DEVELOPING RESILIENCE & LOCAL SUPPLY CHAINS FOR PRECISION DESIGN ENGINEERING TECHNOLOGY IN RESOURCE CONSTRAINED ENVIRONMENTS

Prof Dominic Eggbeer & Dr Katie Beverley, PDR, Cardiff Metropolitan University. UK. Deggbeer-pdr@cardiffmet.ac.uk
Peter Evans, Maxillofacial Lab Manager, Swansea Bay University Health Board, UK
Prof Divya Mehrotra, DEAN, Quality Control, Assessment, Accreditation & Future Planning, King George's Medical University, India

In part, this work has been supported by the UK India Education Research Initiative (UKIERI) project number UKIERI-UGC 2017 18. This is a collaborative fund between the governments in the UK and India. www.comeddi.com

COLLABORATIVE MEDICAL DEVICE DESIGN INITIATIVE

HEALTHCARE, DESIGN & FUTURE MANUFACTURING

1) Introduction

Advanced 3d precision design and engineering technologies have revolutionised the way patient specific implants are made. These methods are proven to improve clinical outcomes and reduce the duration of surgical procedures compared to traditional "artisanal" methods.[1-4] As access to 3d design tools increases, there has been a marked increase in hospital specialists collaborating with specialists in design/engineering to design their own devices in house [5,6]. However, setting up service provision for 3d patient-specific implants is a complex task, particularly in resource-constrained hospital environments. The effective introduction of new precision design and engineering technologies requires the careful consideration of the views of multiple stakeholders, identification of numerous key factors to address and a structured approach that avoids building on assumptions.

Design research methods are suited to the exploration of such complex situations. The Deign Council's 'Double Diamond' [7] process is commonly adopted for design research, and is a National Institute for Health Research (NIHR) - recognised method for the application of design to healthcare challenges. It describes the design process in four phases: *discover* – the divergent and exploratory stage in which a problem is investigated from the view of different stakeholders; *define* – where the findings from the discovery phase are synthesised and the project team converge on the desired outcome and an initial strategy to achieve it; *develop* – where potential alternatives are created, prototyped, tested and iterated; and *deliver* – where the 'best' option is selected and realised. The 'Double Diamond' is often used as a framework to support multidisciplinary project teams; different disciplinary research methods can make a contribution at each stage, whilst the design thinking approach it encourages helps to overcome traditional disciplinary boundaries when understanding and synthesising the findings[8]. However, there are particular challenges in its use, particularly during the convergent phases. For example, the volume, diversity and depth (or lack of) of data generated in the *discover* phase can be intimidating. In the absence of a structured approach to managing the data, often delivered by expert facilitation [9] there is a tendency for disciplinary norms to take over, and the opportunities revealed through the multidisciplinary collaboration may be missed. This is particularly a problem in projects where circumstances dictate that analysis and synthesis is being conducted at different times, by different people and in different geographic locations. The Design Research Methodology [10] offers a systematic approach to synthesising the information gathered during the research phase and (through the development of a reference model). The reference model establishes possible key factors that lead to an improvement of the existing situation, differentiates between assumptions and evidence-based relationships and proposes measurable success criteria.

This poster reports on how this method was applied within the Co-Meddi project, a collaboration between partners in India and the UK which is exploring how a locally-appropriate service for the democratised treatment of facial deformities can be developed [11].

