A biodesign process – Identifying an unmet need in the recurrence of aspiration pneumonia in people with late-stage Parkinson's disease

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A Biodesign Process – Identifying an unmet need in the recurrence of aspiration pneumonia in people with late-stage Parkinson's disease

A thesis submitted to the University of Galway for a Masters in BioInnovation August 2023

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Lastly, to my husband Mick and our three wonderful children, Hannah, Finn & Jack – I am so fortunate to have your continued encouragement, support and love – I dedicate this accomplishment to you – Thank you.

Abstract

This thesis discusses some of the challenges of recurring aspiration pneumonias in people with conditions like late-stage Parkinson's disease and Motor Neuron Disease.

A description of the experience of needs-finding in the clinical area of Respiratory & Anaesthesia during clinical immersion, filtering, needs refinement, market analysis, and solution ideation during the BioInnovate program is presented.

A thorough literature review revealed that aspiration pneumonia is the leading cause of death for people with Parkinson's disease, and stakeholders want a solution. Some suggestions for the future work and challenges of this project are discusses further.

While this thesis contributes to the understanding of unmet needs in the recurrence of aspiration pneumonias, it also highlights the value of using the Biodesign process in addressing these unmet clinical needs. The Identify, Invent, Implement stages of the Biodesign process are discussed throughout this thesis, regarding the innovative potential solution direction.

Declaration

I declare that I am the sole author of this thesis and the presented work is my own, unless referenced or indicated otherwise. I confirm this work has not been submitted, in whole or in part, to any other institution as part of a degree or any other qualification.

Introduction & motivation

Introduction

This thesis focuses on ***a way to*** *reduce the recurrence of aspiration pneumonia* ***in*** *people with Parkinson's disease* ***in order to*** *reduce hospital admissions and hospital costs*. Using a Biodesign approach, explained further below, the author identified and screened the need and brainstormed for potential solution directions, with other innovators from her team, past alumni and mentors from the University of Galway. Below, there's an introduction to the Biodesign process we used during the 10-month program and to our team of 4, The Respiratory and Anaesthesia Team, led by Dr John Laffey, Consultant in Critical Care and Anaesthesia at Galway University Hospital.

Three chapters are discussed in this thesis, which include a description of the Biodesign process in Chapter 1. This chapter will also discuss the BioInnovate needs-finding and screening process as well as the evolution of the resulting Top Need – aspiration pneumonia in people with Parkinson's disease. A literature review and description of the Top Need will feature in Chapter 2. Chapter 3 discusses the Solution Direction, as well as the various aspects to consider when creating an innovate solution for an unmet clinical need. Considerations, challenges and limitations to developing and growing a business are also mentioned.

Overview of the BioInnovate Program

Biodesign, Stanford

The Biodesign process, originating in Stanford, California consists of three key steps (shown in Figure 1) – (1) Identify the need, (2) Invent a solution for that need or problem and (3) Implement the solution by developing a strategic planning and integration (Yock et al., 2010). Throughout the fellowship, the Biodesign innovation process was used to identify unmet clinical needs, invent potential solution directions and preparation to implement the potential solution directions. The journey of the author, as part of the Respiratory & Anaesthetic Team, is further outlined below. The evolution through the three phases of the Biodesign process, to the top chosen need, is also discussed.

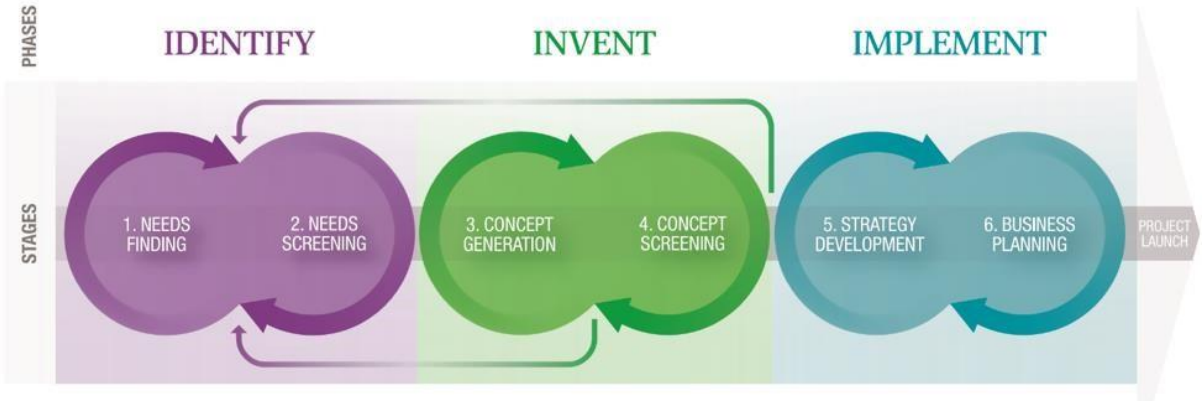

Figure 1 - Graphical representation of Biodesign process (Yock et al., 2010)

BioInnovate, Ireland

The BioInnovate program, a Stanford Biodesign affiliate, is a 10-month needs-led innovation fellowship at the University of Galway which is co-funded by Enterprise Ireland. The BioInnovate program in Galway brings teams together, who come various professional backgrounds, including clinical, commercial and engineering experience. There has been 144 BioInnovate fellows and 32 successful spin-out companies. Currently, 1 in 8 Irish Med-Tech companies come from BioInnovate (UG, 2023). The network and ecosystem that has stemmed from this is invaluable during the Biodesign process. None of this would be possible were it not for the support and funding from Enterprise Ireland, which allows fellow the time and space to identify the needs and create novel solutions.

Our team

The Respiratory & Anaesthesia Team consisted of 4 members who brought various contributions and vast experiences from their respective fields, they were:

- ***Clinical*** – Breege Donegan – has a BSc in Nursing from University College Dublin, PgDip in Respiratory Nursing from the Royal College of Surgeons, Dublin, and MSc in Nursing from the University of Limerick. She has worked as a nurse for over 10 years, in the areas of Respiratory and Urology care.
- ***Clinical*** – Shashwat Hora –medical degree from Grant Government Medical College & Sir JJ Group of Hospitals in Mumbai. He holds a Masters of Biomedical Innovation and Development from the Georgia Institute of Technology, Atlanta, USA.

- ***Engineering*** – Liam O'Brien – BSc in Mechanical and Manufacturing Engineering from Cork Institute of Technology and a PgDip in Innovation Management from the University of Limerick.
- ***Commercial*** – Edel Mitchell – has a BSc in Business Studies, a Masters in Sports Leadership and has over 20 years' experience in international business development and project management.

Chapter 1

Biodesign process phase I – Identify: Needs finding & Screening

This phase is about finding the unmet need, during direct observation of healthcare, including from diagnosis to treatment, and payment. Here, the innovator observes what is being done, how it is being done and how this impacts the patient, provider and overall healthcare system (Yock et al., 2010).

Clinical immersion

Our 8-week clinical immersion took place in Galway University Hospital (GUH), with two days in St James's Hospital, Dublin. As Breege had over 7 years' experience previously working at GUH, she took the lead on this part of the program. This facilitated greater networking and access to various clinicians, nurses and other allied health care professionals at GUH and for interviews with other colleagues in hospitals all over Ireland, namely Sligo General Hospital, Beaumont Hospital and St James's Hospital. This gave us the opportunity to gain insight from these stakeholder, into their biggest pain points or concerns in their area of work. Although we were assigned the areas of Respiratory & Anaesthesia, we did not limit our insights to these fields – for example, we found various needs in the subject of wound care while we were on clinical immersion in critical care, operating theatres, general wards and outpatient clinics, which one of the team members is currently pursuing.

Led by Dr John Laffey at GUH, we were fortunate to be facilitated during our clinical immersion by a wonderful team of clinicians, nurses, hospital engineers, speech and language therapists, physiotherapists, in-patient and out-patient service-users, patient support groups and general practitioners. As a team of 4 we conducted hundreds of interviews, observed 7 surgical procedures, attended 7 out-patients clinics and liaised with 3 patient groups which gave us greater understanding of patients' needs. A summary of the clinical areas and location of our observations is contained in Table 1.

Table 1: Summary of clinical area observation locations accessed during clinical immersion.

Clinical Area	**Engagement Locations**
ICU / Critical Care	Galway University Hospital
	St James – Dublin
	Mater Hospital – Dublin
Post ICU Clinics	Mater Hospital - Dublin
Theatre	Galway University Hospital
	St James - Dublin
Respiratory Procedures / Clinics	Galway University Hospital
	Merlin Park Hospital
	Cork University Hospital
Patient Advocacy / Support Groups	ICU Steps
	Irish Lung Fibrosis Association Asthma Society
	CF Patient Advocacy
	COPD Support
Professional Societies	Irish Sleep Society
	National PH Unit

Clinical immersion, or needs-finding, including observing the journey to the patients diagnosis, aftercare (post treatment) and recurrences, while asking the patient, provider and other stakeholders for their insights into the perceived need. As a team of 4, we initially collected 953 observations, without judgement or bias and before duplicates were removed. A summary breakdown of where these observations were obtained is outlined in Figure 2.

