

JANUARY 2023

MONASH HEALTHCARE INNOVATION SUMMER SCHOLARSHIPS

Project Lymb



Monash Partners
Academic Health Science Centre



**MONASH
YOUNG
MEDTECH
INNOVATORS**

Current Team: Mohairees Idzhan
Clinical Champion: Dr Robyn Sierla
Affiliations

Executive Summary

Lymphoedema is a common disease which occurs after cancer-related surgeries, such as breast cancer, as lymph nodes are often removed or damaged during the surgical process and this causes lymph fluids to build up in the tissue under the skin [6]. The lymph fluid is then drained during a lymphoedema consultation. However, surgical scars can obstruct lymphatic circulation which causes fibrosis [7]. Currently, lymphoedema therapists are using pen and paper to manage and update their patient's details, which can be a slow process and are prone to being lost or physically damaged. In addition to that, lymphoedema therapists have to consult a physical catalogue of measurement charts from compression garment manufacturers and match those numbers to the limb sizes of the patients, which is a long and tedious process. Therefore, there is a need to reduce the workload of lymphoedema therapists in a clinical setting so that a more appropriate level of care can be given to patients diagnosed with lymphoedema. There is no major competitor, except for the resistance to change as we are trying to implement a new way to do things. The platform can save up to 15 minutes of a clinician's time with each patient, and this frees up time for hands-on treatment. It also facilitates the consideration of off the shelf garments, due to an efficient garment search system, which can be 1/5 of the cost of a Made-To-Measure (MTM) garment. This is appealing in terms of healthcare cost savings for the health sector and for insurers as off-the-shelf garments only take 3 days to be delivered while MTM can take up to 3 weeks to be delivered.

Acceptance Criteria

1. Saves clinician at least 15 minutes with each patient
2. Integrates seamlessly into clinician's workflow
3. Solution will be able to quickly filter for appropriate compression garment based on patient
4. Solution will enable patient's data to be easily accessed by the clinicians

Gaps analysis

The Gold Standard:

Current gold standard is to **use a measuring tape** to measure the width and circumference of limb, and using that information to **manually calculate limb volume** by approximating the shape of a limb to a simple geometrical shape. Following that, should a compression garment be required to manage the symptoms, the physiotherapist will need to **manually consult physical catalogues of compression garments from various manufacturers** in order to find one that is suitable for the patient's limb size. Finally, the physiotherapist prescribes the patient some exercises if necessary as part of the treatment if necessary and subsequently a treatment plan before discharging the patient.

Existing solution 1: SOZO Impedimed

The SOZO Impedimed machine uses bioimpedance spectroscopy (BIS) to measure and track critical information such as the patient's fluid levels to aid clinicians in managing chronic disease and maximising patient's health. The results appear in less than 30 seconds [2]. Patient steps on the device and places their hand on a dedicated area where an extremely low-strength electrical current passes through the body and impedance is measured. Algorithms are used to determine fluid levels and tissue composition [2]. The SOZO device costs \$9995, the L-DEX software costs \$1500 for 36 months. The hospital/clinic pays for the device and software subscription and the costs charged to the patient is covered by Medicare [1]. It is a quick, easy and accurate way of gathering important information from the patient, therefore providing clinicians with a fast and easy way to track lymphedema progress in a patient. It also comes with necessary software features such as graphing results and automatically syncs with electronic medical record. This solution however does not offer the ability to select an appropriate compression garment for the patient's needs.

Existing solution 2: Pen and paper

A pen and paper or whiteboard and markers can be used by clinicians record and store measurements of patient's limbs. A pen costs \$1, while an A4 sized notebook with 240 pages costs around \$4. Health specialists can purchase their own ones or use the ones that are available at the hospital where the hospital acts as the purchaser. Health specialist will measure limb dimensions with a measuring tape and note it down in a notebook. Next, clinicians can calculate the volume of the limb by approximating the limb to have a certain simplified geometry. It is an easy and convenient method to learn and also to use when tracking the progression of a patient's limb size. However, it lacks an easy to use method to find the appropriate compression garment. Can be time consuming. Manual measurement is prone to clinical errors. Papers are also prone to being damaged/lost easily when not kept properly.

