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Title: Fidelity Scales and Performance Measures to support implementation and quality assurance for First Episode Psychosis Services.

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Abstract: (248)

Aim: The purpose of this paper is to review fidelity and outcome measures which can be used to support broad implementation of first episode psychosis services and ensure quality of existing services. First Episode Psychosis Services use a combination of evidence-based practices to improve the outcome of a first episode of psychosis and the early stages of schizophrenia. Now that there is an established international evidence base to show that they

are effective, efforts are being made to make such services widely available as a routine part of health care. **Methods:** We provide an overview of the literature from the perspective of an expert task force that was commissioned to report to the board of the International Early Psychosis Association IEPA. First, we examined the evidence- based components that underpin first episode psychosis services and identified common elements. Next, we reviewed the availability of fidelity measures and outcome indicators, finally we reviewed how broadly these services are delivered internationally, and the barriers to ensuring broad access to quality services. **Results:** There is a growing consensus about the elements required to deliver effective services. Fidelity scales and performance measures are available to assess quality, access, and outcome. First episode psychosis services are variably offered in high-income countries and rarely with attention to access and quality of services. Several strategies to promote implementation are identified. **Conclusions:** Fidelity scales and outcome measure are valuable resources to support widespread implementation and quality assurance for first episode psychosis services.

Introduction:

The Board of the International Early Psychosis Association (IEPA), now the (Early Intervention in Mental Health), at its 2014 Annual Meeting in Tokyo convened a Fidelity Task Force comprised of an international group of clinical researchers and a health economist with expertise in health services quality and outcome. The members of the task force are the authors of this paper. The directive to the task force was to review the current state of implementation of early psychosis services internationally and identify tools such as fidelity scales and performance measures that can be used to support broader implementation of services. This paper represents a summary of the task force findings.

Early psychosis intervention programs are programs which combine early intervention, evidence based pharmacological and psychosocial interventions to improve the outcome of a first episode psychosis. Such programs have been widely implemented over the last 20 years (McGorry, Edwards, Mihalopoulos, Harrigan, & Jackson, 1996). Several large randomized controlled studies of programs in different health care systems have demonstrated improved outcomes across several domains compared with treatment as usual (Kane et al., 2015; Petersen et al., 2005; Ruggeri et al., 2015). The programs that have been tested in randomized controlled studies have a number of common components which have been identified through

a process of systematic review and consensus (Addington, Mckenzie, Norman, Wang, & Bond, 2013). A systematic review of randomized controlled trials of specific pharmacological and psychosocial treatments also found significant benefits in the specific outcomes of relapse prevention and employment (Alvarez-Jimenez, Parker, Hetrick, McGorry, & Gleeson, 2011; Bond, Drake, & Campbell, 2014). Despite the substantial evidence supporting the effectiveness of such programs their implementation has been variable. In some countries, such as England, there is a consistent national service delivery model and services funded based on estimates of the annual incident rates in the population. In other countries, there are programs in academic centres but with no formal standards of care (Csillag et al., 2015). Assessment of services shows that even when there are program standards and allocated funding, delivery of effective first episode psychosis programs can be challenging (Cheng, Dewa, Langill, Fata, & Loong, 2014; Csillag et al., 2015).

Problems in implementation of evidence-based practices into every day clinical practice are not restricted to mental health services. Grol and Grimshaw use the challenge of implementing hand washing as an example on their paper on implementation of change in patient care (Grol & Grimshaw, 2003). Empirically supported programs may not be implemented at all or in the real-world may not deliver the outcomes expected based on research findings (Greenhalgh, Robert, Macfarlane, Bate, & Kyriakidou, 2004). A Consolidated Framework for Implementation

Research (CFIR) has been proposed that provides a pragmatic structure for understanding and promoting implementation in health care (Damschroder et al., 2009). Within this framework, the identification of core elements, the flexibility to adapt the service to local conditions, the presence of an agreed upon evaluation framework and an economic justification are all important ingredients for successful implementation.

In addition to supporting implementation, process and outcome measures are important for maintaining quality and ensuring accountability of mental health services (Kilbourne, Keyser, & Pincus, 2010). Donabedian conceptualized quality of care in terms of structure, process and outcomes (Donabedian, 1988). The team-based components of a first episode psychosis program including the team members and how they work together comprise the structure. The evidence-based components comprise the processes of care. The combination of fidelity scales and performance measures, can be used to measure these three components of quality of care. In this paper, we have identified a list of essential components of early psychosis services, a set of fidelity scales and 13 easily collected outcome measures which can be used to support implementation and quality assurance of first episode psychosis services internationally.

