Institution: King's College London		
Unit of Assessment: 3		
Title of case study: Co-design of medical devices and technologies with the ultimate users		
Period when the underpinning research was undertaken: 2001 – 2020		
Details of staff conducting the underpinning research from the submitting unit:		
Name(s):	**Role(s) (e.g. job title):**	**Period(s) employed by submitting HEI:**
Professor Patricia Grocott Dr Tanya Graham Dr Yan-Shing Chang	Professor of Nursing Technology & Innovation Research Fellow Lecturer	2001-present 2012-present 2013-present
Period when the claimed impact occurred: October 2014 – December 2020		
Is this case study continued from a case study submitted in 2014? N		

1. Summary of the impact

Patients with incurable, progressive conditions need medical devices to mitigate condition-related deformities. King's research enabled patients to reform their devices, improve independence and outcomes. Over 300 patients and families worked with clinicians, academic engineers, and manufacturers to co-design alternatives to 'making-do' with existing devices: dressing gloves instead of bulky dressings and bandages wrapped around fingers; adjustable splint gloves versus fixed splints to straighten contractures; co-designed visors, rather than home-made ones, for UVR protection. Patients can record their outcomes in digital patient-record systems, enabling patient-clinician communication, management, and routine outcome measurement, whilst saving travel and clinic time. Commercial opportunities were also created for UK companies through King's work.

2. Underpinning research

Since 2001 King's researchers have developed and evaluated novel medical devices using innovative design methodologies comprising:

1. Participatory co-design methodology, involves patients, parents, carers, clinicians, engineers and manufacturers collaborating to design and evaluate devices, and outcome measures **(1)**

2. Patients record their outcomes online using the TELER© Method **(2, 3)** to establish whether the devices perform to the standard they require

3. Case studies test device performance and capture individual experiences and costs, with routine clinical follow-up to off-set small study samples **(4, 5, 6)**

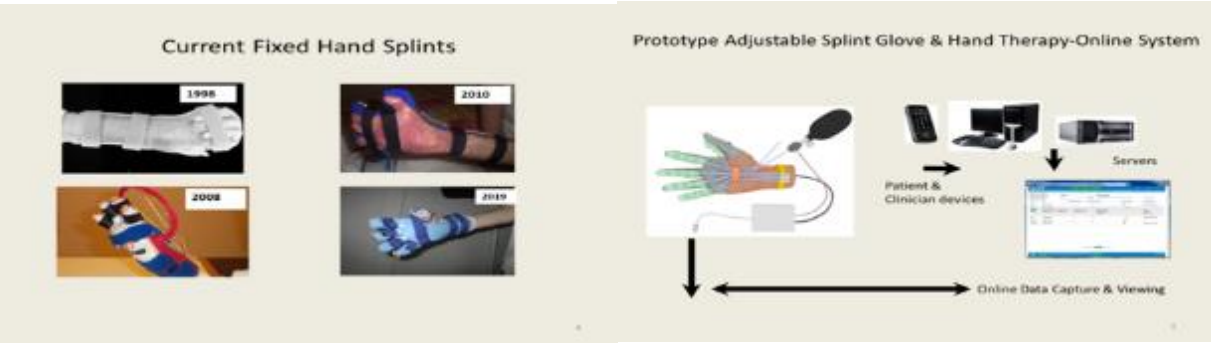
The methodologies have been applied to develop novel devices with people with wounds. Epidermolysis Bullosa (EB) is a rare inherited condition (5,000 people in the UK: 50,000 globally). People with severe types, including Recessive Dystrophic EB (RDEB), experience extremely painful skin and extensive wounds. This requires the use of pre-sized and shaped dressings over their wounds held in place with layers of flat and tubular bandages. Dressing changes take hours, and often require patching-up and replacement dressings. On the hands, post-healing scarring makes fingers conjoin and contract with loss of dexterity, function, and independence. Scarring is managed with dressings, bandages, reinforced gloves and fixed splints. However, patients do not tolerate current versions and often abandon them, resulting in contractures recurring.

