Irish Health Research Forum

Briefing Paper

The Health Research Landscape in Ireland: Where are we now?

November 14th 2017

Table of Contents

Introduction

In 2014 a report entitled 'The Health Research Landscape in Ireland: What Researchers Say'[1] was commissioned by the Medical Research Charities Group and undertaken by Prof Bernie Hannigan. The major recommendation from this report was the establishment of an Irish Health Research Forum (IHRF), which was enacted later that same year. The IHRF, guided by its expert steering group, and overseen by the MRCG, has hosted four Forum events, focusing on the topics of patient and public Involvement, research prioritisation, health research careers and legislation relating to health research[2].

Now, 3.5 years on from the initial report on the health research landscape, it is timely to take stock of progress to date, in some of the key areas addressed at previous Forum meetings. The upcoming Forum event on November 14th will revisit the topics of previous events, except for that of health research prioritisation, which might be appropriate to address in more depth at a future Forum event.

The following are some of the key developments in the areas that the event will address.

Patient and public involvement (PPI) in health research

This is one area of health research where we have seen enormous progress over the intervening years since the 2014 Hannigan report. The **first meeting of the IHRF focused on PPI**[3], bringing a number of experienced PPI practitioners from the UK to speak on the topic. Many leading organisations and individuals have since demonstrated a commitment to implement the principals of PPI.

Willingness however does not always translate into an effective adoption of practices and there remain many hurdles to overcome throughout the health research environment. Researchers are frequently unsure how to approach PPI and patients (and the public) are often unequipped and unsupported in PPI activities. This, combined with the fact that there is not a one-size-fits all model, means that examples of meaningful PPI in Irish health research remain limited. However, rapid adoption of best practices from elsewhere, together with a broad range of initiatives to support PPI will ensure that those positive examples start to become the norm.
Below are some initiatives, which are slowly and steadily contributing to the adoption of PPI as a fundamental element of health research in Ireland:

- The Health Research Board (HRB) and Irish Research Council (IRC) are jointly supporting a €1.75 million initiative, **PPI IGNITE**[4], to help researchers involve the public in the health research process. It will support research institutions in developing and strengthening their PPI activities in research from the earliest stages. Five universities, UL, NUIG, DCU, TCD and UCD have been recipients of this award, all of which are due to start to in the latter half of 2017.
- Early in 2017 the **HRB put out a call for members of the public** to review research grants proposals[5] and received a very enthusiastic response.
- **Patient organisations** are perfectly placed to lead and facilitate PPI activities. The MRCG is supporting its members in strengthening their PPI initiatives via a Shared Learning Group, which is linked to an equivalent group of medical research charities in the UK.
- **IPPOSI** have been taking the lead on training patients to participate in all areas of research, including health technology assessments. This has partly been done through the EUPATI programme and more recently through national initiatives[6].
- A **national Clinical Research PPI Working Group** has been established to support the PPI activities of all stakeholders in clinical research, through a shared repository of PPI materials and regular meetings.
- Many **researchers** in Irish Institutions are taking a strong lead in developing PPI activities and directly involving patients in their research activities, even to the extent of including them as co-researchers.

Research careers in academic and health service settings

The Hannigan report highlighted the issue of research careers as a major challenge in the health research environment. The **third meeting of the Irish Health Research Forum**[7] focused on careers for health researchers, bringing experiences from the frontline together with examples of best practice from the UK. Discussions were fruitful but tinged with the frustration of those currently struggling to survive in an unsupportive system. In the area of health research, it is important to acknowledge that there is a distinction between research careers within traditional academic settings and those in clinical settings. While there is overlap, each brings its own distinct challenges. With some notable exceptions, progress in both environments has unfortunately been limited and support for those who wish to make health research a career remains limited. Below are some of the key elements that currently define health research careers in Ireland.

Academic research careers

- While universities are relying very heavily on contract staff, **lack of a career structure** for these staff remains a major challenge.
- It is widely accepted that a degree of movement in the workforce and the chance for researchers to experience working in different institutions is valuable but health research, and therefore patients, are suffering due to **high staff turnover and the concomitant loss of valuable skills**.

