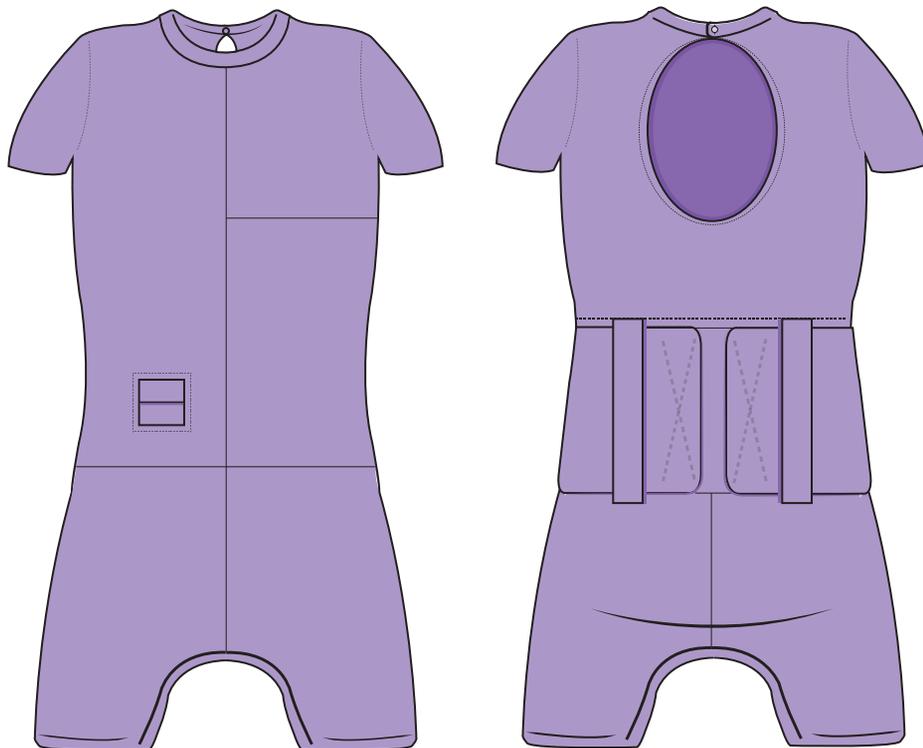


A Tookie Research Case Study
for
Peritoneal Dialysis Special & Complex Needs Patient
featuring
Enteral Mic-Key Button Integrated Security

“Patient and Family Engineered”



Introduction

Through an introduction by the NIHR CYP MedTech Co-operative MIC to Alder Hey Children's Hospital Renal Services, Tookie was introduced to a seventeen-year-old female Peritoneal Dialysis and Enteral patient with special and complex needs. Tookie was invited to engage with her family and clinical team supported by the Hospitals' Innovation Centre to research into her un-met need to explore the potential of providing a 'bespoke' wearable garment to prevent her access to her lines and provide security for her Gastro Mic-Key button for which she has a long history of repeatedly self-removal but delivers her modesty and dignity and yet clinical and family access to her lines; vital for hospital and home treatment.

This research case study sets how Tookie in collaborative partnership with the patient, family and Alder Hey Hospital led by Mr Iain Hennessey, Consultant Paediatric Consultant as Clinical Champion have understood the patient's un-met need; and that of the wider family and care team to co-design a solution which the patient is now wearing and using to prevent the problem of self-removal.

During the research period from December 2018 to 28 May 2019 the patient 'self-removed' her Gastro Mic-Key Button eleven times. Since Tookie provided her a 'bespoke garment' to suit her needs to date she has not once 'self-removed' her button nor catheter.

The case study reports on the steps taken through focus groups with the family and clinical team which informed the sequence of prototype design and development evolution to deliver a final solution – often with failure before success.

Tookie is delighted to have in collaborative partnership with 'Patient and Family Engineering' assisted in resolving this single patient and families need and that of her care team. However, what is really interesting is that this research project has informed the wider emerging Tookie portfolio of products which will address the needs of the Enteral patient population globally; who have similar un-met needs and have high financial costs on their care.

What were the identified un-met needs?

