

Devices for Dignity (D4D) MedTech Co-operative: Unmet Needs...

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Theme Lead**

EPSRC NIHR Medical Devices and Vulnerable Skin
Network PLUS: Celebrating our Collaborations

Southampton - 29th May, 2019

The Device for Dignity MIC is funded by the National Institute for Health Research (NIHR) as part of its infrastructure. The views expressed are those of the author(s) and not necessarily those of the NIHR or the Department of Health and Social Care.



Plan:

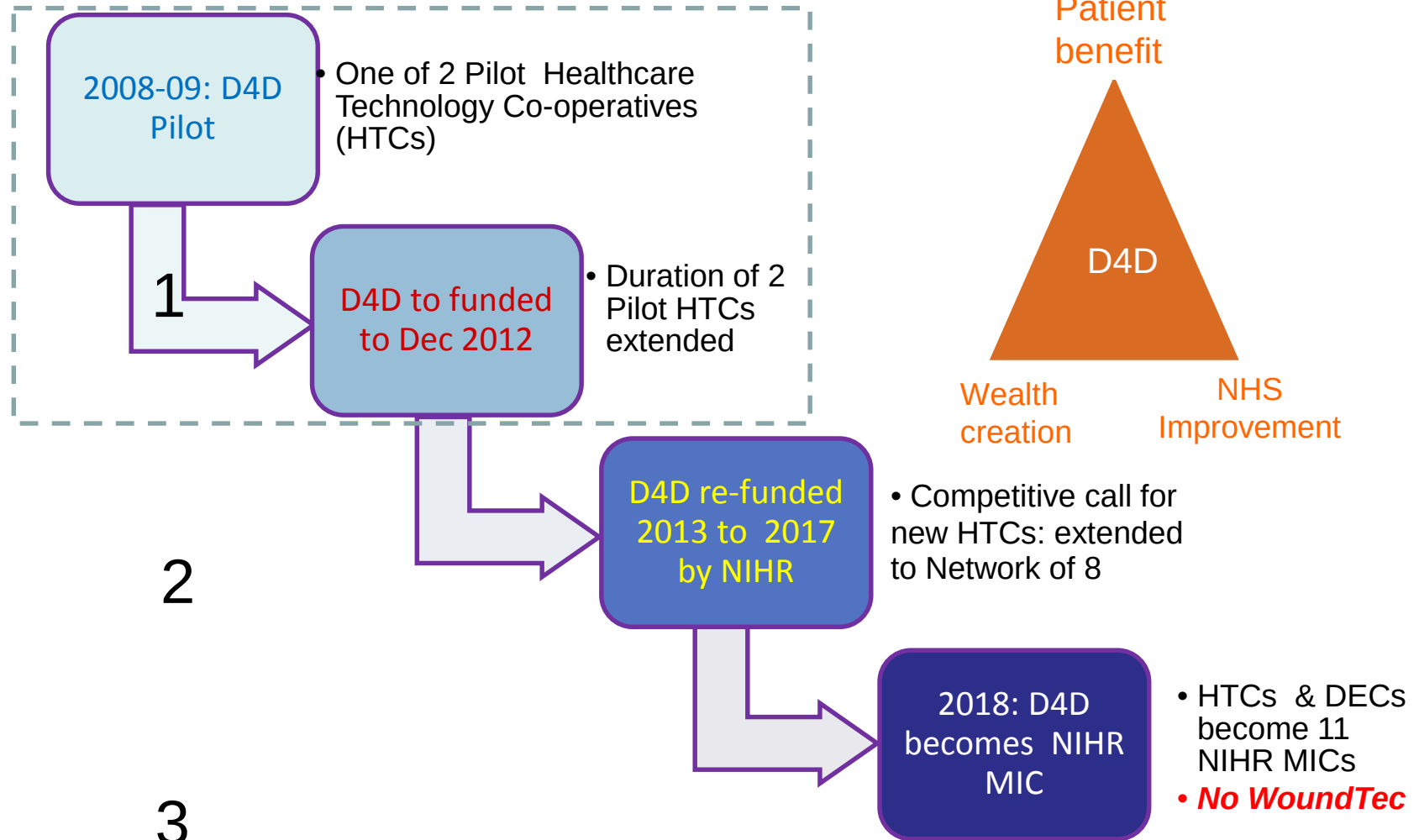
- Who is D4D
- D4D's model
- Projects
 - HeadUp
 - NIV
 - Starworks
- Summary