To address the need for an alternative to bandages King's researchers developed the Skinnies WEB™ dressing retention range **(A-B)**. Participants reported greater comfort, healing of persistent wounds, and enhanced self-esteem using the new garments, Patients reported the Skinnies™ gloves, fit better than other gloves, leading to the **GLOVE project (1-6)**. Working with patients, parents, carers and clinicians from Guy's and St Thomas NHS Foundation Trust, Great Ormond Street Hospital for Children NHS Foundation Trust, academic engineers from Cardiff University, health economists from University of Surrey, Skinwear Limited (knitwear manufacturer) and TELER (IT company), King's researchers co-designed and tested:

1. A disposable dressing glove to protect blistered skin (Skinnies™) **(C)**

2. A knitted glove with reinforced knitting at finger bases and around the thumb to keep fingers separated (Skinnies™ Reinforced web-spacer glove) **(C)**

3. A prototype adjustable splint glove with detachable robotics (to straighten bent fingers), wrist supports and digital sensors to measure range of movement with wireless data exchange between the splint glove and a digital data capture system called Hand Therapy-Online (HTO).



The methodologies have been applied for a common condition requiring hand splints. King's researchers extended prototyping the adjustable splint glove to include people with Dupuytren's Contracture in the **GLOVED Project (1-6).** Dupuytren's is a common condition (20% men over 60; 20% women over 80; some earlier onset age >30) where lumps and string-like cords develop in the palm of the hand, pulling the fingers inwards so they are unable to straighten. Treatment includes surgery followed by splinting. People with Dupuytren's report similar problems tolerating fixed splints as people with EB; current splints have not changed for decades. The Adjustable Splint Glove enables therapists to customise splinting to individual fingers and hands with digital measurements of finger curvature downloaded to an App with data transferred to the HTO system or NHS clinical electronic patient record systems. This enables clinicians and patients to react to deteriorating hand function, facilitating intervention to reverse this without being face-to-face, to maintain a functioning hand.

The methodologies have been applied to develop a device for people who cannot tolerate exposure to daylight. King's researchers were invited by clinicians to codesign and test a specialised visor providing ultraviolet radiation (UVR) protection for people with Xeroderma Pigmentosum (XP). XP is inherited, rare and incurable, affecting around one in 250,000 of the global population. People with XP cannot repair damage from UVR in daylight and some artificial lights. Miniscule exposure causes lethal skin and eye cancers. Life expectancy is around 30 years unless individuals cover themselves in UVR-protective clothing and headwear. Of more than 100 patients registered with the UK National XP Service, 26% of children and 85% of adults do not cover their faces, with disastrous consequences. There is no provision of visors for people with XP; families make their own. During qualitative interviews with King's researchers in the **XP project**, patients and families said homemade visors steam-up, interfering with sight and speech, and reported cruel jibes from the public. Eleven prototypes were developed with Cardiff University academic engineers and tested with patients of different ages to create acceptable designs for people with XP. King's is now working in collaboration with The Manufacturing Technology Centre to advance commercially manufactured visors **(D.1, D.2)**.

Home-made Visor

Home-made Visor

Prototype 3 'On the Face'

Prototype 4 'Off the Face'

Codesigning digital online systems to measure needs, therapeutic benefits, and outcomes. King's researchers have developed The HTO system with software company TELER, for the

routine recording and monitoring of treatment, patient recorded outcomes, and costs. Clinicians monitor outcomes remotely, detect deteriorations and adjust treatment online without needing to be face-to-face, thereby avoiding long journeys to specialist centres **(E)**.

