

Evaluation of Procurement Practice for Digital Health

POSITION FROM THE INDUSTRY PERSPECTIVE



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A strategic approach to the procurement of effective digital health solutions is key to the transformation of the health service of Ireland and many other countries. Faced with an international pandemic in 2020, the increasing challenges of an ageing population and limited public resources, it seems prudent and timely to review the criteria used for the evaluation of digital health solutions.

This review is intended as a contribution to a consultation process for an updated and standardised approach to procurement in order to benefit procurers in selecting the best in class product(s) in terms of value, outcomes, cost and other important factors for consideration.

HealthTechIreland

About HealthTech Ireland

Ireland's HealthTech Industry provides medical Diagnostics, Devices and Digital solutions to help people live healthier lives.

As an independent trade association, we represent the manufacturers, developers and distributors of health technology products and solutions provided to the health system in Ireland.

HealthTech Ireland provides a forum for the development and advocacy of policies that support innovation in health technology to address patients' healthcare needs. Our member companies include the full spectrum of health technology supply and service companies from Small/Medium Employers to Multi-National Companies, many of whom have Research and Innovation and /or manufacturing facilities in Ireland.

Our members provide safe, effective and innovative health technologies that save and enhance lives, benefiting people and society. If a health product is proven to be safe, clinically efficacious and cost-effective patients should have access to it, no question.

HealthTech Ireland aims to connect the industry and the health system through collaboration, education and advocacy. HealthTech Ireland is a member of MedTech Europe and of Global Medical Technology Alliance.

This paper has been prepared in collaboration with HealthTech Ireland members, SGS Ireland.

Foreword

HealthTechIreland

The power of digital healthcare solutions shone bright during 2020 against the backdrop of a global pandemic. It transformed how care is delivered to patients, how clinical decisions are made and how effective information is communicated. Here in Ireland, the Health Service Executive (HSE) were able to rapidly adopt new technologies to solve the immediate problems they faced.

Whether it was establishing tele-health consultations, connecting digital imaging throughout the country or deploying Covid-19 tracking apps, the solutions were there, ready to be implemented. Ireland is fortunate to have on its doorstep the World's leading healthcare companies, technology companies and highly innovative SMEs involved in Digital, Diagnostics and Devices. Many of these companies look outside the country to successfully deliver their solutions, as they encounter difficulties in breaking through the barriers in Ireland. They invest in many "proof of concept" projects within the system but rarely see this translate into national deployments. With its size, structure and access to technology, Ireland is uniquely positioned to be a leader in Digital Healthcare. Ireland is small enough that we should be able to harness the capabilities of the organisations mentioned above, however big enough to be recognised internationally in making an impact.

During my time supporting HealthTech Ireland, I have seen the commitment of our members to play their part in making this Digital Transformation happen. We are joining the dots so that we won't have to wait for the next crisis to avail of what's on our doorstep.

I welcome the publication of this report which articulates the current experiences of members engaged in the procurement process. It is essential that digital technology is evaluated when we seek to identify solutions to addressing healthcare challenges. We do not want to be left behind. The need to evaluate technology appropriately, based on criteria that measures the value and impact it can play in the delivery of healthcare rather than simply the traditional "lowest price", will enable better outcomes. Understanding where we are today is a great place to start as we partner to deliver better healthcare for Ireland tomorrow.

Colin MacHale,

Chair HealthTech Ireland Leadership Forum EMEA Territory Sales Director, Intel Corporation

Recommendation Summary

- 1. The establishment of a collaborative task force within the HSE and supported by the Department of Health, the regulators and industry to develop and propose a standardised evaluation framework with appropriate criteria and weighting for digital health interventions. This task force must be empowered, upon providing appropriate evidence for these criteria, to prepare a roadmap for adaptation of existing procurement processes, taking into account the specificity of digital health and guidelines for procurement experts and officers. It is important to recognise the Office of Government's (OGP) strategy and the need to introduce efficiency in standardised, repetitive processes and use RPA to do so. This could help efficiency and transparency in procurement and may help to drive standards and evidence of compliance, but several criteria will continue to require human judgment. In support of the framework and roadmap, it is vital that associated standards and comprehensive guidance are developed. This task force can only benefit from the inclusion of industry representation working together with all relevant stakeholders.
- 2. Upskilling and education is recommended across policymakers, to procurers, healthcare providers, professionals and industry, in order to harness innovation linked to unmet needs and issues faced by our health system. This is not something that can happen quickly, but the standards and guidance produced by the recommended task force forms the basis for this upskilling, with identified knowledge gaps addressed. In order to bring new innovations to our health system, upskilling with regard to new and established criteria in procurement practice and the deployment of new procurement frameworks and processes is necessary. Transformation brings about significant change, and education on adapting to change is a key component towards digital health transformation.
- 3. Willingness within industry to embrace appropriate standardisation and to implement design principles around privacy, quality, security and other important criteria that support value within the system. Transparency in these regards are critical to building trust so that industry may build partnership relationships with our health service.