- She feels little or no pain
- She is unable to communicate with speech
- She has urinary and fecal incontinence and wears incontinence garments
- She is unable to properly stand or walk
- She repeatedly pulls out her Gastro 'Mic-Key' button leading to patient and family spending many days in hospital for button revision
- Her Peritoneal Dialysis Catheter has always remained vulnerable and a concern that it could potentially be pulled out
- QOL for the family is very poor with high levels of anxiety
- Cost to NHS for this patient is significant - not yet quantified but is under investigation

The Tookie Solution?

- A one-piece wearable garment designed to restrict patient access to the button and catheter, but access remains available for clinicians and family through hidden and secured apertures
- Access to the catheter is through apertures located on both sides, slightly behind the patient's hips and further security is achieved with a wrap-around belt which is back fastening
- Dialysis treatment without garment removal achieved through a line access aperture on the right-hand side sited over where the Tenckhoff catheter is located
- Access to the gastro mic-key button is through a side opening aperture on the left side of the garment
- This access arrangement allows continuous treatment without the need to remove the garment
- Consideration for potential future X-Rays, non-metallic poppers used to ensure the garment need not be removed
- To prevent the patient pulling the gastro mic-key button a large piece of 6 mm neoprene has been encapsulated between two layers of the cotton fabric which rests over the area where the button is located
- The garment is high in the neck and short sleeved to prevent patient access
- The garment is short legged again to prevent patient hand access
- The garment fully opens underneath to allow toileting
- To reduce over-heating the garment is open in the back
- The garment is made of cotton with 5% lycra for comfort and stretch
- The family chose the patient's favourite colour for the garment – purple!
- No removal still after six months

'Patient and Family Engineering'

In total, four prototypes were created, trialled and tested before the offered solution was confirmed. Tookie wishes to acknowledge the contribution in this research project by the patient, the family and the clinical staff; especially Tracy Dagler, Specialist Nurse PD Renal Services, Mr Ian Hennessey, Consultant Paediatric Surgeon and Clinical Director for Innovation and Ms Jen Bowles, Innovation Facilitator at Alder Hey Children's Hospital.

Additionally, Tookie wishes to thank the NIHR Children and Young Persons MedTech Co-operative MIC based in Sheffield for their continued support and mentoring throughout this project.

Furthermore, Tookie wishes to acknowledge the incredibly generous sponsorship by Renal Services UK for the purchase of future garments as the patient benefactor.

Tookie is delighted that this patient engineered solution in collaborative partnership will appear as a future article in Nursing Times.

Testimonials

"We are delighted that Tookie Limited have worked with the family of a severely disabled 17 year old girl to co-design a one-piece wearable garment to help protect her Gastrostomy Feeding Mic-Key button which is used to provide a means of accessing the stomach to provide nourishment, liquids and medication. All life-saving treatments.

The family have been battling for years to try and find a solution to help prevent their daughter removing the button, which results in replacement at great cost, time and extra anxiety for the family. The Tookie ethos is very much in line with our own of supporting children and young people live their lives as well as possible through the innovative use of technology and design thinking.

Through our networks, Tookie were able to connect with the family at Alder Hey Children's Hospital and work with the clinicians to understand the need for the button and what the implications are of its constant removal. We were also happy to support with the bringing together of stakeholders to allow Stephen to meet the family and come up with a transformation solution in response to the families need.

The outcome for this family is priceless."

Professor Paul Dimitri. BSc, MBChB, FRCPCH, PhD
Clinical Director, NIHR Children & Young People MedTech Co-operative
NIHR National Children's Specialty Lead

"It is fantastic to see a company that is so focused on children and improving their quality of life. Healthcare technologies for children are too often adapted from adult oriented solutions and it is great to see the inverse in action."

Mr Iain Hennessey
Consultant Paediatric Surgeon
Clinical Director of Innovation
Alder Hey Children's NHS Foundation Trust

Testimonials

"It has been fantastic to meet and work with Tookie at Alder Hey Children's Hospital. We have worked together with them and the family of a 17 year-old young lady who has complex needs and been under our care in renal for two years.

She has a peritoneal dialysis catheter and we had many concerns as she has historically pulled out her Mic-Key gastrostomy when upset or distressed. Her family had tried many different techniques to stop this but before Tookie became involved the NHS had run out of suggestions. This has led to much distress and trauma for the patient, anguish and anxiety for the family and addition costs for the NHS.

