Identifying research and development priorities for an in-hospital 3D design engineering facility in India

Abstract

Advanced three-dimensional (3D) design and engineering technologies have revolutionised patient-specific implants, prostheses and medical devices, particularly in the cranio-maxillofacial and oral medical fields. Lately, decreasing costs, coupled with the reported benefits of bringing design and production technology closer to the point of healthcare delivery, has encouraged hospitals to implement their own 3D design and engineering services. Most academic literature reports on the factors that influence the sustainable development of such services in high-income countries. But what of low- and middle-income countries where demand for custom cranio-facial devices is high? What are the unique challenges to implementing in-hospital services in resource-constrained environments? This paper reports the findings of a collaborative project, Co-MeDDI (Collaborative Medical Device Design Initiative), that brought together a UK-based team with experience of setting up and running a hospital-based 3D service in the UK with the Maxillofacial Department of a public hospital in the Uttar Pradesh region of India that had recently received funding to establish a similar capability. We describe a structured design research approach consisting of a series of exchange activities taking place during the lifetime of the project that compared different aspects of the healthcare innovation ecosystem for 3D services in India and the UK. Based on the findings of the different activities, we identify key factors that influence the adoption of such services in India. The findings are of relevance to healthcare policymakers and public hospital managers in resource-constrained environments, and to academics and practitioners engaging in collaborative export of healthcare initiatives.

Introduction

This paper uses design thinking to explore factors influencing the sustainability of a three-dimensional (3D) design and engineering service in a hospital environment and recommends actions. We focus on facial deformity medical disciplines within the Indian public healthcare system, but the findings have application in other low-middle income regions or resource-constrained healthcare environments.

Facial deformities caused by disease, trauma and burns are common in India and disproportionately affect those close to or below the poverty line (Choudhary *et al*., 2019; Gupta *et al*., 2014; Kumar *et al.*, 2001; Kumar *et al*., 2019; Roychoudhury, 2014; Weihsin *et al*., 2014). Studies have shown that they have a significant impact on quality of life (Khandelwal *et al.*, McMahon *et al.*, 2019; 2017; Ranganathan *et al.*, 2018; Rattan *et al.*, 2017) and also carry a significant cost burden (Ahuja 2013; Jain 2008; Malik 2017; Ramireddy 2017).

Visualising the complex architecture of cranio-facial anatomy has become easier with the advent of 3D design and engineering technologies. These include 3D scanning, 3D computer aided planning of surgical procedures, 3D Computer Aided Design (CAD) of medical devices and 3D printing (also known as additive manufacture). Typical applications include the production of patient-specific anatomical models, transient use guides to aid cutting/drilling and osteotomy procedures, production of long-term implants and extra-oral maxillofacial prostheses made specifically for a named patient (Bibb *et al.,* 2010; Budak *et al.,* 2018; Chandra *et al.,* 2005; Eggbeer *et al.,* 2012; Mankovich *et al.,* 1990; Peel *et al.,* 2016; Salmi *et al.,* 2012). 3D technologies have also been applied to the development of facial burn/injury splints to compress hypertropic scar tissue and reduce its prominence over time (Pilley *et al.,* 2011; Visscher *et al.,* 2018). Reported benefits of patient-specific implants and devices include improved clinical outcomes and reduced procedure duration compared to traditional "artisanal" methods of producing custom implants (Peel *et al.,* 2016).

The decreasing cost of 3D design engineering technologies (and particularly printing hardware) has encouraged the development of in-hospital capability. A cursory literature search identified hospital-based facilities in the UK (Aleid *et al.,* 2010; Sugar *et al.,* 2004), Japan (Kamio *et al.,* 2010), North America (Sheikh *et al.,* 2017), Europe (Lanzarone *et al.,* 2019; Pierreville *et al.,* 2018) and Australia (Lanzarone *et al.,* 2019). To our knowledge, though, public hospital-based facilities in India are rare, although internet-based articles indicate growing interest in the application of advanced 3D technologies in the Indian healthcare system (Chandavarkar, 2020; Pathare, 2017; Romeo, 2018).

Bringing 3D design engineering technologies closer to the point of healthcare delivery has potential merits: device designers and producers can work more closely with the prescribing medical specialists, which can be important in time-constrained hospital environments (Louvrier *et al.,* 2017, Truscott *et al.,* 2007); and there is better opportunity to monitor outcomes and improve designs, which is important, given the relative infancy of custom medical device design using 3D design engineering methods (Tuomi *et al.,* 2014). However, several practical, technical, economic, institutional and regulatory barriers to the implementation of such methods in different regions have been reported (Burton *et al.,* 2018; Martelli *et al.,* 2016; Polykarpou *et al.,* 2017; Polykarpou Barrett, M. and Faraj, 2018).

