Project title: Open-access Prosthetics Provision and Repairs Registry

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1. The nature of the challenge and need for the registry

This project focuses on a real-world need for recording data on prosthetic provision and repairs, addressing one of the ongoing issues highlighted in a recent report by the World Health Organization in the field of prosthetics and orthotics (P&O) (WHO, 2017). Our recent studies on prosthetic maintenance data from the limb-fitting centres in Oxford and Bangalore (Nagaraja et al. 2022; Nagaraja et al. [under preparation]) highlighted the value of recording information on prosthetic device repairs. Frequent repairs and device breakdowns reduce user satisfaction and diminish the potential impact of prosthetic aids. Details of ongoing prosthetic care—captured in the patients' medical records—are often fragmented across localised databases in different rehabilitation centres. A common central databank is vital to help aggregate/crowdsource (anonymised) data on the ever-changing service provision, repair, and maintenance activities of prostheses linked to respective patient demographics.

Capturing data on provision, device usage, and repair can inform on device designs that are more durable and better meet various user requirements (Nagaraja et al. 2022; Chadwell et al. 2020; Kohler et al. 2021; Ranson et al. 2022). Such data can also help identify and support under-served groups (Dickinson et al. 2024), and help improve prosthetics services and surrounding policies by shedding light on the practical and financial requirements of service provision (Berthaume et al. 2023; Kaufman et al. 2024; Barth et al. 2021). Additionally, the NHS intends to achieve a "Net zero" emissions service by 2040 and has identified specific targets to achieve this goal (NHS 2022). Prosthetic devices typically come with relatively short-duration, but tightly defined, warranties (Davidson et al. 2025), and devices are retired once they fall outside warranty cover. Some types of prostheses are associated with high abandonment rates, and frequent repairs/breakdowns appear to be common experiences. These factors have a considerable environmental impact (through carbon emissions, waste disposal, etc.) and pose direct and indirect cost implications to patients and service providers. These negatives can potentially be mitigated via research driven by large, high-quality datasets in the sector. In the area of joint replacements, the UK *National Joint Registry* has greatly improved the efficacy of care (Porter et al. 2019), setting a precedent for such work.

Some of the envisaged real-world impacts of this project are – (i) changing the way P&O professionals (and manufacturers in the future) perform record-keeping of prosthetic service provision, thereby generating evidence for impact on patient lives; (ii) a repair registry can help generate evidence to support remote triaging of repairs and informing patients on what to expect in terms of cost/time/etc.; (iii) the proposed registry helps provide 'big data' on device prescription practices, understand the past patterns of repair, repair demands, and differential practices to help forecast spares and consumables requirements. Understanding prosthetic provision and repair patterns (at a regional or national level) is crucial for effective treatment, resource allocation, reducing device abandonment, and more. By co-creating the registry with stakeholders across the prosthetic field, we hope to bridge a gap between healthcare providers, service commissioners, prosthetics manufacturers, policy-makers, and patients.

2. Literature Review

Several regional and national limb loss and prosthetic provision registries, such as the American Limb Loss and Preservation Registry and the SwedeAmp, exist (Kaufman et al. 2024; Kamrad et al. 2020); however, most countries still lack a national registry. The International Committee of the Red Cross (ICRC) provides a data management system to centres they support globally (Barth et al. 2021; Dickinson et al. 2022), though the data is not easily accessible due to logistical restraints. Local limb-fitting centres keep their own records; however, there is a paucity of reliable and comprehensive data globally, and this is not helped by the fact there appears to be a lack of standardisation surrounding data collection. There has been a recent consensus-building attempt led by the International Society of Prosthetics and Orthotics to standardise some aspects of data collection for lower-extremity amputees, as seen in the LEAD and COMPASS report (Kohler et al. 2021). However, this report is not exhaustive, especially regarding whether to collect details on repairs and maintenance, and if so, what data should be collected. To summarise, there is a lack of comprehensive, publicly available prosthetic service data from many parts of the world; one barrier to creating such datasets is the lack of consensus on what information should be captured during prosthetic care.

