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Led by Reed, this research programme investigated the possibility of developing a customisable product for children requiring non-invasive ventilation (NIV).

Non-invasive ventilation (NIV) is the delivery of breathing support via a facemask. Mass-produced masks are available for the adult market but in children it is often difficult to find one that provides an adequate seal necessary to deliver effective treatment. The consequences of poorly fitting masks are severe: at best this can result in pressure sores and impairment of facial bone growth, at worst the outcome is respiratory failure and premature death. In spite of these serious consequences, to date primary research has been unable to find cost effective solutions meeting stringent health service requirements and acceptability to children and their families. This enquiry brought together a multi-stakeholder group with representation from families of children requiring ventilation, clinicians, consultants from Sheffield Children's hospital and industry. As testing propositions on end users was not ethically possible the development of rigs and protocols became paramount and developed concurrently through the research.

The outcome of the research uses a combination of parts that are both standardised and bespoke. Soft and biocompatible materials, from the mass manufacture industry, are used in conjunction with the harder biocompatible 3D printed customised components. The novelty of the work was in how these parts work and fit together to produce a mask with a good, reduced leak fit that are comparatively cost-effective. This research was funded by NIHR I4I.

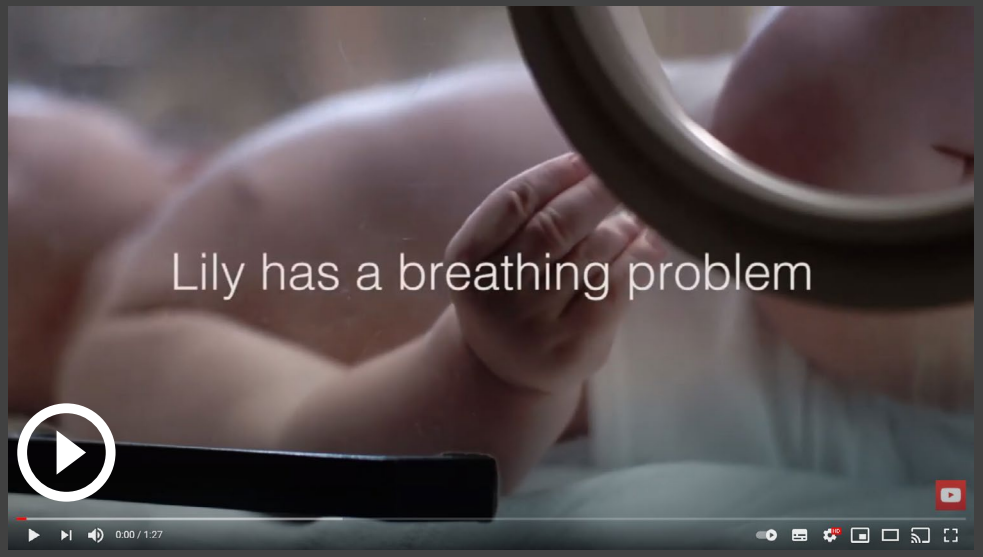


Figure 1. 'How can a 3D printer help this child breathe?'
Please press play to watch

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This research has proposed and developed a physical design configuration (figures 2 and 3) for NIV masks enabling high levels of topographic conformity and associated know-how (IP) pertaining to custom mask provision. This included process specifications, facilitation processes and detailed manufacturing technologies. The research further contributed to new knowledge in the field, in particular relating to the means by which new technologies may be evaluated for technical performance and practice efficacy. The research methods used, evaluation techniques and systems developed to date have been significant in facilitating stakeholders' understanding of the processes of developing bespoke masks from scan data.

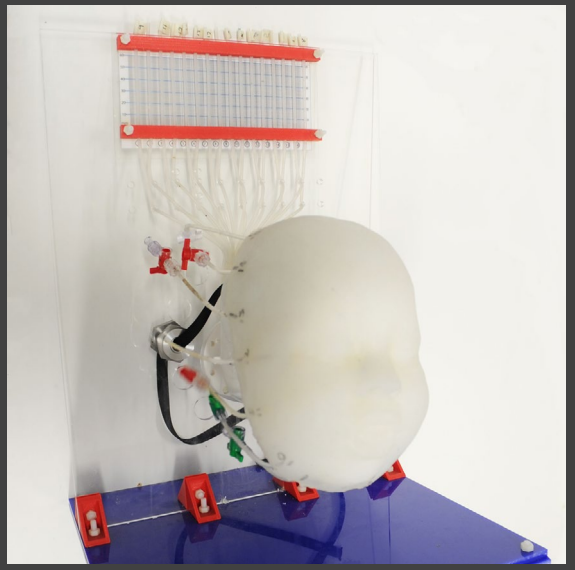

Figure 4. One of a series of 'paediatric test heads' (Manometer type).