I am pleased and proud to have worked with the research team that has reacted to the challenge in a very positive manner, they always worked very closely with the family listening to their concerns and taking on board their ideas. They have produced a fabulous garment that is not noticeably a medical garment but still meets all the medical/access requirements that the family and clinicians have asked for. Both the patient and the family have a better quality of life which is great to see.

I would like to thank Tookie and congratulate them on their fantastic garment."

Tracy Daglar
Associate Nurse Specialist Nephrology
Alder Hey Childrens NHS Foundation Trust

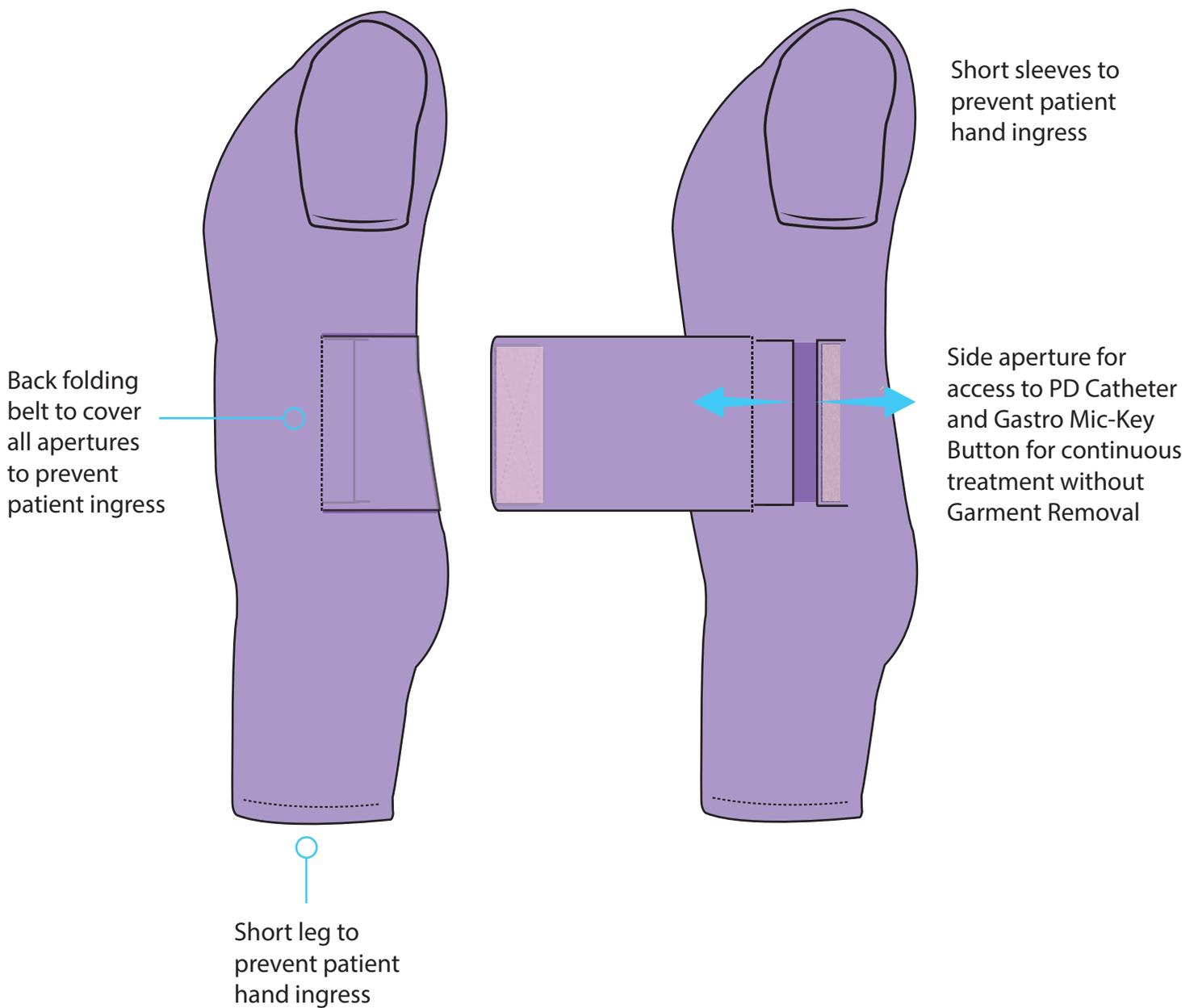
"The Alder Hey Innovation team has had the pleasure of working with the team from Tookie as part of our current ERDF project. I was introduced to the family by the team earlier this year and was astounded how difficult life had become for them, with their daughter needing constant supervision to prevent harming to herself.

