

Original citation: Addington, D., Chiachen, C., French, P., Killackey, E., Melau, M., Meneghelli, A., Nordentoft, M., Nossel, I., Preti, A. and Smith, Jo (2020) *International application of standards for health care quality, access and evaluation of services for early intervention in psychotic disorders*. Early Intervention in Psychiatry. ISSN 1751-7885 (In Press) https://doi.org/10.1111/eip.12990

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Title: International application of standards for health care quality, access and evaluation of services for early intervention in psychotic disorders.

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Abstract: Aim: Standards for health care quality, access and evaluation of early intervention in psychosis services are required to assess implementation, provide accountability to service users and funders and support quality assurance. The aim of this paper is to review the application of standards in Europe and North America. Methods: Descriptive methods will be used to illustrate the organizational context in which standards are being applied and used, specific measures being applied and results so far. Results: Both fidelity scales and quality indicators of health care are being used. Fidelity scales are being applied in Australia, Canada, Denmark, Italy and United States. In England, Quality Indicators derived from National Institute for Health and Care Excellence guidance are being used. Conclusion: In the last four years, significant progress has been made in the development and application of measures that assess quality and access to evidence-based practices for early intervention in psychosis services. This represents an important step towards providing accountability, improving outcomes and service user experience. The methods used allow for comparison between the services that are assessed with the same methods, but there is a need to compare the different methods. Further research is also required to explore links between quality of care and outcomes for community mental health services that deliver early intervention in psychotic disorders.

Key Words

Early Intervention
Psychotic Disorders
Implementation Science
Quality Indicators, Health Care
Health Services Accessibility
Community Mental Health Services

Introduction,

Systematic reviews support the effectiveness of team based coordinated care for patients with a first episode psychosis compared with standard care (Fusar-Poli, McGorry, & Kane, 2017) and programs have been implemented internationally (Csillag et al., 2017). The level of implementation has varied in different countries (Dixon, Goldman, Srihari, & Kane, 2018; McDaid, Park, Lemmi, Adelaja, & Knapp, 2016). There are two broad approaches to assessing quality of mental health services: first, use of specific quality indicators of health care and second, assessment of evidence-based practices using fidelity scales (Hermann, Chan, Zazzali, & Lerner, 2006). Quality indicators are used by many hospitals and health plans and measure specific indicators such as wait times and 30-day readmission rates. Evidence-based practice assessment focuses on implementation of evidence-based practices. These practices can be assessed with a fidelity scale, defined as a set of indicators for a specific evidence-based practice that are reliable, valid, feasible and related to outcomes (Bond, Becker, & Drake, 2011). Both methods depend on quality indicators of health care, but the evidence-based practices approach uses predetermined indicators to assess quality (Excellence, 2016; Mainz, 2003). Fidelity scales and quality indicators are available for first episode psychosis services (D. Addington, Birchwood, et al., 2018). In this paper the authors aim to describe large scale initiatives in different countries that use fidelity scales or quality indicators to measure quality of care delivered in first episode psychosis services. We selected all the countries that we could identify were undertaking large scale projects.

The United States of America, Federal Government:

In the United States, the Federal Government has provided financial assistance in the form of a block grant to States to support implementation of evidence-based services for first episode psychosis known as Coordinated Specialty Care (CSC) programs (Heinssen, Goldstein, & Azrin, 2014). In 2018, this program partially funded 236 CSC programs, 163 of which indicated that they use some form of fidelity assessment using 107 different measures (Lutterman, Kazandjian, & Urff, 2018). In order to assess implementation of first episode psychosis services funded by the Federal Mental Health Block Grant, the Substance Abuse and Mental Health Services Administration (SAMHSA), in collaboration with the National Institute of Mental Health (NIMH), and the Office of the Assistant Secretary for Planning and Evaluation (ASPE) are supporting the national Mental Health Block Grant (MHBG) 10% Set-Aside Early Intervention Study for addressing first episode psychosis (FEP). (https://tenpercenteval.samhsa.gov/). This 3-year longitudinal multi center study assesses fidelity and outcomes at 36 sites across the United States. Study sites were selected to represent all the regions of the US. Fidelity to the CSC model is being assessed with the First Episode Psychosis Services Fidelity Scale (FEPS-FS) which covers all the domains of care outlined in the CSC model (D. E. Addington et al., 2016; Heinssen et al., 2014). Fidelity is assessed from a central site, using data from three sources: administrative data, data abstracted from a random selection of ten health records and telephone interviews with program managers and staff, using a semi-structured protocol.