2) Methodology

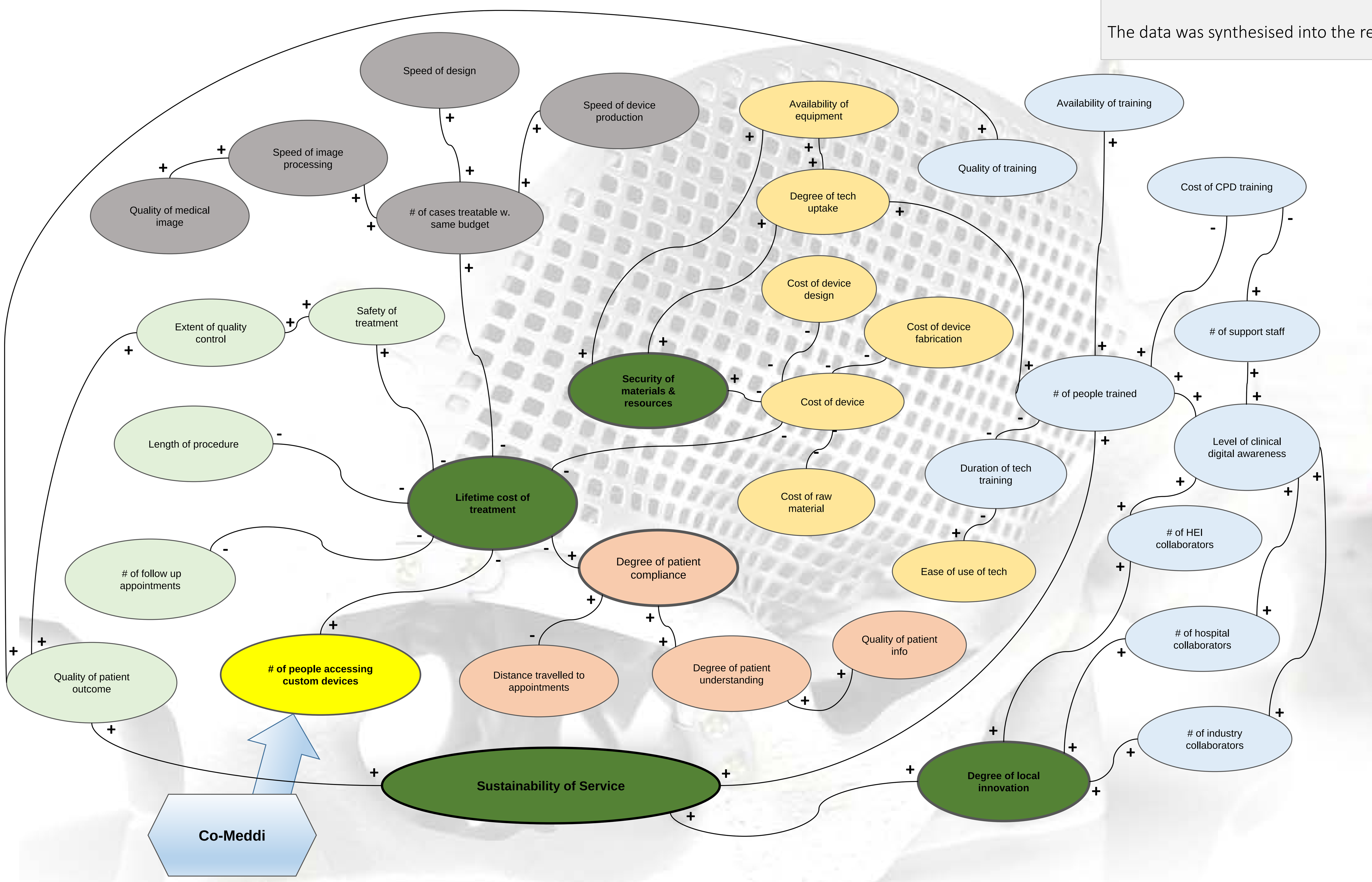
The aims of the Co-Meddi Project are expressed through a tailored version of Double Diamond phases:

1. *Discover* the needs and concerns of patients receiving devices and how improvements in design and services would lead to better outcomes in the short and long term.
2. *Define* the limitations of existing 3D design and production services and assess the feasibility of a range of potential improvements.
3. *Develop* cost effective solutions for challenging clinical environments through collaboration between researchers, clinicians, hardware and software developers.
4. *Deliver* case studies of how new solutions can be applied and identify the education and training requirements that need to be addressed to maximise sustainability and effectiveness.

The *discover* phase was conducted over three exchange visits (one with UK researchers visiting India, two where India researchers visited the UK). A number of different research tools were used to gather relevant data. This included:

- Stakeholder mapping for a design service
- Problem definition brainstorms with different stakeholders
- A focus group of surgical and clinical staff which explored how patients are currently treated, the most common facial deformities presenting, and the extent to which clinicians consider patient-specific implants relevant to their work
- Patient journey maps for the different patients presenting at the hospital with different facial deformities
- Patient case reviews
- Discussions with those with responsibility for procurement on product and material supply chains
- Reviews of documentation regarding hospital processes and the strategy for 3D surgical provision
- Reviews of existing quality requirements in the UK and India
- Visits to existing specialist 3D
- Literature reviews on identified data gaps including: healthcare provision in resource-constrained environments; the status of quality regulations in the UK and India; and innovation in resource-constrained environments.

The data was synthesised into the reference model presented here.



Spin off benefits

- Research status
- Number of high quality research papers
- Number of research projects

Key Factor

Primary Project Aim

4) Discussion & Conclusion

Adoption of the design research method has allowed the development of a reference model and ensures a shared understanding of the existing situation across a diverse group of researchers and practitioners. The reference model identifies key factors that will influence the design and implementation of a 3d service in an Indian hospital context that improves the outcomes for patients presenting with facial deformities. The model is being used to establish a research agenda to increase the impact and sustainability of the service.

