



Medical Research Charities Group (MRCG)

Submission on Health Information Policy Framework Consultation

November 2017

Introduction

The Medical Research Charities Group (MRCG) welcomes the opportunity to make a submission to the Department of Health in relation to the development of a National Health Information Policy. The MRCG is an umbrella group of 36 medical research charities (appendix 1) which, together, represent over one million patients in Ireland.

The MRCG believes that patient organisations should lead and stimulate health research that is driven by patient need. We seek to identify and remove any barriers to health research and to work collaboratively with our members, policy makers, the research community and other stakeholders to improve the research infrastructure. We view health information as a valuable underpinning for research into human health and illness. We look to a day when there is the possibility for all health information to be used to build our knowledge of human health and improve patient care.

Our standpoint on this policy framework could be broadly described as a patient perspective, with a focus on health research.

Our submission

We commend you on the health information policy framework, welcoming both the core principals and the policy pillars. In particular we commend you for the following aspects:

- The **person-centred** approach at the centre of the policy
- The **involvement of patients** in all governance structures
- The efforts to bring **clarity to the processing of healthcare information**, for all stakeholders
- The focus on the importance of **safe-guarding patient data**
- The acknowledgement that **education and transparency** will be key to the success of the policy

While we welcome the policy framework as currently outlined, we provide below recommendations for inclusion in the final policy.

Key messages

- **Research needs to feature more strongly in the policy** and should be considered in a broad sense, to include the analysis of data to generate hypotheses as well as studies undertaken to test them.
- It is important that the **overlap between patient care and research** is recognised – a strong health information policy can help to blur the lines between the two.
- As a key tool underpinning health research and enabling the capturing and sharing of health information, the importance of **patient registries** should be addressed.
- **Rare diseases** need special consideration which should be acknowledged.
- All decision-making bodies and processes around health information need to **involve patients**.
- Patients need to have **access to their data and control over their data**.

1. Policy Pillar: Legislation

We welcome the clarity that a legislative basis will bring to the processing of health information for care and research. Informed consent should be at the heart of all relevant legislation and the policy. The sharing of non-identifiable data for research purposes needs to be facilitated and encouraged and those sharing the data need clear guidance on how to do this legally and appropriately. A legal basis for consent exemptions for the sharing of identifiable information for research purposes is also important. This will help to ensure that valuable data with the potential to improve lives is not lost, without careful consideration.

Some additional points on legislation:

- While the term '**duty to share**' is being used in the context of patient care, it is also applicable in the research context.
- We encourage you to bear in the mind that the sharing of anonymised/pseudonymised data in the case of **rare diseases** can cause challenges to protecting anonymity. While this needs to be acknowledged, it should not be a deterrent to sharing health information under carefully considered criteria.
- **Decisions on consent exemptions** and the reasons for such decisions should be transparent and easily accessible by the public.
- We encourage a move towards **dynamic consent** whereby there is ongoing communication between researchers and patients, supported by digital solutions. This allows patients to retain control over their data and researchers to have the potential to use the data for previously unforeseen purposes.

2. Policy Pillar: Governance

Good governance is essential to the management and sharing of health information and we welcome the statement that governance structures should be built on transparency, accountability and patient safety. The proposed roles and committees are welcome but need to be appropriately resourced and committees need to include all relevant stakeholders, including patients. The proposal within this section to 'progress a standardised approach to health information exchange, data modelling...' could possibly be moved to the Operations policy pillar, for the purposes for clarity.

Some additional points on governance:

- We prefer the term National Data Guardian (as used in the UK) for the proposed **national data advisor** role. This term makes the purpose of the role clearer and emphasises the importance of the role in representing the interests of patients.
- The phrase '**expert and patient representatives**' implies that patients are not experts in their own right. This could perhaps be re-worded to 'medical and other relevant experts, including patients'.
- Patient involvement on the **confidentiality advisory committee** needs to be explicitly stated.
- **Codification** of diseases/health conditions (e.g. through the use of ICD-11) and medical terminology (e.g. through the use of SNOMED TC) is essential, in order to facilitate sharing and interpretation of data. The use of standardised codes will also enable international sharing of data (interoperability), as will be required in the case of the European Reference Networks (ERNs).
- It is also imperative that **Rare Diseases** are coded as they are currently often invisible in the system. Orphacodes are widely considered the best approach for this.
- Any technical solutions to recording personal health data will need to look ahead to a time when **genetic testing** is more routine and when whole genome sequencing will become commonplace.

This will bring with it a requirement to link families, for the purposes of tracking inheritance and supporting genetic counselling.

- A mechanism, along with defined criteria for assessment, needs to be established to assess **research requests for access to non-identified** data. Ideally this mechanism would be centralised for all major repositories.
- Patient data is a valuable resource and those who collect it have an onus to ensure it is used in the best interests of the patients who provided it and broader patient communities. The principals of **open data** should be encouraged in the policy, to allow the reuse of data, in accordance with FAIR data principals (<https://www.nature.com/articles/sdata201618>) and with respect to patient consent and confidentiality.

3. Policy Pillar: Operational Arrangements

We agree with the need to provide optimal oversight arrangements for the 120 national health and social care data collections, along with the need for a consolidated approach to data warehousing. Information silos are a major deterrent to health research and every effort should be made to link data, where legally possible.

