PARADISE

Psychosocial fActors Relevant to brAin DISorders in Europe

RECOMMENDATIONS

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The **PARADISE** Coordination Action is an EC-funded project involving eight European countries (Germany, Spain, Italy, Belgium, United Kingdom, Poland, Finland and Switzerland) with the goal of testing and implementing a novel approach to collecting comparable data about psychosocial difficulties experienced in common by individuals with brain disorders or neuropsychiatric conditions. To test this approach, the PARADISE project selected a representative and heterogeneous selection of conditions: dementia, depression, epilepsy, migraine, multiple sclerosis, Parkinson's disease, schizophrenia, stroke and substance use disorders.

The context for PARADISE is recent European initiatives in mental health – from the EC 2005 Green Paper 'Improving the mental health of the population: Towards a strategy on mental health for the European Union' to the Resolution of 19 February, 2009 on Mental Health at the European Parliament – calling for 'an integrated and coordinated' mental health strategy to serve the needs of people with brain disorders.

The theoretical foundation of PARADISE is that the lived experience of persons with brain disorders is only partially explained by the specific signs and symptoms of any given health condition. Rather, and in addition, the difficulties people with these conditions experience in their day-to-day lives – the difficulties and problems that matter to them – are outcomes of an interaction between their health conditions and physical, social and attitudinal features of the world in which they live, as well as psychological factors that make up their individuality. These difficulties and problems – called disabilities in the *International Classification of Functioning, Disability and Health* (ICF, WHO, 2001) – are experienced as obstacles to full participation in all areas of life, such as self-care, education and employment, family and community life. The working hypothesis of the PARADISE project is horizontal epidemiology – the claim that the psychosocial difficulties that matter to people and shape their lives, are experienced across brain disorders and, hence, need to be measured comparably in order to understand the relative burden of brain disorders.

Building on systematic literature reviews for each of nine brain disorders, patient focus groups and interviews, and extensive input from clinical experts, PARADISE identified salient psychosocial difficulties and environmental and psychological determinants of the onset and course of these difficulties that are experienced in common across conditions. This information was used to build a draft data collection tool called the PARADISE Protocol that collected harmonized data with a coherent conceptual basis, generating comparable data across brain disorders, and was used to construct a metric of psychosocial difficulties.

The final product of PARADISE is a Protocol with 24 questions on psychosocial difficulties, from which a profile of psychosocial difficulties of patients can be generated and compared, or a summary score created as a measure of the extent of difficulties. The Protocol in addition includes 11 determinants of the extent of difficulty identified, which also have been operationalized by clear, easy to comprehend questions.

The PARADISE Protocol, and the harmonized data that it collects, creates the scientific evidence for PARADISE's principal contribution to a mental health strategy: that such a mental health strategy should augment purely medical interventions and open the door to a wide range of health and social interventions that address the psychosocial difficulties that are most relevant to people with those conditions.

This document sets out the PARADISE recommendations to guide European countries in the collection and analysis of data concerning psychosocial difficulties associated with brain disorders, as well as environmental and individual psychological determinants of the onset, extent and course of these difficulties. These recommendations in addition focus on the feasibility and importance of systematic data collection and analysis for the development and evaluation of health and social interventions that can address the psychosocial difficulties experienced in common by individuals with brain disorders. These difficulties are associated with the underlying health conditions, but are shaped by social and attitudinal environmental factors and individual psychological factors. Although the features of brain disorders constitute serious health problems that must be addressed, the PARADISE results show that, in addition, psychosocial difficulties constitute the obstacles individuals with these conditions confront in their lives – obstacles that limit their inclusion and full participation in society.

RECOMMENDATIONS

Recommendation 1: Harmonize data about psychosocial difficulties and their determinants in brain disorders by adopting the approach of horizontal epidemiology.

A significant obstacle to an integrated and coordinated mental health strategy is the incomparability of data. Without data harmonization it is impossible to exploit differences or similarities in data about population characteristics to identify patterns in data or to draw valid conclusions across diverse data sets. The horizontal epidemiological approach states that there is a common set of psychosocial difficulties and their determinants across brain disorders. Collecting data about these common difficulties and determinants by using the PARADISE Protocol produces harmonized data. This generates a common metric for measuring the burden of brain disorders on people's lives in a comparable manner. From the collected clinical or population level data valid comparisons of the impact of brain disorders can be derived and common interventions across conditions developed.