3. What you had already accomplished prior to the TIDAL funding

Prior to the TIDAL funding, we conducted two studies analysing the patient demographics and repair patterns of upper-limb prosthetics from two separate limb-fitting centres based here in the UK and in India (Nagaraja et al. 2022; Nagaraja et al. [under preparation]). These studies built the groundwork for this work. Prior work on this project was pump-primed by Dr Nagaraja's research research start-up grant from March to August 2024. During that period, we hosted semi-structured one-on-one interviews with 12 stakeholders from the field of prosthetics (n=12; eight academics, three healthcare services, and one prosthetics manufacturer). During these interviews, we discussed the following: the current state of prosthetic-limb provision and repair data collection and how the data is (or is not) utilised; what the key issues are in this field that can be addressed with well-streamlined provision and repair data; and ultimately, what data needs to be captured to address those issues. The information synthesised from this stage then informed a consensus survey (https://forms.gle/HYTfminHKPfCvF9LA), which was distributed at the TIDAL AT Repairs Workshops in May and June 2024, as well as through other relevant research networks and NGOs, such as the ISPO and the Exceed network. Overall, the consensus survey received 35 responses (18 academics, 13 healthcare services, and four prosthetic manufacturers). The survey was structured such that the responses would help create a minimum data set schema for the registry.

4. What the TIDAL funding has enabled you to accomplish – outline of the work carried out, outcomes/outputs of that, and why it is important/benefits

With the invaluable support from TIDAL Network+, we were able to analyse the survey responses, and create a manuscript pinpointing crucial types of data to collect on prosthetic provision and repair, and propose a schema for a registry in this field. Table A.1 shows all the data fields included in the proposed schema. Our manuscript submission, "*Co-creating a Schema for a Prosthetic-limb Provision and Repair Registry: A Data Standardization Proposal*", is currently under review in a peer-reviewed journal.

Table A.1: Data Fields for the Registry Schema by Categories

Patient Characteristics	Age; Sex/Gender; Address; Current Occupation; Occupation before Limb Loss (if applicable); Number of Limb Absences; Side of Limb Absence; Level of Limb Absence; Date of Limb Loss; Etiology; Hand Dominance (before and after limb loss); K-Level
Device Characteristics	Date of First Limb Fitting; Number of Devices Owned (past and current); Type of device; Date of Device Fitting; Location of Device Fitting; Terminal Devices; Socket; Suspension; Cosmetic Covering; List of Components (Material, Design, Manufacturer, and Model Number); Instances of Self Repair; Instances of Professional Repair
Repair Details	Component Repaired; Repair Category; Severity of Damage; Reason for Failure; Description of Damage; State of Device (after repair); Date of Repair Requested; Date and Time of Repair Appointment; Date and Time of Repair Completion; Date of Device Returned to Patient; Location of Repair Job; Device End of Life Info
Cost Details	Cost of Device; Device Cost Coverage; Cost of Repair; Repair Cost Coverage; Warranty by Limb-fitting Center; Warranty by Manufacturer; Did Device Breakage Result in Patient Harm; Did Device Breakage Result in Patient Missing Work

Additionally, the TIDAL Network+ funding helped us reach out to the limb-fitting centres in both the UK and India, and plan for a series of isolated short-term usability tests. These short-term usability tests will allow us to gather further external stakeholder input, which will give us insights into how the registry can be integrated into the service provision workflow, all while providing feedback that will help us iron out inefficiencies and inaccuracies and learn about desirable features to include when implementing the registry. Ultimately, these short-term studies funded by TIDAL will aid us in pursuing further grant funding to carry out long-term usability tests and registry pilots and eventually bringing the registry to life.