Gaps analysis

Existing solution 3: Electronic Medical Record

A digital record of a patient's medical record. Clinician enters data into the system or data can be synced from supported services. Paid for by the government, according to The Guardian, the government has spent \$2bn on EMR [3]. When a clinician wants to update a patient's record, the clinician can log into the system and open the patient's history where the clinician can then update the patient's details. This improves time efficiency for clinicians by providing a means for data to be safely stored and easily shared and accessible by clinicians, therefore improving convenience. However, it does not offer compression garment search capabilities and is not widely adopted therefore causes inaccessibility issues.

Systems Map

Project LYMB Systems Maps

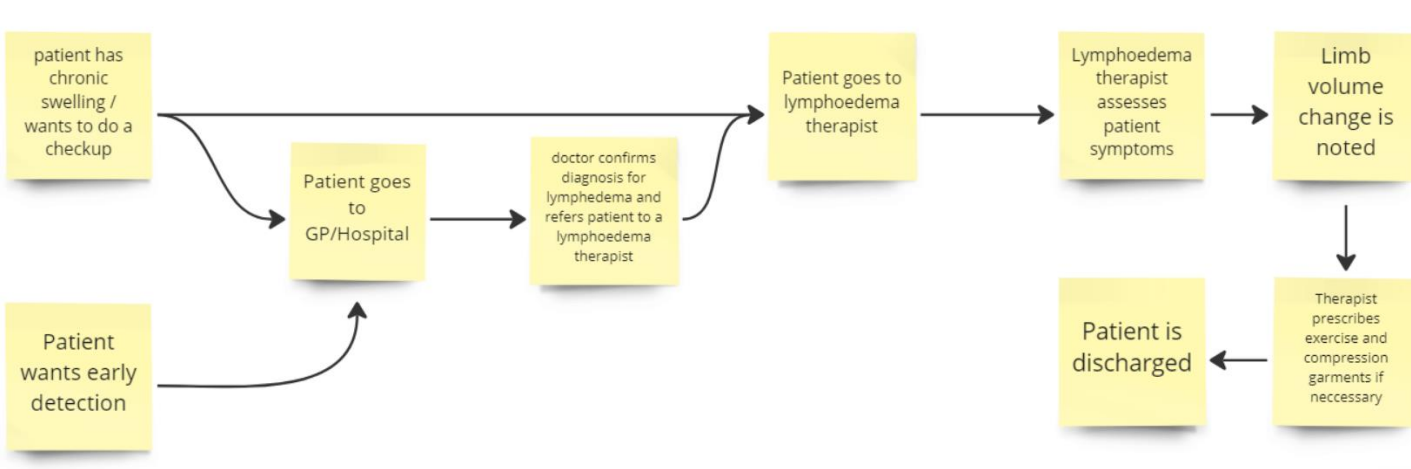


Figure 1: Systems Map

The system map depicted above shows the journey of a patient that has symptoms of lymphedema. The key information here is that the lymphedema therapist is responsible for obtaining accurate measurements in the limb, prescribing a suitable compression garment to patient and to teach the patient of any exercising necessary.