Introduction

A strategic approach to the procurement of effective digital health solutions is key to the transformation of health services across the world, including Ireland. Faced with an international pandemic in 2020, the increasing challenges of an ageing population and limited public resources, it seems prudent and timely to review the criteria used for the evaluation of digital health solutions during procurement.

This review is intended as a contribution to a consultation process for an updated and standardised approach to procurement in order to benefit procurers in selecting the best in class product(s) in terms of value, outcomes, cost and other important factors for consideration.

This research was commissioned by the HealthTech Ireland Leadership Forum, chaired by Mr. Colin MacHale, Intel. The Forum membership includes senior leaders from many of the largest industry operators in digital health, including Change Healthcare, Vodafone, UiPath, Stryker, Irish Life Health, Athena Lifesciences, Novartis, Critical Healthcare and Amazon Web Services (AWS). The Forum also includes senior representation from Enterprise Ireland and the health service. The primary goal of the Forum is to help drive forward the adoption of digital health in Ireland in a safe, meaningful and sustainable way in partnership with the health system and aligned with implementation of the Department of Health current ten year strategy to improve our health and social care services; Sláintecare, and the eHealth Ireland digital health strategy.

This paper explores procurement approaches in digital health, reviewing international practice with a particular focus on Ireland in our supporting research. Industry members of HealthTech Ireland were surveyed anonymously to establish their experience and perceptions, following the conduct of an international literature review to establish key factors used in procurement when assessing or evaluating digital health solutions. The survey data and review forms the basis of this position paper and recommendations arising from the research.

The industry response has been significant with views shared on the articulation of procurement requirements, inclusion of smaller suppliers, and procurement criteria and selection methods that are taken into account by procurers. The findings have enabled HealthTech Ireland and its members to gain important insights into current procurement practices, most especially the procurement of digital health products and services, and to make more informed recommendations to policy makers and others to aid further the development and futureproofing of the procurement process in Ireland.

This position paper builds on recommendations made in published HealthTech Ireland papers, New Approaches for Procuring Effective Healthcare Solutions, published in 2015 and, Assessing the Value of Medical Technologies in the Prevention, Diagnosis, Treatment and Rehabilitation of Disease in Ireland, published in 2018.



Criteria used for Assessing Healthcare Products and Services

In terms of procurement, it is vital that the key criteria for selection of a digital health solution are considered and weighted, and take into account both the innovative nature of digital health, the breadth of the industry, wider social concerns including those that are triggered by deployment of digital health solutions and the importance of ensuring efficacy and efficiency, strategic value and longer term impact.

While the literature search was particularly focused on approaches to digital health evaluation for procurement, the net was cast wider to gather findings to include the broader health sector and other sectors where digitalization is influencing change. The review included peer reviewed research, grey literature and references to relevant standards, where these were used to support procurement choices. This enabled the generation of a number of criteria which are used in procurement including well established criteria such as price and emerging criteria such as cyber security standards. Table 1 below lists the criteria discovered. They have been categorised into overarching headings (See Table 1), which are discussed in detail. An outline of all other criteria is available at Appendix II.

TABLE 1: CRITERIA USED IN PROCUREMENT		
Cost of purchase & implementation	Transformation potential	Product quality
Extent & cost of systems & process integration	Environmental impact	Trust
Cost of operation	Usability	Service quality
Cost of upgrades/maintenance	Safety (patient)	Privacy
Security	Safety (staff/users)	Project delivery quality
Scalability	Safety (reputation)	Dependability

Transformation potential

The literature offers little insight into how procurement practices review or rank transformation potential and how implementation of digital health may impact health services transformation, yet this criterion forms the foundation of defining value. As highlighted in our previous position paper on procurement, defining the value of any intervention (patient health outcomes per unit of currency spent) is vital to spending well. What is surprising is the absence of references to transformation potential being included as a selection criterion in the procurement process. *Transformation potential offers a measurable key performance indicator in defining the value of a digital health innovation.* A case study of transformation of health service and systems impact resulting from the adoption of digital health from HealthTech Ireland member, Syncrophi is detailed below:

eHealth as a new paradigm relies on mass acceptance of digital health solutions by nursing and medical staff, who are often working in highly resource-constrained and pressurised environments. This can lead to very slow engagement with new digital health systems as staff frequently feel overwhelmed by their existing situation and do not feel that they have the time or cognitive resources to dedicate to embracing new things. This of course is quite ironic as optimally designed systems which meet medical-grade standards of performance and usability would serve to alleviate some of the difficulties faced by frontline workers in a measurable way.

KEWS300 as a case-in-point, is a Class IIb certified Vital-signs Automation and Workflow Support system for application at the Hospital Ward Point-of-Care. This system which may be deployed in any hospital, whether or not they have embarked on the eHealth journey, relieves nurses of much rote work and cognitive burden while saving them time and eliminating the vast bulk of opportunities for human error in the application of complex Early Warning Score systems and Escalation Protocols. The result is safer patients, better outcomes and staff who are both more productive and less burdened. Furthermore, the system patient charts and data to be accessible remotely such as at the Central Station or in doctor's offices, for the benefit of medical and ward-management staff.

