Technologies to Enhance Quality and Access to Prosthetics & Orthotics: the importance of a multidisciplinary, user-centred approach

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Abstract:
This paper presents the story behind developing the Cambodia-UK prosthetics and orthotics (P&O) project ‘LMIC Limbs’. We describe the methods employed in identifying and iterating the project scope, the principles underpinning our collaboration, and our reflections on the process. In the context of growing digital technology possibilities for P&O services (CAD/CAM, 3D scanning, and 3D printing or additive manufacturing), this set of principles addresses issues of:

- ensuring the project is defined by a technology pull, instead of a technology push,
- objectively mapping project stakeholders and the value proposition, and
- consulting these stakeholders on the potential benefits and disadvantages of these technologies, and the barriers and facilitators associated with their implementation.

These issues are addressed simultaneously through approaching the project development by co-design of research with equal status partnerships across nationalities and multidisciplinary team professions. As such, the project deliverables are designed according to the definition of Appropriate Technology (1) in the context of UN Sustainable Development Goal 3: Good Health & Wellbeing (2).

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This study highlighted the importance of carrying out in-depth scoping and preparatory work in a user- and value-led framework before undertaking work to develop and introduce new technologies within an LMIC service. This enabled us to challenge our prior assumptions, and redesign our project as co-researchers for far broader and sustained potential benefit, and potentially prevented unintended harm.

Background:
Approximately 100M people worldwide need prosthetic or orthotic devices (3). An estimated 80-90% do not have access to P&O services "due to a shortage of trained personnel, service units and health rehabilitation infrastructures" (4). P&O service access is particularly poor for people in Lower and Middle Income Countries (LMICs), who are typically younger and have higher physical working demands than those in high income countries, for whom most prosthetics technology has been developed. The demographics of those affected also differs, with some LMICs having high levels of traumatic amputation from accidents, conflict and landmine injuries, and humanitarian crises (5). By contrast, the primary reason for amputation in high income countries is vascular compromise associated with diabetes, although the prevalence, predicted at 500M people by 2035, is growing fastest in LMICs (6). The UK government’s Global Challenges Research Fund (GCRF) was launched in 2016 with £1.5Bn available over five years as part of the UK’s Official Development Assistance, and in 2017 a GCRF ‘Engineering and Healthcare Technologies’ funding call was announced, specifically targeting Diagnostics, Prosthetics and Orthotics.

There is a history of harm caused in LMICs by direct application of inappropriate technologies, or implementing technologies in the wrong way (7). The concept of appropriate technology has been defined in various ways, with key themes including compatibility with the “human, material and resources of the (local) economy”, “with tools and processes maintained and operationally controlled by the local population” (1). More recently, this has incorporated open source principles (8), and the concept focuses on implementation for sustained benefit.

In the absence of better alternatives, people may construct their own devices using local materials (Figure 1). While these offer some advantages (e.g. reparability), it is likely that they are both uncomfortable and sub-optimal from a functional perspective. One clear potential technology contribution to the 2017 GCRF call was the development of LMIC-specific P&O componentry, to complement the substantial improvements made in device design for LMICs through the International Society for Prosthetics and Orthotics (ISPO), supported by the International Committee of the Red Cross (ICRC) (4,9) and others (Figure 2). However, appropriate P&O componentry is only part of the access problem. An overwhelming patient-clinician ratio remains and "the development of the sector is too slow ... to meet existing needs or keep pace with the growing populations of people with disabilities" (4). Even with ISPO accredited training, in Southeast Asian LMICs it is estimated that three times the current number of clinicians are required to provide services for the affected population, based on current working practices (10).
Our team recognised that some of the access barriers mentioned above might be addressed by technology. The efficiency of clinicians could be improved through appropriate tools to enhance P&O data and uncover the meaning behind it, and to educate clinicians and service users, both in urban and rural community settings. The context of P&O services makes this work challenging. Experience shows that particular care must be taken in delivering aid, healthcare and technologies in LMICs, especially if directly applying technologies developed in high-income countries. Considering P&O in particular, as well as users' different needs, their relationship with clinicians and prosthetics are different for complex cultural, social and environmental reasons. Therefore, we decided to frame our scientific research using an ethnographic study of P&O service providers and users, to evaluate the practicality of our project ideas. This paper describes the project’s development, and the principles with which we established its scope.

