Commercialising connected health solutions in the Irish public health system - Key barriers and enablers

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Abbreviations

Abbreviation	Explanation
AdvaMed	Advanced Medical Technology Association
ARCH	Applied Research Connected Health
CIO	Chief Information Officer
CPV	Common Procurement Vocabulary
DiGA	Digitale Gesundheitsanwendungen
DBEI	Department Business Enterprise Innovation
DoH	Department of Health
DPER	Department of Public Expenditure and Reform
EHR	Electronic Health Record
EI	Enterprise Ireland
HBS	Health Business Services
HIHI	Health Innovation Hub Ireland
HSE	Health Service Executive
QIC	HSE Quality Innovation Corridor
IH	Individual Health Identifier
ICT	Information and Communication Technologies
IMO	Irish Medical Organisation
IMSTA	Irish Medical Surgical and Trade Association
KOLs	Key opinion leaders
MEAT	Most economically advantageous tendering
MEAT VBP	MEAT Value-Based Procurement
OGP	Office of Government Procurement
UK	United Kingdom
US	United States

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Abstract

Anecdotal evidence abounds that the Irish health system is not a viable market for connected health solutions. Publications to date largely focus on the health systems readiness for eHealth and one review of the digital health sector in Ireland. This research seeks clarity on the ability to commercialise connected health solutions in the Irish public health system, with the research question –can you commercialise connected health products in the Irish public health system? Drilling into this, the research then investigates the pathway to market through key barriers and enablers. It is the first research to explore the experiences of Irish connected health companies in the Irish public health system through key barriers and enablers to commercialisation. Employing a mixed methodology approach to investigate the commercialisation pathway for connected health products in Ireland, the research captures both companies' experiences of selling into the system and attitudes of senior Irish health leaders. The findings show that current barriers to commercialising connected health solutions in Irish public health are more than four times the current enablers.

Introduction

Global health care spending is projected to increase at an annual rate of 5.4 per cent in 2018–2022, a considerable rise from 2.9 per cent in 2013–2017. This increase reflects the strengthening of the dollar against the euro and other currencies, the expansion of health care coverage in developing markets, the growing care needs of elderly populations, advances in treatments and health technologies, and rising health care labour costs (Deloitte, 2019). In Europe, the medical technology industry generates over €115 billion annually and employs approximately 650,000 people. As many as 95 per cent of these companies are small to medium enterprises (Ibec, no date).

The medtech sector employs over 40,000 people in Ireland and is the second largest employer of medtech professionals in Europe, per capita. Ireland is one of the largest exporters of medical products in Europe with annual exports of €12.6 billion with Irish companies directly exporting to over 100 countries worldwide. As many as nine of the world's top 10 medical technology companies have a base in Ireland and 60 per cent of the 450 medtech companies based here are indigenous (Ibec, no date). There are an estimated 130 Irish connected health companies (IMSTA, 2019).

As the industry grows, the challenges facing healthcare are many: increasing health care costs; changing patient demographics; evolving consumer expectations; complex health and technology ecosystems (Deloitte, 2019). Equally so are the commercial opportunities to surmount these challenges. Many of these opportunities arise in the connected health space. An economic impact analysis for Ireland estimates that a properly executed connected health strategy, leading to the development of commercial and export-oriented opportunities, can add between 2 and 2.9 per cent to national GDP and contribute a significant number of highly skilled jobs to the economy. Overall, connected health needs to be seen as an infrastructural investment in Ireland's future, not only for the transformation of the Irish healthcare sector, but also for the economy as a whole (IMSTA, 2019).

The healthcare system is critical to successfully scale and sustain healthcare innovation. To achieve impact from the value-add offered to healthcare by connected health solutions, innovative processes must be implemented to ensure a dynamic health system that is open to disruption (WHO, Europe, 2018). Governments around the world see connected health as a critical and essential means to improve citizens' access to quality, lower-cost healthcare.

Connected health has gained a high level of acceptance and there is a prevailing view that without a solid connected health platform, it will be difficult to meet the health challenges of today and the future (Accenture, 2012). Despite this, anecdotal evidence mounts that the Irish public health system is not a viable market for connected health solutions. Companies wishing to target the Irish public health system as a market find commercial return difficult at best and at times impossible. The researcher works in the area of connected health development, supporting clients in verification, validation and piloting of solutions. The inspiration to investigate the commercialisation pathway for connected health products in the Irish public health system came from the commercial struggles these clients seemed to encounter in this space.

The key questions underpinning this research are, can you commercialise connected health solutions in the Irish public health system – does a market exist in this area – and what are the barriers and enablers to commercialization? The research is divided into seven chapters. First, a literate review considers theory relevant to connected health; the connected health market; connected health systems in comparable markets; revenue generation and connected health purchasing system as pathways for commercialisaion. Following this, the research methodology chapter describes the mixed method process used to collect and analyse data. The next chapter presents the findings and discussion of the data collected, identifies key barrier and enablers and acknowledges limitations of the research. Subsequently, the conclusion summarises the principal findings and the implications of these. The final two chapters cover recommendations and areas for further study respectively.

Chapter 1: Literature review

This literature review considers theory relevant to connected health and clarifies connected heath segments. It looks at the connected health market value, the high technology market and successful connected health systems in comparable EU markets are examined. Next securing revenue on connected health solutions is explored, where some challenges are identified. Subsequently, current connected health purchasing systems as pathways for commercialisation, namely reimbursement/procurement, are considered.

1. Connected health

Over a decade ago, Poon and Zhang (2008) described a paradigm shift in health care, one that suggests that preventive, pre-emptive and predictive healthcare decisions should be made in a pervasive, participatory and personalised manner. Carroll et al., (2016) define connected health as:

- An emerging model of care engaging technology to improve patient care.
- Encouraging self-efficacy developing client-centred care pathways.
- Evidence-based interventions that reduce the need for hospital-led care and empower patients in their homes.
- Promoting improved 'connectivity' between healthcare stakeholders by means of timely sharing and presentation of accurate and pertinent information about patient status.
- Connected health initiatives that can achieve this through smarter use of data, devices, communication platforms and people.

Similarly, Caulfield and Donnelly (2013) define connected health as a conceptual model for health management where devices and services are designed around the patient's needs, and health related data is shared, in such a way that the patient can receive care in the most proactive and efficient manner possible. Richardson (2015) corroborates this, describing connected health as patient-centred care resulting from process-driven health care delivery undertaken by healthcare professionals, patients and/or carers who are supported by the use of technology - software and/or hardware. Carroll et al., (2016) consider connected health to be a socio-technical healthcare model that extends healthcare services beyond traditional healthcare institutions.

1.2 Connected health segments

In order to clarify related definitions and concepts, Table 1 below organises connected health into seven segments. This provides a general overview of connected health, its main services and applications areas.

	Mobile health: mhealth -health practice supported by mobile devices, such as mobile phones, patient monitoring devices, personal digital assistances and other wireless devices).
	Software as a Medical Device: SaMD - software intended to be used for one or more medical purposes that perform these purposes without being part of a hardware medical device.
	Health Information Technology: HIT -supports health information management across computerized systems and the secure exchange of health information.
	Wearable devices: Electronic devices that consumers can wear designed to collect the data of users' personal health.
	Telehealth: Use of tech such as computers and mobile devices, to access a broad scope of health care services remotely and manage your health care.
	Telemedicine: Refers specifically to remote clinical services. Caring for patients remotely when the provider and patient are not physically present with each other.
	Personalised medicine: Products being tailored to the individual patient based on their predicted response or risk of disease.

Table 1: Connected health segments (Caroll et al 2016 : Deloitte, 2019, Gilbert et al 2019, Hunink et al., 2014)

1.3 Connected health companies in Ireland

A 2019 report (Irish Medical Surgical and Trade Association (IMSTA), 2019) examining digital health in Ireland concluded that Ireland has an ideal eco-system to capitalise on this emerging market. This is due in part to Ireland's strong base in medical technologies, Information and Communication Technologies (ICT), pharmaceuticals/ biopharmaceuticals and financial services and the increasing number of indigenous connected health companies. The report estimates that there are 130 indigenous connected health companies in Ireland.

2. High technology markets and the connected health market value

Over the past five years, services and technology have become the fastest-growing profit pool in the healthcare industry, a trend driven by the significant value creation potential of technology-based and enabled innovations (Onitskansky et al., 2008). Mohr et al., (2006) define companies operating in high technology environments as confronted by a triple threat of market, competitive and technological uncertainty. These companies stand to benefit disproportionately from effectively gathering and using market based information.

In a high-tech company where market intelligence is shared and valued, it can create a knowledge-based competency, offering superior marketplace advantage. The high technology market has a number of defining characteristics. Rapidly changing technologies indicate shorter product lives. Increased customer choices, product customisation, rapid technological improvements and global competition all contribute to volatile demand patterns (Mohr at al., 2006); Vairdot, 2014). With high demand comes high rewards. The global digital health market is expected to reach $223.7 billion within five years based on increasing penetration of mobile devices, remote patient monitoring and growing demand for advanced information systems (Liclolai, 2019).

3. Leading EU connected health systems

Looking beyond Ireland, in November 2019, the German Federal Ministry of Health passed the Digital Care Act (Digitales Versorgungsgesetzt – DVG) (Brickwood, 2020). The act improves healthcare provision through digitalisation and innovation. From 2020, doctors will be able to prescribe digital health applications (Digitale Gesundheitsanwendungen – DiGA) to the statutory healthcare insured citizens in Germany.

Furthermore, the new Digital Care Act will expand the 'telematics infrastructure' within the health sector (Halim, 2019). The Act aims to increase the use of remote/video consultations by patients, legally used in Germany since 2017. In the current Covid-19 health crisis, this seems particularly prescient. According to the new act, patients should be able to use digital health services such as the 'electronic patient file' throughout Germany as soon as possible. The electronic patient file is the equivalent of the Individual Health Identifier (IHI) in Ireland, a number that identifies each person who has used, or may use a health or social care service in Ireland. An 'IHI Commencement Order' was signed by the Minister of Health Simon Harris TD, in 2017, allowing for the operational use of the IHI throughout the Irish healthcare system in line with the terms of the Health Identifiers Act 2014 (HSE, 2017).

The Digital Health Index (2018) identified both Estonia and Denmark as leading in connected health adoption, attributable to positive national frameworks and multiple paths to adoption. An EU report (2017) also highlighted Denmark as a success case study. In 2012, €6 billion was invested to modernise the country's healthcare system, make hospitals more efficient, and move patient care from the hospital to the home. In Norway the health ministry has rolled out the 'National Program for Personal Connected Health and Care' to deliver health and social services to the ageing population.

4. Connected health - securing revenue

4.1 Reimbursement, strategy and technology

Despite the unprecedented growth in funding of the digital health market over the past few years, reimbursement remains a key obstacle for those trying to establish their place in the market (Madden, 2018). 'Reimbursement' is the system, unique to each country, of payment for healthcare products and services. It is largely based on clinical and cost effectiveness evidence. An ever-changing reimbursement landscape and lack of uniformity in systems approach, makes markets difficult to navigate. This indicates a challenging return on investment for connected health companies. An EU report (2019, p.4) by an expert panel on effective ways of investing in health concluded:

"Decisions to adopt, use or reimburse new digital health services, at different levels of the health care system, are ideally based on evidence regarding their performance in the light of health system goals."

In the EU, coverage of connected health solutions varies greatly on an individual country basis. A recent EU report (2017) revealed that 55 per cent of countries indicated there are mechanisms of reimbursement, and that 80 percent of these are from public health insurance companies, followed by 50 per cent from government. Prior to the Covid-19 health crisis, use of telemedicine services in Ireland was rare and there was no reimbursement system. A fact brought into sharp focus recently as a package of emergency supports were reached between the Irish Medical Organisation (IMO), Health Service Executive (HSE) and Department of Health, to cover video consultations (Cahill, 2020).

Along with challenges to connected health adoption, through lack of specific legislation/regulation on reimbursement procedure, the EU report highlighted the absence of a national strategy and lack of technical standards that ensure interoperability, as issues still to be resolved across EU member states. Again, there is a clear example of the latter issue when applied to the deployment of Electronic Health Records (EHR) in Ireland. In 2016 the HSE announced a spend of €875m rolling out a national EHR system, overseen by eHealth Ireland, to enable patient information to be instantly accessed by approved medical personnel (Leogue, 2016). To date there is an EHR system in St James' Hospital Dublin and a handful of hospital maternity services.

4.2 National strategy

The last available national strategy for Ireland in the area of connected health was published by the Department of Health in 2013. A core focus for implementation was concerned with moving health services away from a hospital-centric model of care to a more efficient primary and preventative-based model. The focus is on treating patients at the lowest level of complexity and integrating care across settings, supporting community-based care.

The strategy outlined the key enablers for successful eHealth implementation (2013, p.8):

- Willingness to reorganise and redesign existing work practices.
- Effective and authoritative leadership and clinical champions.
- The availability of healthcare informatics resources and the development of appropriate health informatics skills and/or staff training/re-training for all staff impacted by eHealth deployments.
- A standards-based, multi-layered information and technical infrastructure needs to be in place to provide a common platform for eHealth deployments.
- A national health identifier number for citizens, professionals and organisations.
- Appropriate legislation around privacy and security and data protection.
- The presence of an 'Open', authoritative and internationally linked collaborative Innovation 'Ecosystem'. The development of such a collaborative Ecosystem will be an important mechanism for developing innovative solutions to classic eHealth proliferation issues such as procurement issues, technical interoperability and testing and legal enabling."