Evidence from PARADISE results:

In PARADISE we carried out nine brain disorder-specific literature reviews, patient focus groups and interviews about psychosocial difficulties and their determinants. This approach reflected the existing disciplinary fragmentation in research and practice in which the difficulties are described in silos defined by each disorder.

After a harmonization of these data, we found a considerable extent of commonalities of psychosocial difficulties across disorders, confirming the hypothesis of horizontal epidemiology, and making possible the harmonization of data and the identification of differences and similarities in psychosocial difficulties and their determinants. Data from 700 patients across disorders and in different countries confirmed that these difficulties were highly prevalent across disorders and that it is feasible and more efficient to collect harmonized data initially rather than collecting data in silos and harmonizing afterwards.

Implementation actions:

Recommendation	Clinicians	Researchers	Policy makers
1. Harmonize data and adopt the approach of horizontal epidemiology	- Recognize that psychosocial difficulties that are important to people's lives are not condition-specific but are common across brain disorders. - Include data on common psychosocial difficulties when documenting and planning interventions. - Foster a horizontal perspective on brain disorders when training clinicians and health professionals. - Use the PARADISE Protocol to collect information on psychosocial difficulties of patients and the determinants of these difficulties in a practical and efficient manner.	**Recognize that there is a need for horizontal epidemiological research in brain disorders.** **Investigate more efficient mechanisms for collecting harmonized data about psychosocial difficulties across brain disorders.** **Complement the study of the determinants of brain disorders by investigating the environmental and individual psychological determinants of psychosocial difficulties.** **Refine methods for tracking the impact of environmental and psychological determinants of psychosocial difficulties.** **Test whether the PARADISE Protocol is valid for brain disorders other than the nine selected in the project.**	- Recognize horizontal epidemiology as the governing principle for the collection of mental health information. - Use the PARADISE Protocol to collect information about the needs of persons with brain disorders and use this information to guide resource allocation. - Foster the development of mental health information systems that ensure comparability of data about the burden of brain disorders. - Use horizontal epidemiology to coordinate health and social sectors for mental health intervention planning. - Ensure that the perspective of horizontal epidemiology is captured in population-based surveys. -

Recommendation 2: Go beyond medical interventions that primarily target biological and physiological processes of brain disorders to health and social interventions that target psychosocial difficulties as outcomes of the interaction of the brain disorders and environmental and psychological determinants.

Most brain disorders are chronic and incurable; the substantial advances in, for example, genetic and biochemical research to identify precursors of depression and schizophrenia and pharmaceutical advances in symptom reduction, however vital, nonetheless are restricted to the domain of purely medical interventions that have only a partial impact on the individual's overall life. Many in the mental health community – clinicians, researchers and individuals with brain disorders themselves – have argued that exhaustion of medical interventions should not lead to resignation that nothing more can be done to improve the lives of persons with these conditions. Psychosocial difficulties associated with brain disorders include but also go beyond impairments and point to obstacles in fundamental areas of life, such as self-care, educational and employment participation, social isolation and lack of viable social networks, and the exclusionary effect of stigma, discrimination and absence of accommodations. Environmental and psychological determinants of psychosocial difficulties can be addressed by social policy and changed or ameliorated by tailored interventions targeted at the individual. Often, what are needed are not medical interventions, or even health interventions, but social interventions that can achieve substantial and positive effects on the lives of persons with brain disorders. With a sufficiently well-developed evidence base, and facilitating policies, the benefits of these social interventions in terms of increased inclusion and participation can be realized.

This is the message of the PARADISE project: unless we recognize the importance of psychosocial difficulties in the lives of persons with brain disorders, and unless we develop interventions that address these problems - whether they be individual or public health or social interventions – as a society we will not be living up to our obligation to improve the lives of those among us with brain disorders.