- Universities have reacted to the **implications of the Protection of Employees (Fixed Term Work) Act 2013** in different ways. Some have taken a hard line on the length of time that a contract researcher can remain in employment and will not employ beyond 4 years. Others have taken the approach that, due to the nature of research, and those that undertake it, there will not be an enormous demand for contracts of indefinite duration and allow researchers remain in post, for as long as funding continues.
- **Career development offices** within academic settings are generally seen as supportive but contract researchers often do not have the time to undertake courses that might develop transferable skills.
- A recent report, referred to as the **Cush Report**[8]**,** has recommended to the Minister for Education and Skills that the fixed-term workers act be applied after a period of two years for lecturing staff. Research roles do not come under its remit however, although it noted that 'this is the group which suffers most from insecure employment'.
- Steps are being taken by funding agencies to address **gaps in the career path** that leave researchers without support. The HRB identified the need for career development as a key enabler to deliver its current strategy and is taking a structured approach to supporting researchers at all career stages[9]. Notably it's Emerging Investigator Awards will support new investigators ready to transition to independence. The IRC supports early stage researchers and strives to equip them with the relevant skills to equip them in pursuing diverse career paths[10].
- There is a strong focus on research careers in the Government's **Innovation 2020** strategy[11], which emphasises the need for transferable skills and includes actions to 'develop a coherent national policy on structured progression for researchers' and to 'ensure career support for Ph.D.'s and post docs', in addition to an aim to address gender equality in research.
- In line with the Innovation 2020 objective above, the IUA are currently developing a **Researcher Career Development and Employment Framework**. Several universities and Institutes of Technology already have Frameworks in place, but the IUA proposal will provide a national approach. The training and career development aspects of the Framework will require some additional national investment.

Health service research careers

- While there are some indicators that research is being increasingly viewed as a **driver of improved patient care**, tangible changes are not yet being felt by most in the health service with a research focus.
- Most clinicians in Ireland have **no protected time for research** and, on the rare occasions where they are granted time, lack of cover for clinical commitments is a huge challenge.
- **Posts that support the undertaking of research**, such as research nurses or data managers are not supported, which is a serious barrier to clinical research.
- **Research nursing is not viewed as a career** in its own right and research nurses are not provided with opportunities to secure substantive posts or to become principal investigators.
- Where funding is available specifically for research roles, **recruitment restrictions** and a lack of candidates willing to take on short term roles can be challenging.
- Valuable support from the **HRB-Clinical Research Coordination Ireland (CRCI)**[12] for clinical research centres and the Wellcome-HRB **Irish Clinical Academic Training Programme (ICAT)** are gradually improving the situation. ICAT is a comprehensive national programme for clinician scientists which provides an integrated programme of 6-7 years mentored academic and clinical training, for future clinical academic leaders. Approximately 40 fellowships will be awarded over a 5-year period, commencing in July 2017[13].
- **Medical research charities** are also acknowledging the need to support healthcare professionals to undertake research with organisations such as the National Children's Research Centre[14] and the Irish Cancer Society providing funding for clinical research posts[15].
- One of the major challenges to developing research within the health service is that there hasn't been **a point of contact within the HSE with responsibility for research** to date. A new Head of Research and Development[16] has been appointed within the HSE

however, with the appointee due to start in post in November 2017.

- A **Head of Research and Development and Health Analytics was appointed in the Department of Health**[17] in 2015, at Assistant Secretary level. This post provides a valuable touch point on research topics, in addition to someone to drive the research agenda and eHealth agenda.

Legislation relevant to health research and the policy context

The current Programme for Government[18] specifically mentions a commitment to two relevant pieces of legislation – the Health Information and Patient Safety Bill and the Human Tissue Bill. It also states that the Government will increase funding for the HRB and implement the National Rare Disease Plan[19], a large section of which is focused on the need for more support for research into rare diseases.

Another source of insight into the Government's level of commitment to health research is the HSE Service Plan for 2017[20]. While it does state specific financial support for the National Health Innovation Hub and provides mention of the UL Clinical Education and Research Centre, other mention of health research is notably lacking. The HSE's commitment to implementing the eHealth strategy for Ireland[21] and the Department of Health's initiative to develop a National Health Information Policy[22] in 2018, will hopefully provide a basis however, for a health service based on data and, over time, lead to a stronger evidence base for care. eHealth also features strongly in Sláintecare report, developed by the cross-party Oireachtas Committee on the Future of Healthcare[23].