NIHR D4D MIC

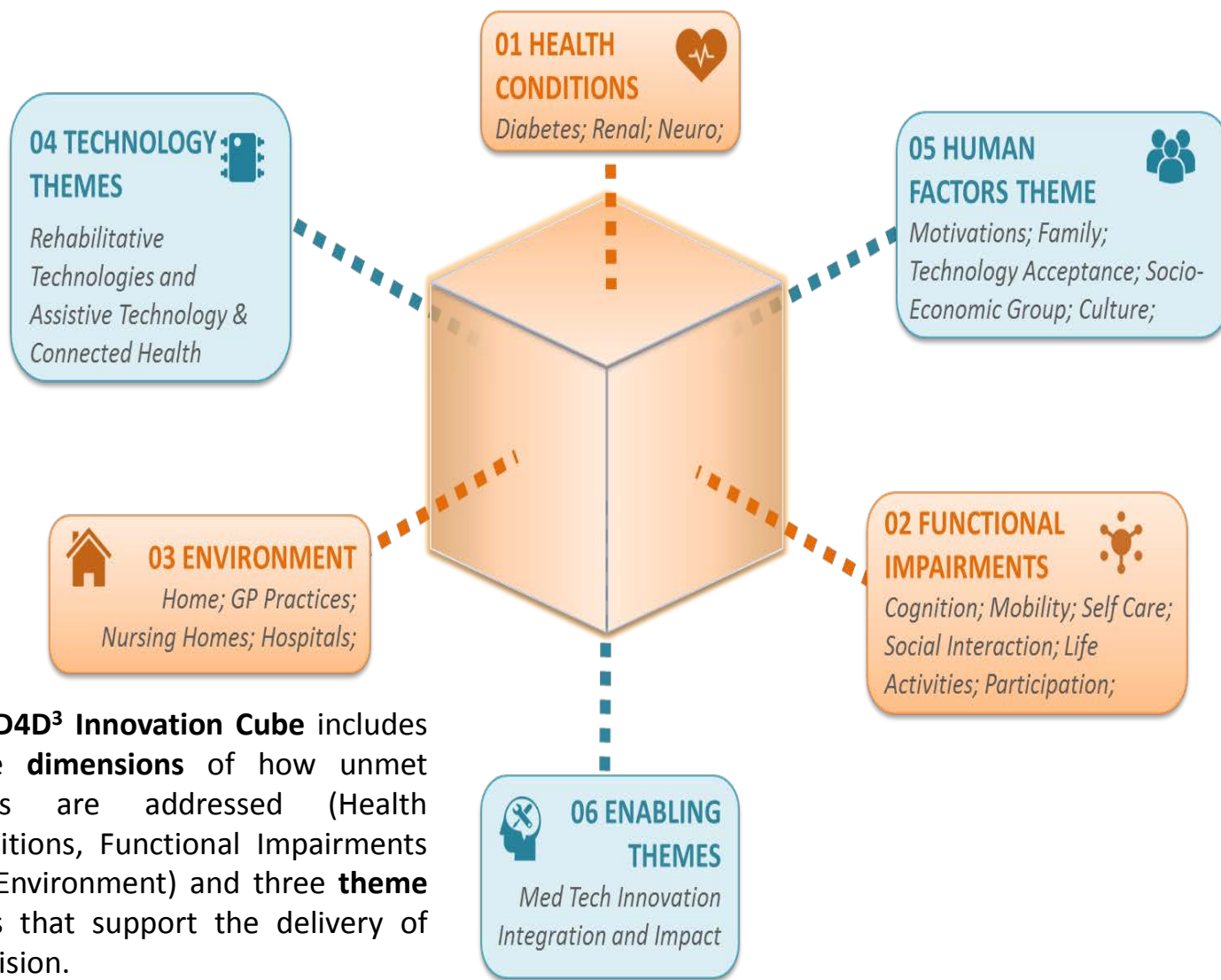
“Living my life well for longer”

Improving outcomes and quality of life for people
of all ages living with long-term conditions