In order to carry out the short-term usability tests (see Appendix for the protocol developed), we created a minimum viable data collection tool during the project. This was accomplished using an online form-building tool called Tally (https://tally.so/). The forms are designed to capture all the information listed in the table above and are to be filled at the completion of each device provision or repair job. To collect structured feedback on the burden associated with collecting repair and maintenance data from our clinical partners, and thereby inform the design of the registry interface, we used the System Usability Scale (Brooke 1996), the NASA Task Load Index (NASA-TLX) (Hart 2006), and a usability questionnaire based on the Nielsen model (Nielsen 1994). Towards the end of the TIDAL funds, we managed to arrange a short-term study with *Mobility India – Rehabilitation Research and Training Centre*, a world-renowned NGO prosthetic limb-fitting centre based in Bangalore (see Appendix for protocol). The study protocol and registry forms have been developed/finetuned based on numerous meetings and consultations with relevant staff members at Mobility India. We carried out an initial assessment of the registry schema with members of the clinical staff at Mobility India (i.e., pilot testing), and we are now beginning to carry out the next stage of the actual usability testing. We are also currently in conversation with a number of limb-fitting centres in England and Scotland regarding short-term usability studies; however, due to the fact that the NHS is understaffed, progress with these centres has been slow in comparison, and we have yet to move past the initial engagement phase of the studies with the UK-based centres.

We believe that in the long term, this work will be able to positively impact the following:

> **Prosperity and Productivity & Healthy Living**: The WHO estimates that there are over 40 million amputees globally, and only 3% of them have access to quality rehabilitation care. For many, whose primary source of income is derived from manual labour in developing countries, the lack of an appropriate prosthetic device often results in reduced productivity and reduced quality of life. This also holds in poor communities in the Western world. Besides a moral and political imperative, it has been suggested that developing countries find that treating disabled persons is a fiscally responsible strategy in the long term (Staats 1996; Cummings 1996). It was estimated in an American study that every $1 spent on rehabilitation (including prosthetic care) saves more than $11 in disability benefits alone and offers numerous nonfiscal benefits to the patient (Amputee Coalition 2016).
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> Better record-keeping practices of service provision are critical to helping understand the problem's magnitude and make systematised repair/maintenance front and centre in follow-up service provision. This helps generate evidence on the current gaps in prosthetic device durability/reliability and opens avenues for improving prosthetic services and devices as well as reducing prosthetic rejection in the long term. These aspects are helpful in improving the productivity, satisfaction, and quality of life of patients.
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> **Sustainable environment**: Providing a comprehensive database/registry for recording prosthetic provision and repair patterns can help drive future prosthetic designs, make devices more durable and reliable, reduce repair-related travel, etc. A prosthetic device is for life – our registry can help improve evidence base and decision-making in device prescription and life-long care. Besides, device abandonment and non-use/reduced use of prosthetic arms have been a known problem, and providing robust/appropriate devices and

quality care longitudinally that better suit user requirements are likely to promote device use as well as improve patient outcomes and quality of life. Finally, evidence generated through our work can help minimise repairs and waste in this field.

Finally, we are happy to report that, with TIDAL's support, we were able to begin a conversation with many other like-minded researchers across the UK about starting a new research network with a core focus on data-driven research in prosthetic services. In terms of sustaining the project in the long term, grant bidding is planned. A workshop on data-driven prosthetic research was organised by Nagaraja and Cheng at King's College London in January 2025. This workshop brought together key research academics, students, and clinicians working on prosthetic service and repair data in the UK (and elsewhere)—many of whom have been funded by or associated with the TIDAL Network+ in the past. This day-long workshop also helped explore synergy and future avenues of collaboration and bidding, and some relevant grant schemes have been identified to this end. For instance, we are considering a Network grant to help the new network become operational. We are grateful for the opportunities afforded to us by TIDAL, and we will continue to strive toward creating a Prosthetic Provision and Repair Registry for improving future prosthetic research.

5. Next steps and future plans for the registry

Our key learning is that engaging with some UK-based centres has been difficult. Due to the fragmented nature of NHS care, the structure of franchises, and staffing issues, there is limited-to-no data-sharing. These limb-fitting centres are typically understaffed (also noted by Leone et al. 2024), and generally, have limited time for other activities like research. However, we are continuing to engage with them despite the barriers to undertaking usability testing in the UK.

