HEALTH INFORMATION
ROUND TABLE MEETING:
DEVELOPMENTS & NEXT STEPS

SEPTEMBER 2015
IPPOSI Outcome Report

Health Information: Developments & Next Steps:
Annual Round Table Meeting with the Secretary General

Patient involvement in medicines development; Health information, electronic care records, patient registries, health research policy

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Introduction

If a theme emerged at the Health Information round table meeting, it was crystallized informally as ‘Groundhog Day’. This phrase expressed the frustrations felt by people in every quarter of the health system: patients, clinicians, scientists, regulators, industry and decision-makers. Everyone expressed their disappointment with the pace of change, but perhaps none more so forcefully or frankly than Paul Carey from Move4Parkinson’s:

“You’re looking at the macro picture and you have to, but somewhere out there are all these microchips and we’re making up the macro picture. Are we just the collateral damage while you all get some years to sort out this business? If the Troika wanted it, you would be doing it tomorrow.”

The Department of Health’s Secretary General Jim Breslin and the HSE’s new Chief Information Officer, Richard Corbridge, acknowledged these frustrations and also the important role patients play. As Mr Corbridge pointed out, it was patients who were critical to compelling GPs in the UK to share patient data—which they were reluctant to do, until a patient spoke out in favour of it.

There is no doubting the appetite in Ireland for Individual Health Identifiers (IHI), electronic health records, and gold standard patient registries, but the journey to achieving these goals remains a long one, and the obstacles are significant and varied. In spite of this, areas like Cork and Kerry have implemented an e-referrals system through their own efforts.

Equally, and despite other frustrations expressed and the continued delay of the Health Information Bill, the Department and HSE do deserve some credit for their efforts in the past 12 months, which include the Individual Health Identifiers Bill and the appointment of Richard Corbridge and his subsequent work. There is also recognition that establishing a functional eHealth system that has the confidence of the Irish public is a challenge that cannot be rushed, particularly in light of the (potential) uses of patient information. Bearing this context in mind, IPPOSI will continue to represent patient interests in this key emerging area of healthcare through our meetings, consultations and events.

The first section of this report contains:

- A review of policy issues relating to the Health Information Bill and its provisions.
- Concerns around the Research Ethics Committees component, and how they are being addressed
- The key priorities and progress of the HSE’s Chief Information Officer

The second section concerns research, and specifically:

- The upcoming EU Data Protection Regulation, and its potential impacts on health research in Ireland and Europe
- Local data protection issues

These data protection issues are directly relevant to section three—patient registries—which is structured as follows:

- A strategic overview of patient registries in Ireland delivered by HIQA,
- Irish patient experience of establishing and operating a patient registry
- A clinician’s view
- The industry perspective

IPPOSI would like to thank everyone who participated in our meeting for contributing their time and expertise. IPPOSI is mindful of how much it relies on the community of our membership in order to be effective and we are indebted to all of you for making this possible.

Dr Derick Mitchell,
IPPOSI Chief Executive
Section 1: Policy & priorities

Department of Health

What then is the status of eHealth and related issues in Ireland today? We begin with the contribution of Secretary General of the Department of Health, Mr Jim Breslin.

Mr Breslin outlined how Departmental ICT funding went up in 2015 by almost 40% (from €40m to €50m), but he noted that this increase will need to grow in order to deliver the ambitions that the HSE’s Chief Information Officer has set out (see: page 6). In recent years the Department has lost 40% of its staff through retirement and other causes, which has led it to reflect on its own organisation and skills. One of the positives of this refocusing has been provision for a new member of the Department’s senior management team whose responsibility will be research and development and health analytics.

More broadly, in order to support the wider modernisation of ICT infrastructure, the much anticipated Health Information Bill must be enacted, and Mr Breslin updated attendees on progress to date. He noted the extraction of the Individual Health Identifiers Act in 2014, before addressing ‘information and data resources’, which will be critical for developing Electronic Health Records (EHR) in the future. Mr Breslin outlined how the Minister will be able to insist that people mandatorily return to a limited number of gold standard registries, analogous to the National Cancer Registry, and similarly the Minister will be able to consent to data-matching exercises using different databases. Overall, the Bill and these powers will help to set the standard of interoperability while ideally enabling an environment that supports EHR.

The Bill also covers a ‘considerable’ amount of patient safety, and also streamlining of ethics committees - a topic that triggered a lot of discussion among attendees, particularly in light of Mr Breslin’s hope that the ‘General Scheme’ for the Health Information Bill is planned to go to Cabinet in September 2015.