Stakeholder Map

Project Lymb Stakeholder Map

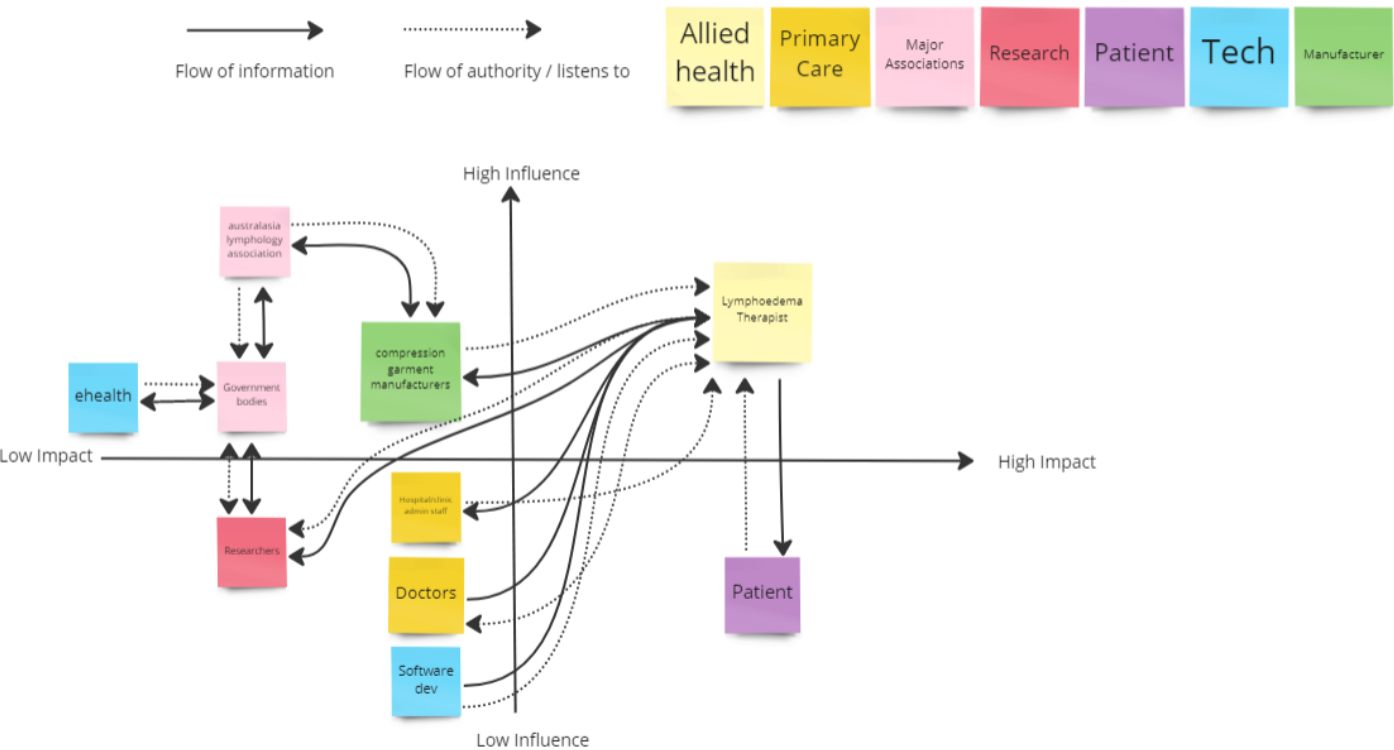


Figure 2. Stakeholder Map

Depicts the range of stakeholders and the position they hold in terms of the direct influence they have on the project, and the impact the project will have on them. There are four major stakeholder categories: stakeholders who are involved in the research of the problem and development of the solution, beneficiaries of the solution, HISS program contacts, and competitors - existing solutions. Stakeholder bubbles are also sized according to their importance, with healthcare workers being the largest stakeholder as they are not only involved in the research and development phase, but they will also benefit from the solution, as it may potentially reduce the amount of time they spend on each patient, therefore increasing the quality of care which can be given to each patient.

Outcomes of Qualitative and Quantitative Research

Epidemiology

Primary lymphoedema is caused by abnormal development of lymphatic development while secondary lymphoedema occurs when there is injury to the lymph nodes. Around 300,000 people are currently experiencing lymphoedema [8]. Prevalence of primary lymphoedema is rare, at around 1.15/100,00 while secondary lymphoedema is more common and primarily affects cancer survivors, about 20% for breast cancer and about 40% of vulvar cancer survivors [8].

Anatomy, physiology and pathophysiology

The function of the lymph nodes is to transport lymph fluids from body tissues back into the bloodstream. When lymphatic vessels/nodes are damaged/not formed correctly, lymph fluid cannot be drained fast enough from the lymphatic system therefore causing swelling at lymph nodes.

Clinical Presentation and Outcomes

According to conversations with various lymphoedema therapists, patients often find it hard and painful to move the affected limbs as it swells up in the early stages of lymphoedema. In the later stages lymphoedema however, the skin tissue gets harder and skin changes such as thickening, hyperpigmentation, increased skin folds, fat deposits and warty overgrowth develop. Lymphoedema increases the risk of cellulitis, which is the most common avoidable hospitalisation cause, therefore exposing the patient to systemic and sometimes life-threatening infections if left untreated [9]. Patients often must wear compression garments and undergo lymphoedema therapy sessions to manage the swelling.