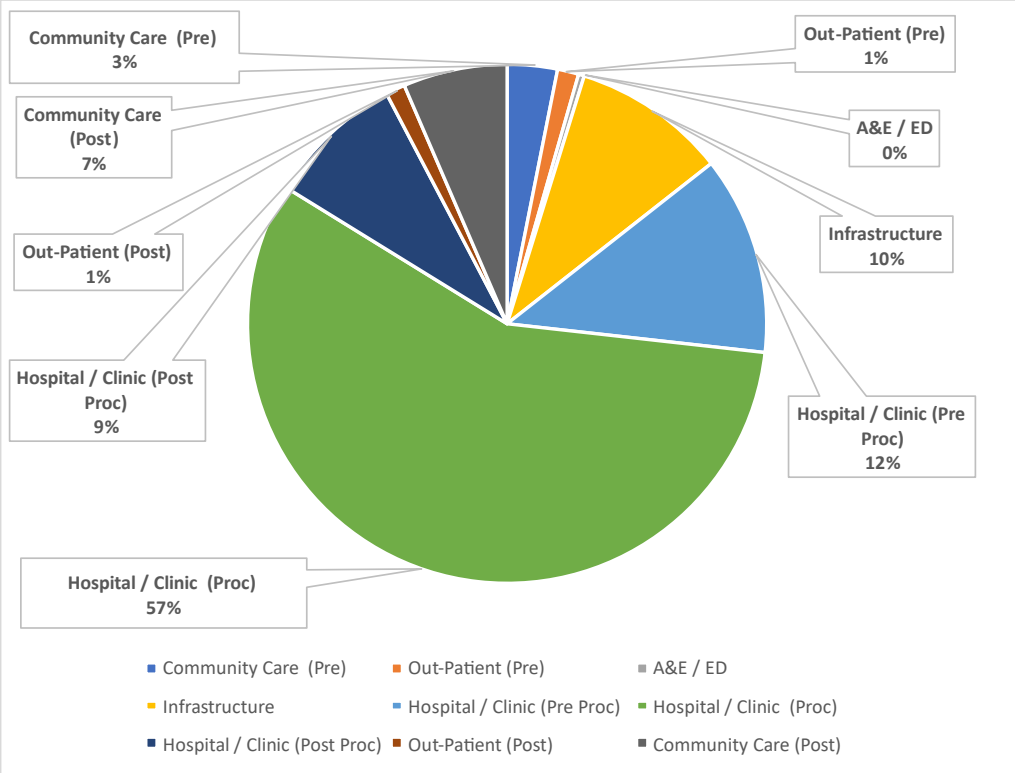

Figure 2: Pie chart outlining the percentage breakdown of observations obtained in each clinical area during clinical immersion.

The pie chart in Figure 2, outlines the percentage breakdown of observations obtained in each clinical area – "Pre" refers to the part of the patients journey where they visit their outpatient or community healthcare provider, perhaps at the early stages of their investigation of diagnosis, for example the patients being seen at the Sleep Clinics undergoing investigations for a potential diagnosis of sleep apnoea. "Post" typically refers to the part of their journey where they are being reviewed again after their treatment or surgery, either in the hospital, the community or outpatient department. "Proc" is shortened for procedure, at which point noted the observations during a procedure. "A&E/ED" refers to Accident & Emergency or the Emergency Department.

Figure 3 shows the observation/needs grouping in Respiratory & Anaesthesia, as observed by our team during immersion. Approximately 39% of our needs were observed in Anaesthesia, 40% in Respiratory and the remaining 21% in Other clinical areas (Table 2).

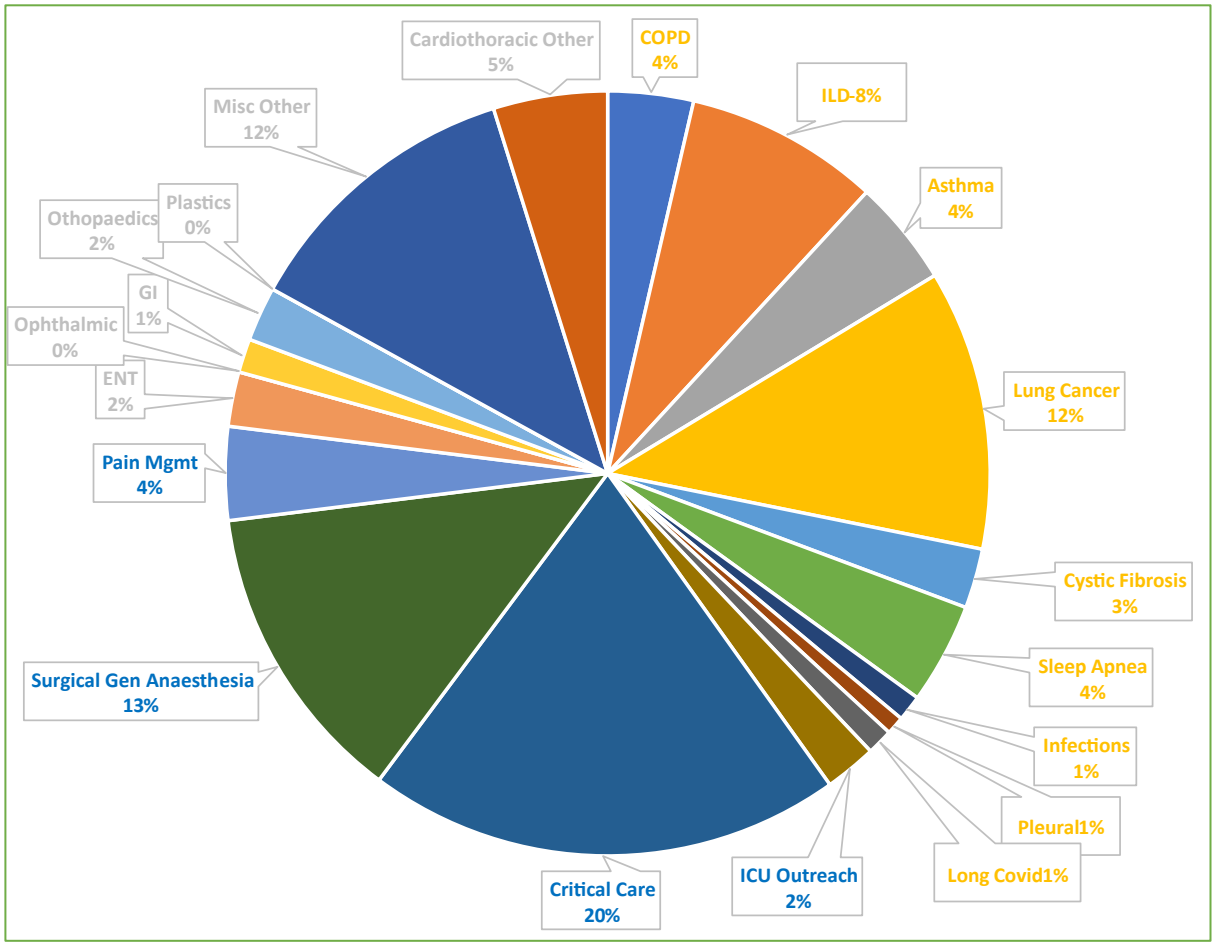

Figure 3: Summary of total number of needs observed and the clinical areas these were observed during clinical immersion.

Table 2: Table outlining the quantity and percentage of needs observed in Anaesthesia, Respiratory and Other areas during clinical placement.

Area	Observations
Anaesthesia	**370 –> 39%**
Respiratory	**381 –> 40%**
Other	**200 –> 21%**
Total	**953**

Observation Screening and Needs Generation (from 953 observations to 267 unique needs)

After our 8-week clinical immersion, we categorised, grouped and removed duplicate observations. This resulted in the removal of 686 observations which ended in a total of 267 remaining unique needs. Needs generation was an iterative process, translating the initial observation into a meaningful Needs Statement. Needs Statements were drafted, using the Biodesign process, based on the ***problem***, ***population*** and ***outcome.*** Examples of need statement development is shown in Table 3. Here, the root observation was recorded during a visit to a hyperbaric chamber treatment for a patient in the intensive care unit (ICU) at GUH. The observation was that the "hyperbaric chamber in the hospital can be utilised for patients with critical limb ischemia and that tissue damage (is minimised) as the pressure conditions allow for better uptake of blood and oxygen to the tissue". After interviewing the consultant at the hospital and conducting our own literature research, this observation was turned into a low order needs statement, reading as follows:

'A way to *initiate local arteriogenesis healing* ***in*** *patients with diabetic foot ulcer wounds* ***in order to*** *reduce infections and surgical removal of tissue / amputations'.*

This and other needs statements were presented weekly to a mentoring panel who would critique and help the team refine the needs into higher order needs. This refinement process allowed for a more accurate targeting of the patient, problem and desired outcome of the different needs statements. This gave a clearer understanding of the identified needs and, inturn, the overall impact and feasibility of solving these needs.