The next stage of this work is clear. First and foremost, we will go forward with the short-term usability testing at Mobility India. This information can be found in the Appendix and the corresponding manuscript write-up is under progress. Work at Mobility India is to help progress the work and be a testbed for similar usability studies in UK-based limb-fitting centres. The outcome of this study will be leveraged to apply for further funding to support the project in Spring/Summer 2025. And in the meanwhile, we will continue to plan short-term studies with the UK-based centres we are in contact with. We will also be planning visits to various limb-fitting centres to observe their daily workflow, which will help us better understand how the registry can be integrated into the existing system. This will be followed by a couple of long-term (year-long) pilot testing. In the longer term, we hope to seek national/regional mandate to roll out two prosthetic-limb registries, one in the UK and one in India, that are compatible with one another data-structure-wise, while keeping our mind open to opportunities in other parts of the world. We will also seek contributions from existing databases (and perhaps, other assistive technologies), with the aim of harmonising them into one large dataset.

References:

Amputee coalition [Internet]. The economic benefits of prosthetic coverage. Available at: https://www.amputee-coalition.org/wp-content/uploads/2016/01/economic-benefits-prosthetic-coverage_amputee-coalition.pdf. [Last accessed on 14 February 2025]

Barth, C.A., Wladis, A., Blake, C., Bhandarkar, P., Perone, S.A. and O'Sullivan, C., 2021. Retrospective observational study of characteristics of persons with amputations accessing International Committee of the Red Cross (ICRC) rehabilitation centres in five conflict and postconflict countries. *BMJ Open*, *11*(12), p.e049533.

Berthaume, M., Barnes, S., Hettiaratchy, S., Clasper, J.C., Kumar, A., Sathiadas, G. and Ganeshamoorthy, J., 2023. Demographic, medical, and financial statistics from the Jaffna Jaipur Centre for Disability Rehabilitation (JJCDR) database, 1987-2018: a prosthetics, orthotics, and mobility clinic in northern Sri Lanka.

Brooke, J., 1996. SUS-A quick and dirty usability scale. *Usability evaluation in industry*, *189*(194), pp.4-7.

Chadwell, A., Diment, L., Micó-Amigo, M., Morgado Ramírez, D.Z., Dickinson, A., Granat, M., Kenney, L., Kheng, S., Sobuh, M., Ssekitoleko, R. and Worsley, P., 2020. Technology for monitoring everyday prosthesis use: a systematic review. *Journal of Neuroengineering and Rehabilitation*, 17, pp.1-26.

Cummings, D., 1996. Prosthetics in the developing world: a review of the literature. *Prosthetics and orthotics international*, *20*(1), pp.51-60.

Davidson L, Kenney L, Galpin A, Chadwell A, Donovan-Hall M. 'Only if the user complies' - Repair and maintenance in myoelectric user documents. In 2025 Trent International Prosthetic Symposium (TIPS 2025), Rotterdam, Netherlands.

Dickinson, A., Gates, L., Metcalf, C., Owen, C., Kheng, S., Heang, T., Sam, B., Harte, C., Simpson, S., Worsley, P. and Ostler, C., 2024. Understanding repair and replacement of prosthetic limbs using routinely-collected data: a retrospective study over three decades in Cambodia. *medRxiv*, pp.2024-10.

Hart, S.G., 2006, October. NASA-task load index (NASA-TLX); 20 years later. In Proceedings of the human factors and ergonomics society annual meeting (Vol. 50, No. 9, pp. 904-908). Sage CA: Los Angeles, CA: Sage publications.

Kamrad, I., Söderberg, B., Örneholm, H. and Hagberg, K., 2020. SwedeAmp—the Swedish Amputation and Prosthetics Registry: 8-year data on 5762 patients with lower limb amputation show sex differences in amputation level and in patient-reported outcome. *Acta orthopaedica*, *91*(4), pp.464-470.

Kaufman, K.R., Bernhardt, K., Murphy, S., Archer, M., Brandt, J.M., Bowman, L., Phillips, B. and Board, R.E.A., 2024. Creation of a Limb Loss and Preservation Registry for Improving the Quality of Patient Care in the United States. *Archives of Rehabilitation Research and Clinical Translation*, *6*(3), p.100356.

