EBC RESEARCH PROJECT

THE **VALUE OF TREATMENT** FOR BRAIN DISORDERS

"Bridging the early diagnosis and treatment gap: exploring the potential clinical and socioeconomic impact of targeting unmet needs - reflections on new research developments including the benefits of alternative approaches such as seamless, integrated care in the prevention and treatment of brain disorders"

OUTLINE AND OBJECTIVES - JANUARY 2017

CONTENT

A MULTIPLE GOAL

"**Bridging the early diagnosis and treatment gap**: exploring the potential clinical and socioeconomic impact of targeting unmet needs - **Reflections on new research developments including the benefits of alternative approaches** such as seamless, integrated care in the **prevention and treatment** of brain disorders"

A BOTTOM-UP METHOD

Setting the scene from case studies data analysis towards evidence-based policy recommendations

EBC Value of Treatment Coordination Team:

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The European Brain Council (EBC) is a non-profit organisation gathering patient associations, major brain-related societies as well as industries. Established in March 2002, its mission is to improve the lives of those living with brain disorders by advancing the understanding of the healthy and diseased brain through bringing together science and society.

OUTLINE AND EXPERTS ROUNDTABLE OBJECTIVES

Wednesday, 18 January 2017 - The Value of Treatment Experts Roundtable

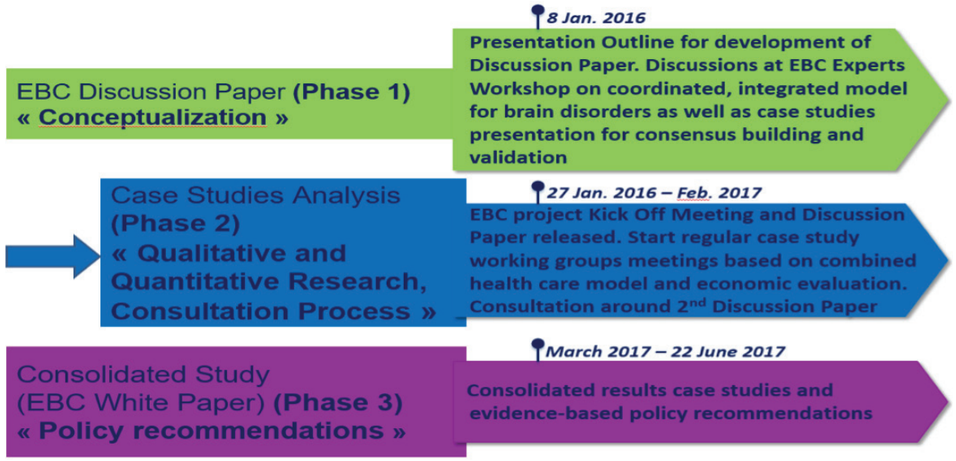
For all Working Group Members together with additional experts, will take place as part of the consultation process for the **«Bridging the early diagnosis and treatment gap for brain disorders - Towards EBC Policy White Paper»**.

We are approaching the end of the research project phase 2 "case studies analysis" (**see fig. 1:** EBC Value of Treatment research phases and deliverables).

It is therefore important to start reflecting on an **overarching healthcare model for brain disorders** (based on common denominators that could link diseases) **and conclusions for further policy recommendations**.

22 June 2017: EBC will launch the Policy White Paper at a final conference under the auspices of the Maltese EU Presidency. Scientific publications will also be released in 2017.

Figure 1: EBC Value of Treatment three expected deliverab
(see detailed planning with milestones in the annex, p. 15)



RESEARCH METHODOLOGY

18 January 2017 The Experts Roundtable will aim at generating collective thinking on pre-final results presented during the morning Plenary WGs Meeting: **concepts and evidence** highlighted so far around **early diagnosis and timely intervention. It will then confront (test) hypotheses** with the experts and case studies Working Groups.

The outline for the further development of the EBC Discussion Paper 2[1] raises **the following questions to examine the best options towards three goals: to make an impact on public health policy, to improve the patients' quality of life and to reduce the socio-economic burden**.

- What is the amplitude of current unmet needs in health care in Europe? What is the width and breadth of so-called "treatment gaps", or obstacles such as misdiagnosis, delayed treatment, non-adherence, unaffordable access to care and pricing incl. innovative therapies, reimbursement and social safety net cutbacks[2]…), not only within the provision of medicines and medical devices, but also within health care systems and services? What is the socio-economic impact of targeting these gaps (e.g. avoidable costs…)? What have we learned from the "Patient Journey" (clinical care pathway) analysis?
- What are the new research developments with regards to timely intervention to improve (primary and secondary) prevention and treatment, knowing that, as of today, there is no cure? What about the potential benefits for integrated, coordinated care combining effective team care and care planning? What are the priorities for policy making in the current context of health systems reforms (articulating their impact investment social return) and legislation implementation?

