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European Psychiatric Association (EPA) guidance on quality assurance in mental healthcare

W. Gaebel [a,*,b,c], I. Großimlinghaus [a], R. Heun [d], B. Janssen [a], B. Johnson [e], T. Kurimay [f], P. Montellano [g], M. Muijen [h], P. Munk-Jorgensen [i], W. Rössler [j,k], M. Ruggeri [l], G. Thornicroft [m], J. Zielasek [a,b,c]

[a] Department of Psychiatry and Psychotherapy, Heinrich Heine University, LVR-Klinikum Düsseldorf, Bergische Landstr. 2, 40629 Düsseldorf, Germany
[b] LVR-Institute for Mental Healthcare Research, Düsseldorf, Germany
[c] WHO Collaborating Center for Quality Assurance and Empowerment in Mental Health, Düsseldorf, Germany
[d] Derbyshire Mental Health Services, Royal Derby Hospital, Derby, UK
[e] European Federation of Associations of Families of People with Mental Illness, Leuven, Belgium
[f] Department of Psychiatry and Psychotherapy, Semmelweis University, Budapest, Hungary
[g] GAMIAN Europe, Brussels, Belgium
[h] WHO Regional Office for Europe, Copenhagen, Denmark
[i] Aarhus University Hospital, Risskov, Denmark
[j] Leuphana University, Lüneburg, Germany
[k] University of Zürich, Zürich, Switzerland
[l] Section of Psychiatry, Department of Public Health and Community Medicine, University of Verona, Verona, Italy
[m] Institute of Psychiatry, King's College, London, UK

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ABSTRACT

Purpose: To advance the quality of mental healthcare in Europe by developing guidance on implementing quality assurance.
Methods: We performed a systematic literature search on quality assurance in mental healthcare and the 522 retrieved documents were evaluated by two independent reviewers (B.J. and J.Z.). Based on these evaluations, evidence tables were generated. As it was found that these did not cover all areas of mental healthcare, supplementary hand searches were performed for selected additional areas. Based on these findings, fifteen graded recommendations were developed and consented by the authors. Review by the EPA Guidance Committee and EPA Board led to two additional recommendations (on immigrant mental healthcare and parity of mental and physical healthcare funding).
Results: Although quality assurance (measures to keep a certain degree of quality), quality control and monitoring (applying quality indicators to the current degree of quality), and quality management (coordinated measures and activities with regard to quality) are conceptually distinct, in practice they are frequently used as if identical and hardly separable. There is a dearth of controlled trials addressing ways to optimize quality assurance in mental healthcare. Altogether, seventeen recommendations were developed addressing a range of aspects of quality assurance in mental healthcare, which appear usable across Europe. These were divided into recommendations about structures, processes and outcomes. Each recommendation was assigned to a hierarchical level of analysis (macro-, meso- and micro-level).
Discussion: There was a lack of evidence retrievable by a systematic literature search about quality assurance of mental healthcare. Therefore, only after further topics and search had been added it was possible to develop recommendations with mostly medium evidence levels.
Conclusion: Evidence-based graded recommendations for quality assurance in mental healthcare were developed which should next be implemented and evaluated for feasibility and validity in some European countries. Due to the small evidence base identified corresponding to the

* Corresponding author. Department of Psychiatry and Psychotherapy, Heinrich Heine University, LVR-Klinikum Düsseldorf, Bergische Landstr. 2, 40629 Düsseldorf, Germany. Tel.: +49 211 922 2001; fax: +49 211 922 2020.
E-mail address: wolfgang.gaebel@uni-duesseldorf.de (W. Gaebel).

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practical obscurity of the concept and methods, a European research initiative is called for by the stakeholders represented in this Guidance to improve the educational, methodological and empirical basis for a future broad implementation of measures for quality assurance in European mental healthcare.

1. Introduction

Conceptual models of quality assurance reviewed by McMillen et al. [67] concentrate on searching for key causes of identified quality problems, devising creative solutions to these problems, implementing these changes, and continuing to monitor and learn from these implementation efforts. For mental health services, Jessee and Morgan-Williams [48] suggested that performance evaluation, resource management, risk management and patient satisfaction together formed an operational definition of quality. Reviewing the history of quality assurance in mental healthcare up to 1988, Zusman stated that the field had widely adopted the three-part evaluation process proposed by Donabedian [19] of structures, processes and outcomes [125]. Box 1 provides an overview of current concepts and definitions of "quality assurance".

It shows that quality assurance is a multi-step process involving three levels of assessments [123]. The first level (macro-level) is the level of national or regional mental health policy and its organization, including topics like equity, continuity and comprehensiveness. The second level (meso-level) is the specific setting where mental healthcare is delivered, such as primary care facilities, and outpatient and inpatient psychiatric facilities. The third level (micro-level) is the individual direct care for people with mental disorders, including specific interventions such as psycho-pharmacotherapy and psychotherapy.

Quality assurance is an essential element of any project or program aiming at an improvement of the mental health and well-being of persons with mental disorders. Designing standards of care, monitoring the quality of care and integrating quality improvement into the ongoing management and delivery of mental healthcare services are essential steps in improving mental healthcare [120]. A number of international and national initiatives deal with measuring the quality of mental healthcare [69]. The WHO European Mental Health Action Plan, endorsed by all Ministries of health in the European region, proposes a set of measures to guarantee quality. A challenge for these initiatives and for the European Psychiatric Association (EPA) guidance on quality assurance is that "quality assurance" needs to be conceptualized and defined.