Approach and Findings:

**Reflections on Appropriate P&O Technologies for Lower & Middle Income Countries**

- We have a responsibility to evaluate low cost technologies against the state-of-the-art. This might include reliability of low-cost 3D scanners, and endurance tests of 3D printed devices.
- A reminder: appropriate technologies must address sustainable implementation (i.e. operation and maintenance by the local community), as well as functional factors (e.g. low capital cost, robustness in harsh and diverse environments).
- We uncovered a risk of harm arising from unsustainable implementation of technology-driven design and fabrication methods, if they alter or replace expert skill in traditional fabrication methods, and then become unavailable.

Iteration 1: Developing Collaborations, Observations, and Reflection on Appropriate Technologies

In the context of growing adoption of Computer-Aided Design and Manufacturing technologies (CAD/CAM) in Europe and the USA, and interest in 3D printed P&O devices, we set out to form a project...
There is growing evidence that CAD/CAM methods can improve P&O services, from Europe and the USA (11,12), but fundamental questions remain due to limited research funding, capacity and culture. Prosthetic limbs comprise standard modules and a bespoke socket, designed by skilled prosthetists through plaster casting and rectification, and manufactured by technicians. CAD/CAM is used in a growing number of clinics. A 3D surface representation of the residuum’s shape is captured, and used to design the socket in a software environment (CAD). A Computer Numerical Controlled (CNC) carver can then be used to machine a mould from polyurethane foam (CAM), upon which the socket is vacuum-formed or ‘draped’. The traditional plaster methods are subjective, time-consuming, and the design record is destroyed during fabrication. Many people are considering 3D printing as an alternative direct CAM fabrication method, although questions remain around the durability of available materials (13) and logistical issues around 3D printing in-house (14). Especially where clients are farmers and labourers, the mechanical reliability demands placed on their prostheses are high, and thicker walls may be required to achieve adequate strength. This may have an undesirable impact on cosmesis, if the brim of the socket becomes visible through the person’s clothes. Proposed benefits of the CAD/CAM approach are a data-rich device design process with automated, repeatable fabrication, and therefore more efficient use of staffing resources. In principle, these are justifiable benefits for high and low resource economies alike. Whilst CAD/CAM is considered expensive versus plaster methods, recent developments in 3D scanners suggests that the shape capture element of the CAD/CAM process might become feasible with far lower-cost equipment ($100s, vs. $10,000s) (15), whilst retaining a clinically acceptable level of accuracy.

Therefore, our first plan was to build a project proposal around identifying the requisite level of accuracy for clinical effectiveness and selecting appropriate scanners. Furthermore, research to enhance the CAD/CAM workflow would incorporate tools to survey residuum tissue compliance, sensitive points and regions at risk of damage, which is a fundamental part of the prosthetist’s manual skill. We wanted to create an ethos of co-research and co-production from the outset (16), so prior to applying for a large grant we secured pump-priming funding to build collaborations and evaluate our project ideas. We used a Patient and Public Involvement (PPI) framework, as distinct from formal research, which includes service users and other stakeholders in the project’s design in order to avoid predetermining research questions or solutions. As such, the research is carried out with and by its intended beneficiaries, instead of about
or on them. We formed a collaboration with Exceed Worldwide, who provided extensive advice and cultural training, and in December 2016 we visited their school and three clinics in Cambodia, in Phnom Penh, Sihanoukville and Kampong Chhnang, to meet our potential collaborators and understand their work, environment and service delivery model. To better understand the manufacture of prosthetic components, we also visited the Orthopaedic Component Factory (OCF) run by Persons with Disability Foundation (PwDF) and the Ministry of Social Affairs, Veterans and Youth Rehabilitation (MOSVY), and the Artificial Leg Production and Rubber Processing (ALRP) Foot Factory. In addition, we joined community workers on visits to provincial service users’ homes and places of work, to understand the technical, environmental, social and cultural service issues involved.