Members of the research ethics community expressed concerns that the Bill was reaching the General Scheme stage when there was still confusion about the research ethics component of the Bill. One contributor felt that there was insufficient buy-in from ethics committees and was concerned that the only avenue of influencing the Bill would be through recourse to a Dail Committee.

Grace Cunningham, a Research Ethics Manager within HIQA outlined how HIQA had liaised with the Department on the research ethics content of the Bill over the past three to four years. HIQA has been engaging with stakeholders on issues arising as the legislation has been evolving, including through meetings of its Research Ethics Advisory Group. HIQA established the Advisory Group in 2011, with representatives of the different stakeholder groups and seven meetings have taken place to date. HIQA also engages with stakeholders directly, and has met with many stakeholders individually to discuss the future legislation and to listen to any issues or concerns the various groups may have. HIQA would be happy to hear from stakeholders on any issues or concerns they have relating to research ethics, and the contact email for this is researchethics@hiqa.ie.

The Department also indicated its willingness to consult on this matter, and more broadly, Mr Breslin reiterated that the Health Information Bill was one of the Minister for Health’s priorities for 2015, and progress will be publicly reported by year end. Mr Breslin could not provide a precise timeframe since the General Scheme will be referred to the Oireachtas Committee on Health and Children for input and the Committee may well wish to consult with stakeholders before finalising its views.

In summary, there may be positive signs, but there is no end in sight to Groundhog Day for the foreseeable future.
On a more upbeat note, the appointment of Richard Corbridge has been a very positive development for eHealth in Ireland. He outlined his six programmes and priorities for 2014/2015:

1. Individual Health Identifiers (IHI)
2. E-referrals
3. Ensuring that the National Children’s Hospital is born a digital hospital in 2019
4. Creating the Electronic Health Record (EHR) – and procuring same
5. Putting IT into cancer
6. Creating a primary care IT programme – specifically a primary care (i.e. not GP alone) IT programme

Mr Corbridge believes that these six priorities will provide the building blocks for connected health in Ireland. This ambition is the responsibility of his team, which include a primary care IT person; an acute care IT person and a community care IT person to ensure there is an ability for care settings to engage with technology.

His team’s work is also supported by the recently created Chief Clinical Information Officers Council, whose role is to ensure that the steps towards achieving connected health successes are not technology-led, but are based on clinical return and clinical benefit. Additionally, the eHealth Ireland Council, which will meet for the first time in December will offer further guidance to Richard and his team, while the eHealth Ireland website was launched in June (www.ehealthireland.ie).

One of the Information Team’s next big priorities will be ‘business intelligence’ (i.e. how the HSE can better turn the data it collects into clinical insights). Meanwhile the case for change for EHRs was due to be published in August, following engagement with industry, and again the ambition is to introduce EHRs with the opening of the National Children’s Hospital in 2019.

The immediate focus at the meeting however was on IHI. Mr Corbridge outlined the challenges of a having a system where money follows the patient without any IHI, and was happy to announce that IHI would be live in July. What this means, he explained, is that the HSE can issue a number to every patient in an index and this then will be piloted with the GP system, the epilepsy system and some hospices who have made their systems available for connection with IHIs.

The IHI works through an index associated with patient demographics, and access to it will be built to be as open as possible so that other systems can query the IHI database, find the IHI of a patient, and bring that back to its own system. For example, when a patient registry is communicating more widely with a GP system, the IHI can be referenced back out of there.

In line with the philosophy of patient care ahead of technology use, the HSE will roll out the IHI where there is a clinical benefit in doing so. Mr Corbridge noted that the IHI wasn’t just for hospitals or HSE services, but for wherever healthcare is provided in Ireland, and what it will do, he says, is change the way technology is delivered (moving away from the old health board structure where IT was neglected during the transition to the HSE) while ensuring that the new IT structure reflects the clinical settings.

Furthermore, two consent flags will be attached to the IHI – one for sharing with clinicians, one for health research. This simplified approach was created by learning from the mistakes made in the UK system where 17 consent flags were associated with IHI. This highlights the importance of getting things right, both from an operational point of view, and in terms of public confidence, but this necessarily slows the process and contributes to the ‘Groundhog Day’ dynamic that surrounds health information in Ireland.

However as Mr Corbridge pointed out, the good thing about Groundhog Day is that you can learn from your and others mistakes. Mr Breslin noted that in New Zealand where there is a similar sized population to Ireland, the health system there generated more than 11m IHI numbers in a short space of time.