Economic Impact

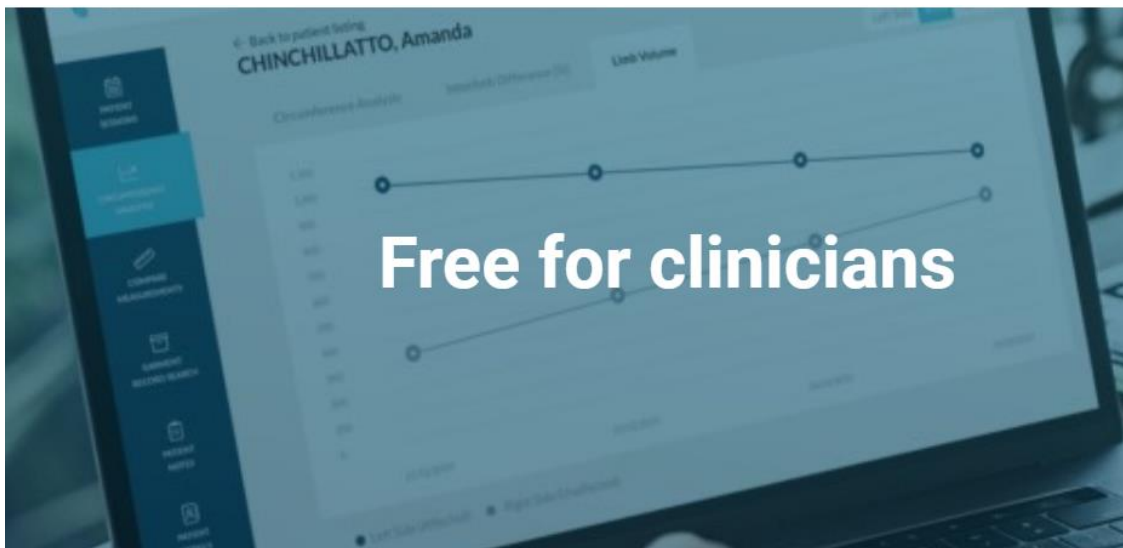
Hospitalisation costs around \$1300 to \$4000 in non-ICU cases, which can be avoided when timely care is given [10]. Additionally, the Morrison Government has committed \$2 million in 2020 for lymphoedema support at national level while Marshall Liberal Government has committed \$2.5 million from 2020 to 2022 [11].

Solution Concept Discussion

- top 2

lymbase.com

A digital platform which allows clinicians to monitor and track a patient's lymphedema progress and quickly offer suitable compression garments for the patient. It is mostly used during the treatment process where it is crucial to monitor how a patient is responding to prescribed treatment. It is free for patients and clinicians to use and the business model involves getting compression garment manufacturers to pay in order to have their products listed on the website. The platform improves time efficiency for clinicians by providing a means for data to be safely stored and easily shared and accessible by clinicians, therefore improving convenience. This idea, while convenient and practical to use, offers a limited range of compression garments.



Solution Concept

patients

The idea behind this concept is for the compression garment process to be automated in order to save the clinician’s time. The calculator will have inputs such as patient’s limb volume and desired compression pressure and will use this information to determine the appropriate compression garment size for the patient. This saves the clinician’s time as they do not need to physically look up measuring charts when determining an appropriate compression garment for the patient.

Size Finder

Measurement

Centimeter

Gender

Male

Limb

Arm

Final Concept

Regulatory considerations and strategy

The final concept is a digital platform titled “lymbase.com”, a clinical decision support tool for clinicians treating lymphedema. The platform will support clinicians as all of patient’s data will be stored in the cloud and can be easily accessed by clinicians, which removes the issue of having to manage physical documents which can be easily lost. In addition to that, it also comes with a compression garment search function which allows clinicians to determine an appropriate compression garment for patients a lot faster than by manually looking at measurement charts from compression garment manufacturers. Even though the algorithm used to determine an appropriate compression garment size is not patentable, the series of steps that led to the algorithm is patentable under the patentable “process” category. The device does not need medical regulatory approval as it is a clinical decision support system, in that the responsibility of making clinical decisions are still left to the clinicians and that the platform is a tool which is used to help the clinician make decisions.

