Health Policy Proposal

Healthcare Innovation could create 1,000 jobs

July 2015

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Summary

1. The Problem

Currently no funding mechanism is in place to facilitate the development of innovative solutions by the medical device industry for unmet needs in our healthcare system. The needs to be addressed include unnecessary GP or hospital visits and undue length of stays, excessive treatment costs and recurring preventable issues. The solutions can be process, treatment or IT related.

2. The Proposal

IMSTA **proposes a new initiative for innovation in healthcare** that has the capacity **to create over 1,000 jobs** in the medtech sector over the 5 year period to 2021 in small and medium sized businesses (SMEs) in all parts of Ireland.

Specifically:

- The Department of Health should initially allocate €1-2 million from its procurement budget in 2016 to fund a Health SBIR programme
- The fund would be reviewed and adjusted annually to reflect the success of the programme
- This policy for healthcare innovation could be included in the Action Plan for Jobs 2016.

3. This initiative can be **funded from a small percentage of the existing health budget for procurement** of medical technology and as a result will not require additional resources. The budget would be specifically allocated to innovation.

4. **It could also generate €400m in savings** in our healthcare system over the same period as a result of the efficiencies gained and in addressing unmet health needs[1].

5. This initiative proposes using **the Small Business Innovation Research (SBIR) mechanism**, a tried and tested government programme, initially developed in the USA 25 years ago, widely used in UK & Europe and more recently in Ireland. It is intended primarily to help SMEs conduct research and development (R&D) but is not restricted to SMEs only.

6. It is **a "whole of Government approach" to job creation**, whereby the Department of Health, the Department of Jobs, Enterprise and Innovation and the Department of Public Expenditure and Reform would work together under the Action Plan for Jobs initiative.

7. This initiative will **enable/encourage the public sector to partner with industry** to solve problems for which no solutions currently exist. It will be facilitated under the new EU Procurement Directives due to be introduced into Irish law soon.

This policy initiative has been endorsed by Enterprise Ireland and discussed with the Department of Health

[1] 'Unmet health needs' can be defined as problems identified in the public health system which cannot be resolved by purchasing existing health products. Problems can be associated with major healthcare issues, unnecessary hospital visits / stays, excessive treatment costs, recurring preventable issues etc. and can be process, treatment or IT related.

The Detail

1. The Problem

Currently no funding mechanism is in place to facilitate the development of innovative solutions by the medical device industry for unmet needs in our healthcare system. The needs to be addressed include unnecessary GP or hospital visits and undue length of stays, excessive treatment costs and recurring preventable issues. The solutions can be process, treatment or IT related.

The current procurement system does not encourage SMEs/MNCs/Third level institutions to engage with the health system to create solutions for patients unmet needs.

No funding currently facilitates the procurement of innovative solutions from the medical device industry.

2. The Proposal

IMSTA proposes a new initiative for innovation in healthcare that has the capacity to create over 1,000 jobs in the medtech sector over the 5 year period to 2021 in small and medium sized businesses (SMEs) in all parts of Ireland.

Specifically:

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- The fund would be reviewed and adjusted annually to reflect the success of the programme
- The policy for healthcare innovation could be included in the Action Plan for Jobs 2016.

The proposal aims to encourage the public health sector and the medical device industry to collaborate in order to innovate solutions for patients' unmet health needs.

The SBIR mechanism (see below for more detail) enables 'an innovation partnership' where innovative healthcare solutions are developed which cannot be met by purchasing existing products. This also helps to identify more effective and efficient alternatives for current challenges.

For example, an initial fund of €1.5m, increasing at the rate of 25% per annum, could lead to job creation of over 600 direct and 400 indirect jobs over the period to 2021 in all areas of the country. It will further enhance the critical mass of the medtech sector in Ireland, it's importance in the Irish economy, the overarching imperative of advancing public health and the need to create jobs in our recovering economy.

3. This initiative can be funded from a small percentage of the existing health budget for procurement and as a result does not require additional resources. The budget would be specifically allocated to innovation.

The HSE spends at least €500 million annually procuring medical technology[2]. This proposal is that 1-2% of this procurement budget be ring-fenced to find solutions for identified healthcare problems.