King's application of the TELER methodology for patient-recorded outcomes involves co-creating observable outcomes in the form of valid indicators. For example, one participant in the GLOVE project requested surgery to regain lost hand function. When asked what function he had lost he replied: *"My only measure is I can't pick up a pint of beer..."* He had to pick up a pint with his left hand and then force it into his right hand, illustrating the importance of the primitive grasp reflex which, if impaired, affects independent living. King's researchers, GLOVE clinicians and patients explored objective signs of progressive loss of grasp function and developed this simple code indicator for patients to measure and record their hand function onto the HTO system (*Indicator title: Ability to grasp a can of drink; 330ml for adults; 150ml for children*):

Code 5 - Able to grasp a can independently with one hand. Code 4 - Able to hold a can in one hand using the other hand to push it into the hand. Code 3 - Able to hold a can in one hand, using the other hand to push it into the hand and support it. Code 2 - Able to hold a can with two hands using fingers/thumb to support. Code 1- Able to hold a can using hands/arms or against the body, but not able to use fingers and thumbs. Code 0 - Unable to hold a can at all **(Fig 2, p4; E)**.

An online Delphi validation process has been developed by the King's researchers with TELER to facilitate remote development of the XP and Dupuytrens patient recorded outcomes **(F)**. The HTO system has been evaluated in routine care at Guy's and St Thomas NHS Foundation Trust in a Service Evaluation, funded by DEBRA (UK charity for those affected by EB), to advance adoption in UK EB specialist centres and international DEBRA organisations. The Senior Clinical Specialist Occupational Therapist for EB using HTO said: *"…if people aren't attending clinic for six months they can go on and score which means you can collect data, people can upload images onto the system, then you can view and that enables troubleshooting..."* **(G.1)**. HTO data compared with Electronic Patient Record data are objective, systematic, tracing responses to treatment over time.

3. References to the research

1. Grocott P, Weir H, Bridgelal Ram M. A Model of User Engagement in Medical Device Development *International Journal for Health Care Quality Assurance* 2007; 20(6):484-93. https://pubmed.ncbi.nlm.nih.gov/18030966/.

2. Browne N, **Grocott P**, Cowley S, Cameron J, Dealey C, Keogh A, Lovatt A, Vowden K, Vowden P. Woundcare Research for Appropriate Products (WRAP): validation of the TELER method involving users. *International Journal of Nursing Studies* 2004; 41(5):559-71. https://pubmed.ncbi.nlm.nih.gov/15120984/.

3. Grocott P, Graham, T, Blackwell R, Currie C, Pillay E, Clapham J, Graham-King P, Hon J, Snelson K (2013) Individualising wound care research: The wound care for epidermolysis Bullosa project. Wounds UK Vol 9 (3) 23-32. https://www.wounds-uk.com/journals/issue/35/article-details/individualising-wound-care-research-the-woundcare-for-epidermolysis-bullosa-project

4. Grocott P. Blackwell R, Currie C, Pillay E, Clapham J, Graham-King P, Hon J, Snelson K. Woundcare research for epidermolysis bullosa: designing products with users. *Dermatological Nursing* 2013;12(1):30-5. https://www.ingentaconnect.com/contentone/bdng/dn/2013/00000012/00000001/art00003.

5. Graham T, Sooriah S, Giampieri S, Box R, **Grocott P**. Iterative co-design and testing of a novel dressing glove for Epidermolysis Bullosa. *Journal of Wound Care* 2019; 28(1): 5-14. DOI: 10.12968/jowc.2019.28.1.5

6. Graham T, Sooriah S, Box R, Gage H, Williams P, Clemett V **Grocott P**. Participatory co-design of patient-reported outcome indicators and N-of-1 evaluation of a dressing glove for Epidermolysis bullosa. *Journal of Wound Care* 2020; 29(12): 751-62. https://doi.org/10.12968/jowc.2020.29.12.751

4. Details of the impact

King's research has led to patients, parents and clinicians reforming medical devices. Members of The British Dupuytren's Society from the UK, USA, and Canada appreciated being

able to voice their negative experiences of current splints and influence a novel approach **(I.1)**. One said *"…as you can see, my hand is essentially velcroed to a board and so, just everyday things - if you want to touch your wife's face, or if you want to ride a bike it's just renders your hand pretty useless. So, I would love the fact that maybe you could have, a, uh, splint glove that allowed some flexibility and support. I want to say thank you…"* **(G.2)**. The parent of a child with EB said *"… it is great you guys accommodated and made the changes until it was suitable for him…"* **(H)**.

