

## CASE STUDY: Patient and Family Engineering

A collaboration between Tookie Limited, NIHR Children and Young People MedTech Co-operative, and Sheffield Children's NHS Foundation Trust



**NHS patients and families across the UK face a number of challenges when securing and maintaining the array of enteral feeding lines and devices that are vital to patients' survival and management of their conditions, including preventing children pulling and removing their devices.**

No product exists to resolve this clear need; consequently, parents are often driven to develop bespoke solutions to secure their children's feeding lines and carry the weight of their fluid bags, or having to resort to purchasing expensive online products which may not be fit for purpose.

These makeshift solutions generally fail to provide children with sufficient dignity and quality of life, and result in frequent and unnecessary hospital visits due to infection, induced through pulling and interference from children and young people.

Tookie Limited, NIHR Children and Young People MedTech Co-operative (NIHR CYP MedTech), and the Gastroenterology Services Clinical Team at Sheffield

Children's NHS Foundation Trust (SCH) have met several times during early 2020 as a clinical focus group to consider these unmet needs and to investigate the design of a wearable medical device to be offered to patients to improve patient well-being and safety, which is fit for purpose.

Enhanced security of the Mic-Key button, feeding tube, central line (CVC) and stoma bag whilst in treatment (both in hospital and at home) were identified through a research project case study as vital to improve patient experience, which has been supported by the SCH Clinical Team and subsequent literature review.

It is understood that over 16,000 children (0-18 years) nationally receive nutritional feeding, a significant proportion of whom may benefit from these products, which are aimed at 0-8 years initially with solutions for older age groups currently in development. A solution to these unmet needs therefore has the potential to transform the lives of many children, ensuring they remain as healthy and active as possible throughout childhood.

# PATIENT AND PUBLIC INVOLVEMENT FOCUS GROUP

A patient and public involvement (PPI) focus group was held on 24th January 2020 at SCH, with five families attending along with Tookie Limited, the SCH Gastroenterology Clinical Team, and NIHR CYP MedTech.

One family present at the event highlighted that the proposed designs would not account for their son's highly complex enteral needs and autism. A unique opportunity therefore arose for NIHR CYP MedTech and Tookie Limited to work with this family to produce a bespoke garment that would improve the health and quality of life of this young patient.

The PPI focus group was organised to allow families and clinicians to review the current design prototypes together and discuss the suitability of the designs in improving their children's quality of life and health.

The families were also encouraged to make any recommendations from their

own experience which they believed would progress the usability of the garments for children of other ages within this patient group.

The event also gave families the opportunity to discuss the garment design and aesthetics with Tookie Limited, which proved to be a valuable learning experience, which went on to inform the next iteration of garment designs.

Feedback from the families was gathered through a structured questionnaire, asking the families to consider the impact

**“ Being provided with a wearable garment to improve my child's safety and security is an excellent idea and there is such a gap in the market for something like this. ”**

- Parent, Focus Group

**“ Better protection of the Mic-Key button and feeding tubes will absolutely help to prevent trauma and reduce the risk of them being pulled out by little fingers. ”**

- Parent, Focus Group

of differing components of the garment designs as well as feedback on whether they believed the proposed designs would improve the quality of life and overall health of their children. Feedback from the PPI event indicated that two garment designs were required to suit the variability in age range seen across this patient group.

Incorporating this feedback, Tookie Limited have developed a babygrow (Fig 1.) and a jumpsuit (Fig 2.) design for ages 0-2 years and 2+ years, respectively. Both

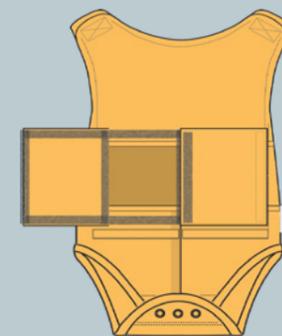
designs include a central pouch opening to allow universal line access, with added design features tailored to provide further ergonomic and functional support for each age group.

The central pouch opening features embedded neoprene which prevents the wearer from grasping the vital Mic-Key button and associated lines.

The final designs are currently undergoing CE Marking prior to their official NHS launch and added to Tookie Limited's current NHS contract.

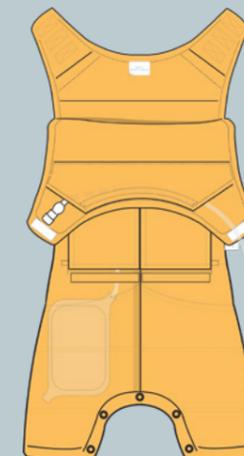
**“ What I like best about the garment is that I can access what I need to easier, whilst maintaining my child's dignity and privacy. ”**

- Parent, Focus Group



**Fig 1. Enteral Feeding Tube Babygrow**

Multifunctional babygrow garment designed for babies with enteral feeding tubes. The garment incorporates central line (CVC) and stoma security.