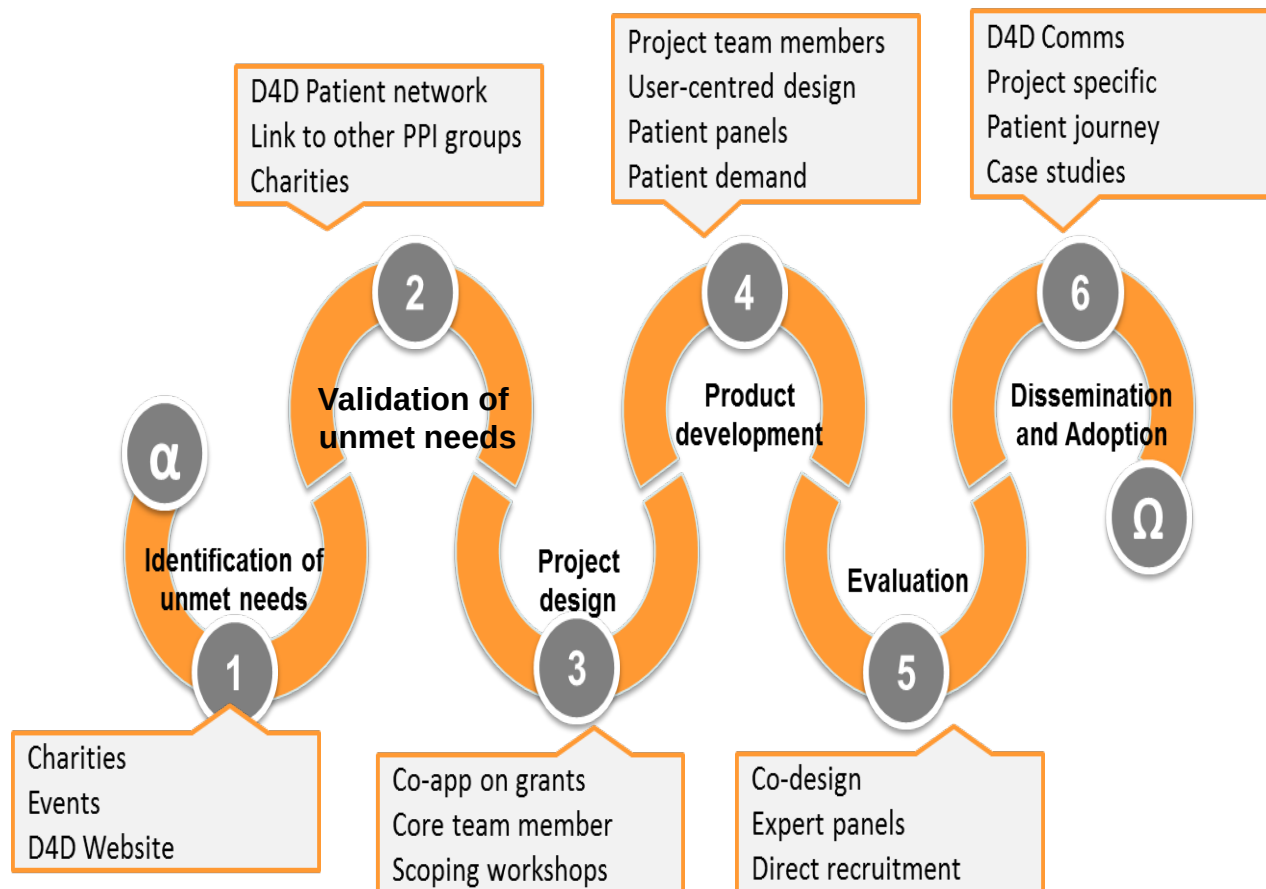
Overview/Evolution of D4D:



2018 – 2022 Programme for NIHR D4D MIC



Collaboration at every stage of innovation



Head Up Project

Background: Unmet clinical need

- Need for improved head support identified by a group of people with MND in South Yorkshire and North Derbyshire



- *I couldn't see my computer or T.V. screen or make eye contact with my wife when talking"*
- *"I hate, absolutely hate, the current collars, I feel like an Egyptian Mummy, being choked by it..."*