An example of a need statement that was refined as a result of the mentoring process is shown at the bottom of Table 3. This example highlights how the output of the need was made better by highlighting that the initial problem was the cumbersome nature of the therapy for the patient. The change in the 'problem' part of the need statement is then reflected in the outcome – if the device delivering the therapy was less cumbersome then compliance is likely to increase and this is easily measured using the devices delivering the therapy. Finally the patient cohort was also refined by adding the word "obstructive" – this allows a more accurate patient population to be determined.

Table 3: Needs development - from initial observation to higher order need.

A Way To	Do X	In	Population (Y)	In Order To	Do Z
Root Observation Use of a hyperbaric chamber in the hospital can be utilised for patients with critical limb ischemia/ tissue damage as the pressure conditions alone for better uptake of blood and oxygen to the tissue.					
A way to	Initiate arteriogenesis healing	in	patients with diabetic foot ulcer wounds	in order to	reduce infections and surgical removal of Tissue/amputations
Root Observation 1- Patient meets requirements for airway protection given that she is vomiting and has been having seizures and there is a risk of aspiration. However the downside is that patient will pharmacologically be compromised in terms of diagnosing the neuro symptoms. 2- Confirmed that aspiration protection without full intubation is practiced as that only thing that securely protects against aspiration event currently. Agrees that intubation does then necessitate sedation of patient which drives other compromises to the patient.					
A way to	provide aspirate protection without sedation	in	ICU patients meeting criteria for airway protection	in order to	manage risk of aspiration without intubation and to reduce overall time in ICU
Higher & Lower Order Need Statement Example					
A way to	maintain patent airway during sleep	in	patients with sleep apnoea	in order to	reduce apnoea episodes and improve quality of life
A way to	deliver less cumbersome localised positive	in	patients with obstructive	in order to	deliver effective therapy and improve patient therapy compliance
	airway pressure		sleep apnoea		

Filtering - Round 1 (from top 267 needs to 87)

For each observation obtained during clinical immersion, we were mindful of the perspectives of the various stakeholders and how much a solution to each need or observation would improve care or benefit the healthcare system.

At each stage of filtering, we were able to conduct deeper dives into the research of the needs that we believed had great potential. Filtering allowed us to unbiasedly assess each needs statement and rank these against other. Our team used Market Size, Clinical Impact and Likely Burden of Proof as our first round of filters (Table 4). This filtering system is utilised in order

to ensure rigor and to eliminate any potential bias. Each of these three filters were used to rank the needs based on the criteria set out in Table 4 with a value from 1 to 5. The sum of these values were then used to compare the needs and eliminate the ones with the lowest overall rankings.

Table 4: Filter Criteria and Ranking Values for Round 1 Needs Filtering.

Ranking Value	Calculated Market Size	Clinical Impact	Burden of Proof
5	High (>$1Bn)	Life saving impact to patients	Solution success Immediately selfevident
4	Medium High ($800M > x > $1Bn)	Reduced mortality and/or eliminate risk of serious complication	Solution success confirmable by test / outcome (Weeks)
3	Medium ($600M > x > $800M)	Reduce or eliminate symptoms & improve quality of life – no impact on mortality	Solution success confirmable by test / Outcome (Months)
2	Medium Low ($200M > x > $600M)	Patient convenience – no impact on symptoms or mortality	Clinical trial evidence (Medium / Small Trial Size <1 year follow-up)
1	Low (<$200M)	No impact on patient	Significant clinical trial evidence (Large Trial Size + >1 year followup)

At the beginning of our first round of filtering (Round 1) we started out with 267 needs statements, which we then assessed based on filtering criteria, as agreed by our team (as per Table 4). The needs are ranked and scored according to the research carried out by our team members. This iterative assessing & ranking process led us to remove 180 needs statements leaving 87 workable Needs Statements to bring forward in to Round 2 filtering.

Our team presented our work to a mentoring panel every week who would critique our process and discuss our filtering process, ensuring unbiased second opinions were heard as we progressed through this and subsequent rounds of filtering.

An example of some needs ranking is shown in Table 5. Agreement was made amongst the team as to how many needs to cut from the process at this point. Our team agreed to eliminate 180 needs as this left us with a manageable number of retained high ranking needs spread across our clinical areas, in which we could research further. The red line in the table below indicates the cut-off point for our higher-ranking needs statements. The top need that evolved through the Biodesign process, originated during our observations in ICU and centered around clinicians fear of patients aspirating while receiving ventilatory care. While this particular need is not shown in the table below, our top need evolved from this observation, which is discussed further in Chapter 2.

Table 5: Example of filtering process as carried out in Round 1 filtering.

A WAY TO	do X	n	population Y	in order to	do Z	Filter 1.1 Market	Filter 1.2 Impact	Filter 1.3 Burden	Filter 1 Total
A Way to	initiate local arteriogenesis healing	n	patients with diabetic foot ulcer wounds	in order to	reduce infections and surgical removal of tissue	5	5	3	18
A Way to	prevent muscular atrophy that impedes successful extubation	n	in mechanically ventilated ICU patients	in order to	reduce re-intubation and follow on ICU length of stay	4	4	4	16
A Way to	reduce general muscular atrophy	n	in critically ill ICU patients	in order to	reduce recovery time from critical illness post discharge	4	4	3	15
A Way to	non-surgically treat ENT papillomas	n	in patients requiring surgical interventions due to HPV	in order to	reduce the need for surgical intervention	3	5	2	14
A Way to	Detect nerve involvement	n	patients undergoing spine surgery	in order to	Reduce complications resulting in paralysis	3	4	2	12.5
A Way to	confirm effective wound debridement	n	patients with infectious crush injury	in order to	prevent re-infection and procedure revisions	3	3	3	12
A Way to	provide accurate point of care sodium monitoring	n	patient at high risk (Women / Elderly pts) of Hyponatremia	in order to	reduce occurrence of hospital admissions with hyponatremia	3	2	4	11.5
A Way to	provide single point (repeat use) blood sampling	n	patients currently requiring repeat venous blood samples	in order to	ensure simplified blood sampling in patient to reduce infection risk/ discomfort and healthcare staff burden	3	2	4	11.5
A Way to	non invasively monitor routine blood outputs	n	patients currently requiring repeat venous blood samples	in order to	eliminate patient blood draws and healthcare resources	3	3	2	11
A Way to	Orient x-ray to pathology	n	cases requiring intra-operative fluoroscopy	in order to	reduce time and visualize area of interest	2	2	5	11
A Way to	improve fertility	n	male CF patients	in order to	improve patient quality of life	2	4	1	10
A Way to	less invasively neutralizing parotid gland Cancer	n	patients with parotid Ca	in order to	save time and reduce risk of facial nerve injury	3	3	1	10

A way to	reduce time for voice recovery	n patient with vocal cord injury	in order to	improve quality of life	3	1	3	9
A way to	prevent nose bleeds	n patients undergoing hyperbaric treatment	in order to	increase patient comfort	1	1	5	8
A Way to	reduce side effects	n CF patients	in order to	increase medication compliance and reduce healthcare costs	2	2	1	7

With each layer of filtering, we decided to divide the research amongst the team and to crossreference the literature at least once with one of the other team members and we presented the information we found to each other – making arguments for or against killing the need, depending on our filtering criteria used for each round, Table 4. A summary of the disease states associated with the remaining needs is shown in Figure 4.

