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POLICY DEPARTMENT
ECONOMIC AND SCIENTIFIC POLICY **A**

Economic and Monetary Affairs

Employment and Social Affairs

**Environment, Public Health
and Food Safety**

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Living with a Neurological Brain Disorder: Taking Control of Your Life

Study for the ENVI Committee

DIRECTORATE GENERAL FOR INTERNAL POLICIES
POLICY DEPARTMENT A: ECONOMIC AND SCIENTIFIC POLICY

WORKSHOP

Living with a Neurological Brain Disorder: Taking Control of Your Life

Brussels, 12 October 2016

PROCEEDINGS

Abstract

This report summarises the presentations and discussions of the workshop on the neurological brain disorders, held at the European Parliament in Brussels on Wednesday 12 October 2016. The aim of the workshop was to provide background information about the main characteristics of neurological brain disorders, as well as to identify new strategies and innovative tools to better support the prevention and treatment of these diseases.

The latest data, trends, and challenges in the field of neurological brain disorders were highlighted during the first part of the workshop. Moreover, speakers illustrated how mHealth tools can better support treatment for patients affected by brain disorders. Successful examples of mHealth tools, such as the app “MyDystonia”, were also presented.

The second part of the workshop focused on the potential offered by mHealth for patients with neurological brain disorders. Relevant initiatives carried out by the European Commission were presented, and the importance of involving patients in the designing of new mHealth tools for the treatment of brain disorders was also discussed.

This workshop and the respective document were prepared by the Policy Department A at the request of the Committee on Environment, Public Health and Food Safety.

This document was requested by the European Parliament's Committee on Environment, Public Health and Food Safety.

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LIST OF ABBREVIATIONS

| | |
|-------------------|--|
| App | Mobile Applications |
| CMDS | Complex Motor Disorder's assessment and management Service |
| CNS | Central Nervous System |
| DBS | Deep Brain Stimulation |
| DE | Dystonia Europe |
| DG CONNECT | Directorate General for Communications Networks, Content & Technology |
| DG JUST | Directorate General for Justice and Consumers |
| DG EAC | Directorate General for Education and Culture |
| DG ENVI | Directorate General for the Environment |
| DG RTD | Directorate General for Research and Innovation |
| DG SANTE | Directorate General for Health and Food Safety |
| EBC | European Brain Council |
| EC | European Commission |
| ECL | European Cancer Leagues |
| EFNA | European Federation of Neurological Associations |
| EFPIA | European Federation of Pharmaceutical Industries and Associations |
| eHealth | Information and Communication Technology for health and wellbeing |
| ENSI | Environment and Schools Initiatives |
| EU | European Union |
| EUPATI | European Patient Academy on Therapeutic Innovation |
| FP7 | Seventh Framework Programme, European Union research and development funding programme |

| | |
|------------------|---|
| GPS | Global Positioning System |
| HEPA | Health-enhancing Physical Activity |
| IARC | International Agency for Research on Cancer |
| ICT | Information and communications technology |
| ITB | Intrathecal baclofen |
| ITU | International Telecommunication Union |
| ME | Myalgic Encephalomyelitis |
| MEP | Member of European Parliament |
| mHealth | Mobile Health |
| MRC | Medical Research Council |
| NCD | Non-communicable diseases |
| NHS | National Health Service |
| PSP | Progressive Supranuclear Palsy |
| RADAR-CNS | Remote Assessment of Disease And Relapse in CNS disorders |
| R&D | Research & Development |
| SDF | Swedish Dystonia Association |
| UPDRS | Unified Parkinson's Disease Rating Scale |
| VoT | Value of Treatment |
| WHO | World Health Organisation |
| WFN | World Federation of Neurology |

EXECUTIVE SUMMARY

On 12 October 2016, the European Parliament's Committee on Environment, Public Health, and Food and Safety (ENVI) held a workshop entitled: "Living with a neurological brain disorder: Taking control of your life". The workshop was co-chaired by Mr Alojz PETERLE (MEP), Ms Linda McAVAN (MEP), and Nessa CHILDERS (MEP).

Mr Peterle opened the discussion by stressing that living with a neurological brain disorder is a great challenge, given that these disorders are difficult to diagnose and treat; in addition, they affect both patients and their families alike. At the same time, he underlined that mobile health (mHealth) is a rapidly developing field that has the potential to fight some of the challenges stemming from neurological brain disorders.

Ms McAvan began her intervention by describing her personal experience with supporting people who have neurological brain disorders. She explained that neurological brain disorders have a direct economic impact – both for the patient as well as their families. In this regard, Ms McAvan stressed that the role played by patient organisations is an extremely important one, given that they can provide strong support for patients and their family members.

Mr DESTREBECQ, Executive Director of the European Brain Council, opened the workshop's first session, which focused on the latest data, trends, and challenges in the field of neurological brain disorders. He first remarked that brain disorders are one of the greatest challenges for Europe. In particular, brain disorders affect one out of three people in the course of their lifetime, and the costs associated with the disease in Europe are around €800 billion per year. Mr Destrebecq outlined that, in order to tackle the challenges posed by brain disorders, further research that adopts a multidisciplinary approach is needed. Moreover, European research priorities should be redefined and the pharmaceutical industry should be encouraged to carry out more research in this area. Finally, he stressed that collaboration, among all of the stakeholders involved, is necessary to ensuring an adequate translation of research into concrete applications.

Ms BENSON, Executive Director of Dystonia Europe, focused her presentation on dystonia, a neurological brain disorder that causes continuous muscle contractions. Ms Benson – suffering from dystonia herself – explained that people living with this disease usually face difficulties in remembering their symptoms and that they often only have limited time available to discuss their disease, and its related symptoms, with their treating physician. Dystonia Europe developed a mobile app called "MyDystonia" in order to tackle these issues. This app is an electronic diary that facilitates communication between patients and physicians and that allows patients to monitor their dystonia by documenting their own symptoms. This, she explained, can lead to better treatment outcomes, which can ultimately allow people affected by dystonia to have a better overall quality of life.

The final speaker of the first session, Dr MEYER, a Clinical Research Training Fellow at the Institute of Psychiatry, Psychology, and Neuroscience of the King's College London, illustrated how mHealth can better support treatments for patients with brain disorders with three examples. Firstly, he recalled the wearable sensor platform developed by the Michael J Fox Foundation, which allows for the monitoring of large populations of Parkinson's disease patients. Secondly, he cited a system developed by Dr Tsanas, aimed at telemonitoring Parkinson's disease symptoms using nonlinear speech signal processing and statistical machine learning. Thirdly, he presented a study carried out by Dr Poh and other researchers, who, in 2012, improved convulsive seizure detection using a wrist-worn electrodermal activity and accelerometry biosensor. Finally, Dr Meyer observed that, despite the advantages offered by mHealth, several challenges have yet to be addressed.

Dr LIN, a consultant Paediatric Neurologist at the Evelina London Children's Hospital, opened the second part of the workshop, which focused on the future potential represented by mHealth. He remarked that young people with neurological brain disorders often have difficulties in attaining independence in adult life and, consequently, need lifelong support from parents as well as from healthcare and social care services. In order to meet their specific needs, Dr Lin stressed that an ad hoc service approach is necessary, given that it is likely to enhance the participation of young people in society. In this regard, he illustrated the complex motor disorder's assessment and management Service (CMDs), which is available at the Evelina London Children's Hospital. The CMDs improves the quality of life of young people with complex motor disorders by delivering deep brain stimulation (DBS) for children with dystonia and intrathecal baclofen (ITB), pump implants for children with spasticity alone or mixed spasticity-dystonia.

Dr PEETSO, Programme Officer at the Commission's Directorate General for Communications Networks, Content, & Technology (DG CONNECT), spoke next, and gave an overview of EU initiatives in the area of mHealth. Among them, she mentioned the Code of Conduct on mobile health apps, as well as the public consultation on the safety of apps and other non-embedded software. Dr Peetso also underlined that the European Commission has recently started developing guidelines to assess the validity of data yielded and the reliability of mHealth apps. In addition, she stressed that the European Commission is developing a European quality standard to be followed by developers throughout the app's development lifecycle. Lastly, she recalled that the European Commission's eHealth Action Plan 2012-2020 provides a roadmap to empowering patients and healthcare workers to link up their devices and technologies.

The final speaker of the session was Ms BEDLINGTON, Secretary General of the European Patients' Forum (EPF). She started her presentation by presenting the EPF and the eHealth projects in which it is involved. She then outlined that, despite all of mHealth's benefits, there are still challenges that need to be addressed, such as the quality and safety of the apps, the reduction of health inequalities, and the issues concerning data protection. In her conclusions, Ms Bedlington highlighted that, in order to tackle these challenges and to improve how mHealth apps work, the role of the patients and their empowerment need to be fostered. In particular, she stressed that the development of mHealth apps should be centred on patients' needs. Moreover, patients need to be involved in the evaluation of these services' safety and quality.

In his closing remarks, Mr Peterle thanked the speakers for their presentations. He acknowledged that, with regards to neurological brain disorders, several challenges remain to be addressed. However, he also believed that there are tools, such as those provided by the mHealth field, which can improve the quality of life of patients. Finally, Mr Peterle remarked that, in order to tackle the challenges posed by these disorders, a strong collaboration among the EU institutions, EU Member States, and stakeholders is needed.

LEGAL AND POLICY BACKGROUND

The brain, source of intellectual capacities and emotional behaviour, is essential for people's professional and personal lives, as well as their participation in society. When the brain is damaged, it can affect different functions of the human body and can lead to disorders impacting both the individual as well as society at large. A recent analysis estimated that about 13% of global disease is due to disorders of the brain, surpassing both cardiovascular diseases and cancer¹. The economic impact is significant too: the total cost of brain disorders in Europe is around EUR 800 billion per year – which is an average cost of EUR 5,550 per inhabitant – and is expected to increase drastically².

Brain disorders encompass all of the conditions and disabilities affecting the brain, caused by illness, genetics or traumatic injuries. It refers to a wide variety of diseases, varying greatly in their symptoms and level of severity. Brain disorders can be classified into different categories, including neurogenetic diseases, neurodevelopmental disorders, degenerative diseases, metabolic diseases, traumatic brain injury, brain tumours, and psychological/mental disorders³. Neurological brain disorders are defined as diseases of the central and peripheral nervous system. Disorders include Alzheimer's, dementia, epilepsy, headache, multiple sclerosis, neuro-infections, Parkinson's disease, stroke, traumatic disorders of the nervous system due to head trauma, and neurological disorders as a result of malnutrition. Examples of symptoms include paralysis, muscle weakness, poor coordination, loss of sensation, seizures, confusion, pain, and altered levels of consciousness⁴.

According to the World Health Organisation (WHO)⁵, one billion people are affected by neurological disorders worldwide, irrespective of their age, sex, education or income. In particular, 50 million suffer from epilepsy and 24 million suffer from Alzheimer's and other dementias. Moreover, 6.8 million people die as a consequence of these disorders each year. It is also worth noting that access to appropriate care is often difficult for people with neurological disorders, their families, and caregivers. The reasons for the unavailability of treatment include inadequate health delivery systems, lack of trained personnel, the absence of essential drugs, and the prevalence of traditional beliefs and practices.

Additionally, investments made by the pharmaceutical industry in drug development for neurological disorders have been decreasing. In particular, the lack of understanding of brain diseases – e.g. caused by neurodegenerative processes like Alzheimer's or mental disorders like schizophrenia – has discouraged industry greatly. Moreover, the development of drugs for brain diseases is more complex, requires more time, and is more expensive than alternative research and business areas, and therefore leads to lower returns on investment⁶. For all of these reasons, neurological disorders are considered to be one of the greatest threats to public health and tackling them will be crucial to keeping

¹ Collins PY, *et al.*, 2011, 'Grand challenges in global mental health Nature', 475 (7354), p. 27.30, available at: <http://www.ncbi.nlm.nih.gov/pubmed/21734685> (accessed August 2016).

² Olesen J, *et al.*, 2011, 'Cost of disorders of the brain in Europe 2010'. European Journal of Neurology, Vol.19 (1), pp.155-162, available at: <http://www.ncbi.nlm.nih.gov/pubmed/22175760> (accessed August 2016).

³ Gross M, 2011, 'Brain Disorders', in Encyclopedia of Child Behavior and Development, pp 288-289, available at: <http://www.springer.com/us/book/9780387775791> (accessed August 2016).

⁴ WHO, official webpage, 'What are neurological disorders?', official webpage, available at: <http://www.who.int/features/qa/55/en/> (accessed October 2016).

⁵ WHO, official webpage, 'Neurological disorders affect millions globally', available at: <http://www.who.int/mediacentre/news/releases/2007/pr04/en/> (accessed August 2016).

⁶ European Commission, 2013, 'Brain Research supported by the European Union 2007-2012', available at: http://ec.europa.eu/research/health/pdf/brain-research_en.pdf (accessed August 2016).

the ageing society and the economy in a healthy state⁷.

In order to address these challenges, as well as to keep stimulating advances in neurosciences, the European Commission has provided extensive financial support, mainly through its Framework Programmes for Research and Innovation⁸. For example, in 2013, an ambitious 1 billion EUR flagship project was launched by the European Commission called the “Human Brain Project”⁹. The project, which brings together 116 partners from various European organisations, aims to put in place a cutting-edge, ICT-based infrastructure for brain research, cognitive neuroscience, and brain-inspired computing. Moreover, the 7th Framework Programme (FP7 2007-2013) included a specific activity on ‘Research on the brain and related diseases’¹⁰ and dedicated nearly two billion EUR of its total budget to brain research. In total, 1,268 projects and 4,312 participations were funded by the Programme, as well as the Joint Programming Initiative on Neurodegenerative Diseases¹¹. Other EU-support for brain research and innovation comes through the European Research Council, public-private partnerships (e.g. Innovative Medicines Initiative¹²), global cooperation (e.g. International Initiative for Traumatic Brain Injury Research¹³), training and mobility schemes for young researchers.

Additionally, the European Union has adopted and implemented a wide range of policy documents and strategies related to a variety of specific neurological and mental disorders. For example, in 2009, the European Parliament launched an Interest Group on Mental Health, Wellbeing, and Brain disorders¹⁴, providing a forum for debate and advocating for the development of sound EU policies to contribute to the prevention of brain disorders. Another example is the European pact for mental health and well-being, launched in 2008, which called for action to be taken in five priority areas by Member States and for stakeholders to address common challenges and tackle health inequalities. In 2013, the European Commission organised the first European Month of the Brain¹⁵, aiming to raise awareness on the topic and to promote brain research.

With regard to the initiatives at the international level, the WHO has launched a number of global public health projects, including the Global Initiative on Neurology and Public Health¹⁶, the purpose of which is to increase professional and public awareness of the frequency, severity, and costs of neurological disorders and to emphasise the need to provide neurological care at all levels including primary health care. Furthermore, the WHO and the World Federation of Neurology (WFN) collaborated in an international Survey of Country Resources for Neurological Disorders, involving 109 countries and covering over 90% of the world’s population¹⁷. Moreover, in response to the European Region’s evolving mental health needs, the WHO Regional Office for Europe has developed the European

⁷ WHO, official webpage, ‘Neurological disorders affect millions globally’, available at:

<http://www.who.int/mediacentre/news/releases/2007/pr04/en/> (accessed August 2016).

⁸ The current Framework Programme for Research and Innovation is Horizon 2020, which runs from 2014 to 2020. Website: <https://ec.europa.eu/programmes/horizon2020/> (accessed August 2016).

⁹ Project website: <https://www.humanbrainproject.eu/> (accessed August 2016).

¹⁰ European Commission, DG RTD, official webpage, ‘FP7’, available at: https://ec.europa.eu/research/fp7/index_en.cfm (accessed August 2016).

¹¹ Programme website: <http://www.neurodegenerationresearch.eu/> (accessed August 2016).

¹² IMI website: <https://www.imi.europa.eu/> (accessed August 2016).

¹³ InTBIR website: <https://intbir.nih.gov/> (accessed August 2016).

¹⁴ Website of the EP Interest Group on Mental Health, Well Being and Brain disorders: <http://www.gamian.eu/interest-group/> (accessed August 2016).

¹⁵ European Month of the Brain, official webpage: http://ec.europa.eu/research/conferences/2013/brain-month/index_en.cfm (accessed August 2016).

¹⁶ Janca A, *et al.*, 1997, ‘The World Health Organization’s global initiative on neurology and public health’, *Journal of the Neurological Sciences*, available at: <http://www.ncbi.nlm.nih.gov/pubmed/9073021> (accessed August 2016).

¹⁷ World Health Organization & World Federation of Neurology, 2004, ‘Atlas – country resources for neurological disorders’, available at: http://www.who.int/mental_health/neurology/neurogy_atlas_lr.pdf (accessed August 2016).

Mental Action Plan¹⁸, which proposes effective actions to strengthen mental health and well-being.

Complex challenges remain to be addressed, despite these initiatives. Most importantly, significant knowledge gaps exist concerning the range of brain disorders that can occur, and which require specific, preventive, therapeutic, and rehabilitative interventions of different types and intensities in different age groups. The current availability of effective, though frequently sub-optimal treatments, the absence of absolute cure, and the dearth of preventive interventions for mental, and neurological disorders demand concerted efforts at all levels. This includes innovative research into the causes, as well as the identification of new targets for psychological treatments and pharmacological drug interventions¹⁹. Additionally, a rethinking of the current standards of provision for mental health care is required. The prevalence of brain disorders is expected to increase further, as a result of increased life expectancy, and there is therefore an immediate need to move the topic of brain disorders to the top of the EU's policy priority list.

¹⁸ World Health Organization (WHO), Regional Office for Europe, 2015, 'The European Mental Health Action Plan 2013–2020', available at: <http://www.euro.who.int/en/health-topics/noncommunicable-diseases/mental-health/publications/2015/european-mental-health-action-plan-20132020-the> (accessed August 2016).