This work indicated that directly embedding a CAD/CAM prosthetic fabrication workflow would not have been an appropriate use of technology in the environment where the study was conducted. Pushing this technology directly on high volume plaster technique expert clinicians would have caused a period of reduced quality socket fitting. Whilst training would overcome this issue, we identified a greater barrier to sustainable implementation. Available materials for mould carving would have been more expensive than plaster, and might increase non-reusable fabrication consumables, where extensive use of recycled materials as a critical aspect of present fabrication practices and the clinics’ business model (Figure). Furthermore, with many LMIC P&O services using a charitable donation service model, the process for funding the maintenance and replacement of carvers or 3D printers was not clear. A worst-case outcome would be that this well-meaning project would result in the clinicians replacing their skills in manual plaster techniques with CAD/CAM expertise, and becoming less able to deliver an effective service should their CAD/CAM technologies become unavailable, ultimately at the expense of their clients’ comfort and quality of life. These findings do not preclude the use of CAD/CAM methods in the future, or in other environments, but demonstrated a need to redesign our project aims.

**Iteration 2: Co-Design to Re-Focus on Data Technologies to Enhance Access**

Based on these observations and our collaborative research planning, we pivoted, and co-designed the project with our new partners. The scoping work revealed that greater benefits might be offered by a simpler but broader approach using digital assessment technologies both to evaluate the effectiveness of P&O components and services, and improve the efficiency of clinical practice at centres and in users’ own communities. Our objectives were re-framed, and focused on technologies with the potential to address these more fundamental challenges around tools to improve access to P&O service, train clinicians and optimise the efficiency of service funding use.

Whether national health and social care services are free at the point of delivery or privately funded, the sustainability of any health service relies on leveraging evidence of its effectiveness. Therefore, our revised objectives were motivated by the importance of data-led solutions towards addressing the UN Sustainable Development Goals, helping at a government level to evidence the effectiveness of health systems. This required technologies in two areas:

- Technologies involving digital measurement tools to assess a user's residual limb anatomy, typical daily prosthetic limb use, and measures of functional outcome and quality of life; and
• A robust and secure data architecture for prosthetists, physiotherapists and community workers visiting provincial areas to collect these data (Figure 4), which might also be used as a platform for evidence-based treatment for those in remote communities who cannot afford to travel.

A more portable P&O service may enable people to access provision, fitting, adjustment and repair of their prosthetics devices, whilst limiting social impacts such as time off work - essential where many service users are subsistence farmers, spending their day’s earnings on the same day’s food.

On this foundation, a more detailed study was carried out in March 2017 to explore the potential benefits of data-based technologies within the Cambodian P&O service, and barriers to their use. We designed a mixed-methods exploratory study, to ensure the potential technologies for our final project bid would be beneficial within this specific context, and meet the needs of the user and wider stakeholders. We obtained approval from the University of Southampton institutional ethics board (ERGO25100) and the Cambodian National Ethics Committee for Health Research (073NECHR) for:

1. Qualitative semi-structured interviews with healthcare professionals working in P&O services, to gain a wide range of perspectives regarding the potential use of technologies to meet client and service needs, alongside additional PPI work with service users;
2. Retrospective analysis of client notes to provide requirements for documentation and rehabilitation outcomes; and
3. A cohort study focusing on reliability assessment of one example technology (3D scanners for residual limb shape capture), with comparison to manual plaster casting (Figure 5).

Figure 5: One way of assessing whether a low-cost scanner is an appropriate technology is its repeatability in comparison with the expert clinician plaster casting, but the associated sustainability issues are more complex.

The following thematic trends around these technologies were identified in the PPI work and interviews, and subsequent collaborative discussions:
3D Scanning:
Instead of proposing to use 3D scanning as part of a CAD/CAM workflow, or a central design and fabrication, the technology was identified as a potential limb assessment tool for people in provincial communities. Prosthetists and travelling community workers might collect scan data to monitor residual limb volume and shape change to understand changes in socket fit over time, identify the optimal time at which to prescribe a definitive socket, and the optimal time of day and environmental conditions to cast when residuum volume and shape would be most stable. Their residuum and socket could be assessed quantitatively at their home or place of work, alongside a self-reported comfort score, so that unnecessary visits to central clinics might be avoided. The scan data can be post-processed to provide key metrics of residual limb size and shape (i.e. volume, length, perimeter), with high accuracy, which would normally be performed by hand using callipers and tape measures. In this way, the most highly trained clinicians could spend a greater proportion of their time on higher value-added work. The foundation would be in place for clinic- or community-based CAD and CAM at a central fabrication facility, once appropriate technology is identified, i.e. with a sustainable funding model.