Adoption of healthcare innovations is dependent on the effectiveness of local innovation ecosystems (Mitra *et al.,* 2020). In 2015/16, around 75% of medical devices and diagnostics were imported into India (Chaturvedi *et al.,* 2015; Dixit *et al.,* 2018). A recent analysis of the Indian healthcare innovation ecosystem identified key barriers to strengthening the Indian healthcare sector and highlighted the need for rapid development of locally developed medical technologies (Deloitte and the Healthcare Federation of India 2016). A structured design process that identifies and involves actors within the healthcare ecosystem can support the development and implementation of regionally-appropriate medical innovations (Chaturvedi *et al., 2015*; Co-MeDDI, 2020; Deloitte and the Healthcare Federation of India, 2016; Dixit *et al.,* 2018; Iyawa, 2016).

This paper reports the findings of a collaborative project between partners in the Uttar Pradesh region of India and the UK, called Co-MeDDI (Collaborative Medical Device Design Initiative). Co-MeDDI was funded by the UK India Education Research Initiative, which aims to enhance educational linkages between India and the UK. The UK partners were a university-based design research centre with nearly twenty years of experience in using 3D design engineering technologies in medical applications and a local university

hospital in South Wales, UK with an in-house 3D design engineering service. The Indian partners were based within the Maxillofacial Department at King George's Medical University (KGMU) in Lucknow planning to implement a public hospital-based 3D design and engineering service for the treatment of facial deformities.

Methods

Co-MeDDI used design thinking methods to engage with stakeholders involved in the production and use of devices to correct facial deformities. Qualitative data on factors influencing the development of an in-house 3D design and engineering facility was collected through semi-structured interviews, group discussions and service design tools. Service design is an iterative approach to the creation or improvement of services that explores stakeholder wants and needs and proposes service-based solutions to meet them (Blomkvist *et al*., 2010). It has been increasingly applied in healthcare environments to support the development of sustainable patient-focused services (Prendeville, 2019). Qualitative data generated during the project was structured based on the design research methodology (DRM) (Blessing and Chakrabarti, 2009). DRM offers a structured approach to the mapping of influential factors surrounding a given research challenge and subsequent identification of research priorities. It has been previously used to identify key factors influencing 3D design and production technology uptake in healthcare (Peel and Eggbeer, 2016). It provides a practical way to illustrate and reimagine a complex situation. We report on work that falls under the *Research Clarification* stage of the DRM (Figure 1).

Insert Figure 1

Figure 1: stages of the DRM and the research clarification focus of this paper

Co-Meddi was conducted over four exchange visits:

2.1. Visit 1: King George's Medical University

The first exchange visit established a clearer understanding of project aims, outcomes and key impacts and context in which the 3D design and technology service would operate.

2.1.1. Challenge definition

A 1-hour workshop was held with internal stakeholders at KGMU, including the Director, professors, clinical leads, academic research manager and health economics specialist from the Maxillofacial units. Participants wrote down their desired impact from the implementation of a 3D design and technology service on sticky backed notes. The notes were clustered into thematic impact areas that represented a shared vision of the ideal service. The stakeholders used the Challenge Definition Tool (Figure 2), to articulate the vision as a 'how might we' question, in order to encourage a solution-focused mindset in subsequent activities.

Insert Figure 2

Figure 2: The Challenge Definition tool

2.1.2. Stakeholder mapping

The stakeholder mapping tool (Figure 3) was used as the basis for a structured brainstorm in which key stakeholders who could realise the vision were identified.

Insert Figure 3

Figure 3: The Stakeholder Mapping tool

2.1.3. Clinical insight through user journey mapping

Limited time, patient confidentiality and language barriers limited the opportunity for gathering primary data on user experience. Instead, an overall picture was developed through expert interviews with lead clinicians from the different maxillofacial specialisms, guided by a user journey map (Figure 4a and 4b). The interviews explored the different interactions between patient and hospital, the time taken and the user experience throughout the process. User journeys were collaboratively developed for patients engaging with the paediatric dental and maxillofacial surgical specialisms. The process allowed 'pain points' positively or negatively affecting the 3D design and technology service to be identified. The patient journey maps were used to inform discussions about the 3D design and technology service throughout the process.