¹⁹ Wittchen HU, *et al.*, 2011, 'The size and burden of mental disorders and other disorders of the brain in Europe 2010', *European Neuropsychopharmacology*, Vol. 21, Issue 9, pp. 655–679, available at: [http://www.europeanneuropsychopharmacology.com/article/S0924-977X\(11\)00172-6/abstract](http://www.europeanneuropsychopharmacology.com/article/S0924-977X(11)00172-6/abstract) (accessed August 2016).

PROCEEDINGS OF THE WORKSHOP

1.1. Introduction

1.1.1. Welcome and opening

MEP Mr Alojz PETERLE, Co-Chair, ENVI Health Working Group

Mr Alojz PETERLE, MEP, opened the workshop and the first panel session by explaining that living with a neurological brain disorder is a great challenge. These disorders, which are often misunderstood and difficult to diagnose, can disable patients chronically and significantly affect their daily-life activities. However, Mr Peterle added that he believes that the emerging and rapidly-developing field of mobile health (mHealth) has the potential to address some of these challenges in a significant way, and to increase both the quality and efficiency in the fight against neurological brain disorders.

Subsequently, Mr Peterle explained that the workshop would focus on the challenges posed by neurological brain disorders and the impact they have upon the lives of patients and their families, as well as the wider healthcare systems. He ensured the audience that the outputs of the workshop would be widely disseminated, including to those MEPs, who could not be present at the workshop, in order to raise awareness about the importance of tackling neurological brain disorders in the EU.

Mr Peterle then passed the floor to Ms Linda McAVAN, MEP, indicating that she had been the rapporteur of similar dossiers in the past.

Ms Linda McAVAN, MEP

Ms McAvan, MEP, started by passing on the regards of Ms Glenis WILLMOTT, MEP, who could not participate in the workshop due to another pressing assignment, but who was following the discussion closely and had requested that Ms McAvan, MEP, transmit a few points.

Firstly, while neurological brain disorders pose a significant disease burden, the debate about this burden only started a few years ago, following the increase of rates of Alzheimer's disease and dementia being reported among the elderly. Ms McAvan added that, while brain diseases are diverse and may result from damage in the brain, spinal cord or nerves, they are equally serious in every age and severely impact both the lives of patients and those of their carers.

Ms McAvan then shared her personal experience with a case of neurological brain disorders with the audience, as her mother passed away in her early 60s from Progressive Supranuclear Palsy (PSP). She explained that PSP leads to a progressive physical incapacity, even while brain functions remain intact. The seriousness of the condition gravely affected the daily lives of her family, as the disease forced her father to abandon his paid employment in order to attend to her mother's needs.

Additionally, Ms McAvan explained that she has several relatives suffering from Multiple Sclerosis and Parkinson Disease, all of whom had to give up their jobs in their early 30s and late 40s. She stressed that neurological brain diseases can, thus, have a large impact on a person's life and economic situation because people may not only lose their income, but they may also need to make adaptations to their homes, for example.

Ms McAvan welcomed the workshop, as it provided her with an opportunity to get to know different systems and good practises that address neurological brain disorders across

different countries. Moreover, she pinpointed the importance of patient support organisations.

1.2. Part I: Living with a Brain Disorder

1.2.1. Neurological brain disorders in the EU: the latest data, trends and challenges

Mr Frédéric DESTREBECQ, Executive Director, European Brain Council

Mr Frédéric DESTREBECQ started his intervention by explaining that he would present the European Brain Council's (EBC) vision of the challenges posed by neurological brain disorders, as referred to previously by Ms McAvan in her opening remarks. He briefly introduced the European Brain Council, which is a multi-stakeholder platform composed of patients' groups, scientific societies, industry partners, and national brain councils. One of his organisation's key-members, he explained, is the European Federation of Neurological Analysis (EFNA), on behalf of which he would present part of his presentation's content.

Next, Mr Destrebecq explained that the brain is an important, complex, and transversal organ with impressive capabilities. At the same time, the brain is also a very fragile organ: once it starts deteriorating, as a result of a neurological brain disorder for example, the complete restoration of brain functions is highly unlikely. According to a study released by the EBC in 2011²⁰, one in three people living in Europe have a brain disorder, which amounts to around 179 million people. Brain disorders cost about 798 billion euros per year, which Mr Destrebecq illustrated as the equivalent to bailing out Greece seven times a year.

Mr Destrebecq also stressed that the field of neurosciences is a challenging one, particularly because scientists still do not understand the complete picture. He recommended multidisciplinary approaches and collaborations between stakeholders from different fields in order to arrive at solutions, both in the short and in the long term. As for the EBC, Mr Destrebecq explained that it has progressively raised awareness of the importance of brain disorders, during the Polish Presidency of the Council of the European Union for example and, two years later, through collaboration with DG RTD in the framework of the European Month of the Brain²¹.

One of the EBC's key recommendations, Mr Destrebecq explained, was to start developing national strategies within the EU context that address extant needs. He explained that the EBC launched the Pan-European awareness campaign "Together under the umbrella"²², aiming to change the overall perception of the brain and to reduce its stigma. The campaign aims to educate society about the wide range of neurological and other brain-related disorders, and to raise awareness of these disorders' impact and prevalence. Mr Destrebecq considers the campaign to have been quite successful: about 200 organisations have pledged their support and several politicians are supporting it as well.

Mr Destrebecq then described an interest group, set up by the EFNA, aiming to combatting the stigma of those affected by neurological disorders and chronic pain, particularly where access to employment is concerned. This activity raised awareness and addressed the "quality of life" agenda. Concerning the latter, Mr Destrebecq explained that a written

²⁰ Olesen, J. *et al.*, 'The economic cost of brain disorders in Europe', in *European Journal of Neurology*, Vol. 19, Issue 1, January 2012, pp. 155-162, available at <http://www.braincouncil.eu/wp-content/uploads/2015/07/Cost-of-Disorders-of-the-Brain-in-Europe-economic-costs-EurNeuro2012.pdf> (accessed October 2016).

²¹ European Month of the Brain, official webpage: http://ec.europa.eu/research/conferences/2013/brain-month/index_en.cfm (accessed August 2016).

²² Project website: <http://undertheumbrella.eu/> (accessed October 2016).

declaration will be released on the 24th October 2016, and that MEPs are kindly invited to support it.

As for the EBC, Mr Destrebecq explained that the organisation developed the project “Value of Treatment for Brain Disorders (VoT)”²³, which explored the lack of adequate treatment for brain disorders. The project focused on the need to close the “gap” in Europe in terms of diagnosis and treatment (‘unmet needs’) of brain disorders in particular²⁴. The project estimated that three to eight out of ten patients with a brain disorders are not able to access adequate treatment. The project also identified clinical interventions that would improve the situation and analysed the impact a proper standard of care for society and the economy would have. As a result of the project, a White Paper²⁵ was put forward, which included recommendations for improving patient pathways in terms of access to treatment and to diagnosis.

Next, Mr Destrebecq presented the “EBC Consensus Statement”²⁶, which summarises the opportunities that the EBC believe need to be explored in order to expand and improve brain research in Europe. In the Statement, the EBC recognises the efforts and achievements made by DG RTD and other actors that finance brain research. However, as stressed in the statement, the EBC believes that research must be well directed, developed, and implemented in a context of strong coordination between all of the relevant stakeholders.

Another key element of the EBC’s advocacy work was a Call to Action²⁷, launched in November 2015, which called upon decision-makers and stakeholders to take a collaborative approach towards prevention and the promotion of healthy behaviours. According to the call, National Brain Plans should provide a comprehensive approach to the brain by bringing stakeholders together, streamlining existing resources, coordinating sectoral policies, improving patient care (by building on the successful cases of cancer and diabetes for example), and by approaching cross-cutting themes, such as stigma and economics.

Finally, Mr Destrebecq declared that “our brain holds the key to our future”, and for this reason, ensuring and maintaining a healthy brain is of utmost importance.

1.2.2. How mHealth has helped me live with a brain disorder

Ms Monika BENSON, Executive Director, Dystonia Europe

Ms BENSON started her intervention by requesting the participants at the workshop to take part in a small experiment, in order to “walk in her shoes” and those of other dystonia patients. The experiment consisted of placing a tennis ball – that each participant had received at the beginning of the event – between the cheek and the shoulder, which forced the head to twist. Participants were requested to keep the ball in this position for a few

²³ Discussion Paper on the project, available at <https://www.researchgate.net/publication/299411550> (accessed October 2016).

²⁴ Ibid., p. 10.

²⁵ Council of Europe, « White Paper » on the protection of the human rights and dignity of people suffering from mental disorder, especially those place as involuntary patients in a psychiatric establishment’, DIR/JUR (2000) 2, 3 January 2000. Available at [http://www.coe.int/t/dg3/healthbioethic/activities/08_psychiatry_and_human_rights_en/DIR-JUR\(2000\)2WhitePaper.pdf](http://www.coe.int/t/dg3/healthbioethic/activities/08_psychiatry_and_human_rights_en/DIR-JUR(2000)2WhitePaper.pdf) (accessed November 2016).

²⁶ European Brain Council, ‘EBC Consensus Statement. The need to expand brain research in Europe: ‘Improved Collaboration to expand brain research in Europe Better understanding for better brain health’. Available at <http://www.braincouncil.eu/wp-content/uploads/2016/03/EBC-Consensus-Document.pdf> (accessed October 2016).

²⁷ Available at <http://www.braincouncil.eu/wp-content/uploads/2015/11/EBC-Call-to-action2.pdf> (accessed October 2016).

minutes. Ms Benson indicated that the feeling the participants were experiencing was similar to the discomfort felt by cervical dystonia patients.

She continued by describing the disease dystonia, which is a neurological brain disorder causing uncontrolled and sustained muscle contractions and, very often, pain. Ms Benson explained that the disorder affects children, women, and men alike and the cause is unknown in most cases. She mentioned that at least half a million Europeans live with dystonia and that there is no cure for the disorder - only treatments to alleviate symptoms and which consisting of botulinum toxin injections and, in worse cases, deep brain stimulation (DBS).

She then described the current situation for dystonia patients across Europe, which consists of short and limited time with treating physicians and neurologists as well as strict treatment regimes. In most cases, treatments consist of botulinum toxin injections in intervals of, at least, three months. Due to these circumstances, patients find it hard to accurately remember - in-between injections and doctor appointments periods - their symptoms, levels of pain, and the impact of the disorder on their daily life.

In order to help patients remember these factors, as well as to optimise treatment, Dystonia Europe has developed an app called “MyDystonia²⁸: by patients for patients”. The app allows for the daily or weekly capture of symptoms, such as twisting muscles or having an abnormal posture. The app can also register the pain suffered by the patient, the quality of his/her sleep, the treatment received, and provides an overview of daily activities and exercise. The patient can visualise their respective progress in reports, his or her well-being, exercise and activity level, as well as the overall effect of the disorder on his or her health.

Ms Benson listed several benefits of keeping such a dystonia diary. These included: the facilitation of patient/physician communication; the better use of limited time available with healthcare professionals through the availability of an accurate picture of the patient’s daily life, including symptoms, pain, and impact that the app provides; the individualisation of treatment options, such as muscle selection, injection intervals, physiotherapy, psychological therapy, etc.; and, finally, the improvement of the therapy outcome, the daily exercise routine and well-being in general. Additionally, the reports produced by the app may help discover other symptoms, such as depression or insomnia, which may lead to a differentiated and better treatment.

The “MyDystonia” app, Ms Benson explained, is a unique project that can be used as a template for the facilitation of collaboration between patients, physicians, and the pharma industry. The app was developed based upon a survey that was circulated among 300 dystonia patients in Europe, who were asked about the features they would like to have in such an app, the questions they would like to see solved, etc. Ms Benson informed the audience that the app is available on the web in ten languages²⁹, both in IOS and android formats. Additionally, she mentioned the “MyDystonia” Ambassador Programme, bringing together local support providers for dystonia patients. Ms Benson further explained that the app is 100% owned by Dystonia Europe and that its development was supported by Merz.

Feedback received after the launch of the app has been quite positive. For example, as explained by Ms Benson, a physician from Norway had stressed the app’s usefulness for scoring symptoms and treating patients, and a patient from the same country considered the utility of the app in the communication with health providers to be very useful. Finally,

²⁸ Available at: <http://www.mydystonia.com/index.php/App/index> (accessed October 2016).

²⁹ Namely, English, French, German, Danish, Norwegian, Swedish, Spanish, Italian, Russian, and Finnish. See: <http://www.mydystonia.com/> (accessed October 2016).

Ms Benson also cited the feedback from a patient from The Netherlands, who said that “it only takes a minute or two to answer all the questions, so daily usage is not that hard” and that “it is easy to use the overview for trend analysis”.

The goal of Dystonia Europe is that, one day, all dystonia patients will use the MyDystonia app, in order to improve communication between patients and physicians, optimise treatment outcome, and to improve the overall quality of life of patients. Additionally, Ms Benson indicated that Dystonia Europe is seeing a more far-reaching potential for the app. It could promote social connection between patients, become a disease hub with news from various channels, and simultaneously a registry-type data base for analysis and future research. Ms Benson concluded by saying that she expects that, in the future, this app will help every dystonia patient.

1.2.3. How mHealth can better support treatment for patients with brain disorders

Dr Nicholas MEYER, MRC Clinical Research Training Fellow, Institute of Psychiatry, Psychology and Neuroscience, King's College London

Dr MEYER started by presenting a brief overview of the use of mobile devices and wearable technology in the field of neurological sciences. He explained that King's College London has recently launched an EU-funded collaboration with EFPIA partners on the use of mHealth to track multiple sclerosis, epilepsy, and depression³⁰.

Dr Meyer recognised that the application of mHealth for brain disorders is a new, upcoming field, and that it is still in its infancy. He explained that most of the studies in mHealth are “proof of principle” or feasibility studies, and that a lot of this movement is driven by the development of new telecommunications and micro-computing technologies.

For Dr Meyer, the most important technological device, with the greatest potential to become a medical device, is the smartphone. The gap of smartphone ownership between developed and emerging countries is low and is becoming less pronounced. Moreover, one of the advantages these devices have is that, with the current, increasingly qualitative and affordable network coverage in most parts of Europe, they can be used by people living in poor settings and in rural areas.

Next, Dr Meyer explained, mobile phones have two capabilities. One capability is “passive sensing”, which refers to the collection of information in the background, without the need for the active participation of the user. Phones with such functionalities have specific sensors, such as an accelerometer or a GPS that can measure motor activity. These devices are potentially very useful sources of information that can generate information on disease status and progression. They also allow for the collection of metadata, such as registries of how many times the user interacts with his/her phone. This data can provide important information on the user's social functions and emotions.

The second capability of mobile phones is “active data”, which is facilitated by the touchscreen technology. Active data allows patients to score their symptoms and to track their movement for location purposes. Moreover, mobile devices with active data functionalities can promote patient-physician interaction, as they can allow some treatments, such as psychological therapy, to be made through video calls. The use of these devices, Dr Meyer explained, also often involves the use of a wearable device which is controlled via Bluetooth. The wearable is, in most cases, used on the wrist. The contact

³⁰ Project: ‘Remote Assessment of Disease and Relapse – Central Nervous System (RADAR-CNS)’, available at <http://radar-cns.org/> (accessed October 2016).

the wearable makes with the skin allows the device to monitor the person's heart rate and helps to improve the fidelity of the motor signal.

Next, Dr Meyer explained that in the study he was running, data was collected and encrypted in the mobile phone and it was stored in a cloud database for analysis. In the future, this information shall be made available and sent in real-time to patients and their medical professionals. For the patients, this will enhance their self-management and may lead to a better understanding of their disorder, and for medical personnel it can support their clinical decision-making and support the prevention of relapsing.

Dr Meyer then mentioned the "digital phenotype", which consists of a new class of information provided by mobile phones. He referred to Ken Kubota, from the Michael J Fox foundation, who has suggested that there is a huge disparity between the amount of genomic and molecular data that is available and the rather limited data that is being collected in the clinics. He suggested that such imbalances should be addressed through the use of technologies. Another useful feature of technologies is that they allow for the monitoring of the patient's (often fluctuating) symptoms in-between visits to the doctor. Symptoms cannot always be recalled by patients themselves and technologies can, thus, avoid the "recall bias". Thirdly, devices make predictability possible and doctors can, thus, use them to prevent the deterioration of the patients' condition.

Next, Dr Meyer described examples of wearables that communicate with smartphones, which are aimed at assisting in the management of Parkinson's disease. One such mechanism resulted from a collaboration between the Michael J Fox Foundation and INTEL³¹ and consists of a wearable that communicates with a smartphone. The wearable monitored the patient's activity, tremor, and sleep. Dr Meyer also mentioned a study conducted in Oxford³², which resulted in the creation of a device that used retrospective analysis and monitoring of the voice for the diagnosis of Parkinson's disease. The study involved the use of simple, self-administered, and non-invasive speech tests. Speech was characterised with signal processing algorithms, and these were statistically mapped to the unified Parkinson's disease rating scale (UPDRS).

The data collected by this device suggested that dysphonia³³ correlates very strongly with disease progression.

Finally, Dr Meyer explained that similar work has been done in the field of epilepsy, where the ultimate goal is to detect seizures remotely. He indicated that there is evidence showing that wearable devices, namely wrist-worn devices, may be able to do this in the near future. However, an issue that still needs to be tackled is the relatively high number of "false positives" detected by these devices.

1.2.4. Questions & Answers

Ms Heather CLARK (European Federation of Neurological Associations, EFNA) thanked the speakers for their presentations and asked Dr MEYER how much patient input had been used during the development of the device by the Michael J Fox Foundation and INTEL.