Figures 2 and 3. The unique design arrangement the research yielded.

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Participatory design methods were utilised to build insights into acceptance issues and a series of prototypes were created in response to these which were refined using an iterative research through design cycle. As prototypes were developed key questions emerged in terms of how to test these with such a vulnerable population. An important element of the enquiry was the creation of a series of test rigs to evaluate proposals effectiveness, the quality of fit and seal against the face.


Figure 5.


Figure 6.

Figures 5 and 6: Focus groups were held with stakeholders (including children requiring NIV and their families) to build insights of experiences and challenges relating to use of existing designs.

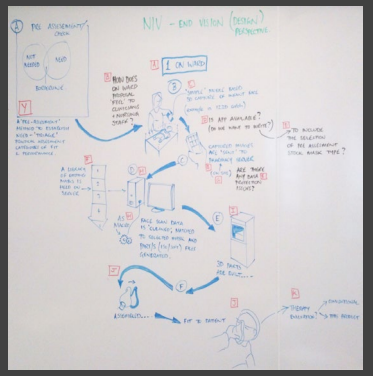

Figure 7.

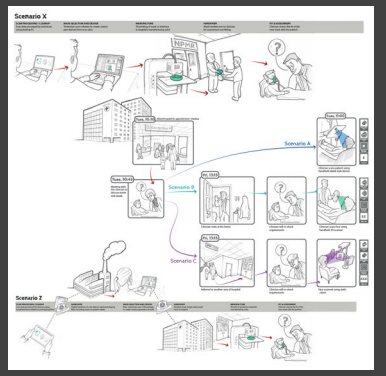

Figure 8.

The research brought together multiple stakeholders to build understanding of implementation processes. This informed potential exploitation and commercialisation strategies.

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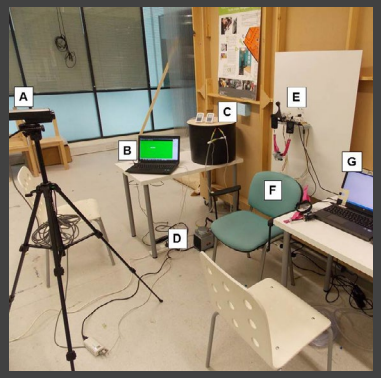


Figure 9.

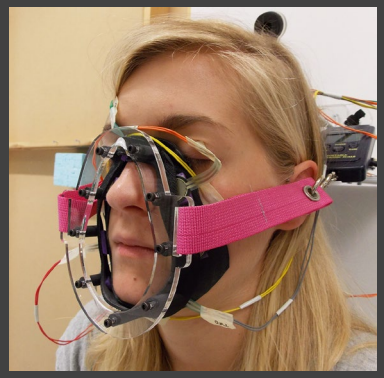

Figure 10.

Figures 9 and 10: Rigs were designed for testing and the data generated through these pro-vided understanding of the technical parameters of NIV therapy.

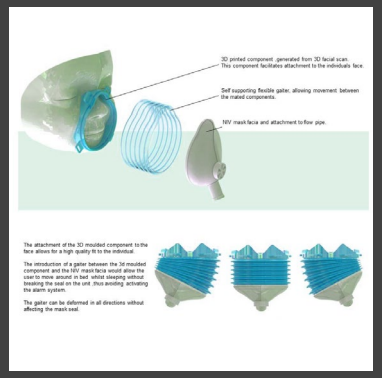

Figure 11.

Figure 12.

Figures 11 and 12: Concepts generated through the research process were visualised and shared with stakeholders. Through this process, insights were gained in relation to specific biocompatibility requirements, manufacture, and importantly service delivery considera-tions. This informed further designs. Ultimately, a hybrid design assembly involving both non-custom and customised componentry was detailed and produced for testing (figures 13 and 14).