Godfrey Fletcher, Chair of IPPOSI, asked if any legal framework existed for the consent flags and here Mr Corbridge acknowledged that in this respect, technology had to come ahead of clinical or patient engagement. Mr Corbridge explained that there will be an index off the IHI where consent can be recorded, but how and what that consent means, in terms of research and other areas, needs to be worked through. He also confirmed that the IHI was being built with compatibility and integration with other existing systems (e.g. registries) in mind.

The matter of consent is central to section two of this report, but overall we can see that as with the Health Information Bill, while progress has been made it will be years before Mr Corbridge’s six priorities can be realised.
As we have seen, research issues crop up at every level of the discussion on eHealth and health information - whether research ethics concerns at the policy level, or at an operational level where matters such as consent within IHI, or sharing patient information arise. Consent is a key issue in light of the upcoming EU Data Protection Regulation, and this issue was addressed in detail by Dr Graham Love, CEO of the Health Research Board.

Dr Love pointed out that using patient data is critical to achieving the architecture that Mr Breslin and Mr Corbridge had described. Dr Love explained that the upcoming EU Regulation could, if guided by the position of the European Parliament, present a significant challenge to future health research in Europe. While the European Commission made provision for health research and consent within its initial draft, the Parliament amendments would, if enacted, make the issue of consent extremely difficult.

In order to lobby against these amendments, which were driven by data protection concerns relating to wider privacy issues (such as Edward Snowden) health research, academic and research institutions across Europe have worked together to raise these concerns with all relevant stakeholders, in particular the third party involved in the development of an EU regulation – the Council of Ministers.

Now that the Council of Ministers has had the opportunity to consider the matter, the three parties are engaged in a ‘trilogue’, or tri-party discussion, and two trilogue sessions have already occurred – one on June 24th and one on July 14th. Further trilogue sessions will take place before the end of 2015. It is therefore possible, though perhaps unlikely, that the matter could be completed by the end of this year.

From a health research perspective, the best outcome would be an EU Regulation that is as close as possible to the original European Commission position which gave an exemption in effect for scientific and health research data for this very specific consenting issue, and a number of associated conditions. If something closer to the EU Parliament position is adopted, accessing the information needed for health projects, and the secondary and tertiary use of data, will be made extremely difficult.

For more information on the issue of data protection you can download the position paper of the Article 29 Working Party, which is made up of member state data protection authorities.

Meanwhile, Professor Seamas Donnelly of Trinity College Dublin explained how his own research would be impacted by a Data Protection Regulation that did not accommodate health research through exemptions and other provisions. Professor Donnelly noted that with respect to patient databases, the greater the number of patients enrolled, the higher the chances that clinically significant information may be identified. By accessing such large numbers, and by being able to look back five, ten and twenty years into anonymised patient data, big advances were made in areas like smoking, lung cancer, cholesterol and heart disease, blood pressure and heart disease. The EU Parliament position would jeopardise this model by requiring a degree of consent that would be very difficult to obtain.

As Professor Donnelly put it, there are three types of data:

1. Identifiable data – i.e. a patient’s hospital records (name, address, date of birth, and any coded numbers that directly link your data to your clinical status)
2. Anonymised data – where your medical information is extracted from your records, and there is nothing to directly link you to your name, date of birth etc.
3. Pseudo-anonymised data – where data is extracted and given a coded number on a database. This means an individual cannot be identified through this database, and the coded number is kept securely.

The value of pseudo-anonymised data, Professor Donnelly explained, is that while data is collected at a certain point-in-time, researchers are able to go back years, even decades, and break the code (i.e. reverse it and identify the patient) and see which patients got better or worse – and crucially, why. This is currently possible under Article 83 of the current EU Regulations, as applied in the UK and Ireland, and this has allowed research to flourish, says Professor Donnelly. It is this, or its equivalent in the new regulation, that must be protected, he maintained.

Professor Donnelly also expressed misgivings about the extra bureaucracy and red tape that the new regulation might bring, including (privacy) impact assessments that would have to be cleared through the Data Protection
Mr Garret O’Neill of the Data Protection Office touched on the European issue also, if only to say - as with other issues in health information – that little had happened in the past year, and that he had no update to give that was not covered by Dr Love or Professor Donnelly.

Mr O’Neill did however note that if and when the new Data Protection Regulation comes in, (probably the end of 2018) there will be an onus on all data controllers / holders / processors to have a more transparent explanation of how they hold data, what they use it for, who can access it, and what its primary / secondary purposes are. There may also be an end to the registration process with the Data Protection Office. There will be an introduction of administrative sanctions for non-compliance with key data protection principles – the biggest one being a fine of €1m or 2% of gross annual turnover.