These first two enablers are echoed in an EU report (2017) which discusses a lack of willingness to adopt new solutions as a barrier to innovation. In particular, the report highlights the shortage of necessary digital skills among clinical personnel as one of the main factors hindering the uptake of connected health solutions and services across the EU. Quinlan (2016) found similar various organisational-level barriers to the change required to embed new connected health processes and technologies in Ireland.

In a summary of economic stakeholder benefits upon strategy implementation, the 2013 strategy recognises that:

"Investment in eHealth brings new markets and encourages business start-up and entrepreneurial activities - services that are imminently exportable once developed.

Development and innovation of eHealth services will lead to extensive research and development - new product and job opportunities (2013, p.22)."

The annual HSE Service Plans covers ICT objectives as part of overall service delivery for one year. This year (2020) the plan commits to:

- "Commence delivery of individual health identifiers and Eircodes into patient administration and other key systems" (2019, p.98).
- "Commence the programme of procurement of the EHR for the Irish health service" (2019, p.100).

7. Connected health – purchasing

The goal of procurement is to maximise public purchasing power to enable patients to receive the best, most cost-effective, life-saving and innovative treatments across all phases of health care (IMSTA, 2015).

7.1 Values Vs Volume

Broadly, the differences between the two purchasing models in healthcare - volume means that every time a patient visits a doctor, has a medical test, or a procedure, the system or patient's insurance pays for each part of the process. This is the model widely followed in Irish healthcare. According to Leonhardt (2009) the economic incentives in health care are still pointing in one direction - as long as doctors and hospitals are paid for each extra test and treatment, they will err on the side of more care and not always better care. No doctor or no single hospital can change that. It requires action by the government. Similarly, Bloem at al., (2019) assert that the predominant fee-for-service and diagnosis-related group models incentivise volume and are widely considered to be an important reason for rising costs in healthcare.

In contrast, the value-based care model, broadly followed in the US, focuses on lowering cost through improving health outcomes. Quality of care is assessed on outcome metrics - reducing acute readmissions, increase preventative care, engaging certified health technology (Rosenberg et al., 2015). The Affordable Care Act has led to a major shift to value-based purchasing in the U.S. Medicare system. The Medicare fee-for-service payments are tied to quality or value (Gilbert et al., 2019), see Table 2 overleaf. In a value-based model of care, more information and transparency of outcomes, ongoing wellness and preventative treatment are prioritised –all central features of connected health solutions (Friedman, 2019).

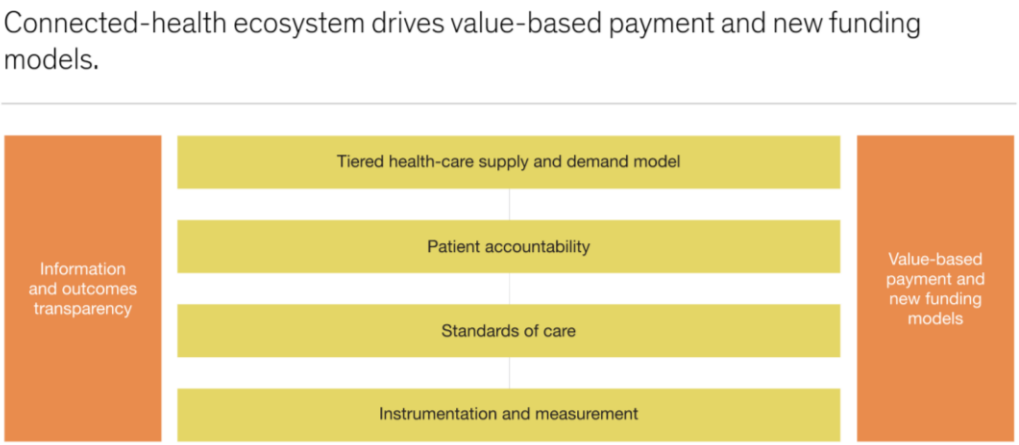

Table 2: Connected heath - values based payment, (Gilbert et al., 2019).

7.2 Global health technology procurement

The 2014 EU Public Procurement Directive (2014/24) encourages innovation and seeks to improve SMEs' access to public sector markets, integrating environmental and social considerations into procurement policy. In 2014, the global Advanced Medical Technology Association (AdvaMed) published a report citing good practices for the procurement of innovative health technology, including (AdvaMed, 2014):

- Clear processes to identify needs and early engagement with the market.
- The pre-tender phase is critical. To produce appropriate specifications, thorough research should be conducted at an early stage should identify both products available on the market currently and those products expected to be available in the near future.
- Key opinion leaders (KOLs) with clinical experience of using relevant technology should play a central role in drafting specifications.
- Specifications should be drawn up by a diverse and multi-disciplinary procurement committee.

Many of these recommendations are echoed by Prada (2016) in research pertaining to values based healthcare in Canada, which cites fostering collaboration and cooperation between public and private stakeholders and engaging clinicians and other key opinion leaders in the procurement process as vital.

7.3 Irish procurement and reimbursement

The Office of Government Procurement (OGP) commenced operations in 2014 and, together with four key sectors (Health, Defence, Education and Local Government), has responsibility for sourcing all goods and services on behalf of the Public Service (no date). However, it should be noted that the OGP does not have statutory or regulatory status.

The Health Business Services Strategy (2017) includes a Memorandum of Understanding (MOU) between the HSE's Health Business Services Procurement and the OGP that states:

"HBS Procurement is responsible for the development and delivery /management of a three Year Rolling Procurement Plan covering all categories of expenditure for the HSE regardless of who executes the procurement process."

This means that purchases such as healthcare technology are sector led and seem to be the sole purvey of HBS.

7.4 HBS processes

HBS comprises five sourcing and contracting portfolios as set out in the presentation (Swords, 2018):

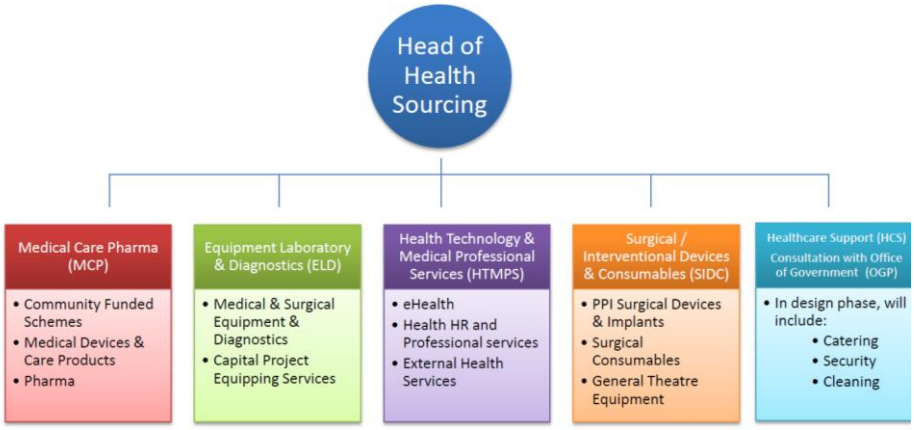

Figure 1: HBS sourcing and contracting (Swords, 2018)

The pathway for procurement is designed according to cost threshold outlined in Figure 2 overleaf:

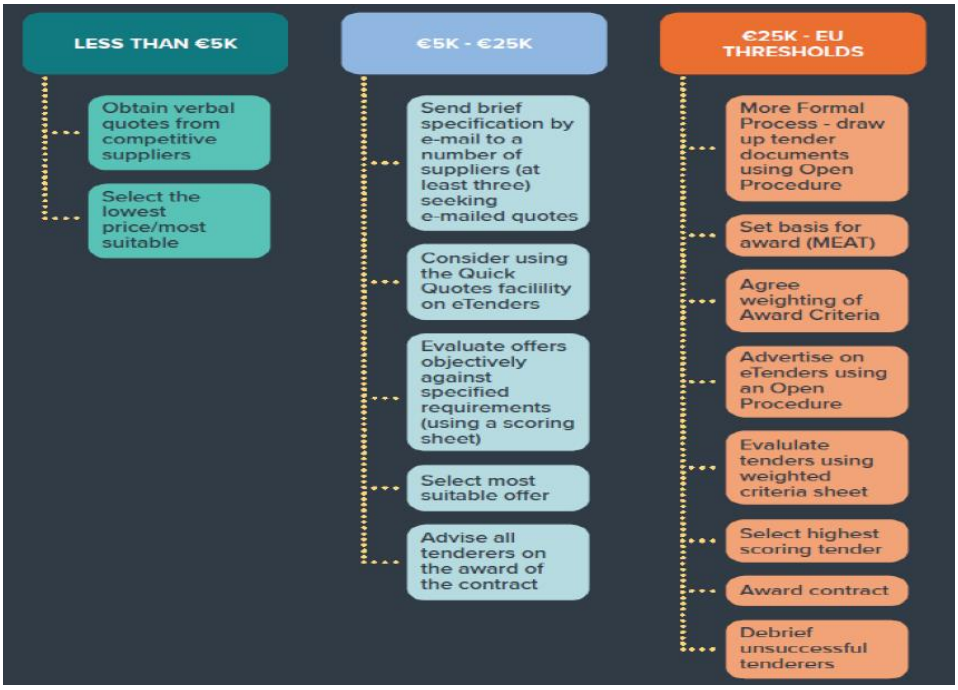

Figure 2: Procurement thresholds (Swords 2018)

As outlined in Figure 2 all contracts above €25,000 must be advertised on eTenders - the Irish Government's electronic tendering platform administered by the Office of Government Procurement. eTenders (no date) CPV codes are a system of classification for public procurement. Using standardised vocabulary, CPV codes support procurement personnel classify their contract notices consistently. This is deigned to make it easier for suppliers and contracting authorities to find notices and follow codes relating to their industry or product area.

The procurement process can differ between HSE (statutory) hospitals and voluntary hospitals. HSE statutory hospitals are owned and funded by the HSE, while voluntary public hospitals, receive some HSE funding but are often owned by private bodies, for example, religious orders. As a result, voluntary hospitals have more autonomy as the HSE procurement processes do not entirely bind them, though the thresholds are the same. Private hospitals do not receive any HSE funding and can execute individual bespoke procurement processes. Rapid assessment and implementation of a connected health solutions are possible, suggesting the private pathway is the most commercially viable route.

The general HSE process outlined on the HBS website (no date) is that hospital budget holders - staff authorised to source suppliers - can complete an online 'Procurement Support Request Form', which is then assessed by HBS. It is not clear what follows this process.

7.5 Purchase to pay

In exceptional circumstances, as with the current Covid-19 situation, sourcing options relevant to value thresholds may not apply. These include 'Extreme Urgency' cases (HSE, no date):

All urgent cases must:

- Have been unforeseeable
- Not arisen due to lack of planning or action by HSE
- Must be approved by Assistant National Director/CEO/CO and co-signed by ACFO
- Head of Procurement must also be notified of all cases

7.6 HSE procurement and direct industry engagement

HSE driven methods of direct industry engagement were difficult to find contradicting best practice as outlined by AdvataMed (2014), Prada (2016) and IMSTA (2015).

7.6.1 HSE Quality Innovation Corridor

For a short period from 2016 -17 the HSE Quality Innovation Corridor (QIC) digital innovation program was designed to open up innovation pathways facilitating collaborations between clinicians, industry, academics in collaboration with eHealth Ireland expertise, could seek seed-funding for creative digital solutions. Agile approval, rapid procurement and swift deployment of digital technologies within the healthcare settings was the aim. However, it seems the programme is no longer running. An email to the general QIC account returned:

"The QIC programme is no longer active and there are currently no plans to reinstate it. This email account is no longer being monitored."

7.6.2 Health Innovation Hub Ireland

Mandated by the Department of Business Enterprise and Innovation (DBEI) and the Department of Health (DoH), HSE and Enterprise Ireland partnership, Health Innovation Hub Ireland (HIHI), drives collaboration between the health service and enterprise, offering testing and development to companies and clinical teams the opportunity to use innovative products. HIHI runs pilot and clinical validation studies for companies across clinical settings in Ireland. HIHI has run 60 studies since 2016 (Donnelly, 2020).

Conclusion

The literature review extended and deepened knowledge of connected health products, markets, Irish and global health systems and commercialisation pathways in the frame of reimbursement and procurement. An analysis of the literature reveals that there is enormous opportunity for connected health products to improve healthcare and commercialise a product once implemented, as demonstrated by comparable EU systems and the values based US system. It is clear that local procurement and purchasing processes are key to commercialisation in public health systems, while private health systems have the freedom to pursue individual purchasing models and a more commercially viable option for businesses. An apparent lack of national vision, without an identified connected heath pathway and an opaque procurement system, appear to present connected health products with significant challenges to success in Irish public health. The knowledge gathered in this section will inform areas of the data collection described in the research methodology.