From the start, the Tookie team became emotionally invested in improving this family's life. All measures were taken to ensure that the final design would be exactly what the family and clinical staff needed. It has been an interesting journey to be a part of, from original concept to final product. The impact on the day to day life of the family has been instantaneous, with initial reports back of a calmer household. This has been a fantastic example of collaboration between industry and the NHS and very gratifying to be a part of."

Jen Bowles-Smith
Innovations Facilitator
Alder Hey Children's NHS Foundation Trust

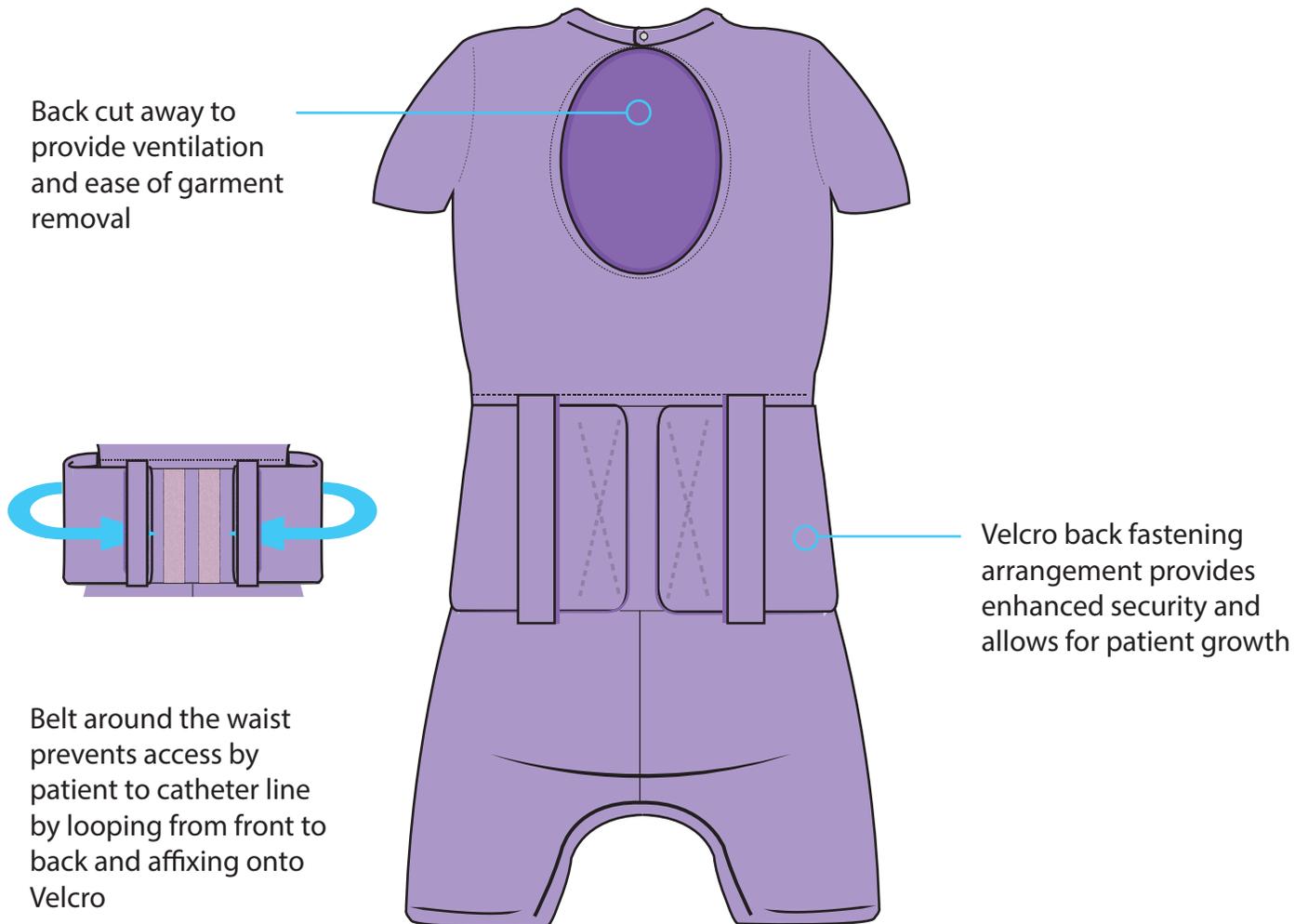
Design No. 4 (Final Version)