Insert Figure 4a

Figure 4a: The User Journey Map tool

Insert Figure 4b

Figure 4b: Working with KGMU clinicians to complete the User Journey Map

2.1.4. Case reviews

Case reviews supplemented the understanding of the medical needs of patients attending the Maxillofacial Unit gathered through the journey maps. Medical case histories for two patients identified as potential recipients of custom implants were reviewed. Custom implants designed at KGMU and associated published case studies were also reviewed. This provided insight into the specific clinical needs that the service would be expected to meet.

2.1.5. Observations

The Co-MeDDI team were situated at the Maxillofacial Unit for the five-day visit. This allowed informal observation of hospital activities and surroundings.

2.2.6. Facility specification review

Proposed specifications for materials and equipment associated with the service were reviewed. Costs and availability were compared between India and the UK.

2.3. Visit 2: South Wales, October 2018.

Representatives from KGMU visited a university-based medical science and research facility (the Institute of Life Science, Swansea Medical School, Swansea University, UK) to discuss how tissue engineering and medical imaging research was undertaken between medical specialists and academics.

2.3.1 Observations at a hospital-based 3D design engineering facility

The Co-MeDDI team visited the Maxillofacial and Prosthetics laboratory at Morriston Hospital, Swansea for one day to observe the working practices of the team. Think aloud protocol was utilised to understand the specific tasks that were undertaken by different actors in the workflow of a typical case. This provided insight into job roles, necessary skills and task order.

2.3.2. Visits to equipment and material providers

Visits were organised to a local metal additive manufacture equipment provider and small entrepreneurial polymer materials research and manufacture facility that support advanced 3D design and engineering facilities in the UK. This provided an insight into the capabilities and the relationships between suppliers and users in the UK innovation ecosystem.

2.4. Visit 3: South Wales, May 2019

The focus for the third visit was on skills and knowledge acquisition for KGMU staff.

2.4.1. Training days

Training days were held at Morriston Hospital and PDR. The training days used Computer Tomography (CT) data brought from KGMU. KGMU received training on manipulating CT scans and designing implants on industry-standard software (figure 5).

Insert figure 5

Figure 5: Training on digital design engineering technologies

2.5. Visit 4: Bangalore and KGMU, February 2020.

2.5.1. Visit to equipment provider

The UK Co-MeDDI team members visited a major 3D additive manufacturing equipment provider based in Bangalore. The team interviewed the innovation manager to gain insight into the drivers and barriers for equipment manufacturers to enter the medical market in India.

2.5.2. Design Challenge workshop

A three-day workshop was convened at KGMU in February 2020. Recruitment was via an online application process in which participants submitted proposals for 3D design and

engineering-enabled responses to three challenges aligned to the Co-MeDDI vision. The three themes were: custom temporal mandibular joint designs; facial prostheses; and resource efficiency. Twenty-two proposals were received from ten research, practice and education institutes, all of whom were invited to attend the workshop. The workshop supported the researchers to identify key research themes and build collaborations. During the discussions, the broader perceptions of India-based researchers about key challenges to be addressed and desirable outcomes were explored. Informal discussions with the researchers provided further insight into the research and practice environment in India.

3. Results

3.1. Challenge definition

The stakeholder workshop established the desired outcomes for a 3D design and engineering facility at KGMU as: improved patient outcomes; nationally leading research opportunities for faculty staff; nationally leading education opportunities; resilient material and equipment supply chains; and cost neutrality. This was refined into the following challenge:

"*How can we design and implement an effective and sustainable facility for all patients that surgeons at KGMU identify as requiring custom cranio-facial medical devices?"*

Stakeholders agreed that cost neutrality would represent economic sustainability and could be achieved through a combination of income from surgical procedures on paying patients, income from education activities facilitated by the service, commercial production of implants, and cost-effective operation of the service. Threats to economic sustainability of the service were perceived to arise from costly materials and equipment.

The KGMU stakeholder group explained that Uttar Pradesh is one of the poorest regions of India. Approximately 50% of KGMU's patients live below the poverty line, and most paying patients are just above the threshold. Higher income patients usually attend private healthcare facilities. Custom implants have been used on KGMU patients, obtained via a costly global supply chain, but lack of evidence on efficacy makes it difficult to justify their use to paying patients and healthcare funders when alternative treatment options are available. Access to affordable state-of-the-art medical care that led to improved outcomes for KGMU patients would represent success in terms of social sustainability for KGMU stakeholders.