Previous neck support provision



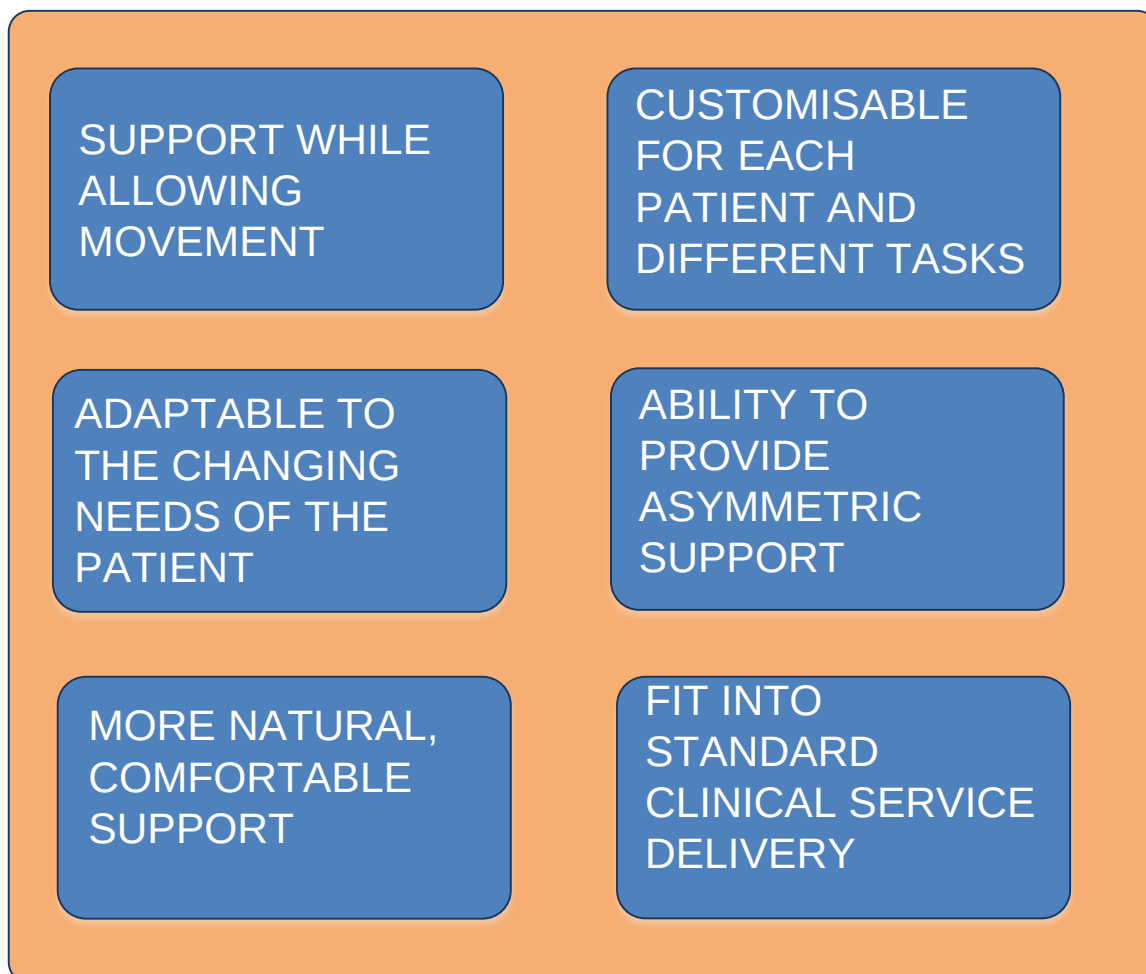
**FREE MOVEMENT BUT
INSUFFICIENT SUPPORT**



**MAXIMUM SUPPORT BUT
DISCOMFORT & LIMITED MOVEMENT**

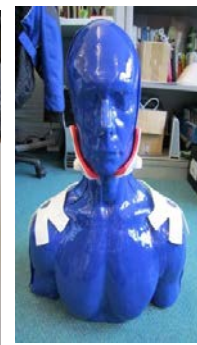
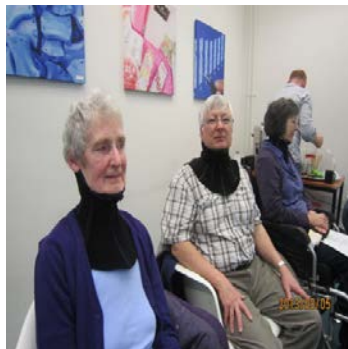


User requirements:



NIHR i4i Project:

Work Package 1: Iterative co-design, April 2012 – 12 months
Work Package 2: Prototype production and shaping – 4 months
Work Package 3: Clinical Trials (1&2) – completed December 2016
Work Package 4: Commercialisation – product launch April 2018!