EBC scope and vision: promoting a holistic healthcare approach (versus fragmentation and results in silo)

A large body of research links early intervention to **measurable health gains** such as improved survival rates, reduced complications, **and lower treatment costs**. However, effective implementation of early diagnosis and treatment varies widely across health systems and many European countries are still lagging severely behind (with clinical practice variations even within countries).

The Value of Treatment case studies will address this.

The vision is clear: mental and neurological disorders, or "disorders of the brain"[3] are complex and interlinked with hundreds of specific diagnoses, codified in diagnostic classifications systems (WHO International Classification of Diseases, ICD-10[4] and American Psychiatric Association Diagnostic and Statistical Manual of Mental Disorders, DSM-V[5]). Until recently, brain disorders were associated with disciplinary fragmentation in research and practice using different concepts and approaches. Today, there is greater awareness on their burden, the challenges of managing them, and increasing ability **to prevent** some of them (modifiable risk factors reduction).

All this emphasizes the need for:

> **At healthcare level**, improving **the patient flow** in the whole process of care (care pathway)[6] for better outcomes;
> **At macro health system governance level,** developing an EU-wide research and public health combined Plan to **address brain health in a comprehensive (biopsychosocial approach), transversal (across diseases) and collaborative way**[7]**.**

Case studies research objectives, process and tools

The Value of Treatment (VoT) research project draws from the EBC Report "The Economic Cost of Brain Disorders in Europe" published in 2005 (Balak and Elmaci 2007) and updated in 2010 (Gustavsson et al. 2011) that **provided a solid estimation on the costs of brain disorders in Europe and enlightened necessary public health policy implications**.

'Patient-centeredness' for 'shared clinical decision making'

In the continuity of these findings and as highlighted in EBC Discussion Paper[8], VoT aims to propose the best return on investment solutions as well as provide evidence-based and cost-effective policy recommendations for a more patient-centred and seamless care model for brain disorders. Outcomes are assessed using clinical indicators and patient outcome indicators for defined patient groups.

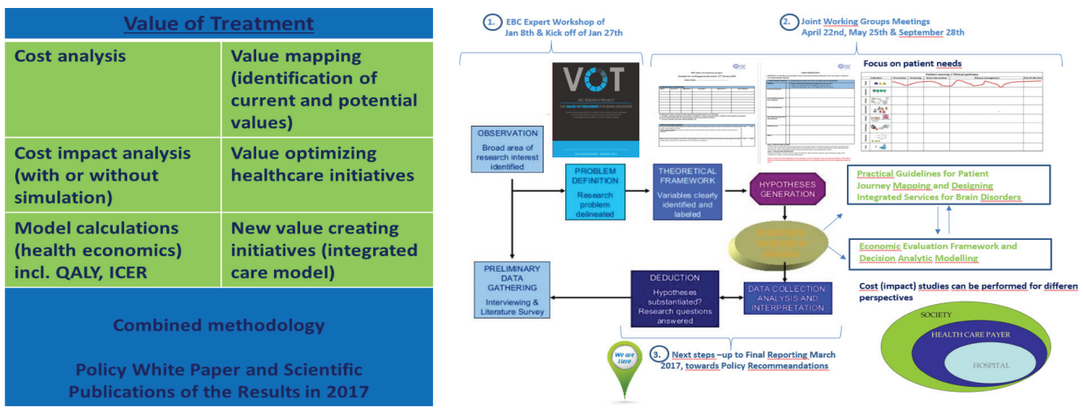
Based on **research methodology** defined by two Academic Partners (the London School of Economics for the "economic evaluation" and the Rotterdam Institute of Health Policy and Management for the "patient journey analysis"), VoT is developing **case studies analysing (i) health gains and (ii) socio-economic impacts resulting from best practice health** (pharmacological, nonpharmacological and psychosocial) **interventions** (see **fig. 2**: EBC Value of Treatment research framework and data analysis).

The benefits of best clinical practice interventions will be compared with the current standard of care or, where appropriate, non-treatment. The comparisons will take account of **cost burdens** (including socio-economic costs) to **assess value**.

Case studies analyses are being conducted for **the following disorders: mental illness comorbidity, schizophrenia, dementia, idiopathic normal-pressure hydrocephalus, AF stroke, Parkinson's disease, epilepsy, headache, multiple sclerosis and restless legs syndrome.**

Working groups are formed with **experts** within the network of EBC member organizations (e.g. European Academy of Neurology) as well as other industry and patient associations representatives. The setting up of the groups has been a building process to ensure **a high level of expertise** (participation of clinicians, health economists, epidemiologists…) and **an innovative "bottom-up" approach**.