Kohler, F., 2021. LEAD and COMPASS: Tools to map the way forward for people with lower limb absence. *Prosthetics and Orthotics International*, 45(5), pp.369-372.

Leone, E., Eddison, N., Healy, A., Jackson, C., Pluckrose, B. and Chockalingam, N., 2024. The national profile of the prosthetic and orthotic workforce in the UK: Sociodemographics and employment characteristics. *Prosthetics and Orthotics International*, 48(3), pp.348-357.

Nagaraja, V.H., Cheng, R., Slater, D.H., Thompson, M.S. and Bergmann, J.H., 2022. Upper-limb prosthetic maintenance data: A retrospective analysis study. *JPO: Journal of Prosthetics and Orthotics*, 34(4), pp.223-232.

Nagaraja, V.H., et al., A Nearly Two-decade-long Maintenance and Cost Analysis of Prosthetic arms in a Low-resource Setting: Case for More Appropriate Medical Device Service Systems. (In preparation)

NHS England (2022), Delivering a 'Net Zero' National Health Service. Available at: https://www.england.nhs.uk/greenernhs/publication/delivering-a-net-zero-national-health-service/ [Last accessed on 14 February 2025]

Nielsen, J., 1994. Usability engineering. Morgan Kaufmann.

Porter, M., Armstrong, R., Howard, P., Porteous, M. and Wilkinson, J.M., 2019. Orthopaedic registries–the UK view (National Joint Registry): impact on practice. *EFORT Open Reviews*, 4(6), pp.377-390.

Ranson, G., Morley, M., Corsial, N., Sathiadas, G., Ganeshamoorthy, J. and Berthaume, M., 2022. The mechanical failure of locally manufactured prosthetic feet from the Jaffna Jaipur Centre for Disability Rehabilitation (JJCDR), Sri Lanka. *Prosthetics and Orthotics International*, pp.10-1097.

Staats, T.B., 1996. The rehabilitation of the amputee in the developing world: a review of the literature. *Prosthetics and orthotics international*, *20*(1), pp.45-50.

WHO, Standards for prosthetics and orthotics (2017). Available at: https://www.who.int/publications/i/item/9789241512480 [Last accessed on 14 February 2025]

Appendix: *Short-term usability study protocol*

Study participants: Key dedicated personnel at the limb-fitting centre will be *data contributors* (recording the data on prosthetic service provision and repairs on the Registry forms) and *supervisors* (who will check whether the data captured is complete and correct).

Duration: Four weeks

Data collection: Prospective

Registry forms (working prototype ready for current usability testing)

- Patient information (R1): https://tally.so/r/nPGpLe
- Device information (R2): https://tally.so/r/nrk5RR
- Terminal device information (R2.1): https://tally.so/r/w4pQRY
- Maintenance and repair information (R3): https://tally.so/r/3xlrE5

Usability test forms

- *To be filled by data contributors on the last days of pilot testing and usability testing*
    - System Usability Scale (T1):
        - Note: To be filled on paper