Dr Meyer answered that, in every project he had described in his presentation, the concept of co-design or the direct involvement of the patient had been considered. However, he

³¹ The use of a wearable and smartphone is promoted by the online research study 'Fox Insight: Your experience fueling research', available at <https://foxinsight.michaeljfox.org/> (accessed October 2016).

³² Tsanas, A. *et al.*, 'Accurate telemonitoring of Parkinson's disease progression by non-invasive speech tests', available at http://www.cabdyn.ox.ac.uk/complexity_PDFs/Network%20Journal%20Club%20PDFs/athanasios.pdf (accessed October 2016).

³³ Dysphonia is the medical term for disorders of the voice: an impairment in the ability to produce voice sounds using the vocal organs.

indicated that there is a problem of “drop-off” by users after the initial phase, when patients are still excited about the new device. But he stressed that the work he is doing embeds the patient’s input from an early stage, as he considers this to be of key importance, particularly for the validation of devices.

Dr Terje PEETSO (DG CONNECT) asked Ms Benson in which countries the “MyDystonia” app is currently being used.

Ms Benson responded, with the assistance of Mr Eelco UYTTERHOEVEN (IT advisor at Dystonia Europe), that MyDystonia is officially used in almost every EU country, even where a translation into the official language is not yet available. Moreover, it is used beyond Europe as well, namely in the US, Australia, and Brazil.

The chair of the panel asked Ms Benson about the average set age for dystonia.

Ms BENSON answered that, for cervical dystonia, it is around 40 years of age, but that for generalised dystonia, it can start during childhood as well.

1.3. Part II: Future potential for mHealth

1.3.1. Following the patient pathway – mHealth from Childhood to Adulthood

Dr Jean-Pierre LIN, a Consultant Paediatric Neurologist, Evelina Children’s Hospital

Dr LIN started his intervention by explaining that the purpose of his talk was to show the importance of promoting physical activity and encouraging social participation among young people living with a disability. Next, he showed a video concerning the disease evolution of one of his patients suffering from dystonia due to a genetic disorder. The first images showed a crippled child, who was only able to use a voice device with his feet. The second images showed the child’s unsuccessful attempts to speak and more aggravated movement disorders. The last images showed the progression of the child’s condition following deep brain stimulation (DBS). Dr Lin described DBS as a neuro-surgical process through which an electrode is placed in the brain and a pacemaker device is implanted in the chest or abdomen of the patient, sending a continuous series of impulses. The images showed that the patient recovered mobility and communication capacity and learned to dress by himself, for the very first time. He, ultimately, went to Arts College as well.

After describing this successful treatment case, Dr Lin showed a graphic that illustrated the correlation between disability and deformity, and the age of onset. The second and third curves on the graph showed that the focal and segmental disability and deformity have their onset towards adult life. It also showed that, the younger the age of onset, the greater the risk that dystonia will become generalised and, thus, extend to the whole body. Dr Lin stressed that, indeed, once the disability or deformity starts during childhood, the patient must live with it for life, but that an active social life is still possible.

He added that mobile technologies can play an important role in promoting social activities, as well as in capturing and recording patient’s health and activity. For example, the medical devices implanted, which are currently pre-programmed by physicians could, in the future, be controlled by individuals and allow for a more integrated approach to the disability.

Next, Dr Lin described a study³⁴, comprising 250 young adults with neuro-disabilities, that compared the cost-effectiveness as well as the ability to enhance participation in society of young people with physical disabilities of two types of healthcare services: the “ad hoc service approach” (random access to health services) and the “young adult team approach”

³⁴ Bent, N *et al.*, ‘Team approach versus ad hoc health services for young people with physical disabilities: A retrospective cohort study’, The Lancet Volume, 360, Issue 9342, 26 October 2002, p. 1280-1286.

(access to specialised services). The study showed that those who had access to specialised services were two and a half times more socially active compared to the other group.

Dr Lin concluded his presentation by saying that we need a more efficient, reliable device for capturing and providing data and information. Moreover, mHealth is going to be a crucial step in the journey towards efficient patient information, support, and better research & development (R&D). Moreover, he believes that mHealth can help to improve efficiency and add focus to healthcare delivery, by putting the patient at the centre of this through the use of mobile technologies.

Mr Peterle commented that he particularly liked Dr Lin's final words on a patient-centred healthcare approach. He mentioned that the European Disability Strategy 2010-2020³⁵ includes a plan to provide health services to everyone, but that it is difficult to achieve, particularly in the aftermath of the European economic crisis.

1.3.2. EU initiatives in the area of mHealth

Dr Terje PEETSO, Programme Officer – EU policies, e-Health, Well-being & Ageing, DG CONNECT, European Commission

Dr PEETSO, programme officer at DG CONNECT, gave an overview of the European Commission's activities in the area of mHealth. She started her presentation by recalling a public consultation, held in 2014³⁶, which was run by the Commission following the green paper on mHealth³⁷. The responses received allowed the Commission to identify four areas of major concerns for the EU citizens in the field of mHealth.

The first area of concern outlined by the respondents of the public consultation was data privacy. In response, the European Commission established a working group³⁸ that defined a code of conduct on privacy for mHealth apps. The code of conduct brought together the principles that should be followed in the development of mHealth apps and described how the privacy issues related to the mHealth apps should be addressed³⁹. Dr Peetso also informed the audience that the Code of Conduct has been submitted for comments to the Article 29 Data Protection Working Party⁴⁰. Depending on the comments, the European Commission will either revise the code or make it available for mHealth apps developers.

The second area of concern identified through the public consultation was about the safety of the apps. In order to tackle this issue, Dr Peetso explained that the European Commission organised another public consultation on the safety of apps and other non-

³⁵ European Commission, 2010, Communication from the Commission to the European Parliament, the Council, the European Economic and Social Committee and the Committee of the Regions. European Disability Strategy 2010: A Renewed Commitment to a Barrier-Free Europe, COM(2010) 636 Final. Available at <http://eur-lex.europa.eu/LexUriServ/LexUriServ.do?uri=COM:2010:0636:FIN:en:PDF> (accessed October 2016).

³⁶ European Commission, DG CONNECT, official webpage, Public consultation on the Green Paper on mobile Health, available at: <https://ec.europa.eu/digital-single-market/en/public-consultation-green-paper-mobile-health> (accessed October 2016).

³⁷ European Commission, 2014, Green Paper on mobile Health ("mHealth"), Brussels, COM(2014) 219 final, available at: <https://ec.europa.eu/digital-single-market/en/news/green-paper-mobile-health-mhealth> (accessed October 2016).

³⁸ European Commission, DG CONNECT, official webpage, New EU working group aims to draft guidelines to improve mHealth apps data quality, available at: <https://ec.europa.eu/digital-single-market/en/news/new-eu-working-group-aims-draft-guidelines-improve-mhealth-apps-data-quality> (accessed October 2016).

³⁹ European Commission, DG CONNECT, official webpage, Code of Conduct on privacy for mHealth, available at: <https://ec.europa.eu/digital-single-market/en/news/code-conduct-privacy-mhealth-apps-has-been-finalised> (accessed October 2016).

⁴⁰ European Commission, Directorate General for Justice and Consumers, official webpage, Data Protection, Article 29 Working party, available at: http://ec.europa.eu/justice/data-protection/article-29/index_en.htm (accessed October 2016).

embedded software not covered by sectorial legislation⁴¹. The purpose of this public consultation, which closed on 15 September 2016, was to gather stakeholder input in order to obtain a better understanding of the risks and problems that non-embedded software poses. Furthermore, the inputs received will help the Commission in defining the potential next steps to be taken and future policies at the EU level.

The third area of concern identified was the validity and reliability of mHealth apps. In this regard, Dr Peetso explained that the European Commission appointed, in February 2016, a working group to draft mHealth assessment guidelines⁴². The aim of the guidelines is to agree on a common set of criteria and assessment methodologies, which could be used by public authorities, health care providers, professional and patient associations, developers and assessment bodies when evaluating the validity and reliability of apps. Dr Peetso mentioned that the working group is currently focusing on the third draft of the guidelines, which are expected to be made available to the wider public at the beginning of November.

With regards to the fourth area of concern, Dr Peetso underlined that the public consultation demonstrated a need for a European quality standard for the development of health and wellness apps. Dr Peetso informed the audience that the European Commission is currently working on a standard to provide guidance to app developers on the quality criteria to be followed throughout the app development lifecycle.

In addition to the initiatives carried out by the European Commission addressing the concerns raised during the public consultation of 2014, Dr Peetso also presented other Commission's strategies in the area of mHealth. Firstly, she illustrated the mHealth hub, which is a four year plan established in cooperation with the World Health Organisation (WHO) and the International Telecommunication Union (ITU) under the EU Framework Programme for Research and Innovation 'Horizon 2020'⁴³. The goal of the hub is to identify trends and gaps in policies, standards and regulations, to gather evidence and to facilitate the exchange of knowledge and best practices in the field of mHealth. In addition, the hub aims at supporting the development and implementation of mHealth strategies tailored to the needs of Member States and regions.

Secondly, Dr Peetso highlighted the importance of the mHealth field in the European Commission's most recent work plan under the Horizon 2020 Programme⁴⁴. In particular, she stressed that mHealth is an important aspect both for patients (mHealth can support them throughout their treatments and can help them maintain a good health condition) as well as for health care professionals (mHealth can support the decision-making process concerning the selection of optimal treatment programmes or to find appropriate information concerning specific diseases).

Finally, Dr Peetso mentioned the eHealth Action Plan 2012-2020, which aims at providing smarter, safer, and patient-centred health services⁴⁵. The Action Plan consists of four

⁴¹ European Commission, DG CONNECT, official webpage, Public consultation on the safety of apps and other non-embedded software, available at: <https://ec.europa.eu/digital-single-market/en/news/public-consultation-safety-apps-and-other-non-embedded-software> (accessed October 2016).

⁴² European Commission, DG CONNECT, official webpage, Current initiatives to unlock the potential of mobile health in Europe, available at: <https://ec.europa.eu/digital-single-market/en/news/current-initiatives-unlock-potential-mobile-health-europe> (accessed October 2016).

⁴³ European Commission, Directorate General for Research & Innovation, Horizon 2020, official webpage, available at: <https://ec.europa.eu/programmes/horizon2020/en/what-horizon-2020> (accessed October 2016).

⁴⁴ European Commission, 'Horizon 2020 – Work Programme 2016-2017', available at: http://ec.europa.eu/research/participants/data/ref/h2020/wp/2016_2017/main/h2020-wp1617-health_en.pdf (accessed October 2016).

⁴⁵ European Commission, DG CONNECT, official webpage, eHealth Action Plan 2012-2020: Innovative healthcare for the 21st century, available at: <https://ec.europa.eu/digital-single-market/en/news/ehealth-action-plan-2012-2020-innovative-healthcare-21st-century> (accessed October 2016).

chapters, covering matters such as interoperability, research and innovation, deployment, and international cooperation.

In her conclusions, Dr Peetso stressed that in order to improve activities in the field of mHealth, which is a field that is subject to fast changes, it is important to not only draw inspiration from Europe, but also from other continents such as Africa, where several successful mHealth initiatives are being carried out.

1.3.3. Involving patients in the design of new tools for the treatment of brain disorders

Ms Nicola BEDLINGTON, Secretary General, European Patients' Forum

Ms BEDLINGTON started by introducing the European Patients' Forum (EPF), which is an umbrella organisation based in Brussels that works with patients' groups on public health issues and health advocacy across Europe. The vision of EPF is that all patients with chronic and/or lifelong conditions in the EU should have access to high quality, patient-centered, and equitable healthcare and social care⁴⁶.

Ms Bedlington explained that the EPF has been involved in several eHealth and mHealth projects. She referred to the *Calliope project*⁴⁷ and the *eHealth Governance Initiative*⁴⁸, which focus on issues around interoperability and cross border eHealth challenges. Secondly, she mentioned the *Renewing Health*⁴⁹ and *United4Health*⁵⁰ projects, which analyse the scope of telemedicine. Moreover, the *Sustains project*⁵¹ explores the role of electronic health records in contributing to patients' empowerment, and the *ChainofTrust project*⁵² which addressed user's perspectives concerning telehealth. Finally, Ms Bedlington referred to the *Smartcare project*⁵³, which investigated the potential of technologies offered by eHealth and mHealth in moving forward an integrated care.

Next, Ms Bedlington highlighted patients' expectation vis-à-vis eHealth and mHealth. She emphasised that patients are expecting eHealth and mHealth tools to facilitate chronic diseases management, as well to improve the quality of their life. She also remarked that patients want eHealth and mHealth to facilitate their involvement in the healthcare process and to support them in becoming equal partners to health care professionals. Furthermore, Ms Bedlington pointed out that patients expect mHealth and eHealth apps to address their needs and to fit into their lifestyles.

Ms Bedlington then highlighted some of the mistakes frequently made by eHealth and mHealth service deployment. In particular, she explained that developers should never forget to consider the human dimension during the development of eHealth and mHealth services and, thus, should ensure that the services are patient-centered. Moreover, she stressed that eHealth service developers should assess the added value of apps and to carefully take their quality and safety into consideration. Furthermore, she added that eHealth and mHealth service developers should always involve users when developing apps, and that their services should contribute towards reducing health inequalities and

⁴⁶ European Patients Forum (EPF), official webpage, available at: <http://www.eu-patient.eu/> (accessed October 2016).

⁴⁷ Calliope – Call for Interoperability, official webpage, available at: <http://www.calliope-network.eu/> (accessed October 2016).

⁴⁸ eHealth Governance Initiative (eHGI), official webpage, available at: <http://www.ehgi.eu/default.aspx> (accessed October 2016).

⁴⁹ Renewing Health, official webpage, available at: <http://www.renewinghealth.eu/> (accessed October 2016)

⁵⁰ United4Health, official webpage, available at: <http://united4health.eu/> (accessed October 2016).

⁵¹ Sustains, official webpage, available at: <http://www.sustainsproject.eu/> (accessed October 2016).

⁵² European Patients Forum, official webpage, available at: <http://www.eu-patient.eu/whatwedo/Projects/Chain-of-Trust/> (accessed October 2016).

⁵³ Smartcare, official webpage, available at: <http://www.pilotsmartcare.eu/home.html> (accessed October 2016).

promoting diversity. Finally, Ms Bedlington remarked that developers should make sure that patients feel comfortable when using digital tools.

Next, Ms Bedlington outlined some of the main challenges faced by the mHealth sector. The first challenge she brought to the attention of the audience was the quality and safety of the mHealth apps. In this regard, Ms Bedlington stressed that one of the main issues in the mHealth sector is the failure to assess its impact on the quality and safety of the care received. Moreover, she remarked that there is still a blurred line between lifestyle apps and medical/patient supporting apps. This creates uncertainties about the legal and regulatory framework that should be applied to the different apps. Furthermore, the accuracy of the information provided by mHealth apps is not always thoroughly monitored and checked. Ms Bedlington, therefore, welcomed the code of conduct initiative of the European Commission⁵⁴.

The second challenge presented by Ms Bedlington concerned the relationship between mHealth apps and patient empowerment. She explained that in cases where mHealth apps provide the wrong information, do not address patients' needs or do not provide information about the quality and safety of app in an easily accessible manner, the app will disempower patients rather empower them to use the application.

The third challenge in the mHealth sector that, according to Ms Bedlington, should be addressed is equity. While mHealth has a significant potential in terms of equity - especially concerning reaching out to specific population groups such as people living in rural areas, young people, and patients with a disability - mHealth app developers have, thus far, have failed to take the diversity component into account.

The last challenge highlighted by Ms Bedlington concerned data protection. She explained that it is inevitable that patients share data when using their apps and that it is, therefore, critical for developers to ensure and to obtain patient consent. Moreover, she remarked that the validity and the quality of the data collected by public authorities, health care providers, professional and patient associations, assessment bodies should be ensured, and the EPF, therefore, welcomes the development of the EU mHealth assessment guidelines⁵⁵.

Ms Bedlington then focused on how to involve patients meaningfully in the development of eHealth and mHealth apps. Firstly, she stressed that patients should be seen as experts with direct, experiential knowledge of what it is like to live with a specific disease, who could directly contribute to the development of eHealth tools. Moreover, patients should be involved throughout the entire design cycle of the app and in various ways (e.g. not only through a satisfaction survey). In addition, Ms Bedlington highlighted that all of the processes involving patients in the development of eHealth app should be appropriately resourced, planned, and evaluated.

Ms Bedlington also underlined some of the changes that EPF believes are the key to moving forward in the mHealth and eHealth fields. Firstly, the involvement of patients should be the main criterion according to which eHealth or mHealth services should be developed. Moreover, patients' involvement should happen from the start of the process, particularly since involving patients at a later stage is usually more complex and costly. Ms Bedlington also stressed the importance of involving patients in the evaluation of the safety and quality

⁵⁴ European Commission, DG CONNECT, official webpage, Code of Conduct on privacy for mHealth, available at: <https://ec.europa.eu/digital-single-market/en/news/code-conduct-privacy-mhealth-apps-has-been-finalised> (accessed October 2016).

⁵⁵ European Commission, DG CONNECT, official webpage, Current initiatives to unlock the potential of mobile health in Europe, available at: <https://ec.europa.eu/digital-single-market/en/news/current-initiatives-unlock-potential-mobile-health-europe> (accessed October 2016).

of the services, as this will support developers in accurately identifying the added value and impact of new tools and services.

Ms Bedlington concluded her presentation by stressing that issues related to the trust and acceptance of end users should be addressed, as these are well-known barriers to the deployment of eHealth and mHealth in the EU. Furthermore, she again stressed that the development of mHealth apps should be centred on patients' needs and remarked that mHealth can contribute to patients' empowerment, as well as supporting patients in the management of their own condition. However, in order to reach these goals, there is a need for a culture change, given that patients' involvement in the design of mHealth tools is, at present, still the exception rather than the rule.