[2] HSE Annual Report & Financial Statements 2013 Note 8 Non-Pay Clinical Expenditure, excluding drugs/medicines, blood/blood products and education & training, was €557 million.

The Detail

The funding would be provided, primarily to SMEs, to fund the development of specific solutions for unmet health needs. In return, the Government would receive access to the innovative solutions created. This would be a smarter use of the procurement budget that has proven to be cost-efficient and effective at treating unmet health needs in the UK. For example, it leads directly to healthcare system savings and improvements in patient care in addition to the economic benefits brought about by the multiplier effect.

4. It could also generate €400m in savings in our healthcare system over the same period as a result of the efficiencies gained.

The proposed initiative focuses on solutions that not only provide improvements in patient care but are also cost effective.

For example, as part of a UK SBIR competition a company called Umotif developed a mobile phone App which helps patients track and self-manage their conditions. As a result of this innovation, the savings to the NHS were estimated at £20 million per annum.

Future savings to the NHS from technologies currently in development from the SBIR initiative are estimated to be as high as £1.5 billion over the next 10 years by the UK Office of Health Economics.

Based on the investment assumptions above, a proportionate saving for the Irish healthcare system here would be in the order of €400m over the period to 2021.

5. This initiative proposes using the Small Business Innovation Research (SBIR) mechanism - a tried and tested government programme - initially developed in the US 25 years ago. This is widely used in UK & Europe and more recently Ireland. It is intended to help SMEs, but not just SMEs, conduct research and development (R&D).

The SBIR process as outlined in **Appendix II** is a mechanism for funding innovation in the private sector to produce solutions for public sector problems. The process provides funding to SMEs and other private sector organisations to develop fully functioning solutions to problems that have been identified in the public sector. At the end of the SBIR process the Government has the opportunity to procure the innovated product which has been proven, through the SBIR process, to be an effective and efficient solution to the stated problem.

The SBIR process operates as an open competition for funding. This allows any organisation with an idea for solving the stated problem the opportunity to compete for funding. This includes start-ups, SMEs, MNC's, third level institutions, a combination of these or indeed others.

The SBIR process has proved successful in many other countries and across a number of different sectors such as health, energy and the military. Furthermore the SBIR process has been tried and tested in Ireland. The first Irish SBIR competition took place in 2014 under the aegis of the energy sector and was by Enterprise Ireland, ESB innovation and the Sustainable Energy Authority of Ireland **(see Appendix III).**

Funding innovation through pre-commercial procurement is a process which challenges industry to come up with solutions for identified healthcare problems.

Harnessing innovation has the potential to improve the health, well-being and economic productivity of the population and slow the growth in the cost of care.

The Detail

6. It involves a "Whole of Government approach" to job creation, whereby the Department of Health, the Department of Jobs, Enterprise and Innovation and the Department of Public Expenditure and Reform would work together under the Action Plan for Jobs initiative.

This initiative provides an opportunity for Government Departments to work together in partnership with industry to produce jobs, as is stated in the Action Plan for Jobs 2015[3].

In particular, it will provide a specific opportunity for the Department of Health to engage with the medical device industry and be part of the Action Plan for Jobs for the first time.

Ireland has one of the world's biggest medtech hubs with 17 of the worlds' top 25 medtech companies operating here, providing over 27,000 jobs and exports over €8 billion of health products. This new initiative will allow for closer links between a number of Government Departments and the medtech industry with a focus on creating jobs and boosting innovation.

7. This initiative will enable/encourage the public sector to partner with industry to solve problems for which no solutions currently exist. It will be facilitated under the new EU Procurement Directives due to be introduced into Irish law soon.

Currently the public sector relies on the private sector to independently produce solutions to unmet health needs. As a result, many existing solutions do not specifically address problem areas facing the health service.

This new initiative will link the public and private sectors so they can work together to innovate effective solutions for identified healthcare problems. This is a proactive way for the Government to fund solutions to specific problems that are cost-efficient and improve patient care.