Physical Activity Measurement:
Our Cambodian partners identified additional challenges around the assessment of P&O device use in real community-based settings. Whilst advanced movement analysis methods such as motion capture offer detailed insights into gait quality, our partners reported a greater need to assess more general patterns of longer-term device use. People may receive training to use their devices in a clinic, but their continuing use after returning home is completely unknown, as is the potential change in physical behaviour which their prosthetic or orthotic device may enable. It can be argued that the true measure for any assistive device is the extent to which it is actually used in everyday life. Physical activity monitors are established (17), and they have been used in the field with proximity sensors to indicate activity and prosthesis removal (18). It was therefore hypothesised that these technologies might assist in the unobtrusive assessment of device use and activity classification, as a priority over more complex movement quality characterisation.

Our PPI work revealed that some people were concerned that physical activity monitors would use GPS to track their location rather than the intended more generic assessment of their level and types of activity whilst wearing their prosthetic device. Anecdotally we were informed that others had concerns that these devices might be used to check a person’s work or personal activities. Others suggested concerns that individual judgements would be made on the basis of their activity level, fearing that low usage would be used to justify the removal of their device, and that this may lead to a reporting bias. This concern may be exacerbated by cultural issues and where, unlike any health intervention, these devices are provided free of charge. This demonstrated the need to reconsider how potential study participants are educated about the research objectives and technologies, in order to make an informed decision regarding consent. Taking into account these practical considerations, physical activity measurement in community settings offers valuable potential solutions to the third key issue we uncovered: what outcomes are meaningful to service users, and how can we measure them?

Meaningful Outcomes, and How to Measure Them
Perhaps one of the largest challenges is the complex connection between health and social support interventions, and quality of life. A very broad range of objective and subject P&O outcome measures is available, many of which are difficult to contextualise or compare. There is a lack of consensus around which measures should be used, and a high data collection workload on busy clinicians (19). This is indicative of a larger problem, as extensive research on how we measure outcomes might distract us from evaluation of what defines a meaningful outcome for the different stakeholders in P&O services.
The link between gross activity level and quality of life is almost certainly not simple. Actimeters may indicate changes in patterns and quantities of activity. For example, they could be used to quantify changes in activity enabled by provision of a device, gradual impairment arising from device wear or loss of adequate fit, and more marked changes due to injury, device breakage or psychosocial factors such as depression. If self-reported activity estimates provided by service users are subject to the same reporting bias mentioned above, actimeters used in a community setting may provide a measure of validity or allow these estimates to be scaled or corrected. However, the sensor technology also needs to be able to withstand the harsh environment more rural data collection might pose, and be minimally invasive to users. There are also challenges in retrieving logged data, particularly in rural areas where internet access is limited.

Further, physical activity monitoring data interpretation for LMIC users is highly complex: agricultural workers spend long periods standing and walking on uneven ground, and there could be challenges in identifying sedentary behaviour (20). The proprietary software associated with determining activity from sensor data often uses data from a healthy cohort to define parameters. The movement patterns of prosthetic limb users in rural areas of Cambodia are likely to be vastly different from a healthy European or American cohort, creating the potential for activity classification error, which will be addressed in this project.