Mr O’Neill’s cited the delay of the Health Information Bill as one of the factors preventing clarity on the issue of patient consent. He agreed that this is a key question for health registries and health research – to provide an exemption for patient consent where it is in the public interest, health research interest, and where the case is made on good evidence. As things stand now there is an exemption available if the case for it is demonstrated. He added that the patient must come first and last. This is a fundamental right, and research may only take place where the patient provides fully autonomous, informed consent so that they know exactly what their data is being used for.

When the question of data ownership arose, Mr O’Neill stressed that while this was a very difficult issue, the matter should be viewed as one of ‘control’, rather than ownership, and that anyone who exercises control over data must be able to show why this is so, and what contractual / statutory / legal right they have to collect, process and retain personal data.

Consent, then is the key issue threaded through all of these concerns – from conducting new research, to accessing old pseudo-anonymised data, to data ownership and control. However consent is not the only challenge facing the research community in Ireland.

Professor Tom Fahy of the Health Research Board Centre for Primary Care Research pointed out that in spite of his group collecting valuable data across 20+ studies from various patient groups, there was no mechanism in the HSE, the Department of Health or the clinical care programmes to use this data – and that the debate about health in Ireland was essentially ‘data-free’.

This is relevant to Richard Corbridge’s future priority of HSE Business Intelligence, as described on page six, but the point was also taken up by Jim Breslin, who recognised what Professor Fahy described, albeit from a different perspective. It is not, Mr Breslin said, simply that we have insufficient research (some areas undoubtedly do need further research), but rather it is about taking the existing knowledge and evidence and applying it to clinical practice and policy.

To this end, Mr Breslin stated that this is why they are putting in place a dedicated part of the Department of Health that mines the data, looks at the research, and tries to synthesize what is coming from that. Supporting this, the Department of Health had advertised a position for a member of the senior management team dedicated to research, development and health analytics. This position which will bring together the Department’s own need for research and information to inform its business and provide a natural fit to work with Richard Corbridge and the wider health system on information, and Dr Love in the HRB to turn ‘business intelligence’ objectives into a reality.

The effective use of data, and its access, interoperability and compatibility are critical factors for realising the full potential of patient registries, and it is to the registries themselves that we now turn.
Strategic overview

As is typical of IPPOSI Round Table Meetings, contributors to the session on patient registries were drawn from our principle stakeholder groups, including:

- Patients
- Regulators
- Clinicians
- Industry

In order to understand the strategic picture for patient registries in Ireland we begin with the contribution of Ms Rachel Flynn, acting director of Health Information with the Health Information and Quality Authority (HIQA).

Ms Flynn identified three areas for discussion:

1. HIQA’s regulatory role of inspecting and monitoring health and social services
2. Recommendations that HIQA made to the Minister for Health in relation to a more co-ordinated approach to ‘national data collections’ including (but not exclusive to) patient registries
3. Work HIQA wishes to pursue in improving the data quality of national data collections in the next few years

Health Information is one of HIQA’s four functions (the others being setting standards; monitoring those standards, and a Health Technology Assessment function). Ms Flynn pointed out that 70% of HIQA’s work is regulation - performing inspections, monitoring activity and investigations. One of the key questions that inspectors ask is how health staff assure themselves that the services they provide are safe and effective.

Delivering improvement depends on service providers having the capacity and capability in areas such as governance leadership and management, workforce, use of resources and use of information. In particular information should be actively used as a resource for planning, delivering, monitoring, managing and improving care. If organisations are not using information to monitor and assure themselves, then how do they know if their service is safe? Therefore, information from national data collections such as registries are very important sources of information.

In 2014, HIQA catalogued 109 ‘national data collections’. National health and social care data collections are defined as ‘national repositories of routinely-collected health and social care data, including administrative sources, censuses, surveys, and national patient registries in the Republic of Ireland’. Examples of national data collections include the National Cancer Registry of Ireland which collects comprehensive information on cancer incidence and deaths in Ireland and the Hospital In-patient Enquiry Scheme (HIPE) which collects demographic, clinical and administrative data on discharges and deaths from acute hospitals nationally. So the definition of a national data collection is much wider than registries and also includes national information systems. Registries are patient-driven rather than event-driven and each individual person on the register is registered once as a unique entity (i.e. not duplicated).