Results so far indicate that the remote fidelity assessment process has proved to be feasible and the fidelity scale has adequate inter rater reliability (D. Addington, Bond, & Noel, 2018). This study should provide data on fidelity assessment methods, an indication of the fidelity of the programs assessed and indications about the relationship between fidelity and outcomes.

United States of America, New York State:

New York State has a population of 19.5 million. The New York State Office of Mental Health has developed the OnTrackNY network of Coordinated Specialty Care (CSC) teams. The network was developed by building upon positive findings in the Recovery After an Initial Schizophrenia Episode (RAISE) initiative. Since its inception in 2013, the program has grown to include 21 CSC teams across the state and 1,385 individuals have received services to date. The treatment model has been previously described (Bello et al., 2017). OnTrackNY teams are funded by a combination of state and federal grants, including the Community Mental Health Block grant, and by insurance billing for those who have private or public insurance.

Methods: OnTrackNY's approach to fidelity assessment evolved in phases. Fidelity assessment investigators adapted the RAISE Connection Program's fidelity tool (Essock et al., 2015) for OnTrackNY, informed by Addington's FEP fidelity scale (D. E. Addington et al., 2016). The fidelity process using the OnTrackNY Fidelity Tool combines both client- and program-level data and a site visit, comprised of staff, patient, and family interviews; team meeting observation; and review of client charts and program records. The scale was pilot tested, and then the tool and process were refined to maximize efficiency. The OnTrackNY Fidelity Scale includes 25 domains, comprised of 83 sub-items. Each domain has one "critical" sub-item that must be met to meet fidelity for that domain. To date, 12 of 21 teams have had an initial fidelity assessment and all teams have demonstrated high fidelity with 19-23 domains being met. Findings are provided to site leadership and a collaborative action plan is developed for any domains for which fidelity is not met. Findings are also shared with OnTrackNY trainers to inform ongoing technical assistance. The plan is for each team to have an annual fidelity assessment. Site visits have been a useful adjunct to data review, particularly for domains related to care processes, such as shared decision making and cultural competence.

Italy:

The healthcare system in Italy is a regionally based national health service known as Servizio Sanitario Nazionale (SSN). The central government controls distribution of revenue for publicly financed health care and defines national statutory benefits. The 20 regions and two autonomous provinces have the responsibility to organize and deliver health services through local health units. Mental health services are delivered through 127 Departments of Mental Health. The Italian Association for EIP (Associazione Italiana Interventi Precoci nelle Psicosi – AIPP) is a scientific association not a government or regulatory agency but it has published Italian National guidelines and conducted a series of voluntary surveys of EIP services (Cocchi et al., 2018). A self-report version of the Italian version of the FEPS-FS was included in the fourth survey on the state of the early intervention in psychosis services (EIPs) in Italy.

Overall, 73 Departments of Mental Health (DMHs) out of 127 (57%) DHMs operating in Italy took part in the survey (summer 2017 – spring 2018). Among the participating DMHs, 41 reported that one or more EIPs were operating within the department. The chairs of these EIPs were invited to evaluate their own programs by completing the FEPS-FS. Twenty nine out of the 41 (70%) EIP centers that are currently operating in Italy took part in the survey, using the Italian translation of the FEPS-FS as a self-report measure.

Twenty nine centers returned the self-report fidelity measures. Reliability, measured as internal consistency, was reasonably good: 0.83.

Preliminary analysis of the survey indicates that just one of the 29 participating centers had a mean score above 4 or above, the requirement for good fidelity (D. E. Addington et al., 2016).