Chapter 2: Research Methodology

2.1 Introduction

The previous chapter defined connected health products, markets, examined the most recent data on connected health in Ireland and considered reimbursement/procurement as the commercialisation pathway. The literature review offered material to compile interviews and polling questions. By reviewing leading EU health systems, efforts at shifting the purchasing process in Europe and volumes Vs values based healthcare, a basis of comparison can be drawn between these and themes that may emerge through data collection on the Irish system and experience.

2.2 Methods

Qualitative research embraces a number of approaches, theories and methods while quantitative retains an emphasis on measurement and analysis of causal relationships between variables. Quantitative focuses on quantity, amount frequency and intensity (Denzin and Lincol, 1998). Mixed method research employs both approaches iteratively or simultaneously to create a research outcome stronger than either method individually. Qualitative research typically answers research questions that address "how" and "why" whereas quantitative research typically addresses "how often" and "how many". This suggests that a mix of quantitative and qualitative methods can result in new insight (Malina et al., 2010).

A mixed method approach was applied to the collection of primary data for this research topic, both qualitative and quantitative. Sequencing was considered in integrating the methodologies (Carvalho, 1997). Prior to Covid-19 the aim of the survey questions, experiences of connected health companies collectively, was to inform some of the interviews, particularly with HSE procurement. However, as the pandemic affected the planned process of this research, some interviews took place before the survey was disseminated. This means that variables, which arose during the interviews, also informed some questions in our quantitative data collection. None of those interviewed - companies or healthcare - completed the survey.

2.3 Quantitative

Quantitative research adheres to the standards of a strict research design developed prior to the actual research (Adams et al., 2014). Perception variables are not often captured by quantitative data, so when paired with qualitative data collection this can yield an additional insight (Carvalho, 1997).

2.3.1 Data collection: Polling surveys

Surveys may be used for descriptive, explanatory and exploratory purposes (Babbie et al., 2009). An online survey can widen the reach to prospective respondents and administration is relatively inexpensive, however response rates can be low.

The connected health survey informed by the literature review and some interview data is a one point in time cross-sectional view. The survey allowed multiple variables to be analysed simultaneously. The survey was piloted by a group of five individuals working in the connected health industry. This served as a sense check to assess the clarity of the questionnaire, suitability of contents, time required and any potential issues prior to wide dissemination. There were no issues beyond some spelling amends and the functionality of one question. Both were resolved prior to dissemination.

2.3.2 Participant selection

A well-selected representative sample in combination with a standardised questionnaire offers the possibility of making refined descriptive assertions about a group (Babbie et al., 2009). IMSTA (2019) estimates that there are 130 indigenous connected health companies in Ireland. To achieve a reasonable size of the total market the questionnaire aimed for over 35 respondents as this figure is over one quarter of the population size of 130. The anonymised survey was designed in Survey Monkey and a sample frame of these companies was randomly selected through dissemination of professional contacts of the researcher, industry groups – HIHI, IMSTA, Irish MedTech Association - contact lists and social media channels. The survey was anonymous to capture as much input as possible.

2.3.3 Data analysis: Polling surveys

Each participant answered questions on their experience and/or knowledge of commercialising a connected health product in Ireland. Informed by the literature review, the questions focussed on experience prior to Covid-19 to assess the current system rather than the ‘emergency system’. Answers were predominately through a five to seven point Likert scale, allowing each company to express individual level of agreement or disagreement with a particular statement. Some questions were open-ended multiple choice, presenting a statement with suggested answers and a text box for expansion if required. The quantitative data was analysed using Survey Monkey tools. Percentages provided overall averages on themes that were used to inform parts of the qualitative interviews.

Filters were applied to assess the experiences of sub groups that emerged through company size. The data controller for the research is the author, all data is anonymised and is held in a password-protected file. The survey questions are contained in Appendix 3.

2.4 Qualitative

Qualitative research employs methods of data collection and analysis that aims towards the exploration of social relations, and describes reality as experienced (Adams et al., 2014). As such, it is not a statically representative form of data collection. The qualitative approach can serve as a follow-up data collection instrument, pursuing "exploratory" aspects of analysis. Qualitative work can sometimes explain unanticipated survey results (Carvalho, 1997).

2.4.1 Data collection: semi-structured interview

Interviews are among the most frequently successfully used qualitative research tools (Bryman, 2001). For this research, semi-structured interviews were chosen for flexibility. Questions were structured to address specific dimensions of the research, which arose through the literature review and quantitative data analysis, but left space for study participants to offer new meanings to the topic (Cross et al., 2013). This allowed the researcher to pose questions on the unfolding Covid-19 response and the longer-term effects this may have on the Irish public health system.

2.4.2 Participant Selection

Creswell (1994) holds that the premise for qualitative research is to purposefully select documents, informants or visual material that will best answer the research. Given the period available to the researcher and the limitations for observation and interview that this imposes, the sample chosen was ‘purposive’ - selection was based on characteristics of a population and the objective of the study (Maykut and Morehouse, 1996). Eight senior level interviews were conducted and participant details are anonymised for publication.

2.4.3 Data analysis: semi-structured interview

All interviews were analysed for themes. Denscombe (1998) asserts that the coding of data is a major task but a valuable one that brings the researcher closer to the research. Saldaña (2009) defines coding as symbolically assigning a summative or evocative attribute for a portion of qualitative research. Using coding for analysis allowed patterns, similarities and relationships as to emerge.

In the process of researching the current field through the literature review and the quantitative analysis, codes and themes began to emerge naturally. Consequently, deductive coding was applied for the qualitative analysis. A codebook had already started to form prior to analysis that would clarify the research question. The researcher applied Saldaña's (2009) streamlined codes to theory model for qualitative enquiry, as outlined in Figure 3 below.

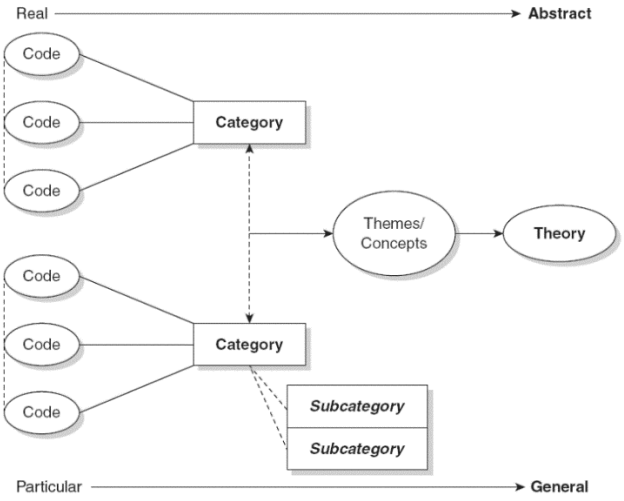

Figure 3: Theory model for qualitative enquiry (Saldaña, 2009)

2.5 Ethical Considerations

Blaxter et al., (2001) describe the critical ethical areas as: anonymity, informed consent, secrecy, being truthful, and the desirability of the research. The researcher applied three of these four as the participants are not anonymous. Permission was obtained for this.

Each healthcare participant was specifically chosen to share their views because they are informed senior stakeholders in connected health development across the entire public system. The companies were chosen because they have products in use in the system. The researcher has anonymised all participants for publication. All participants involved were fully aware of the purpose and scope of this research. Contact was made via email to secure agreement and appoint a date for conduction of each interview.

Permission was sought from all participants to record the interview. Each agreed and was fully aware of the process. Prior to the beginning of each interview the researcher explained the topic and the reason why the individual in question was chosen. Each participant understood that they are entirely identifiable in their contributions, named in the research and the possible impact the research may have for them. (Please note that for wider publication these participants have been anonymised)

All were clear on the purpose of the research, their relation to the topic, the method of interview and how the information is being used. Equally, each was aware that they could withdraw at any stage of the interview process. Each interview recording is held by the researcher in a dedicated password protected Dropbox account and has been deleted from all other devices.

Chapter 3: Results

3.1 Overview

It is necessary to acknowledge that the Covid-19 health crisis occurred during a critical time for fieldwork. All targets for data collection for the project were largely unavailable from mid-March until the end of May. This affected the number of survey respondents and the interviews secured. Irish connected health companies spent the crisis period of Covid-19 pivoting their product(s) as solutions to the crisis. The healthcare interviewees were focused entirely on the frontline response to Covid-19 and so were unreachable. At the time of submission, this remains the case with HSE procurement. A planned interview with a senior individual from HSE procurement could not be facilitated.

There were 36 respondents in total to the survey questionnaire, which was open from May 20, 2020 to June 3, 2020. It is the opinion of the researcher that had the survey been open for a longer time-period this number would have increased. A 2019 IMSTA report estimates there are 130 connected health companies in Ireland. The survey captured opinions and experience of over a quarter (28 per cent) of the connected health companies in Ireland.

There were eight interviews completed. One of the interviews was in person pre-Covid and recorded on an iPhone. The remainder took place via video, recorded on Web ex or Microsoft Teams. Three companies that have products in use in the Irish health system offered additional insight into the system from a company perspective, through individual experience. This allowed the researcher to discuss emergent themes from the quantitative data collection. The remaining four interviews were with present or former senior HSE employees covering perspectives on: IT and systems; eHealth Ireland; senior management; senior budget holder and clinical perspectives. These interviews delved deeper into the experiences recorded by the companies. The data was deleted from all devices and held in a password protect Dropbox. Appendix 1 details the participants. Gathering experiences from inside the system and their reflections on the quantitative data collected, achieved a more balanced framework to assess key barriers and enablers of the commercialisation pathway in Irish public health.

3. 2 Quantitative

All of the 36 respondent connected health companies are Irish. 31 are owner led, 75 per cent had less than 10 employees and turnover of less than €3million in the last business year. Five respondents had an annual turnover of more than €5 million, with over 250 employees. Three of these are management led with two being owner led. Over a third of the 36 respondents described their offer as 'product', 25 per cent as 'service' and almost half identify as both. The connected health segments represented by respondents are displayed in Figure 4 below. There is natural sector crossover in a connected health solution. For instance, 'wearable' can also be 'mhealth' and this is captured in the percentages in Figure 4.

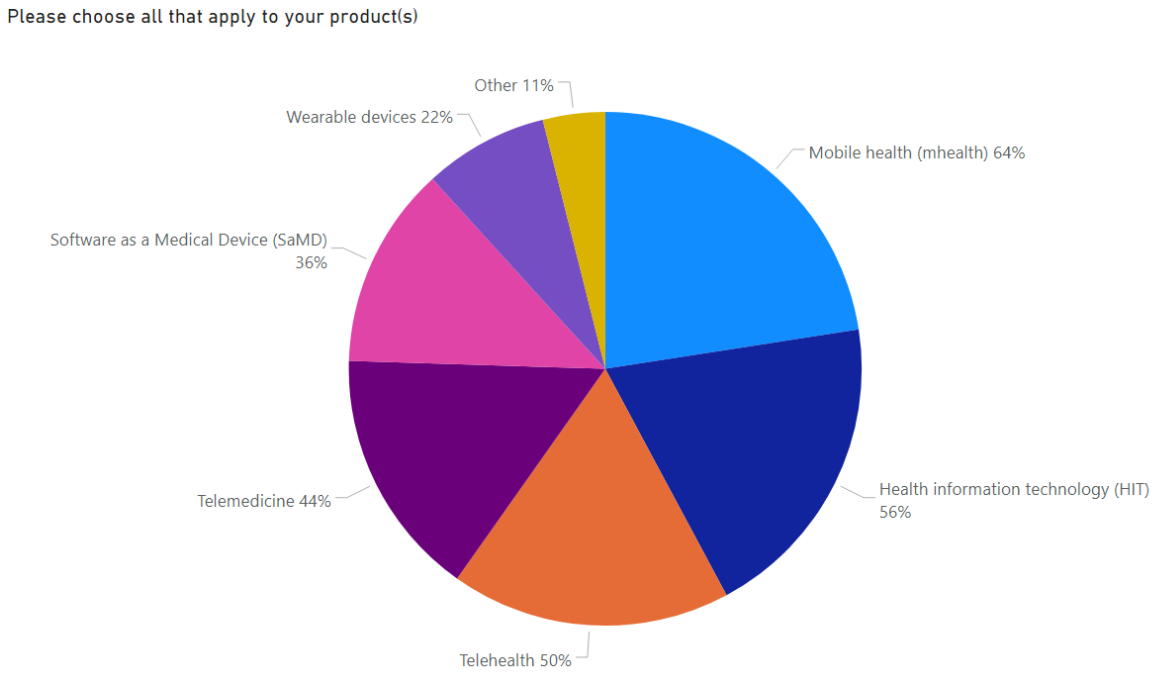

Figure 4: Respondent connected health segments

20 per cent of respondents target the US market only. Almost half target EU markets only and over one-third targets both. Figure 5 overleaf shows that the majority of respondents (30) have been procured by 'a health system' across either Ireland private or public, United Kingdom (UK) or United States (US). The majority, 61 per cent, are in-use in the Irish private health system.