Figure 2: EBC Value of Treatment research framework and data[9] analysis



Objectives of the combined case studiues methodology are twofold:

- **Patient's care pathway analysis** to assess needs and identify gaps and opportunities for improvements in the current care pathway.
- **Economic modelling** assessing the socio economic impact of specific clinical interventions targeted to close some of the gaps identified in the patient journay analysis.

BRAIN DISORDERS AND THE BURDEN OF DISEASES
Will affect almost 40 % of European citizens

Depression, stroke, dementia, alcohol dependence, schizophrenia or anxiety will affect **at least one in three European citizens during their lifetime - currently 165 million people in Europe** (estimated **38.2%** of the EU population annually)[10]. With an incomplete understanding of their cause(s), brain disorders[111] **are highly prevalent medical conditions[12] , being the seat of many chronic disabling diseases[13]: today, mental disorders and other brain disorders across the lifespan represent 35% of the burden of all diseases in Europe[14_15].**

And the burden of diseases is increasing.

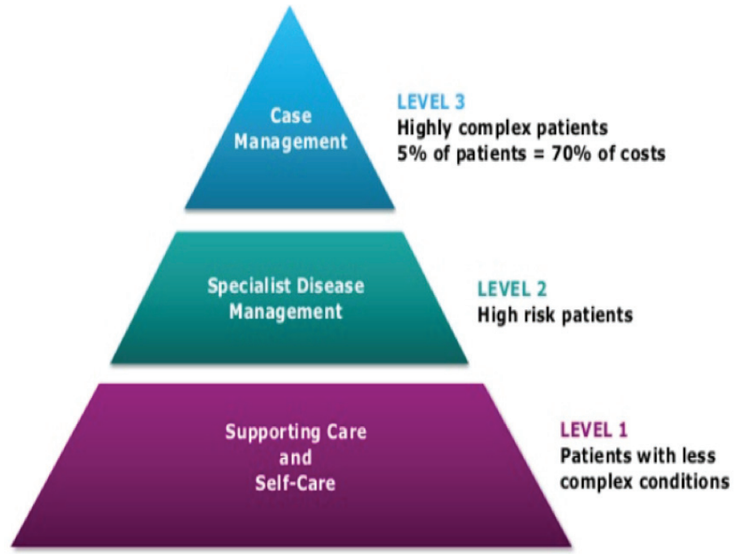
Direct costs of brain disorders make up for **60%[16] of the total costs** – which EBC estimated at **800 bln€/year in Europe**[17]. At European level, this health budget far exceeds that of cardiovascular diseases, cancer and diabetes together[18]. To compound this major issue in public health and on top of the escalating costs of brain disorders, out of 10 individuals with a brain disorder, **around 3 to 8 remain untreated although effective treatments exist** (except in the case of dementia where no effective, substantial symptom relieving treatment is available)[19].

The **relentless demand for healthcare services** is set to continue for the foreseeable future, fuelled by **population growth** and **increased longevity**. Since 2010, **health system reforms** in Europe are calling for **more efficient savings with high societal value and re-organization of care**: **new models of care, including a societal benefits approach, are being examined for a better coordination and integration of care. A key policy driver, therefore, is the need to look at the outcomes or health benefits and to optimize healthcare services delivery (with high quality standards, better use of resources and interaction).**

This is particularly **challenging for brain disorders** considering the **management of long-term conditions including co-morbidities, loss of independence, occurrence of acute, relapsing episodes and rehabilitation phases (motor, cognitive, social)**.

The complex basis of these conditions requires **constantly assessing the situation and the patient's level of risk (risk stratification and case identification, see fig. 3)**[20], which may vary according to the **severity** of the pathology, and r**edefining the care plan**[21].

Figure 3: Kaiser Permanent risk stratification pyramid



A « PARADIGM SHIFT »
TRANSFORMATION OF HEALTH CARE FROM FRAGMENTED CARE TOWARDS PATIENT-CENTERED AND SEAMLESS CARE

The whole spectrum of care, from prodromal, early diagnosis to disease management

From the patient perspective, timely detection and diagnosis can prevent unnecessary pain and suffering. Early diagnosis and treatment make not only clinical but also economic sense. Diagnostic testing is an integral part of the healthcare system, providing **essential information to enable providers and patients** to make the right clinical decisions. Indeed, some **75% of clinical decisions** are based on a **diagnostic test[22].**

Computed tomography (CT) and magnetic resonance imaging (MRI) have revolutionized the study of the brain by allowing healthcare practitioners and researchers to look at the brain noninvasively. These diagnostic imaging techniques evaluate the brain structure, allowing healthcare providers to infer causes of abnormal function due to different diseases.