Analysis of the model identifies four key areas to be addressed that correspond to the quadruple bottom line concept, in which sustainability is defined in terms of economic, social, environmental and innovation performance (also referred to as 'The 4 Ps' - people, planet, profit and progress). Examples of key influencing factors identified for each of the bottom line concepts are:

- **People**: - Democratic provision of implants can only be achieved if two core criteria are met: first, that the Government is able to see the lifetime socio-economic benefits for patients qualifying for free care (around 50% in this context); and second, that initial costs are low enough that those patients just above the qualification are able to afford treatment. Reducing immediate costs of the service (materials, equipment etc.) and reducing lifetime costs contribute to achieving to both objectives. In particular, The reference model identified that a significant problem in relation to the adherence to treatment plans for patients in rural areas who have to travel to city hospital facilities. Better education, awareness and understanding of the lifetime costs of treatment, higher quality initial outcomes and extended provision through hub-and-spoke hospital models could reduce the social and economic impacts of non-adherence. Reducing the costs for patients just about the qualification threshold is also dependent on them presenting as early as possible.
- **Planet –** materials security is important to ensure that the services are cost-effective in the short-term and can be long-term sustainable. The development of locally available sustainable materials (for example, bio-based polymers derived from food and forestry industry waste) or recycling of waste materials (for example deriving PET-G from locally-recycled PET) could provide greater levels of material security whilst simultaneously addressing existing waste management and land use challenges on the Indian sub-continent
- **Profit –** The difficulties encountered in establishing a business case for patient-specific implants are not unique to India, although they are exacerbated by higher equipment and material, and lower labour costs. The economic rationale is strongest when lifetime costs of treatment can be illustrated. A robust approach to lifetime costing for the various patient contexts in India is necessary
- **Progress** – The higher material and machine costs in India are a challenge to the sustainable development of a custom implant service. A strong research and practice culture exists in India regarding Jugaad and frugal innovation contexts. Building collaborative links with researchers and innovators in materials science and engineering can be used to develop an innovation agenda that will reduce existing infrastructure risks.

This reference model will form the basis for the *develop* and *deliver* phases of the Co-Meddi project.

References

1. Sugar, A., Bibb, R., Morris, C. and Parkhouse, J. (2004), "The development of a collaborative medical modelling service: organisational and technical considerations", British Journal of Oral and Maxillofacial Surgery, Vol. 42 No. 4, pp. 323-330.
2. Peel S., Bhatia S., Eggbeer D., Morris D., Hayhurst C. (2017). Evolution of design considerations in complex craniofacial reconstruction using patient-specific implants. Proceedings of the Institution of Mechanical Engineers, Part H: Journal of Engineering in Medicine (early cite). http://journals.sagepub.com/doi/abs/10.1177/0954411916681346?url_ver=Z39.88-2003&rfr_id=ori%3Arid%3Acrossref.org&rfr_dat=cr_pub%3Dpubmed&
3. Peel S., Eggbeer D. (2016). "Additively Manufactured Maxillofacial Implants & Guides - Achieving Routine Use." Rapid Prototyping Journal. 22(1) 189-199.
4. Peel S., Eggbeer D., Sugar A., Evans P. "Post Traumatic Zygomatic Osteotomy and Orbital Floor Reconstruction Using Digital Tools and 3D-Printing – A Case Report." Rapid Prototyping Journal. 22(6) 878-886
5. The Centre for Applied Reconstructive Technologies in Surgery. www.cartis.org. Accesses 6th Nov. 2017.
6. Aleid, W., Watson, J., Sidebottom, A.J. and Hollows, P. (2010), "Development of in-house rapid manufacturing of three-dimensional models in maxillofacial surgery", British Journal of Oral and Maxillofacial Surgery. 48(6),pp. 479-481.
7. The Design Council. "A study of the Design Process - Eleven lessons: managing design in eleven global brands. Available online at: https://www.designcouncil.org.uk/sites/default/files/asset/document/ElevenLessons_Design_Council%20(2).pdf [Accessed 31st August, 2019]
8. Maciver, F., Malins, J., Kantorovitch, J. & Liapis, A. (2016). "United we stand: a critique of the design thinking approach in interdisciplinary innovation". 2016 Design Research Society 50th Anniversary Conference: 27 - 30th June, Brighton, UK.
9. Mosely, G., Wright, N. & Wrigley, C. (2018). "Facilitating design thinking: A comparison of design expertise". Thinking Skills and Creativity, 27, pp. 177 - 189.
10. Blessing, L.T.M. and Chakrabarti, A. (2009), DRM, a Design Research Methodology, Springer London Ltd, London.
11. Co-Meddi project - www.comeddi.com .