Greater complexity arises because a positive health outcome is based on multiple factors, many confounding. Health is not monodimensional and an improvement in one domain, such as activity, does not necessarily transfer into the wider context of health or quality of life. For example, common clinical measures of mobility (such as the ability to walk for 10 meters, distance walked in 2 minutes, or number of steps per day) do not necessarily translate into the ability to stand in a market, factory or rice field, or get in and out of a car or ride a motorcycle, which may be far more meaningful to an individual. Little is currently understood about how patients define a successful recovery or outcome following amputation, although a growing body of research has sought to document the experience of amputation and prosthetic use from the service user’s viewpoint (21). Our scoping work indicated that, although increased activity may indicate improvement in an individual’s ability to work or social engagement, other important indicators include marital status and having children in education. These and other impacts may not be reflected in typically-used Quality of Life measurement tools, and may be achieved with no notable change in physical activity. There would appear to be a benefit in identifying a minimal effective suite of measures, both in terms of LMICs and western populations. By employing the user-centred approach, we are considering whether an individual’s perception of the value behind physical, psychology, social, cultural and economic activities could be different from our expectation as professionals working in health sciences and engineering. If we can evaluate their satisfaction compared to their perceived value and evaluate correspondence with the data from their physical activity measurement, we may be able to gain subjective understanding of their personal success after rehabilitation.
Access to services also relies on patient data being available. While computer-based systems have been in use in clinics for decades, the main patient record was still paper-based. This means duplicate effort has to be put into recording episodes and patient data, and full record duplication when people make their first visit to a clinic in a different geographical location. This was highlighted as a particular issue presently in Cambodia, where migration is reported to be common: a young person living in an urban area might be injured in a road traffic accident, return to their family to recuperate, in a rural area, and return to the city after rehabilitation. Data exchange between different sites can happen sporadically, often relies on spreadsheet reports or paper forms, which may be insecure and prone to error due to factors such as handwriting or language skills. Electronic patient record systems are not typically designed for use in LMICs and do not address many of the issues that are specific to this environment:

- computer systems in rural locations are often not constantly connected, due to high cost and unreliable power supplies;
- because of the lack of connectivity, data are not held centrally as is the case in many modern patient management systems; and
- data may be sent via proxies, instead of synchronising directly.

Sharing patient data across clinics, organisations or even countries also brings up a question of privacy and whether adequate measures, such as encryption, have been taken. Furthermore, problems arise around consent, where patients may not understand the implications of distributed data and consequently are unable to give informed consent. As well as making careful culture-specific considerations for informing participants and obtaining their consent to participate in research (Figure 6), this is a requirement of by data protection regulations such as the gold standard General Data Protection Regulation (GDPR).

Raising our targets: sustainable approaches to stakeholder challenges

We are now applying business modelling and data science methods to ensure the technologies are cost effective and can be implemented sustainably, and to support their translation into other countries and services. Long term, we intend that the data collected using this project’s deliverables will enable providers to become more efficient and evidence-based, selecting more appropriate P&O devices and components, seeing service users on a data-informed basis rather than at predetermined dates, and making best use of limited budgets (22). However, as described there is a remaining challenge in the complex correspondence between health and social care interventions and the delivered changes in quality of life, further confounded by what is readily and unobtrusively measurable. Biological, physical, psychological and social measures, and an understanding of their complex dynamic and impact on a person’s ability to participate in society, are required for establishing meaningful health outcomes.
Health outcomes can be contextualised within the World Health Organisation’s International Classification of Functioning, Disability and Health (23). In Lower- and Middle-Income Countries (LMICs), poverty, sociocultural bias toward difference and environmental factors all affect an individual’s ability to access health services. To date, the global emphasis has been appropriately focused on improved access to services through inclusion initiatives and development strategies, such as the Universal Health Coverage, part of realising the UN Sustainable Development Goals (2) and WHO Rehabilitation 2030 strategy (24) covering both health and social inclusion. However, in order for these initiatives to be sustainable, we need to understand what ‘success’ looks like, and at the moment this is poorly understood (25). The challenge globally is to effectively manage inclusive access to - and assured quality of - health and social care systems, and ensure continuity between health and rehabilitation services, with data that supports both. Equitable access to sustainable, quality and meaningful health outcome data becomes the barometer for improvement, failure and success of those services, and ultimately translates into the quality of an individual’s life through function, activity and participation.

Current P&O evidence is built on results from rather traditionally designed clinical studies, the majority of which are conducted in high income countries. This approach is arguably not fit-for-purpose, even for those populations: it is slow, where P&O technologies evolve faster than we can evaluate them using traditional methods, and the results cannot easily be generalised to LMIC populations. New approaches are needed that can improve quality of care, but also efficiency and quality of service, allowing for scale-up of services broadening their reach and impact. There is a global increase in ageing, chronic illness and non-communicable diseases illustrated through trends in demographic and epidemiological data (26), and these trends indicate that functioning will be a key indicator of population health (27) even though, as discussed, the mapping between function and health, wellbeing and quality of life is not simple.