As such, this single system, when deployed in a hospital will be used by over 50% of the hospital employees multiple times every day (since nurses and doctors typically make up 55% to 60% of the employees of a hospital). Because the KEWS300 system interfaces with the vital-signs equipment in use in the Wards and also with any other relevant hospital information system, such as the PAS or the EHR, it can be implemented in a mature eHealth environment or as the first investment on the route to a comprehensive eHealth system. In the latter case, due to its major emphasis on 'usability' (it complies with the Medical Device Usability Standard EN62366) it can have a transformative impact on the acceptance of digital health systems by this very large cohort of staff.

Evidence of Transformation

Large Irish Hospital (Per Study)

- Error-rate dropped from 49% to 0%
- Patient Care 4.86/5
- Staff productivity 4.71/5
- Ease of Use 4.57/5



Criteria used for Assessing Healthcare Products and Services

Cost of purchase & implementation

Not surprisingly, the review pointed to cost of acquisition/implementation as the number one factor in procurement decisions. It appears most frequently in Requests for Proposals (RFPs), and most RFPs attach a strong weighting to the cost element. RFPs rarely ask suppliers to estimate buyer resource requirements, for example the expected internal staff time requirements, even though these may be significant if the product or service is completely new or a process change is required. This is particularly important now, as our health system is currently exploring wide adoption of Robotic Process Automation, (RPA), a digital innovation with broad applicability across healthcare processes.

In order for successful deployment of RPA and benefits realisation, detailed process mapping is required. There is significant cost associated with this, of an order of magnitude higher than the cost of the RPA solution itself. The literature did not shed any light on costs incurred after initial contract in the light of discovery during the implementation process and how effectively contingencies in tenders anticipate these.

Product quality

Product quality covers compliance with internationally recognised standards (where they exist), robustness, scope of function and traceability through development, test and change logs. A challenge with all innovations is that new standards may not emerge and be formally recognised until the 'product' becomes a recognised market product. Until such time, quality indicators may be driven by the innovator rather than the buyer and may be the subject of intellectual property protection.

Again, there is a need to undertake further research here to assess how procurement officers ensure quality in all aspects (for products and services), the presence of agreed standards and the need for adaptation and development of standards in digital health to ensure transparency. In this respect, there is a need to explore how suppliers and buyers can collaborate to ensure confidence of the latter while respecting the confidentiality of the former, not least in the absence of recognised, appropriate standards in a sector where there is so much innovation.



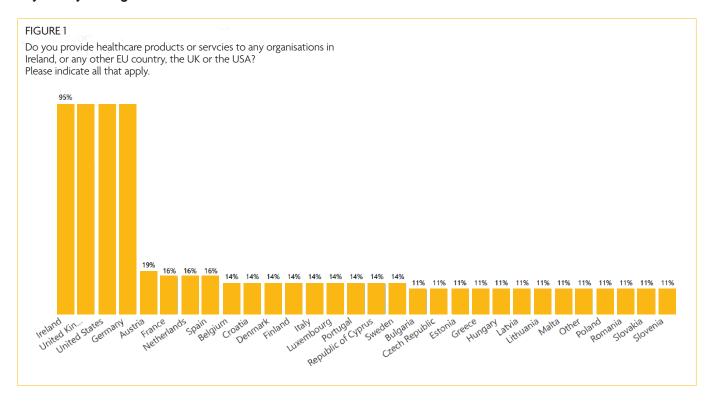
Survey

The criteria extracted during the international review informed the creation of an industry survey to elicit views on the criteria¹ currently considered during procurement of digital health products and services in the Irish Health system.²

The industry response has been significant with views shared on the articulation of procurement requirements, inclusion of smaller suppliers, experience of buyers' priorities of procurement in practice and perceived variables that are behind the criteria used in current procurement practice.

Responses were supplied by a broad and widely representative cohort of HealthTech Ireland members from start-ups right through to large multinational businesses. The survey aimed to provide a (limited) profile of the respondents, their experience in qualifying as suppliers and the variables on which they are asked to provide information and/or are being assessed in the procurement process.

Key Survey findings



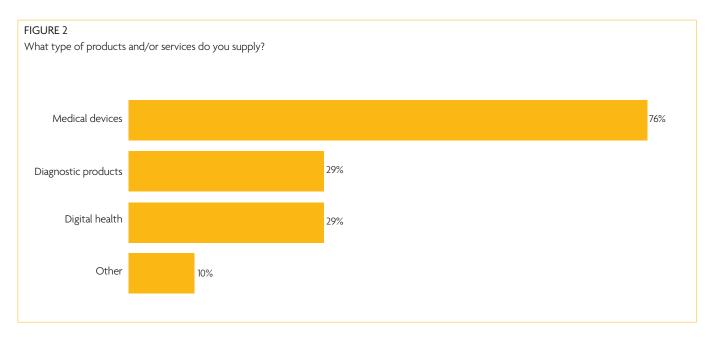
The range of markets

95% of the respondents supply to the Irish market, followed by the UK (68%). The majority of respondents provide distribution and value-added services in Ireland with a small number of respondents supplying products for other EU and global markets. A large number of countries are supplied by a small number of Healthtech companies in Ireland.