3.2. Stakeholder mapping

Five key groups who would play a major role in supporting a sustainable service were identified: government, education, public hospitals, private clinics and industry (Table 1).

Table 1: Stakeholders and their assumed roles

STAKEHOLDER GROUP	STAKEHOLDER	ROLE
Government	Ministry of Health and Family Welfare (Department of Health)	Sets policy for healthcare and determines key investments.
	Ministry of Health and Family Welfare (Central Drugs Standard Control Organization)	Regulates health care providers and medical devices.
	Ministry of Health and Family Welfare (Department of Health Research)	Promotes and co-ordinates basic, applied and clinical research in areas related to medical, health, biomedical and the medical profession. Develops infrastructure, manpower and skills for medical education in cutting-edge areas. Administers and monitors the Indian Council of Medical Research.
	Government of Uttar Pradesh	Provides governmental grants for recurring and non-recurring (e.g. equipment and infrastructure) costs at KGMU.
	Medical Council of India	Sets and monitors standards for university medical education.
	Indian Council of Medical Research	Provides funding for medical research in line with the priorities of the Ministry of Health and Family Welfare.
	Department of Science and Technology	Supports technology research, including medical sciences and technology, and powder metallurgy and new materials.
Education	Higher Education Institutes (Institutes of Technology)	Research projects and education initiatives in 3D printing, design technology, Industry 4.0 and novel materials.
	Medical Universities	Research projects and education initiatives supporting state-of-the-art oral and maxillofacial medicine.
Public hospitals	Maxillofacial and oral clinicians/ surgeons	Conduct surgical planning and operations. Set surgical plans for patients and insurance companies. Make the case for procurement of devices and technologies. Bear liability for success/ failure of surgery.
Private clinics		
	Medical technicians	Conduct/ support the design and production of medical devices.
Industry	Indigenous medical device suppliers	Manufacture medical devices that are commonly at the lower end of the value chain. Import high value products for use in India. Can benefit from the 'Make in India' scheme.
	Indigenous advanced manufacturing equipment manufacturers/ suppliers	A blend of global multi-national enterprises and start-up companies who can supply equipment and training to the medical sector.
	Indigenous materials suppliers	Can support the development of a local, resilient supply chain for device manufacture.

3.3. Key factor definition

Through discussion and the exercises, the Co-MeDDI team identified three key factors that would support the sustainability of KGMU's 3D design and engineering service:

- Number of people accessing custom devices
- Lifetime cost of treatment
- Extent of local innovation ecosystem

3.3.1. Number of people accessing custom devices

The number of people accessing custom devices is more properly explained as the number of people experiencing improved clinical outcomes as a result of custom devices from the 3D design and engineering facility at KGMU. Greater degrees of local innovation, higher levels of public awareness and reduced lifetime cost directly contribute to the number of people able to access custom devices.

Patient journey mapping identified three touchpoints that influence the likelihood of patients accessing custom devices: initial presentation; referral; and treatment planning. Meanwhile, post-operative outpatient touchpoints influence the extent to which clinical outcomes are improved.

For low-income patients in India, clinicians reported that initial presentation was typically later than for patients in the UK. In the case of progressive diseases such as temporal mandibular ankylosis (identified by surgeons as particularly prevalent within the Uttar Pradesh region) and oral and facial cancers, this means that surgery is often the only viable option. Late cases were often extremely complex and standard implants gave poor aesthetic outcomes. We observed many patients at the Maxillofacial Unit who would have derived benefit from custom implants. These reports and observations were supported by the reviews of typical cases at KGMU and CT data used in the training days.

The Maxillofacial Department at KGMU is a public tertiary care provider. Patients are referred via primary and secondary healthcare providers. Clinician stakeholders identified referral as a key point determining the number of patients accessing custom implants at KGMU. They reported that there is a poor perception of the public healthcare system in India, with those who can afford to pay for healthcare usually choosing to attend private healthcare facilities. The internal stakeholders were concerned that lack of awareness of a state-of-the art facility in a public hospital might lead to higher income patients with complex presentations opting for more standard care at a private facility. This would simultaneously deprive patients of a potentially improved outcome KGMU of a valuable income stream to support the 3D design and engineering facility. Discussions during the 'Design Challenge' workshop suggested that there was a similar lack of awareness in the private healthcare sector, which would limit the potential for KGMU to generate income from the commercial manufacture of implants for the Indian market.

