided Design (CAD) software for increasing prosthetic forming efficiency, and optimising 3D printing materials and processes for robust and low-cost prosthetic socket parts. To build on recent project successes, the research team will continue working towards the project aims, as well as characterising novel materials through mechanical testing, computerised design and simulation to evaluate their performances.
    - *Key take away message:* The novelty of the project is to create a scientifically validated design and manufacture workflow that will provide children with comfortable and adaptable socket and liner components, which will be bespoke at a fraction of the current cost.

- 016 aims to develop a method to 3D print bespoke silicone liners for child prosthetics wearers in order to address issues of comfort and performance for those children as they grow. The team have made considerable progress by using 3D scanning technology to create the desired shape of the liner, and have created a way to 3D print silicone into complex shapes including embedded sensors and cooling channels. The next steps of the project are to make a first prototype liner and to test its performance at Stanmore with a child lower-limb prosthetics wearer.
    - *Key take away message:* Through our work we hope to improve the satisfaction of children with their prosthetics, reduce skin infections, and reduce rejection rates.

- 018 aims to develop a user-friendly device that will allow parents and prosthetists to improve myoelectric prosthesis electrode pressure and alignment on the skin's surface. Several design concepts have been proposed and are currently being prototyped while an ethics application for the pilot study has been submitted. Upon ethics approval, the finalised designs will initially be trialled on the team, then on professional patients and finally on children.
    - *Key take away message:* We anticipate that by allowing adjustments to electrode's pressure and orientation, the overall functionality and control of myoelectric prostheses will be improved.

- 020 aims to develop affordable, high quality 3-D printed customisable covers for children's prostheses that are easy to remove or change according to the child's choice and activity. Progress to date includes background research (investigating the use of 3D printing in prosthetics and any existing, similar products), design work (identifying the optimal method of CAD shape capture, materials and printing methods), extensive software analysis and comparison, manufacture of prototypes and an ethical application to provide covers in a one centre trial. Next steps will include the purchase of software, IRAS ethics application and testing in an NHS limb centre.
    - *Key take away message:* Designing a cover will be a fun process that improves the child's engagement with the prosthetic rehabilitation process, promote positive discussion with the child's family and friends, and we think will change the perception of the look and appeal of children's prostheses.

Each project has been sent tailored feedback on their reports and additional information requested where appropriate. The Starworks Team are satisfied that each PoC project is meeting expectations (in the context of challenges individual projects have experienced).

***The main challenges identified in the reports echo those mentioned in the Industry Forum discussions discussed in the next section (i.e. seeking ethical approval to involve families in research, access to families and children, etc). This arguably highlights the importance of bringing these groups together to learn from each other's experience, and the role of the Starworks team in providing additional guidance and/or support.***

## 3. Industry Forums

Through the University of Sheffield, the Starworks team has been successful in its application for MRC Proximity to Discovery support. The scheme is designed to foster the establishment of new collaborations by specifically providing support to early interactions and knowledge exchange between external partners and academic researchers.

The Starworks Team proposed to utilise the P2D support by hosting a series of meetings for PoC projects, and individuals from related research areas, to meet and share experiences, knowledge and ideas. We invited academics from the University of Sheffield and Sheffield Hallam University to the events in order to identify new areas for collaboration.

Outcomes

- Multiple knowledge exchange activities have been undertaken, these include two 4 hour workshops and an active online facilitation approach
- The meetings included presentations from all the proof of concept projects on their objectives and technical approaches and challenges faced (challenges summarised below). We sought to identify issues and challenges in order to utilise the expertise available through the P2D initiative.
- Academics from the University of Sheffield and Sheffield Hallam University presented on their areas of expertise. Attendees then had round table discussions for collaboration, whilst considering the challenges outlined.
- Outputs from each group were reported after each meeting, and offered a focus on defining specific opportunities/areas for collaboration and unexpected benefits of the these meetings
- As anticipated, by bringing various experts together to share and collaborate, issues identified by the proof of concept projects at this stage in development, were supported and advice given. This included areas around regulatory issues, ethical issues and problems encountered when reaching out to children and families.

Reports from each meeting are available on request.

**Added value – Regulatory and ethical issues**

- It was clear not only from our work engaging all the stakeholders but also from applications to the PoC funding call that there is uncertainty regarding the regulatory requirements relating to limb prostheses (within and outside of EU) and of the impending impact of the Medical Device Regulation (EU 2017/745; MDR). This was indicated over a cross-section of 11 companies, plus UK NHS Trusts and Universities).
- In addition, it became apparent that some providers of limb prostheses for children, and those delivering clinical care for young prosthesis users, may not be fully aware of ethical requirements processes for research. In particular, distinctions between NHS and academic ethics and understanding the boundaries and differences between standard clinical practice, service evaluation and research.

- Some of the regulatory uncertainty arises from:
    - Not appreciating the need for a stated 'intended purpose' for a prosthetic related product and the impact its wording or claims may make on medical device classification. The Starworks projects provided real examples demonstrating the impact on classification, particularly in the area of innovations with potential to qualify as medical device accessories
    - Innovators not having a background in medical devices
    - Innovators pushing the boundaries and challenging current regulatory frameworks
    - Use of novel manufacturing techniques and materials, such as additive manufacture (3D printing, etc) and implication for quality and process assurance (e.g. load-testing, biocompatibility for new sockets) and understanding how to meet current Essential Requirements and upcoming Safety & Performance Requirements, including for non-CE marked devices (custom-made or investigational)
    - Researchers wishing to use marketed consumer tracking products for research project efficiency and value and discovering that various devices investigated failed to meet applicable non-medical CE standards
    - Not knowing in what form current 'in-house' healthcare institution exemptions from CE Marking will continue under the MDR/IVDR, and
    - Ongoing consultations relating to future healthcare institution requirements (e.g. mandatory quality management systems such as ISO 13485:2016) for in-house manufactured custom-made medical devices
    - Needing to understand impact of device integration e.g. compatibility of systems which might interact with components from different manufacturers
    - Understanding the impact and risk-benefits of designing to permit non-professional adaptations (e.g. for growth, oedema)
    - Different uses of embedded software and sensors within prostheses for function and versus evidence generation (usage, value, post market surveillance, etc)
    - Evolutions in custom-made implants (e.g. extended application of percutaneous osseo-integrated limb prosthetics – currently for adults and typically military service personnel)
- In conjunction with the Medicines and Healthcare products Regulatory Agency (MHRA), we have clarified many of the researchers' queries and are looking to co-produce a number of recommendations and support documents to disseminate the knowledge gained more widely.