¹ For the survey, a variety of variables were presented in order to help understand the actual criteria experienced by respondents from HealthTech Ireland members.

It should be noted that several survey respondents supply to other countries and their responses are not solely based on experience in the Irish market. Where possible, the analysis cross referenced to note any differences between those that supply to Irish as well as non-Irish markets and those that only supply Irish markets.

Survey



Overall, medical devices constitute the largest (76%) proportion of HealthTech products & services, with an equal number providing diagnostic and 'digital heath' (29%) products & services.

Section 2

The next series of questions were focused on gathering suppliers' experience of the procurement process. Responses were scaled over 5 points from strongly agreed to strongly disagreed.

Part A

Statement one:

"Procurement decision are almost always based on cheapest price"

73% fully agreed (27%) or agreed (46%) that procurement decisions are almost always based on cheapest price. 19% disagreed or strongly disagreed with this statement. 8% were neutral. This is also reflected in responses to the statement 'Purchasers generally only focus on cost and delivery schedules'; 77% either strongly agreed or agreed and only 8% either strong disagreed or disagreed.

Statement two

"Procurement requirements exclude smaller suppliers"

40% agreed or strongly agreed, 36% strongly disagreed or disagreed and 24% were neutral.

Statement three

"Procurement requirements are generally very well-articulated with respect to delivery & service requirements"

Note this statement refers to delivery and service requirements. 57% either strongly agreed (3%) or agreed (54%). However, slightly worrying is that 25% either strongly disagree or disagree with the statement.



Statement four:

"Procurement requirements are generally very well-articulated with respect to patient & service user outcomes"

The responses to this statement concerning patient and service user outcomes show a rather different picture than statement three. Some suppliers have experienced a focus on patient & service user outcomes (35%) but more have not (44%).

Part B

This section of statements is framed around the question:

'How would you describe attitudes of healthcare purchasers/procurement officers with respect to new digital health options?'

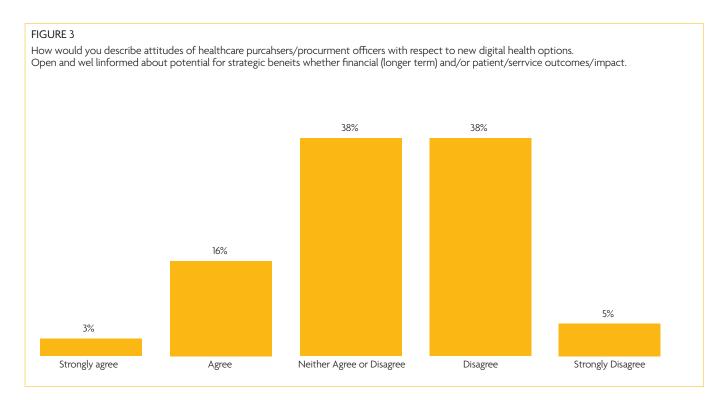
Statement five

'Open and well informed about potential for strategic benefits whether financial and/or patient/service user outcomes/impact'.

The results suggest a transactional rather than a transforrmational or value-based approach with 19% agreeing and 43% disagreeing.

Statement six

'Knows the research but won't take the risk of investing in something new unless mandated', shows only 6% disagreeing.

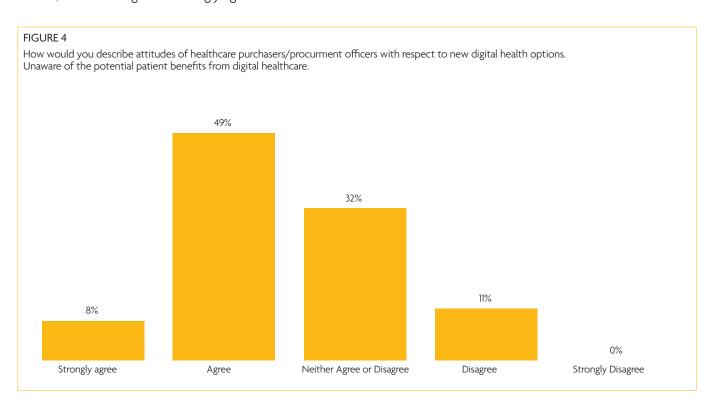


Survey

Statement seven:

"Unaware of the potential patient benefits from digital healthcare".

Overall, 57% either agree or strongly agree with this statement.



Where suppliers are exclusive, this percentage rises significantly which is not surprising.

Statement eight:

'Unlikely to consider as they believe staff won't like it, management too risk averse, decision is not one for procurement' shows only 3% disagreeing, reinforcing supplier experiences of the challenges faced when introducing digital health products and services.

These above responses may be a result of where in the decision making process strategic decisions are taken and would benefit from further research to understand the relationship between strategic decision making and procurement decision making to support the evolution towards a more value based approach in digital health.