The application of the guidelines as assessed by the self-report version of the FEPS-FS was uneven, with some criterion well satisfied by the majority of the centers, especially those that are predictably found in Italian community psychiatry services, such the role of the psychiatrist and case manager, communication with the inpatient services and establishing a treatment plan. The most evident deficit concerned specialized treatments, such as client and community outreach, clozapine prescribing, Cognitive Behaviour Therapy (CBT) and crisis support. Lack of resources, on one hand, and differences in managing the culture of Italian psychiatry may explain these findings.

The Danish context:

The Danish health care system serves a population of 5.8 million and consist of five Regions, which deliver public health services financed partly by block grants from the central government and partly by taxes collected by municipalities. Regions must use the block grant for the purposes that are specified by the state.

Methods: In Denmark, the OPUS treatment model demonstrated significant efficacy (Jeppesen et al., 2005; Petersen et al., 2005). The evidence-based OPUS treatment has been implemented nation-wide, and today there are 23 teams. A voluntary initiative between researchers was used to develop the Danish fidelity scale (Melau, Albert, & Nordentoft, 2017) and to conduct The Danish fidelity study (Melau, Albert, & Nordentoft, 2018). Development of the scale was based on core EIS elements proven effective compared to standard treatment used in the OPUS trial and in international literature (D. E. Addington, Mckenzie, Norman, Wang, & Bond, 2013; Marshall, Lockwood, Lewis, & Fiander, 2004; Thorup et al., 2005) and interviews with experts from Danish EIS teams using an adapted Delphi consensus process (Fiander & Burns, 2000). This resulted in an 18-point fidelity scale, covering two dimensions: team structure and treatments provided. We identified five mandatory components including: 1) Independent management, 2) Multidisciplinary teams, 3) Low patient to case manager ratio, 4) Assertive outreach including home visits, and 5) Systematic engagement of family and relatives. The total maximum score is 18 points, and satisfactory fulfilment of program-fidelity can be obtained at an 'Elite' and an

'Adequate' level. Using the fidelity scale, we assessed the program fidelity in 22 SEI using site visits.

Results We found the fidelity scale to be both feasible and manageable. Ninety six percent (N=22) teams participated in the study, Fifty nine percent (n = 13) met criteria for adequate or elite level fidelity. We found significant geographic variability between SEI teams on the structural domain of the scale, (Table 1). There was greater homogeneity between teams in case of fulfilling items referring to treatment (Table 2).

A detailed report on the fidelity of each team was sent to directors in the five regions. The fidelity scale and data from the study was used to inform the preparation of the Danish treatment package for first episode schizophrenia but was not implemented as a national standard.

Table 1 Percentage of all teams (N = 22) meeting the criteria for team functioning fidelity measures, and the percentage of teams not complying with the requirements

Table 2 Percentage of all teams (N = 22) meeting the fidelity criteria for content of the treatment, and the percentage of teams not complying with the requirements

Canada, Ontario:

In Canada, each province is responsible for health care delivery. In 2003/4, the province of Ontario, with a population of 14 million, expanded Early Psychosis Intervention (EPI) programs from 5 to 45, covering every region of the province. The Early Psychosis Intervention Ontario Network (EPION) is a network of programs funded by the Ministry of Health and Long-Term Care with a mandate to advocate for and support knowledge exchange, provincial standards and research. It has no formal administrative role in the management of health services. In 2017, EPION initiated a fidelity study to measure adherence of EPI programs to the 2011 Ontario EPI Standards using the First Episode Psychosis Fidelity Scale (FEPS-FS) (D. E. Addington et al., 2016; Durbin et al., 2019).

Nine volunteer programs participated in this study. Fidelity was assessed during a two-day site visit by trained peer reviewers. Sixteen volunteer assessors were drawn from experienced program staff and implementation specialists from the Provincial System Support Program (PSSP). The fidelity assessors participated in a 2-day training workshop and worked in a three-person teams comprised of 2 EPI clinicians and one implementation specialist. Following the visit, the assessors participated in a consensus call with the author of the FEPS-FS to ensure consistency across teams. A full fidelity assessment report was prepared including item ratings, narrative feedback and quality improvement suggestions.