- Some of the ethical uncertainty arises from:
    - The funding call provided a rare opportunity for frontline clinicians such as prosthetists and enthusiastic 'lay' innovators to get involved in research for the first time. Due to the contractual arrangements for NHS prosthesis provision, many prosthetists are employed by prosthetics manufacturers and do not necessarily understand NHS research processes as this would not be part of their typical provision.

**Dissemination activities include:**

*Conference presentations:*

- 001 - Tang J, Jiang L, Meng Z, Hale N, Head J, Twiste M, Morley E, Moser D, Zahedi S. "A preliminary study of socket interface loading and socket fit for children with lower limb absence", ISPO Annual Scientific Meeting, Southampton, Oct. 12-13, 2018.
- 006 - "Low cost at home myoelectric training using biofeedback and off-the-shelf hardware," Matthew Dyson and Kianoush Nazarpour. International Society for Prosthetics and Orthotics (ISPO) 2018
- 006 (pending) - "Home-based myoelectric training using biofeedback gaming," Matthew Dyson and Kianoush Nazarpour. Trent International Prosthetics Symposium (TIPS) 2019
- 010 – Initial results presented at recent meeting of the International Society for Prosthetics and Orthotics (ISPO-UK 2018)
- 016 - Research on 1D stretchable sensors presented at Robosoft 2018 (*April 2018)*
- 016 - UCL Cross-Disciplinary Network on Soft Materials Presentation (*June 2018*)
- 016 - Research on 2D stretchable sensors to be presented at MRS Society Conference 2018 (*Nov 2018)*
- 016 (pending) - TIPS2019 Conference paper on bespoke intelligent liners with cooling submitted.

*Conference posters:*

- 002 – 2nd place poster prize at BAPO conference 2018 (available on request)
- 018 - Poster presentation at ISPO conference at University of Southampton

*Magazine articles:*

- 002 – Article published in BAPO magazine (available on request)

*Journal papers:*

- 016 - Research paper on stretchable sensors currently under review for publication by the Frontiers Robotics and AI journal

*Public engagement:*

- 016 - Stanmore Public Open Day, *Royal National Orthopaedic Hospital, Stanmore (April 2018)*
- *Hosting a Fundamental Skills day in Sheffield in collaboration with Sheffield International Venues and Limbpower (September 2018)*

## 4. Match funding

Prior to the announcement of 'Starworks 2', some projects leveraged other sources of funding in order to ensure continuation of their projects. This includes:

- 006 - Five year Newcastle University Research Fellowship (NURF) to work in child prosthetics.
- 016 - AT 2030: Life Changing Assistive Technology For All (Department for International Development): https://www.disabilityinnovation.com/at-2030

## 5. Next steps

- PoC projects who have received a short extension will be asked to deliver their belated interim reports shortly.
- Planning is underway for the Celebration event in early March. All projects have been advised that attendance is mandatory, and PoC projects with extensions have been advised that they will be expected to contribute as much as possible at that time.
- A business case for 'Starworks 2' has been approved by NIHR, with more detailed planning scheduled for the Starworks Team in the coming weeks.

## 6. Starworks 2

Starworks 2 will build on the significant challenges and opportunities identified In Starworks 1. The continuation and development of expert networks with the relevant stakeholder groups will allow Starworks 2 to nurture exciting ideas and collaborations to enhance research and development in this area. In collaboration with our partners we will continue to empower and champion the voice of the children and their families.

Starworks 2 will :

- Support the very best of the funded projects from Starworks 1 to allow them to reach children and families and make a difference for the child living with a prosthetic limb.
- Support new ways and methods of working across stakeholder groups to produce cutting edge research methods for clinicians, academics and industry. This will allow the best advances in research in this field to interface with the NHS to accelerate development towards clinical use.
- Look to develop long-term advanced evaluation processes such as a database of unmet needs, advanced methods of capturing relevant information, and a research-ready register of clinicians, centres and families that would be willing to collaborate to enhance child prosthetics.
- Work with funders from across the funding spectrum to offer sustainable and long-term research approaches for stakeholders to access.
- Work with industry to explore mechanisms that help them to bridge the gaps between innovation and adoption.

***Each of these approaches will speed up the development and translation of new technologies by facilitating collaborative research projects involving academia, industry and the NHS, whilst ensuring the voices of children and families are heard and understood.***

### *Contact details*

Nathaniel Mills – Paediatric Programme Manager at Devices for Dignity MedTech Co-Operative, Royal Hallamshire Hospital
Email: Nathaniel.Mills@sth.nhs.uk

Gemma Wheeler – Design Researcher at Lab4Living, Sheffield Hallam University
Email: G.Wheeler@shu.ac.uk

***Visit our website at: https://devicesfordignity.org.uk/starworks_cp/***

***Or follow us on Twitter: @starworks_cp for regular updates and information***