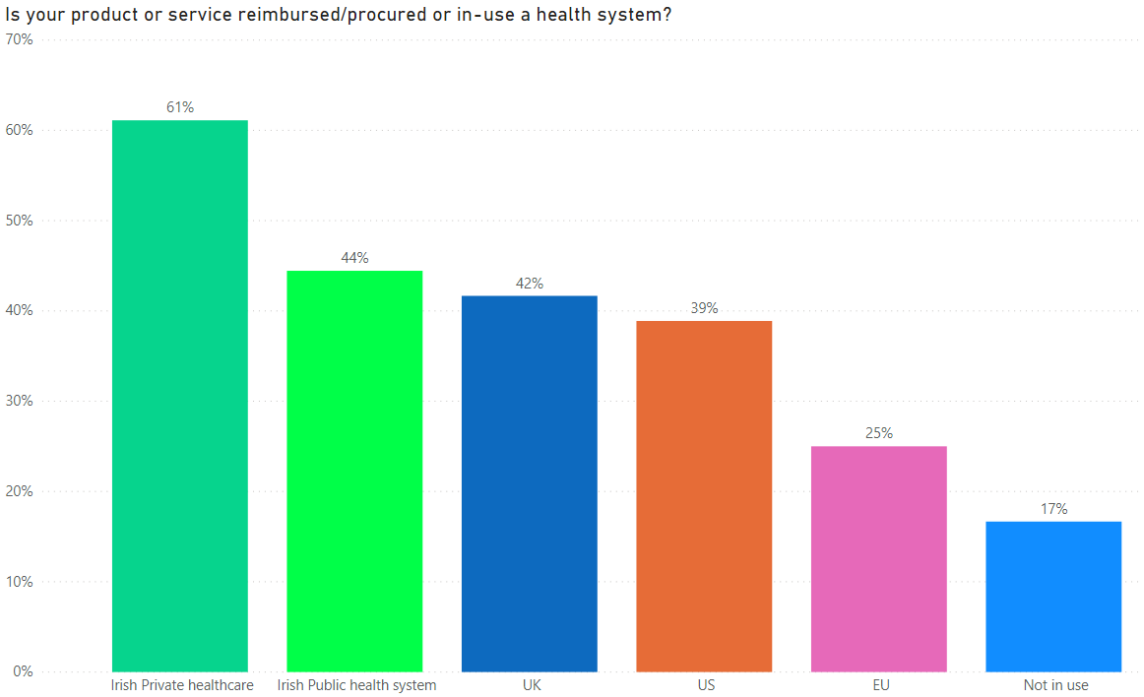

Figure 5: Respondents with procured products

Anonymised comments captured in Table 3 shows the difference in the experiences of selling into a private provider and the public system:

Public
"Currently being piloted. Exceptionally slow process of engagement due to internal power-play politics within upper echelons of HSE." – Respondent 1.
"*Under very lengthy discussions with unqualified procurement personnel."*- Respondent 17.
Private
"*Our product is in use by a Private Provider and there was no competitive procurement process*." – Respondent 11.
"*Private sector 1 - 2 month's implementation*." - Respondent 24.

Table 3: Respondent comments

For those respondents with a product is 'in-use' in the Irish public health system, the process of engagement from 'procurement' through to 'use' took on average 24 months.

Means of engagement with the Irish public health system for companies varied as displayed in Figure 6 below. Respondents could tick as many avenues as apply to them. Almost all agreed that ‘personal contacts’ are their primary route.

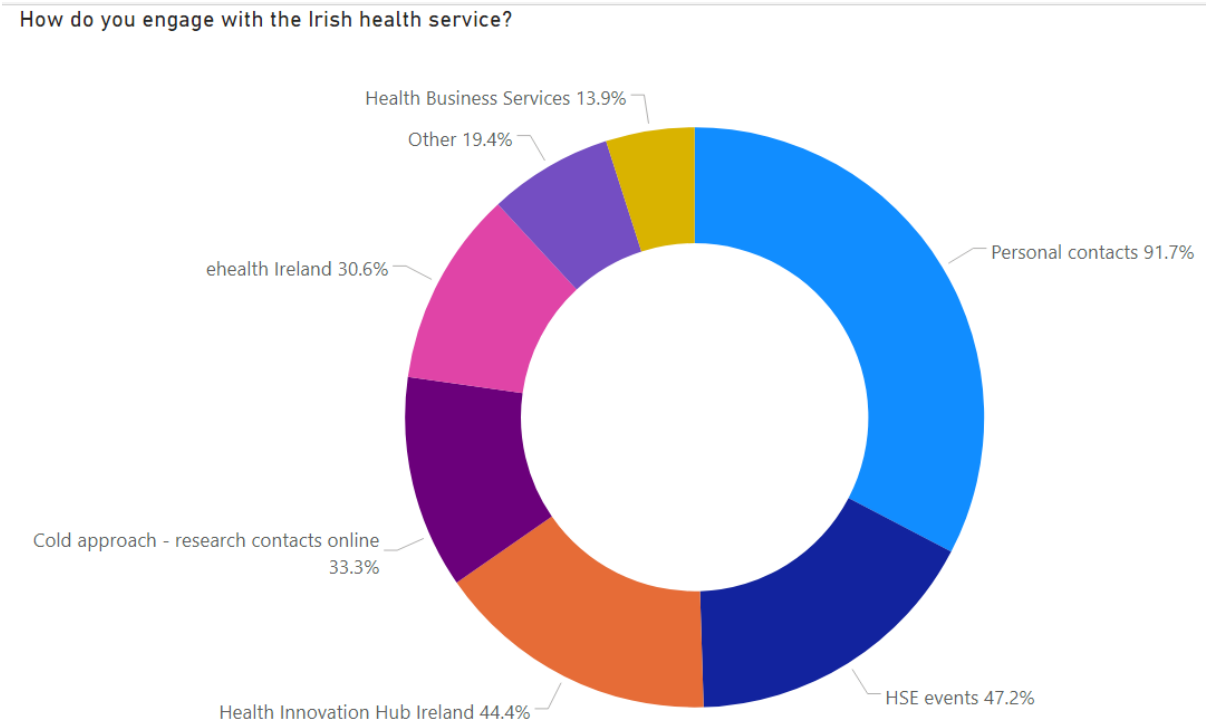

Figure 6: Engaging with the Irish health service

Almost half of all respondents were satisfied with their access to the clinical experts in the area where their product or service can be applied, though one third were somewhat dissatisfied with their level of access. The majority, more than three quarters, are dissatisfied with lack of access to the budget decision makers in the area where their product or service can be applied.

In terms of reimbursement, over one third of respondents think that the health system should pay for connected health products. Almost half (45 per cent) favoured the introduction a “value-based digital health” reimbursement model. Since health systems hold the data needed to measure outcomes, use this information to measure the outcomes of digital-health services - e.g developers are paid based on the system’s savings. More than half (55 per cent) are dissatisfied that reimbursing connected health products and services in Ireland is currently based on evidence regarding their performance in the light of health system goals.

80 per cent of all respondents are dissatisfied with the lack of clarity on the pathway to procurement for connected health products in the Irish public health system. Despite this, the same amount admit to not following any CPV codes, designed by procurement to engage the market in live tenders. 85 per cent of respondents agree it could benefit Ireland to shift to a values based model of care delivery. The same amount agreed that an effective national electronic health record system would be helpful for their product/service and three quarters felt the same for IHI implementation. Respondents differed in awareness of a national health strategy as outlined in Figure 7.

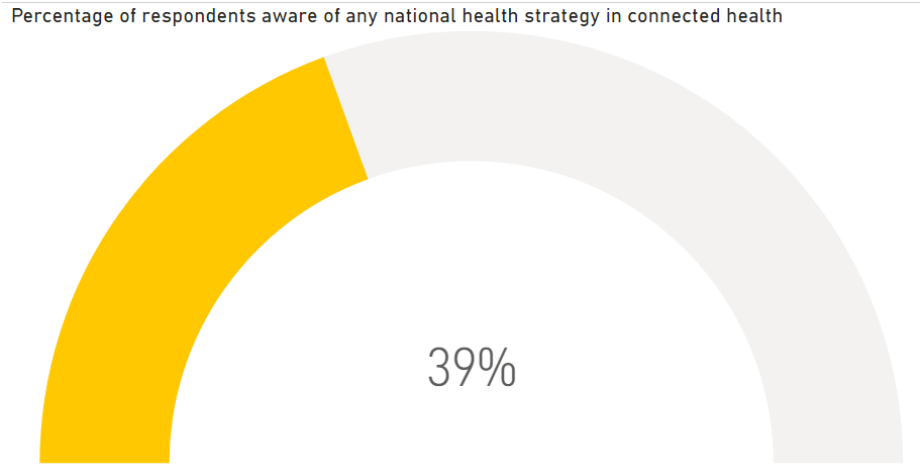

Figure 7: National health strategy in connected health

61 per cent of respondents to the survey were unaware of a national strategy with the 39 per cent that are aware identifying Sláintecare as the strategy in comments as detailed in Table 4 overleaf.

National Strategy
"*Sláintecare obviously covers aspects of connected health but at a high-level."* – Respondent 5
"Many parts of Sláintecare rely on connected health for implementation."– Respondent 33.
"The national ehealth strategy has been in existence for years." – Respondent 18
"Delivery of Sláintecare." – Respondent 2
"Sláintecare and eHealth Ireland." – Respondent 35

Table 4: Respondent comments

Figure 8 below outlines the challenges respondents face to commercialisation of their product/service in the Irish Health system. Procurement, access to budget holders, system interoperability, health system processes and lack of long-term investment are the top five identified.

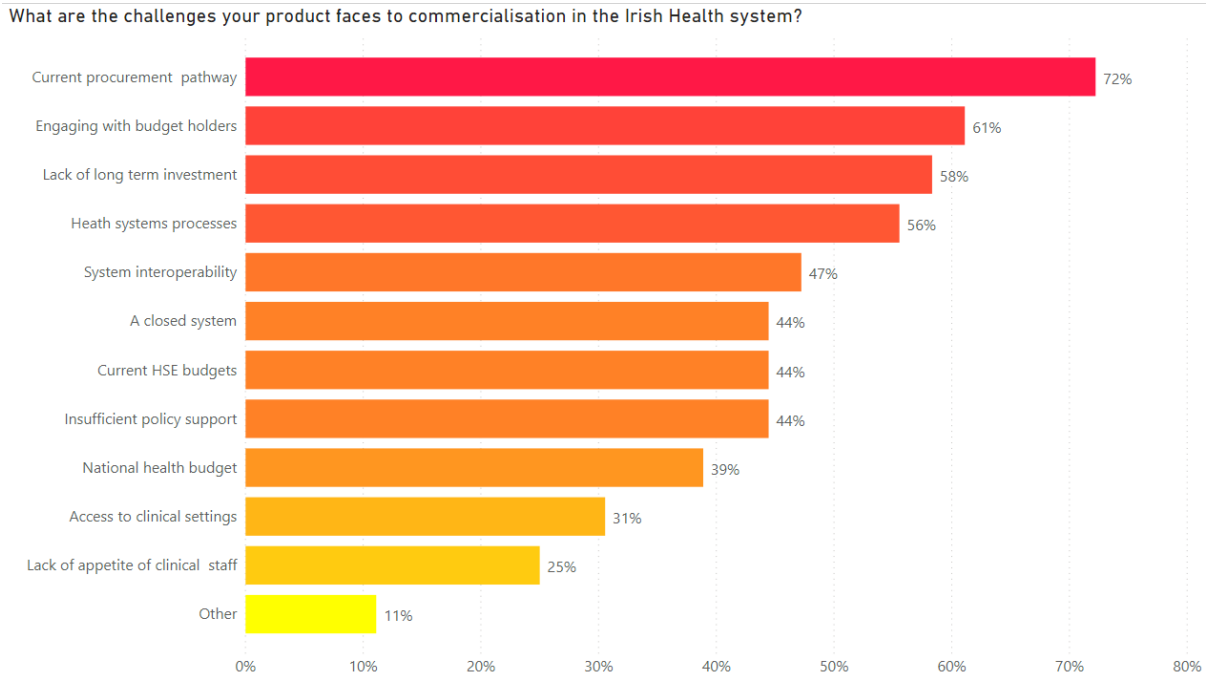

Figure 8: Challenges to commercialisation

Almost 85 per cent agree that specific policy support for connected health, as with the German Digital Care Act 2019, would help their product/service to be successful in the Irish public health system.

3. 3 Qualitative

The codebook that had already started to form prior to analysis, through the literature review and quantitative data collection, informed the coding of some of the qualitative data. A number of themes became clear during the interview process that added depth to the survey responses and new patterns emerged. The qualitative data is colour coded according to ten colour coded themes:

1. **Voluntary Vs Statutory**
2. **Systems interoperability**
3. **National EHR system**
4. **IHI**
5. **eHealth Ireland**
6. **Budgets**
7. **Tender process**
8. **Company size**
9. **Reimbursement for connected health**
10. **Key enablers**

1. Theme: Voluntary Vs Statutory

"We are a little bit more agile, we can obviously work and obviously prioritise what we need to. If we sit down with a company and we do commit we can put the processes in place to actually make something happen."