The initiative has been successfully tried and tested in other EU jurisdictions and adheres to existing EU procurement laws. Furthermore the initiative follows the new EU Procurement Directive, soon to be introduced into Irish law, by encouraging the public sector to partner with industry to solve problems for which no solutions currently exist.

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[3] Note: Action 281 of the Action Plan for Jobs 2015 specifically states "Following on from the launch of the SBIR in 2014, identify a pipeline of potential SBIR projects and expand SBIRs to 2 new contracting authorities"

Appendices

I. **Background on IMSTA**
II. **SBIR process**
III. **List of UK health SBIR competitions 2008 - 2013**
IV. **Case studies - Ireland and UK**

Appendix I

Background on IMSTA

IMSTA is the representative body for the Medical Technology supply industry in Ireland.

IMSTA is a member of GMTA, the Global Medical Technology Alliance, whose members are national or regional medical technology associations which represent innovative companies that currently develop and manufacture 85 percent of the world's medical devices, diagnostics and equipment. It provides a forum for the development and advocacy of policies that support innovation in medical technology to address patients' healthcare needs.

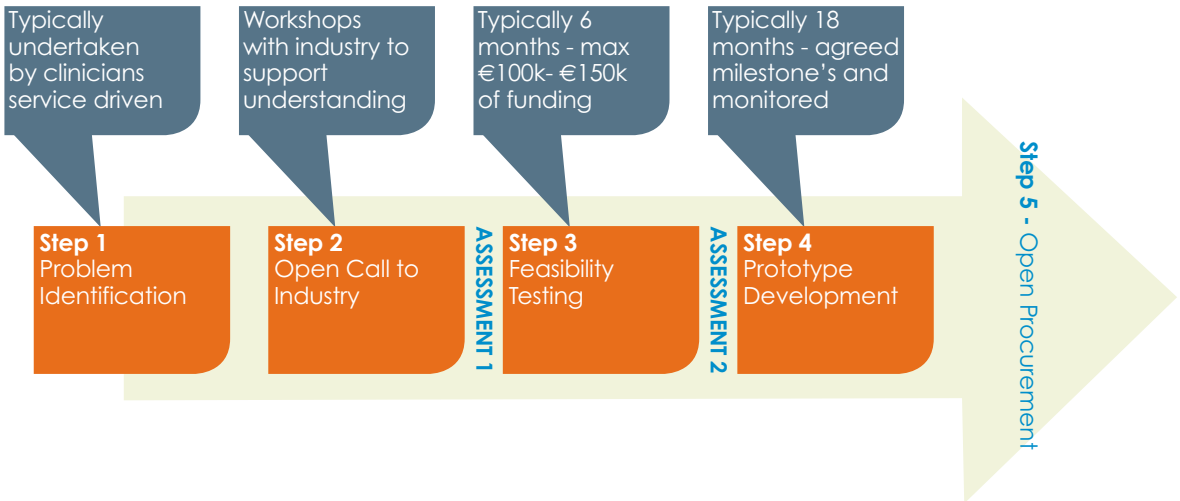
IMSTA member companies in Ireland include the full spectrum of medical technology supply and service companies from SMEs to MNCs, many of whom have R&D and/or manufacturing facilities in Ireland.

IMSTA member companies provide highly trained clinical professionals, biomedical / clinical engineers and medical scientists to support the medical technology in use in the Irish health service. They provide training for clinicians, nurses, biomedical and clinical engineering and other health care professionals in the application and the use of innovative medical technologies.

Appendix II

The SBIR Process

Step 1 - Problem Identification



Appendix II

Step 1

The first stage of the SBIR process involves identifying a specific challenge within the public sector (in this case the Department of Health / HSE) that needs to be solved. The selection process for this specific challenge is influenced by the following:

1. **Political pressures:** High profile challenges, (for example, in Ireland maternity care or quality of patient care in hospitals are currently high profile challenges) and this would be given a high level of consideration when choosing a specific SBIR challenge
2. **Financial factors:** The scale of the financial burden of a specific problem or problem area such as chronic diseases
3. **Unmet patient needs:** The ability for a patient to get access to a solution that provides cost effective improvements to patient health
4. **Industry capacity to produce a solution:** The ability of the industry to identify and develop an appropriate solution to the stated problem area.