1.3.4. Questions & Answers

Mr Peterle opened the floor for discussion.

Mr Yannick GROSSKREUTZ (Merz Pharmaceuticals) remarked that, according to him, there are two main hurdles when developing mHealth apps for patients. The first hurdle concerns data protection and the second one is about how to improve patients' and physicians' awareness about the existence of specific mHealth apps. With regard to this second hurdle, Mr Grosskreutz explained that a long timeframe usually exists between the moment a patient gets diagnosed with a certain disease and the moment the patient becomes aware of specific mHealth apps that may help him/her deal with their disease. He stressed that the lack of awareness is an issue that physicians struggle with too. Physicians usually become aware of potentially useful mHealth apps at an advanced stage in the disease's treatment. In order to reduce this gap, Mr Grosskreutz asked Dr Peetso whether the Commission has considered the development of a system, which would improve awareness among both patients and physicians by providing them with an overview of all of the mHealth apps currently available on the market.

In response, Dr Peetso specified that it is important here to distinguish between medical apps and lifestyle & wellbeing apps. She stressed that, while the development and application processes of medical apps have to follow the rules set out in the Medical Devices Directive⁵⁶, the situation concerning lifestyle & wellbeing apps is still uncertain. This topic is, therefore, currently being discussed by the working group in charge of drafting the mHealth assessment guidelines⁵⁷. Dr Peetso stressed that, if approved, the guidelines may become a useful tool for healthcare providers and app developers on how to develop a database containing an overview of all of the mHealth apps available. She also stated that, nowadays, there are several websites that provide information on available mHealth apps, including patients' views and opinions.

After Dr Peetso's intervention, Mr Peterle suggested broadcasting three videos, prepared and commented upon by Dr Lin, about children affected by lifelong neurological brain disorders. While showing the videos, Dr Lin stressed the role technology plays in empowering patients to be connected and to make them feel that they are involved in their healthcare. Dr Peetso reinforced Dr Lin's statement by highlighting that an important dimension of mHealth tools is their ability to foster social inclusion. In particular, according to Dr Peetso, mHealth apps enable patients affected by disabling disorders to become

⁵⁶ Council Directive 93/42/EEC of 14 June 1993 concerning medical devices, available at: <http://eur-lex.europa.eu/legal-content/EN/TXT/?uri=CELEX:31993L0042> (accessed October 2016).

⁵⁷ European Commission, DG CONNECT, official webpage, Current initiatives to unlock the potential of mobile health in Europe, available at: <https://ec.europa.eu/digital-single-market/en/news/current-initiatives-unlock-potential-mobile-health-europe> (accessed October 2016).

connected with other people, to become socially active and, ultimately, to improve their quality of life.

The next question came from Ms Nancy VAN HOYLANDT (European ME Alliance), who remarked that, while eHealth and mHealth are certainly useful tools for patients, they are also necessarily linked to the purchase and use of expensive mobile phones, which not all patients are able to afford. She asked the panel of speakers how this issue could be tackled.

Dr Peetso acknowledged that the issue raised by Ms Van Hoylandt is important, especially with regards to the reimbursement of medical apps. However, she also commented that, at present, the majority of mHealth apps available on the market are affordable. Moreover, she stressed that the baseline of digital health is not to create additional costs, but rather to support a better use of existing resources. With mHealth apps, patients usually receive good quality services at affordable prices.

Ms Bedlington supported the statement made by Ms Van Hoylandt and explained that, according to her, mHealth and eHealth have to be embedded in the debates around the sustainable healthcare systems of the future, including in the context of the UN sustainable development goals⁵⁸. She stressed that mHealth and eHealth should offer long term benefits as well as long term savings. .

1.3.5. Closing remarks by the Chair

Mr Peterle thanked the speakers for their contributions. He acknowledged that, regarding neurological brain disorders, several challenges remain to be addressed. At the same time, he also believed that there are tools, such as those provided by the mHealth field, which can improve patients' quality of life. In this respect, he welcomed the initiatives carried out by the European Commission. Mr Peterle also recognised that, together, the European Parliament and the European Commission are willing to tackle the challenges posed by neurological brain disorders. In addition, he remarked that while the European Union does not have the exclusive competence in the area of health, the EU Institutions can support and integrate measures adopted at the Member State level. In particular, he encouraged the EU Institutions and individual MEPs to strengthen cooperation among Member States through recommendations, guidelines, workshops, and the exchanging of best practices, with the ultimate goal of improving the lives of patients affected by neurological brain disorders.

⁵⁸ Sustainable Development Goals, official webpage, available at: <https://sustainabledevelopment.un.org/?menu=1300> (accessed October 2016).

ANNEX 1: PROGRAMME

WORKSHOP

Living with a Neurological Brain Disorder: Taking Control of Your Life

Wednesday 12 October 2016 from 12.30 to 14.45
European Parliament, room A1G-2, Brussels

AGENDA

CO-Chairs: Mr Alojz PETERLE (MEP), Ms Linda McAVAN (MEP), and Nessa CHILDERS (MEP).

12:30 – 12:35 Opening and welcome

Part 1 – Living with a brain disorder

- | | |
|----------------------|--|
| 12:35 - 12:45 | Neurological brain disorders in the EU: the latest data, trends and challenges Mr Frédéric DESTREBECQ, Executive Director, European Brain Council |
| 12:45 – 12:55 | How mHealth has helped me live with a brain disorder Ms Monika BENSON, Executive Director, Dystonia Europe |
| 12:55 – 13:05 | How mHealth can better support treatment for patients with brain disorders Dr Nicholas MEYER, MRC Clinical Research Training Fellow, Institute of Psychiatry, Psychology and Neuroscience, King's College London |
| 13:05 – 13:35 | Question & Answers |

Part 2 – Future potential for mHealth

- 13:35 – 13:45 Following the patient pathway – mHealth from Childhood to Adulthood**
Dr Jean-Pierre LIN, a Consultant Paediatric Neurologist, Evelina Children's Hospital
- 13:45 – 13:55 EU initiatives in the area of mHealth**
Dr Terje PEETSO, Programme Officer – EU policies, e-Health, Well-being & Ageing, DG CNECT, European Commission
- 13:55 – 14:05 Involving patients in the design of new tools for the treatment of brain disorders**
Ms Nicola BEDLINGTON, Secretary General, European Patients' Forum
- 14:05 – 14:35 Questions & Answers**
- 14:35 – 14:45 Closing remarks by the Chair**

ANNEX 2: SHORT BIOGRAPHIES OF EXPERTS

Mr Frédéric Destrebecq

Mr Frédéric Destrebecq has been the Executive Director of the European Brain Council since October 2014. Prior to this position, he served the European Union of Medical Specialists (UEMS) as its Chief Executive Officer, and previously as the Director for European Affairs. Mr Destrebecq holds a Master Degree in Political Science and International Relations from the Université Catholique de Louvain (Belgium). He also studied at the Institut d'Etudes Politiques (Paris) and University of Wales College (Cardiff), in the framework of the former EU Socrates exchange programme.

Ms Monika Benson

Ms Monika Benson has been the Executive Director of Dystonia Europe (DE) since 2013. DE is the platform at the European level for all dystonia stakeholders in Europe. DE works in partnership with patient advocacy groups, healthcare professionals and researchers, as well as the pharmaceutical and medical device industries.

Since 2001, Ms Benson has been affected by the neurological brain disorder, cervical dystonia. After the diagnosis, she became involved in her local dystonia support group in Sweden and joined the Board of the Swedish Dystonia Association in 2006. In 2007, she was elected President of Dystonia Europe. After the maximum term of six years came to an end, Ms Benson began working as the Executive Director for Dystonia Europe. She is also board member of the EFNA (the European Federation of Neurological Associations) and of SDF – the Swedish Dystonia Association. Ms Benson has also held roles at Medborgarskolan in Sweden (Education Management) and the American College of Switzerland in Switzerland.

Dr Nicholas Meyer

Dr Meyer is a Specialist Registrar in Psychiatry at the South London and Maudsley NHS Foundation Trust, and MRC Clinical Research Training Fellow at the Institute of Psychiatry, Psychology, and Neuroscience, King's College London. Dr Meyer's primary research interest is in harnessing mobile and wearable technologies for the remote measurement of biological rhythms including sleep and circadian rhythm, which may form objective markers of relapse in schizophrenia. Additionally, he collaborates with the RADAR-CNS (Remote Assessment of Disease And Relapse in CNS disorders) consortium, which uses mHealth approaches to improving treatment in depression, epilepsy, and multiple sclerosis. Dr Meyer graduated in Experimental Psychology (2002) and Clinical Medicine (2007) from the University of Oxford.

Dr Jean-Pierre Lin

Dr Jean-Pierre Lin qualified in medicine in 1983 from Edinburgh University Medical School. After further training, including adult neurology and paediatrics, he obtained an Edinburgh University George Guthrie Research Fellowship from 1990-1994, leading to a PhD within the Department of Physiology at Edinburgh University on 'Motor Assessments in Cerebral Palsy', supervised by E Geoffrey Walsh, motor physiologist, and J Keith Brown, paediatric neurologist. In 1994, Dr Lin left Scotland to become a Senior Registrar in Paediatric Neurology at Great Ormond Street Hospital for Children proceeding to his current permanent post as Consultant Paediatric Neurologist at Guy's & St Thomas' NHS Foundation Trust.

Dr Terje Peetso

Dr Terje Peetso joined the Unit Health and Wellbeing in DG Communications Networks, Content, and Technology in 2011. Her main responsibilities are related to the coordination of the implementation of the eHealth Action Plan 2012 -2020 as well as the overall coordination of the policy group in the Unit. In 2014, she was the EU Fellow in the University of Southern California, USA, where her research focus was on the obstacles that hinder the introduction eHealth in healthcare systems. Dr Peetso has been working in the European Commission since 2003 and holds a diploma in medicine from the University of Tartu, Estonia.

Ms Nicola Bedlington

Between 1996 and 1999, Ms Nicola Bedlington was the founding Director of the European Disability Forum, an umbrella organisation uniting over 70 European disability NGOs and National Councils of Disabled People, to advocate for the human rights and the inclusion of disabled citizens in Europe. Prior to this, she worked as an external expert for the European Commission, heading the NGO unit within the HELIOS Programme, a European Commission Action Programme promoting equal opportunities for disabled people (1991-1996).

From 2004 to 2006, Ms Bedlington worked for the Swiss Government, leading the Environment and Schools Initiatives Secretariat (ENSI), an international government-based network set up by the OECD focussing on innovation, action research, and policy development in the field of Education for Sustainable Development. While in Switzerland, she also worked as an independent consultant/evaluator, specialising in European social and development policy and health advocacy. Ms Bedlington joined the European Patients' Forum as its first Executive Director in June 2006. In this capacity, she is the Co-ordinator of the European Patient Academy on Therapeutic Innovation (EUPATI).

ANNEX 3: PRESENTATIONS

Presentation by Mr Frédéric Destrebecq



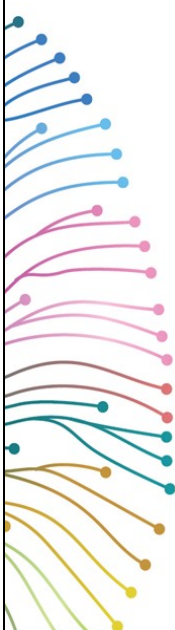
This image shows the interior of the Sistine Chapel, a masterpiece of Renaissance art. The ceiling is a deep, vibrant blue, decorated with a pattern of stars and planets, a motif inspired by the Voynich manuscript. The walls are covered in a series of frescoes, including the famous 'The Last Judgment' by Michelangelo, which depicts a dramatic scene of souls being judged. The architecture features a large central archway and smaller arched windows, all framed by intricate decorative elements. The overall atmosphere is one of awe and historical significance.



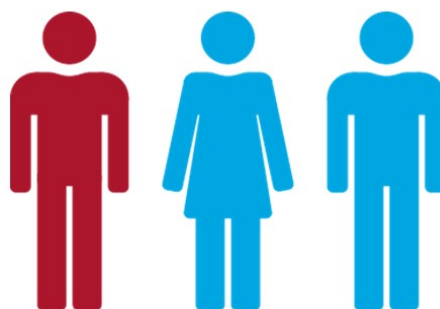
Brain Comprehension

BRAIN SCIENCE

Mapping the Landscape of Brain and Neuroscience Research

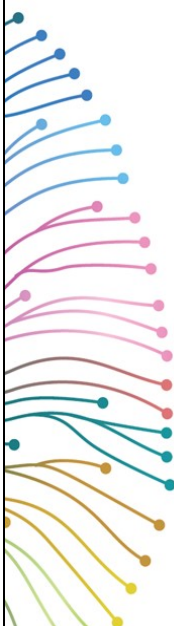


179 mlns
citizens over
the EU



€ 798 bln /year

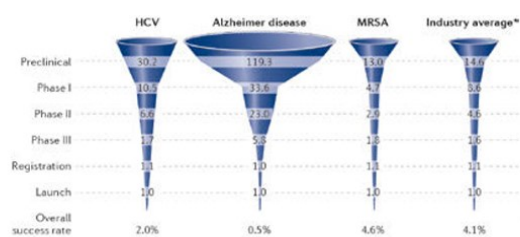




Lack of understanding brain diseases

Industry leaving the brain area

Few new drugs → learn from the attrition analysis



© Calcoen et al. & R.Jong, 2015

Complexity requires multidisciplinary approach

Solutions needed on both short & long term

© EC RTD



All stakeholders need to Act



Over 120 events organized in more than 25 countries
Coordination by DG Research & EBC
Policy recommendations for brain research and healthcare



Call to develop national strategies within EU context



A pan-European campaign that changed our perception of the Brain



200 organisations have pledged their support

Main themes:

- Education
- Awareness
- Research
- Ethics

Extensive brain ambassadors campaign



EBC
European Brain Council

Branding the Brain under the same umbrella





EBC
European Brain Council

We call on better access to employment

WRITTEN DECLARATION

ACCESS TO EMPLOYMENT FOR THOSE AFFECTED BY NEUROLOGICAL DISORDERS AND CHRONIC PAIN CONDITIONS

1. Brain disorders and chronic pain conditions are two of the leading causes of long-term sick leave; growing in impact as Europe's workforce ages.
2. We call upon DG SANTE, DG EMP, DG REGIO and DG-ECFIN to collaborate on developing, consolidating and consistently implementing EU legislation which will ensure equal access to employment for those affected by neurological disorders and chronic pain conditions.
3. Best-practices to retain and reintegrate people with chronic conditions are widespread. The Commission and Member States are called upon to work, with their social partners, to clarify patients' rights, highlight successful workplace adjustments and reintegration actions – e.g. flexible working hours – and to promote subsidies for such actions through the European Social Fund.
4. Integrating people with these chronic conditions in employment is socio-economically beneficial. The Commission is called upon to use the EU Semester's country-specific recommendations to encourage Member States to implement cost-effective retention, reintegration and rehabilitation actions.
5. The Commission and Council are called upon to encourage Member States to acknowledge that accurate early diagnosis and appropriate treatment and management are necessary to enable employees affected by these chronic conditions to avail of equitable employment opportunities.

MEP CO-AUTHORS

| | | | |
|-----------------|---------------------|---------------------|-------------------|
| Jeroen Lenaers | Marian Harkin | Osciana Serbu | Heinz Becker |
| Jana Žitňanská | Bogdan Wenta | Jose Blanco Lopez | Glenis Willmott |
| Roberta Metsola | Bljuna Borzan | Eva Kaili | Sirpa Pietikäinen |
| Sofia Ribeiro | Jutta Steinruck | Brian Hayes | Ivo Vajgl |
| Jean Lambert | Miroslav Mikolajcik | Elena Gentile (TBC) | |



Member of the
European Parliament
INTEREST GROUP ON
BRAIN, MIND AND PAIN



European Federation of Neurological Associations





European Brain Council

Value of Treatment Optimizing our model of care





European Brain Council

Europe needs to “expand brain research”

- Recognizing recent efforts & achievements
- Redefining European Research priorities
- Restating clear expectations across & beyond

Brain disorders

EBC CONSENSUS STATEMENT



Europe needs to “expand brain research”

*“If we can fly to the Moon, we should be able
to cure brain disorders...”*

...It’s just slightly more complicated”


EBC CONSENSUS STATEMENT



EUROPEAN BRAIN COUNCIL Call To Action

on the European Commission to come up with a European plan to tackle brain health in a coordinated, integrated and comprehensive manner, as well as to further support European Union Member States and non-EU countries in their efforts to combat the burden of brain disorders.

on European Union member states and non-EU countries to implement public health strategies for addressing brain health in a systematic and coordinated manner, making the best possible use of available resources to stimulate more and better co-ordinated brain research and to foster strategies for prevention, early diagnosis and adequate treatment.



National Brain Plans must provide a comprehensive approach to the Brain

- Bringing together various stakeholders
- Streamlining existing resources
- Coordinating sectoral policies
- Improved patient care
- Cross-cutting themes

e.g. *Stigma – Prevention – Research*
– Carers – Economics – Education



Our Brain holds the key to our future

“Innovation is central to EC priorities”



**Opportunity now:
Europe’s mission**

Healthy Brains = National Wealth

• **Health**

We focus on curing the sick but do not do enough to support good mental as well as physical health.

In cognitive and emotional wellness, the European Brain Council’s Year of the Brain¹ remade the positive case for investing in brain well-being. This is a goal that covers the full gamut of innovation, from genomics^{2,3} and high-throughput neurological databases to web-based virtual reality support for psychotherapy. Yet these issues of stigma are woefully underfunded.

Physically, too, we can feel proud about average overall longevity, but we should not ignore the stagnation and in many places marginal decline in the share of our lives spent in good health (Healthy Life Years). This state of affairs implies both avoidable illness for fellow-citizens and a work-force shrunk by impaired physical mobility and an unduly early end of productive activity.



