



Irish
Brain
Council

BUILDING A SUPPORTIVE FRAMEWORK FOR BRAIN RESEARCH IN IRELAND

**INAUGURAL POSITION PAPER
THE IRISH BRAIN COUNCIL**

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NEW THINKING
2017



FOREWORD

Brain disorders are a grand challenge of our time, a challenge that is growing with our changing demographics. To meet the challenge, we need new thinking, thinking that crosses the divide and, at first glance, challenges us. Improving how we generate evidence from research and how we use that evidence in practice to transform prevention, treatment and management of brain disorders is central to addressing this challenge. Crossing the divide requires communities to come together; patients, clinicians, policy makers, researchers and more.

I welcome this inaugural paper from the Irish Brain Council as it represents a coming together of major players in the brain research/disorder area for the first time. New thinking will pose challenging ideas, ideas that may not find agreement with all stakeholders but will nonetheless ignite the debate and progress the agenda.

This Irish Brain Council position paper is an important first step in promoting debate and I congratulate the Irish Institute of Clinical Neurosciences (IICN), Neuroscience Ireland (NI), the Neurological Alliance of Ireland (NAI), the Psychological Society of Ireland (PSI), the College of Psychiatrists of Ireland (CPI), the Irish Consultant Neurologists' Association (ICNA) and MS Ireland in forming the Council and starting the conversation as we collectively search for solutions to the grand challenge of brain disorders.

Dr Graham Love,
CEO, Health Research Board

SUMMARY

THE IBC IS AN INDEPENDENT GROUP OF ORGANISATIONS WHICH HAVE COME TOGETHER TO INFLUENCE AND IMPACT UPON BRAIN RESEARCH IN IRELAND

The purpose of the Irish Brain Council is to promote and advocate for brain research in Ireland. It aims to harness the expertise and experience of its membership to provide a platform for public outreach, legislative engagement and strategic partnership to foster a supportive environment for brain research that ensures Ireland's competitiveness in this area going forward and enables the attraction, retention and development of research initiatives in the understanding and treatment of brain conditions.

This first inaugural position paper by the IBC aims to outline the challenges and opportunities for brain research in this country and calls for a supportive infrastructure to attract future investment, retain highly qualified personnel and ensure that research findings are effectively translated into better outcomes for people with brain conditions.

Brain research was the initial focus of the European Brain Council (EBC) when it was launched 15 years ago; since then, however, the EBC has expanded into many other areas such as prevention, education, the patient's journey etc. The EBC has therefore recently adopted an alternative term "brain health" in place of "brain research", which is more holistic and more representative of their broader remit. For the remainder of this paper, we will use the term "brain health and research" to mirror the aims of the EBC in the goals of the Irish Brain Council.



The purpose of the Irish Brain Council is to promote and advocate for brain research in Ireland.



IBC aims to be inclusive of all areas of brain health and research aimed at improving the quality of life for people living with brain conditions

THE IRISH BRAIN COUNCIL

THE IBC AIMS TO BE INCLUSIVE OF ALL AREAS OF BRAIN HEALTH AND RESEARCH AIMED AT IMPROVING THE QUALITY OF LIFE FOR PEOPLE LIVING WITH BRAIN CONDITIONS

The Irish Brain Council is a group of representative organisations with the overall aim of influencing the landscape of scientific research into brain conditions in Ireland.

The IBC adopts a broad definition of brain health and research covering the spectrum from basic science and translational research through clinical research, clinical trials to health service interventions and research into health systems aimed at improving treatment and responses to the needs of those with brain conditions.

The membership of the IBC is currently constituted as follows:

- The Irish Institute of Clinical Neurosciences (IICN)
- Neuroscience Ireland (NI)
- The Neurological Alliance of Ireland (NAI)
- The Psychological Society of Ireland (PSI)
- The College of Psychiatrists of Ireland (CPI)
- The Irish Consultant Neurologists' Association (ICNA)
- MS Ireland

The IBC is an affiliated member of the European Brain Council



PURPOSE OF THE IBC

THE MISSION OF THE IBC IS TO PROMOTE BRAIN HEALTH AND RESEARCH TO IMPROVE THE QUALITY OF LIFE OF THOSE LIVING WITH BRAIN CONDITIONS

The IBC will strive to work in partnership with other representative organisations to influence the research landscape in Ireland so that the needs of all stakeholders, including those living with brain conditions, are recognised and addressed.