Methods: The task force review method can be described as an overview; a generic term which is used to describe a summary of the literature that attempts to survey the literature and

describe its characteristics (Grant & Booth, 2009). The task force did not conduct a comprehensive search or undertake new systematic reviews, but, made use of existing reviews and practice guidelines. The results are presented in narrative and tabular form and there is an analysis of the findings. The Task Force met at a face to face meeting in December 2015 to establish the framework of a report which was refined on line by the task force members. The outline was reviewed and refined at a second face to face meeting in April 2016, during which the more specific content was agreed to by an informal consensus approach. The results of the second meeting were then reviewed and revised on line by the task force members. The findings were presented at a symposium at the IEPA meeting in 2016 and submitted to the Board of the IEPA and then for publication. The purpose of this paper is not to provide a detailed justification for each performance measure or program component for which detailed discussion can be found in the references.

Results:

Essential Components

Essential components of first episode psychosis services were identified by the task force members, who compared the essential elements of program models described in the literature and offered in clinical settings. A list of essential interventions is included in Table 1

A review of specific interventions such as pharmacotherapy and cognitive behaviour therapy that should be available to patients in early intervention services, identified a number that were supported by systematic reviews (Alvarez-Jimenez et al., 2011; Alvarez-Jimenez, Hetrick, Gonzalez-Blanch, Gleeson, & McGorry, 2008; Penn, Waldheter, Perkins, Mueser, & Lieberman, 2005; Addington et al., 2013). Some, such as pharmacological interventions for substance use disorders are included in Clinical Practice Guidelines which address the range substance used disorders and specifically address the need to promote smoking cessation recommendations 1.1.3.3 and 1.1.3.4 (National Institute for Health and Care Excellence, 2014). Other components such as the integration of care using a team model and providing continuity of care have not been isolated and investigated in early psychosis research, but do have significant research that supports these practices (Adair et al., 2005; Burns, Catty, & Wright, 2006). Components such as team-based care and continuity of care are being used in practice and have been included in fidelity scales (Addington et al., 2016). A self-report survey of 31 programs in the United States demonstrated that out of 32 essential components (Addington et al., 2013), the most common ones were individual psychoeducation and outcomes tracking; the least prevalent were

outreach services and communication with inpatient units (White, Luther, Bonfils, & Salyers, 2015). Individualizing treatment and care plans is an important aspect of developing care plans so not all essential elements apply to all patients all the time.

Fidelity Scales

In health services research fidelity to an intervention has been defined as the degree of to which it adheres to the defining elements or features of an evidence-based practice (EBP) (Bond, Evans, Salyers, Williams, & Kim, 2000). Fidelity scales provide a list of objective criteria by which a program or intervention is judged to adhere to reference standards interventions.

Fidelity scales can be developed based upon a program that has been established to be effective in randomized, controlled studies, from systematic review of multiple sources of evidence or by consensus (Mowbray, Holter, Teague, & Bybee, 2003). We identified all the available first episode psychosis fidelity scales through a survey of the literature and the knowledge of the task force members. We identified six scales, each of which had been developed using one or more of the above processes. See Table 2.

In England, the Early Intervention Scale (EIS) was developed as part of a national evaluation program using a consensus process (Lester, Birchwood, & Marshall, 2006). In Australia, a fidelity scale the EEPIC Model Integrity Tool (Killackey, 2016) was developed to support the national implementation of early intervention services. The scale was based upon the core components of the Early Psychosis Prevention and Intervention Centre model (Hughes et al., 2014). In Denmark, the successful OPUS model of care has been disseminated nationally and a fidelity scale based on the successful research program has been developed to monitor program quality (Nordentoft et al., 2015). In the US, a fidelity scale based on a program model has been used to characterize or measure the specific treatment model at two sites of an early psychosis service (Essock et al., 2015). The Early Assessment and Support Alliance (EASA) has developed a fidelity scale that supports routine quality management and implementation of first episode psychosis services in the state of Oregon (Melton et al., 2012). These scales have been developed using different methodologies, while some are based on programs that have been shown to be effective, they have not been formally tested for reliability or validity.

The First Episode Psychosis Fidelity Scale (FEPS-FS) was not developed from a specific program model; rather it was developed from a systematic review and grading of first episode psychosis research literature, followed by an international consensus process that identified the essential components (Addington et al., 2013). It has demonstrated inter rater reliability and face validity

when tested in two countries. Furthermore, it has a manual to support reliable ratings. Although it has fewer components than the other scales, it has the highest proportion of components common to all the scales (Addington et al., 2016).