There was variability in the FEPS-FS scores where a score of 4 is considered 'satisfactory' performance. Mean overall fidelity ratings ranged from 3.1 to 4.4, and exceeded 4 in five programs. Item ratings ranged from 2.1 to 5, and exceeded 4 in 14 of 31 items. Programs with

fewer staff had more difficulty meeting the Standards. Some items such as use of clozapine and cognitive behaviour therapy were more challenging.

The programs considered the fidelity results to be credible and found the reports helpful. The participants valued having peer EPI clinicians on assessment teams; assessors valued the opportunity to visit other programs, providing a model for peer learning and mentorship. Although peer assessment model was found to be feasible, there was assessor attrition with 30% of trained assessors leaving their positions over the study period. The study supported the feasibility and acceptability of the peer assessment process using the FEPS-FS, but raised questions about sustainability given staffing turnover.

Australia:

In 2018, the population of Australia was 25 million. The 2011 Australian Federal Budget, committed AUD\$244M to the establishment of 16 Early Psychosis Intervention Services for young people aged 12-25 years (Hughes et al., 2014). The Australian Early Psychosis fidelity model was initially developed through a combination of the EPPIC model developed in Melbourne and consultation with international and national clinical and academic experts, young people and families (Orygen Youth Health Research Centre, 2011). This was further refined into a 16 component model underpinned by 3 levels of standards for each component (Stavely, Hughes, Pennell, Mcgorry, & Purcell, 2013).

Table 3, 16 Core Components of Australian Early Psychosis Model

Methods:

The scale was developed by taking the minimum standards underpinning each component and operationalising them. For example, one of the standards for the component Continuing Care Case Management states: The EPPIC service has a designated multidisciplinary continuing care case management team. This was operationalised as:

Multidisciplinary case management team - In addition to medical staff and consultant psychiatrist

- 1. Case management team has 1 discipline
- 2. Case management team has 2 disciplines
- 3. Case management team has 3 disciplines
- 4. Case management team has 4 disciplines (SW, Psych, OT & nursing)
- 5. Case management team has 4 disciplines and makes use of discipline specific skills.

Each item either is a 5-point scale or, in the case of dichotomous items, scores can be 1 or 5. There are 80 items covering 14 components. Because the items are not evenly distributed across components, each component score is weighted so that each component is of equal value in the scale. Assessment uses administrative data and interviews with managers, team leaders, clinicians, families and young people.

Results: There have been three rounds of assessment. After each assessment, feedback is provided and advice on addressing weaker areas. This has seen fidelity rising to be reasonably

uniform across the 6 services. Feedback from sites has been that they find the process of assessment and feedback to have been useful in the development stage of their services.

In 2019, the process of revising the Australian Early Psychosis Guidelines will commence. This is likely to see changes to the Australian Early Psychosis Model. For example, there will probably be an increased focus on physical health and online interventions. This will lead the model to evolve and revision of the fidelity scale is likely to follow.

England

England has had uniform EIP service implementation driven by national mental health reforms since 1999 (Care, 1999). This was followed by a series of detailed policy guidance supporting EIP services development(U. K. D. o. Health, 2000) (D. o. Health, 2006; United Kingdom, 2001) (Pinfold, Smith, & Shiers, 2007) (D. o. Health, 2007).

In October 2014, Department of Health and NHS England published 'Achieving better access to mental health services by 2020 which introduced the first set of mental health access and waiting time standards within the NHS (England, 2014). From April 2016, EIP teams were required to meet these Access and Waiting Time Targets (AWT) and to deliver on National Institute for Healthcare Excellence (NICE) guidelines for psychosis (Excellence, 2016). EIP teams in England have been audited annually since 2015.