© European Union, 2016



Presentation by Ms Monika Benson

HOW M-HEALTH HAS HELPED ME LIVE WITH A BRAIN DISORDER

ENVI workshop:
Living with a neurological brain disorder:
Taking control of your life

Wednesday 12 October 2016
European Parliament, Brussels

Monika Benson, Executive Director

**DYSTONIA
EUROPE**

WALK IN MY SHOES...

MY DYSTONIA



**DYSTONIA
EUROPE**

WHAT IS DYSTONIA?

MY DYSTONIA

- Neurological **brain disorder**
- Causing **uncontrolled** & sustained **muscle contractions**; pain
- Affecting **children, women and men**
- At least **half a million Europeans** live with dystonia
- **No cure**; treatments available – botulinum toxin injections, dbs



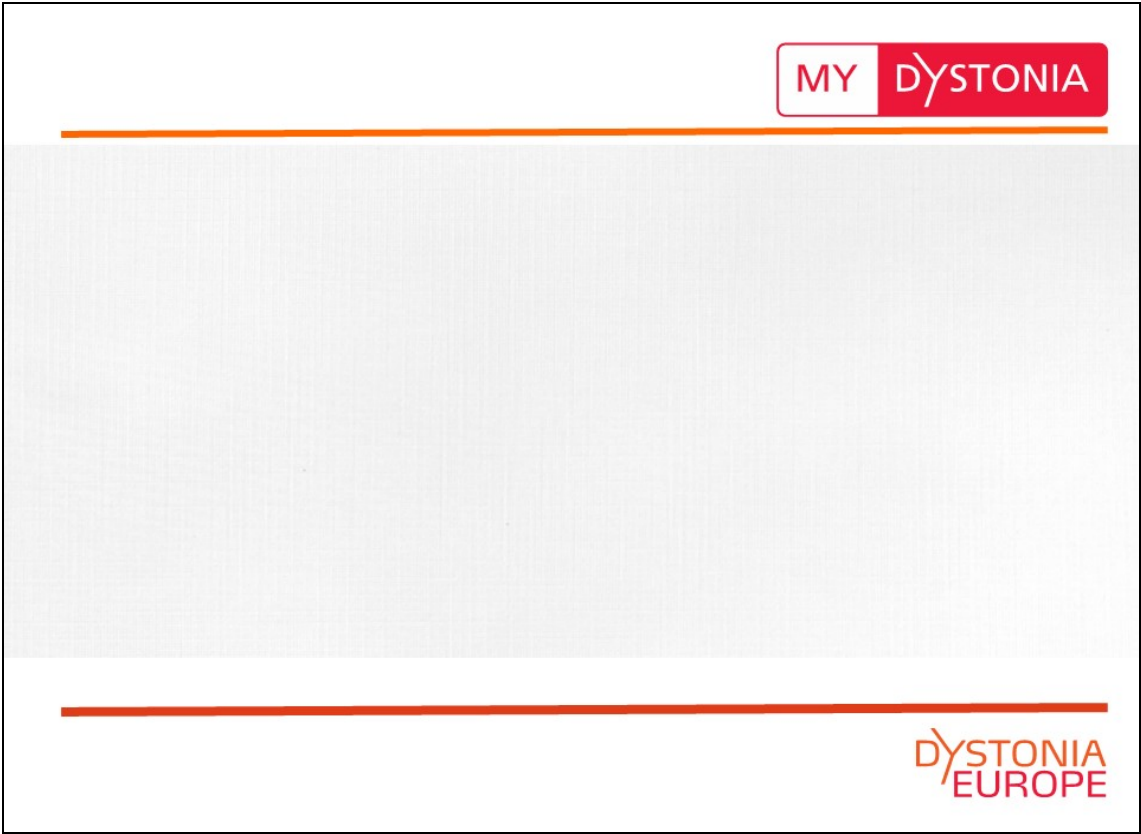
DYSTONIA
EUROPE

THE CURRENT SITUATION FOR DYSTONIA PATIENTS

MY DYSTONIA

- Short and limited time with the treating physician
- Strict treatment regime
- Symptoms, pain, impact on daily life cannot be accurately remembered

DYSTONIA
EUROPE



BY PATIENTS. FOR PATIENTS.

MY DYSTONIA

CAPTURE

VISUALIZE



DYSTONIA EUROPE

Personal benefits of a diary

MY DYSTONIA

A personal report that can be used for:

- Facilitation of patient/physician communication (efficient usage of the limited time)
- Providing an accurate picture of the patients' daily life incl. symptoms, pain, impact on daily life
- Individualization of treatment options: muscle selection, injection intervals, physiotherapy, psychological therapy
- Improvement of therapy outcome
- Improvement of daily exercise routine in order to feel better
- Improvement of well-being and other symptoms (e.g. depression)



DYSTONIA EUROPE

BY PATIENTS. FOR PATIENTS.

MY DYSTONIA

**With better treatment outcome
I can do the things I like to do:**

- Go hiking
- Dance
- Swim
- Go and see a movie
- See friends & family
- Work



BETTER QUALITY OF LIFE!

DYSTONIA
EUROPE

BY PATIENTS. FOR PATIENTS.

MY DYSTONIA

FACTS ABOUT MYDYSTONIA...

- Unique project: template for collaboration between patients, physicians and pharma
- Survey 300 dystonia patients in Europe about features, questions...



The
dystonia
society

- On-line, ios and android
- Available in 10 languages

DYSTONIA
EUROPE

BY PATIENTS. FOR PATIENTS.

MY DYSTONIA

FACTS ABOUT MYDYSTONIA...

- MyDystonia Ambassador Program
- 100 % ownership of Dystonia Europe



- Supported by



An Initiative of DYSTONIA EUROPE

BY PATIENTS. FOR PATIENTS.

MY DYSTONIA

This is a very useful scoring tool for dystonia symptoms and treatment of patients.

Physician from Norway



It only takes a minute or two to answer all the questions, so daily usage is not that hard. Easy to use overview for trend analysis.

Patient from the Netherlands

I think the APP will be very helpful for many people including myself in the communication with healthcare providers and others.

Patient from Norway

DYSTONIA EUROPE

MYDYSTONIA – OUR VISION

MY DYSTONIA

All patients with dystonia will use MyDystonia:

- To improve patient/physician communication
- To optimize treatment outcome
- For a better quality of life

DYSTONIA
EUROPE

BY PATIENTS. FOR PATIENTS.

MY DYSTONIA

MYDYSTONIA HAS THE POTENTIAL TO DEVELOP INTO A CENTRAL HUB FOR DYSTONIA



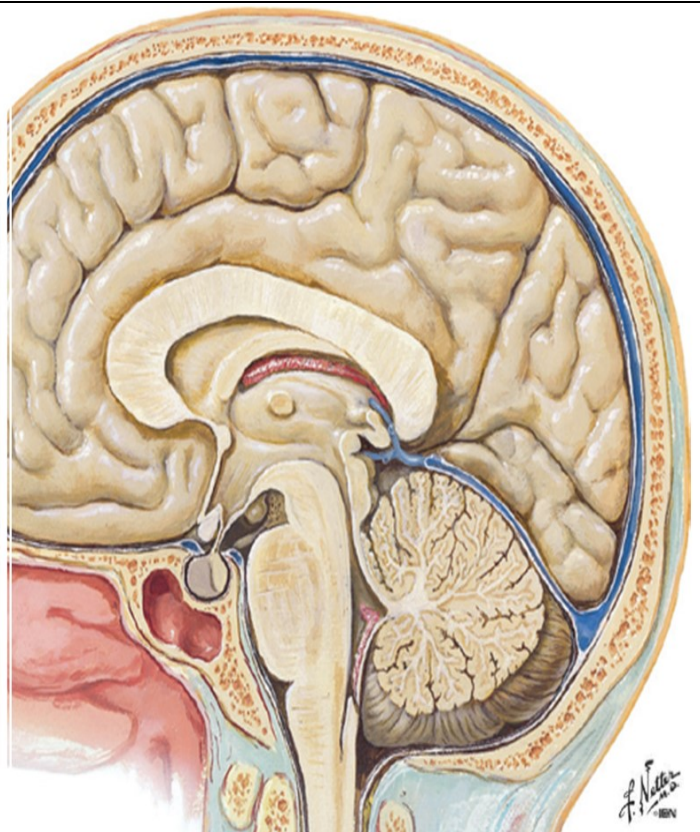
DYSTONIA
EUROPE



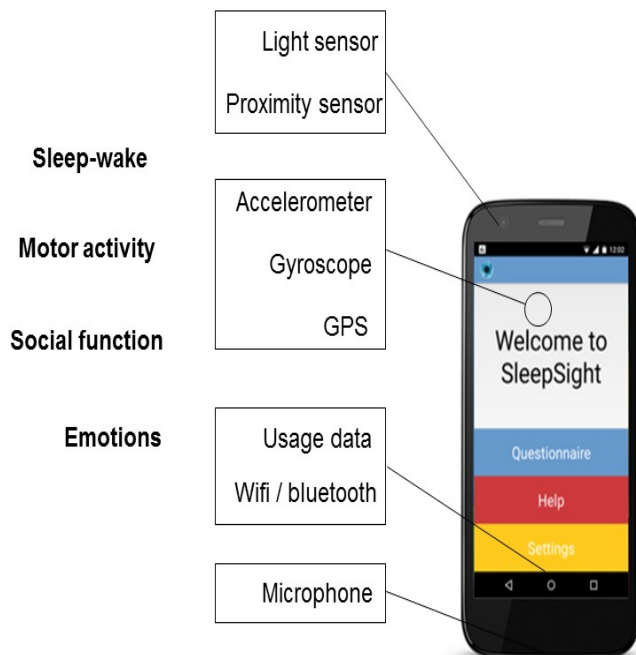
Presentation by Dr Nicholas Meyer

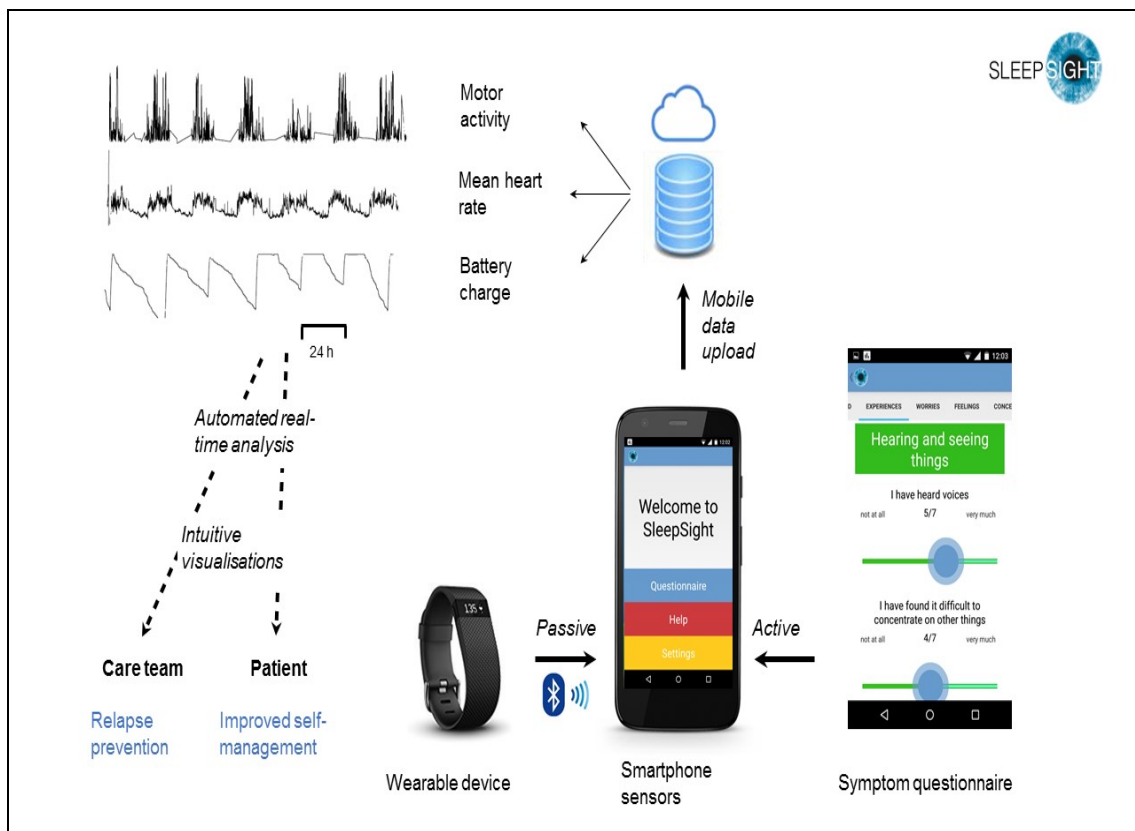
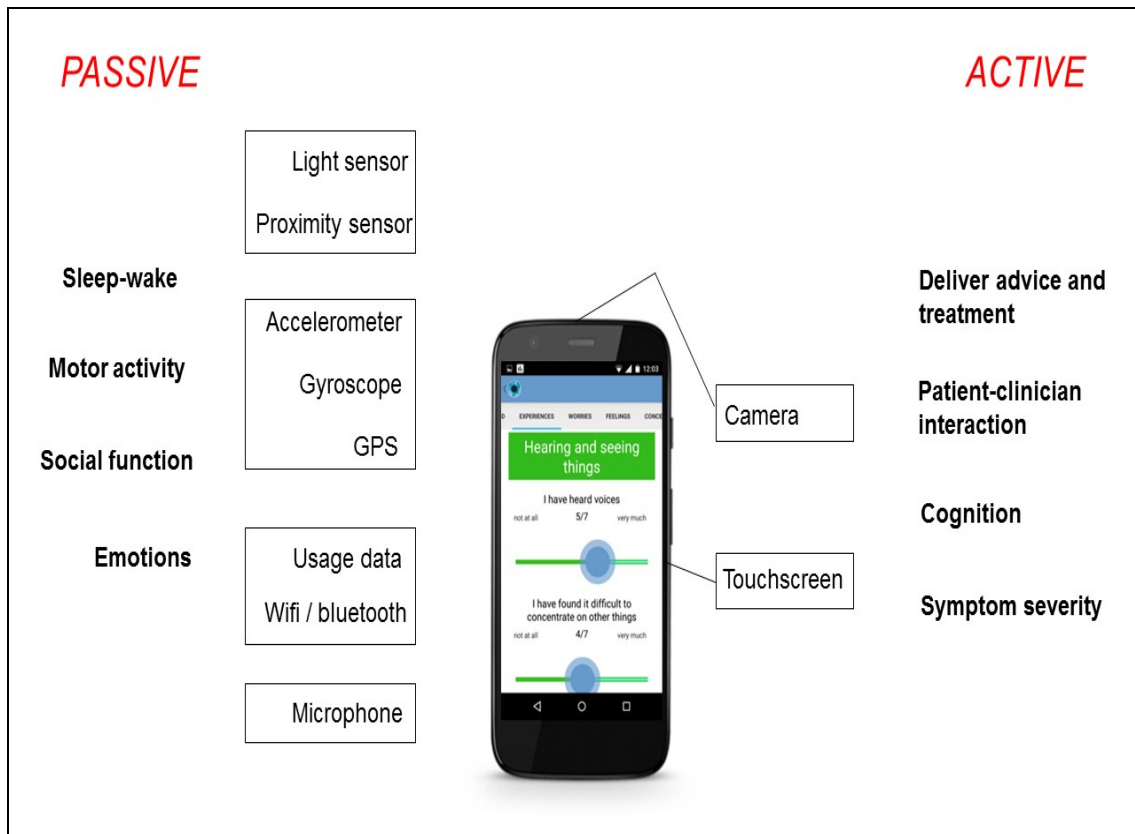
How can
mHealth better
support
treatment for
patients with
brain disorders?