The items common to these fidelity scales are listed in Table 3. The common elements can be considered to represent a consensus on core components. Other non-core components found in the scales with a larger number of elements reflect policies and practices which are not in themselves evidence-based practices specific to first episode psychosis, but which are considered standards of care, for example having all patients sign off on a plan of care or ensuring that family education materials are available in the languages of people to whom services are available.

Performance Measures

Although fidelity scales can be used to show that a program delivers care as planned and to a certain quality, performance measures that assess outcome are required to demonstrate their impact in the real-world (Hermann, 2002). Health care performance measurement has been defined as "the use of statistical evidence to determine progress toward specific defined organizational objectives" (Adair, Simpson, & Casebeer, 2006). The US National Library of

Medicine Medical Subject Heading (MeSH) uses the term Quality Indicators, Health Care defined as, "Norms, criteria, standards, and other direct qualitative and quantitative measures used in determining the quality of health care". Performance measures can be assessed at the level of the consumer, clinical service or program, the health care system or the population (Tansella & Thornicroft, 1998). When consistent data is available across programs, this can be used to establish standards and norms (Addington et al., 2009; Hermann & Provost, 2003). A standard is defined as a numerical threshold for performance that is established by individuals or groups. The standard can be set arbitrarily or by consensus or be based on a statistically derived threshold (Hermann & Provost, 2003). Risk adjustment can be used to correct for baseline sociodemographic or clinical characteristics in order to compare outcomes in different programs (Hermann, Rollins, & Chan, 2007). A risk adjustment algorithm was shown to provide good discrimination and was relatively robust in predicting hospitalization of first-episode psychosis patients (Addington et al., 2010).

A set of performance measures for first episode psychosis services was identified by systematic review and prioritized by multiple stakeholder groups (Addington et al., 2005). These performance measures were operationalized (Addington et al., 2007) and then used to compare two programs serving defined populations (Addington et al., 2009). In England, the National Institute for Health and Care Excellence (NICE) has identified 8 quality measures based on quality standards for first episode psychosis services. For example one standard is that 50

percent of new referrals to mental health services with a first episode psychosis should be seen within two weeks (National Institute for Clinical Excellence, 2015).

Based on this available literature we identified a list of 13 key performance measures that are easy to measure and can be used to assess first episode psychosis services. These were selected by the task force members on the basis of three key attributes of performance measures "meaningful, feasible and actionable" (Hermann & Palmer, 2002). See Table 4.

International application of fidelity scales and performance measures

United States of America

Fidelity scales have been most extensively developed and used in the United States to support implementation of evidence-based practices in mental health services. Fidelity scales were a key tool for a large-scale implementation study of five evidence-based practices in 35 mental health centres (McHugo et al., 2007). In a recent survey of state mental health authorities about 70% provided access to three specific evidence-based practices for adult mental health services and 67% used fidelity scales to promote adoption of these evidence based treatments (Bruns et al., 2015). Two fidelity scales have been used to monitor first episode psychosis services in the US. The EASA fidelity scale has been used across the state of Oregon for several years to support implementation and then quality assurance (Melton et al., 2012). In New York State data from two pilot programs was used to assess service implementation (Essock et al.,

2015). In the United States a model of services adapted for use in routine mental health systems has been shown to be effective (Kane et al., 2015). Individual States have collaborated to implement services based on the model (Essock et al., 2015) and mechanisms for funding services within existing funding mechanisms have been identified (Goldman, Karakus, Frey, & Beronio, 2013). In its Fiscal Year 2014 appropriation, Substance Abuse and Mental Health Services Administration (SAMHSA) was directed to require that states set aside 5 percent of their Mental Health Block Grant (MHBG) allocation to support "evidence-based programs that address the needs of individuals with early serious mental illness, including psychotic disorders." These set aside funds are being used to support the establishment of First Episode Psychosis programs within 39 states. More recently the set aside grant has been increased to 10% for each of the next two years (Dixon, 2016; Hermann & Provost, 2003). A formal evaluation of the implementation using a fidelity scale and outcome measures has also been commissioned by SAMSHA.

Europe

The degree of implementation of early psychosis intervention services in Europe has been investigated (McDaid, Park, Lemmi, Adelaja, & Knapp, 2016). This broad survey found that there is significant service provision with mainstream funding in a handful of countries. The provision is most extensive in England and Denmark, however, the existence of programs in countries

where they have been established, including England, does not mean that they are always fully staffed or implemented as intended. Furthermore, there is great variation in coverage across different regions of Europe, for example, there are few programs in Eastern Europe. The authors recommend several steps that would support broader implementation including pilot evaluation of different models of EI services that reflect the existing structure of publicly funded mental health services. For example, embedding specialist skills within existing community mental health team in Italy (Ruggeri et al., 2015). Another step would be to strengthen the evidence on effectiveness and cost effectiveness of early intervention including impacts on physical health and impacts beyond health care, such as completion of education and rates of employment (Knapp et al., 2014). They also propose the use of fidelity assessment to ensure appropriate quality of services.