Demand for access to quicker, more accurate diagnosis is rising. Making detection more efficient, timely and accurate will contribute to generate savings required by health systems. For instance, in order to address this, the integration of specialist neurological services into the primary care system needs to be a significant policy objective in countries. Moreover, the gate keeping "referral" function of community nurse/GP practice in pro-active screening is to be fully effective[23]

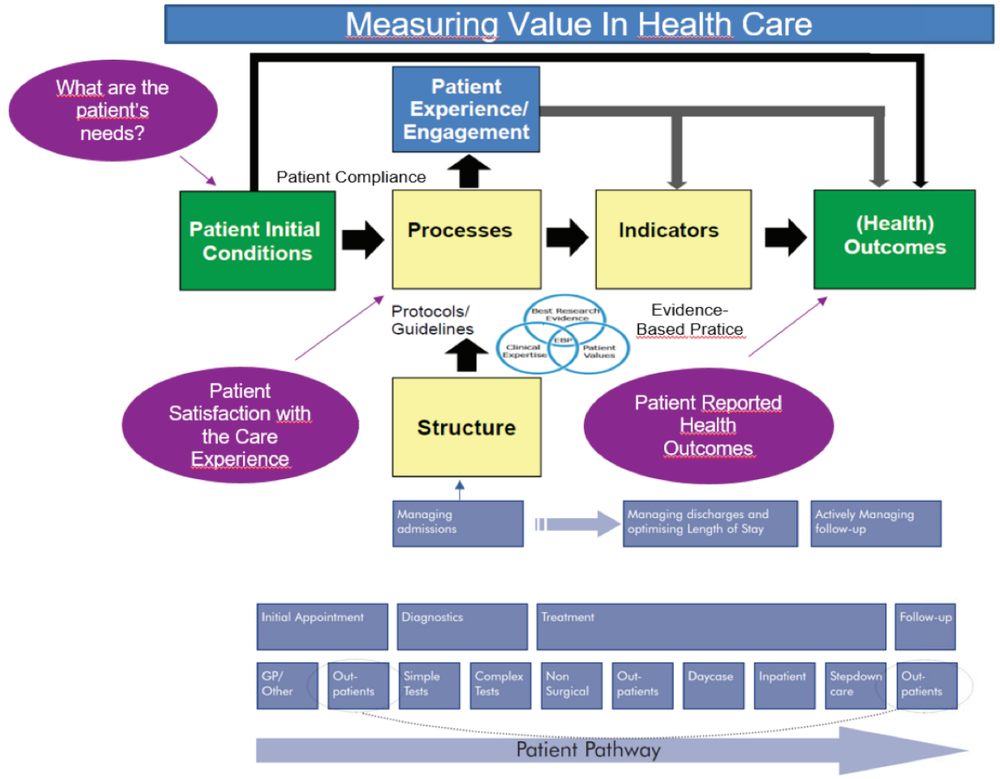
Value in health care: measuring health outcomes

Each age group according to disease stage has specific needs to be addressed along the care process (biological, psychological, health care services, social needs)[24]. Care for brain disorders usually involves multiple specialties and numerous interventions, with **final outcomes** determined by interventions **across the full cycle of care.**

Measuring, reporting, and comparing outcomes is crucial **to improve outcomes** and **make informed choices about how to optimize healthcare and rationalize costs** (see **fig. 4**: patient-centered, measuring value in health care and the patient pathway)[25]. Efforts to **empower patients** to be engaged in responding to their health needs may improve health outcomes, adherence to treatment, and has the potential for patients to make more informed decisions with regards to their health[26]. Research shows that **adherence** among patients suffering from chronic conditions is only 50% on average[27]. To ensure that health care

is **centered on patients**, the **patient journey approach** aims at giving patients a "voice" through enhancing collaborative multidisciplinary teamwork, shared ownership and decision-making, providing evidence to substantiate change, and achieving results[28].

Figure 4: Measuring Value in Health Care by achieved outcomes, starting with defining the patient's needs



Value is the combination of reducing symptoms, guaranteeing safety, cost-effectiveness, improving quality of live and respect of patients' rights. It cannot be reduced to economic, financial aspects.

> Value = treatment based on the **demand** (the needs of the patient) <-> treatment based on the offer/supply of treatment structures

> Value = optimization of the networking, easy transfer between different treatment structures (e.g. in mental health care, hospitals – community centres – psychiatrists – psychologists - GP's – self-help groups). **The changing nature of the demands made on hospitals means that it is particularly important for them to work closely with the different health and social care services.**

Illustration: optimizing healthcare in the chain of survival
The extreme importance of time

Every step of the patient trajectory from symptoms onset to start of treatment should be optimized in order to decrease loss of time.

VOT example: identifying the treatment gap and improving care for ischemic stroke patients

An illustration of the EBC approach, and one of the VoT case studies, is acute stroke care.

> Intravenous thrombolysis (IVT) with recombinant tissue plasminogen activator (rt-PA) is one of very few effective treatments for acute ischemic stroke. In most centres, however, only a small proportion (2%–7%) of patients with ischemic stroke receive this treatment.