Dr Nicholas Meyer MRCPsych
Institute of Psychiatry,
Psychology and Neuroscience
King's College London, UK



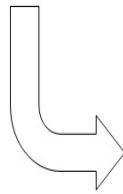
PASSIVE





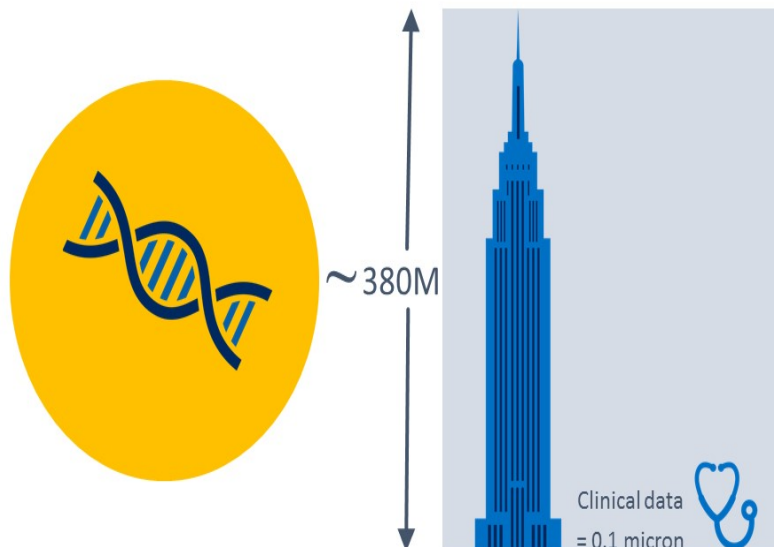
The promise of digital technologies

Real-time, remote, real-world
High frequency, high-velocity data
Non-invasive, low burden
Low-cost, ubiquitous, scalable

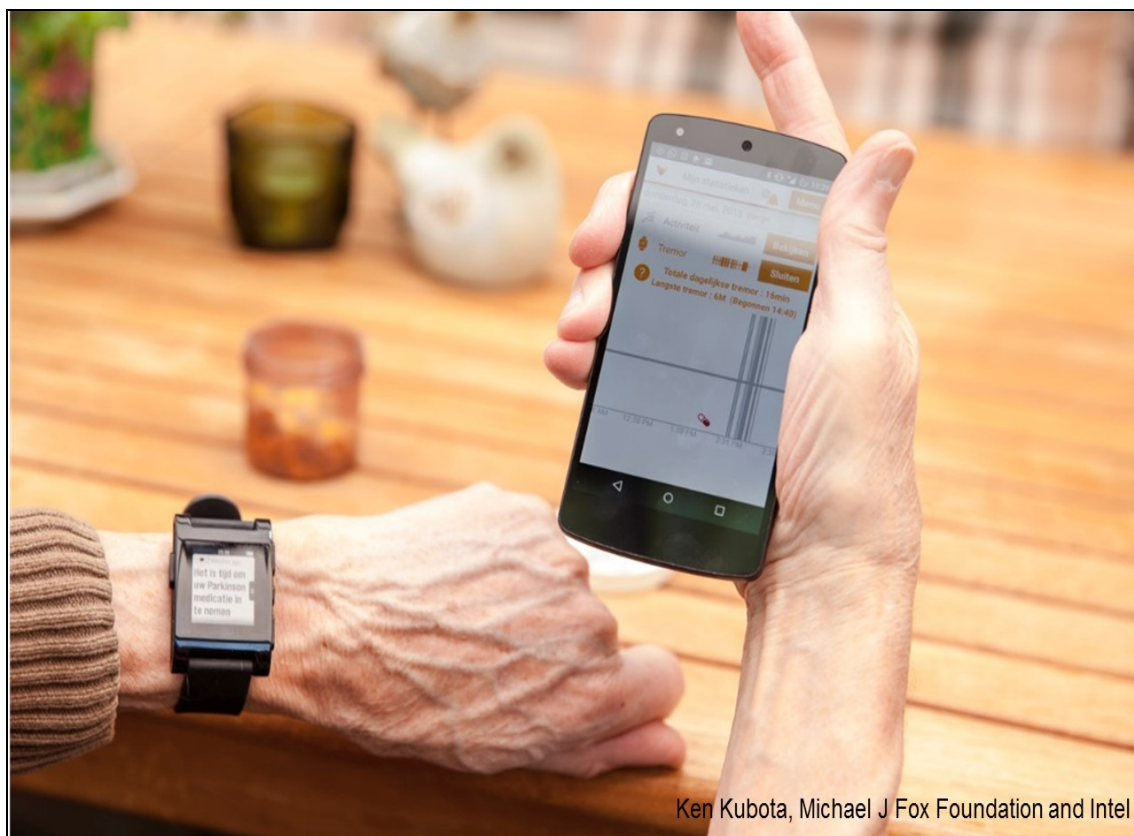


Diagnose and treat → pre-empt and predict model
Enhances self-management
Potential for innovation – new ways of doing research
'Digital phenotype'

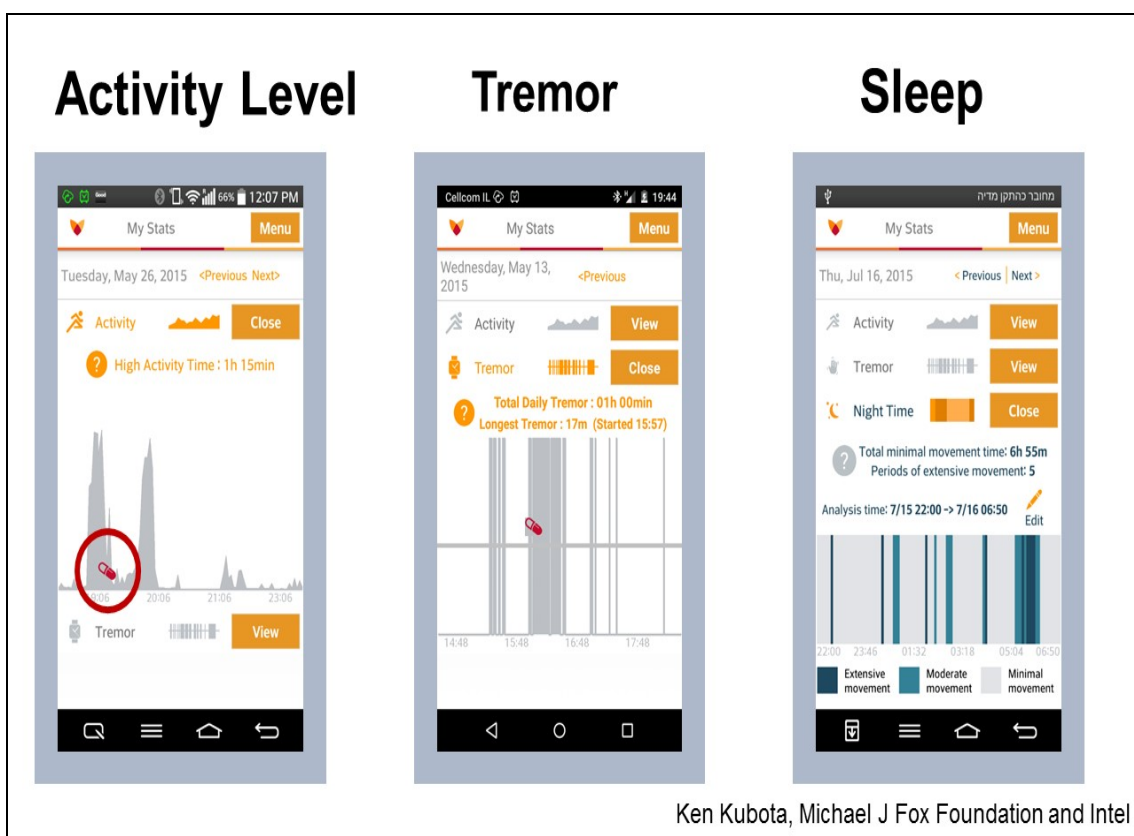
The Digital Phenotype



Ken Kubota, Michael J Fox Foundation

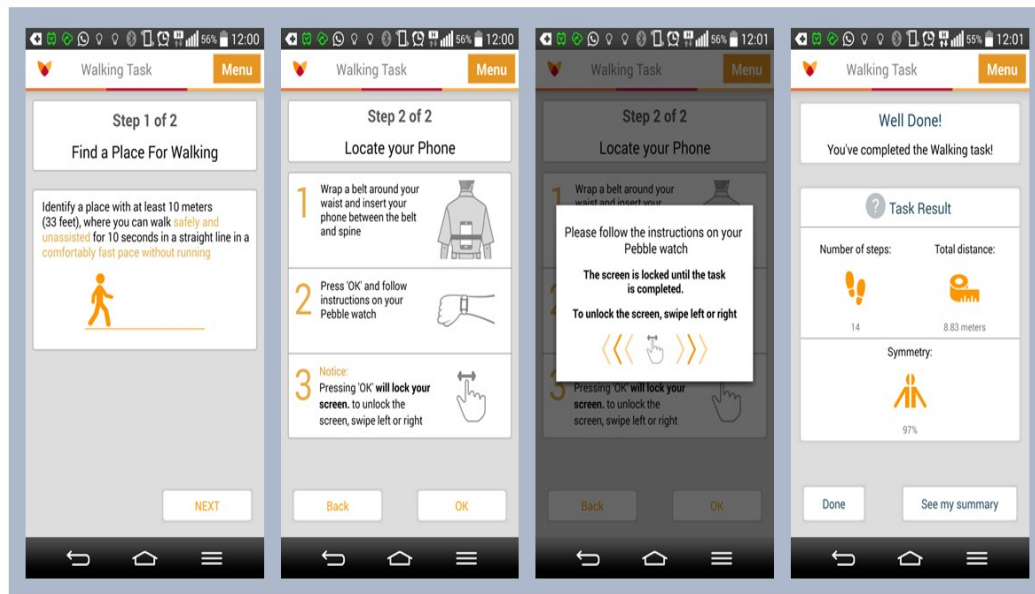


Ken Kubota, Michael J Fox Foundation and Intel

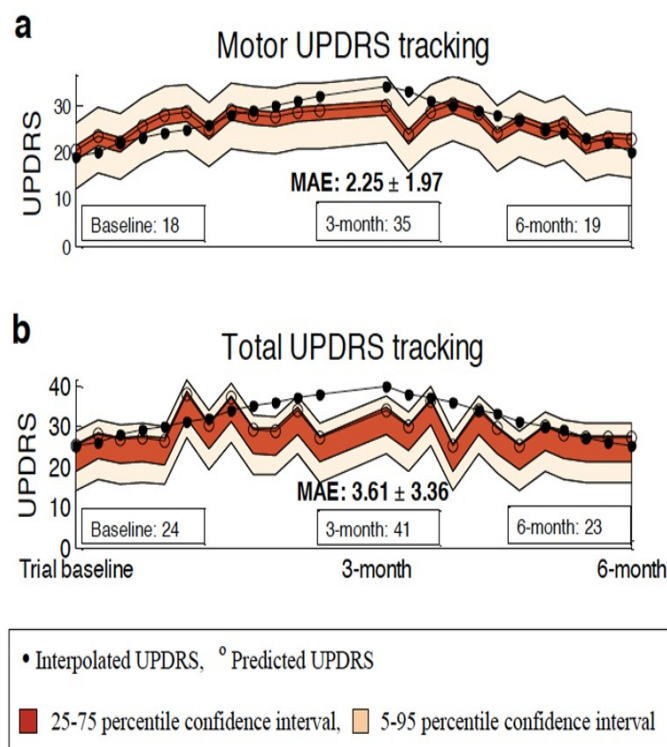


Ken Kubota, Michael J Fox Foundation and Intel

Structured Tests



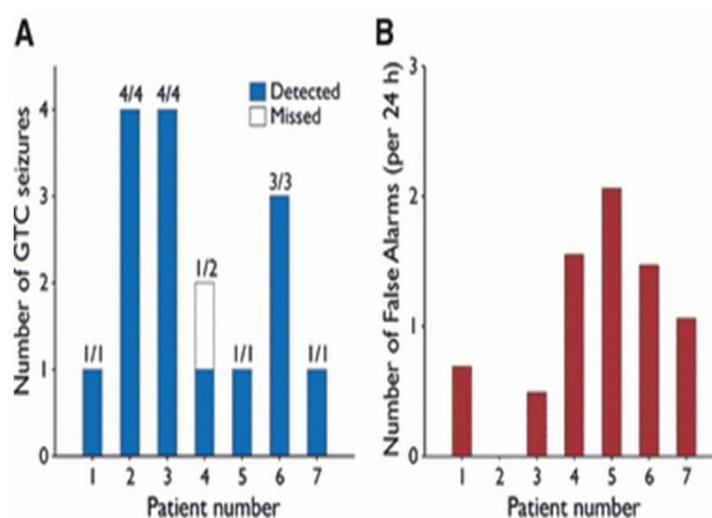
Ken Kubota, Michael J Fox Foundation and Intel



Athanasios Tsanas, University of Oxford

Convulsive seizure detection using a wrist-worn electrodermal activity and accelerometry biosensor

*†Ming-Zher Poh, ‡Tobias Loddenkemper, §Claus Reinsberger, †Nicholas C. Swenson,
†Shubhi Goyal, †Mangwe C. Sabtala, ¶Joseph R. Madsen, and †Rosalind W. Picard



Epilepsia, 53(5):e93–e97, 2012
doi: 10.1111/j.1528-1167.2012.03444.x

Challenges

- Data quality and quantity
- Sensor validity and reliability
- New approaches to analysis
- Data sharing, ownership, control
- Data security
- Device usability, drop-off and battery life
- Device regulation
- Overcoming resistance to 'disruptive' innovation

Presentation by Dr Jean-Pierre Lin

Following the patient pathway – mHealth from Childhood to Adulthood

Developing a Flexible Transitional Service for young Adults with Complex Motor Disorders