Evidence from PARADISE results:

The qualitative information gathered in the focus groups and interviews demonstrated that what really matters to people with brain disorders are psychosocial difficulties, such as mobility, joining in community activities or coping with everyday activities. Many of these difficulties cannot be appropriately treated with purely medical interventions, but require complementary psychological and social interventions. All data collection efforts in PARADISE, including the qualitative studies and the empirical study with 700 patients, indicate that information about psychosocial difficulties can be collected effectively and directly from patients or their proxies. The literature reviews also showed that there are already interventions in place that target these difficulties, although these are condition-specific.

Implementation actions:

Recommendation	Clinicians	Researchers	Policy makers
2. Enhance existing social and psychological interventions to complement medical interventions for psychosocial difficulties	- Initiate and enhance the multi-disciplinary team approach to service provision in brain disorders. - Recognize that, even after exhausting all medical interventions, social or psychological interventions targeting psychosocial difficulties may still be useful.	- Evaluative the effectiveness of successful social and psychological condition-specific interventions when applied to other brain disorders. - Identify or develop - interdisciplinary methodologies that bridge health and social research addressing biological and social dimensions of brain disorders. - Involve people with brain disorders when developing social and psychological interventions for psychosocial difficulties. - Promote qualitative research to better understand the lived experiences of people with brain disorders from their own perspectives.	- Recognize the need for both medical and social interventions in brain disorders. - Foster and implement public health and social interventions targeting psychosocial difficulties. - Finance more research in social and psychological interventions targeting psychosocial difficulties for persons with brain disorders. - Encourage and facilitate the involvement of persons with brain disorders in policies designed to address psychological difficulties.

Recommendation 3: Measure the psychosocial difficulties associated with brain disorders for intervention evaluation.

The best outcome measure of an intervention is the improvement of the person's daily life in all its dimensions. In order to evaluate interventions against this standard it is essential to be able to measure the change in the extent or number of psychosocial difficulties a person experiences, before and over the course of the intervention. Comparison of the effectiveness and efficiency of different interventions requires a metric or scale of psychosocial difficulties that is valid across brain disorders. Such a metric allows researchers and clinicians to compare intervention results over time, compare the effectiveness of the same intervention for persons with different brain disorders and different interventions for persons with the same disorder.

Evidence from PARADISE results:

With the data of 700 patients on psychosocial difficulties and their determinants, a metric of psychosocial difficulties was developed using item response theory methodologies (in particular, graded response model). We showed that psychosocial difficulties can be built on a single dimension ranging from 'no difficulty' to 'severe difficulty' and that the 24 items included in the final PARADISE Protocol can be used to validly and reliably address that dimension. The result is that a summary score can be provided at both the individual and population levels for an accurate estimation of the extent of psychosocial difficulties and can be used as an outcome measurement for the evaluation of interventions and other applications.

Implementation actions:

Recommendation	Clinicians	Researchers	Policy makers
3. Measure the psychosocial difficulties associated with brain disorders for intervention evaluation	- Use the PARADISE metric for assessing the effect of interventions on the level of psychosocial difficulties. - Use the PARADISE metric for bench-making for performance comparison, need gap identification and changes in management processes.	- Evaluate the effectiveness of clinical, health promotion and disability interventions using the PARADISE metric. - Further refine the PARADISE metric by collecting data on persons with brain disorders other than those already analysed in PARADISE.	- Encourage the use of the PARADISE metric to monitor the implementation of policies on brain disorders. - Encourage the use of the PARADISE metric to evaluate national efforts to reduce disability for persons with brain disorders.

Recommendation 4: Engage in prospective data collection efforts to collect longitudinal information on psychosocial difficulties associated with brain disorders to capture the complexity and dynamic interactions between these difficulties and environmental and psychological factors over time.

The longitudinal studies on brain disorders that are currently available do not systematically collect information about psychosocial difficulties or their determinants of onset and change over time. Yet this longitudinal information is required, not only to understand the complexity of the trajectories of psychosocial difficulties in brain disorders over time, but also to form the evidence base for designing and evaluating interventions.

Evidence from PARADISE results:

The systematic literature reviews in PARADISE showed that there are very few initiatives to collect longitudinal information on psychosocial difficulties in brain disorders. The few attempts there are focus on single or a few disorders and are not carried out from the perspective of horizontal epidemiology. In PARADISE, we tried to collect longitudinal information on psychosocial difficulties and their determinants retrospectively, but because this information is difficult to obtain from patients, and is subject to recall bias, we concluded that the only way to reliably collect this information is prospectively.