In 2018/19, NHS England will utilise the National Clinical Audit for Psychosis EIP spotlight audit to collect data from EIP teams on progress made since 2017. This audit round commenced in September 2018 and is due to report in July 2019. Audit results will be compared to Mental Health Minimum Data Set (MHSDS) entries to support improved data quality.

Table 4. EIP Audit standards

Figure 1

A scoring matrix was developed. Each item, each domain and an overall rating could be scored at one of four levels: Level 4: 'Top performing', Level 3: 'Performing well', Level 2: 'Needs improvement', Level 1: 'Greatest need for improvement'. The score is based on meeting specified thresholds, calculated for each intervention individually based on studies into take-up of interventions. The overall score for an EIP team is calculated based on the number of domains rated as 'top performing', 'performing well', 'needs improvement' and 'greatest need for improvement'.

Table 5. Percentage of programs meeting specific standards over time

National EIP benchmarking audits (HQIP and CCQI 2017, 2018)

The first audit data collection period was July to September 2016 and the second from October 2017 to January 2018. Self assessment data was obtained from 144 EIP teams on over 2,700 patients (range 11-100, median 52 patients per team). These audits showed marked improvements in the number of people starting treatment within 2 weeks. The majority of EIP services achieved level 2 ('Needs improvement') in their overall scores with a small number of teams achieving levels 3 and 4. The extent to which services were able to deliver evidence-based psychological and medical interventions varied considerably between services and across regions.

The national audit has shown improvements year on year but few EIP services are fully concordant with all of the standards. The audits revealed workforce skills gaps, with a shortage of staff, in some teams, with competences to deliver specialist CBTp, FI and IPS. Mapping program fidelity in England has also demonstrated significant geographic variability between teams. There are still challenges in translating positive EIP AWT policy developments into improved outcomes for people with first episode psychosis and their carers.

Discussion

There are two important aspects to these initiatives, the measures they use to assess quality and the overall context in which the measures are used. The measures used include both fidelity scales and a set of quality indicators reflecting two approaches, measurement-based quality improvement and implementation of evidence based practices (Hermann et al., 2006). Reassuringly the measures used share a strong link with the same evidence base, and are meaningful, feasible and actionable (Hermann & Palmer, 2002). The context or system of accountability in which they are used vary significantly and reflect a previous review of international systems of accountability for mental health care. The programs should measure quality or performance in an ongoing, substantial, and organized manner, rather than being one-time initiatives or assessments (Parameswaran, Spaeth-Rublee, Huynh, & Pincus, 2012).

Conclusions

Significant progress has been made over the last four years in the development and application of fidelity scales and quality indicators of health care for EIP services. This represents an important step towards implementing, sustaining and disseminating quality services for intervening in psychotic disorders. Future progress requires more research on the psychometric properties of the measures being used because the measures are new and little has been published. Further research is also required to compare measures used in different countries. At the system level we need to demonstrate that repeated measurement leads to quality improvement.

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Table 1 Percentage of all teams (N = 22) meeting the criteria for team functioning fidelity measures, and the percentage of teams not complying with the requirements

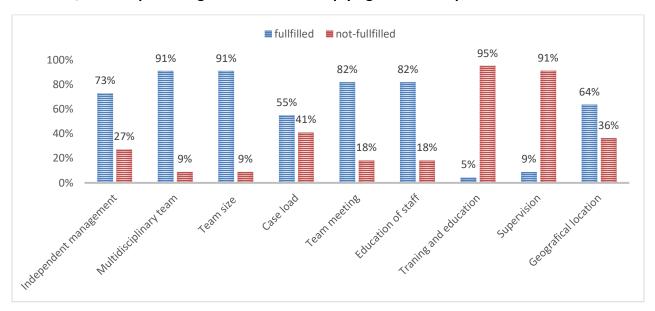


Table 2 Percentage of all teams (N = 22) meeting the fidelity criteria for content of the treatment, and the percentage of teams not complying with the requirements