HIQA made recommendations to the Minister of Health in 2014, identifying three key challenges facing national data collections in Ireland.

1. The absence of a strategic framework and any national oversight for national data collections
2. The need for standardisation and improvement in data quality, and
3. The use of information, which is not being optimised – reflecting the points made by Professor Fahy, Mr Breslin and Mr Corbridge under the heading of ‘business intelligence’.

Regarding the strategic framework, HIQA noted that there is no one body within the HSE that has oversight of these national data collections, and as such they were fragmented, having evolved in silos. Ms Flynn also noted that 20 of the 109 national data collections fell outside of the HSE (for example the HRB runs five of these) – and that HIQA does not have a role in setting standards for these data collections. Many of these data collections were created for a specific need, or by special interest groups, and this fragmentation contributes to reduced value for money.

This formed the backdrop for two recommendations:

1. (Developing) a strategic framework
2. Establishing an oversight organisation for all data collections, inside and outside of the HSE
With respect to the second challenge, HIQA concluded that if data quality was not good, then the data being collected was effectively useless, and their inspections have found varying degrees of data quality in the past. Additionally, HIQA found only two data dictionaries for the 109 national data collections. These dictionaries are simple, useful tools for defining each of the data elements within a registry. This was described as a very basic element that allows people to collect data to a common definition and also to allow others (e.g. researchers) to use the data.

Furthermore, data collections often sat in isolation, were not the responsibility of ICT or clinicians and therefore ‘fell between two stools’. HIQA also made recommendations around the need to comply with legislation on data protection, to have good frameworks for information governance and data quality.

With respect to existing health information not being optimised, HIQA noted that information is not being made available to patients or the public, with a few notable exceptions, such as HIPE (Hospital In-Patient Enquiry) data, where a portal has been developed to allow researchers and service providers access to the data. If the other 100+ national data collections were to develop portals there would be huge cost implications, so again, Ms Flynn noted, the strategic oversight provided by a national body overseeing these data collections could reduce the burden to taxpayers.

Ms Flynn noted that similar moves have taken place abroad, but that such changes take time and cannot be expected to happen overnight. HIQA has developed guiding principles for national data collections (see the HIQA website here), and hopes to convert these principles into standards, develop an assessment framework and use it to look at the quality of the data within the national data collections that fall within the HSE.

### Patient perspective

Godfrey Fletcher acknowledged that a varying standard of data quality and governance exists between registries, and one of the first pitfalls he cautioned against was having a sole ‘data champion’ (i.e. someone who set up a registry for a specific research or disease interest, and who was central to the management of a registry, or database in a given field or area). Often when a data champion moves on to another role, or retires, important data sets are lost with them.

Similarly, he mentioned data discontinuation as another hazard, where for example a database formed as part of a clinical trial is discontinued when the trial ended. Indeed it was this very circumstance that triggered the formation of the European Cystic Fibrosis Registry (when a trial ended), so the clinicians sponsored the establishment of a new registry to ensure that valuable data was not lost.

If those are some of the existing challenges for patient organisations considering creating a patient registry, Mr Fletcher also described some of the future challenges and some opportunities to make patient registries sustainable in the future. Are there common underlying technologies for registries? Are there opportunities for shared resources? Is there a role for patient registries in supporting the national clinical programmes? Is there a need for patient registries if and when Electronic Health Records become a reality? Mr Fletcher believes there is.

Furthermore, and in light of the significant costs, data management and data collection challenges that exist for the creation and maintenance of good quality patient registries, Mr Fletcher believes that there are resources and platforms that the patient community can and should share in order to keep Irish registries functional to a high and useful standard. This was supported by Dr Dmitri Wall of the Irish Skin Foundation, who agreed that much of the work needed in a registry is applicable to all registries – and that registries needed to be integrated, interoperable, dynamic, and capable of working in real time.

As to the role the CF Registry plays now in supporting services for CF in Ireland and Europe, the organisation supports HSE data requests on a quarterly basis. Mr Fletcher also outlined how the CF Registry has received funding for a two-year research project investigating how patients interact with a registry.

Elsewhere, Mr Declan Noone from the Irish Haemophilia Society described how the society’s registry allows patients to track their own treatment, and this data goes straight to the doctor, so during a consultation with the doctor, the information is current and informs patient care effectively. In terms of cost savings, Mr Noone described how by being able to identify exactly how much medicine their patients would need, the Haemophilia Society were able to help reduce the price of the medicine by 20-40% year on year. If volume can be predicted, payers are happy, companies are happy and patients get the treatment they need.