The **fourth meeting of the IHRF asked 'How can legislation facilitate health research?'**[24] and addressed the impact of forthcoming legislation on aspects of health research such as clinical trials, patient consent, ethics committee and patient registries. In the intervening period, the legislative environment has further evolved and the key forthcoming bills and regulations are outlined below.

Health Information and Patient Safety Bill

At the time of publication of the Hannigan report, a draft Health Information Bill had been in preparation for some time. The general scheme of this key piece of legislation was subsequently published[25] but it has yet to be enacted. The purpose of this Bill is to strengthen the legislative base for the more effective use of personal health information and to better streamline the process for research ethics approval; an area of huge concern for the health research community, due to the current need for multiple ethical approvals in the case of multi-centre research.

Key elements of the Bill:

- It will facilitate **effective information systems** in the health system, to encourage care built on a foundation of data.
- It will legislate for the **exchange of electronic data**, thereby supporting patient registries and broader eHealth research initiatives.
- As EU law governs research ethics approval for clinical trials the Bill will not apply to that research. It will however, provide for a **research ethics structure** for other health research.
- It will allow a tightly controlled **data protection consent exemption** for the requirement that individuals give explicit consent for the processing of their health information. These exemptions are likely to be determined by Confidentiality Advisory Committee, as proposed in a draft National Health Information Policy Framework[22].
- The Department of Health is working to ensure that there is consistency between this Bill and the **GDPR**.

The General Data Protection Regulation (GDPR)

GDPR[26] brings with it very welcome reform in the area of data privacy. In the context of health, it will allow patients to have more control over their data and will increase transparency in relation to how their data is being used. Its mandatory implementation by May 2018 will bring with it some challenges for the health research community however. The regulation includes some provisions directly related to health research and EU member states need to draft their own legislation,

in relation to patient consent and consent exemptions for research purposes.

Implications of GDPR:

- There is the potential for some **legacy research datasets to become unusable** for purposes other than what patients have explicitly consented to.
- **Re-consent** might be possible in some cases but is fraught with logistical and ethical difficulties.
- Compliance with the GDPR will bring with it a **heavy administrative load** and a need for increased data security which many research groups will struggle to find the resources for.
- **Dynamic consent**, while challenging, is viewed as a possible future mechanism to ensure both compliance with GDPR and the best possible use of patient data, including for purposes which might not have been envisioned at the outset of a project.

The Clinical Trials Regulation

The EU Clinical Trials Regulation[27], which will govern the undertaking of all clinical trials in the EU, will come into force in 2019. Its key purpose is to harmonize clinical trials processes between all Member States and to streamline and speed the approval process.

- Rather than making multiple clinical trial applications to individual countries, in the case of multi-national clinical trials, investigators will make a **single application**, through an EU clinical trials portal and associated database.

- Greater **transparency** surrounding clinical trials will also be afforded by the database, to which it will be mandatory to submit data and information about clinical trials. The database will be publicly accessible and easily searchable

The Human Tissue Bill

The Government has recently approved the preparation of the General Scheme and Heads of a Human Tissue Bill[28]. In addition to providing for an opt-out system of consent for organ donation, the legislation will deal with the removal, retention, storage, use and disposal of human tissue from deceased persons and living persons for the purposes of transplantation.

- While it doesn't currently appear that the Bill will specifically address issues relating to research, it is likely to **have implications for research involving human tissue and biobanks**.

The Medical Device Regulation (MDR) and the In Vitro Diagnostics Regulation (IVDR)

In 2016, two new proposed EU Regulations on medical devices (MDR) and *in-vitro* diagnostics (IVDR)[29] were agreed. Since then these texts have been undergoing final review and formal approval. Being regulations, there is no need for transposition through specific national legislation and both regulations will enter into force at the end of May 2017, with a staggered transition period thereafter.

- The legislation now should allow for **greater legal certainty** and prevent variation in the approach taken to medical devices and diagnostics in EU Member States.
- The MDR provides for **enhanced requirements for clinical studies** on medical devices and both regulations emphasise the need for the on-going capturing of clinical data. This will offer greater protection for patients and is likely to result in increased research activity in medical devices and diagnostics.