The Senior Clinical Specialist Occupational Therapist for EB said the Projects allowed her to critically assess hand therapy practice, develop research and teaching skills, present at international conferences and lead a clinical guideline development group *"…working in a really busy clinical environment you don't have time to reflect on practice…working with the research team you can really thrash out what can we do to try and improve things…"* **(I.2)**. The Clinical Nurse Specialists for XP said "*…There has been extensive involvement and consultation by Kings, not only ourselves but importantly patients and their families, which includes the Support Groups, so every patient had the opportunity to participate, give views on the visor even if they didn't want to take part…"* **(I.3; I.4)**.

Novel therapeutic gloves developed with King's researchers improve outcomes for people with EB. Our co-design approach enables patients, parents, and carers to articulate their unmet needs through their projects, and researchers and commercial partners can successfully redesign medical products that aren't fit for purpose, and thereby enhance quality of life.

Fig 1. Adult patient with EB hands without dressings

Fig 2. EB hands constrained in ordinary dressings and bandages

Fig 3. Adult in Skinnies™ dressing glove and reinforced web spacer glove

Fig 4. Child in Skinnies™ dressing glove and reinforced web-spacer glove

The disposable dressing glove is an alternative to patchworked dressings and bandages **(Fig 2.)** It is knitted without seams in an absorbent yarn including silicone and antimicrobial finishes and wicks excessive heat and moisture avoiding their skin damaging effects. It is designed for easy removal, which is important given the constant contact of hands with surfaces and fluids. The washable web spacer glove is breathable with reinforced knitting at the base of the fingers and around the thumb to prevent the scarring from blisters, conjoining fingers, and the thumb from contracting inwards **(C)**. GLOVE participants did not want to revert to dressings and bandages. This is illustrated in the following notes added to the HTO system by a parent *"…Had a fall this week with his hands landing first on the floor, injured his forehead but the hands were fine. We think it was because of the gloves as they are thick - so very happy with it"* **(H)**. An adult participant reported *"…The whole experience is much better. Ten minutes per hand. Before it was 25 minutes per hand. Leaving dressings for 4 to 5 days is not good for EB. I still have blisters but now I just remove the glove* [to drain blisters]*. It's so easy…"* He reported less skin maceration and a dramatic improvement in hand function. His hands were now unconstrained by bulky dressings and bandages and he could hold a pen **(6, H)**. Another adult participant wrote in the 2015 DEBRA *InTouch* magazine "*the fingerless gloves help keep my fingers from becoming webbed together. When I used bandages webbing and contractures would recur far more frequently, meaning I would need corrective surgery sooner rather than later. I can't imagine my life back in bandages..."* **(J)**. Bespoke gloves are provided via the Bespoke Supply Services at Guy's and St Thomas and Great Ormond Street Hospital for Children NHS Foundation Trusts **(G.1, K.1, K.2)**.

The Senior Clinical Specialist Occupational Therapist for EB *reported "…when I see people post-operatively, I get people into the gloves. I've started doing that and also advising that patients are wearing the Web Spacer gloves for 24 hours a day ideally…"* **(G.1)**. **DEBRA** funds research and healthcare to support individuals and families affected by EB. They have collaborated in the WEB and GLOVED projects since 2009. The Skinnies WEB™ range is recommended in the DEBRA sponsored EB Woundcare International Guidelines, updated in 2017 **(B)**. The DEBRA Community

Project Lead said "*Participation delivers tangible, beneficial medical devices and opportunities for them and clinicians to make the daily lives of individuals and their families easier. They would not have alternatives to bandages wrapped around their fingers, which constrain normal hand movements and are desperately unpleasant to live with and to change…"* **(I.5)**.