A short list of challenges is compiled and workshopped by industry professionals such as clinicians, consultants and other relevant people. These workshops often use "what if" analyses to determine what the effect of a solution to each of the shortlisted challenges would be. By the end of the workshop a specific challenge is selected for the SBIR process based on which challenge will have the greatest impact overall.

Step 2 - Open call to industry

At this stage an open call to industry is made, inviting organisations to come forward with their proposed solutions to the stated challenge. This includes SMEs, MNCs, start up companies, third level institutions or a combination of these. Organisations put together formal proposals, demonstrating what their solution is, why it can solve the stated problem and how it can be commercially viable.

ASSESSMENT 1

The proposals are compiled and each is scored by [3] different judges using a structured scoring mechanism. The judges are independent experienced industry professionals. The highest scoring proposals are then sent to a clinical assessment panel who shortlist [5-8] candidates to go forward to interview stage.

Successful candidates are given 30 minutes to present their proposal to a panel of industry experts, clinicians and a SBIR Programme Board. The panel chooses the winners based on the proposed solution's ability to improve patient care and the ability to be successfully commercialised.

Step 3 - Phase 1 funding - feasibility testing

The winners are awarded the first phase of funding (up to €100,000) and approximately 6 months to conduct a feasibility study and to develop the solution further. Ideally early stage prototypes of the product will be developed as well as early user feedback and technical feasibility studies. It is not expected at this stage that the company will have completed clinical testing of their solutions. This step should focus on developing the product and should not be used purely for research. Much of the background research should be completed before an organisation approaches the SBIR process.

Appendix II

ASSESSMENT 2

At this stage the proposed solutions are assessed again. This time the companies are given an hour to present their products to the panel. It is important that the company has returned with solid evidence that their solution can work and that it can be produced for the market on a commercial basis. The panel can then award Phase 2 funding to one or more of the candidates to further develop the solution into a fully functioning product.

Step 4 - Phase 2 funding – prototype development

The winning candidate(s) are awarded up to €1 million to produce a fully working product. As many candidates are small businesses or start-ups they often use contractors to undertake a proportion of the work. The time frame of this phase is agreed between the successful candidate and the SBIR Board, it is generally between 6 - 18 months. The SBIR Board regularly visit the successful candidates and review the progress being made which is compiled into quarterly reports.

Step 5 - Open procurement

At this stage the proposed solution has been developed into a fully functioning product. Due to procurement laws there is no formal process that allows SBIR products to go straight to procurement, they have to go through official procurement channels. The government puts out a tender for a solution to the stated problem and any company or organisation with a solution can come forward with a proposal.

The companies who partake in the SBIR process must compete with other solutions (if there are any other solutions), for a procurement contract but the SBIR participants have a number of advantages over the competition:

- Their solutions have been tailor-made for the stated problem
- They have already demonstrated on a number of occasions that their product works and solves the stated problem
- They have already demonstrated that their solution is feasible and commercially viable

At this stage the Government decides if it wants to procure the solution that has been developed during the SBIR process. An important aspect of the SBIR process is that the intellectual property rights of the products that are created remain with the candidates. The candidates are now also able to market their products to other potential customers such as foreign health departments or private healthcare providers.

It is worth noting that In the six years of operation of the SBIR in the UK, a solution has always been found.