1. I think that I would like to use this system frequently.

1. Strongly Disagree	2.	3.	4.	5. Strongly Agree
○	○	○	○	○

2. I found the system unnecessarily complex.

1. Strongly Disagree	2.	3.	4.	5. Strongly Agree
○	○	○	○	○

3. I thought the system was easy to use.

1. Strongly Disagree	2.	3.	4.	5. Strongly Agree
○	○	○	○	○

4. I think that I would need the support of a technical person to be able to use this system.

1. Strongly Disagree	2.	3.	4.	5. Strongly Agree
○	○	○	○	○

5. I found the various functions in this system were well integrated.

1. Strongly Disagree	2.	3.	4.	5. Strongly Agree
○	○	○	○	○

6. I thought there was too much inconsistency in this system.

1. Strongly Disagree	2.	3.	4.	5. Strongly Agree
○	○	○	○	○

7. I would imagine that most people would learn to use this system very quickly.

1. Strongly Disagree	2.	3.	4.	5. Strongly Agree
○	○	○	○	○

8. I found the system very cumbersome to use.

1. Strongly Disagree	2.	3.	4.	5. Strongly Agree
○	○	○	○	○

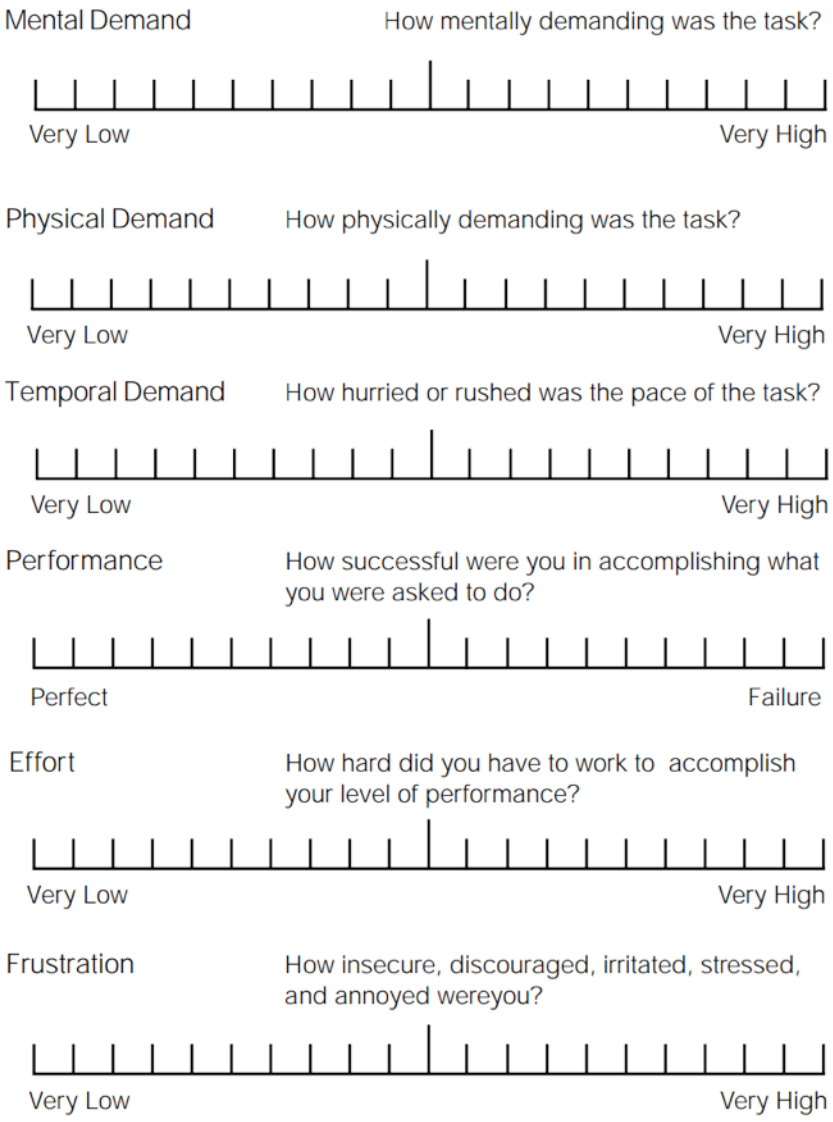
9. I felt very confident using the system.

1. Strongly Disagree	2.	3.	4.	5. Strongly Agree
○	○	○	○	○

10. I needed to learn a lot of things before I could get going with this system.

1. Strongly Disagree	2.	3.	4.	5. Strongly Agree
○	○	○	○	○

- NASA Task Load Index (NASA-TLX): Post-Task Workload (T2):
  - Note: To be filled on paper



- Nielsen model and open-ended feedback (T3): https://tally.so/r/3jGg24

- *To be filled by supervisors on last days of pilot testing and usability testing*
  - Data completeness and correctness forms (T4): https://tally.so/r/nrkBgL

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