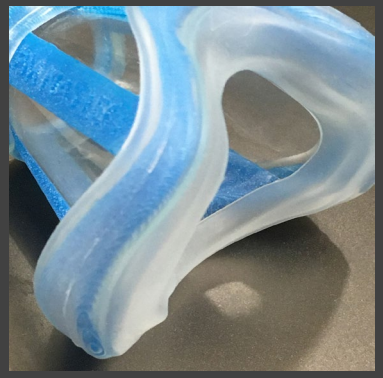

Figure 13.

Figure 14.

Figure 15.

The research team concurrently engaged with materials science and clinical engi-neering partners to undertake materials investigations. A design selected for progression utilised two principal materials and the safety and efficacy of those options was explored. Investigation showed how this product configuration may form a composite fabrication (figure 15, early-stage composite investigation) where harder, non-porous, sterilisable (BS EN ISO 10993 compliant) may union with softer components. A range of additive manufacturing methods were considered for the interface, in direct contact with the skin and indirect contact with the mucosal membranes of the respiratory system. A rigid nylon (medical grade Poly-amide), using a selective laser sintering (SLS) process, was specified as it was one of the few that could meet a combination of require-ments for a custom-made medical device, and be produced within a quality-managed process (to BS EN ISO 13485:2016).

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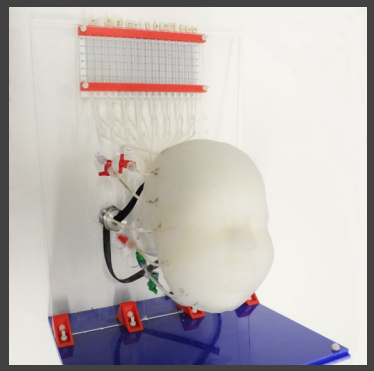

Figure 16.

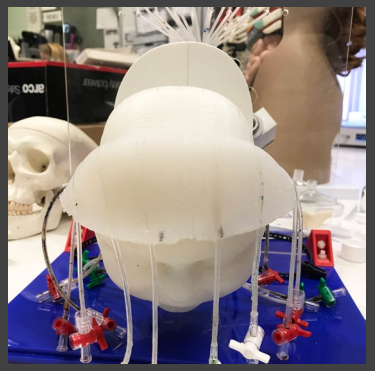

Figure 17.

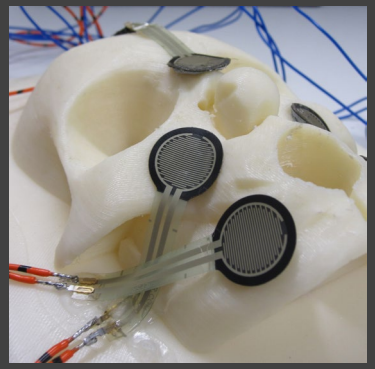

Figure 18.

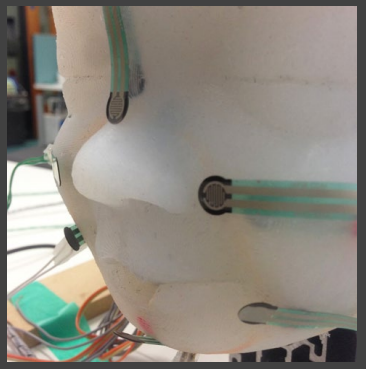

Figure 19.

Three primary phases of testing design proposals were planned involving non-human, human adult, and paediatric trialling. Our early-stage parameter research identified the com-plex requirements and effects of masks on a user's face (comfort, impeded bone growth, leak, pressure on face management, quality of therapy). To test design proposals prior to human use the design research team developed a series of paediatric mannequins exhibiting aspects of human physiology relating to softer and harder structures of the face.

Anonymised and composite (10 subject scan data amalgamation) child skull structures were 3D printed and a skin of silicon simulating its elasticity and thickness was constructed. Into the simulated skin were embedded (figures 16 and 17, manometer head) a series of deformable, liquid filled tubes in a radial array, such that an applied prototype mask would deform and influence the inner tube liquid level against a graph.