**Fig 2. Enteral Feeding Tube Jumpsuit**

Multifunctional jumpsuit garment designed for children aged 2+ years with enteral feeding tubes. The garment incorporates central line (CVC) and stoma security.

# THE TOOKIE SUPERHERO PRODUCING A BESPOKE GARMENT FOR A PATIENT WITH COMPLEX NEEDS



Tookie Limited, NIHR CYP MedTech, and the SCH Clinical Team have worked closely with the family to design a garment (Fig 3) that is fit for purpose, ergonomic and will improve the patient's quality of life, preventing him from accessing his devices and preventing recurrent infections and consequent hospital visits.

This work has progressed rapidly during the COVID-19 pandemic to ensure that the patient has no unnecessary admissions to hospital during this time to reduce his risk of COVID-19 infection.

Following on from the PPI focus group, the use of pioneering 3D body-mapping technology was used to map the lines and devices on the patient's torso, thus negating any undue emotional stress that the patient would have experienced by encroaching upon his personal space (due to his high level of sensory difficulties) to take repeated physical measurements. These measurements were combined with photo images of the

“ We absolutely love the colour and the superhero graphic! The poppers are easy to access, the neoprene has been absolutely brilliant at stopping him breaking the dressing and scratching his line sites, whilst the front opening pouch is fantastic for access to his colostomy, gastrostomy and jejunostomy and is well protected from him pulling or knocking them. The drainage pocket in the shorts has also been so helpful. The garment is already making such a difference to us, he looks great in it and its age appropriate, which really has meant a lot to us. ”

- Patient's Parents

patient, to provide accurate marker points during the design process. Several design features were developed with maximum

input from the family before a prototype was provided and trialled, followed by the production of a finished garment.

Feedback from this trial period was gathered by the SCH Clinical Team at routine home visits and by Tookie Limited during regular check-ins. The garment proved to be functionally sound, receiving great praise from the family, with only minor aesthetic amendments proposed (to alter the shirt top length and decrease the number of press studs on the torso).

A final garment will now be produced and provided to the family, with whom Tookie Limited will remain in close contact to monitor their progress.

Indicative of the need for such innovative products for this patient group, Tookie Limited, NIHR CYP MedTech, and the SCH Clinical team are also collaborating to produce a Health Economic Impact Assessment of the bespoke Tookie Superhero garment, detailing the cost savings to patient care and staff time in order to further strengthen the case for

NHS services to adopt these products for patient benefit. The assessment will be published upon completion.

You can see the patient, Zach, wearing the Tookie Superhero here.

“ Given these uncertain times with the COVID-19 pandemic and the additional importance of keeping patients away from hospital settings where possible, the Tookie garment has proven to be invaluable. I also believe the garment has given the family and patient the reassurance and confidence they need to be able to move forwards with all of their lives. I personally wholeheartedly endorse this product and have been impressed by the dedication of the whole Tookie team. ”

- Arun Urs, SCH Clinical Lead for Nutrition



**Fig 3. The Tookie Superhero**

This bespoke, multifunctional garment was designed for a patient with complex needs and incorporates CVC, enteral, and drainage security.

# CLOSING STATEMENT

**Development of Tookie Limited's range of garments continues with support from long time collaborators as well as commercialisation and dissemination support from the Academic Health Science Network (AHSN) who are continuing to innovate in this field.**

Sophie Bates, Programme Manager for the Yorkshire and Humber AHSN, said, "The Yorkshire & Humber AHSN has supported Tookie's development for the last few years and has seen them diversify their offering to support a wide range of patient needs. Tookie's ability to adapt their offering and design bespoke garments has had a positive impact on patients. Tookie's recent project involving 3D Scanning provides a truly innovative solution, and the benefit that the patient and his family have seen from the bespoke garment is extremely positive and heart-warming. This is a great example of positive collaboration between clinicians, companies working in complimentary fields, and most importantly, patients and their families."

Dedication to achieving the best of outcomes for patients, along with robust engagement and support from Clinical services and patient families, has enabled our collaborative to work efficiently (in a relatively short space of time) to develop effective medtech solutions for this patient group. Our projects therefore

highlight how the expertise and agility of SMEs and the NIHR MedTech and In Vitro Diagnostics (NIHR MIC) network, along with meaningful PPI initiatives can enable the development of novel products, which have immediate benefits on the health and well-being of patients and their families, which will last for years to come.

**“ This case study shows how when everyone comes together the very best outcome can be achieved. Within NIHR CYP MedTech, we strive to put children and their families at the centre of an innovation by understanding their needs and requirements from the start to finish.**

**We know that this ethos is shared by Tookie Limited, who have gone the extra mile to support our young patients' needs and to understand the issues that he and his parents face on a daily basis. The efficiency, pace and expertise offered by all the partners involved shows what can be achieved for the benefit of our patients and our NHS. ”**

- Nathaniel Mills, NIHR CYP MedTech Programme Manager

Find out more:

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