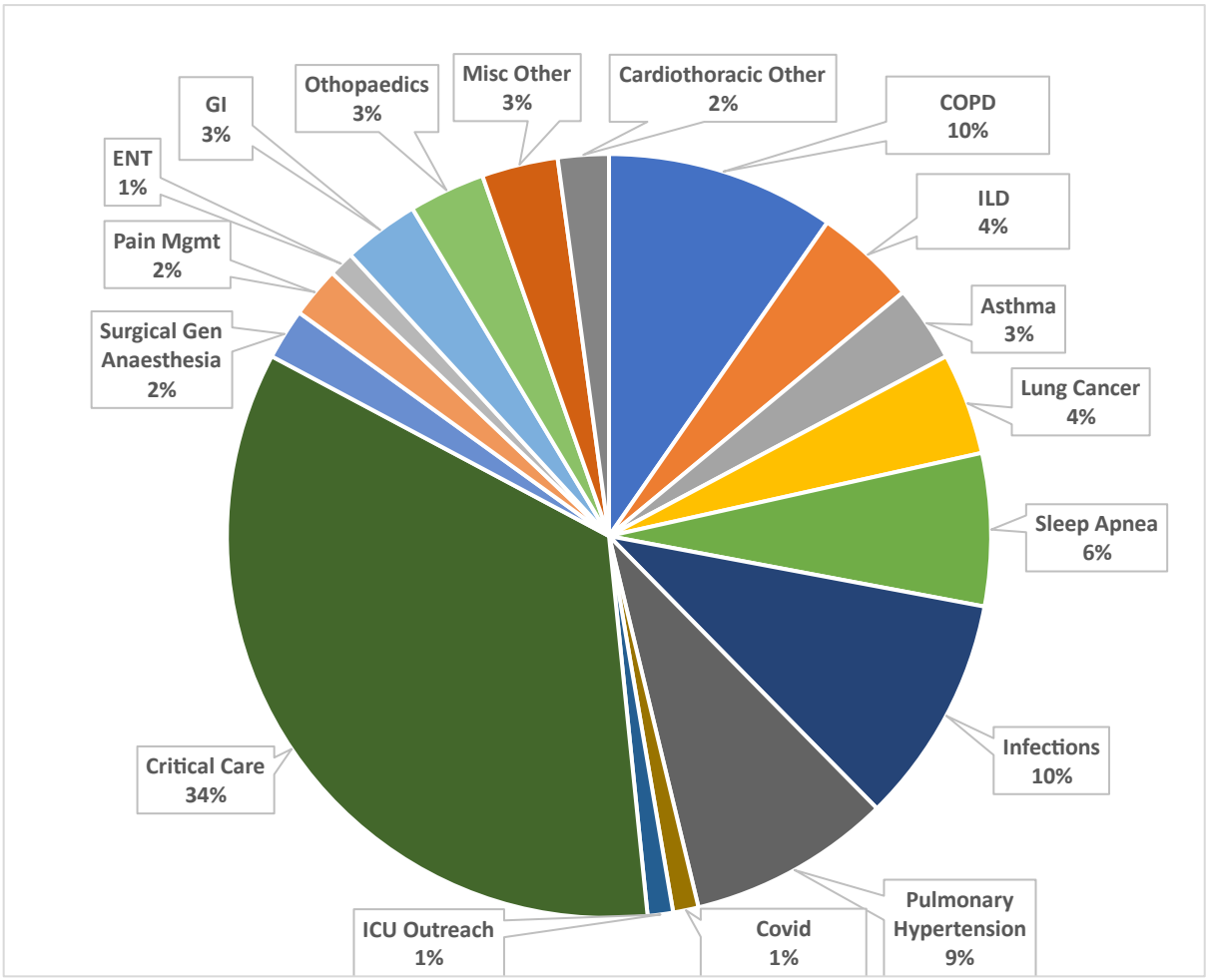

Figure 4: Summary of the disease states of the top 87 needs after filtering Round 1.

Filtering – Round 2 (from Top 87 needs to top 30)

As a team, we wanted to be impact-led, potentially improving healthcare and changing lives globally. We divided the various research topics amongst the 4 team members in an effort to conduct deeper dives into various aspects/ criteria of the needs – such as market analysis, existing solutions and current costs of the illness or treatment. Hence, our filtering criteria was weighted accordingly.

To ensure we were impact-led, we weighted each filter to reflect this, weighting Calculated Market Size and Burden of Proof as "2" and Patient, Payer and Provider Impacts as "1", as outlined in Table 6. This filtering round led us to our Top 30 Needs Statements.

Table 6: Filtering Criteria, Rating Criteria and Weighting for Round 2 Filtering.

Ranking Value	**Calculated Market Size ($) (Weight 2.0)**	**Patient Impact (Weight 1.0)**	**Payer Impact (Weight 1.0)**	**Provider Impact (Weight 1.0)**	**Burden of Proof (Weight 2.0)**
5	High (>$1Bn)	Life Saving Impact to patients	Positive Impact on payer (>50% reduction on annual costs) (change to 1 & done from continuous)	Positive clinical benefit New procedure available	Solution success immediately self evident
4	Med High ($800M > x > $1Bn)	Reduced Mortality and/or eliminate risk of serious complication	Positive Impact on payer (>20% reduction on annual costs)	Positive clinical benefit @ major reduction in time required	Solution success confirmable by test / outcome (weeks)
3	Med ($600M > x > $800M)	Reduce or eliminate symptoms & improve Quality of life – no impact on mortality	Neutral Impact on payer	Positive clinical benefit @ incremental shorter time required	Solution success confirmable by test / outcome (months)
2	Med Low ($200M > x > $600M)	Patient Convenience – no impact on Symptoms or mortality	Small Negative Impact on Payer	Positive clinical benefit @ same time required	Clinical trial Evidence (Med / Small Trial Size <1 year followup)
1	Low (<$200M)	No Impact on patient	Significant Negative Impact on Payer	Positive clinical benefit @ longer time required	Significant Clinical trial Evidence (Large Trial Size + <1 year follow-up))

Filtering – Round 3 (from top 30 needs to top 10)

Going into Round 3, our Top 30 Needs remained, which encompassed a variety of disease states in the clinical areas of Respiratory & Anaesthesia.

For Round 3 filtering we retained the filters used in Round 2 and also added "Treatment Landscape" and "Insight Challenge"(Table 7). Figure 5 outlines the process employed in Round 3 of filtering.

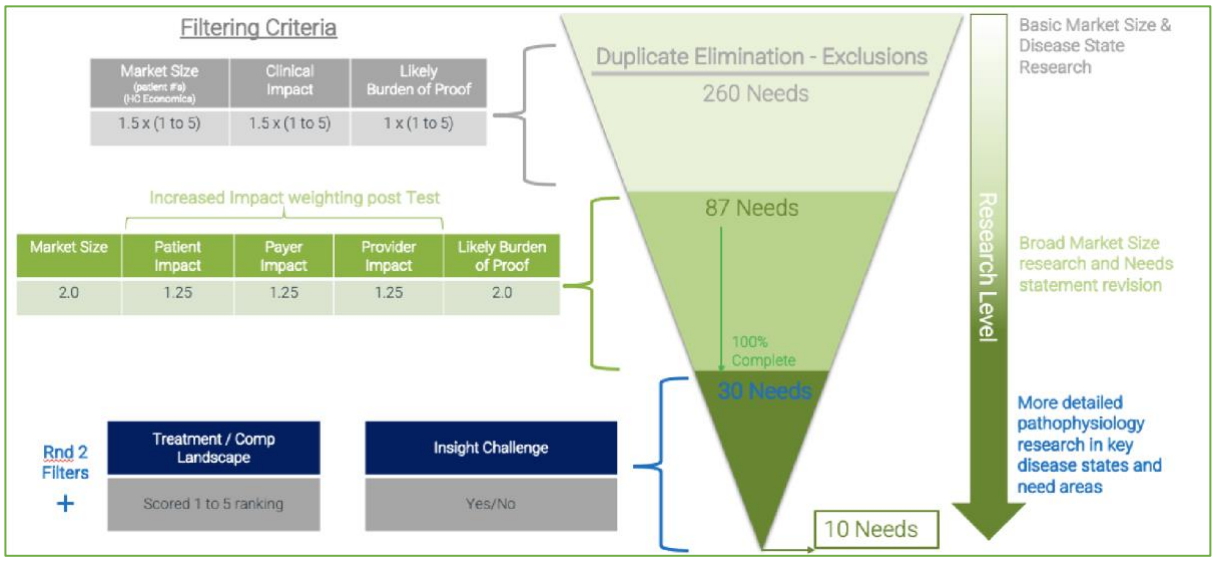

Figure 5: Summary graphic of filtering criteria, weighting and approach for Round 1-4 filtering.

Table 7: Filtering Criteria and Value Ranking for Round 3 filtering process.