- While 120 national health and social care **data collections** have been defined, there are also many more small collections which should be acknowledged.
- **Patient fatigue**, caused by the need to repeatedly give the same information to healthcare providers is a deterrent to research. Research intended to improve the lives of patients can quickly become yet another requirement to answer questions asked many times before. This is particularly so in chronic and serious illnesses. Efforts to reduce this will make the lives of patients, healthcare workers and researchers easier.
- We welcome the acknowledgement that **data must be of high quality**. It should be recognised that this presents particular challenges in rare and complex diseases, or in smaller healthcare settings, where medical expertise might be limited.

4. Policy Pillar: Patient and Professional Awareness

The health research community have been struggling with a lack of clarity in how best to manage and share health information. Patients are unsure of how to get access to their own data and how their data is being used. An investment of time and money is required to bring clarity and increase understanding among all stakeholders of the power of health data and to address concerns that could result in patients not being willing to share their data.

- There needs to be mention in the policy of the importance of **patient trust**, emphasising that such trust is the product of investing time to communicate with patients and investing in education initiatives.
- It is important to recognise the existence of the '**language barriers**' that exist in relation to health information and to take steps to minimise those barriers. Phrases such as 'health information architecture', 'data modelling', 'secondary uses' etc. make it difficult for most of the population to truly engage in conversations around health information.
- It is essential that **patients can access their health data digitally and have the ability to input their own data** for research purposes. This will empower them in their own care and also provide for richer data collection, in keeping with wider moves towards citizen science. The importance of this

is demonstrated by the increased use of wearable and home-based health sensors. Online banking shows us what is possible in providing the public with secure access to sensitive information.

- We encourage an **audit function whereby patients can see who has accessed their data** and when. We believe this to be particularly important in the case of Ireland, where degrees of separation within the population are very small. It will also become increasingly important as health data becomes more and more valuable to for-profit making enterprises.
- **Education** is critical and needs to be resourced. The 100,000 Genomes project (<https://www.genomicsengland.co.uk>) provides a positive example of clear and informative educational material, to support a large health information gathering initiative.
- The Irish public are less supportive of fund-raising activities for research than for patient care, which is an indicator that much needs to be done to **communicate the benefit of health research** and the associated need to gather health data.
- **Medical Research Charities** and the MRCG are well-placed to play a role in education and promotion in relation to the importance of health information for research purposes. The **Irish Health Research Forum** (supported by the MRCG) also provides a possible avenue for conversations among all stakeholders on the topic.

5. Other important aspects, not included in the draft framework

The importance of research

While the policy framework does acknowledge the need for health data to be used for research purposes, research as a core theme relating to health information could be strengthened. Research is not currently sufficiently valued within the health service and changing that culture starts with making research a central tenet of policies such as this.

Patient registries

Patient registries should no longer be considered static repositories of patient data. They have evolved to now have the potential to be extraordinarily valuable tools that can span research and care and support all types of research. Patient registries can integrate seamlessly with clinical management systems, with electronic health records and with patient portals. Modern registries can be built upon over time to allow data for research studies to be captured and seamlessly integrated with patient data which already exists. Excellent examples demonstrating such seamless integration and the value of registries include the Irish Skin Foundation Registry of Skin Diseases and the Cystic Fibrosis Registry of Ireland.

Patient registries can:

- Capture disease demographics, clinical outcomes and survival rates
- Support patient recruitment for clinical research
- Support the undertaking of research studies and clinical trials
- Support pharmacovigilance
- Allow patients access to their own data, through patient portals
- Allow patients to submit their own data e.g. quality of life data or patient reported outcomes.

For all these reasons, patient organisations recognise the great need for patient registries and many already support registries or have plans to do so. Given their relevance to all aspects of health information, patient registries should feature strongly in the final policy.

Finally

Thank you for the opportunity to make this submission. Given its enormous importance, we would urge you to adhere to the timelines for the finalisation of this policy, to resource it appropriately and to ensure its effective implementation thereafter.

Appendix 1

Medical Research Charity Group Member Organisations

Alpha One Foundation
Alzheimer Society of Ireland
Arthritis Ireland
Breakthrough Cancer Research
Central Remedial Clinic
CLAPAI
COPD Support Ireland
Croí, the West of Ireland Cardiac Foundation
Cystic Fibrosis Ireland
Cystinosis Ireland
DEBRA Ireland
Diabetes Ireland Research Alliance
Disability Federation of Ireland
Duchenne Ireland
Epilepsy Ireland
Fighting Blindness
Friends of the Coombe
Heart Children Ireland
Irish Cancer Society
Irish Heart
Irish Nephrology Society
Irish Thoracic Society
MSD Action Foundation
MS Society of Ireland
Muscular Dystrophy Ireland
National Children's Research Centre
Research & Education Foundation, Sligo General Hospital
Research Motor Neurone - The Irish Motor Neurone Disease Research Foundation CLG
Royal Victoria Eye and Ear Research Foundation
St John of God Research Foundation
St Vincent's Anaesthesia Foundation
St. Patrick's University Hospital
Temple Street Foundation
The Heartbeat Trust
The Saoirse Foundation
The Rotunda Foundation

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