Australia

In Australia, there are several established early psychosis services in academic centres and across the states and territories. Commonwealth funding to support broader implementation across the country has been identified. Researchers have developed a fidelity scale based on the core components of services identified through experience with the Early Psychosis Prevention and Intervention Centre to support implementation of quality services (Hughes et al., 2014; Killackey, 2016; Hetrick et al., 2017).

Canada

In Canada, provincial early psychosis service networks exist in Ontario, British Columbia, and Quebec. The network in Ontario has established program standards (Ministry of Health and Long-Term Care, 2011) and the network in British Columbia has published guidelines (Ministry of Health Services, 2010). Fidelity has been assessed using self-report surveys of the degree of program implementation (Cheng et al., 2014; Durbin, Selick, Hierlihy, Moss, & Cheng, 2014). A self-report survey of programs affiliated with academic centres across Canada found that most of the surveyed programs offer similar services, in line with published expert recommendations (Nolin, Malla, Tibbo, Norman, & Abdel-Baki, 2016). A few studies have examined the fidelity of first episode psychosis services using self report surveys (Corbiere et al., 2010; Durbin et al., 2014; Randall, Wakefield, & Richards, 2012). These studies demonstrate the challenge of implementing services in public mental health services especially in rural and remote areas. At a national level fidelity scales were not identified as a source of health system quality or performance (Kisely, Adair, Lin, & Marriott, 2015)

Asia

In Asia, early intervention programs were first introduced in Hong Kong and Singapore in 2001.

Since then several other similar programs have been established across Asia (Asian Network of

Early Psychosis Writing Group, 2012). The Asian Network of Early Psychosis identified the policy and cultural challenges associated with implementation of both individual components of early psychosis services and whole programs. They have developed an Early Psychosis Declaration to address these challenges (Asian Network of Early Psychosis Writing Group, 2012). The group also developed an evidence-based set of 10 pragmatic recommendations that could be applied across the diversity of the Asia-Pacific region to support more consistency in implementation of services in Asia.

Viewed from an international perspective, EI programs are heterogeneous and there is limited data on fidelity of implementation in the literature. Although there is an extensive literature that describes the outcomes of individual programs, we could not identify the application of routine outcome measurement. England is the first country that has developed and is implementing a performance management framework, but the measures are all process measures that reflect the care provided rather than the outcomes of care (National Institute for Health and Care Excellence, 2015; NHS Group, 2014). There is a growing interest in evaluating not just the cost effectiveness of any health care intervention, but also the cost effectiveness of the implementation process (Thompson, Pulleyblank, Parrott, & Essex, 2016). In this respect in future it will be important to assess the value for money of investing in measures to encourage greater fidelity in the delivery of EI services. In an encouraging study from the UK, a survey of

programs using a fidelity scale, found that soon after implementation of programs that met fidelity standards there was a reduction in the duration of untreated psychosis (Marshall et al., 2014).

Discussion: There is a growing consensus about the elements required to deliver effective personalized care to individuals with a first episode psychosis. This consensus is reflected in the overlap in components assessed by various fidelity scales. At the same time different service models adapted to different health care systems have been shown to be effective and cost effective in different continents (Petersen et al., 2005; Garety et al., 2006; Kane et al., 2015; Ruggeri et al., 2012; Tsiachristas, Thomas, Leal, & Lennox, 2016).

Several fidelity scales have been developed to support implementation and quality assurance. Some scales have been developed to support implementation of a specific program model and these often have more detailed requirements that focus on specific policies relevant for those services. The more compact First -Episode Psychosis Fidelity Scale is focused on the common elements and has been formally tested in two countries, so it may have a broader application and be more suitable for comparisons across different models of service delivery.

The task force achieved a useful consensus on key performance measures for evaluating the real-world performance of such services. These performance measures were drawn from several countries and are independent of the model of service delivery.

The combination of fidelity scales to assess the structures and processes required to deliver evidence-based services and outcome measures provide a robust framework for program evaluation. These technical supports for implementation and quality assurance have been developed at the time that there is a need for broader program dissemination and quality control. Both performance measures and fidelity scales have the potential to be used for setting standards. Fidelity scales have implied standards and to the extent that they are used for accreditation or quality assurance they reflect a set of standards. Standards can be recommended by researchers and professional groups but formalized standards with required reporting are only being applied in England and Denmark. There is also an opportunity for collaborative international research to use these tools to establish international evidence-based standards for early psychosis intervention services.