King's research creates commercial opportunities and partnerships with manufacturing companies and service providers in the UK and internationally. The UK population of people with EB is small, c.5,000. Those with extensive blistering and wounds have Recessive Dystrophic EB, a smaller proportion of the overall population. Under a King's licence **Skinwear Limited** manufactures the gloves **(K.1)**. Between 2013 and 2020, 1986 units of web spacer and dressing glove orders were supplied by **Dermacea Limited** to patients with EB within the NHS **(K.1, K.2)**. This has generated approximately GBP129,090 in revenue based on average cost per unit **(K.1)**. The gloves (dressing and web spacer) are currently bespoke as even the children have very deformed hands. Skinnies garments are provided at no cost to patients with EB by the Danish and Norwegian governments. The CEO of HECO-Laboratorieutstyr AS, Oslo, communicated *"…Skinnies was approved by the National Health Authorities for reimbursement two years ago and today it is available to everyone diagnosed with EB…"* **(K.4)**. **Speciality Fibres and Materials Limited** is working with King's to prototype an advanced disposable dressing glove and other dressing garments for serious EB wounds and burns. They said they value being able to develop the products with patients and clinicians **(K.3)**. **TELER** is a Community Interest Company and registered King's service provider since 2014. King's projects have created opportunities to develop applications of their TELER methodology, IT platform and Online Delphi indicator validation system, including the DEBRA funded HTO system service evaluation **(E, F, G.1, K.5)**. Visor prototypes for people with XP have been taken forward to commercial prototyping with **The Manufacturing Technology Centre (D.1, D.2)**.

5. Sources to corroborate the impact

A. Sources that corroborate creation of WEB Dressing Gloves: A.1 Skinnies™ WEB Dressing Retention Garments website; **A.2** Listing on the Drug Tariff from January 2020 NHS Business Services Authority Part IXA, p582 [PDF]; **A.3** Sample WEB Dressing Gloves [physical items - retained by institution but can be provided in case of audit]

B. Denyer J, Pillay E, Clapham J. Best practice guidelines for skin and wound care in epidermolysis bullosa. An International Consensus. Wounds International, 2017. p25;55 [PDF]

C. Infographic with Skinnies™ gloves; Skinwear Limited computerised knitting [PDF]

D. The MTC XP Visor Ideation and Discovery for manufacturing [PDFs]: D.1 Work Package 1; **D.2** Work Package 2

E. Hand Therapy-Online system patient Guide TELER Limited [PDF]

F. Online Delphi system for TELER Indicators Guide [PDF]

G. Sources that corroborate impact of GLOVED project on patients [PDFs]: G.1. Interview transcript Clinical Specialist Occupational Therapist for Hand Therapy at Guy's and St Thomas NHS Foundation Trust [p.2]; **G.2.** Interview transcript research participant with Dupuytrens [p.7]

H. The GLOVE Project Film: Designing clothing for rare skin conditions. June 2018.

I. Testimonials from Organisations that work with patients [PDFs]: I.1 Chair of the British Dupuytren's Society; **I.2** Clinical Specialist Occupational Therapist for Hand Therapy at Guy's and St Thomas NHS Foundation Trust; **I.3** Clinical Nurse Specialist National XP Service; **I.4** Chair of the XP Support Group; **I.5** DEBRA Community Project Lead

J. Debra Magazine InTouch. Summer 2015. p15 [PDF]

K. Testimonials from Industry [PDFs]: K.1 Skinwear Limited Managing Director; **K.2** Dermacea Limited Managing Director; **K.3** SFM Limited R&D Project Lead; **K.4** CEO of HECO-Laboratorieutstyr AS; **K.5** TELER Managing Director