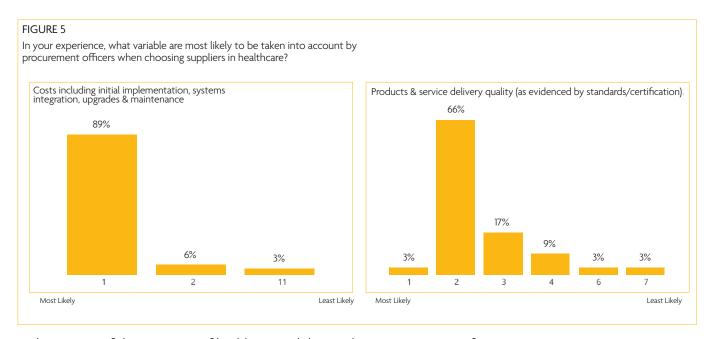
Section 3

The third section of the survey aimed at collecting supplier experiences of the variables that are taken into account in the procurement process and what is and is not included when healthcare organisations seek suppliers. The question asked was:

'In your experience, what variables are most likely to be taken into account by procurement officers when choosing suppliers in healthcare?'

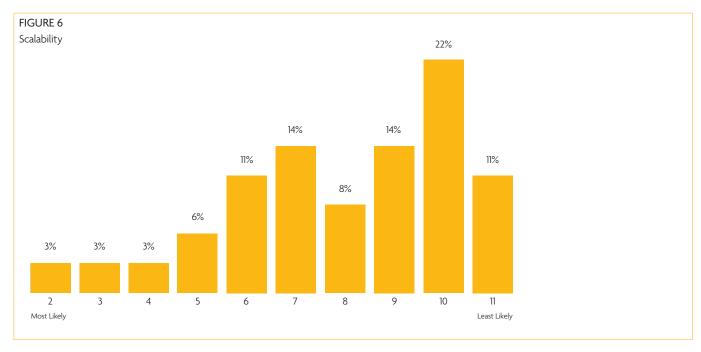
Respondents were provided with a range of variables drawn from the literature review. It is important to note that this question did not ask specifically about their experience in digital health but more broadly in healthcare. The results present some extremely valuable insights which both reinforce and add to the picture described above in Section 2.

A selection of results is provided below. The results are self-explanatory but it is worth pointing out a few specifics. Additional survey findings are available in Appendix III.



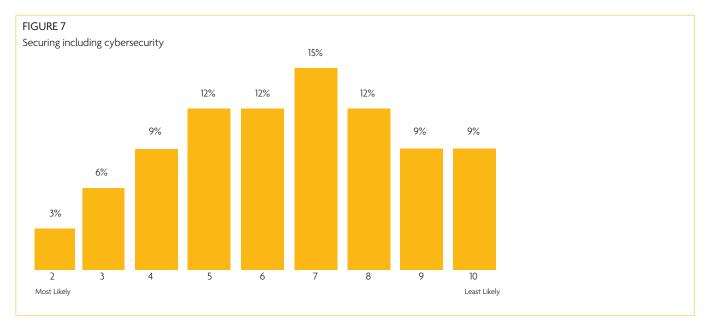
In the context of the rising cost of healthcare and the need to ensure patient safety, understandably cost and quality rank as the highest priority.

Survey



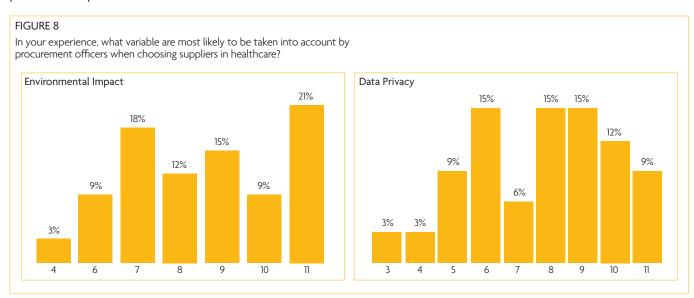
Usability and user experience along with safety also rank highly. On the other hand, evidence of patient outcomes has slightly more responses on the least likely end of the scale. (6-11 inclusive). A surprise is the question of scalability with almost all respondents ranking it on the least likely end of the scale.

This may suggest the immaturity of the market and the cautious adoption of digital health solutions as well as the fragmented nature of the demand side. On the other hand, supply dependability has a significant majority indicating it is most likely as a variable in the procurement process.

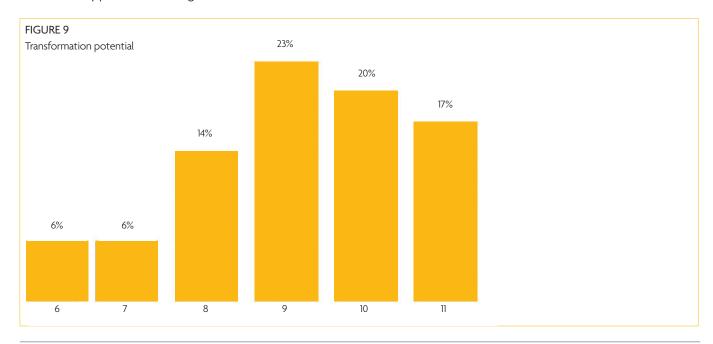


Rather significantly and given that these suppliers come from the digital health sector, a very large majority have experienced security including cyber security, as among the least likely variables to be considered as a priority during the procurement process.