> The most important factor limiting IVT administration is **time**: it has to be administered within 4.5 hrs of symptom onset. Even within that window, **reducing 'time-to-needle'** (the time between symptom onset and IVT administration) can improve functionality and reduce complications for the patient.

> The clinical benefit from IVT declines rapidly however. **Time is brain, and every minute counts**[29_30]:

- If IVT is started within 90 minutes after stroke onset, the number of patients that need to be treated (NNT) in order to achieve an excellent clinical outcome (based on modified Rankin scale – a measure of disability and dependence in daily activities) is 4.
- Within the 180–270-minute time window, the number of patients that need to be treated to achieve an excellent outcome increases dramatically – to 14.

Put simply, a shorter delay from symptom to IVT (the so-called symptom-to-needle **time**) can make **the difference between being independent and being dependent**.

Policy implications

> **Reducing the symptom-to-needle time is vital**. Most **time** is lost in the prehospital period (patients waiting before they seek medical attention). Unfortunately, awareness campaigns have been found to have limited impact in addressing this.

> **Inside the hospital, the focus should be on decreasing the time** from arrival to IVT administration – the so-called door-to-needle time (DNT). In most countries, national guidelines recommend that the DNT should not exceed 60 minutes. However, 15 years after IVT was proven to be clinically effective, in most institutions, the DNT is still more than 60 minutes for the majority of patients.

> **Reducing DNT** will also increase the proportion of patients eligible for IVT, because more patients can be treated within the 4.5-hour time window.

KEY ELEMENTS TO BE RETAINED

In the absence of cure, there is increasing focus on risk reduction, early detection and diagnosis, and timely intervention to slow down disease progression rate. It has also proved essential to put scientific evidence into care standards.

An adequate implementation of evidence-based guidelines[31], cost-effective healthcare interventions and more research evidence to develop better prevention and treatment options definitely appear to be necessary, such as:

- **The availability of biological markers (biomarkers) for early disease diagnosis will impact the management of Alzheimer's Disease in several dimensions. It will:**
  1) help to capture high-risk individuals before symptoms develop, a stage where prevention efforts might be expected to have their greatest impact;
  2) provide a measure of disease progression that can be evaluated objectively[32];

- **There is solid evidence on stroke unit care and integrated, multidisciplinary care team**, early use of intravenous thrombolysis with alteplase, and more recently, mechanical endovascular thrombectomy in acute ischemic stroke due to occlusion of the large arteries of anterior circulation[33];

- **Treat early and effectively new treatment paradigm**: precocious diagnosis and disease-modifying treatments (DMTs) at the early stage of the disease to slow down the progression rate are available to manage relapsing-remitting multiple sclerosis[34].

- In the case of **schizophrenia,** one of the most severe and disabling mental illnesses, the treatment success rate with antipsychotic medications and psycho-social therapies can be high. Still, early identification and intervention at the prodromal phase is paramount[35].

As referred by the WHO[36], a patient-centered, coordinated care model (see **fig. 4**) **addressing the integration between the different healthcare providers and settings**, is an interesting solution to overcome the health services delivery fragmentation and deficiencies. **Efforts to empower patients** to be engaged in responding to their **health needs may improve health outcomes, adherence to treatment**, and has the potential for them to make **more informed decisions with regard to their health**[37].