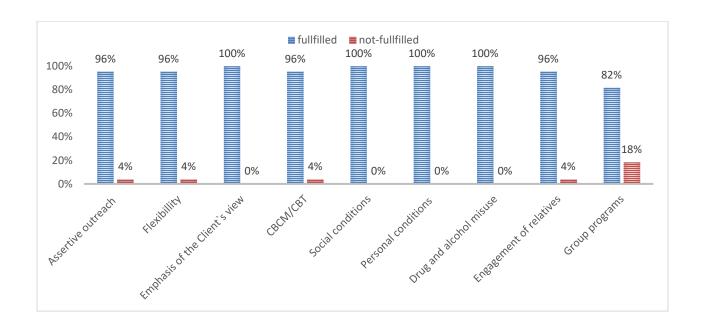




Table 3, 16 Core Components of Australian Early Psychosis Model

Co	m	n	o	n	Р	'n	ı
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- 1. Community Education and Awareness
- 2. Easy Access to Service
- 3. Home-based Care and Assessment
- 4. Access to streamed youth-friendly inpatient care
- 5. Access to youth friendly sub-acute beds
- 6. Continuing care case management
- 7. Medical treatments
- 8. Psychological Interventions

- 9. Functional Recovery Program
- 10. Intensive Mobile Outreach
- 11. Group Programs
- 12. Family programs and family peer support
- 13. Youth participation and peer support program
- 14. Partnerships
- 15. Workforce development
- 16. UHR for psychosis populations

Table 4. EIP Audit standards

- Service users with first episode of psychosis start treatment in early intervention in psychosis services within 2 weeks of referral (allocated to, and engaged with, an EIP care coordinator)
- Service users with first episode psychosis take up Cognitive Behavioural Therapy for psychosis (CBTp)
- Service users with first episode psychosis and their families take up Family Interventions (FI)
- Service users with first episode psychosis who have not responded adequately to or tolerated treatment with at least 2 antipsychotic drugs are offered clozapine
- Service users with first episode psychosis take up supported employment and education programmes
- Service users receive a physical health review annually. This includes the following measures:
 - Smoking status, Alcohol intake, Substance misuse, BMI, Blood pressure, Glucose, Cholesterol
- Service users are offered relevant interventions for their physical health for the following measures:

- Smoking cessation, Harmful alcohol use, Substance misuse, Weight gain/ obesity, Hypertension, Diabetes/ high risk of diabetes, Dyslipidaemia
- S8 Carers take up or are referred to carer-focused education and support programmes

Outcome indicator

Clinical outcome measurement data for service users (two or more outcome measures from DIALOG, QPR and HoNOS/HoNOSCA) is recorded at least twice (assessment and one other time point)

Figure 1

Early Intervention in Psychosis Self-assessment tool Scoring Matrix

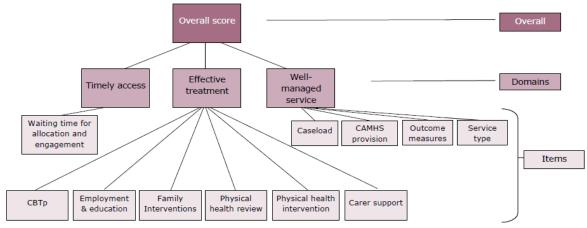


Figure 1. Hierarchy of items, domains and overall score.

As seen in Figure 1, there are 11 items placed into 3 domains, which in turn inform the overall score for an EIP team.



Table 5. Percentage of programs meeting specific standards over time

Early intervention in psychosis standard	2016/17	2017/18	2018/19	2019/20	2020/21	Measured by
% of people receiving treatment in 2 weeks	50%	50%	53%	56%	60%	UNIFY data collection Moving to MHSDS as soon as possible
Specialist EIP provision in line with NICE recommendations	All services complete baseline self-assessment	All services graded at level 2 by year end	25% of services graded at least level 3 by year end	50% of services graded at least level 3 by year end	60% of services graded at least level 3 by year end	Royal College of Psychiatrists College Centre for Quality Improvement (CCQI) annual quality assessment and improvement scheme.