– Senior management voluntary hospital

There was no distinction between voluntary and statutory hospitals made in the quantitative data collection. The theme emerged during qualitative data collection. Participants discussed the differences between HSE statutory hospitals and voluntary hospitals and the perceived effect of this on operations and freedom to engage with connected health solutions. It was recognised generally that the difference between the two entities affords voluntary hospitals more agility and freedom. These hospitals have their own procurement departments which makes for a swifter, smoother process.

A more progressive culture of 'doing' was noted in voluntary hospitals with positive implications for budget holders. The higher level of ICT skills in voluntary hospitals is also seen as a significant advantage, which affects integration for any connected health product. The theme data is captured in Table 1, Appendix 2.

2. Theme: Systems interoperability

"Our goal is always and the holy grail for us is a system in the HSE that goes across the organisation. For us, it is always a challenge because whatever the system is we have 20 of them. Now we have different processes and procedures."

- Senior management eHealth Ireland

Challenges around interoperability emerged as a theme during quantitative data collection. Interview participants' confirm that this is a challenge in the current public health system. Frustration was expressed that there are a number of different systems in operation. The fact that patient interaction with different hospitals and primary care sites cannot be shared digitally. Lack of national standards is also an issue. A sense that Ireland has fallen behind in international standards whereas progress was previously made by eHealth Ireland. One participant shared that unblocking a fire wall in a community hospital required approval from the highest national level. The theme data is captured in Table 2, Appendix 2.

3. Theme: National EHR system

"The lack of joined up thinking at this stage in the process I think is a little bit alarming. And we see it all the time with the HSE. I mean we see it all the time."

- Founder and CEO connected health company one

Both quantitative and qualitative data reflected the importance of an EHR system. On the current situation concerning a national EHR system for Irish public health, participants largely agreed this would not happen, as originally hoped, in a 'big bang' method of one system implementation. This has resulted in different systems being put in place by different acute sites, with one participant admitting that the HSE was just too slow and another that this is limiting in terms of connected health companies. Cost was discussed with one participant asserting a 'big bang' is too expensive but another felt that overall the piecemeal approach being applied now may result in higher costs. The theme data is captured in Table 3, Appendix 2.

4. Theme: IHI

"An IHI would be amazing to support interoperability and integrating systems across the spectrum."

- Founder and CEO connected health company two

The importance of the IHI shown in the quantitative data collection is supported by the qualitative data. Data was gathered on the current state of play for IHI in Irish public health, the advantages that this offers patient care and the positive impact this could have for the use of connected health solutions in the system. It was confirmed by eHealth Ireland that the IHI in a technical sense is ready to be rolled out. However, it requires business ownership to drive and implement it – central IT cannot roll this out. One participant felt that the lack of IHI is the biggest single barrier to system progression. Another felt that making it a priority for hospital CEOs, would expedite implementation. The theme data is captured in Table 4, Appendix 2.

5. Theme: eHealth Ireland

"eHealth Ireland are managing an existing system perhaps with not enough money, resources, and frankly not always with the most up to date skills to do this. They need to hire more software engineers, project managers, and professionals with training in data analytics. I think there is a gap there."

- Commercial Director connected health company three

The literature review showed that most of the eHealth Ireland activity relevant to the research took place in the past. As such, the researcher judged it a theme best explored in qualitative data collection, with those who have experience of both past and current. The data captured under this theme spans a broad timeframe. From the experiences during the changes of the mid 2010s and the organisation successes such as the QIC programme, to current views. One participant felt there is more required of this office to drive change operationally in Irish hospitals around technology process and implementation. Similarly, another asserted that the CIO office (part of eHealth Ireland) is the most powerful position to influence policy to change the system. Another felt that in the context of connected health adoption eHealth requires more software engineers, project managers, and professionals with training in data analytics.

eHealth Ireland asserted that many of the programmes of the mid 2010s will restart with a 'new innovation unit'. No start date was confirmed. The theme data is captured in Table 5, Appendix 2.

6. Theme: Budgets

It's not the executive ability to buy…you can spend money in our system, you have the authority. Some hospitals are not very progressive and not very interested in buying some new product that someone has seen. So innovation and new products aren't their thing."

- *Senior clinician and budget holder*

Budget holders and access to budget holders were all challenges identified in the quantitative data collection. This is supported by the qualitative data that shows the influence of budgets and budget holders in the Irish public health system as considerable. This data identified three leads in the areas of clinical, business, and ICT lead required for a successful purchase. One participant feels that the business lead is the most important, as budget holder. The lack of capacity to write the tenders required to use budget, coupled with some less than progressive management approaches were also shared as challenges to adopting connected health solutions. The single year budget applied in the Irish system deemed as inadequate by many participants for the long term planning required for a move to a digital health system. This only emerged through qualitative data collection. The theme data is captured in Table 6, Appendix 2.

7. Theme: Tender process

"Procurement is a long process - need identified, business case, line up the stakeholders, into official procurement stages. Each of those stages can take between two and six months. And procurement is longer, say you have to go for an EU procurement. For alot of small companies, it is quite challenging dealing with us."

- eHealth Ireland senior management

Issues with tender process in Ireland from lack of clarity to the length of time revealed in the quantitative data are supported by the qualitative results. The length of time and lack of experience of those involved in the process both clinical and procurement, specifically concerning connected health solutions, are noted impediments in the qualitative data.

Commodity buying was criticised as not conducive to connected health solutions as was the thresholds for formal tender, which was considered to be too low in comparison to the UK. One respondent described the process as: the need identified, business case, line up the stakeholders, Department of Public Expenditure Reform (DPER) sanction, into official procurement stages - each of those stages can take between two and six months. Participants felt that for many – both company and health managers - this is just too long. A small team of dedicated people who do tenders for new innovative products for each hospital group was suggested as a solution. The tender process in a voluntary hospital can sometimes be as swift three months. One participant noted a move towards agile procurement for some purchases in the system as progress. The theme data is captured in Table 7, Appendix 2.

8. Theme: Company size

"No start-up company could go through that process and survive, they just couldn't. You can't wait four years and not have revenue coming in the door."

- Founder and CEO connected health company one

Company size was defined in the quantitative data collection so comparisons could be made in analysis. Company size arose in the qualitative data collection, as relative to the potential for successful procurement in Irish public health. A number of respondents were of the opinion that the Irish public health system as a market is not hospitable to smaller entrants. SMEs and start-ups can be precluded from entering a tender process due to size and liquidity. Some suggested that a partnership approach to contracts between larger and smaller companies may work, but one participant felt that SMEs do not want to partner. A two-tier model to procurement and digital was suggested - one for small-scale change and innovation and one for the 'mega vendor'. Another participant felt that a start-up company would simply not be able to withstand the length of time for procurement in the Irish public system. The theme data is captured in Table 8, Appendix 2.

9. Theme: Reimbursement for connected health

"I'm not aware of a standardised assessment process for connected health solutions."

- Senior management, voluntary hospital

Values based reimbursement was widely favoured by quantitative respondents but less so by qualitative participants.

A budget holder during qualitative data collection expressed that reimbursement is simply down to demonstrating the savings that a product will make for the system. There was no awareness from participants of a standardised assessment process for connected health solutions. Quantitative data described the reimbursement pathway as opaque, which supports the opinions captured in the qualitative data. Some participants felt that the HBS did not have the necessary ICT skills to deal with connected heath solutions. Policy and reimbursement change to embrace connected health in Germany was invoked as a positive example. The theme data is captured in Table 9, Appendix 2.

10. Theme: Key enablers

"Since Covid, the value being delivered by telehealth is incredible – young people with chronic illnesses don't have to take a half day off work to come up from Wexford or Waterford to attend St James for a visit that takes 20 mins. They also want their information to be shared with them and I think it's that expectation will drive it more."

- Senior Informatics Manager, voluntary hospital

Qualitative data collection allowed the researcher more time to discuss enablers with participants. Some of the perceived enablers, as identified by the participants, are currently in place, such as HIHI, HSE events and the potential for the necessary shift in the patient pathway since Covid-19. Much more are recommendations on how the system can put in place enablers such as national standards, ICT upskilling, utilising the HSE CIO role, requiring a minimum spend on ICT projects, policy support making digital maturity an annual measure for hospitals. Patient demand was also captured as an indirect enabler of system change. The theme data is captured in Table 10, Appendix 2.

Chapter 4: Findings and discussion

4.1 Can you commercialise connected health products in the Irish public health system?

The results of this research show that it is possible, with the caveat that there are key barriers and enablers to this market. Both the qualitative and quantitative data expose the context in which companies are trying to sell into the Irish public health system. Through triangulation of the data, these key barriers and enablers are revealed. Triangulation crosschecks multiple research sources for regularities, offering a more detailed and balanced picture of a situation (Altrichter et al., 2008; O'Donoghue et al., 2003). The consistency of the findings through the two data collection methods is examined under headings devised through triangulation.

4. 1.1 Limitations of research

- Covid-19 meant that HSE procurement were unavailable for interview. Consequently, a direct source of data on the system was closed to the researcher. However, senior healthcare participants offered informed insight into the procurement process through qualitative data collection.
- It is reasonable to surmise that Covid-19 affected the sample size of the quantitative data. Nonetheless 36 respondents from an estimated population of 130 (IMSTA, 2019) can be considered a representative sample.
- The lack of Irish specific previous research in the area of connected health limited the academic references of the researcher, but also created an opportunity to investigate an under-researched area in Ireland.

4.2 Target markets

The survey data captured opinions and experiences of more than one quarter of the connected health companies in Ireland. Irish private healthcare was the largest target market for respondents with Irish public healthcare, UK and US all averaging similar amounts as valid targets. Almost half of the companies have had products procured in the Irish public health system and 60 per cent in the private health system. This means respondents are informed and have active experience across the Irish health landscape. For the survey respondents whose product/service is ‘in-use’ in the Irish health system, the process of engagement from 'procurement' through to 'use' took on average 12-24 months. A lag time confirmed by the detailed experience of three company interviews.

This means that some healthcare sites endure a wait of two years before a need identified is met by a product. Healthcare implications aside, this lag will negatively effect revenue streams for connected health companies.

Interview participants cited the flexibility within voluntary hospitals coupled with a more progressive culture as an advantage to statutory sites. In fact, a senior manager in a large voluntary hospital confirmed that having its own procurement system meant that a product could be in use in a matter of three months. Similarly, survey respondents cited one to two months before a product was applied in the private system. This is stark by comparison to statutory hospitals that must go through the HSE. One company interviewed had a four year wait for reimbursement from a community (statutory) hospital. This does not reflect well on centralised control and shows a clear imbalance in the two systems.

Mohr et al., (2006) define companies operating in high technology environments as confronted by a triple threat of market, competitive and technological uncertainty. Viewing this through the lens of the Irish public health system the delay in procurement, which can be two years, should be included to make a quadruple threat. Interestingly, company size and resource did not affect the delay. Respondent companies with turnover in excess of €5million and below €3million are both subject to this. However, any delay will more negatively affect start-ups who have less revenue streams to support the lag in procurement time.

4.3 Market access

Viewing the Irish public health system as a market, the fact that almost half of all respondents were satisfied with their access to the clinical experts is encouraging. It suggests that clinical contacts, who are critical to the development of an effective connected health solution that will have market impact, are accessible to Irish companies. This offers companies an opportunity to gather market intelligence and create knowledge-based competencies (Mohr at al., (2006); Vairdot, 2014). Notably, there was no distinguishable disparity of access between established companies (more than €5million) and the smaller players (less than €3million). Personal contacts, HIHI and only one from the HSE – events - are the top three avenues of engagement for companies with the Irish health system. This confirms the evidence found in the literature review that the level of standardised HSE driven pathways of direct industry engagement is low.

Personal contacts being the top means of engagement for companies who are trying to sell into the system necessitates time and skill in relationship building. HSE events in a post-Covid environment are for the foreseeable not possible. Despite being cited in the data collection, the researcher found little information on dedicated HSE/industry events.

One of the companies interviewed, with a product in use in Irish public healthcare, identified the QIC programme as its route into the public health system. According to eHealth Ireland, this programme will be restarted under a new innovation unit, though no date has been given. QIC was one of a number of initiatives that started with the eHealth strategy of the mid 2010s, which simply seemed to collapse. eHealth Ireland ascribe this to personnel change in data collection. Initiatives that are built to support a national healthcare system and industry engagement for the benefit of this system should withstand a shift in personnel. It suggests that there was not sufficient internal or policy support (as part of a DoH published strategy) for these programmes.

Aside from the documented impact of the length of tender process, this research found evidence that the size and liquidity of companies means that smaller entities are often precluded from the procurement process entirely. This was also a concern expressed by SMEs in a 2019 report by IMSTA. Size, scale and robustness are described as key national criteria for healthcare procurement, which is found lacking in smaller companies in the opinion of some interview participants. However, it is often the case that smaller companies produce more innovative products, which suggests that, the system is closing itself off to these solutions. Simultaneously denying these companies an opportunity to scale and grow.

4.5 Budgets and budget holders

Qualitative data on budgets largely centered on the allocation and negative implications that the single year budget has on strategic planning and creating an environment that can benefit from connected heath solutions. Lack of long-term investment was one of survey respondents' top challenges to commercialising connected health products in the Irish public health system. Leading EU connected health systems such as Denmark and Norway have seen significant long-term investment packages to transform healthcare delivery to one with connected health at the core of the health service.