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Table 1. Essential Evidence Based Interventions

Psychosocial Interventions			
	Cognitive Behaviour Therapy for symptoms of psychosis,		
	anxiety, and depression		
	Illness self-management including psychoeducation,		
	coping with symptoms and relapse prevention		
	Family Interventions		
	Supported Employment and support for a return to education		
	Integrated treatment of substance use disorders		
Pharmacological Interventions			
	Continuous antipsychotic pharmacotherapy for achieving		
	and maintaining remission of psychosis		
	Use of lowest effective dose of low side effect potential		
	medications		
	Routine monitoring and recording of metabolic,		
	extrapyramidal, and endocrine side effects		
	Use of second line treatments such as clozapine when required		
	Pharmacological treatment of substance use disorders		
	Continuous antipsychotic pharmacotherapy for achieving		
	and maintaining remission of psychosis		
Health Promotion	h Promotion		
	Monitoring weight and triglycerides		
	Promoting physical activity and health eating		
	Delivering smoking cessation programs		
Monitoring of key process and			
outcome measures			

Table 2. List of Fidelity Measures

First Episode Psychosis Services Fidelity Scale	(Addington et al., 2016)			
Early Intervention Service Fidelity Scale	(Lester et al., 2006)			
Danish First Episode Psychosis Fidelity Scale	(Nordentoft et al., 2015)			
Recovery after an Initial Schizophrenia Episode,	(Essock et al., 2015)			
Connection Fidelity Scale				
Early Assessment and Support Alliance Fidelity Scale	(Melton et al., 2012)			
EPPIC Model Integrity Tool (EMIT)	(Hughes et al., 2014) ((Killackey, 2016)			

Table3 Items Common to FEPS-FS and Four Fidelity Scales ^{1,2,3,4}

Table3 Items Common to FEPS-FS and Four Fidelity Scales 37,577		
FEPS-FS (31 items)		
Individual Evidence Based Practices		
1. Timely Contact with Referred Individual:		
2. Patient and Family Involvement in Assessments:		
3. Comprehensive Clinical Assessment:		
4. Psychosocial Needs Assessed for Care Plan:		
5. Individualized Clinical Treatment Plan After initial assessment:		
10. Patient Psychoeducation:		
11. Family Education and Support:		
14. Annual Formal Comprehensive Assessment Documented:		
15. Assigned Psychiatrist:		
16. Assignment of Case Manager:		
17. Motivational Enhancement or Cognitive Behavioral Therapy for Co-Morbid Substance Use		
Disorder (SUD):		
19. Active Engagement and Retention:		
21. Crisis Intervention Services:		
Evidence Based Team Practices		
22. Participant/Provider Ratio:		
24. Psychiatrist Role on Team:		
25. Multidisciplinary Team:		

¹Early Intervention Service Fidelity Scale (Lester et al., 2006)

26. Duration of FEP Program:

²Danish First Episode Psychosis Fidelity Scale (Nordentoft et al., 2015)

³Recovery after an Initial Schizophrenia Episode, Connection Fidelity Scale (Essock et al., 2015)

⁴Early Assessment and Support Alliance Fidelity Scale (Melton et al., 2012)

Table 4: Key Performance Measures for First Episode Psychosis Services

DOMA	IN & Parformance Measure	
DOMAIN & Performance Measure		
	Domain: Early intervention	
1.	Proportion seen within two weeks	Percent
2.	Median duration of untreated psychosis (DUP)	Median
3.	Population-based program enrollment rate (age 15 to 55). Program	Percent
	enrollment or admissions as percentage of expected population based	
annual incidence		
4.	Proportion of new referrals to FEPS first admitted to inpatient services	Percent
Domain: Patient outcome		
5.	Proportion in follow-up at one year, two years and three years	Percent
6.	Antipsychotic medication doses within national guidelines	Percent
7.	Cumulative admissions to hospital at one year, two years and 3 years	Percent
8.	Education (% participating in education) at one year, two years and 3	Percent
years		
9.	Work (% in competitive employment) at one year, two years and 3	Percent
	years	
Domain: Health and Safety		
10.	Assessment of tardive dyskinesia (TD)	Percent
11. Weight (% with BMI< 25) at one year, two years and 3 years		Percent
12. Attempted Suicide % at one year, two years and 3 years		Percent
13.	Annual monitoring of metabolic parameters	Percent

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