The strategic goals of the IBC are as follows:

- To promote a strong advocacy for investment in and support of development of brain health and research in Ireland
- To promote the development of an infrastructure for brain health and research in Ireland that ensures that the sector can attract, retain and develop high quality research initiatives and researchers.
- To ensure that the views of all stakeholders are reflected in the work of the IBC, including those living with brain conditions and patient representative organisations
- To encourage the use of research findings to inform health policy, practice and services for people with brain conditions

THE COST OF BRAIN DISEASE AND PROPORTIONAL INVESTMENT IN BRAIN HEALTH AND RESEARCH

In November 2015, the European Brain Council produced a Consensus Statement on the Need to Expand Brain Research in Europe.¹ Brain disorders affect over 179 million individuals in Europe, impacting on one in three Europeans during their lifetime.

The cost of brain disorders to the European economy and national health budgets is in the region of €800 billion per annum, representing 45% of the annual European health budget and comparable to that of cancer, cardiovascular disease and diabetes together. Indeed, it is estimated that over 1.1 million people in Ireland are living with a brain condition with an economic cost of €3 billion per year.² The societal cost of multiple sclerosis alone in Ireland was recently estimated at €429m per year.³ However, research investment in the neurosciences/brain research remains behind cancer and cardiovascular research and there is currently no directly targeted funding for neuroscience research.

IN IRELAND

1.1 MILLION
PEOPLE ARE LIVING WITH A BRAIN CONDITION

BRAIN DISORDERS AFFECT OVER

179 MILLION

1 IN 3

INDIVIDUALS IMPACTED IN EUROPE



€800
BILLION
PER ANNUM

45%
OF THE ANNUAL
EUROPEAN HEALTH
BUDGET

COSTING
€3
BILLION
PER YEAR



EBC CONSENSUS STATEMENT (2015)

It is imperative to improve the prevention, treatment and management of brain disorders for humanitarian, scientific, societal, political and economic reasons.