Appendix III

List of UK health SBIR competitions 2008-2013

	Competition	Launch Date	No. of entries received	Contracts Awarded Phase 1 & 2		Competition Value
1	Pathogen detection (DH)	Oct 2008	15	7	2	£2m
2	Hand Hygiene(DH)	Oct 2008	38	6	4	£3.1m
3	Managing Long Term Conditions	Apr 2009	89	5	2	£1.2m
3	Patient Safety	Apr 2009	46	5	2	£1.25m
4	Keeping Children Active	Apr 2009	42	1	0	£0.1m
5	Dementia	June 2010	28	7	3	£1.2m
6	Hospital Admissions	June 2010	69	5	2	£0.4m
7	Long Term Conditions	Feb 2011	73	8	5	£2.2m
8	Medicines Management(DH)	Apr 2012	49	5	4	£2m
9	Behaviour changes (DH)	April 2012	108	8	2	£2m
10	End of Life	Jan 2013	97	5	3	£2.5m
11	Mental Health	Jan 2013	80	4	2	£2.5m
12	Cancer	Sept 2013	22	4	TBC	Approx. £16m across 7 categories. Phase1 Awards £2.8m
13	Patient Safety	Sept 2013	55	5	TBC	
14	COPD	Sept 2013	31	5	TBC	
15	Diabetes	Sept 2013	48	6	TBC	
16	Research & Diagnostic tools	Sept 2013	44	6	TBC	
12	Mental Health	Sept 2013	56	4	TBC	
13	Cardiovascular	Sept 2013	27	5	TBC	
14	COPD	Sept 2013	31	5	TBC	
15	Diabetes	Sept 2013	48	6	TBC	
16	Research & Diagnostic tools	Sept 2013	44	6	TBC	
12	Mental Health	Sept 2013	56	4	TBC	
13	Cardiovascular	Sept 2013	27	5	TBC	
14	Renal (DH)	Oct 2013	41	TBC	TBC	Approx. £3.6m
15	Genomic (DH)	Dec 2013	TBA	TBC	TBC	Approx. £10m
16	Phase three offer	Dec 2013	10	8	TBC	Approx. £5m
TOTALS TO DATE			**1068**	**109**	**31**	**£23m contracted**

Appendix IV
SBIR Case Studies Ireland and UK SBIR

SBIR has been tried and tested in many other jurisdictions including Ireland, Northern Ireland, UK and the USA Case Study – Sustainable Energy Authority Ireland

Case Studies

Sustainable Energy Authority Ireland

- Ireland has already begun to use SBIR as a pathway to sourcing solutions in other sectors
- Under the 2013 Action Plan for Jobs, Enterprise Ireland was tasked with launching a pilot SBIR programme for 2014
- SEAI (Sustainable Energy Authority of Ireland) in collaboration with ESB Innovation and Enterprise Ireland, targeted the energy sector and challenged business to provide a smart technology solution for charging Electric Vehicles in shared access parking areas[4].
- Up to €200,000 was made available to develop the prototype.
- Four companies were successful in providing evidence of the viability of their solution and were provided with the initial €25,000 investment in April of 2015. After a six month development period, the two most promising solution will receive a further €100,000 investment.

[4] http://www.winningtenders.eu/scoop-it/seai-small-business-innovation-research-electric-vehicle-smart-charging/

Appendix IV

Case Studies

uMotif

Company:	**uMotif Digital Health**
Competition Entered/ Phase:	**Medicines Management**
Innovation:	**Parkinson's Tracker platform**
Total award:	**£571k awarded across Phase 1 & 2 product development stages**
Savings to the NHS:	**Estimated at £20 million per annum**
Product availability:	**Q2 2015**

Overview

uMotif is a health technology company improving the way patients track and self-manage their conditions and make shared decisions with their clinicians. The underlying idea behind uMotif is that health self-management can strengthen the patient-clinician relationship to improve outcomes and save costs.

With SBIR Healthcare funding uMotif has developed a software platform with smartphone apps and a web portal designed to help people with Parkinson's Disease manage their medication and improve their health behaviours through self-tracking. The app also represents an interesting new research platform for in-situ testing of cognitive performance. Detailed daily tracking provides the potential to empower and motivate patients with long term conditions, encouraging them to engage positively with the management of their conditions while providing better data to healthcare professionals to enhance shared decision making.

The technology and its highly intuitive user interface has been developed in close collaboration with a range of patient groups, academic and clinical partners and was designed from the patients' perspective.

It is estimated that one in 500 people are affected by Parkinson's disease, which means there are an approximately 127,000 people in the UK with the condition. Less than 50% of patients adhere to the medications prescribed by clinicians, resulting in lower quality of life, impaired outcomes and increased costs.