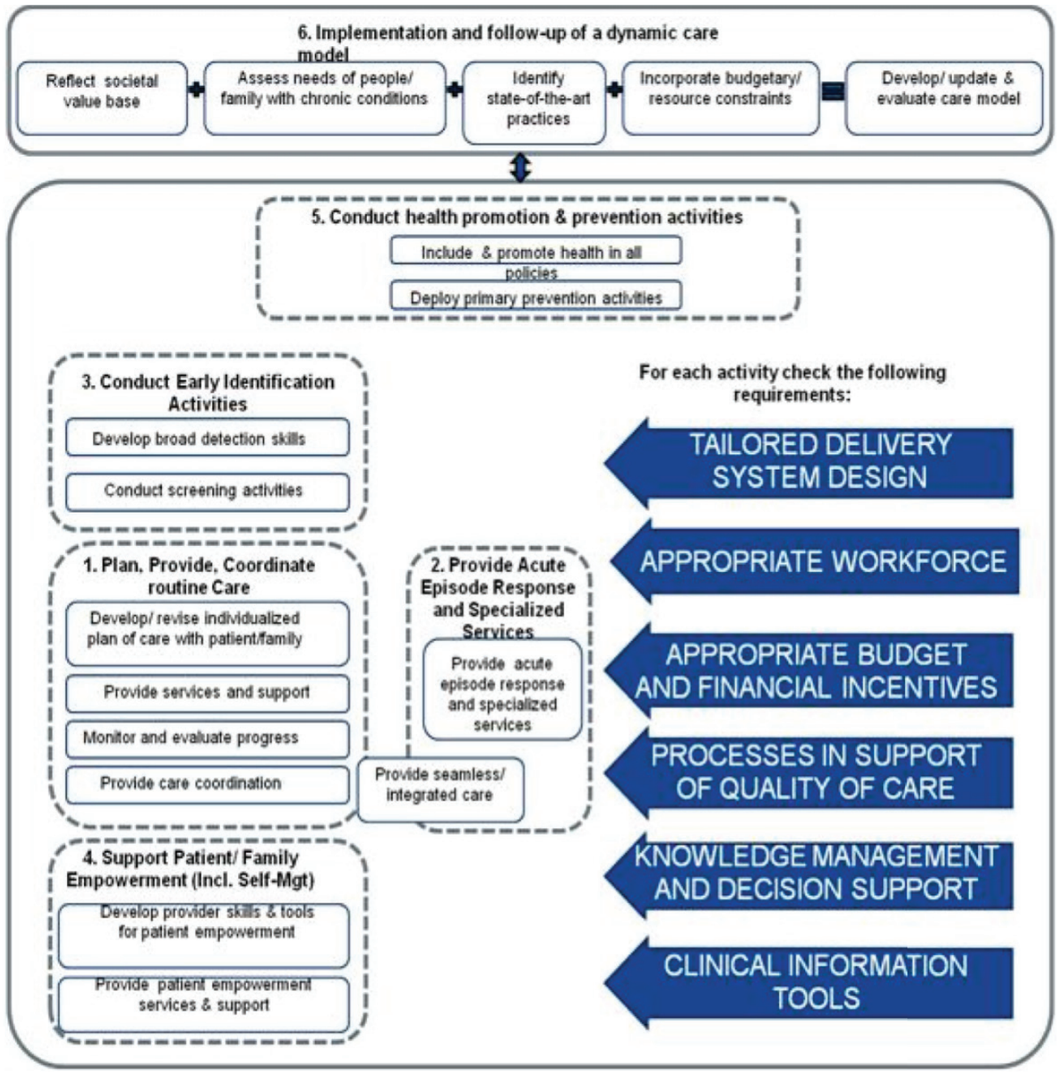
Figure 4: Coordinated/integrated health services delivery defined model (WHO)

- ✓ Holistic model of care (whole spectrum of care)
- ✓ Life course and patient segmentation based on risk assessment
- ✓ The patient as partner with his/her environment
- ✓ Brain disorders and co-morbidity appropriate
- ✓ Multi-disciplinary and workforce support and redesign
- ✓ Medical, socio-economic and technology dimensions
- ✓ Care-based networks and pathways (intra&extra muros)
- ✓ Seamless care with possible acute episodes

Translate this paradigm shift into concrete outcomes: various forms of effective provider networks and interventions have been set up at country level across Europe. The aim is, for instance, **to close the gap between primary and hospital services combining information and communication technology (eHealth) as a facilitator** (in-hospital patient journeys, intra-extra *muros* care pathways, multidisciplinary care models based on the bio-psychosocial approach…) **with promising health outcomes and indication of worthwhile investment: evidence on cost-effectiveness and sustainability is increasingly researched. Illustrations will be shared during the Roundtable discussions**.

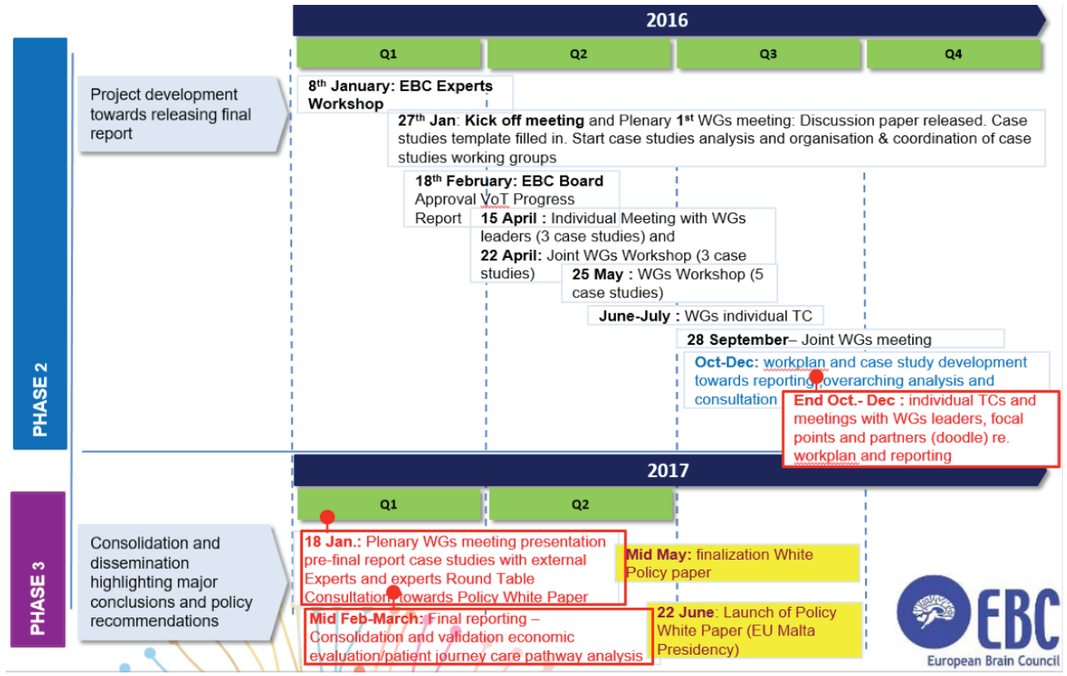
EBC aims to continue the reflection towards developing an overarching care model for brain disorders. It seeks to strike a balance between hospital, home and community care (see **fig. 5**: Illustration - Conceptual model for a chronic care system)[38].