Post clinical trial:

- 88% of patients chose to keep their snood

Patient quotes:

- *“Everyone who see’s me in it says it looks brilliant – like a polo neck – I am less self-conscious now”*
- *“No comparison to other collars – it works!”*
- *“It’s so comfortable, I’m really happy with it”*
- *This collar gives support but also more freedom of movement – I can wear it to drive”*



Commercialised & available from TalarMade Ltd

What is non invasive ventilation - NIV?

- Breathing support via face mask
- Poor fitting:
 - Poor outcomes and reduced life expectancy
 - Increased hospital admissions
 - Pressure sores
 - Restricted mid-facial growth
 - Disturbed sleep for child and family
- £100kpa cheaper than invasive ventilation (*tracheostomy*)



Craniofacial anomalies
Neuromuscular conditions
Airway conditions

Strong Clinical & PPI underpinned need for improved interfaces

Clinical Feedback

- Focus group MDT of paediatric clinicians
 - (n=5)
- On-line survey of clinicians / HCPs
 - (n=46, 70% adult, 30% paediatric)

PPI Feedback

- Focus group
 - (7 parents, 1 teenage user)
- Charity-led Patient / Parent On-line Survey
 - (33 parent responses in 48 hours)



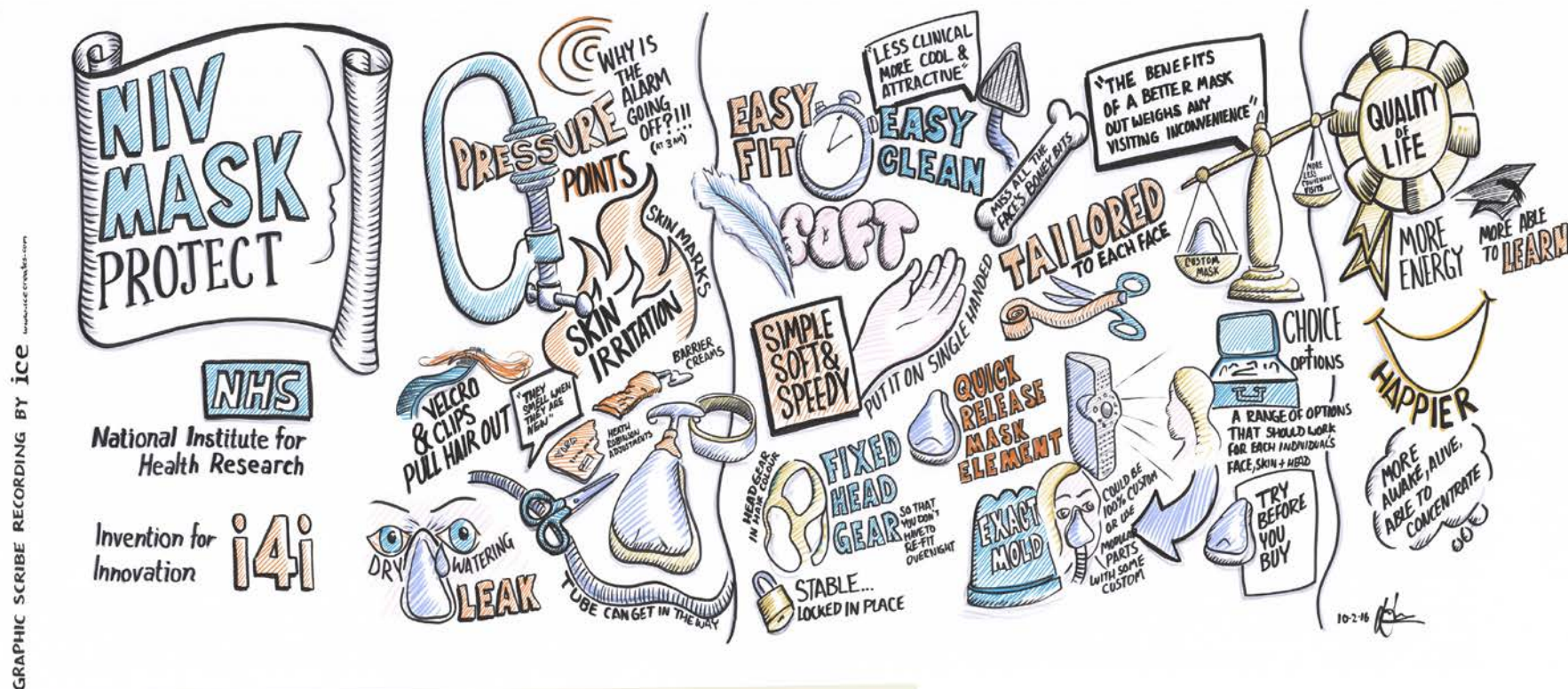
Most significant ranked as:

1. Pressure Sores
2. Sleep quality (child & family)
3. Comfort
4. Reducing family stress / parental anxiety

Helped evidence successful NIHR i4i grant application



Focus groups with children & parents...



This research is funded by the National Institute for Health Research (Invention for Innovation, i4i; II-LB-0814-20004; Development of customised non-invasive ventilation interfaces for children for whom current commercial masks are unavailable or unsuitable to improve ventilation therapies and reduce complications.). The views expressed are those of the author and not necessarily those of the NHS, the National Institute for Health Research or the Department of Health and Social Care.

Quotes from events:

*"I would feel **less guilty** about making him wear something which **hurts his skin**. I would get **more undisturbed sleep** with less leaks/hose dramas.*

*Which in turn might help me to be able to **reduce my anti-anxiety meds.**"*

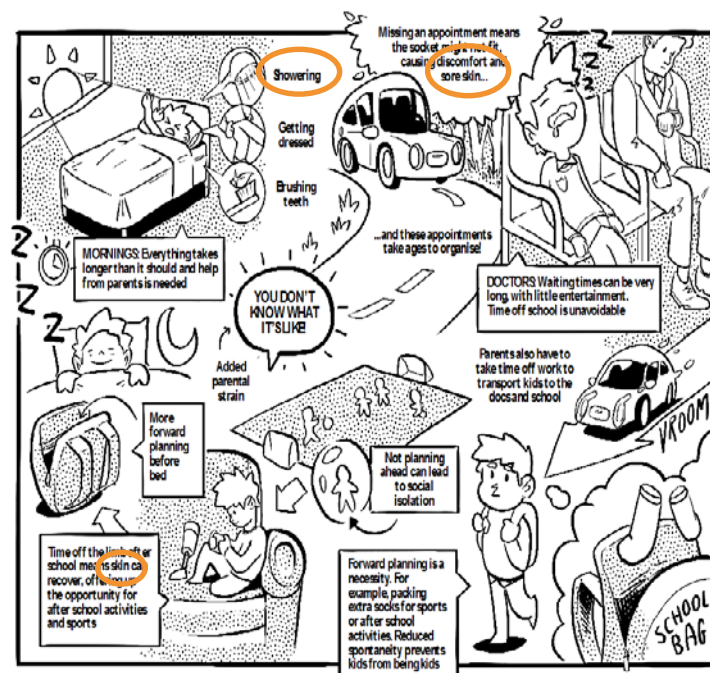
*"It would be **amazing** if we could have the chance of a made-to-measure mask.*

*The main thing it would do is give "J" **comfort** and in doing that **improve her sleep** giving her a **better quality of life**, something we all strive for."*

Starworks: Child limb prosthetics projects

STARWORKS

- Activity limbs vs **new research**
- D4D managed a research call for projects related to paediatric limb prosthetics
 - TITCH Network / D4D unmet needs methodology driver for STARWORKS invite
 - Key opinion leaders pulled together
 - Unmet needs process across all stakeholder groups
- 23 applications – 10 funded



Starworks 1 process...



Phases:

Phase One: Needs Assessment

Children &
Families
Academia
Industry
Healthcare

Stakeholder Meeting

Phase Two: 4 Sandpit Events – across England

1) Socket
Interface
2) Upper limb
personalisation
3) Lower limb
personalisation
4) Digital innovation

Call for applications

Phase Three: Project Funding

10 Proof
of Concept
projects
selected &
funded
These
began in
early 2018



Sandpits & Beyond

Problem



Inspire



Ideate



Develop



**Apply for proof of
concept funding**

Each stakeholder group is represented,
points of reference displayed

Start thinking abstractly, how can we
approach the challenges differently?