On a macro level, Mr Fletcher suggested the establishment of a national centre of excellence for patient registries in the form of a foundation. This would support the development of shared resources, platforms, and methods of best practice, and would also provide patients with an independent trusted third party that could act as an objective data controller.

If these are some of the challenges and opportunities that exist for patient registries when they are up and running, what if you are considering starting a patient registry, or have recently begun one?

Dr Maria Meehan, research manager with Fighting Blindness provided some insight here. She began by describing the bleak historical situation for patients with a retinal degenerative disease, where no cures or therapies existed. With no means of treatment, patients had no cause to engage with the health system, so even though there are an estimated 5,000 people with a retinal degenerative disease in Ireland, there was no record of where these people are. In more recent times, as
Patient registries are a step towards this. Research and clinical practice should be one and the same. He reiterated that research should not be an afterthought but a definition of the practice and its potential. Bringing disparate voices together on certain issues in the clinical environment is essential for the advancement of patient care. Professor Veale stressed the importance of different groups working together to ensure that research and clinical practice are aligned.

Nevertheless, Professor Veale oversaw the development of a registry for patients on the new biologic treatments, and this contributed to finding that patients on these new treatments had up to 60% chance of full remission. This work also fed into European guidelines for treatment use when the evidence showed that these treatments could reactivate TB. It is now routine practice for patients to be screened with a chest X-ray and a blood test for TB before starting on biologics treatments.

There is now agreement at the national level for the establishment of a registry of patients commencing on biologics drugs which includes Dublin and regional centres across Ireland. Professor Veale finished by stressing the importance of different groups working together to change policy, and he credited IPPOSI with successfully bringing disparate voices together on certain issues in the past. He reiterated that research should not be an afterthought but should be a primary focus for a registry.

The value of patient registries to patient organisations is obvious, whether it is helping to attract research, inform service planning, lower the cost of treatments, or improve patient outcomes. Against this, the challenges of creating patient registries are stark – patient consent, data management, governance, the cost of capturing data to name but a few. Perhaps, as Mr Fletcher suggests, some of these issues could be addressed by a national centre of excellence, or a foundation for patient registries.

As with the other central issues of this report, and in the absence of any strategy or oversight, a solution seems not only distant, but undefined.

Clinical perspective

Professor Doug Veale of University College Dublin and St Vincent’s Hospital, began by saying that patients, doctors and other health professionals all want the same thing: information on diagnoses, tests and safe, effective treatments to deliver good outcomes.

Whether Professor Veale sees a patient in a clinical or research practice is one and the same to him, because good clinical practice is ‘research in action now’, with today’s research being tomorrow’s good clinical practice. Professor Veale suggested that the key point is integration, from the very beginning and whether it’s a registry or a database or an Electronic Health Record – what matters is good quality data to inform what we have at present and what we will do in the future.

Professor Veale went on to describe the evolution of a registry for Rheumatoid Arthritis (RA) following on from the emergence in 2003 of great new ‘biologics’ treatments for RA, psoriasis and ankylosing spondylitis which led to registries being established in the UK, Sweden, Germany and the USA, though not in Ireland. Professor Veale suggested the failure to establish a national register for Ireland occurred as healthcare professionals and management were unable to agree on the technology and data protection issues.

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Patient registries are a step towards this.
Industry perspective

From an industry perspective, the problem and opportunity are one and the same thing, according to Linda Tormey, Clinical Research Manager and Head of Clinical Operations for Bayer Ireland. Without good quality data available, Ireland is not on the map for industry-led clinical trials. If industry cannot identify and track patients and their outcomes, they simply will not conduct clinical trials in Ireland.

We can see that where such patient data is available there are huge benefits (such as with the CF Registry and certain CF patients in Ireland) but for those disease areas without equivalent patient data, there is little chance of patients benefitting from clinical trials. As Dr Meehan noted, one of the objectives of the Fighting Blindness registry was to grow the visibility of patients with retinal degenerative diseases in Europe, so Linda Tormey’s observation echoed this point - visibility is key.

The absence of data leaves industry struggling to perform small feasibility studies that can justify companies placing trials in Ireland. As this changes under the new legislation, Ms Tormey believes Ireland will become much more competitive in attracting clinical trials. By contrast, she noted the success of the National Cancer Control Programme, and the relative advances accruing in Irish cancer care as a result.