Figure 5: Illustration - A conceptual model for a chronic care system



ANNEX

RESEARCH PROJECT MILESTONES:
ACTIVITY PLANNING - DEADLINES AND DELIVERABLES



> For more info on the Value of Treatment research project:
http://www.braincouncil.eu/activities/news/value-of-treatment-project-report-from-2016-first-semester/

ENDNOTES

1 EBC Discussion Paper 2, "Bridging the early diagnosis and treatment gap: exploring the potential clinical and socioeconomic impact of targeting unmet needs - reflections on new research developments including the benefits of alternative approaches such as seamless, integrated care in the prevention and treatment of brain disorders" will be released at EBC Board meeting on 8 February 2017.

2 This relates to health inequalities. Research shows that there is a direct correlation between out-of-pocket medication costs and use of medication and health care services and stopping treatment. P. Karaca-Mandic et al. Out-of-pocket medication costs and use of medications and healthcare services. JAMA. 2012; 307 (12) :1284-91. Dci: 10.1001/Jama.2012.340

3 P.Y. Collins et al. Grand challenges in global mental health. NIH. Nature; 475(7354) :27-30. Doi:10.1038/475027a. 2011.

4 The WHO International Classification of Diseases « ICD-10 » is the standard diagnostic tool for epidemiology, health management and clinical purpose. ICD chapter V focuses on « mental and behavioral disorders » and consists of 10 main groups. WHO is revising their classifications as part of the ICD-11 (revision of the 10th edition due by 2017). With regard to neurological disorders, ICD chapter VI focuses on « diseases of the nervous system ».

5 The Diagnostic and Statistical Manual of Mental Disorders, Fifth Edition (DSM-5) is the 2013 update to the American Psychiatric Association's (APA) classification and diagnostic tool.

6 G. Schrijvers et al. The care pathway: concepts and theories: an introduction. Int J Integr Care (Special Edition Integrated Care Pathways). PMCID: PMC3602959A 2012. Care pathway is « a complex intervention for the mutual decision-making and organization of care processes for a well-defined group of patients during a well-defined period from the prodromal phase and diagnosis to the treatment and care that is available to the individual ».

7 EBC Call to Action launched in 2015, advocating for the development of National Brain Plans (NBP) to reduce the burden of diseases and disabilities under the umbrella of an EU-wide plan addressing brain health and covering the whole spectrum of care from surveillance (patient registries) to prevention, care and support, access to treatment, evaluation and research.

8 In the continuity of the first EBC Value of Treatment Discussion Paper released on 27th January 2016 "Exploring the potential for a holistic care model for brain disorders to close the treatment gap in Europe: development of a workable care model and case studies analysis".
See http://www.braincouncil.eu/wpcontent/uploads/2016/01/EBCdiscussionpaperA4FINAL3.pdf.
EBC General Assembly approved the release of a 2nd discussion paper (26 May 2016).

9 Data sources: published evidence, evidence from secondary data (national registries, administrative data, surveys, RCTs...), and expert opinions.

10 A. Gustavsson et al. The economic cost of brain disorders in Europe, Journal of Neurology 2012.

11 Brain disorders or neuropsychiatric disorders are referred to mental, neurological and substance use disorders.

12 Brain disorders prevalence is increasing, not only because life expectancy of the population increases but also because of a multiplicity of factors (health determinants such as socio-economic, genetic, environmental, and behavioral areas in which research still stammers). Understanding the causes of these diseases, to correct and to prevent them is a necessity.

13 H.U Witchen et al. The size and burden of mental disorders and other disorders of the brain in Europe, ECNP/EBC Report 2011.