Ranking Value	Calculated Market Size	Patient Impact	Payer Impact	Provider Impact	Burden of Proof	Treatment / Comp Landscape
5	High (>$1Bn)	Life Saving Impact to patients	Positive Impact on payer (>50% reduction on annual costs) (change to 1 & done from continuous)	Positive clinical benefit New procedure available	Solution success Immediately self evident	There are no existing treatments available to address the need and the field is not littered with Companies who tried but failed to address the need
4	Med High ($800M > x > $1Bn)	Reduced Mortality and/or eliminate risk of serious complication	Positive Impact on payer (>20% reduction on annual costs)	Positive clinical benefit @ major reduction in time required	Solution success confirmable by test / Outcome (Wks)	There are no existing treatments available to address the need but numerous companies have tried but failed to address the need

3	Med ($600M > x > $800M)	Reduce or eliminate symptoms & improve Quality of life – no impact on mortality	Neutral Impact on payer	Positive clinical benefit @ incremental shorter time required	Solution success confirmable by test / Outcome (Mths)	Treatments exist to address the need but have serious deficiencies that must be overcome
2	Med Low ($200M > x > $600M)	Patient Convenience – no impact on Symptoms or mortality	Small Negative Impact on Payer	Positive clinical benefit @ same time required	Clinical trial Evidence (Med / Small Trial Size <1yr FU)	Treatments exist to address the need but have minor deficiencies that must be overcome
1	Low (<$200M)	No Impact on patient	Significant Negative Impact on Payer	Positive clinical benefit @ longer time required	Significant Clinical trial Evidence (Large Trial Size + >1yr FU)	Treatments exist to address the needs that are generally well accepted by the target user population and address the need well.

Filtering – Final round (from top 10 needs to top 4)

At this stage of filtering our top 10 needs statements had been refined into "higher order' needs, had repeatedly stood up to critiquing of our mentors and had shown potential as needs worth solving and had the potential to become commercialisation fund candidates. On reaching our Top 10 Needs Statements, the team agreed that this was the most appropriate stage to identify Red Flags, both for the team and individually, as at this stage the needs were well enough developed that each team member could make an informed decision as to whether or not they were interested in perusing a need into a commercialisation fund and, hopefully, into a spin out company that would develop FDA / CE marked devices to solve the need.

It is important to note here that anticipating potential 'Red flags' is an essential part of Biodesign, particularly if there will be challenges that will hinder successful implementation of the solution directions. For example, if the burden of proof for the solution to a need is more likely to be 5 years and the solution will likely be a Class III device this will require a lot of data for approval through clinical trials and a lot of investor funding. This may not have appeal for certain BioInnovate fellows who may prefer shorter / less risky development cycles. It is important to be aware of this from the outset so the team can be prepared for this in terms of planning timelines to commercialisation and launching the product.

At this point, we decided to focus on the top needs that sparked the most interest for us individually. The top chosen need for this author was ***'A way to*** *reduce the recurrence of*

*aspiration pneumonia **in** people with Parkinson's disease **in order to** reduce hospital admissions and hospital costs'.* This is discussed further in Chapters 2 & 3.

Biodesign Phase II – Invent: Concept Generation & Screening

This chapter focuses on Phase II of the Biodesign process. In this phase, the author discusses how our team used design thinking – a core principle of the Biodesign process - to ideate, then assess and further iterate the proposed solution directions – testing and redesigning as required (Yock et al., 2010). Features of an ideal solution direction are also discussed.

Features for an ideal solution

Based on interviews with clinicians and literature, limited treatment options exist, as discussed in Chapter 2. Treatment and management of recurring aspiration pneumonia is currently to tailored to each individual's needs, underlying conditions and quality of life. It requires a multidisciplinary, holistic approach to care. Currently very little exists for these patients, therefore we chose not to confine the brainstorming sessions by stipulating requirements for a solution direction. We were told by two Consultant Neurologists from GUH "if you could create anything to give these patients even a few more months".

Ideation

Yock describes specific methods and strategies for ideation in Biodesign (Yock et al., 2010). For our top needs, we conducted a number of Concept Generation sessions – brainstorming (Yock et al., 2010). As Yock states "the need to be perfect is the enemy of ideation", they stress the importance of letting go of any pre-conceived notions about the need, being open minded when ideating, and exploring all possibilities for solution directions. With that, our sessions were guided by:

- café style brainstorming (to illicit their own original thoughts and ideas first) Figure 6, and
- twist cards (to build on each other's thoughts and ideas)

Figure 6: Our team during one of our brainstorm sessions.

Potential solution direction

These techniques elicited some exciting ideas amongst fellow alumni and mentors, which we organised objectively and in line with key criteria for satisfying the need. This process led us to a leading concept of '***diverting secretions away from the trachea'***, which we believe could lead to reduced hospital admission rates and a better quality of life for a large number of patients worldwide. Some examples of the existing solutions that were presented during brainstorming include upper airway suctioning (Marik, 2001), endotracheal intubation (Marik, 2001), better aetiology diagnosis testing (Mandell et al., 2007, Bartlett and Mundy, 1995), better antibiotic selection (Makhnevich et al., 2019), enhancing cough reflex treatments (Nakashima et al., 2018), improved patient head positioning (DiBardino and Wunderink, 2015) and post pyloric feeding (DiBardino and Wunderink, 2015). These concepts should be considered for patients who are unable to protect their airway. Some other existing treatments and solutions are discussed in Chapter 2. Our leading concept is discussed further in Chapter 3 Solution Direction.

As part of Phase II, we landscaped the literature to research for existing Intellectual Property and current solutions. We reviewed the potential reimbursement and regulatory pathways and discussed a potential business model considering the Biodesign process by (Yock et al., 2010), discussed further in Chapter 3 Solution Direction.

Biodesign Phase III – Implement: Strategy Development & Business planning

The implementation phase of the Biodesign process consists of prototyping and testing the technology, as well as developing a patent to protect the technology, developing a pathway to regulatory approval and reimbursement, as well as exploring the many ways to achieve the funding to permit this (Yock et al., 2010). Developing "the pitch" to demonstrate how this can potentially become a successful business. There are two key elements to this phase, (1) Strategy Development and (2) Business Planning.

Strategy Development

Strategic development plays a crucial role in making the creative and innovative ideas and solutions a reality. Here, the team needs to meticulously plan for all stages of the product development, considering the regulatory compliance, plans for gathering data and developing clinical trials. Reimbursement pathways also need to be strategically planned as well as the research and development of the product, along with existing patents and intellectual property.

Business Planning

Business planning is vital to ensuring successful launching and commercialisation of the solution. This involves performing a market analysis, knowing the competitive landscape and risks, as well as planning for marketing and sales. Commercial risk and other challenges for this need is discussed further in Chapter 3.

Chapter 2

This chapter will discuss an overview of the existing literature regarding aspiration pneumonia and dysphagia, along with the aetiologies, epidemiology's, links or correlations and current standards of care and treatment, in Ireland and internationally.

Aspiration pneumonia

Pneumonia is defined as inflammation caused by the presence of infection in the lungs. Aspiration pneumonia is caused by breathing or inhaling foreign materials, such as food, drinks and saliva into the trachea and lungs instead of these materials being swallowed into the oesophagus and stomach (Ko et al., 2021). The bacteria in saliva and secretions from mouth and nose may lead to an aspiration pneumonia. Aspiration pneumonia occurs due to swallow dysfunction and aspiration of gastroesophageal reflux and salivary secretions (the least commonly recognised form of aspiration pneumonia – which can result in recurring pneumonia due to the pathogenic bacteria and yeast in the oral cavity) (Ko et al., 2021, Kang et al., 2013, Metlay et al., 2019).

Aetiologies & Risk factors for aspiration pneumonia

There are many risk factors associated with salivary aspirations, including swallowing incoordination, absent laryngeal sensation, excessive salivary production and vocal cord paresis (Kang et al., 2013). Other risk factors for aspiration pneumonia include older age (80% of patients are over 65 years old), lung disease, dementia, male gender, diabetes and poor oral health (Ko et al., 2021).

According to (Ko et al., 2021) aspiration pneumonia is not considered as a distinct disease state, but as a part of community-acquired and hospital-acquired pneumonia, which accounts for approximately 5-15% of cases of community-acquired pneumonia - however its proportion of hospital-acquired pneumonia is unknown. Approximately one-third of patients who have dysphagia will develop a pneumonia (Ko et al., 2021).

Oropharyngeal dysphagia is also a common symptom in older people that can cause aspiration pneumonia, which can be fatal, however, there is no established treatment for oropharyngeal dysphagia (Nakato et al., 2020). Symptoms can include difficulty breathing, cough and fever (Metlay et al., 2019, Marik, 2001, Molfenter et al., 2015).

On top of that aspiration pneumonia is a common problem in patients with brain injury (Kang et al., 2013).