Pictured below are:

Top: Ms Rachel Flynn (HIQA)

Middle: Mr Godfrey Fletcher, CF Registry (left) and Dr Maria Meehan, Fighting Blindness (right)

Bottom: Professor Doug Veale, UCD (left) and Ms Linda Tormey, Bayer (right)
We look ahead with great anticipation to key events later this year and early in 2016 in particular – the publication of the Heads of Bill for the Health Information Bill, which is planned to go to cabinet in September, and also the outcome of the EU’s trilogue on the Data Protection Regulation.

Meanwhile Ireland presses ahead with the implementation of the Individual Health Identifiers, the eHealth Ireland Council, or on a smaller scale as the managers and creators of patient registries. Overall, it is heartening to see within the HSE the driving principle is clinical benefit, rather than technological solutions. Equally, it is encouraging to know that one of the next major priorities for the Chief Information Officer is what he describes as ‘business intelligence’ – optimising the use of the considerable amount of data that is already being generated within the Irish health system. Similarly we are glad to learn that the Department of Health is recruiting a research-specific role to its management team, which will among other things, support the development of improved ‘business intelligence’.

Out in the clinical environment, and beyond, we have seen the appetite that exists to gather and use effective patient data through registries, and we have briefly examined the benefits of this – for patients, good practice, research, and even payers – just as we have identified many of the challenges, and some of their potential solutions around sustainability, shared resources, and the need for oversight.

Overall, there emerges a clear picture of what exists, and what must be done and how long this might take. Given the slow pace of change, the Groundhog Day mantra is unlikely to change but there are significant steps underway, and there is clear recognition of where the Irish system should strive to get to with respect to Health Information and its attendant components - research, ethics, data quality, oversight, consent, data protection.

One of the points to emerge in this report is that data collections have evolved in a fragmented way. This must not happen to the various elements of Health Information. They rely on each other, and are interconnected and interdependent, even if at first glance they may seem miles apart. It is clear also that there are principles that should underpin all of this work – embedding research in clinical practice; driving strong data quality in every aspect of health, sharing resources.

The tragedy is that while these principles are recognised and gradually implemented, patients will continue to suffer and miss out on a better standard of care.

This is a circumstance that exists – it is not a reality that we must or should accept. Co-ordinated, unified patient voices, along with science and industry voices, have together been effective drivers of change. It is up to us to drive this change, and press this agenda – to ensure that government considers this as one of the key policies and pieces of legislation that must be addressed before the next election, if we are ever to see the end of Groundhog Day on the horizon.

It is up to us.
Jim Breslin was appointed Secretary General of the Department of Health on 10 September 2014. Before then Jim was the first Secretary General of the Department of Children and Youth Affairs, which was established in July 2011. As well as providing administrative leadership, he contributed to the major reform of legislation, policy and services in the area, including the establishment of the Child and Family Agency (Tusla); and the publication of The National Policy Framework for Children and Young People 2014-2020 “Better Outcomes Brighter Futures”. He holds two masters degrees in public administration; one from the Institute of Public Administration/Trinity College Dublin and another from Harvard University’s Kennedy School of Government.

Richard Corbridge, Chief Information Officer, HSE. Richard, previously from the NIHR Clinical Research Network, has a wealth of experience in the Health and Clinical Research sector leading various informatics delivery elements; business change, benefits management and Information security projects. He has specialised in IT development, procurement and implementation across national and local health care arenas in the UK for more than fifteen years.

He has taken up the dual role within Ireland of CIO of the Health Service Executive, and the role of Chief Officer of the newly formed eHealth Ireland organisation.

Graham Love (PhD) is the Chief Executive of the HRB since 21 March 2014. He brings 15 years leadership and senior management experience to the HRB, with his most recent role being Chief Executive of Molecular Medicine Ireland. Previous positions include senior posts at Science Foundation Ireland including Interim Director General, Director of Policy and Communications and Director of Discover Science and Engineering. During his time at SFI he was responsible for the development of SFI’s 2009-2013 strategy, Powering the Smart Economy. He graduated with a BSc (Hons) in Pharmacology in 1993, followed by a PhD in vascular cell biology in 1997 from University College Dublin.

Rachel Flynn, Acting Director of Health Information, HIQA. Rachel was appointed Acting Director of Health Information in September 2014. She joined the Authority in November 2007 as the Health Information Manager in Quality and was appointed Head of Healthcare Assurance Programmes in Healthcare Regulation in 2013.

Previously she worked in the Health Research Board (HRB) as Health Information Manager and worked in the Royal College of Surgeons as Research Officer on health information systems and the development of datasets and data dictionaries. Rachel holds a BSc, Higher Diploma in Computer Science and an MSc in Research from Trinity College Dublin.