Treatment planning, and particularly the communication of the outcomes associated with treatment alternatives was an important decision-point in the KGMU patient journey. The KGMU internal stakeholder group reported that most patients paying for care at the unit had limited disposable income and were extremely cost-conscious. Very few trusted or accessed government-provided healthcare insurance, probably as a legacy of the corruption seen in previous schemes. Clinicians considered that a potential advantage of an in-hospital 3D design and engineering facility would be the provision of custom models to be used to illustrate the likely differences in using standard and custom implants for complex cases. These could encourage paying patients to include clinical outcome in their decision-making process.

The journey map revealed if a long time elapsed between a patient agreeing to surgery and undergoing the operation, there was a higher likelihood of dropout for all patients, but particularly for the rural poor for whom the indirect costs of healthcare rapidly accrue. Similarly, non-attendance at post-operative outpatient clinics was common. Attending appointments often means giving up an income for that period and potentially travelling long distances (sometimes with family members for support). This was confirmed during the time spent at KGMU, where the Co-MeDDI team observed families of patients setting up informal encampments in the hospital grounds. A motivation for KGMU stakeholders to use custom implants was the assumption that this would reduce the extent to which post-operative outpatient care would be needed.

Meanwhile, observations revealed that surgeons at KGMU had much larger caseloads than their counterparts in South Wales, and less support for surgical case planning. Reviewing the 3D design and engineering service specification for KGMU revealed minimal budget available for staffing. Surgeons who had used custom implants reported that they had taken

responsibility for design, procurement, planning and surgery, sometimes with support from postgraduate students.

3.3.2. Lifetime cost of treatment

Observations of a typical workflow at the South Wales in-hospital facility illustrated the time-consuming steps required to produce custom devices. This must be factored into the lifetime cost of treatment. The facility has implemented measures to minimise the time allocated to fundamental workflow processes. These include minimising design iterations and modifications through extensive engagement between design engineers, surgeons and other in-hospital functions during the early stages of the design process; protocols for image data collection; sign-off procedures necessitating continued involvement of surgeons throughout the design process; careful planning of in-hospital and external printing processes; and quality management agreements with external providers. The importance of such interventions was highlighted during the training days, when experienced design engineers conducted data processing on CT scans from KGMU. In the South Wales hospital facility, the design engineers worked almost exclusively with fan-beam CT scans. In contrast, KGMU used cone-beam CT (CBCT). CBCT is more challenging to segment into accurate 3D models since contrast resolution between soft and hard tissue is poor, scans are prone to artifacts and scatter from non-bone bodies (for example, dental devices or existing implants, which are common amongst older patients at KGMU) is significant. This considerably increased the time taken to process the data into an accurate 3D model during the training day at the university-based project partner. The training day at the university-based partner, where ISO 13485:2016 (International Organization for Standardization, 2016) was followed, also revealed the considerable time commitment associated with quality management. The Challenge Definition activity identified that there had been little consideration of the human resources required to manage the day-to-day activities of the service. A very small budget was available for recruitment, compared to the equipment and material grants available.

The lifetime cost of treatment is also affected by the device costs. This is comprised of: speed device design and production, and direct costs such as software, equipment and materials. A review of prices quoted to KGMU identified that these costs in India were significantly higher than in the UK.

3.3.3. Extent of local innovation ecosystem

The Challenge Definition workshop identified that difficulty in procuring sufficiently high quality, affordable custom medical devices was a key motivation for the in-hospital 3D design and engineering service at KGMU. Devices sourced from international suppliers were expensive and took a long time to arrive. Meanwhile, clinicians who had experimented with local suppliers reported poor communication, unpredictable delivery times and variable quality of outcomes. The supplier in Bangalore explained that subcontracting occurs routinely in the medical device field. Although KGMU commissions the design from an Indian company, manufacturing will often be by third parties experienced in medical device manufacture in Europe or the USA. If correct, in effect sourcing via local companies is increasing, rather than decreasing, the complexity of the supply chain and making communication between the different actors more difficult.

The supplier in Bangalore explained that an inverted duty system in place for some sectors meant that ordinarily importing manufacturing equipment and materials was less favourable than importing finished items. The Indian Government's 'Make in India' scheme had gone some way to addressing this; reversal of inverted duty on metal powders for application in aerospace and automotive industries had helped the supplier to be competitive in these sectors. However, he reported no such provision for medical device manufacture. This, coupled with the complex regulatory system and unclear levels of demand, disincentivised the supplier from entering the device market.