Based on a thorough literature review some of the more common aetiologies and risk factors of aspiration pneumonia are listed here (Cook, 2009, Cichero, 2013, Garon et al., 2009, Langmore et al., 1998, Aoyagi et al., 2021, Mandell et al., 2007):

- Neurological – such as Parkinson's disease (PD), stroke, multiple sclerosis (MS), amyotrophic lateral sclerosis (ALS), and Alzheimer's disease
- Structural – issues with the oral cavity, including tumours, can make swallowing difficult
- Gastroesophageal reflux (GERD) – a condition where stomach acid flows up into the oesophagus, causing irritation and inflammation, potentially causing damage to the protective lining of the throat, which may lead to an occurrence of aspiration pneumonia
- Medications – such as anti-cholinergic medications (causing dry mouth), sedatives and opiates
- Age – with age, the oropharyngeal muscles can become weakened, therefore increasing the risk of aspiration pneumonia
- Alcohol and drug use – may impair ability to swallow, increasing the risk of an aspiration pneumonia
- Other medical conditions are believed to lead to an increased risk of aspiration pneumonia – such as COPD, congestive heart failure and diabetes

The Need

As shown above, there are many causes and aetiologies for aspiration pneumonia, some of which are difficult to treat. Consultant neurologists agreed that targeting an initial beach head market of aspiration pneumonia patients with Parkinson Disease would be very beneficial for these patients and also highlighted a similar need for patients with Motor Neuron Disease (MND) related aspiration pneumonia. As a result this thesis focuses on ***a way to*** *reduce the recurrence of aspiration pneumonia* ***in*** *people with Parkinson's disease* ***in order to*** *reduce hospital admissions and hospital costs'.* During the Ideation phase of the project however, we will take into consideration the secondary market of Parkinson's Disease when it comes to solution selection, this is discussed further in Chapter 3.

Understanding the problem

One cohort of people most at risk of aspiration pneumonia due to oropharyngeal dysphagia are those with neurological disorders, such as Parkinson's disease. Difficulty swallowing

(dysphagia) and weakened muscles increase their risk. Aspiration pneumonia is a serious complication, and sometimes fatal, with aspiration pneumonia being the leading cause of deaths amongst PD patients, accounting for 70% of the mortality (Won et al., 2021).

Oropharyngeal dysphagia, General pneumonia, and Aspiration pneumonia

Oropharyngeal dysphagia is a disorder of the nerves and muscles associated with swallow. This disorder can frequently lead to the development of aspiration pneumonia (Garon et al., 2009, Mandell et al., 2007, Ko et al., 2021). Aspiration pneumonia, as discussed above, results from foreign particles or materials being inhaled into the trachea and lungs. General pneumonia, on the other hand, is an infection of the lungs which is not necessarily caused by dysphagia or an aspiration. The symptoms for general pneumonia and aspiration pneumonia are the same. Aspiration pneumonia may be suspected if the person has recurrent episodes of pneumonia or a history of diagnosed dysphagia (Garon et al., 2009, Mandell et al., 2007), which is particularly evident amongst our elderly population, regardless of co-morbidities (Ko et al., 2021).

Epidemiology

There are approximately 16’500’000 people in the USA that have oropharyngeal dysphagia (OD) (Nakato et al., 2020). According to (Martinez-Ramirez et al., 2015), approximately 1540% of people over the age of 65 years old are negatively affected by dysphagia and 55% of those over 70 years old who are diagnosed with pneumonia present with clinical signs of oropharyngeal dysphagia. Aspiration pneumonia due to dysphagia is a common complication and reason for hospital admission amongst people with PD. People with PD are at 3.8 times more risk of developing an aspiration compared to the general population (Martinez-Ramirez et al., 2015). More recent research in Korea, which studied 50’000 participants, stated that people with PD are approximately 2.5 times more likely to develop an aspiration pneumonia than the general population (Won et al., 2021).

Pathophysiology of dysphagia in Parkinson’s disease

One of the biggest challenges in innovating for this need is that the pathophysiology and aetiology is not clearly defined amongst this group of patients, or patients with other neurological conditions, such as MND. A variety of mechanisms exist regarding dysphagia in neurological conditions, as well as a variety of mechanisms amongst the PD group of patients, (Kwon and Lee, 2019).

Healthcare cost/ economic burden associated with Aspiration Pneumonia

Patients with an aspiration pneumonia have longer lengths of stays in hospital, a longer duration in ICU, higher risk of needing mechanical ventilation and a higher mortality rate than patients with non-aspiration pneumonia (Ko et al., 2021). This all points towards much higher hospital costs and a greater burden to the healthcare system.

Diagnosis of aspiration pneumonia and the Referral Pathway

The diagnosis of an aspiration pneumonia and a general pneumonia is largely the same as the symptoms are the same. The difficulty is in differentiating the cause – is it a general pneumonia or is it a pneumonia that has been caused due to the inhalation of foreign particles because of dysphagia? The process for diagnosis usually includes a clinical assessment by the treating doctor, monitoring for signs of fever, history taking, imaging, such as a chest Xray or CT and laboratory tests such as a blood test and a sputum culture. If dysphagia is suspected, the patient will be referred to a speech and language therapist for a swallow assessment, (Marik, 2001, Mandell et al., 2007, Won et al., 2021).

Generally, a swallow assessment is conducted by a speech and language therapist (SLT) when a doctor or a specialist nurse refers the patient to the SLT if aspiration is suspected. The assessments by the SLT usually include a clinical swallowing function assessment (Umemoto and Furuya, 2020, Ko et al., 2021). A multidisciplinary approach to care includes input from nursing and medical staff (Sanivarapu and Gibson, 2023), along with physiotherapists, occupational therapists and speech and language therapist. For example, the prescription of oxygen therapy, continuous monitoring of the patients oxygen levels, and rehabilitation on the general ward, as well as the more severe cases, potentially being cared for in ICU with consultants who may perform procedures such as bronchoalveolar lavage, involves input from the whole team. A treatment plan is tailored to each patient's needs, which may include assessments and exercises provided by a speech and language therapist.

Current standard of care for the treatment of aspiration pneumonia

Unfortunately, there is no established cure or treatment for oropharyngeal dysphagia, (Nakato et al., 2020). Therefore, it is vital to have measures in place to try to prevent or reduce the risk of aspirations, thus impacting morbidity, mortality and indeed healthcare costs

(MartinezRamirez et al., 2015). According to (Shahgholi et al., 2017), preventing hospital admissions for the PD patient group is vital, as these patients often deteriorate quickly during their hospital stay. The immediate prevention actions include:

- Prevention of aspiration - ensuring good oral hygiene and mouth care is one such important factor, (Umemoto and Furuya, 2020).
- Treatment of aspiration pneumonia - generally, antibiotics to treat the infection and investigation of underlying cause. May require oxygen therapy if in severe respiratory distress.
- Dietary modifications – other nutritional support if unable to swallow at all, e.g., nasogastric (NG) feeding or Total Parenteral Nutrition (TPN)

Referral for swallow therapy with speech and language therapists (SLT) for dysphagia screening and assessment (Umemoto and Furuya, 2020), which may help to improve the persons swallowing ability (Martino et al., 2012), but this is only useful for some cohorts of patients, e.g., early PD or acutely post stroke, and only up to a point (Umemoto and Furuya, 2020). Although an episode of aspiration pneumonia can be extremely serious, even fatal (Sanivarapu and Gibson, 2023), current standards of care and treatment rely heavily on preventative measures rather than curative. It is important to note that aspiration pneumonia accounts for 70% mortality in the later stages of PD (Won et al., 2021). Treatment in the early stages of PD versus the later stages is quite different, with more emphasis on comfort and palliative care in the later stages (Lokk and Delbari, 2012).

Recurrent pneumonias

Generalised pneumonia and pneumonia caused by an aspiration present with the same symptoms and display the same clinical picture, as discussed previously, which proves as a huge challenge for innovators. It is only with a diagnosis of dysphagia, that the pneumonia can be attributed to an aspiration event. Current methods to diagnose a pneumonia (generalised or aspiration), such as chest x-rays and lab results cannot differentiate between the two.

The recurrence rate varies, depending on the various aetiologies of the dysphagia and the management of the underlying cause. Poor oral hygiene is also a risk factor for these patients. In people with PD, the recurrence rate of aspiration pneumonia generally depends on the stage

of the disease and the extent of the dysphagia. An exact recurrence rate amongst this group has been difficult to determine due to the variety in studies on numbers of participants and followup periods used. While the prognosis for these patients can also vary depending on the stage and severity of their PD, an episode of aspiration pneumonia can negatively impact and reduce this (Marik, 2001, Ebihara et al., 2016).

Unfortunately, for some cohorts of patients, such as those in the later stages of PD, and even more so in MND, patients can aspirate on their own salivary secretions (Marik, 2001, Hammond and Goldstein, 2006, Mandell et al., 2007, Ebihara et al., 2016). The literature shows that aspiration pneumonia is the leading cause of death for these groups (Martinez-Ramirez et al., 2015). Amongst this patient group, two-thirds will die within a year of their first aspiration pneumonia, which accounts for 70% of deaths in the PD population, resulting from oropharyngeal dysphagia (Won et al., 2021). People, particularly in the later stages of Parkinson's disease are noted to have a longer time to swallow as well as impaired swallow function, (Martinez-Ramirez et al., 2015).