Access to budget decision makers was another top challenge to commercialisation highlighted by respondent companies. Breaking this down by respondent turnover, the larger companies returned a neutral to positive response. Contrasting with the smaller entities returning an almost unanimous dissatisfaction rate. Granted the sample size of each sub group is markedly different but this could suggest that those with higher revenue generation have more access to budget holders. The HBS website states that hospital budget holders - staff authorised to source suppliers - can complete an online 'Procurement Support Request Form'. Interview participants expanded on this explaining that behind this process are three important areas - a clinical lead, an ICT lead and a business lead.

Usually the clinician will identify the need but does not have the power to purchase. In almost all cases, the executive sponsor/business lead has this power and must be convinced. A time poor clinician pursuing purchase by convincing a business lead is an unlikely scenario. Data collected from the company interviews implied that clinicians are often unfamiliar with the purchasing process. Qualitative data also confirmed that for some hospital managers' who control purchasing, innovation is simply not a priority. This corresponds with an EU report (2017) which discusses a lack of system willingness to adopt new solutions as a barrier to innovation. It chimes too with Quinlan (2016) that various organisational-level barriers exist to the change required to embed new connected health processes and technologies in Ireland. It is concerning that five years after Quinlan's research, conducted in 2015, there is still evidence of organisational barriers.

4.6 Procurement pathway

An almost unambiguous response was shared by all respondent who are 80 per cent dissatisfied with the lack of clarity on the pathway to procurement for connected health products. This was the top challenge to commercialisation for respondents. It is not a problem unique to Ireland as a 2017 EU report revealed that procurement of connected health solutions varies greatly on an individual country basis. One company interviewed deemed the threshold of contracts of above €25,000 for the formal tender process ridiculous, when compared to the UK where local tender awards of up to £80,000 can be granted. A criticism levelled at the procurement pathway from interview participants was not procurement itself, but rather the lack of capacity within the hospital system to write the tenders. For many of the products categorised under connected health no prior tender exists and so an entirely new tender must be specified.

A divergence of views occurs in this area, with some of the companies interviewed of the opinion that HBS and eHealth Ireland are not centrally equipped to support tenders for connected health products due to lack of data analytics skills, ICT skills and a dearth of software engineers. Another view is that if there was a more qualified resource on the hospital site itself this would clarify and expedite the tender process. A small team, perhaps per hospital group, could specialise in new tenders for innovative products. One company interviewed with a product in use in the US confirmed that this is the process for an acute site that the company sells into. It takes the procurement pressure off the clinician that has identified a need and presents the company with a dedicated, skilled intermediary/team to sell into who are qualified to write specifications. This process corresponds with the recommendations outlined by Prada (2016) and AdvaMed, (2014) for good procurement practice. A process such as this would clear up any ambiguity on procurement for companies and offer clarity on a route to market.

4.6.1 CPV codes

In the initial data analysis, it was surprising that the majority of company respondents do not follow CPV codes. CPV codes support procurement personnel to classify their contract notices consistently, making it easier for suppliers and contracting authorities to follow industry and product codes. A search by the researcher on eTenders reveals that none of the product and service segments identified in connected health are used as CPV codes. If the codes do not use the appropriate terms for connected health, then companies cannot follow. A search for 'telehealth' 'remote monitoring' 'video consultation' 'remote care' was fruitless. The last recorded update for CPV codes was over a decade ago in 2008. A period in which, healthcare needs and delivery have changed considerably. A review of respondent companies by size revealed that those with higher turnover do follow CPV codes. There are a number of consultancy firms such as 'Tender Scout' providing a semantic search service to cover connected health. Thus enabling those that can afford to follow codes in this manner superior access.

4.7 Values based healthcare

In a value-based model of care, more information and transparency of outcomes, ongoing wellness and preventative treatment are prioritised – all central features of connected health solutions (Friedman, 2019). Unsurprisingly 85 per cent of respondents agree it could benefit Ireland to shift to a values based model of care delivery.

In the EU the ever-changing reimbursement landscape and lack of uniformity in systems approach, makes markets difficult to navigate (Madden 2018). The Irish public health system as a market is no different. Although respondents favour the introduction of a "value-based digital health" reimbursement model the system still follows a volume-based model. The qualitative data confirmed that there is no standardised reimbursement model for connected health products, the cornerstone of the German Digital Care Act, which is pushing the country into a position of leadership in connected health. The absence of a standardised process leaves connected health companies with a difficult market to navigate, unable to forecast commercial success as return will vary across the market.

4.8 EHR and IHI

Identified by Department of Health's eHealth strategy in 2013 as key enablers, the majority of survey respondents and interview participants also recognise the importance of both an effective national electronic health record and the IHI to an effective digital health system. Both of these or equivalent are in place across leading EU connected health systems detailed in the literature review – Germany, Demark, Estonia and Norway. Although publicly discussed for the past five years and included in the HSE Annual Service Plan (2020), this research confirms, that there will not be a national implementation of an EHR system. In its place will be a piece-by-piece approach. Each acute site will implement its own system, which poses the risk of different unlinked systems, threatening the purpose of the EHR. This represents challenges for connected health companies attempting to integrate solutions into multiple operating systems. This research confirms that another absent infrastructure piece for connected health, the national IHI, is technically ready, but remains unused waiting for business ownership within the HSE to manage implementation.

4.9 National strategy and technical standards

The EU has highlighted absence of a national strategy and lack of technical standards that ensure interoperability, as issues still to be resolved across many EU member states (2017). This is the case in Ireland too. The superior level of ICT skills in voluntary hospitals compared to statutory hospitals was widely highlighted by interview participants, which makes voluntary sites more amenable and able to consider connected health solutions. Systems interoperability was a top challenge to commercialisation for respondents. Concerns echoed by interview participants at the amount of differing systems in place across Irish healthcare and the lack of national standards.

The implication of multiple systems for connected health companies is that a bespoke product is required for each site/customer to meet the needs and operating standards of various systems. The ongoing integration challenges were also reported by IMSTA (2019) and in the eHealth Strategy (2013). It is striking that the issues documented in a national strategy seven years ago remain prominent. 40 per cent of survey respondents that are aware of a national strategy identified it as Sláintecare. Sláintecare is a 10-year road map published in 2017 to transform Irish health and social care delivery. While connected health solutions are certainly part of this, it is by no means the national strategy required to follow the dedicated 2013 eHealth strategy. This means that the health sector is rudderless in this area, deprioritising it throughout the system making access for companies more difficult. Both qualitative and quantitative data of this research show that increased policy support is required for a shift towards a public health system that can exploit the potential of connected health solutions.

4.10 Key enablers

Qualitative data collection allowed the researcher more time to discuss enablers with participants – what exists in the system that supports connected health and what could help. Participants identified a low number of current system enablers'. A recent key enabler for adoption of connected health solutions in Ireland is Covid-19. The need to reform patient pathways in the wake of the crisis will drive a fundamental shift. The rise in use of telehealth in both acute and primary care was widely seen as a positive. Certainly, this opens up the market to connected health companies. Participants also discussed patient demand as pushing the system to change. Connected health solutions are changing care delivery globally and there is a sense from the data that customer (patient) demand will push hardest for this change in Ireland. ICT upskilling and a minimum ICT health spend nationally were suggested. This shift would need to come centrally. Indeed a push centrally to incorporate a connected health spend into annual purchasing was suggested to force managers/budget holders to consider these solutions. Measuring a hospital on digital maturity, as part of its annual review, was suggested as the push that the Irish system needs to follow EU neighbours lead in connected health systems.

4.11 Key barriers and enablers

This research has examined the Irish public health system through the lens of key barriers and enablers to commercialising connected health products in the Irish public system.

There is a need for connected health solutions in the Irish public health system for many reasons - remote monitoring, reducing the burden on the acute setting, empowering patients, long term cost savings. Data showed that there is an informed willingness and appetite in engaging with these solutions from clinical staff working in the Irish public health system. This goes some way to resolving the challenge cited in a 2017 EU report that a shortage of necessary digital skills among clinical personnel is a main factors hindering the uptake of connected health solutions. This research shows that a market exists and an obvious market need is present. Yet any commercial strategy to meet sales objectives in this market will be fraught. Table 5 below presents the key barriers and enablers as found by this research. All but three of the enablers (voluntary hospitals, HIHI, Covid-19) are hypothetical, suggestions made during data collection. All of the barriers are perceived to exist, as gathered through the data.

Key barriers	Key enablers
Statutory hospitals	Voluntary hospitals
Centralised control	Access to clinical experts
Decline of eHealth Ireland	Personal contacts
Company size	Clinical appetite
CPV codes	HIHI
New tenders	IHI
Tender writing skill	Covid-19
Quadruple threat	Values based digital health
Reimbursement process	Annual measurement- digital maturity
Single year budget	
Long-term investment	
Organisational barriers	
ICT skills	
Perceived lack of policy support	

Table 5: Key barriers and enablers

Chapter 5: Conclusion

This research is the first to investigate the experiences of Irish connected health companies in the Irish public health system through the lens of key barriers and enablers to commercialisaton. The research adds a meaningful dimension to Quinlan (2016) by assessing conditions for connected health companies. Quinlan looked at the system itself and preparedness for the proposed eHealth measures of the 2010s. The review conducted by IMSTA (2019) leant some context to the researcher to build upon – confirming the number of Irish connected health companies and some industry challenges such as lack of EHR, system integration and issues with company size. Overall, this research found that current barriers to commercialising connected health solutions in the Irish public health systems are more than four times the enablers.

Based on the findings of this research the most efficient route to market for a connected health company into the Irish public health system is through a voluntary hospital. Aside from the procurement flexibility detailed in the qualitative data, the higher level of ICT skills required to enable the deployment of connected health solutions are more evident in these settings. The hamstrung situation of statutory hospitals through centralised control in contrast was an unexpected result. From procurement to ICT skills a two-tier system has developed.

Prior to commencing this work, the role of HSE procurement was most prominent in the accumulated anecdotal challenges. The common perception held, as revealed in the quantitative data, is that the procurement process in Ireland requires review to support health system adoption of connected health solutions. This research found that is true. On average, it takes two years from a need identified to a product in-use in the public health system. Some barriers presented by the system are more impactful to start-ups and SMEs, those operating on tight budgets with limited resources. This research confirmed that smaller companies are often precluded from the procurement process. Truthfully, even if it was an open competition most start-ups could not withstand the wait for revenue.

Leadership heretofore shown by eHealth Ireland has been in decline for a number of years. This has manifested in no national strategy, no upskilling of staff and systems, a non-materialised EHR and the non-application of the critical IHI – a system technically ready to go. It is too simple to lay this entirely at the door of one organisation. Rather this research revealed a general lack of accountability.

For some time Ireland was making national strides with a national strategy, QIC, EHR procurement, which simply halted. Ultimately, this failing rests with the DoH. Connected health and digital care pathways pre-Covid have not seemed a priority for this Government. Despite ample evidence of the positive impact recorded in EU neighbouring markets and the DoH's own strategy (2013) acknowledging that investment in eHealth brings new markets, encourages business start-ups bringing new products and job opportunities. A dichotomy of sorts is that EI is funding and developing indigenous connected health companies, which from the outset are unlikely to penetrate the domestic public heath market. The success of HIHI in connecting health innovators with the health system to develop and pilot products is evident. Of 60 HIHI pilot studies; there are 18 products in use in healthcare systems, but only six in Ireland. Three times the exports to domestic adoption.

Some of the barriers in the Irish system are those, which other countries have also encountered. Connected health is a relatively new and rapidly growing way to deliver healthcare and naturally new support structures are required to leverage this. From systems, to standards, to buying. Single year budgets limit strategic planning and consequently the level of change that can be implemented. There is a valid case for creating a dedicated unit in procurement either centrally or per hospital group, qualified in producing new tenders for this growing area of healthcare. Another worthy suggestion from the data collection was including a digital maturity measure in the annual review of hospitals. This is not a panacea but could be one of a number of DoH supported national directives that seek to return digital health to the national agenda. Indubitably, this would have a positive impact on Irish connected health companies to open dialogue and routes into the system.

The strides taken during Covid-19 by the public health system in the areas of telehealth and remote patient monitoring are encouraging. It remains to be seen if these changes are sustained. The current restrictions do dictate an adjustment to patient pathways where possible. Crowded waiting rooms are no longer possible. This presents a viable commercial opportunity for connected health solutions. Beyond this, patients are now better informed and have more choice and a far greater say in their mode of treatment. Advances in technology have empowered consumers across sectors and healthcare is no different. Patient demand will force system change.

The findings of this research demonstrate that while it is possible to commercialise connected health products in the Irish public health system, the current barriers to success considerably outweigh the enablers. For commercial return in this market a company's size, scale, liquidity, resource, ability to adapt to varying systems of integration and target site i.e. voluntary or statutory should inform market approach and commercial strategy.

Chapter 6: Recommendations

As the research concluded, a number of recommendations emerged for both the health system and connected health companies. Table 6 below collates these recommendations.