Appendix IV

Patient perspective

Through the SBIR funding, uMotif are leading a world-leading Randomised Controlled Trial (RCT) working with 7 of the UK's top neurologists. The RCT follows successful Phase 1 trials of the app which demonstrated 70% daily use rates and increases in self-reported medication adherence. Users reported engagement with tracking and ease of use and overall improved health behaviours and patient wellbeing.

Patient comment

"Using uMotif's technology has helped my husband understand for the first time the complexity and reality of my medication regime. He's now better able to support my Parkinson's self-management"

Economic impact

SBIR funding has allowed the creation of four full time roles. In addition to SBIR funding, the company has secured additional investment of £200,000.

Full commercial availability is expected in Q2 2015, with forecasted Year 1 sales of £250,000. In addition to Australia, export of the technology to USA, Europe and Brazil is planned. The platform is now being deployed in primary and secondary care in other patient groups, including diabetes, heart failure, oncology, renal and rheumatology.

Early health economic modelling suggests savings to the NHS of over £20m per annum through use of the uMotif platform.

"SBIR Healthcare has been very good in supporting our early innovation. Through the programme, the uMotif app is being trialled with 7 of the UK's top neurologists in an ethics approved and NIHR Clinical Research Network adopted randomised controlled trial."

Bruce Hellman, uMotif Digital Health

Appendix IV

Case Studies

PolyPhotonix Ltd

Company:	**PolyPhotonix Ltd**
Competition Entered/ Phase:	**Improving the Health of People with Long-Term Conditions**
Innovation:	**Noctura 400 treatment for Diabetic Retinopathy**
Total award:	**£1,458,158 awarded across Phases 1, 2 & 3 development stages**
Savings to the NHS:	**Estimated at £1 billion per annum**
Product availability:	**Q4 2014**

Overview

PolyPhotonix, a bio-photonic research and development company, has developed a light therapy sleep mask, Noctura 400, for the prevention and treatment of Diabetic Retinopathy. Designed as a monitored home-based therapy, the technology offers a patient centric, non-invasive treatment that can be delivered at a fraction of the cost of the current interventions; laser photocoagulation surgery or intraocular drug injection.

Trials of Noctura 400 have shown that eye disease can be reversed with significant results after as little as six months. Approximately 30 clinics around the country are trialling the product including Moorfields Eye Hospital. It is anticipated that Noctura 400 will receive NICE approval by the end of 2015.

Diabetes is the most common cause of preventable adult blindness in the developed world. Treating it costs the NHS about £1bn a year. Patients who develop retinopathy are currently treated at a cost of as much as £10,000 per patient for each eye. By contrast, the PolyPhotonix sleep mask costs £250 for 12 weeks' treatment. With 3.5m diabetes sufferers in Britain, the technology has the potential to save the NHS hundreds of millions of pounds a year.

Appendix IV

Patient perspective

The sleep mask is designed to be worn at night and delivers a precise dose of light therapy during a patient's normal hours of sleep. The Pod contains the light sources which, when worn, emit light into the eyes through closed eyelids. Nothing is inserted into the eyes – the treatment is non-invasive. The mask is programmed to administer the correct dose of light each night as part of a continuing therapy

Patient comment

"There is no contest that I would choose the mask over the laser treatment. It is easy to use and removes any traumatic experience that occurred when having my eyes lasered. I still wear the mask at night and would encourage anyone with diabetes and suffering from retinopathy to do the same."

Economic impact

Following successful patient trials, the sleep mask is now commercially available with sales for 2015/16 estimated to be in excess of £3 million. PolyPhotonix's workforce is expected to triple over the next two years to 60 employees directly created as a result of SBIR funding. Approximately £2 million of additional investment has also been secured by the company.

Based on company forecasts and health/financial modelling, the estimated saving to the NHS is in the region £1billion per year for treatment of diabetic retinopathy and other eye conditions.

"The biggest impact of SBIR funding has been in accelerating the commercial side of the business and to considerably increase the pace of activity with the NHS. Driving adoption of the technology will both save the NHS budget and improve the quality of life for the patient."

Richard Kirk, CEO, Polyphotonix
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IMSTA is an independent representative body for med tech suppliers in Ireland

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