In stakeholder-specific and mixed
groups, supported by design facilitators &
materials

Highest scoring ideas are developed
further and presented to the group

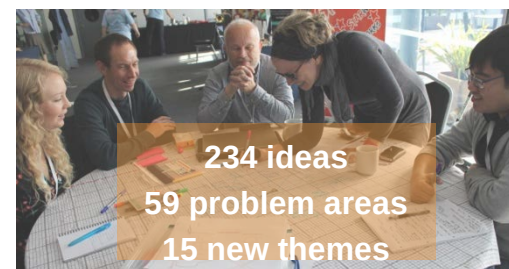
Networking opportunities and collaborative,
creative exploration of real issues led to 23
high quality applications, reviewed by expert
panel



**Approx. 17 new
challenge areas elicited**



**72 professional delegates
15 children & family members**



**234 ideas
59 problem areas
15 new themes**

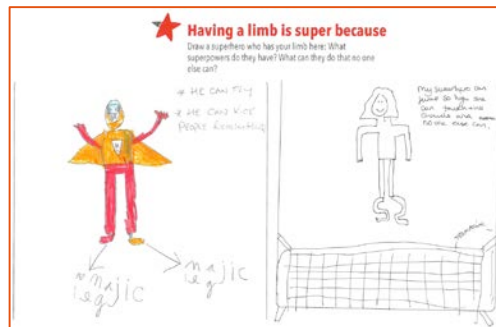


**Potential for
ongoing
network
collaboration**



Research & Identifying Needs

Children & Families



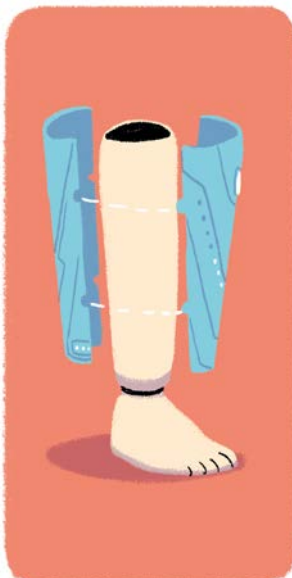
'We have never been asked our opinion about anything to do with our child's prosthetic, this is really exciting,'

- Mother of a child using an upper limb prosthetic.

'We have always been open about Mary's limb which has resulted in a lot of humour! Mary 'owns' her disability in a positive way,'

- Mother of a young adult with a lower limb prosthetic

Projects:



Projects
spanned:

- Education
- Cosmesis
- Play for engaging
- Suspension knees &
- Importantly:



← **Residual limb
– Prosthesis
interface**

Starworks 1 projects relevant to MDVSN^{PLUS}

3D print bespoke silicone liners

Improve satisfaction of children with their prosthetics, reduce skin infections & reduce rejection rates

Robust prosthetic socket that is also comfortable and adaptable to growth

Creating a scientifically validated design & manufacture workflow of advanced composites to provide children with comfortable & adaptable socket / liner components at lower cost

Socket Interface and fit Monitoring System (SIMS)

A new socket fit monitoring tool to help alert children, their parents and clinicians for timely socket adjustments



Starworks 2

Overview:

- Will support the best of funded projects from Starworks 1 to progress them towards reaching children & families to make a real difference
- Will continue to be managed by NIHR Devices for Dignity MedTech Co-operative
- Funding applications in review process
- Will continue to be an open inclusive network by ensuring voices of children & families are heard and understood.

Starworks 2 will build on the significant challenges and opportunities identified in Starworks 1

Continuation & development of expert networks with relevant stakeholder groups will allow Starworks 2 to nurture exciting ideas and collaborations to enhance R&D in this area

Summary

- MDVSN^{PLUS} & D4D have been working together in complementary areas: where devices interface with skin: *orthoses, prosthetics, NIV masks, continence...*
- Lots of unmet clinical needs still and a continuing need for both research organisations
- Many of the needs are unmet because they are challenging – ideal for bright engineers!



Thank you – any questions?

EPSRC NIHR Medical Devices and Vulnerable
Skin Network MDVSN^{PLUS}

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