HEALTH SYSTEM
Budget holders
• Standardise engagement with clinical decision makers. • Consider dedicated resource for connected health purchasing. • Utilise support such as HIHI to engage with the market for solutions to system needs and evidence based purchasing. • Review tender skill and requirements in-house.
Procurement
• Upskilling procurement and tenders to support connected health purchase and assessment tenders. • CPV codes require review and updating. • Consider a two-tier system for digital heath procurement – start-ups Vs established. • Improve information publicly available to companies.
Policy support
• Consider strategic position to support national progress in digital health, including long-term investment. • Explore EU funding options to support digital health growth. • Build in digital maturity measures for annual hospital review. • Review effectiveness of single year budgets.
Covid-19
• Maintain Covid-19 shift in patient care pathways – remote monitoring, virtual consultations. • Consider funding options post ‘purchase to pay’.
CONNECTED HEALTH COMPANIES
Market approach
• Consider markets carefully – resource and time available to dedicate to Irish public health system penetration (quadruple threat).

• Understand the necessity of bespoke products within a multisystem market.
Route to market
• Voluntary hospitals are at an advantage and more attractive route into public health for connected health companies due to agility.
Utilise access
• Findings show clinical experts in Ireland are accessible - onus is on companies to exploit this. • Research, target clinicians and apply user feedback for commercial strategy even if the market is international. • Utilise supports offered by HIHI for access, development and testing.
Covid-19
• Exploit the necessitated shift in patient pathways and examine areas where you products add value in the post Covid-19 health environment.

Table 6: Recommendations

Chapter 7: Areas for further research

- Budget holders

The influence of budget holders on the commercialisation pathway for connected health solutions is considerable. A concentrated review of statuary purchasing patterns could add to the findings of this research. Data collection should include an anonymous frontline survey to capture the experiences of those who identify the need and the impact of the subsequent process required, on having this need met.

- Deeper comparison of statutory Vs voluntary

It is clear from the research that an imbalance exists between the two systems. Further examination of this area is required to measure the difference in ICT skills, procurement patterns and the overall health system impact of this imbalance.

- Private vs Public

Considering the highest proportion of survey respondents have had their products procured by the private health system in Ireland, further research into the experience of companies in this market could yield valuable insight on a profitable market

- Detailed review of HSE procurement processes in light of the global shift to values based procurement

Review the changes required to shift to values-based healthcare procurement, the likelihood of this in the Irish system and conduct a full comparison to current EU systems.

- Audit policy support for future healthcare

Implied by this research is a lack of policy support for connected health despite significant weight behind the initiatives of the mid-2010s. A full audit of DoH support, strategic and budgetary, for digital health from early 2000 to current could produce patterns of interest and recommend actions.

- Consider Covid-19 – post vaccine

Current 2020 estimates have a vaccine for Covid-19 at earliest 2022, a study of patient pathways within the Irish public health system post vaccine would be of merit. Examine if the shifts are maintained and the impact on the commercial pathway for connected health products.

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Appendices

Appendix 1: Qualitative theme data

There is an individual colour for each theme. Each comment is also individually colour coded and attributed to the initial of the participant.

- **Theme 1: Voluntary Vs Statutory**

Participant	Voluntary Vs Statutory
Senior informatics manager voluntary hospital.	*"We do have more flexibility but the HSE hospitals have the advantage of economies at scale, but it means we can try things because we are looking at things from a smaller scale."*
Senior manager, voluntary hospital.	*"We have our own procurement department here. So in relation to it, so obviously we have to follow all the rules associated with it. We are a little bit more agile, we can obviously work and obviously prioritise what we need to. if we sit down with a company and we do commit we can I suppose the processes in place to actually make something happen."*
CEO/founder connected health company three.	*"You have some HSE hospitals who rely only on eHealth Ireland for ICT solutions & support. In those hospitals, especially the smaller ones, it is often the case that there are no ICT managers on site – which makes it harder to get things done quickly."*
Senior clinician and budget holder	*"The difference between the HSE and the voluntary hospitals is not the two systems, but it's the two cultures. The voluntary hospitals they do have more freedom, there's just a culture of doing, that allows them to be more agile."*
CEO/founder connected health company two.	*"I don't understand why they are different. The system needs fundamental re-architecture here."*

- **Theme 2: Systems interoperability**

Participant	Systems interoperability
Senior informatics manager voluntary hospital.	*"We need national standards for how data is gathered and architecture."*
Senior Manager, voluntary hospital.	*"Patients won't know or be able to interact with their medical record elsewhere. And our digital strategy because what we needed to do here, we won't be able to interact with let's say our colleagues down the road in relation to the system they have. So that is a challenge."*
Founder/CEO connected health company one.	*"Working in the community hospitals the domain was blocked on the fire wall. My god almighty, talk about it was not a simple phone call, it's not a simple email, it's not a ticket. We had to go all the way up the chain to get someone onto that."*

CEO/founder connected health company two.	*"This is a big barrier."*
Ex- senior management eHealth Ireland.	*"Around system interoperability, there are international and national standards that exist. A huge amount of work was done under E-health Ireland to become part of those standards and bring those into Ireland. In fact Ireland led the way in some of those at that point."*
CEO/founder connected health company three.	*"There is a need in the system right now for a number of innovative technologies and it is laboriously slow to try to change it. Voluntary hospitals have built up their own ICT systems over the years mainly because they had access and control over their own funds and were able to raise funds over the years. The result is that you've ended up with a two-tier ICT health system among the public hospitals."*
Senior manager eHealth Ireland	*Our goal is always and the holy grail for us is a system in the HSE that goes across the organisation. For us, it's always challenge because whatever the system is we have 20 of them. Now we have different processes and procedures."*

- **Theme 3: National EHR system**

Participant	**National EHR system**
Senior informatics manager voluntary hospital.	*"I held out good hope until Covid but now with a recession looming, I think its s going to be expensive. Everything is so resource driven – we don't have the funding to do it in a big bang and so we try to do it piecemeal, but then doing it that way costs more money anyway."*
Senior manager, voluntary hospital.	*"It is a barrier, but for us we are moving in our own route in the hospital there. So we are going to implement over the next 4 years an E.H.R. I don't think the system as in the wider HSE is able to respond as quickly on the needs. And if we were to wait, it would take too long."*
Founder/CEO connected health company one.	*"The lack of joined up thinking at this stage in the process I think is a little bit alarming. And we see it all the time with the HSE. I mean we see it all the time."*
CEO/founder connected health company two.	*"The lack of a national system is a limitation definitely."* .
Ex- senior management eHealth Ireland.	*"I think there was a lot of promise as I left, we were on the verge of an E.H.R funding, we were on the verge of so many things being there. And frustration hasn't been able to take that to the next stage."*
Senior manager eHealth Ireland	*"There won't be a big bang (EHR) simply because of the cost and the change management. It a vastly expensive implementation that is quite resource intensive."*

- **Theme 4: IHI**

Participant	IHI
Senior informatics manager voluntary hospital.	*"Still not implemented. I think it is being used for some smaller projects."*
Senior manager, voluntary hospital.	*"I think maybe one of the biggest barriers in this system is in relation to not having a unique identifier for patients. I think are more mobile through the health care system at the moment. And I think not having that is a challenge."*
CEO/founder connected health company two.	*"An IHI would be amazing to support interoperability and integrating systems across the spectrum."*
Ex- senior management eHealth Ireland.	*"If you say to the health system of Ireland, the only way you can identify a patient by April 1st of X is through using the individual health identifier, then it becomes a high priority for the chief exec. The top 10 things on the chief exec dashboards in most hospitals in Ireland today in most hospitals in the world, will be the things that they are measured against."*
Senior management eHealth Ireland.	*"Technically the IHI is there. It is sitting there ready to go. What it now needs is a business ownership to drive and implement it. Unless a separate unit is set up that owns manages and delivers IHI, then ICT can't push it out."*

- **Theme 5: eHealth Ireland**

Participant	eHealth Ireland
Senior informatics manager voluntary hospital.	*"Did alot of work in the beginning around culture change, making people more digitally aware. Council of Clinical Information officers to drive change through operations. I think there is still a way to go. While awareness has increased and people want to embrace technology they don't know how to incorporate that into their processes."*
Senior manager, voluntary hospital.	*"As a change driver…I would say probably not. For us a lot of what we have done has been driven on our needs. Go back to maybe Rich Corbridge's time, he was very dynamic in his thinking in relation to what needed to be done, and what investment was required to get there. And I*

	think he came up with a very good strategy around what was needed, but the money didn't follow."
CEO/founder connected health company three.	*"Traditionally there has not been as much investment in ICT PM staff as has been required. EHealth Irl are managing an existing system perhaps with not enough money, resources, and frankly not always with the most up to date skills to do this. They need to hire more software engineers, project managers, and professionals with training in data analytics. I think there is a gap there."*
Ex- senior management eHealth Ireland.	*"The way HSE then restructured E-health and actually it feels like it has died a little bit is perhaps wrong as well. The dilution of the CCIO role which had become so powerful in the re-health Ireland. QIC was led by the CCIO's it wasn't an IT programme it was clinical."*
Founder/CEO connected health company one.	*"I think the CIO of the HSE is the single most senior person with responsibility and talking policy from a technology perspective. I think he has an influence and I think he has the ability then to influence policy."*
Senior management eHealth Ireland.	*"It is restarting again. Some of it came to an end because of personnel changes. We have now brought in an innovation unit and things like QIC will go under that. We want to have an end end process and bring it from innovation through to delivery in as seamless a way as possible."*

- **Theme 6: Budgets**

Participant	**Budgets**
Senior manager, voluntary hospital.	*"If you look at the system, at the moment every hospital in this country gets a budget every year, they don't get a multi year budget. So if you don't get a multi year budget, how can you plan towards those longer term pieces. And centrally the HSE and most public sector areas, there are single year, not multi year budgets. So it's very hard to plan strategically around what longer term investment and this is longer term investment."*
Founder/CEO connected health company one.	*One of our experiences, the buyer has the budget , the money is there, the buyer wants it. A decision had been made about the supplier. But the HBS have allocated all their resources to the children's hospital and can't get it pulled over. So it's not the buyer, it's not the budget, it's four people who look after software in the HBS team are otherwise engaged in buying stuff for the children's hospital."*
Ex- senior management eHealth Ireland.	*"You can't just commit to 12 months money. Because it means that April, May and June are wonderful, the next 3 months are shit because everyone is trying to find out where they have spent the money. The next 3 months are terrible, because everybody is panicking and the last 3 weeks are unbelievable, because everyone has then got money that they didn't know*

	that they had got, that they are trying to spend, in case they have to hand it back at the end."
CEO/founder connected health company two.	*"Although we have had traction during Covid, if you look at the way in which hospitals are funded here, one big capitation grant each year does not lend itself to influence how healthcare is delivered in this country. The budget holder would be a real problem area – trying to understand it."*
Senior management eHealth Ireland.	*"There is a big challenge in this area. In order to deliver something that works in health, which is a multi-disciplinary environment, There are three important areas a clinical lead, a business lead, an ICT lead. You need that business lead/executive sponsorship or it goes no where. The business lead depends if it's a national or local system - HSE or local GM."*
Senior clinician and budget holder	*It's the lack of capacity to write the tenders. It's not the executive ability to buy…you can spend money in our system, you have the authority. Some hospitals are not very progressive and not very interested in buying some new product that someone has seen. So innovation and new products aren't their thing."*

- **Theme 7: Tender process**

Participant	**Tender process**
Founder/CEO connected health company one.	*"The number of people I presented to at senior level in the HSE was just unbelievable. I mean even decision makes. And it went around to houses and around to houses and filling in forms, and it took probably over a year and a half to get the tender written and that's just to define what's needed."*
Senior manager, voluntary hospital.	*"Generally speaking the end end process, probably for us, you could be through it in about 3 months. So, now once you know that you are clear enough at the start, your spec, you get it up, it can be up for a number of weeks. And once that we can make sure that we can get the team together, we can meet. Now that's moving fairly at pace."*
CEO/founder connected health company three.	*"Generally €25,000 for healthcare software is a ridiculously low amount, it should be increased, at minimum to €100k. We deal with trusts in the UK and the rules are interpreted differently or used differently. There are thresholds at 10k, similar to Ireland, but they are often also willing to award local tenders up to 80k Pounds or so, before they go to the EU for wider procurement.*
Ex- senior management eHealth Ireland.	*"If you are a commodity buyer. Because all you are doing is buying on price, which means you are never going to bring digital transformation to your system, because you are just going to buy the cheapest thing that's put in front of you every time."*
CEO/founder connected health company two.	*"We are always going to clinical decision makers to start with. There is no point engaging with HSE procurement if you haven't spoken to them first. A recent tender for us, which wouldn't be the typical - we had been working*

	with Beaumont and the Mater around kidney and lung transplant with a very niche patient population. The time frame from need identified to implementation was a couple of years."
Senior management eHealth Ireland.	*"It (procurement) is a long process - need identified, business case, line up the stakeholders, DPER sanction, then into official procurement stages. Each of those stages can take between two and six months. And procurement is longer, say you have to go for an EU procurement. For alot of small companies, it is quite challenging dealing with us."* *"We want to move away from fixed price, waterfall approach to a more agile type process. You can do this for somethings not for everything. This allow us to bring vendors in and create a sort of framework and get people in to work off of that."* https://fcw.com/articles/2016/12/08/comment-agile-contracts.aspx,
Senior clinician and budget holder	*"I think the potential to speed it up would depend on the hospital side having more capacity to write tenders. I mean one of the reasons they don't is because it's going to take two years and who could be bothered to wait that long, let's just keep going and doing what we are always doing* *"Ideally, you would have a team a small team of dedicated people who do tenders for new innovative products. South west hospital group has a budget of over a billion a year. So they would have a reasonable number of need for new products, brand new that need to be tendered or old ones that are out of date need to re-tender. That's a pretty specialised thing. It would be better done if someone was doing that for the whole group."*