Dr Jean-Pierre LIN

Consultant Paediatric Neurologist

Evelina Children's Hospital

President British Paediatric Neurology Association

GUY'S &
ST THOMAS' CHARITY

Guy's and St Thomas' NHS
Foundation Trust

King's College Hospital NHS
Trust



KING'S
College
LONDON

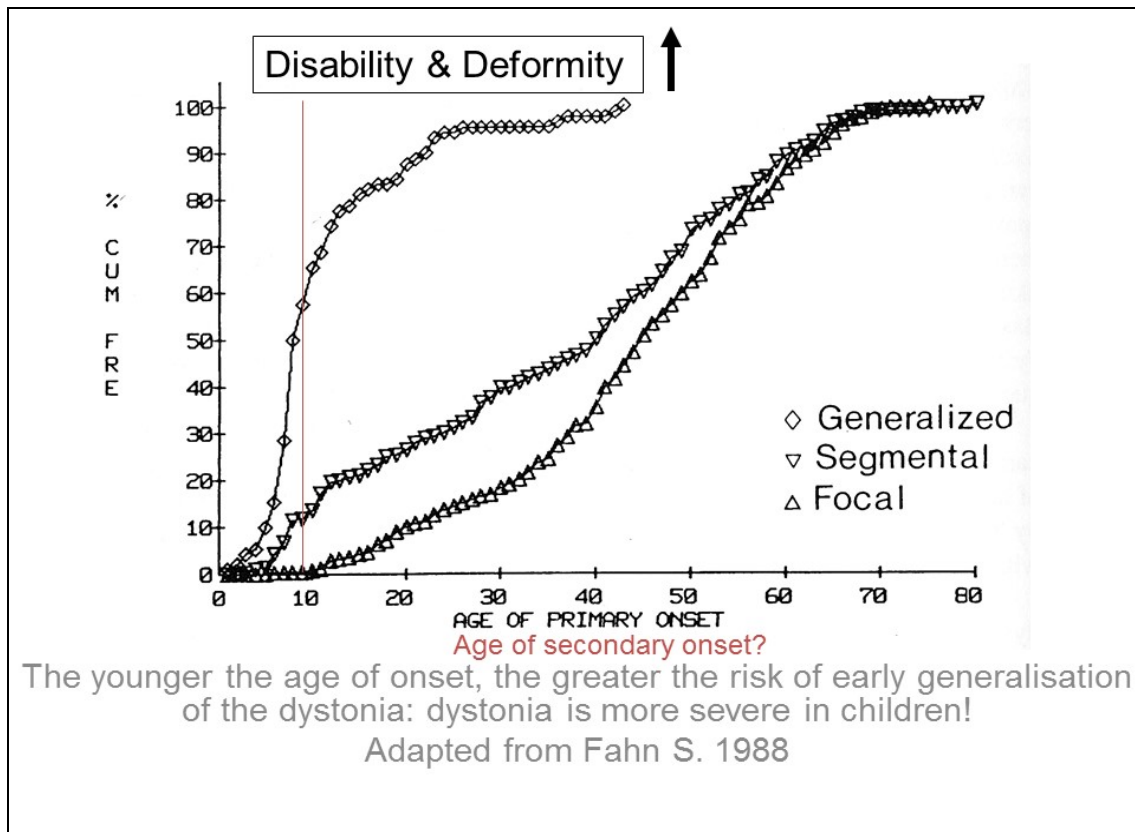


Activity and Participation after DBS for Dystonia

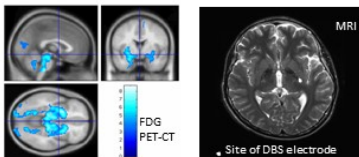

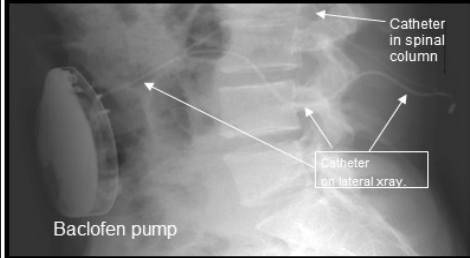


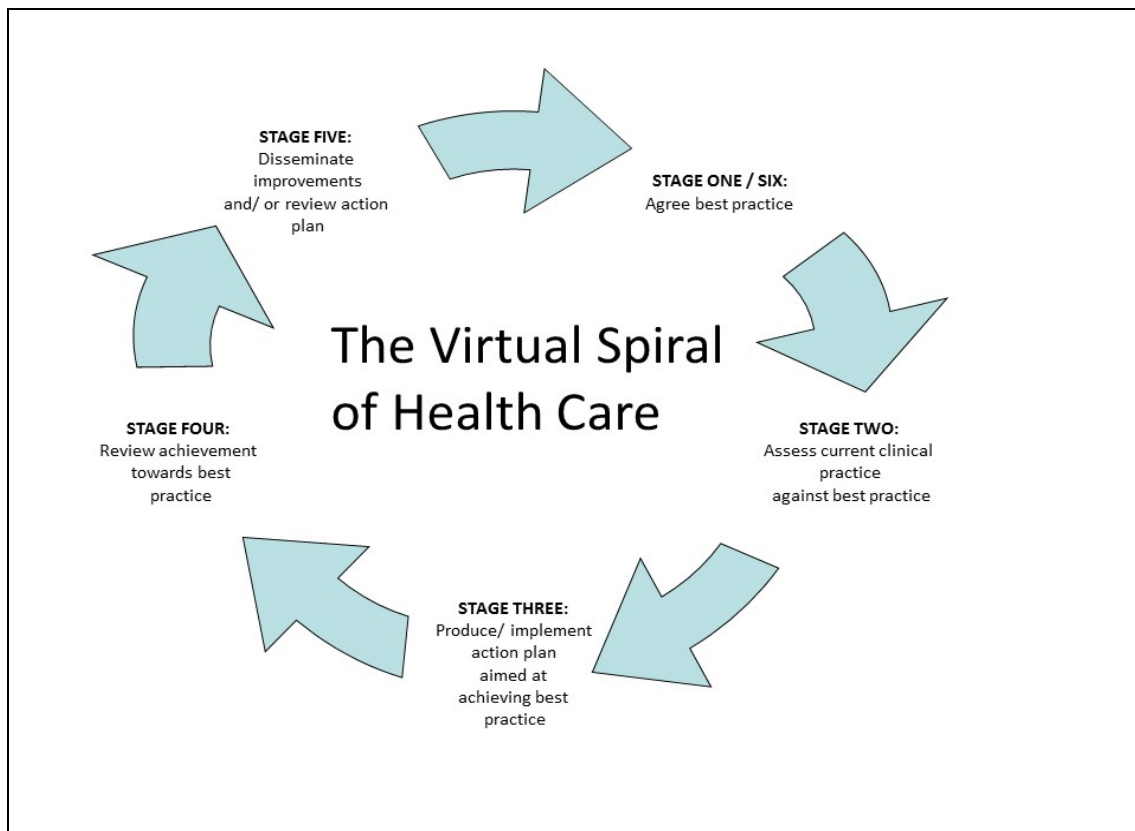
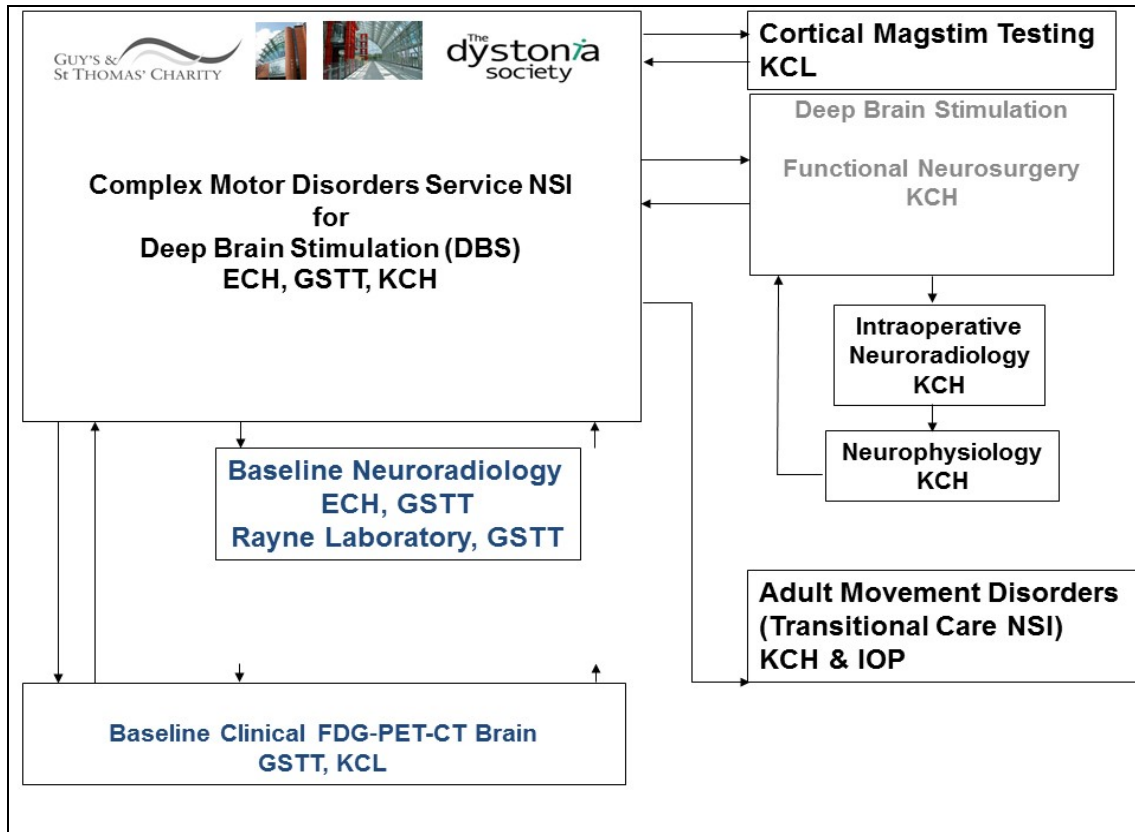
Young-onset
Dystonia:
An ideal
outcome!
Could we
Predict it?





Intrathecal Baclofen (ITB) or Deep Brain Stimulation (DBS):
A collaboration of specialist teams helping children with complex motor disorders

| Dystonia | Spasticity |
|--|---|
| <p>Normal <i>magstim</i> testing of corticospinal tracts? Consider DBS</p> <div style="display: flex; justify-content: space-around;">  <div> <p>Diagnosis criteria met? MRI brain/spine Magstim testing FDG-PET-CT.</p> <p>Establish goals with family.</p> <p>Assess motor, cognitive & psychological function scales.</p> <p>Follow-up outcome with multidisciplinary team.</p> </div> </div> <div style="display: flex; justify-content: space-around;">  <div> <p>Site of DBS electrode</p> <p>Bilateral Deep Brain Stimulation</p> </div> </div> | <p>Abnormal corticospinal tracts on <i>magstim</i> testing? Consider ITB</p> <div style="display: flex; justify-content: space-around;">  <div> <p>Catheter in spinal column</p> <p>Catheter on lateral xray</p> <p>Baclofen pump</p> </div> </div> <div style="text-align: center;"> <p>Guy's and St Thomas' NHS NHS Foundation Trust</p> <p>PET PET Imaging Centre St Thomas'</p> <p>KING'S College LONDON Institute of Psychiatry at the Maudsley</p> </div> |



**Team approach versus ad hoc health services for young people with physical disabilities:
a retrospective cohort study**

N Bent, A Tennant, T Swift, J Posnett, P Scuffham and MA Chamberlain

Background

Young people with physical disabilities often have difficulty attaining independence in adult life and consequently need lifelong support from parents and from health-care and social-care services. There are concerns about the organisation and cost-effectiveness of such services and their ability to meet the independence training and serious health needs of these young people. Our aim was to compare a young adult team (YAT) approach with the ad hoc service approach in four locations in England, in terms of their ability to enhance the participation in society of these young people and their cost.

[The Lancet Volume 360, Issue 9342, 26 October 2002, Pages 1280-1286](#)

Team approach versus ad hoc health services for young people with physical disabilities

Methods

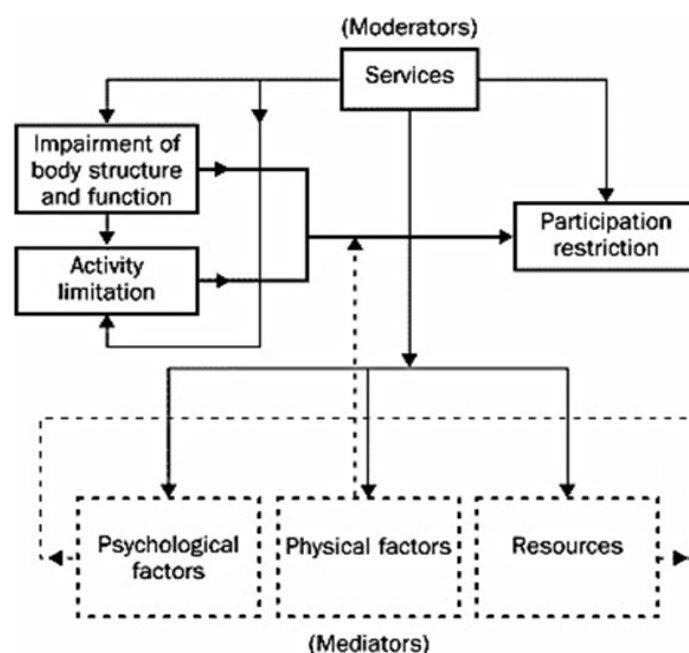
Retrospective cohort study, in which we interviewed 254 physically disabled young people. 124 healthy controls were given a questionnaire.

We interviewed with standardised measures and used logistic regression analysis to test for effects of ad hoc and YAT services.

The Mantel-Haenszel χ^2 statistic was used to test for differences in resource use between areas in which the YAT and ad hoc services were available.

[The Lancet Volume 360, Issue 9342, 26 October 2002, Pages 1280-1286](#)

Barthel Flow Chart



Team approach versus ad hoc health services for young people with physical disabilities

Domain

Body function impairments

Activity limitation

Health

Psychosocial

Participation restriction

Measure

Nottingham health profile²⁸
(pain, sleep, energy domains)

Barthel²⁹

Euroqol³⁰

Rosenberg selfesteem³¹

General perceived selfefficacy³²

Perceived stress scale³³

Proactive attitude scale³⁴

London handicap scale²⁶

[The Lancet Volume 360, Issue 9342, 26 October 2002, Pages 1280-1286](#)

Team approach versus ad hoc health services for young people with physical disabilities

Because of the higher numbers of clients and higher average contacts, the total cost of services in ad hoc areas was 41% higher than in YAT areas. However, the average cost per service contact was £35.40 and £35.74 for ad hoc and YAT areas, respectively.

| Contact | Total contacts | Home visits (%) | Total cost (UK£) | Average cost per contact (UK£) | Average cost per person in sample (UK£) |
|--------------------------------|----------------|-----------------|------------------|--------------------------------|---|
| Family doctor | | | | | |
| YAT | 312 | 12 | 11 611 | 37 | 104 |
| Ad hoc | 288 | 18 | 11 324 | 39 | 89 |
| Other doctor (specialist) | | | | | |
| YAT | 183 | 14 | 7659 | 42 | 72 |
| Ad hoc | 193 | 13 | 8006 | 41 | 60 |
| Physiotherapist | | | | | |
| YAT | 796 | 68 | 26 051 | 33 | 239 |
| Ad hoc | 1318 | 76 | 45 975 | 35 | 348 |
| Occupational therapist | | | | | |
| YAT | 87 | 77 | 3045 | 35 | 27 |
| Ad hoc | 128 | 94 | 5046 | 39 | 39 |
| Speech therapist | | | | | |
| YAT | 315 | 100 | 12 285 | 39 | 106 |
| Ad hoc | 272 | 93 | 10 155 | 37 | 79 |
| Social worker | | | | | |
| YAT | 264 | 79 | 11 352 | 43 | 104 |
| Ad hoc | 128 | 100 | 5504 | 43 | 44 |
| Psychologist or counsellor | | | | | |
| YAT | 19 | 50 | 1131 | 60 | 10 |
| Ad hoc | 210 | 69 | 12 543 | 60 | 96 |
| Other health-care professional | | | | | |
| YAT | 198 | 92 | 3548 | 18 | 32 |
| Ad hoc | 515 | 92 | 9228 | 18 | 71 |
| Total | | | | | |
| YAT | 2166 | 44 | 76 682 | 35 | 650 |
| Ad hoc | 3016 | 51 | 107 780 | 36 | 798 |

[The Lancet Volume 360, Issue 9342, 26 October 2002, Pages 1280-1286](#)

Team approach versus ad hoc health services for young people with physical disabilities**Findings**

The absence of pain, fatigue, and stress increased the odds of participation two-fold to four-fold.

After adjustment for these factors, young people cared for by multidisciplinary YAT teams were 2.54 times (95% CI 1.30–4.98) more likely than those who used ad hoc services to participate in society.

Resource use did not differ between the two service types.

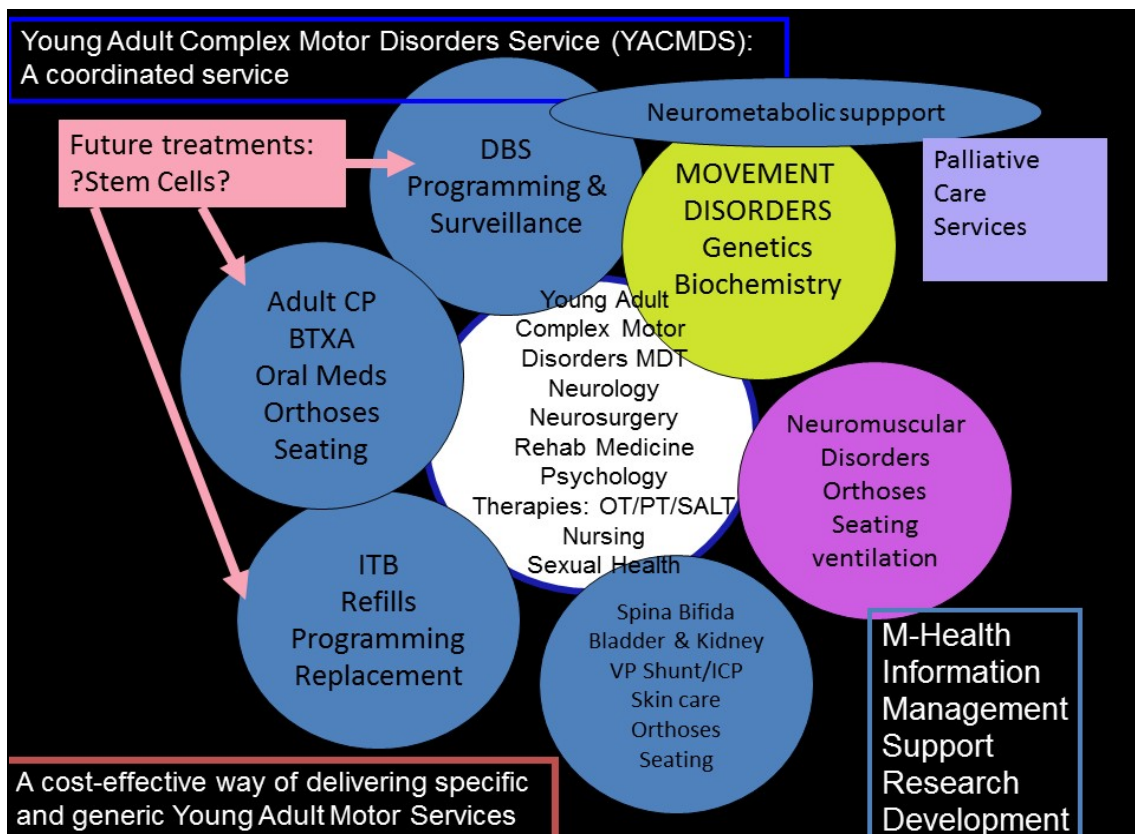
[The Lancet Volume 360, Issue 9342, 26 October 2002, Pages 1280-1286](#)

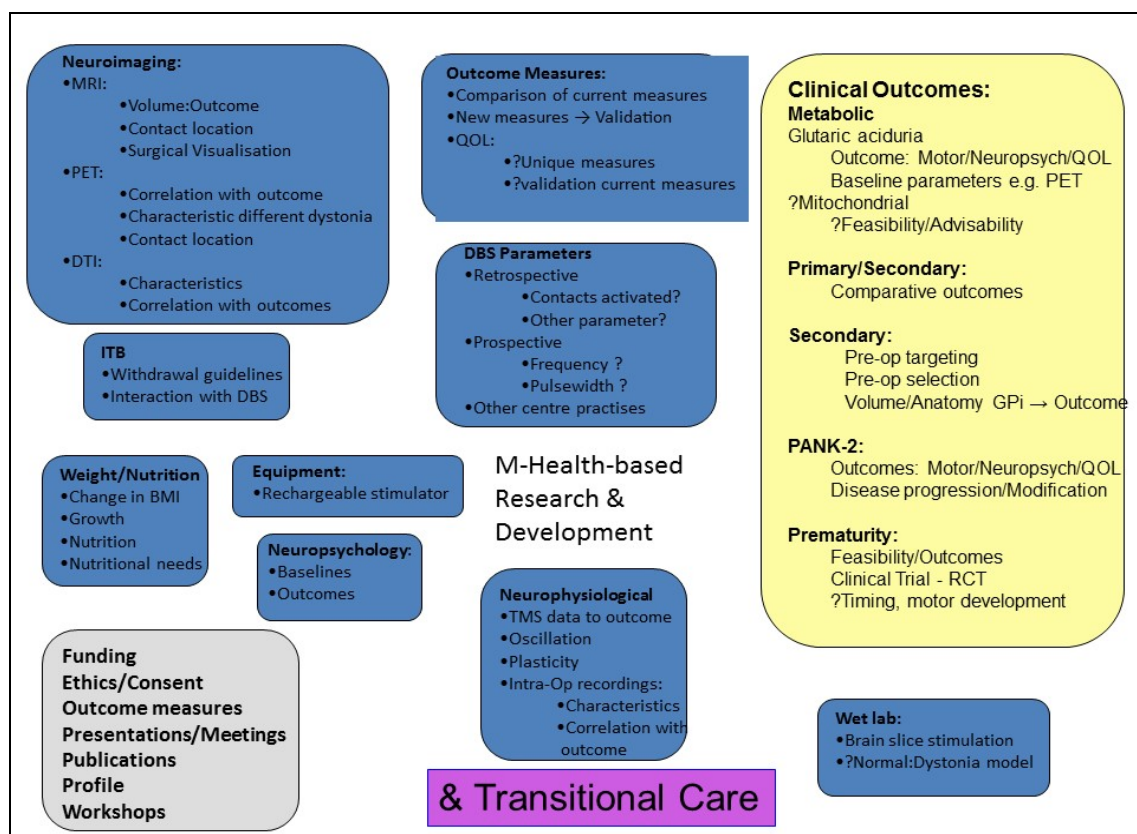
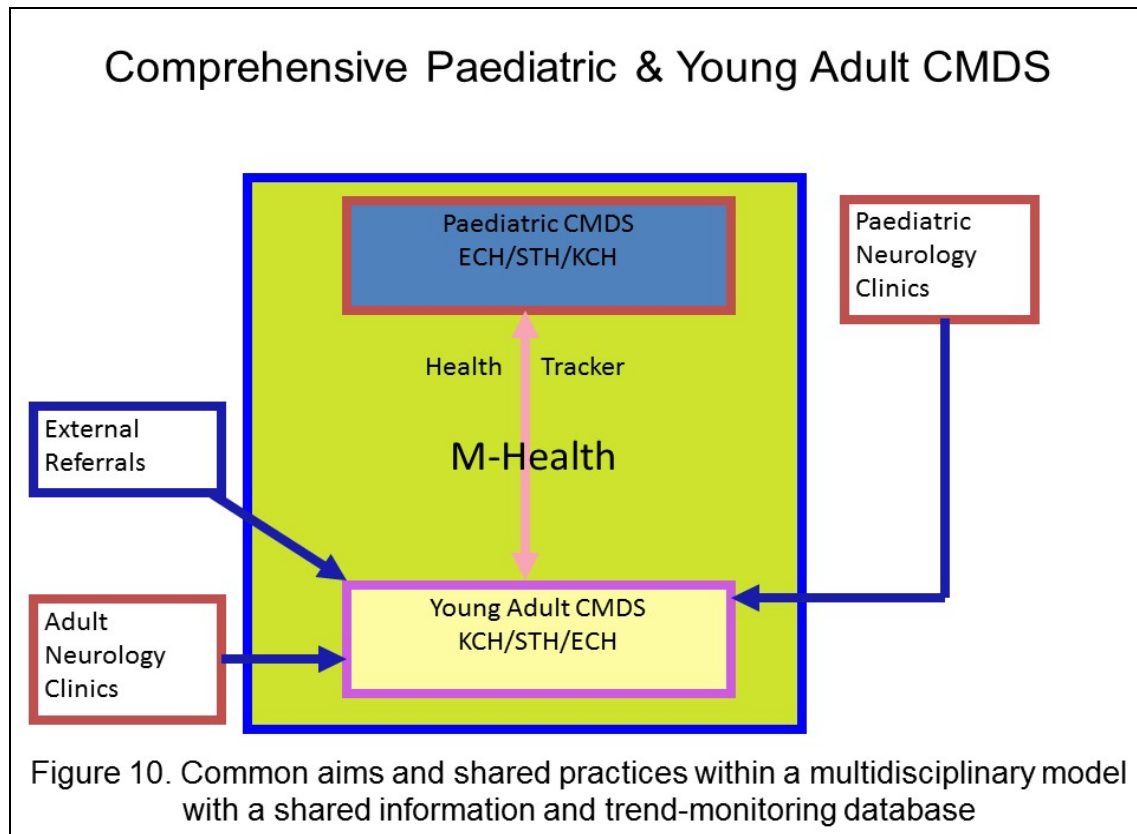
Team approach versus ad hoc health services for young people with physical disabilities