Quality of life with dysphagia and recurrent aspiration pneumonias

Quality of life (QOL) can be greatly impacted by dysphagia and aspiration and thus originated aspiration pneumonia. The frequency and severity of the aspiration can negatively affect a person's psychological well-being, social interactions and other activities of daily living. Even for those people who no longer consume food and fluids orally and use tube feeding instead, these people can unfortunately still aspirate and develop a pneumonia from either salivary secretions of gastric contents. As well as physical implications, oropharyngeal dysphagia can also negatively affect one's social and psychological well-being (Nakato et al., 2020, Ekberg et al., 2002).

(Won et al., 2021) conducted a large retrospective study focusing on aspiration pneumonia in people with PD, using the mandatory South Korean Health Service database. This study analysed 10'159 newly diagnosed cases of PD between 2004 and 2006, focusing on participants' risk of aspiration pneumonia and mortality rates after the first episode of aspiration pneumonia, until 2017. This study showed that people with PD are 2.23 times more likely to develop aspiration pneumonia than the general population (Won et al., 2021) which can lead to huge costs on the healthcare system (Patel et al., 2018, Lindenauer et al., 2018).

Economic impact, Cost and healthcare burden

Throughout the program and in keeping with the Biodesign process, when looking at the market regarding this need, we decided to focus broadly on the US market as it is homogenous and well-established.

Pneumonia is the number one infectious disease related hospital admission, resulting in over 1 million hospital admissions in the US, generating costs of over $10 billion annually (Lindenauer et al., 2018). Approximately 14% of these patients are diagnosed with aspiration pneumonia (Lindenauer et al., 2018) and, using Medicare claim's data, the incremental cost of hospital stays is estimated to be $13,000 per patient (Paranji et al., 2017). Using a top down approach this would estimate the incremental economic burden, due to aspiration pneumonia to be in the region of $1.4-1.8 billion annually. This cost considers a variety of factors, such as the underlying cause of the aspiration, the extent of the pneumonia, other co-morbidities and the attending healthcare facility, and increased length of hospital stay (Paranji et al., 2017, Lindenauer et al., 2018, McHorney et al., 2002, Lin and Shune, 2020, Baijens et al., 2016).

The Need and Gap identified

__A way to__ reduce the recurrence of aspiration pneumonia __in__ people with Parkinson's disease __in order to__ reduce hospital admissions and hospital costs.

This need evolved from having first observed the fear of clinicians and other operating room staff regarding patient's acute risk of aspirating during a general anaesthetic, to being further observed in those with more chronic illnesses, such as PD and MND. On conducting further research into this problem for people with various chronic neurological conditions, this need was strongly validated by two consultant neurologists, a consultant geriatrician and two speech and language therapists. Although the aetiology differs amongst the varying disease states, the team believed we could create a device that would prevent aspiration pneumonia due to the aspiration of salivary secretions. We chose to focus on the risk associated with the aspiration of salivary secretions because even when these patients are using tube feeding or parenteral feeding for nutrition, they remain at huge risk of developing an aspiration pneumonia from salivary secretions, which unfortunately may be fatal.

Chapter 3

Solution direction

Successful ideation processes and brainstorming sessions require the team to have an in-depth understanding of the anatomy and physiology of the targeted area of the solution direction. This knowledge allows the team to ideate for that area of the anatomy and to discuss any potential challenges they foresee. As we were looking at a need regarding the prevention of aspiration pneumonia, we believed it was vital to have a good understanding of the process of swallowing, anatomy and physiology of the oral cavity, pharynx, larynx, chiefly the area where salivary secretions are normally trapped or contained before being swallowed; the vallecula and piriform fossa.

Anatomy and physiology: Deglutition, The Vallecula & Piriform Fossa

Swallowing (or deglutition) is quite a complex, sensorimotor, process that can easily be taken for granted. There are two particular anatomical structures located in the pharynx (see Figure 7) that are key players in ensuring that our food, drinks, salivary secretions and other material travel into the oesophagus rather than into the trachea and lungs – these are known as (Martinez-Ramirez et al., 2015):

1. The Vallecula, and
2. The Piriform Fossa

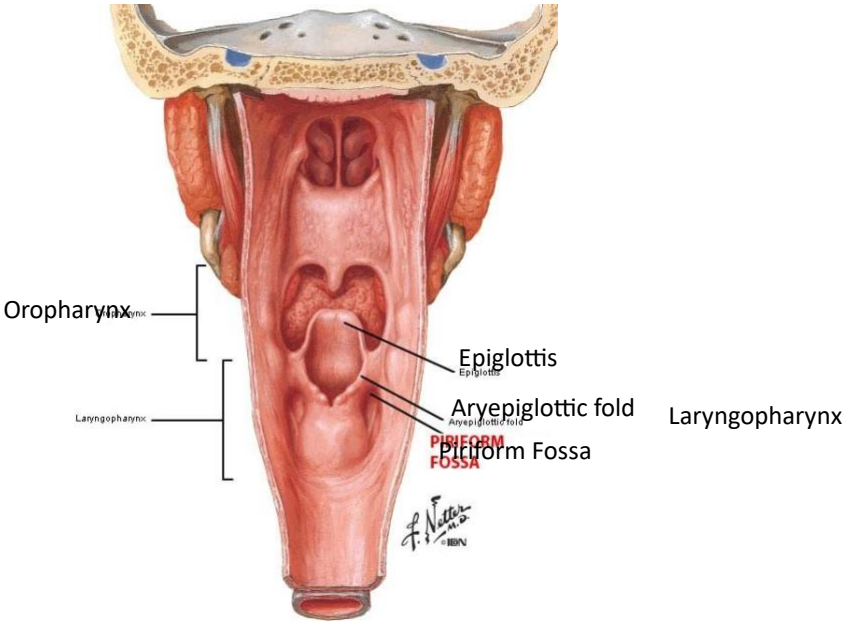

Figure 7:Drawing of pharynx anatomy (Netter, 2018)

The vallecula is a small grove between the base of the tongue and epiglottis, where food, drinks and saliva can be temporarily stored or trapped while the epiglottis covers the larynx and trachea, to prevent food from entering it and to allow swallowing to take place. Closely located, either side of the larynx, is the pear-shaped groove known as the piriform fossa. This is located between the thyroid cartilage and cricoid cartilage and acts as a passage-way for food, drink and salivary secretions into the oesophagus. As shown in Figure 8 there are three phases involved in swallowing – the oral (food moves to the back of the tongue), pharyngeal (food is pushed into the oropharynx) and oesophageal phases (airway closed by epiglottis and food goes into oesophagus and stomach) (Matsuo and Palmer, 2008).

Stages of swallowing: (explain and reference)

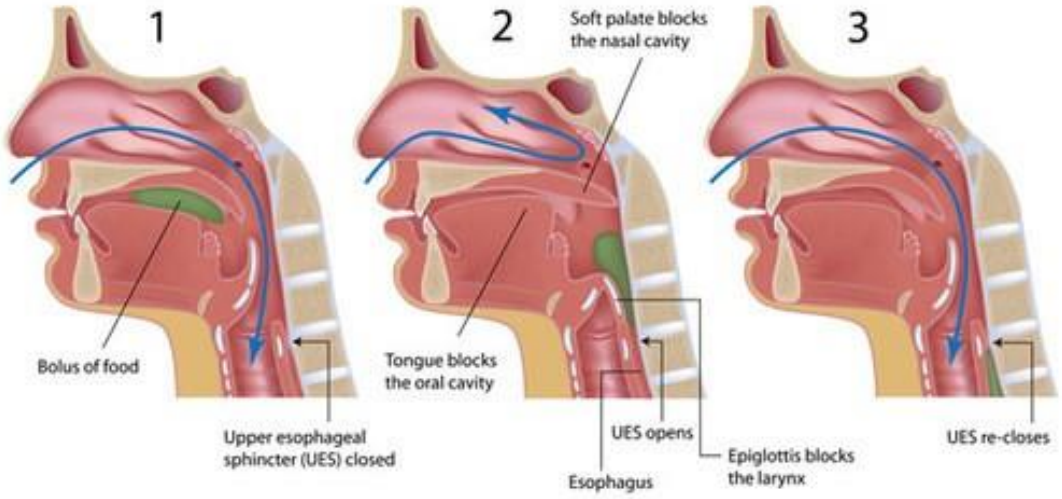

Figure 8: Drawing of typical swallowing process (Center, 2023).