- **Theme 8: Company size**

Participant	**Company size**
Founder/CEO connected health company one.	*"No start up company could go through that process and survive, they just couldn't. You can't wait 4 years and not have revenue coming in the door."*
Senior manager, voluntary hospital.	*"Always, even when you go out to tender, you want to get a strong company whose going to be in the market. And that is a criteria for us in relation to it, to make sure that a company has the ability to be in the market and not go into liquidation or whatever."*

CEO/founder connected health company three.	*"I think in fairness, eHealth Ireland, and ICT executives generally, want to buy something from a company which is going to be around in three or five years' time. With many health tech start-ups that is not a given. An idea is for the larger players to be able to bolt-on innovative technology solutions at a customer's request via a 'change order'. This way, you can still foster innovation via SME's without the risk of doing business with a small company, which may not have the financial backing or certainty required for larger tenders.*
Ex- senior management eHealth Ireland.	*"And some of the, let's face it quite old school behaviours around how big organisations need to be before the HSE can even contract with them. Even if there has to be a two tier model to procurement and digital. One for small scale change and innovation and one for the mega vendor the Microsoft, the Oracles, the E.H.R vendors that are out there."*
Senior management eHealth Ireland.	*"In healthcare when you have a company, that is delivering a critical piece of process, they need to have size, scale and robustness. In my view, a lot of the start-ups that want to sell into the HSE don't want to partner with somebody to give them the size and scale piece. They have the innovation, they have the knowledge but with some there is substantial risk because of the size."*

- **Theme 9: Reimbursement for connected health**

Participant	**Reimbursement for connected health**
Founder/CEO connected health company one.	*"The system, they don't have the skill set, they don't have the competency to understand. I mean it's not that difficult to find a clever IT guy, to put it into the bloody HBS and the head of ICT and say look, when you engage a company you at least know the lingo when you are talking about. The whole system is broken they have not got the ability, not only to not have a consistent process. But there is no process."*
Senior manager, voluntary hospital.	*"I'm not aware of a standardised assessment process for connected health solutions."*
CEO/founder connected health company three.	*"I don't think it is clear. The guidance is not all that defined. If the purchaser wants you then they can figure out a way to buy you under the threshold limits. If they don't, they use the tender limits as an excuse why they can't. I do, however think that when large procurements are run they do their best to run them fairly."*
Ex- senior management eHealth Ireland.	*"Why isn't it clear, why isn't it published what the route is?"*

CEO/founder connected health company two.	*"The reimbursement pathway is the biggest barrier to connected health solutions in Ireland, tied to that is the care pathways. Look at Germany, the big change there was the Act committed to reimbursement through federal public health insurance."*
Senior clinician and budget holder	*"You'd have to demonstrate saving to somebody and it's that's simple…you'd have to demonstrate that your product was actually saving money. I mean all they need to demonstrate is that it saves the global system money to do what they are currently doing and by and large that's enough to get a product in. I mean it isn't that complicated."*

- **Theme 10: Key enablers**

Participant	Key enablers
Founder/CEO connected health company one.	*"What you need is, you 100% need a champion. You need a strong leader and champion inside the HSE system, you need someone that's not just going to feel something is being imposed upon them. You need people in there that are going to fight the case internally. And I think you need that at two levels. You need that at operational level, somebody on the ground that can influence. And then somebody at management level, that tick it and go, I'm going to executives in the HSE, to make sure that there is buy in and I think if you get that, it would be very powerful.* *"We need the right skills and capabilities within the HSE which is that, CIO role I think. And a function underneath. Because I think the functions underneath help, I think they are critical."*
Senior manager, Voluntary hospital	*"A very progressive IT department locally. And actually that's maybe a difference to maybe some other statutory hospitals, where they don't have necessarily an IT department on site. We have companies who are very willing to work with us. And I think part of that is, that they know that maybe the relationship will be easier to navigate, easier to get involved."* *"Demand is going to come from patients. Patients are going to expect this. People don't want to get on a phone. And even at that in relation to the interaction with patients, they want it to be either through apps or through email or whatever, rather than actually by phone. Because it's more efficient and it's on their terms. Which is right. So this is a customer focus piece in relation to delivering health care."*
CEO/founder connected health company three.	*"Events can be good to get to know people and foster conversations. I don't see a huge amount of enablers in the system. That was what was refreshing about Richard Corbridge. The programmes that were offered, like the QIC, got companies into the system, it got things working. In our experience, there is proven clinical benefits, time saving, and financial efficiencies coming from this.*

	"A minimum spend on ICT projects should could be helpful. Spending on eHealth has to be within same lines of European average. Traditionally, that has not been the case."
Ex- senior management eHealth Ireland.	*"The HSE now needs to appoint a CIO, it needs to decide whether it's killing E-health Ireland or not, and it needs to procure the E.H.R.* *"Every hospital system should have a CIO that sits on the board of the hospital. that is believed by the board to be as equal standing as the estates person or the finance person or the HR person."*
CEO/founder connected health company two.	*"The biggest enabler now post Covid is the need to reform patient pathways. That will drive fundamental shift. Every clinician we talk to says we can't go back to waiting rooms full of people.* *"No easy solutions but the rate of change here has been so painfully slow that there needs to be some radical thinking. E prescribing was signed into legislation during the pandemic. It had been sitting waiting to be signed into law for five years."*
Senior informatics manager voluntary hospital.	*"National support, things like the Spark programme Sláintecare funding, HIHI,– raises the profile of companies helps them get started. Lends certain credence knowing that they have gone through a process at certain point means you are engaging with someone who has fully considered their business, their product. A reference site always helps."* *"Since Covid, the value being delivered by telehealth is incredible – young people with chronic illnesses don't have to take a half day off work to come up from Wexford or Waterford to attend St James for a visit that takes 20 mins.* *They also want their information to be shared with them and I think it's that expectation will drive it more."*
Senior clinician and budget holder.	*"Innovation is something that the Department of Health sort of needs to be encouraged to do all the time, or needs to be encouraged to encourage. So if they were to really include that in their engagement with the HSE, it would come through, there's no doubt it would come through. The managers will respond to what he managers will respond to whatever is highlighted in their performance review - digital maturity is part of their performance assessment - we want you to do this and we are going to be asking you every month and performance base, they will respond to that."*

Appendix 2: Survey questions

Postgraduate research: Assessing knowledge, understanding and/or experience of commercialising connected health products in the Irish public health system

As part of a research project for the NUIG Postgraduate Diploma in Technology Commercialisation this survey aims to assess the knowledge, understanding and/or experience of connected health companies with the Irish public health system. Also to identify conditions that support successful connected heath companies with a sustainable business model in public health.The data is anonymous and will only be used for the research project 'Commercialising connected health in the Irish public health system - barriers and enablers'. Survey closes June 2.
Please bear in mind that this research is assessing the 'regular system' rather than the 'emergency system' - answers should reflect pre-Covid 19 experience.

OK

* 1. How many personnel are employed within your company?

- Less than 10
- Between 11-50
- Between 51-250
- Over 250

* 2. During the last business year what was your turnover?

- Less than €3m
- €3m - €5m
- Over €5m

* 3. Is the company owner or manager run?

- Owner
- Management

* 4. Please choose all that apply to your product(s)

- [ ] Mobile health (mhealth -health practice supported by mobile devices, such as mobile phones, patient monitoring devices, personal digital assistances and other wireless devices).
- [ ] Software as a Medical Device (SaMD -software intended to be used for one or more medical purposes that perform these purposes without being part of a hardware medical device).
- [ ] Health information technology (HIT -supports health information management across computerized systems and the secure exchange of health information).
- [ ] Wearable devices (electronic devices that consumers can wear designed to collect the data of users' personal health).
- [ ] Telehealth (use of tech such as computers and mobile devices, to access health care services remotely and manage your health care).
- [ ] Telemedicine (caring for patients remotely when the provider and patient are not physically present with each other.)
- [ ] Other (please specify)

* 5. Please tick which applies to your company's offer

- ◯ Product
- ◯ Service
- ◯ Both

* 6. Are you an Irish company

- ◯ Yes

Other (please specify)

* 7. Is your primary market

- ◯ US
- ◯ EU
- ◯ Both

Other (please specify)

* 8. Is your product or service reimbursed/procured or in-use a health system? Please choose all that apply

- [ ] Irish Public health system
- [ ] Irish Private healthcare
- [ ] UK
- [ ] EU
- [ ] US
- [ ] Not in use

* 9. If your product is in-use the Irish health system, how long did the process of engagement through 'procurement' through to 'use' take?

- [ ] 3-6 months
- [ ] 6-12 months
- [ ] 12- 24 months
- [ ] 24 months +
- [ ] not in use
- [ ] Other (please specify)

* 10. How do you engage with the Irish health service?

- [ ] Personal contacts
- [ ] Cold approach - research contacts online
- [ ] Health Innovation Hub Ireland
- [ ] HSE events
- [ ] Health Business Services
- [ ] ehealth Ireland

Other (please specify)

* 11. How satisfied are you that you can connect with Irish clinical experts in the field where your product can be applied?

- ( ) Very satisfied
- ( ) Somewhat satisfied
- ( ) Neither satisfied nor dissatisfied
- ( ) Somewhat dissatisfied
- ( ) Very dissatisfied

* 12. How satisfied are you that you can connect with budget decision makers in the Irish system where your product can be applied?

- ( ) Very satisfied
- ( ) Somewhat satisfied
- ( ) Neither satisfied nor dissatisfied
- ( ) Somewhat dissatisfied
- ( ) Very dissatisfied

* 13. Are you satisfied that reimbursing connected health products and services in Ireland is currently based on evidence regarding their performance in the light of health system goals?

- ◯ Very satisfied
- ◯ Somewhat satisfied
- ◯ Neither satisfied nor dissatisfied
- ◯ Somewhat dissatisfied
- ◯ Very dissatisfied
- ◯ Undecided

* 14. The pathway for procurement in the Irish public health service is clear to connected health companies that wish to engage with it?

- ◯ Strongly agree
- ◯ Agree
- ◯ Neither agree nor disagree
- ◯ Disagree
- ◯ Strongly disagree
- ◯ Undecided

* 15. Do you follow CPV codes? (CPV codes are a system of classification for public procurement which uses standardised vocabulary to help procurement personnel classify their contract notices consistently and to make it easier for suppliers and contracting authorities to find notices.)

- ☐ Yes
- ☐ No

If yes, please specify the codes

* 16. Do you agree that it could benefit Ireland to shift to a values based model of care delivery? (The value-based care model, broadly followed in the US, focuses on lowering cost through improving health outcomes. Quality of care is assessed on outcome metrics - reducing acute readmissions, increase preventative care, engaging certified health technology.)

- ◯ Strongly agree
- ◯ Agree
- ◯ Neither agree nor disagree
- ◯ Disagree
- ◯ Strongly disagree

* 17. How helpful would an effective national electronic health record system be to your product?

- ○ Extremely helpful
- ○ Very helpful
- ○ Somewhat helpful
- ○ Not so helpful
- ○ Undecided
- ○ Other (please specify)

* 18. How helpful would a unique patient identifier (HSE's Individual Health Identifier) to your product

- ○ Extremely helpful
- ○ Very helpful
- ○ Somewhat helpful
- ○ Not so helpful
- ○ Undecided
- ○ Other (please specify)

* 19. Are you aware of any a national health strategy in the area of connected health?

- ☐ Yes
- ☐ No
- ☐ If yes, please specify

OK

* 20. What are the challenges your product faces to commercialisation in the Irish Health system? Tick all that apply

- ☐ National health budget
- ☐ Access to clinical settings
- ☐ System interoperability
- ☐ Current procurement pathway
- ☐ Lack of appetite of clinical staff
- ☐ Current HSE budgets
- ☐ Heath systems processes
- ☐ Lack of long term investment
- ☐ Insufficient policy support
- ☐ A closed system

- [ ] Engaging with budget holders
- [ ] Other (please specify)

* 21. How helpful would specific health policy support for connected health be to the success of your product in the Irish health system? (For example the German Federal Ministry of Health passed the Digital Care Act last year)

- [ ] Extremely helpful
- [ ] Very helpful
- [ ] Somewhat helpful
- [ ] Not so helpful
- [ ] Undecided
- [ ] Other (please specify)

* 22. Who should pay for connected health applications and services?

- ○ Health System
- ○ Insurers
- ○ Patient/user
- ○ Free, if user agrees to data share with the developer
- ○ Introduce a "value-based digital health" reimbursement model: since health systems hold the data needed to measure outcomes, use this information to measure the outcomes of digital-health services. e.g developers are paid based on the system's savings
- ○ Other (please specify)