Sourcing from resellers for large multinational corporations was perceived by KGMU as lower risk compared to procuring equipment and materials from the small entrepreneurial start-ups that characterise the indigenous additive manufacturing sector. The multinational corporations offered manufacturing support, materials data and existing track record in the medical device industry, acting as powerful incentives to pay the additional costs. The relationships between KGMU and the resellers were purely transactional. In contrast, relationships between the South Wales facilities and the equipment and materials suppliers were more relational. Collaborations had mutual benefits and gave rise to case studies that the companies used to further establish their credentials in the medical device sector.

Although KGMU had established nascent relationships with research facilities experimenting with additive manufacturing, there was little evidence of research collaborations beyond this. This contrasts with the UK situation, where collaborations had been explored with medical researchers, materials experts, health economists, user-centred designers and other specialisms that further understanding in the field. The 'Design Challenge' workshops also highlighted limited awareness and opportunity to build collaborative relationships and draw down funding to foster multidisciplinary partnerships. One attendee reported that their attempts to introduce an affordable indigenous silicone for prostheses had been abandoned for these reasons. Another group had completed successful laboratory trials on a psyllium husk wound dressing, but experienced similar issues with taking their research further.

4. Discussion

4.1. Limitations of the study

The Co-MeDDI project yielded qualitative data from a small number of exchange visits, each lasting around one working week and concentrated on KGMU in Lucknow and the South Wales region of the UK. A limited time was available for cross-disciplinary and cross-cultural engagement, meaning that it was difficult to develop a deep understanding of the true local situation or of wider India. We were unable to gather data from other public and private hospitals in India. The paper is reliant on information gathered through the interviews and structured project activities, which in turn shaped the literature review. The project findings may therefore not translate to other resource-constrained regions. Whilst the 'design challenge' attempted to gather stakeholder opinions from across India, participation was limited to a small number of medical professionals, largely from Northern India states. Notwithstanding, the paper offers insights into factors likely to influence the development of sustainable hospital-based 3D design and engineering facilities in developing economies.

Here, we discuss research and development actions to support a sustainable 3D design and engineering service in relation to the key factors identified in the reference model presented in Figure 6. This is a simplified model of an extremely complex situation.

4.1. Number of people accessing custom implants from KGMU

Benefits of 3D design and engineering of custom implants have been widely reported, but limited evidence supports these assertions (Burton *et al*., 2018). The volume of patients treated at KGMU could improve the evidence base for custom implants. Clinicians could justify more costly interventions for low-income patients at hospital and government level based on their contribution to the research aims of the university, and thus support the vision of more democratic treatment. However, high dropout levels amongst lower-income outpatients makes monitoring progress challenging. The KGMU team may need alternative models for follow-up if they are to realise the research potential. For example, telemedicine has been investigated as an alternative for post-operative follow-up in neurosurgery (Thakar *et al.*, 2018), wound management (Taylor *et al*., 2017) and as an alternative to all outpatient services during the COVID pandemic (Lal *et al*., 2020). It may be necessary to triage patients based on likely clinical benefit to manage demand on the 3D design and engineering service and provide access to a steady flow of novel cases to report in the academic literature.

Referral of the 'right' patients requires awareness of the service capabilities amongst maxillofacial specialists across the Indian healthcare system. A recent survey indicates that Indian dental and maxillofacial surgeons are aware of the basic applications of 3D printing and are adopting digital planning (Parikh, Kulkami and Parikh, 2019). Events and conferences hosted by KGMU could showcase the service to existing practitioners. Incorporating 3D digital design and engineering training into the maxillofacial specialist programmes at KGMU will further develop awareness and skills amongst the future workforce. In the longer term, as the expertise at KGMU becomes recognised, specialist programmes could provide KGMU with additional income from exchange programmes with national and international partners.

The KGMU team has a strong interest in developing specialist training courses for support staff that provide a further income stream and cement their position as a leading research and education provider. The Co-MeDDI team developed training materials for use in the Department of Maxillofacial Surgery's first training course for medical device design technicians in September 2019.

KGMU has also developed a telemedicine clinic in partnership with ECHO India, a not-for-profit organisation which aims to 'democratise medical knowledge and enable doctors to provide best-practice care for underserved people all over India' (ECHO India, n.d.). This could provide a model for telemedicine-enabled presentation of custom implant patient cases to primary healthcare practitioners in rural areas.