As such, it is imperative to establish robust, meaningful and ubiquitous access to health outcome data. Data must be accessible and useable, and presented in a meaningful way for a diverse set of stakeholder profiles. For example:

- individually, service users may want to view data to compare their rehabilitation experiences, progress and problems against their peers;
- locally, clinicians and service providers want to understand the effectiveness of an intervention or expected/predicted outcome, with which to lobby for better or sustained resources;
- regionally, commissioners need to justify funding decisions based on evidence;
- nationally, the health of a population or group can be ascertained; and
- globally, healthcare systems can share standardised approaches and good practice, including sharing resources where possible and appropriate.

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**Health Outcomes: the Big Meaning behind the Data**

- Current P&O evidence is built on traditional clinical studies, most of which are conducted in high income countries. Technologies evolve faster than we can evaluate them, and results may not apply to LMIC populations.
- New approaches are needed to improve care for individuals as well as service efficiency and quality, allowing scale-up of reach and impact.
- We need to establish robust and ubiquitous access to health outcome data. Data must be accessible and useable, and presented in a meaningful way for a diverse set of stakeholders.
- We must make culture-specific considerations to ensure people are truly informed when deciding whether to provide consent, both for participating in research and having their health data stored digitally.
The Broader Context of Social Impact

While there are clear returns to private individuals from P&O processes, adopting a social impact lens allows us to see how they also be can be catalytic in the advancement of not just individual capabilities but collective capabilities (28, 29). These include household and community level capabilities to enter parental labour markets and to liberate education opportunities for children who might otherwise have to work to compensate for labour market exclusion, and other forms of social exclusion. Such capabilities are particularly likely to be enhanced when women are service users, given that they are disproportionately burdened by poverty (30).

A social impact lens also helps us to apprehend the multi-dimensionality of poverty, such as the crucial interlinkages between SDG 3, SDG 5 (gender equality) SDG 8 (decent work and economic growth) and SDG 9 (industry, innovation and infrastructure).

Relatedly, such a social impact lens can help us build an added value chain to P&O processes which can not only enhance their effectiveness, but the identification of meaningful outcomes and sustainability which also help address multiple SDG objectives. Work Integration Social Enterprises (WISE) for example are potentially well suited models, since their primary aim is to provide employability and integration-related opportunities for those disadvantaged within, or excluded from, full access to labour markets. Including service users in the operation and delivery of P&O based WISE models allows them to move from passive beneficiaries to active co-producers and constitutes a form of community economic development (31), which consequent impact on community level capabilities.

Re-orientating our understanding of P&O processes from private healthcare investment to social investments, which broad ranging catalytic impact on a range of poverty and human development indicators allows us to place our interventions into a wider social impact context, and to think more ambitiously about the most appropriate organisational vehicles to scale and replicate them.

The Benefits of this Scoping Work, and a Value-Led Approach

The results from all four parts of this study provided a clear insight into the specific needs of the user and wider service, and were essential for developing the next stage of the work in three key ways:

1. Preliminary study of candidate technologies: healthcare professionals were observed, and their views of candidate technologies’ usability, benefits and barriers were obtained, and used to change the project direction.
2. Remit of the future study: arising from this change to the study’s technical objectives, specific infrastructure needs were identified, with the requirement to address the importance of sustainable implementation factors.
3. Working relationships: through scoping work we built relationships, rapport and trust, identified reciprocal factors, built capacity, and worked as co-researchers. We have since delivered training at each other’s institutions, and co-authored scientific publication of our results.
Conclusions and Recommendations:

- This study highlighted the importance of carrying out in-depth scoping and preparatory work in a user- and value-led framework before undertaking work to develop and introduce new technologies within an LMIC service.
- This scoping work enabled us to challenge our prior assumptions, and redesign our project as co-researchers with far broader and sustained potential benefit, and potentially prevented unintended harm.
- P&O intervention investments are social investments, with collective benefits across families and communities. Engaging these stakeholders as co-producers in research empowers them, builds local capacity and embeds a network able to deliver further, broad and sustainable benefits.
- As a key PPI principle we have an obligation to report back to the clinicians, community workers and clients who have contributed to the project. Empowering, inclusive and participatory technology research should have the professionals on tap, instead of the professionals on top!

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