Environmental impact and data privacy also show very large majorities who have experienced these as least likely variables for inclusion as criteria. Given the growing concerns about data privacy and the green agenda targets, these variables are surprising omissions in the procurement process.



Finally and perhaps most importantly, the variable 'transformation potential' is rated by all respondents as the least likely variable to be considered. When asked to rank the criteria according to experienced or perceived consideration given during the procurement process, transformation potential was rated by most at the least likely to be considered end of the scale. This supports the findings of the literature.





Conclusions

It is apparent from the survey results, that industry experience of practices for procurement of digital health solutions in Ireland leans heavily towards a price-based procurement model. The survey data largely supports the findings of the literature review.

Value-Based Procurement

In order to achieve best in class solutions that take all important and relevant evaluation criteria into account, it is necessary to depart from transactional price based procurement, beyond the Most Economically Advantageous Tender (MEAT) process and towards Value Based Procurement.

Price based procurement is characterised by focusing solely on the cost of the solution, the only evaluation criterion is price, the vendor relationship is transactional and benefits are most likely to be short term.

The MEAT procurement model is characterised by inclusion of needs specification with commercial and qualitative evaluation criteria. The focus is on technical performance and quality versus total cost of ownership.

Value Based Procurement adds an important dimension with a focus on impacts, particularly to the patient, while also looking ahead to cost saving impacts of the solution and other relevant criteria.

Based on the review, the selection of a range of criteria as highlighted in Table 1 is important to explore in detail in order to achieve and future proof value based procurement and deliver measurable outcomes and impact including positive patient impact, cost effectiveness and savings, safety, quality, security and sustainability. It is only by evolving towards a value-based procurement model that we can build relationships between the health system and industry, considering all important criteria aspects and enabling the adoption of and benefits from new innovations in healthcare. This approach is vital to building trust, capacity, transparency and sustainability into our health system.

Digital health and HealthTech in general evolves quite quickly when compared with physical healthcare equipment. Innovation often (although not always) emerges from new market entrants and/or smaller suppliers. In an immature market, with only one or few suppliers, cost of investment recovery may be much higher than in a mature market with many suppliers. Traditional price only based approaches may discourage the smaller and/or more innovative suppliers. Digital health development takes an iterative approach, adopting a process of continuous improvement, often over short timeframes. Innovative solutions require innovative and robust procurement practices in order to ensure ongoing benefits realisation.

Value based procurement involving a wider number of criteria offers the opportunity for procurers and industry to work together in partnership, enabling future benefits to be harnessed at the point of procurement.

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Key Recommendations

- 1. The establishment of a collaborative task force within the HSE and supported by the Department of Health, the regulators and industry to develop and propose a standardised evaluation framework with appropriate criteria and weighting for digital health interventions. This task force must be empowered, upon providing appropriate evidence for these criteria, to prepare a roadmap for adaptation of existing procurement processes, taking into account the specificity of digital health and guidelines for procurement experts and officers. It is important to recognise the Office of Government's (OGP) strategy and the need to introduce efficiency in standardised, repetitive processes and use RPA to do so. This could help efficiency and transparency in procurement and may help to drive standards and evidence of compliance, but several criteria will continue to require human judgment. In support of the framework and roadmap, it is vital that associated standards and comprehensive guidance are developed. This task force can only benefit from the inclusion of industry representation working together with all relevant stakeholders.
- 2. Upskilling and education is recommended across policymakers, to procurers, healthcare providers, professionals and industry, in order to harness innovation linked to unmet needs and issues faced by our health system. This is not something that can happen quickly, but the standards and guidance produced by the recommended task force forms the basis for this upskilling, with identified knowledge gaps addressed. In order to bring new innovations to our health system, upskilling with regard to new and established criteria in procurement practice and the deployment of new procurement frameworks and processes is necessary. Transformation brings about significant change, and education on adapting to change is a key component towards digital health transformation.
- 3. Willingness within industry to embrace appropriate standardisation and to implement design principles around privacy, quality, security and other important criteria that support value within the system. Transparency in these regards are critical to building trust so that industry may build partnership relationships with our health service.



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Appendices

Appendix I - Methodology

The HealthTech Ireland Leadership Forum commissioned the secretariat to explore procurement practices in Ireland relating to the procurement of digital health solutions.

This research has been undertaken with the support of Jane Massy, International Monitoring & Evaluation Consultant at SGS Ireland, (a HealthTech Ireland member), in all stages of the preparation of this paper. SGS is the world's largest inspection, verification, testing and certification company.