A recent review (Glaser *et al*. 2020) of interventions to improve informed consent concluded that interactive use of 3D models and visualisations in consultations improve communication between professionals and patients. However, most studies have focused on reducing risks associated with malpractice. The authors emphasise the need for more research into interventions that (a) are patient-centred and improve patient comprehension of treatment benefits and alternatives; and (b) address vulnerable populations including those with low education and health literacy levels. The use of models at treatment planning touchpoints therefore presents a research opportunity for KGMU. Since financial situation, health

literacy and education levels have all been shown to be determinants of late presentation at public hospitals in India (Sathwara *et* al., 2017; Upadhyaya *et al*., 2017), the department has a good opportunity to address both research priorities. Models developed for communication could also be used with students in treatment planning exercises and to demonstrate best-practice in patient-professional communications.

4.2. Lifetime cost of treatment

One motivation for in-hospital 3D design engineering adoption is to improve efficiency through faster custom device delivery at a lower cost than using a commercial company. 3D design engineering has been proposed to allow more detailed pre-surgical planning and thus better quality control albeit at the expense of high speed (Salmi *et al.,* 2012) and high up-front cost to treatment (Sugar *et al*., 2004; Tack *et al.,* 2016). Improvements in quality of patient outcomes and reduced intensity of follow up appointments are often reported (Peel *et al.,* 2016; Peel and Eggbeer, 2016; Salmi *et al.,* 2012; Singare *et al.,* 2009). However, the challenge of attributing decreases in lifetime treatment cost to design engineering technology adoption have been discussed more critically more recently (Ballard *et al.,* 2019; Diment, Thompson and Bermann, 2017). Correlating safety and speed of treatment to lifetime cost is difficult because of the relative infancy of the research field. Levels of academic reporting in the field are also poor and favour positive outcomes (Burton, Peel and Eggbeer, 2018).

Co-MeDDI increased awareness of the indirect costs of establishing and operating a 3D design and engineering facility at KGMU. The human resources required to manage the day-to-day activities of the service, including the processing of challenging CBCT data and maintenance of a quality management system, had not previously been considered by the KGMU team. Given the relative infancy of the field and the fact that gains in treatment efficiency are often reported in absence of detail that supports cost effectiveness, it is understandable that the indirect costs of establishing and operating a 3D design and engineering facility were not fully detailed. More detailed study on lifetime cost of treatment is required. This represents an opportunity and challenges. High patient volumes could justify research and development to harness potential benefits of economies of scale, making use of design and engineering automation. For this to happen, funding must encourage greater collaboration between industry and the public healthcare systems in India for shared benefit.

4.3 Extent of local innovation ecosystem

Fully realising the benefits of an in-hospital design and engineering capacity requires a supportive innovation ecosystem. This allows the development of flexible and responsive supply chains that are capable of adapting to rapid changes in demand (Avventuroso, Silvestri and Frazzon, 2018), and opens up opportunities for local production systems that make use of indigenous resources and are more easily configured to be sustainable (Srai *et al*., 2016). The UK innovation ecosystem blends global and local supply chains; the recent COVID-19 pandemic has illustrated the benefits of this approach for supply chain resilience (Gereffi, 2020), and the potential role that the "manufacturing hospital" can play in addressing critical shortages during times of crisis (Mananes *et al*., 2020). As such, actions that make global sourcing more affordable, whilst strengthening the degree of local innovation have the best opportunity to support a sustainable service. There were promising signs in this regard.

During the lifetime of the Co-MeDDI project, the Indian Government's 'Make in India' scheme has been extended to the medical device sector, addressing the weak policy environment that previously hindered medical device innovation (Kale & Wield, 2018). This included addressing the inverted duty structure (Dang & Sharma, 2019). This should, in theory, reduce the costs of imported materials for KGMU. In practice, however, they may need to bypass the resellers in order to take advantage of the more favourable import conditions.

The regulatory framework for medical devices has also been clarified. Since 1st April 2020, all medical devices have been classified as drugs and regulated under Section 3 of the Drug and Cosmetics Acts, 1940. The Medical Devices (Amendment) Rules came into force on the same day and require that a manufacturing or import license must be obtained within 36 - 42 months, depending on the risk category of the medical device. This levels the playing field for local innovation. Previous studies on healthcare have identified that clear and supportive regulatory policies have a positive influence on innovation capacity (Faulkner, 2009). Co-MeDDI gave the KGMU team a systematic approach to implementing a robust quality control system that should support them in quickly obtaining a manufacturing license.