Clinical considerations

The solution seamlessly integrates into the workflow of the clinician as the clinician simply has to record observations and limb volume sizes down on a computer instead of on a paper. Since the target market is small, but with a large purchasing power, they can be accessed through professional networks and events such as conferences. For example, we can introduce the software at the annual Australasian Lymphology Association (ALA) conference, where the target audience, which are clinicians treating lymphoedema, would be present. Since the platform is free for clinicians to use, that can be capitalized to encourage clinicians to adopt the platform. Another market penetration strategy would be to extend the target demographic to patients by creating a new feature which has facts on lymphoedema that is tailored to the patient or by creating reminders for the prescribed exercises and any future appointments.

Technical considerations

A great technical risk would be that clinicians often do not have the very best of laptops and computer systems at their workplace, therefore one way to de-risk this is to do the processing and rendering for the platform and website on a server instead of on the clinician’s computer. Another risk is that there might be risk-aversion to the collection of health data to the cloud and resistance to change. One way to de-risk this is to use a trusted cloud server and by following all regulations on medical data in Australia, such as the fact that the location of the data servers must be in Australia. A technical milestone would be that the efficiency of the code is good enough to run on the level of computers that clinicians are using daily and that the algorithm for the compression garment finder is reliable enough to provide good recommendations for compression garments.

Business Model

Business Model and Revenue Generation

The business model proposed is a service model which is attached to the product. It is also a B2B model as it is the businesses which are funding the service. The platform is fully funded by compression garment manufacturers. For each product sold via the platform, a commission of \$3-\$4 is earned. In addition to that, the compression garment manufacturer is charged \$2 for each click from the platform that is redirected to their own website. Unfortunately, there is no medicare code for lymphoedema therapy but there is a Lymphoedema Compression Garment Program (LCGP) by the ALA which includes a \$150 subsidy for Ready To Wear garments and \$300 for Made To Measure garments.

Market Penetration Strategy

One market penetration strategy would be to conduct a pilot study, which is what is currently being done, to evaluate on the efficacy of the platform. This aids in the critical evaluation of the platform which helps when identifying gaps in the solution. A pilot study also provides exposure of the platform to a larger audience which may subsequently drive the sales of the product.

Exit Strategy

Management and Employee buyouts would be the ideal business exit strategy as there will be greater confidence that the business will be run by someone familiar with the business and organization [4].

Market Analysis

The Total Addressable Market is valued between A\$1.8 billion and A\$2.5 billion and is expected to grow due to aging, obesity epidemic, higher 5-year cancer survival rates, increased awareness of lymphoedema by the medical profession and a growing middle class. The Serviceable Available Market would be the global pneumatic compression therapy market, which is valued at around \$250 million. Since the average financial cost of lymphoedema borne by each woman with breast cancer in Australia is roughly \$977, and there are about 3.328 million people in Victoria who identify as females, 1 in 7 women have breast cancer and 20% of breast cancer survivors develop lymphoedema [5], there is about \$92 million in Serviceable Obtainable Market. The market can be expanded to include a clinical support decision platform for other diseases.

Proposed KPIs

Economic profile

The current standard operating procedure for treating lymphoedema simply involves pen, paper, some files, and administrative software, therefore implementing a digital platform to replace pen and paper during lymphoedema consultations will involve costs associated by the clinic to purchase new devices like tablets or laptops. However, in the grand scheme of things, the platform aims to save at least 15 minutes when consulting each patient and this can lead to more patients being treated each day, therefore bringing the clinic more money.

Key Performance Indicators

Since the solution essentially aims to improve the efficiency of the current SOP, the KPIs used can be similar. For example, KPIs can include being able to finish a consultation session faster than with previous methods. This will test the effectiveness of the implemented digital platform.

Another KPI can be about the number of sales of compression garments. Since compression garment manufacturers are funding the program, and that the program has a compression garment search function, the effectiveness of that function can be tested by determining how fast and reliable a suitable compression garment is being prescribed to the patient, which has an impact on the sales of compression garments.