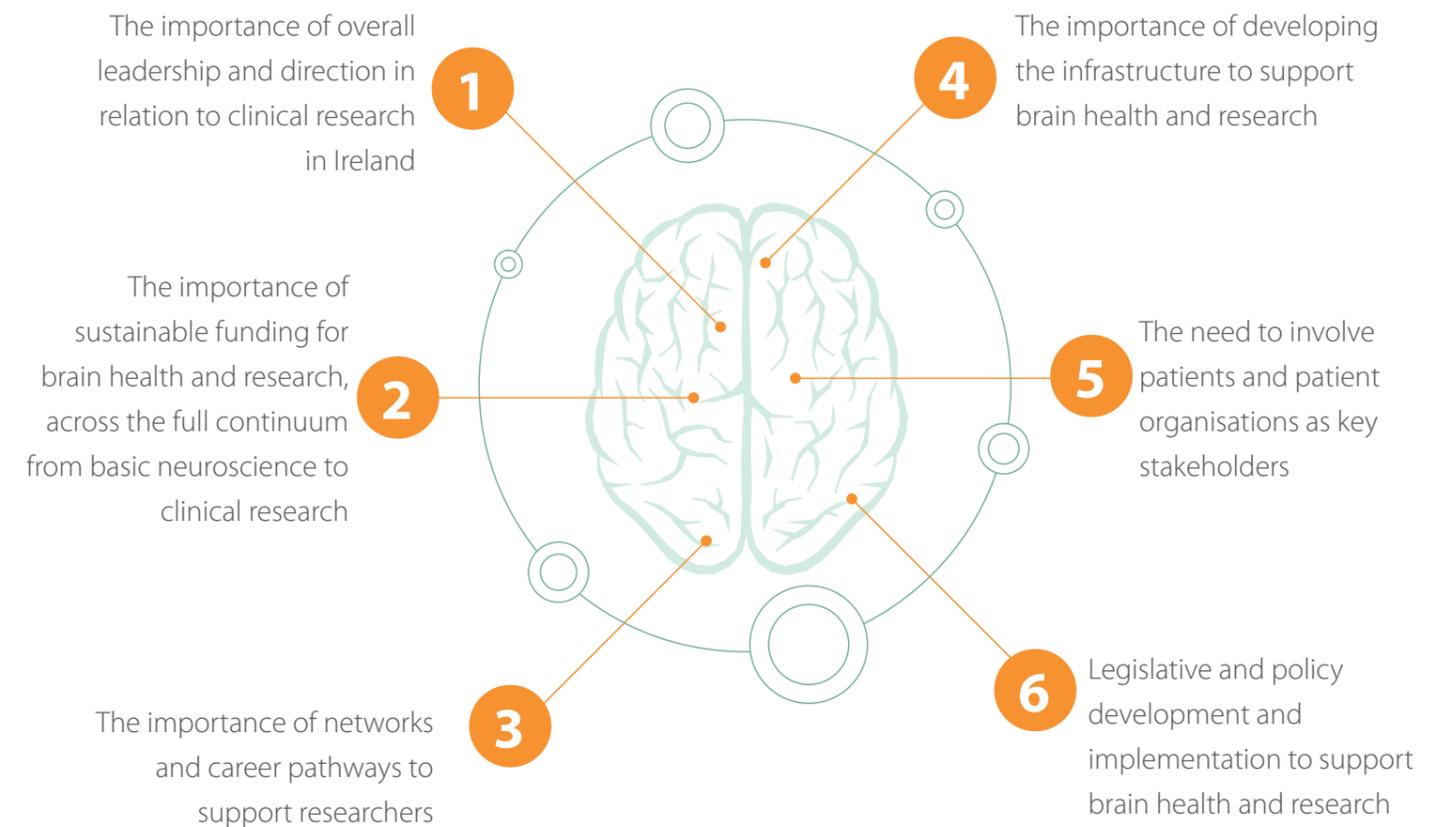
- ✓ WE CALL ON ALL EUROPEAN AUTHORITIES TO DEVISE AND IMPLEMENT A PLAN TO TACKLE BRAIN HEALTH IN AN INTEGRATED AND COMPREHENSIVE MANNER IN CO-OPERATION WITH ALL EU MEMBER STATES
- ✓ WE HIGHLIGHT THE NEED TO AUGMENT THE SUPPORT FOR BASIC AND CLINICAL BRAIN RESEARCH IN EUROPE THROUGH CURRENT FUNDING PLATFORMS, ESPECIALLY TO RETAIN PROMISING YOUNG NEUROSCIENTISTS
- ✓ WE RECOMMEND THE EUROPEAN BRAIN COUNCIL SERVE AS A LIAISON TO OPTIMISE SUPPORT FOR PATIENTS AND RESEARCH AND TO ENSURE FUNDING SUPPORT IS BEST ALIGNED WITH TODAY'S FUNDAMENTAL CHALLENGES AND OPPORTUNITIES
- ✓ WE RECOGNISE THAT IT IS THE JOINT RESPONSIBILITY OF ALL STAKEHOLDERS TO ENSURE THAT BASIC RESEARCH IS ADEQUATELY TRANSLATED INTO CONCRETE APPLICATIONS
- ✓ ONLY BY MAINTAINING BRAIN SCIENCE HIGH ON THE POLITICAL AGENDA CAN BOTH BASIC AND CLINICAL RESEARCH BE FORTIFIED AND THE BURDEN OF BRAIN DISEASES REDUCED, PREVENTING THEM FROM BECOMING A SOCIAL EMERGENCY.

IRISH BRAIN COUNCIL INAUGURAL POSITION PAPER

The factors impacting on the strength and sustainability of brain health and research in Ireland are reflected across the research landscape and require systemic change.

Brain health and research is an area of emerging opportunity in Ireland, but the sector is affected by significant challenges which impact on the entire research landscape. This inaugural position paper from the Irish Brain Council highlights the critical issues facing brain health and research in Ireland. The paper also puts forward a series of recommendations to address these challenges:

The main recommendations focus on the following:



1 The importance of overall leadership and direction in relation to clinical research in Ireland

There is a critical need for a clear vision and strategy for clinical research in Ireland

The current landscape for clinical and biomedical research in Ireland is fragmented with a lack of leadership at national level to support research and translate the findings into improved patient care and practice within the health services. The Irish Academy of Medical Sciences Position Paper “A framework for Irish clinical research in the 21st century”, points out the value of the UK National Clinical Research Institute in providing a coherent approach across the health system in relation to research.⁴ The NIHR plays a key role in promoting career tracks and training for

clinical scientists, developing the information technology necessary to support high quality clinical research and, importantly, identifying specific research areas for prioritisation and development.