With the rapid growth of innovation in digital health, it is of particular interest to establish whether current and established procurement practices in healthcare in Ireland need to be updated for digital health solutions. Evaluation of digital health interventions is complex with many factors for consideration in order to procure the best in class solutions and go beyond piloting to ensure scalable and effective implementation. This research involved an international review of literature, exploring relevant research and the procurement criteria utilised in other jurisdictions for the procurement specifically, but not exclusively, of digital health solutions.

The findings from the literature review informed the development of a survey questionnaire circulated to associated industry members operating in Ireland with an interest in digital health. The aim of this survey was to establish the current industry perceptions on digital health procurement in Ireland and the markets they supply based on their direct experience.

Questions and Responses.

The survey was structured in three sections: the first was aimed at profiling the respondents in so far as was possible in an anonymous survey. The second asked respondents about their experiences in the procurement process by providing a series of statements and asking them to rate their responses on a five point Likert scale (strongly agree to strongly disagree).

The third section asked respondents to rank (from least likely to most likely) a number of variables drawn from the literature that in their experience have been included in the criteria stated in RFPs. In other words, the survey aimed to provide a (limited) profile of the respondents, their experience in qualifying as suppliers and the variables on which they are asked to provide information and/or are being assessed in the procurement process.



Appendices

Appendix II – Criteria used for digital health procurement

Extent & cost of systems & process integration, cost of operation and cost of upgrades/maintenance

These costs are often internal (to the buyer) and the literature on procurement generally does not provide much information about the prevalence of detailed full cost analysis and there were no specific findings for the digital health sector. Given the innovative nature of digital health, there is a strong possibility that the buyer may need to undertake internal changes (whether to processes or capability), and these internal costs may be quite significant.

Nor did the literature provide evidence of detailed future forecasts and any later verification of actual costs of operation and where relevant, upgrades and maintenance. Finally, none of the papers on procurement in this study reveal any insight in general about how costs are treated (operationalised or capitalised) and there is a case for further research to investigate this and whether supplies that are capitalised are treated significantly differently in the procurement process.

Service quality including project delivery quality

There are several references in the literature regarding quality of contract management including support to internal implementation teams, users and assistance in wider communications to support integration and uptake during implementation and thereafter. Most delivery quality should be captured in detail in service contracts with clear timetables, deliverables, review processes and milestones, reporting and if needed, either incentives or penalties spelt out in detail. This obviously requires thoroughly researched requirements documents from which procurement specifications are derived, baselines established (current state), expectations (future state), risks and contingencies regularly reviewed and where possible referenced against standards and how these will be assessed and verified.

Usability

Usability standards are expected to be an integral aspect of product quality. However, usability needs to be fully aligned with user requirements, expectations, capacity and competences (including health care staff, patients and carers) as well as technical teams. The literature suggests limited consideration in the procurement process to ensuring rapid uptake is not hindered by insufficient consideration of users' characteristics and conditions. It is also important to remember that usability includes ease of use AND usefulness to all users.

Safety (patient & staff/users)

Fundamental to all services is safety of users including patients (& carers) AND staff. The number one reason for long lead times in the adoption of any innovation is the need for rigorous testing for safety. Safety by design, staged pilots and peer reviews all contribute to confidence in the safety of the product/service. Safety trumps everything until the product/service is at a sufficient stage of maturity to provide confidence.

The challenges for suppliers are building the robust evidence base and the investment required and gaining confidence (naturally and understandably conservative) on the part of those making procurement decisions to adopt innovation. Safety is a very high procurement variable but how and where procurement teams look for safety assurance with respect to digital health needs further investigation.



Do they look for approved standards and audits evidence only and what happens in the absence of an established standard and audit process? How much and from what sources do they require evidence of rigorous safety assurance?

The European Medical Device Regulations (MDRs) come into effect in May 2021 and this will have significant impact on health technology products, particularly digital health solutions. For the first time, many solutions will be classified as a medical device (Software as a Medical Device, SaMD) under Rule 11 of the new MDRs. Many existing SaMD solutions will also be reclassified under the new MDRs and will require Notified Body audit and certification for the first time. HealthTech Ireland is engaging with the Health Products Regulatory Authority (HPRA) to ensure that guidance and support is available for our members.

Security

Health Technologies present some specific challenges with respect to security, not least when devices are dependent on effective functioning of internal data processing and / or interaction with external data sources. The literature is very limited with respect to data security in health technologies and how this is treated in the context of procurement. In an environment of highly publicised cyber attacks on health systems, it is vital that minimum standards such as ISO27001 are complied with as a requirement for procurement.

Trust

In the literature surveyed for this paper, the subject of trust was rarely referenced. This applies as much to trust in buyer/supplier relationships (which given the innovative nature of healthtech can be a challenge to newcomers to the market) to trust in processes and standards with respect to innovative health technologies. We suggest the absence of discussion in the literature is more to do with the state of research into the topic rather than the importance of trust between buyer/supplier and trust in processes and standards in the procurement process.

Environmental impact

The literature on procurement in general is growing with respect to the importance of environmental impact. However, when the specific health technology sector is considered, there was little reference to evidence of environmental impact data across the supply chain being considered in the procurement process.