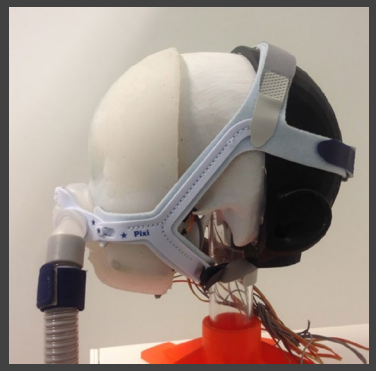

Figure 20.

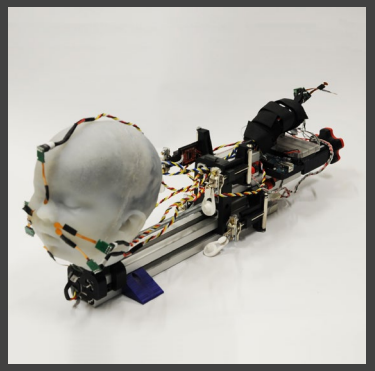

Figure 21.

Different physical mask designs and their features could be tested for evenness of load on face, with less deviation in liquid from a horizonal reading indicating fewer pressure points. Developing this principle further the team embed FSR (pressure force-sens-ing resistor) cells (figure 18) between the hard skull and softer simulated skin material and latterly surface mounted sensors to a mannequin to produce a digital data set (figure 19).

Lastly, based on this learning, test rigs were developed that included further functionality to record mask head strap load (figures 22 and 23), to better understand required loads to form an adequate seal, aiming to improve comfort and fit. In this way masks and mask face interface designs could be tested for efficiency prior to human level testing. These methods proved invaluable in developing knowledge in design research and the wider clinical team.

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Figure 22.

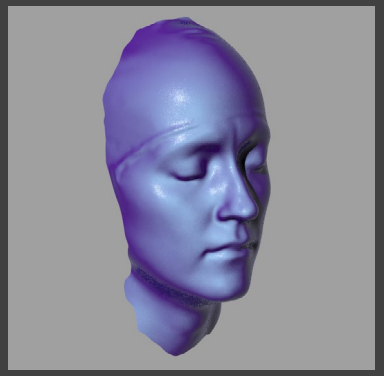

Figure 23.

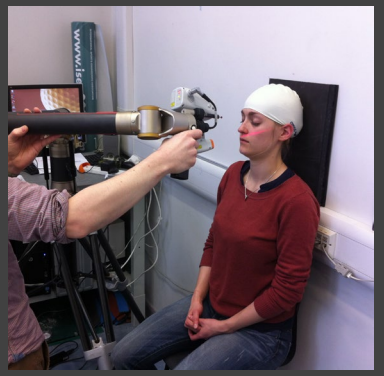

Figure 24.

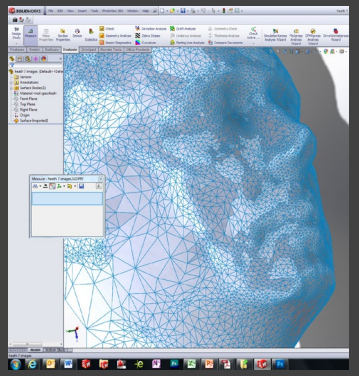

Figure 25.

In the proposed system the customisable, individual topographically compliant mask components is derived from three dimensional scans of the patient. In order to understand 3D scan technology, its appropriateness for use in this context, and at acceptable scale and resolution, a number of commercially available systems have been evaluated. These range from 'gold standard' very high resolution but often static/installation-based systems (figure 23 and 24) to handheld, mobile devices (figure 22, example output).

Each was evaluated for its cost, technical merits in application, and fit with service delivery constraints and intent. Further aspects of this enquiry explored the means by which resulting scan data will be processed (figure 25), identified opportunities for process automation and ethical protocols.

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Figure 26.

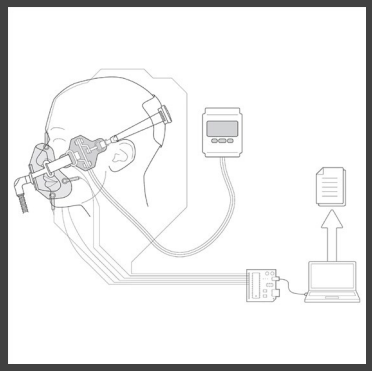


Figure 27.