SIDE ELEVATION



Design No.4 (Final Version)

BACK ELEVATION



tookie

#ALifeMoreNormal

Testimonials

"I would like to start by thanking the team at Tookie our debt to them is huge, thanks also to the Nephrology team and Jen Bowles-Smith from Alder Hey's Innovation team for considering our family.

Our daughter was born with a rare condition now aged 17, has special and complex needs and is severely disabled.

She has little self-awareness and does not feel pain in some areas. She currently has a Mic-Key button fitted for feeding as well as a PD catheter for her dialysis, and it has been an ongoing battle for many years to keep her from pulling out her lines and feeding button if our attention is elsewhere. She has no concept of how seriously this can hurt her.

Since January 2019, she has pulled out her Mic-key eleven times, each time the tube has needed replacing at what I can only assume is a huge cost.

This means that we are limited to what we can do during our day, as she needs constant supervision when at home with us. When home from school, I don't have the ability to get on with normal tasks in the day, I must sit by her side day and night to prevent her pulling her button and tube from coming out. I can't even go to answer the phone.

We have tried everything from wetsuits to bondage tape to make it more difficult for her to grasp it through her clothes. Nothing has been enough to meet her demands. This had become a control issue for us as she knows if she pulls the Mic-Key button out, we will come running to fix it.

This is an issue we have brought up too many of the organisations involved in her care over the years. We have been repeatedly told that this is not an issue as children do not pull their tubes out.

Well, mine does and on a regular basis.

Up until now, I feel like no one has taken the time to listen to what the real problem is and that is when we were introduced to Stephen from Tookie by the Alder Hey Children's Hospital staff. We first met in December 2018 and he was incredibly enthusiastic and excited to undertake the challenge.

I must admit, my husband and I weren't as excited as Stephen, we thought another idea, another failure.

The first prototype drawings were sent to us and we were given carte blanche to amend them to how we saw fit. When the first garment was sent to us, the size and colour were perfect, but she still managed to pull out her Mic-Key button without much thought. Stephen asked for us to return the garment, so sure that he could fix the problem. He fed back to his garment designer. He told us that if we didn't get it right the first time, then we would keep trying until we did.

tookie

#ALifeMoreNormal

Testimonials

On 28th May, we received the new version and it looked promising. The part on the torso that covered the Mic-key button was reinforced with neoprene, the same material of the wetsuit we had tried some time ago. This makes it impossible for her to grab at it and she eventually forgets about it. There is also an opening for us to access her PD catheter without having to take it off nor her being able to access it. Along with the practicalities, they have taken her comfort into account.

The garment is practical, as we can access where we need, and the under-leg opening means we can access from below without having to take the garment off. The material is very soft on her skin and looks like a T-shirt when she has trousers on which provides her some dignity. Tookie have taken into consideration every little detail and it is a perfect job in my opinion.

The new product has taken away some of the pain and worry that we normally feel daily. Her demeanour has been so much calmer since we were given the garment. Although she is still attempting to pull it out, she has not succeeded so far, and we are six months in. The level of control has now been taken away from her; we have more freedom to carry out other tasks as we can now walk away for a minute and know she is safe. I can even indulge in my passion for baking again!

We are very grateful to Stephen and Tookie, as well the team at Alder Hey for choosing our daughter to help. Words cannot express our gratitude".

The Patient's Family

Product Design and Development Provided By Tookie in Association with KB Design.

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