Privacy

As above, the literature on procurement in general is growing with respect to the importance of data privacy. However, when the health technology sector is considered, there was little reference to experience relating to data privacy (including any reference to privacy by design, privacy monitoring in data processing), especially where connectedness and AI need to be taken into consideration in the procurement process.

Scalability

Surprisingly there is little reference to scalability in the literature as a key variable in the procurement process. This should be of a concern not least because of the need to ensure impact from more widespread adoption and transformation of health systems.

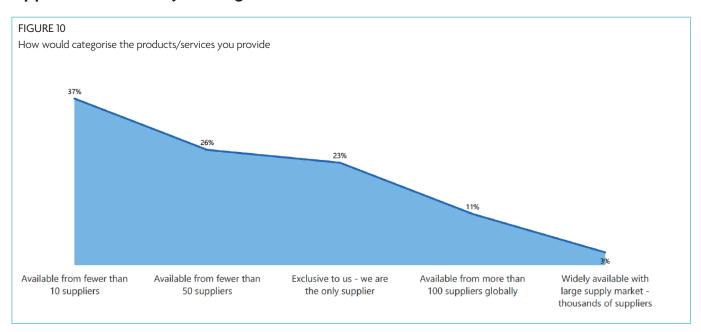
Dependability

This refers to supplier dependability as much as product and service supply dependability as a variable for inclusion in the procurement process and there is little mention of it in the procurement or health technologies literature reviewed.

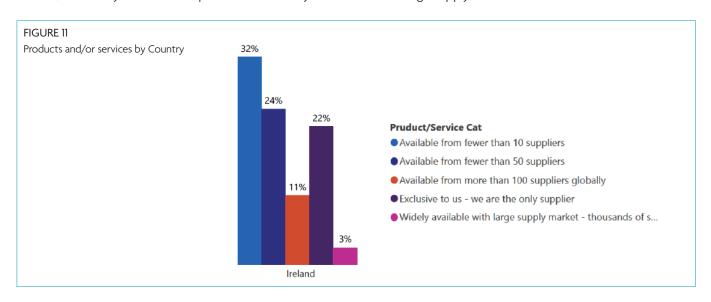


Appendices

Appendix III – Survey Findings



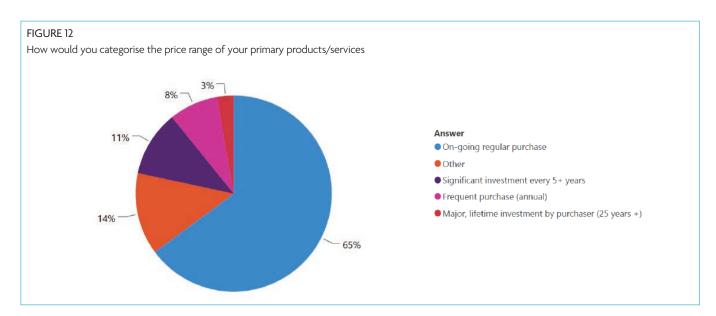
In response to the question 'How would you categorise the products/services you provide?', 23% said their products are exclusive to them, 37% said there are 10 or fewer suppliers in their market, while only 3% said their products are widely available with a large supply market.



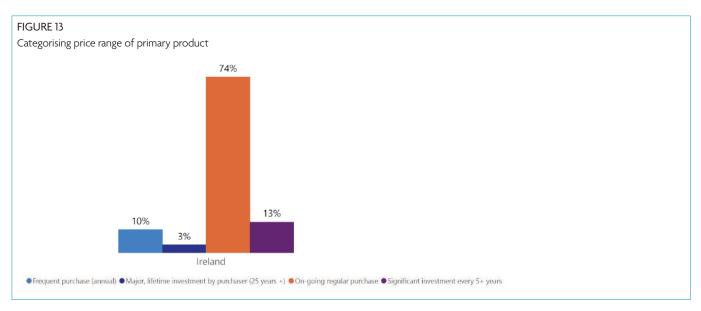
When looking solely at the Irish market, the picture is largely similar. 22% of respondents say they are the only supplier and 32% say their products and/or services are available from fewer than 10 suppliers.

The percentage of respondents providing products services widely available (all markets) is 14%, in Ireland (as above in Figure 11), the percentage drops to 3%.

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Using frequency of investment as a proxy for possible price range, 3% described their products as a major lifetime investment (25+years) and 11% said theirs was a significant investment (every 5+ years). 8% described theirs as annual investments. The majority (65%) were ongoing purchases. Other included 'Both Capital products (5 years' sales cycle) & regularly used consumable products'.



The picture is matched for Ireland with a slightly higher percentage 13% in the category of a significant investment every 5+ years. Also, in Ireland, where the respondents were exclusive suppliers, 16% described their products and services as 'on-going investments'.

When asked about purchasing approaches, 65% said open call tendering applies. However, 54% said they were on a preferred supplier list: this perhaps suggests that the open call applies in the identification of suppliers for a restricted list when goods and services are actually purchased.

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