Ahead of planned user trials with paediatric patients, the project team trialled the feasibility of the process of creating and printing bespoke masks from 3D scan data and carried out testing of the masks in adult volunteers (figure 26, showing test equipment in place on volunteer) to further select the strongest design concept for paediatric trials.

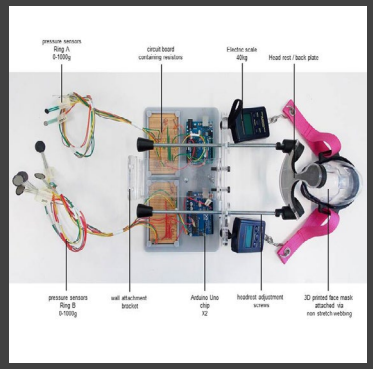


Figure 28.

Figure 29.

Based on the learning from the paediatric mannequins, an FSR and head strap load cell approach to human testing was developed into a human level test rig (figures 27 and 28).

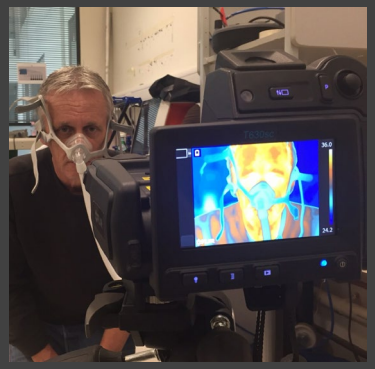


Figure 30.

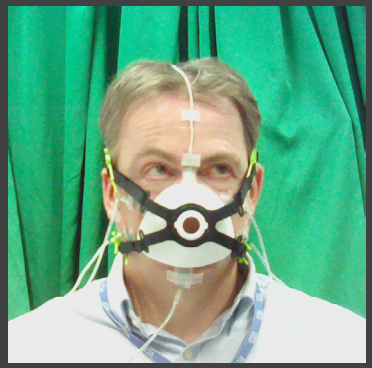


Figure 31.

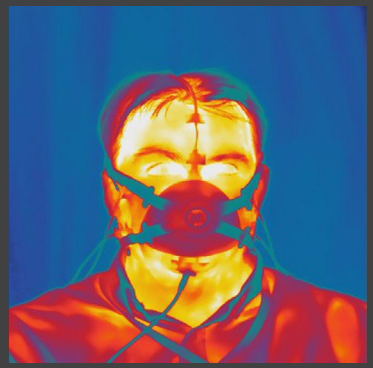
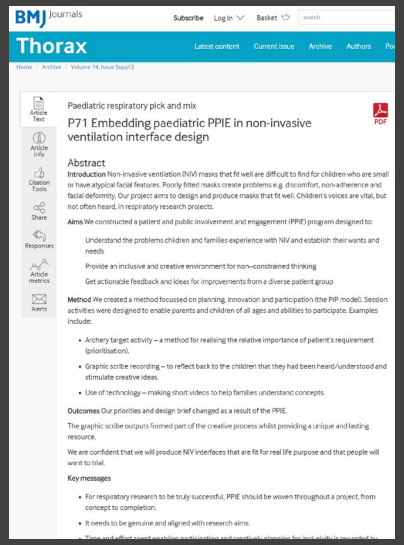


Figure 32.

Custom mask interfaces for adult volunteers were manufactured in medical grade PA (Polyamide). This allowed the team to iteratively refine the techniques and methods involved in mask design production and detail the testing protocol for future patient trials. Alongside user reported comfort and observed leak reporting, thermal imaging was used to create quantifiable data, helping to confirm leak region, tested on one of the mannequins (figure 29), and deployed in study human trials (figures 30, 31 and 32).