Ask and Next Steps



Clinical Champion

Dr Robyn Sierla
BAppSc (Occupational Therapy),
MAppSc (Research), PhD
University of Sydney (Australia)

Founder of Lymbase. Lymphoedema therapist at Royal Prince Alfred Hospital in Sydney. Translational Research Fellow at Sydney Health Partners. PhD topic was the Management of Clinical Data for Lymphoedema. Masters of Applied Science (research) where research topic was the Treatment for Breast Cancer Related Lymphoedema from the Patient's Perspective



Project Lead

Mohaarees Idzhan

Student

4th Year Mechanical Engineering and Commerce (Honours)

Healthcare Innovation Summer Scholar 2022/2023

Has experience with Computational Fluid Dynamics (CFD) software and rapid prototyping physical products.

Needs for the solution

Technical Needs: This project relies heavily on someone who is familiar with UI/UX design and can be extended to someone with software expertise. Additionally, expertise with backend programming would be helpful to ensure that the system has a proper data framework

Other needs: A pilot study is already being conducted, therefore another need would be a larger pilot study or rollouts in other health districts, therefore the assistance of someone with a large network in the medical industry is helpful.

Timeline

Feb 2023

- Summarise findings from current clinical trial
- Implement new features to platform

April 2023

- Begin roll out to other health districts
- Analyse results to evaluate any new features being added and to determine scalability

July 2023

- Further statewide roll out to get as many clinicians on the system
- Further development to the platform

Oct 2023

- Use the increased popularity of the platform to attract more compression garment companies to invest and put their products up on the platform
- Expand to add more features which are useful for patients as well

References

1. Agency for Clinical Innovation. Lymphoedema: A guide for clinical services [Internet]. Chatswood, NSW: NSW Government; 2018. Available from https://aci.health.nsw.gov.au/_data/assets/pdf_file/0008/477998/lymphoedema-guide.pdf
2. Ansarada. Business Exits [Internet]. Choosing The Right Strategy; 2020. Available from <https://www.ansarada.com/business-exits/strategies>
3. Ashforth K. Lymphatic Education and Research Network [Internet]. Identifying Fibrosis in Every Stage of Lymphedema [Internet]. California, USA; 2019. Available from <https://lymphaticnetwork.org/news-events/identifying-fibrosis-in-every-stage-of-lymphedema#:~:text=Sometimes%20these%20scars%20become%20hard,a%20result%20of%20prolonged%20swelling>
4. Australasian Lymphology Association. About Lymphoedema [Internet]. Australasian Lymphology Association; 2015. Available from <https://www.lymphoedema.org.au/about-lymphoedema/what-is-lymphoedema/#Incidence%20of%20LO>
5. Cancer Australia. What is secondary lymphoedema [Internet]. Strawberry Hills NSW: Cancer Australia; 2012. Available from <https://www.canceraustralia.gov.au/clinical-best-practice/lymphoedema>
6. Cancer Council. Lymphoedema [Internet]. Australia: Cancer Council Australia; 2013. Available from <https://www.cancer.org.au/cancer-information/after-a-diagnosis/after-cancer-treatment/lymphoedema>
7. Department of Health and Aged Care. Morrison and Marshall Governments come together to support Australians with lymphoedema [Internet]. Canberra ACT ;2020. Available from <https://www.health.gov.au/ministers/the-hon-greg-hunt-mp/media/morrison-and-marshall-governments-come-together-to-support-australians-with-lymphoedema>
8. Eastern Health. Fees and Cost [Internet]. Box Hill, VIC: Eastern Health; 2022. Available from <https://www.easternhealth.org.au/services/item/940-fees-and-costs>
9. ImpediMed Limited. Know. More. Now [Internet]. California USA: ImpediMed Limited 2022. Available from https://www.impedimed.com/wp-content/uploads/2022/06/PM-173-US-Rev-G-Product-Brief_DIGITAL.pdf

References

10. ImpediMed Limited. SOZO® Digital Health Platform [Internet]. California USA: ImpediMed Limited 2022. Available from <https://www.impedimed.com/products/sozo>
11. Taylor J, Corderoy A. The Guardian [Internet]. Australia: My Health Record: almost \$2bn spent but half the 23m records created are empty; 2020. Available from <https://www.theguardian.com/australia-news/2020/jan/23/my-health-record-almost-2bn-spent-but-half-the-23m-records-created-are-empty>