Speaker biographies

Garrett O’Neill, Solicitor and Legal Adviser in the Data Protection Commissioner’s office. Garrett’s work functions include in-house legal advice and providing assistance for all types of private sector organisations including corporations, companies, trade representatives and interest groups, on all issues relating to compliance as data controllers with the Acts. He also engages with and advises, Public Sectors bodies such as Government Departments, state bodies, HSE etc. on issues concerning data sharing and new legislation that could affect the data protection rights of individuals.

Professor Seamas Donnelly Physician, Clinical Scientist, Educator, is the Professor of Medicine at Trinity College Dublin. He was recently awarded Honorary Professorship by University of Edinburgh for international leadership in Translational Medicine. He is currently Editor-in-Chief of one of the worlds leading medical journals, the Quarterly Journal of Medicine (QJM), and is also responsible for obtaining in Ireland over €30 million in external grant funding as PI/Co-PI. Research interests include partnering industry in the development and validation of novel sensor technologies in healthcare. Partners include Novartis, Intel, ResMed, GE, Vitalograph, Aerogen and Real Time Technologies.

Professor Douglas J. Veale is Director of Translational Research of the DAMC, Professor of Medicine and Consultant Rheumatologist at St Vincent’s University Hospital and a Principal Investigator at The Conway Institute for Biomedical and Biomolecular Research, University College Dublin (UCD). He has established an international reputation in translational research in the areas of angiogenesis, early arthritis, biopharmaceutical therapy, biomarkers and scleroderma, and he has established an excellent research team including senior scientists, post-doctoral scientists, clinical research fellows and PhD students funded by peer-reviewed grants from The American Federation for Ageing Research, the European Union FP6 programme and Innovative Medicines Initiative (IMI), and the Health Research Board of Ireland among others.

Dr Maria Meehan has been with Fighting Blindness since 2012. As Research Manager, she is responsible for coordinating all research activities of the organisation, including providing support to the Target 5000 initiative which is focused on the genetic characterisation of the 5000 people in Ireland with inherited retinal disease. Maria also has extensive expertise in communicating complex scientific information to a diverse patient base. Maria completed her undergraduate degree in Biotechnology at Dublin City University before being awarded her PhD from University College Dublin in 2009. Prior to Fighting Blindness, she was a postdoctoral researcher for three years, employed by the Royal College of Surgeons in Ireland and based in the National Children’s Research Centre in Dublin.
Linda Tormey has been the Clinical Research Manager and Head of Clinical Operations in Ireland for Bayer for almost 13 years. In that time she has been responsible for all of Bayer’s clinical operations activities and for oversight of medical affairs trials and negotiations with investigators and collaborative groups on ISS trials.

Prior to working with Bayer, Linda was a Senior CRA with Pharmacia and ICON, prior to which she was a senior staff nurse in St Vincent’s hospital. Linda recently completed a Diploma in Health Economics.

Eibhlín Mulroe, MBA, former Chief Executive, IPPOSI. In her early career Ms Mulroe worked in Irish Politics and then the NGO sector where she worked as CEO of the Asthma Society of Ireland. In July 2007, she became the first CEO of the Irish Platform for Patients’ Organisations, Science and Industry (IPPOSI). Ms Mulroe was appointed by the Minister to the Department of Health Steering Group on Rare Disease Policy in 2010, she represents patients on the HIQA Research Ethics Advisory Board, and she is a member of the HSE Patient’s Forum and the patient representative on the Legal Consultative Panel of the Irish Medicines Board. Ms Mulroe has a BSSC Hons in Politics from Queens University Belfast and is an MBA graduate from the Smurfit Business School, University College Dublin.

Godfrey Fletcher, MBA, is the Chairperson of IPPOSI. He is also CEO of the Cystic Fibrosis Registry of Ireland and a member of the National Clinical Programme for Cystic Fibrosis Working Group. Godfrey served on the Technical Committee that selected and implemented a new multi-centre pan European registry technology last year. He also served on the HSE’s National Neonatal Screening Working Group and the HSE’s multi-disciplinary Working Group that published the Report “Services for People with Cystic Fibrosis”. He is also a member of the Board of ARCH – Applied Research for Connected Health, Technology Centre. Godfrey has over 35 years’ experience working in the health sector. He has a keen interest in health technology and telemedicine particularly in hosted high definition video services. Godfrey is a graduate of Trinity College Dublin (B.A. Mod) and has an MBA from Dublin City University.