Brainstorming

With this knowledge, we conducted dynamic and collaborative brainstorming sessions and explorations of creative and innovative solutions to the unmet need. Each team member was encouraged to draw on their own unique experiences and ideas individually, using Café style brainstorming, before building on the ideas of others, using twist cards, to illicit a broad range of ideas and concepts. This approach nurtured the collective creativity of the group, and many fascinating concepts were born. All these concepts were then voted on by the group and the top 3 concepts were:

- Diversion of secretions away from the trachea using a suction device
- Use of an interchangeable sponge to soak up any excess secretions

- Sterilising of secretions, in the oral cavity, using a copper plate

Idea/ Concept

For this thesis, one such concept will be discussed – **diversion of secretions away from the trachea using a suctioning device**. There were many iterations of ideas for this concept which resulted in a final solution of designing an implantable pouch into the vallecula with a suction port to divert secretion from vallecula into oesophagus, preventing secretions from entering the trachea.

Some challenges with this potential solution direction/ concept became quickly evident:

1. The first obvious drawback to this concept is that if the person with the implant were to experience emesis (vomiting) our device would not work, as the person would likely aspirate on the gastric contents, unless the device could divert large amounts of fluid away from the trachea at a very rapid pace. This presented further potential technical challenges, like sizing and the potential need for a large motor on the device, in such a small space this would be a major challenge.
2. Secondly, implanting a device near the vocal cords or larynx could cause what's known as laryngospasm, in which the vocal cords suddenly spasm and can block the flow of air into and out of the lungs for a few seconds (Gavel and Walker, 2013). While not usually fatal, it can temporarily cause difficulty breathing and be a tremendously frightening experience.
3. The third major challenge with this type of device would be the regulatory pathway. Looking at an implantable device, this would likely take a Class III and Premarket Approval (PMA) pathway, which would take many years). A Class III device are usually 'implantables' and are used to sustain life, for example a pacemaker. A PMA is a stringent process of scientifically reviewing the device to assess the safety and efficiency of the device (FDA, 2020). This regulatory pathway is discussed further below.
4. Fourthly, adoption of such a device would likely pose a huge challenge, mostly because it would be relatively invasive, approved for a small number of patients, which would require the highly specialised skills of a very experienced otolaryngologist.

Regulatory pathway

As the USA is a more homogenous market when compared to Europe, our research focused on the regulatory pathway for devices used in the US, whose regulatory body is the Food and Drug Administration (FDA). The FDA approval process varies depending on the intended use for and risk classification of the device:

- Class I – low risk, for example, a band aid – requiring only general criteria for approval.
- Class II – moderate risk device – may require a 510K pathway for approval. A 510K pathway is a submission process used by medical device manufacturers to get approval from the FDA, by proving their device is extremely similar to a predicate or another device already on the market (FDA, 2023)
- Class III – high risk, such as a pacemaker – requiring much more scientific, clinical data to prove safety and efficacy of the device, known as Pre-market Approval. The information submitted to the FDA is carefully reviewed, considering the potential benefits and risks of such a device. Successful approval from the FDA then permits the use, marketing, and sales of the device. A common pathway for a Class III device is the PMA pathway. The PMA pathway can take many years and funding for such a timeline would present another significant challenge.

Another potential pathway to regulatory approval is through the FDA's Humanitarian Use Device (HUD) and Humanitarian Device Exemption (HDE). A device approved for use in the US following this pathway is used to benefit, treat, or diagnose those with the more rare conditions, affecting less than 8'000 yearly (FDA, 2022). An example of this is the approval and use of Deep Brain Stimulation for those experiencing dystonia as a symptom of PD (NINDS, 2023a).

Intellectual Property

The Intellectual Property (IP) of a company, particularly a start-up, is the most valuable part of the device and the company. However, the IP landscape can be a difficult one to navigate. It requires meticulous research and requires companies to file patents and be aware of freedom to operate. These patents protect the companies from various competitors. Conducting a highlevel search, we did not find any IP regarding implantable suction devices for use in the vallecula.

Devices on the market

There are some devices on the market that can be used in and around the vallecula, such as:

- Flexible Endoscopic Evaluation of Swallowing (FEES) procedure – a flexible endoscope used to visualise the oropharynx for assessment and dysfunction
- Pharyngeal Electrical Stimulation (PES) – stimulates the muscles of the pharynx to try help improve swallow. This is often used along with swallow therapy, most often after an acute stroke
- Nasogastric tube (NGT) – a narrow tube that passes through the nose and oropharynx into the stomach for feeding, for supplementation or temporary enteral feeding if unable to eat or drink normally
- Laryngeal stent – used in the treatment of laryngeal stenosis, to prevent collapse and to maintain an open airway (Sanivarapu and Gibson, 2023).
- Tracheostomy tube – surgically placed tube which maintains an open airway. Some have cuffs and suction ports to prevent the aspiration of salivary secretions. Often seen in people after head and neck cancer surgeries, traumas to the upper airway and neurological conditions.
- Suction tube – typically used to remove liquids/secretions from the oral cavity

Why take the risk? Why is it worth it?

Pneumonia is the leading cause of death in people with PD (Umemoto and Furuya, 2020, Okunoye et al., 2022). The incidence of Parkinson's disease is 90,000 with approximately 1 million people in the US living with PD, (NINDS, 2023b). There are approximately 60'000 people in the US with MND. Globally, however, this number increases to over 300'000 people (Collaborators, 2018). Sadly, the prognosis for someone diagnosed with MND is between 3-5 years. Although the market appears small because the patient populations for these conditions are small, one consultant neurologist put it "…if you could create something to even give them a few more months…". The main stakeholders here are, of course, the patient, their family and the clinician. A solution that improves quality of life and reduces hospital readmissions would be beneficial to various stakeholders, particularly the patient.

Funding

The Food and Drug Administration (FDA) encourages the development of new treatment options for rare diseases, some late-stage symptoms of PD and MND, through what's known as Orphan Product Grants Program. This includes the Humanitarian Use Device (HUD) and the Humanitarian Device Exemption (HDE), which are grants designed to support the clinical development of potentially beneficial products for rare diseases, affecting no more than 8'000 people in the US per year (FDA, 2022). A HUD can only be sold for profit after receiving HDE approval, which is a type of Pre-Market Approval (PMA) that allows the FDA to exempt the device from PMA requirement regulations. Up to 2021, there have been a total of 79 HDE listings, beginning in 1997, (FDA, 2021).

Challenges & Limitations

Some challenges and limitations became evident on further research. Firstly, it would be tremendously difficult to develop and grow a large business using this type of funding. Secondly, there would be difficulty with and definitively diagnosing (although clinically assumed, as per our interviews with five medical consultants) that the salivary secretions cause the aspiration pneumonia versus another equally valid cause. Thirdly, the referral pathway from the initial treating physician to the Ear, Nose and Throat (ENT) or Oropharyngeal surgeon that would likely be required to perform the procedure may prove to be another obstacle.

Conclusion

The Biodesign process was used during the 10-month program, to guide the team in identifying an unmet need in the area of respiratory care, inventing a potential solution direction and considering the implementation this solution direction.

Reflection

Professionally, BioInnovate has provided me the time, space and mentorship to be creative and innovative. The diversity of each team encourages different ways of thinking, which allowed me to combine my own skillset with those of my team in a unique environment with direct access to the clinical areas and experts. It has opened doors to other career opportunities that I never knew existed. Personally, has taught me the importance of networking, collaborating and how to be more embracing of the collaborations between completely diverse individuals and teams.

Future work

It is well documented that early intervention and treatment for dysphagia will improve quality of life and reduce mortality (Kwon and Lee, 2019). The literature also demonstrates the sheer lack of research investigating the incidence of diagnosed aspiration pneumonia in people with PD, versus the general population (Won et al., 2021).

Accurate data regarding the incidence and mortality of patients with PD, due to aspiration pneumonia is difficult to find (Won et al., 2021), with (Okunoye et al., 2022) stating no largescale studies have been conducted on the rates and reasons for hospitalisations amongst people with PD. There appears to be a huge variation in the prevalence of those with dysphagia in PD, ranging from 18.5% to 100%, depending on the methods of assessment (Umemoto and Furuya, 2020). As some clinical consultants informed us, aspiration pneumonia versus a general pneumonia is very difficult to prove, due to the same presenting symptoms, as well as radiological and laboratory findings – so it is a challenge from the outset. Future work for this project includes further validation of the market and solution direction with key opinion leaders, such as the ENT surgeons and consultant neurologists, as previously mentioned, to assess their appetite for such a device and commercialisation.

Contribution to Knowledge

The key to this research is the insight that these patients continue to aspirate on their own salivary secretions, even if not receiving nutrition orally, and clinicians want a solution. A solution to this problem could greatly impact the lives of thousands of patients and loved ones each year.

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