The Irish Brain Council endorses the need for a focused strategy and vision for clinical research in Ireland led by the Department of Health and addressing key areas of legislative support, funding and infrastructure to support research. The Brain Council welcomes the appointment of a Head of Research and Development and Health Analytics in the Department of Health which provides an important focus for leadership within this area in the health services.

The Irish Brain Council advocates for an Irish Institute for Health Research to integrate hospital and academic based research.

2 The importance of sustainable funding for brain health and research

Sustained public funding for brain health and research is critical to develop vital infrastructure and attract private and international investment

Funding challenges for brain health and research in Ireland include an overall disproportionately low allocation of the research spend across Europe, including Ireland, to brain disease in comparison to other disease areas. Other issues include the challenge of attracting international research funding to Ireland and ongoing threats to funding for basic neuroscience research.

Low levels of public investment continue to impact on the infrastructure for engaging in

translational, clinically-applied and population-based research into brain conditions in Ireland and impact on this country’s overall competitiveness in an area where we can provide international leadership. The strategic decision to prioritise applied/translational research at the expense of basic/fundamental science and to prioritise a limited number of research areas, has proven particularly detrimental to brain health and research in Ireland. Basic scientific research has been shown in other countries to generate a substantially greater economic return over the long term, and an active system of basic research provides the essential expertise, training and absorptive capacity to enable development and adoption of new technologies and translational opportunities.

The Irish Brain Council supports the need for greater overall public investment in biomedical research in Ireland as well as the requirement to target some of this investment to brain disease areas.

3 The importance of networks and career pathways to support researchers

Developing networks and establishing appropriate career pathways to support researchers are crucial in strengthening and retaining research capacity in relation to brain health and research in Ireland

Support for networks both within and between disciplines in brain health and research is crucial. The creation of economies of scale in accessing emerging technologies, ensuring competitiveness, attracting international research and providing training and information through the network structure is of vital importance.

Development of coherent research networks through an Institute of Health Research that can promote greater interaction between laboratory-based research, hospital research

and industry are particularly important in the context of advancing understanding of the brain and development of new treatments. Such an approach could also address the current limitation of career opportunities for Irish researchers. Challenges including short term contracts and funding restrictions impact greatly on training at undergraduate and postgraduate levels. These problems are further compounded by the absence of career tracks for clinical academic researchers, and make Ireland increasingly unattractive for ambitious and competitive researchers. The Irish Health Research Forum in early 2016 has recognized these concerns and has outlined how best to address the very serious problem of emigration of our best researchers.⁵

The Irish Brain Council calls for a national strategic approach to academic and clinical research, integrated by a National Institute for Health Research. The Brain Council calls for the prioritisation of career pathways in the neurosciences, and the provision of core infrastructure that will enable our best neuroscience researchers to remain in Ireland, and which will encourage and provide for structured engagement between academics, hospital-based stakeholders and potential industrial partners.

4 The importance of developing the infrastructure to support brain health and research

Investment in and development of new technologies and information systems to support brain health and research are vital to capitalise on niche areas where Ireland can be a leader in brain health and research.

Ireland's size presents specific challenges around attracting research and engaging in collaboration with international partners. However, Ireland excels as a centre for population based research. Because of its size and genetic substructure, the Irish population is ideally suited to population based studies of complex genetic conditions. Irish researchers have already made significant international contributions in neuroepidemiology, deep phenotyping, population genetics

and care pathways. It is important to recognise the significant return on investment that can be provided to Ireland through the development of research infrastructure in brain health and research. However, there remains a critical need to develop the supportive infrastructure that will allow Ireland to capitalise on its important niche in these areas.