**Peer-reviewed Design dissemination has been undertaken through case study citation (Design for Heath Conference proceedings, 2015) and lectures with PPI level lessons learned presented and published (UNIDCOM/IADE International Conference Senses & Sensibility, 2019). Clinical methods and study outcomes have been reported through discipline specific Journals (BMJ 2019, JMET 2020). A range of public disclosures and communication materials have been achieved through University and affiliate (Sheffield Childrens' Hospital NHS Trust, NIHR, D4D) channels.**

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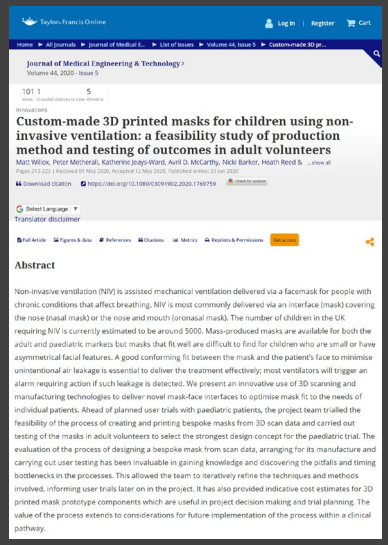


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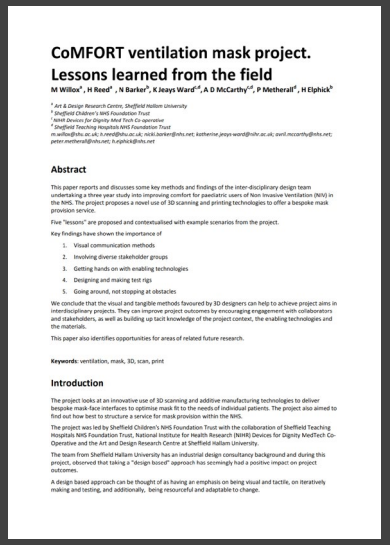


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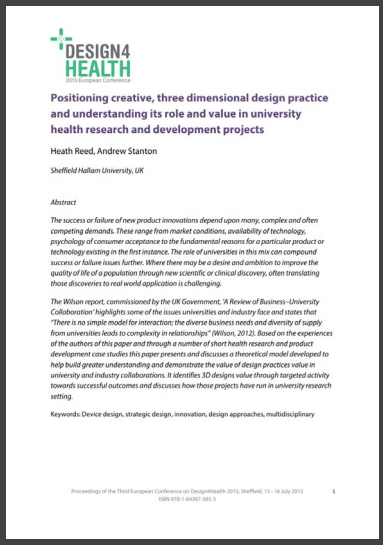


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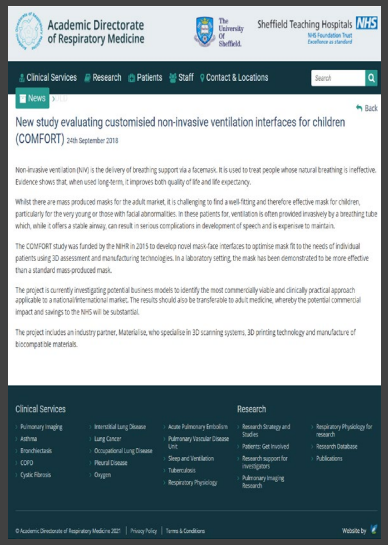


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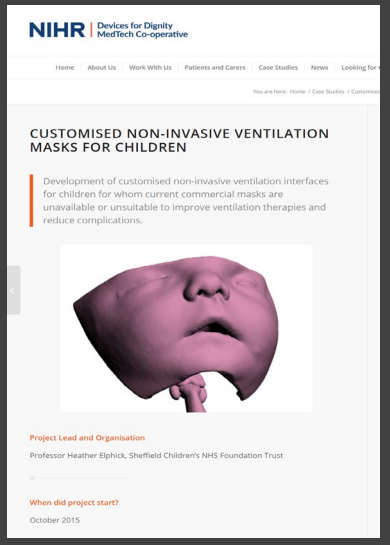


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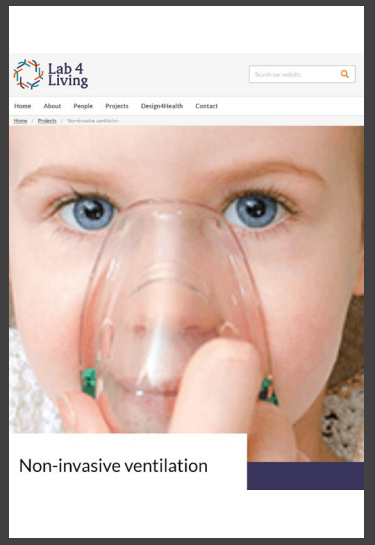


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