Other topics relevant to the current health research environment

While it is not possible to address all possible areas impacting on health research in a single Forum meeting, other key topics identified during the process of preparing this document are listed below. They offer potential focuses for future IHRF events.

- Health research prioritisation and funding
- The implications of Brexit for Irish health research
- Ireland's response to a move towards open science
- The need for more paediatric health research
- The undertaking of clinical trials in Ireland
- The need for an increased focus on ehealth, patient registries and biobanks

References

[1] http://www.mrcg.ie/assets/81/91B816B8-05FF-4C82-F0ECC0332D56BB0F_document/MRCG_Research_Report__1_.pdf

[2] https://www.ihrf.ie/

[3] https://www.ihrf.ie/untitled

[4] http://www.hrb.ie/research-strategy-funding/public-and-patient-involvement-in-research/ppi-ignite/

[5] http://www.hrb.ie/research-strategy-funding/public-and-patient-involvement-in-research/public-review-process/

[6] http://www.ipposi.ie/our-work/education/

[7] https://www.ihrf.ie/an-analysis-of-support-for-health-resear

[8] https://www.education.ie/en/Publications/Education-Reports/Report-to-the-Minister-of-Education-and-Skills-of-the-Chairperson-of-the-Expert-Group-on-Fixed-Term-and-Part-Time-Employment-in-Lecturing-in-Third-Level-Education-in-Ireland.pdf

[9] http://www.hrb.ie/health-research-careers/

[10] http://research.ie/assets/uploads/2017/05/IRC-Researcher-Career-Development-Policy-Statement_29Sept2017.pdf

[11] https://dbei.gov.ie/en/Publications/Publication-files/Innovation-2020.pdf

[12] https://www.hrb-crci.ie/

[13] http://icatprogramme.org/

[14] http://www.nationalchildrensresearchcentre.ie/grants/funding-calls/clinical-research-fellowship-2018-2/

[15] https://www.cancer.ie/research/apply-for-funding/clinician-researcher-award-2017#sthash.6JEtOOQt.dpbs

[16] https://www.maynoothuniversity.ie/sites/default/files/HSE%20Hear%20of%20R%26D.pdf

[17] http://whodoeswhat.gov.ie/branch/health/RDHealthAnalytics/muiris-oconnor/1176/

[18] https://merrionstreet.ie/MerrionStreet/en/ImageLibrary/Programme_for_Partnership_Government.pdf

[19] http://health.gov.ie/wp-content/uploads/2014/07/EditedFile.pdf

[20] http://www.hse.ie/eng/services/publications/serviceplans/Service-Plan-2017/2017-National-Service-Plan.pdf

[21] http://www.ehealthireland.ie/Knowledge-Information-Plan/eHealth-Strategy-for-Ireland.pdf

[22] http://health.gov.ie/consultations/

[23] https://www.oireachtas.ie/parliament/media/committees/futureofhealthcare/Oireachtas-Committee-on-the-Future-of-Healthcare-Slaintecare-Report-300517.pdf

[24] https://www.ihrf.ie/how-can-legislation-facilitate-health-re

[25] http://health.gov.ie/blog/publications/general-scheme-of-health-information-and-patient-safety-bill/

[26] http://www.justice.ie/en/JELR/Pages/PR17000155

[27] https://ec.europa.eu/health/human-use/clinical-trials/regulation_en

[28] http://health.gov.ie/blog/press-release/minister-harris-gets-green-light-to-move-ahead-with-legislation-to-provide-for-an-opt-out-system-of-consent-for-organ-donation/

[29] http://www.hpra.ie/homepage/medical-devices/regulatory-information/new-eu-device-regulations

This document was prepared by Dr Avril Kennan, CEO of the Medical Research Charities Group (MRCG), on behalf of the IHRF Steering Group, with valuable input from members of the Group. The outcomes of the Forum meeting will be used to shape the content into a final report on the current health research environment in Ireland

.

The Irish Health Research Forum is supported by the Medical Research Charities Group, with funding from Pobal and the Department of Housing Planning, Community and Local Government

medical research charities group
Unity is our Strength

pobal
government supporting communities

An Roinn Tithíochta, Pleanála, Pobail agus Rialtais Áitiúil
Department of Housing, Planning, Community and Local Government

Notes