The development of unique patient identifiers, electronic patient records, support for population based registers that collect data from all patients, and access to emerging technologies including advanced neuroimaging, and functional tools for gene manipulation will be essential to remain competitive.

The Irish Brain Council calls for the recognition of Ireland as a country ideally suited to population based research in brain disorders, by providing adequate infrastructure and resources to enable detailed subphenotyping of those consenting to participate in research programmes. This would be best achieved by integration of epidemiology, clinical evaluation and genomics work through a National Institute for Health Research.

5 The need to involve patients and patient organisations as key stakeholders in brain health and research

Patient involvement is key to informing and improving brain health and research while patient organisations represent a vital link between patients, researchers and policy makers

Patient involvement describes a variety of ways in which researchers engage with people for whom their research holds relevance. There is a growing body of evidence that involving patients in research projects improves the quality, relevance and/or speed of that research. It is important that patients are facilitated to become involved at all stages of the research process so that they inform research questions, have input into the design of research protocols and play an active role in translating findings into practice.⁶

Patient organisations play a critical role in promoting and supporting the involvement of patients in research. Patient organisations in Ireland currently provide significant financial support to fund medical research through providing specific research funding awards and fundraising for specific projects.

Patient organisations are also involved in informing their members about current opportunities for becoming involved in research studies, an invaluable support for

recruiting participants. Patient organisations provide a critical conduit for linking patients to researchers, both in terms of recruiting participants and in communicating research findings. Patient organisations have a central role in ensuring that research findings are translated into practice through their engagement with policy makers and advocating on behalf of the people they represent. Most importantly, patient organisations promote a positive image of brain health and research and the value of taking part in research studies in Ireland that should not be underestimated.

A 2015 report by the Neurological Alliance of Ireland found a strong commitment to supporting research among neurological not for profit organisations, including providing direct funding support for research and engaging in ongoing partnerships with individual researchers and research institutions to support participation in research and the dissemination and implementation of research findings.⁷

The Irish Brain Council is committed to promoting the involvement of patients in all stages of research and working in partnership with patient organisations as a key linkage between patients, researchers and policy makers.

6 Legislative and policy development and implementation to support brain health and research

Legislative change, policy implementation and overall leadership are required to support and develop brain health and research in Ireland

Important legislative developments are required to support research into brain conditions in Ireland and provide important assurance for members of the public in areas such as oversight and ethics, data protection, the use of human tissue etc.

The Health Information and Patient Safety Bill makes proposals on data sharing, ethical approval processes, patient registries and the regulation of non-clinical trials health research. A major benefit of the provisions of the Bill for health researchers will be the creation of a single point of contact through HIQA, which will now be the supervisory body for approved ethics research committees. The

general scheme for the Bill was published in November 2015. Introduction of the Human Tissue Bill is important to provide a regulatory framework in this area. Proposals for this legislation were first announced in 2009.

EU regulation on clinical trials takes effect by October 2018 at the latest. This will provide for a single EU portal for clinical trials applications with a single set of documents. The benefits of this regulation is that it will streamline and co-ordinate clinical trials processes across Europe. The European Data Protection Directive will replace the 1995 Data Protection Directive and will come into force at the end of May 2016. Member states of the EU will have a two year period to implement the legislation, and guidance is needed on issues such as how pseudonymised data fits within the scope of the Regulation.

The Irish Brain Council endorses the proposed simplification of regulations around patient oriented research. The Irish Brain Council calls for close engagement with legislators in implementation of the European Data Protection Directive, such that the benefits of population based research for the overall community are balanced with data protection requirements that prioritise the rights to privacy of the individual.



There is a vital need to invest in brain disorders.

CONCLUSION

There is a vital need to invest in brain disorders. This should include funding of career paths for laboratory based neuroscientists while at the same time implementing programmes for clinician scientists. These researchers must be facilitated in the development of bench to bedside research, and in the provision of evidence based models of care for neurology and neuro-rehabilitation within the health services. This would be best achieved through the development of managed clinical networks that are extensively networked with academic centres of excellence engaged in neuroscience research, and with access to information technology and the provision of opportunities for ongoing training and development of staff.

The Irish Brain Council calls for leadership at a national level to drive a focused agenda around brain health and research that provides critical overall strategic direction in relation to all aspects of research within the health services.



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