Implementation actions:

Recommendation	Clinicians	Researchers	Policy makers
4. **Engage in longitudinal data collection efforts about psychosocial difficulties and their determinants**	- Integrate the standardized documentation of psychosocial difficulties in clinical routines and collect longitudinal information. - Follow the changes of psychosocial difficulties of patients over time, and document their determinants.	- Research the differential impact of environmental and psychological determinants on the onset and course of psychosocial difficulties over time. - Refine the statistical methods for measuring the effect of environmental and psychological determinants on psychosocial difficulties across brain disorders and over time. - Engage in cohort studies with persons with different brain disorders and focus on psychosocial difficulties and their determinants. - Engage in prospects for the integration of the PARADISE Protocol in prospective payment systems.	- Ensure the continuity of collection of data about psychosocial difficulties by encouraging the inclusion of questions from the PARADISE Protocol in censuses, disability and other population surveys. - Foster research focusing on the long-term patterns of psychosocial difficulties and their determinants experienced by persons with brain disorders.

Recommendation 5: Enrich European mental health strategies by strengthening the focus on psychosocial difficulties and their determinants that prevent people with brain disorders from living a life of full participation.

Although all of the principal documents setting out the preconditions and criteria of an adequate European strategy on mental health have mentioned the need to address psychosocial difficulties and have proposed interventions (for example, return to work and workplace anti-stress programmes, tracking educational performance of students at risk of depression or substance abuse), none of these documents have proposed outcomes for monitoring or evaluating interventions for these difficulties, or for identifying their determinants. The PARADISE Protocol and metric can enrich the European mental health strategy since they represent a standardised approach for collecting data on psychosocial difficulties that is needed for intervention development and evaluation and describe and measure essential aspects of the lived experience of people with brain disorders. Only by systematically and regularly collecting data on psychosocial difficulties will these and their determinants become essential components of a 'coherent and integrated mental health strategy'.

Evidence from PARADISE results:

The PARADISE Protocol and metric constitute a proof of concept that it is feasible to describe and measure psychosocial difficulties and their determinants.

Implementation actions:

Recommendation	Clinicians	Researchers	Policy makers
5. Enrich European mental health strategies by strengthening the focus on psychosocial difficulties and their determinants	- Empower people with brain disorders and their social network to appreciate that, when medical interventions are no longer effective, there remain other ways to improve their lives through psychological and social interventions. - Develop treatment guidelines that address the psychosocial difficulties across brain disorders and that provide policy-makers with practical insights into the importance of psychosocial difficulties. - Express the need for training for practitioners to understand the importance of psychosocial difficulties and interventions addressing them.	- Carry out research on psychosocial difficulties that provide policy-makers with the evidence required to develop a strategy to meet the need for a coordinated response to psychosocial difficulties across brain disorders. - Express the need to policy-makers for more research into the horizontal epidemiology of psychosocial difficulties, environmental and psychological determinants and the trajectories of these difficulties over time.	Augment the EU mental health strategy by, *inter alia*: - a focus on the description and measurement of the psychosocial difficulties experienced by people with brain disorders; - fostering the implementation of the message that psychosocial difficulties can be treated by a variety of medical, health and social interventions; - launching campaigns to educate the public that the lives of persons with brain disorders can be improved through a variety of health and social interventions; - promoting cross-sectional cooperation for a coordinated response to the psychosocial difficulties experienced across brain disorders; - fostering the application of the PARADISE Protocol and metric for determining the treatment cost of psychosocial difficulties in brain disorders; - encouraging the use of the PARADISE Protocol and metric for evaluating interventions designed to respond to psychosocial difficulties and their determinants; - augmenting mental illness prevention programmes with programmes targeting the prevention of psychosocial difficulties experienced by persons with brain orders; - fostering a mental health information, research and knowledge system that includes information about psychosocial difficulties and their determinants; - encouraging further research into the applications and consequences of the principle of horizontal epidemiology in mental health.