Interpretation


A YAT approach costs no more to implement than an ad hoc approach, and is more likely to enhance participation in society of young people with physical disabilities.

[The Lancet Volume 360, Issue 9342, 26 October 2002, Pages 1280-1286](#)





Presentation by Dr Terje Peetso



EU initiatives in the area of mHealth

**"Living with a neurological brain disorder:
Taking control of your life"
12 October 2016**

Terje Peetso
Unit Health, Wellbeing and Ageing
DG CONNECT, European Commission



Code of Conduct on privacy for mHealth apps

- Covers data protection principles to be followed in the development of mHealth apps (apps processing health data)
 - Practical Guidelines for app developers
 - Data Protection Impact Assessment (template)
 - Privacy policy (sample)
 - A multi-stakeholder governance model to enforce the Code and to monitor its compliance
- State of play
 - Awaiting comments and opinion from Article 29 Working Party under the Data Protection Directive (submitted on 7 June 2016)

2



Consultation on safety of apps and other non-embedded software not covered by sectorial legislation

- to gather input from stakeholders on their experience related to the safety of apps and other non-embedded software;
- to obtain a better understanding of the risks and problems that non-embedded software pose and how these problems are dealt with;
- the views gathered will help to define potential next steps and future policies at the EU level;
- Closed on **15 September 2016**

<https://ec.europa.eu/digital-single-market/en/news/public-consultation-safety-apps-and-other-non-embedded-software>

3



Guidelines on the assessment of validity and reliability of mHealth apps

- Voluntary guidelines that could be used by public authorities, health care providers, professional and patients associations and others
- A core drafting team was set up in February 2016
 - a working group representing civil society, academia, industry, public authorities
 - mandate to draft the guidelines by the end of 2016
- State of play
 - second round of stakeholder feedback was conducted over the summer (comments were received until 31 August, 25 responses)
 - the working group is working on the 3rd draft (due mid-Oct)

<https://ec.europa.eu/digital-single-market/en/news/current-initiatives-unlock-potential-mobile-health-europe>

4



Guidelines – what will it cover?

Discussions on:

- Purpose and target groups – mainly health care organisations vs app developers?
- Scope - health and wellness apps or a broad scope covering also medical devices apps?
- Criteria – focussing on validity and reliability vs a broader scope of quality criteria?
- Assessment methodologies and tools – should a risk assessment approach be included?



5



European quality standard for the development of health and wellness apps

- European standard to provide guidance to app developers on the quality criteria to be followed throughout the app development lifecycle
- Standardisation action to be taken forward in CEN
 - based on PAS 277:2015 on Health and wellness apps – Quality criteria across the life cycle (BSI, UK)
 - Initial discussions in the CEN/TC 251 „Health Informatics“
 - BSI is preparing a proposal for a new working item (support of 4 other MS is needed)

6



WHO-ITU EU mHealth hub

- In cooperation with WHO-ITU under H2020
- The focal point for expertise on mHealth in the EU
 - identifying trends and gaps in policies, standards and regulations
 - gathering evidence and facilitating the exchange of knowledge and best practices
 - support development and implementation of mHealth strategies tailored to the needs of Member States and regions

7



Horizon 2020 (WP 2016 – 2017) Health, demographic change and well-being

- Funding of research and innovation in the field of
 - big data for public health policies
 - digital security for healthcare
 - patient empowerment
 - digital health literacy
- Preparations for the Work Programme 2018 - 2020



eHealth Action Plan 2012 - 2020

- **Actions on**
 - Interoperability
 - Research and innovation
 - Deployment
 - International cooperation
- **Interim evaluation**
 - Public consultation in the end 2016
 - SWD – 1st half 2017

9



Thank you!

Presentation by Ms Nicola Bedlington

INVOLVING PATIENTS IN THE DESIGN OF NEW TOOLS FOR THE TREATMENT OF BRAIN DISORDERS

Nicola Bedlington

EP workshop on Brain Disorder
12 October 2016



“ A STRONG PATIENTS’ VOICE TO
DRIVE BETTER HEALTH IN EUROPE ”



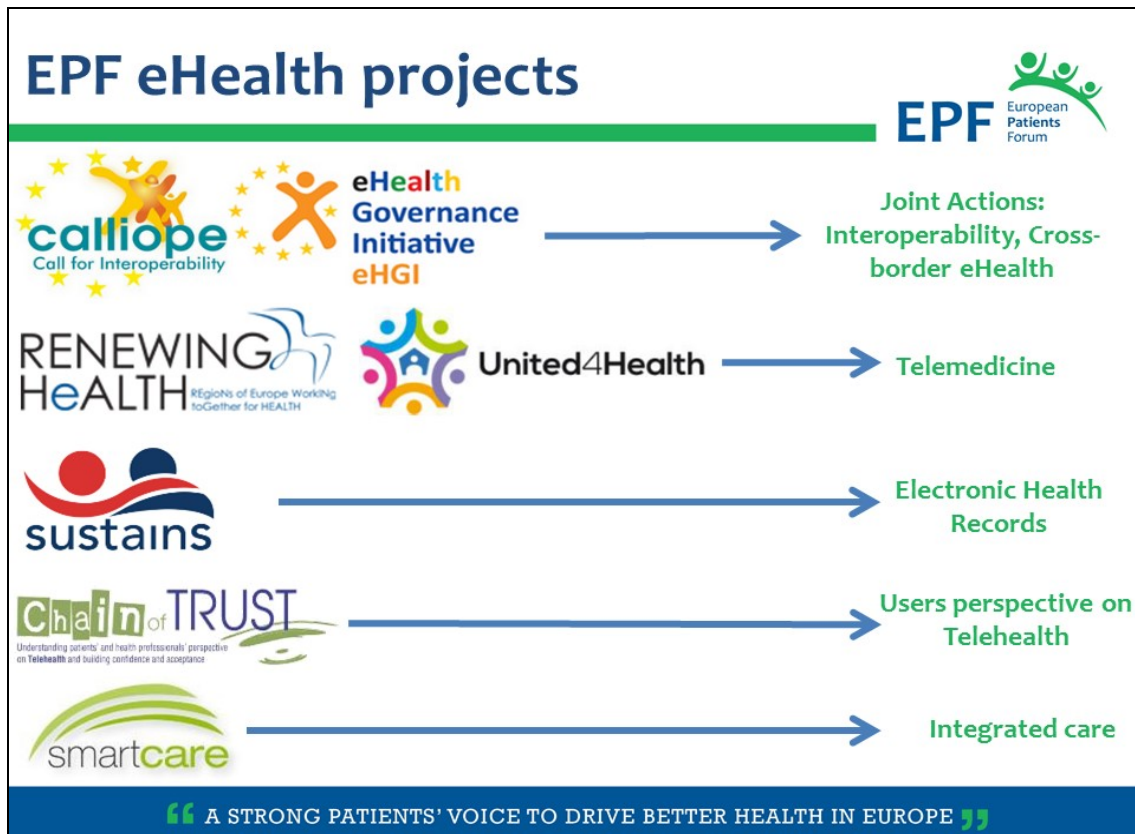
Who is EPF?



- European Patients’ Forum
 - Umbrella organisation
 - Active since 2003
 - Independent & non-governmental
 - EU patients’ voice
- Our members
 - 67 patients’ groups
 - Disease-specific EU & national coalitions
- Our vision
 - All patients in the EU have **equitable access to high-quality, patient-centred** health and social care

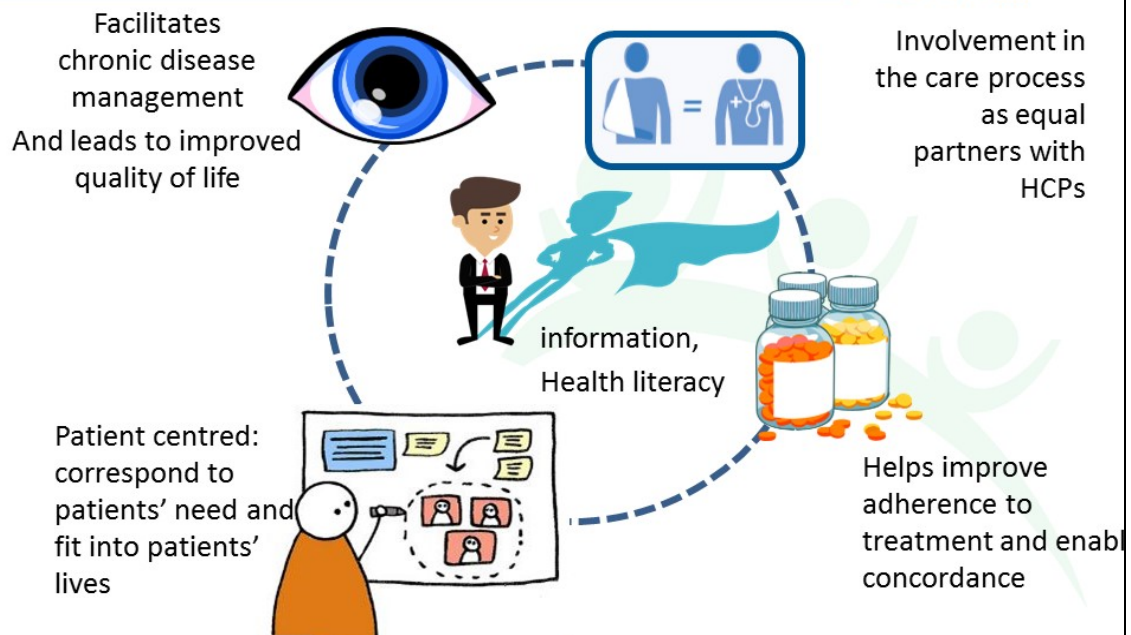


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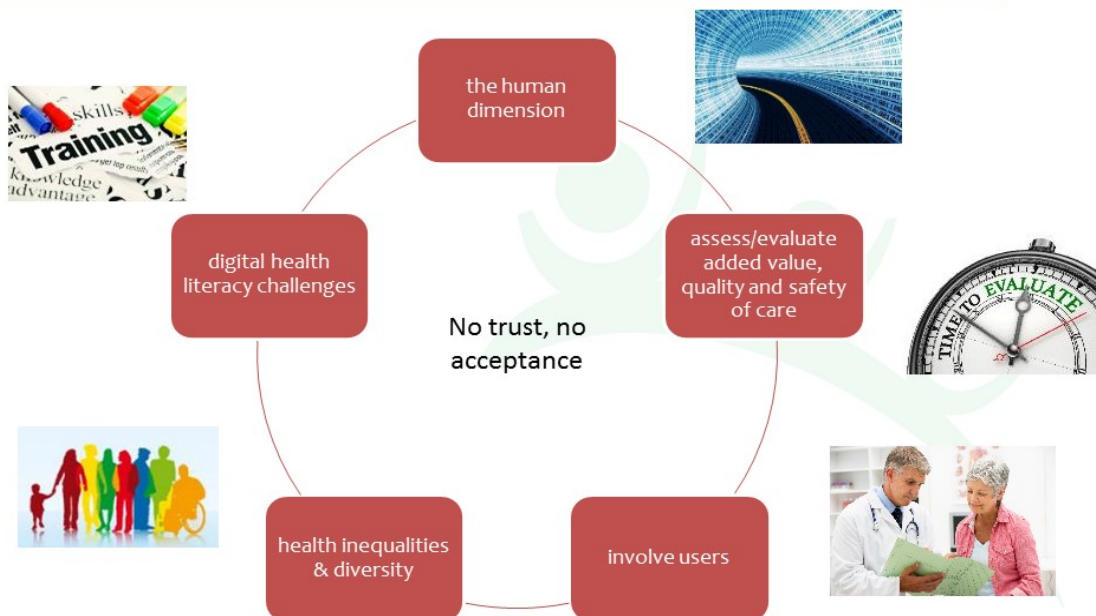
Patient expectations vs reality

Patients' expectation for eHealth



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Common mistakes in eHealth services development and deployment



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Key challenge with mhealth



Quality and safety

- A key issue in eHealth in general is the failure to assess impact on quality and safety of care, and impact on patients relevant outcomes
- Blurred line between lifestyle apps and medical/patient supporting apps: the validity of the information they provide or their safety and quality is not always monitored thoroughly – Code of conduct will help

Empowerment

- Does mhealth=empowerment? Not that simple
- If apps provide wrong information, do not fit in with the patient needs, or if information about quality and safety of app is not easily accessible=> disempowering!

“ A STRONG PATIENTS' VOICE TO DRIVE BETTER HEALTH IN EUROPE ”

Key challenge with mhealth



Equity

- mHealth – important potential in terms of equity – in reaching out to specific populations (remote geographical areas, young people etc..)
- Developers sometimes fail to take into account diversity

Data Protection

- Issue of consent as patients share a lot of data with health apps
- Question of quality of data collected by mhealth apps – guidelines drawn up by a task force at EU level

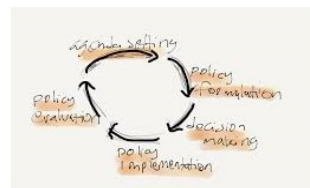
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How to involve patient meaningfully in eHealth development (including mobile health)

What meaningful involvement in mHealth looks like



Patient = Expert



Involve patients throughout the design cycle



Not just a patient satisfaction survey



Appropriately resourced, planned and evaluated

Meaningful patient involvement



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What needs to change?



- Patient involvement = a criterion for the development of eHealth or mhealth services directed at patients - whether its publicly or privately funded projects
- From the beginning, as at a later stage, change becomes more difficult and costly
- Involve patients in the evaluation of the safety and quality of the services, to ensure we identify added value and impact of new tools and services accurately
- Patients can have a role, whether as individuals or organisations - surveys, focus groups, definition of user requirements....

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Conclusions



- Issues around trust and acceptance of end users are a well known barriers to the deployment of eHealth in the EU
- We cannot continue to innovate in the old way – patients' needs should be at the centre, otherwise the app or services will not be taken up.
- Mobile health can contribute to patient empowerment and support patients in the management of their condition...
- ...Need for a change of culture, as patient involvement is still the exception rather than the rule in the mhealth/ehealth sectors

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Our definition of empowerment

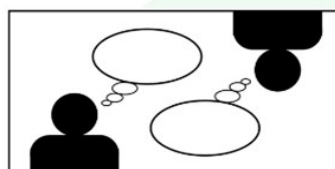


“Patient empowerment is *a process* that helps patients gain control over their lives, increasing their *capacity to act* on issues that *they themselves* define as important”

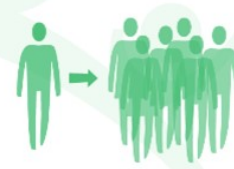
(Adapted from JA-PaSQ, 2012)



A process: non-binary,
non-linear



Cannot be imposed from
top-down



Individual + Collective

“ A STRONG PATIENTS' VOICE TO DRIVE BETTER HEALTH IN EUROPE ”

NOTES

DIRECTORATE-GENERAL FOR INTERNAL POLICIES

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Policy departments are research units that provide specialised advice to committees, inter-parliamentary delegations and other parliamentary bodies.

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