A strong healthcare innovation ecosystem is reliant on collaboration between disciplines and sectors (Dixit *et al*., 2018; Pekkarinen *et al*., 2019; Polykarpou & Barrett 2017; Rao, 2013; Rane & Kirkire, 2016; Truscott *et al* 2007). 'Make in India' has supported the establishment of dedicated medical device manufacturing zones, such as the Andhra Pradesh MedTech. In December 2018, a public-private partnership between the Indian Government and Think3D saw a facility open at AP MedTech that offers access to all the major additive manufacturing technologies on a pay-per-use basis, and also provides access for testing. Such facilities provide opportunities for cost-effective research and development between interested parties, including potential future suppliers. We proposed that moving from transactional to relational business relationships with suppliers will further strengthen the innovation ecosystem.

4.4 Results Synthesis and DRM Factors Model

An initial model of factors assumed to influence the development of a KGMU in-hospital design and engineering facility was developed throughout the project phases. This was refined using a literature review to check the findings and assumptions. The reference model derived through findings of the Co-MeDDI project, our experience and literature review is shown in Figure 6. This model also illustrates where assumptions between factors still exist.

Insert Figure 6

Figure 3: Refined model of factors influencing the success factor for the project: 'design and implementation of an effective and sustainable facility for all patients that surgeons at KGMU identify as requiring cranio-facial medical devices' (summarised as 'Sustainability of Service). The ovals represent influencing factors, formulated as attributes of elements that can be measured, assessed or observed. Causal links between the attributes are indicated by directional arrows. The mathematical operators ('+' and '-') indicate relationships between the values at either end of the arrows.

4.5 List of recommendations

A list of recommendations and suggestions on stakeholders who could support the development are provided in table 2.

Table 2: Recommendations arising from the Co-MeDDI project and literature

RECOMMENDATIONS AND ACTIONS	STAKEHOLDERS WHO COULD SUPPORT
To increase the number of people accessing custom implants	
Develop telemedicine approaches for outpatient monitoring	Collaboration between industry, healthcare specialists and the higher education sector. Ministry of Health and Family Welfare (Department of Health Research).
Develop triage methods to manage patient demand for new technologies	KGMU.
Showcase service offerings	KGMU.
Develop 3d design engineering training programmes that include national and international exchange, and online	KGMU in collaboration with industry and other national and international partners. Supported by the government of Uttar Pradesh.
Extend the research agenda to include the use of 3D models for patient consent focusing on patient autonomy and communication with vulnerable groups	KGMU
To reduce the lifetime cost of treatment	
Identify and plan for personnel and other running costs of a quality managed service	KGMU.
Establish and publish studies that collect data that enables more rigorous healthcare economic analysis	KGMU and collaborators supported by the Ministry of Health and Family Welfare (Department of Health Research).
Undertake collaborative research to improve the efficiency of 3d design engineering methods	Collaboration between industry, healthcare specialists and the higher education sector.
To increase the extent of the local innovation ecosystem	
Leverage the opportunities that 'Make in India' offers for medical devices	KGMU Indigenous materials and equipment providers; Institutes of Technology
Raise the profile of the role of additive manufacturing in medical device manufacturing	KGMU Indigenous materials and equipment providers; Institutes of Technology
Access collaborative funding with cross-disciplinary partners, making use of MedTech enterprise zones	KGMU Indigenous materials and equipment providers; Institutes of Technology
Create funding programmes that enable greater levels of cross discipline and cross sector collaboration	National and government of Uttar Pradesh. Medical Council of India. Indian Council of Medical Research. Department of Science and Technology. Ministry of Health and Family Welfare (Department of Health Research).
Create programmes to improve public knowledge of healthcare options	Ministry of Health and Family Welfare (Department of Health Research).

5. Conclusion

This paper reports on the findings of a project that used a design thinking approach to explore factors that would be influential in establishing a sustainable 3D design and engineering service in an Indian public hospital environment. The findings also have implications for other situations where in-hospital facilities can be established.

Adopting a design thinking approach ensured that research and development were aligned with patient needs throughout the project. For example, identifying key touchpoints in the user journey opened up potential new research avenues in patient communication, identified the relationship between technical factors, indirect costs and the patient experience and emphasised the role of outpatient support systems may play in realising high quality research outcomes.

There is scope for more extensive research that elaborates on the factors identified. We propose that future projects can use the results presented in this paper to understand how impact relates to key factors, which are in turn are linked to the quadruple line approach to sustainable prosperity. This can help avoid the commonly adopted technology-push approach, which neglects the importance of people, profit, planet and progress. Furthermore, we propose that the recommendations and actions described in the Discussion section are undertaken in order to establish a sustainable 3D design and engineering service in a hospital environment.

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