14 J. Olesen et al. European Journal of Neurology 2012.

15 H. A. Whiteford et al. The global bruden of mental, neurological and substance use disorders : an anlysis from the Global Burden of Disease Study (GBD 2010). PLOS ONE DOI :10.1371/journal.pone.0116820. February 2015. Mental disorders accounted for the largest proportion of DALYs (56.7%), followed by neurological disorders (28.6%) and substance use disorders (14.7%). DALYs peak in early adulthood for mental and substance use disorders but are more consistent across age for neurological disorders.

16 Direct costs constitute the majority of costs and threaten to become overwhelming (37% direct healthcare costs and 23% direct non-medical costs). Costs can fluctuate between the direct medical costs and associated burdens of brain disorders (social care, informal caregivers, families…) depending on the disease progression rate.

17 H.U Witchen et al. The size and burden of mental disorders and other disorders of the brain in Europe, ECNP/EBC Report 2011.

18 Sidhu and Kateb. World Brain Mapping and therapeutic Initiative: A proposed G20 priority due to major impact of the costs of neurological disorders on the world economy. Journal Neurological Disorders 2014. For costs associated with other diseases areas, see: Economic burden of cancer across the European Union: a population-based cost analysis (2009); European Cardiovascular Disease Statistics (2012); Economic Impact of Diabetes (2010).

19 There is a considerable gap in terms of diagnosis and treatment. This is particularly blatant for mental illness in Europe (ranging from alcohol use and dependence with the widest treatment gap to schizophrenia but also for neurological disorders such as drug resistant epilepsy).

20 Kaiser Permanent risk stratification pyramid.

21 Case management for highly complex or high risk patients by a healthcare provider being responsible for the assessment of needs and implementation of care plans can be an additional support to coordinate medical care, paramedical care and well-being and therefore can help to avoid unplanned hospital admissions (due to increased frailty, falls, adverse drug events…) and to monitor polypharmacy (medicines optimization). It is usually required for individuals who have a serious and persistent mental illness or severe neurodegenerative disease and need ongoing health as well as social care support (e.g. patients with a major psychotic disorder or with a severe neurological condition, such as Parkinson's disease).

22 E. Abram et al. Screening and Diagnostic Tests. Medscape, December 2015.
23 WHO Neurological disorders : Public Health Challenges. 2008.
24 Belgian Healthcare Knowledge Centre, Position Paper : organization of care for Chronic Patients in Belgium, KCE Report 190c, 2012.
25 Porter ME. What is value in healthcare ? NEJM 2014 ;363 :2477-2481.
26 European patients Forum (EPF), Adherence and concordance – EPF Position Paper, March 2015.
27 McKee M, Chow CK. Improving health outcomes: innovation, coverage, quality and adherence. Israeli J Health Pol Res 2012.
28 Timothy M Trebble et al. Process mapping the patient journey: an introduction. BMJ 2010.
29 Nyika D. Kruyt et al. Door to needle time and proportion of patients receiving intravenous thrombolysis in acute ischemic stroke. Stroke AHAJournals2013. See website : http://stroke.ahajournals.org/content/44/11/3249.full
30 Ahmed N, Wahlgren N, Grond M, Hennerici M, Lees KR, Mikulik R, et al; SITS investigators. Implementation and outcome of thrombolysis with alteplase 3–4.5 h after an acute stroke: an updated analysis from SITS-ISTR. Lancet Neurol. 2010;9:866–874
31 Knowledge gap: there are evidence-based guidelines but effective treatments are not implemented or only available to a small portion of the population;
32 Silvia A. Mandel et al. Biomarkers for prediction and targeted prevention of Alzheimer's and Parkinson's diseases: evaluation of drug clinical efficacy. EPMA Journal June 2010.
33 Nyika D. Kruyt et al. Door to needle time and proportion of patients receiving intravenous thrombolysis in acute ischemic stroke. Stroke AHA-Journals 2013.
34 Professor Gavin Giovannoni, Queen Mary University London, Blizard Institute, Barts and The London School of Medicine and Dentistry, London, UK. November 2013
35 R. Kohn et al. World Health Organization Bulletin, (82) 2004.
36 The Framework for Action towards integrated Health Services Delivery (FFA IHSD) as defined by WHO Regional Office for Europe (2016) is proposed as a generic framework for coordinating care interventions and was referred to for the development of the research framework for the Value of Treatment case studies analysis. http://www.euro.who.int/__data/assets/pdf_file/0010/317377/FFA-IHS-service-delivery-overview.pdf
37 European Patients Forum (EPF), adherence and concordance – EPF Position Paper, March 2015.
38 Belgian Health Care Knowledge Centre (KCE) Position Paper: organization of care for chronic patients in Belgium, Belgian Healthcare Know-ledge Centre, KCE Report 190, Dec. 2012.

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