To implement quality assurance programmes, WHO assumed that three preconditions would be necessary [123]:

- the political will to do so: this concerns not only mental health authorities, decision-makers and managers, but also community and patient representatives;
- the existence of an evaluation culture: accountability determines to which extent care providers share an evaluative culture. It not only depends on the background of care providers themselves but also on the organizational structures of the service setting and its management style;
- the availability of technical instruments: reliable, valid, feasible and widely accepted quality assurance instruments such as guidelines and quality indicators need to be available. The development of such instruments depends mostly on professional organizations and health services researchers.

Thus, quality assurance in mental healthcare emerges as a concept of assessing mental healthcare structures, processes and outcomes using predefined criteria and standards on three levels of analysis (macro-, meso- and micro-level). It also includes a feedback onto all steps of the quality assurance process. Quality assessment tools are necessary to implement quality assurance in clinical practice and to obtain performance data for quality assurance programs. Of growing importance in quality assurance in mental healthcare is the consideration of the patients' perspectives when defining evaluation criteria for mental healthcare services, because obtaining information about patient satisfaction with the provided services is regarded as a necessary component of quality [123]. Patient involvement can be integrated at every step of the quality assurance process. According to Donabedian [18], patients not only contribute to quality assurance by providing useful information about their own experiences, but they can also be integrated in the quality assurance process as reformers of care, for instance, when patient representatives

Box 1. Quality Assurance – Definitions and concept.

There is no unitary definition of ''quality assurance''. A definition was provided by a team of experts commissioned to develop a quality assurance framework for mental health for the Government of Western Australia (http://www.mentalhealth.wa.gov.au/Libraries/pdf_docs/WA_QA_Framework_Final_Report_11_October_2011_FINAL_2.sflb.ashx).
''Quality assurance is generally defined as the process where the performance of a system or service is assessed and evaluated to ensure that a high-quality, safe service is offered and delivered to those using it, and that it complies with agreed standards, accreditation and any relevant legislation and safety requirements.'' WHO [120] formulated that quality assurance was defined as ''Activities intended to ensure the quality of care in a defined setting or programme.'' Quality assurance (QA) is an integral part of quality management, which is a set of coordinated activities to direct and control healthcare organizations. The main goal of quality management in healthcare is to continuously assure and improve the quality of health care. According to Donabedian [17], three aspects of the quality of care can be defined: structure, process and outcome quality. According to this classification, financial, personnel-wise, building-related, technological and informational structures, such as in the form of a hospital or outpatient practice, have to be available, which are suitable for delivering diagnostic and therapeutic state-of-the-art care services that, in turn, enable the achievement of desired medical outcomes (Fig. 1) [25,74].
Quality assurance in healthcare has two different complementary meanings. On the one hand, it refers to an assessment process of care provided. On the other hand, it refers to a mechanism for action to maintain quality improvements [123]. In the WHO quality assurance process model (Fig. 2), planning, implementation and evaluation of quality assurance measures are interconnected. The first three steps of identifying goals, selecting interventions and defining standards fall within the area of policy making. Steps 4 and 7 deal with the implementation of care services and steps 5 and 6 refer to the evaluation of care provided. The model depicts that quality assurance involves a comparison between predefined standards and observed care practices.

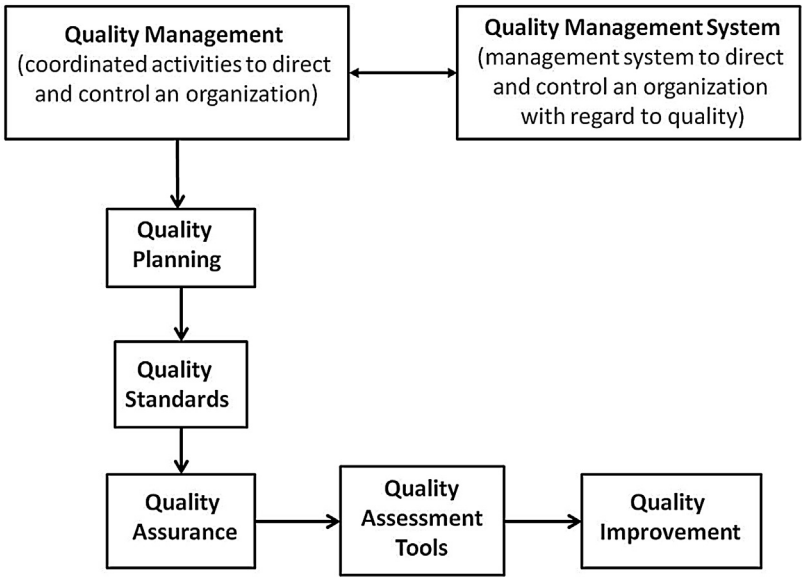

Fig. 1. Quality assurance as an element of quality management. Arrows indicate the steps from quality management to quality improvement and the reciprocal interactions between quality management as coordinated activities and a quality management system, which indicates the complete system of various quality management activities. Modified after [15].

participate in the identification of goals and objectives. Similar considerations apply to the inclusion of the experiences of relatives and friends of patients with mental disorders into quality assurance measures.

1.1. Previous recommendations for quality assurance in mental healthcare

WHO in 1994 and 1997 had published extensive checklists about quality assurance in mental healthcare. These addressed all types of mental healthcare services and all levels of quality assurance, from the micro-level (individual patient healthcare) via the meso-level (healthcare services) to the macro-level (health policy) [122,123]. Mental healthcare systems were slow in implementing such measures. In Scotland, for example, mental health quality and outcome measurement have been defined in the framework of national targets and benchmarking is a central component [10]. As another example, in Germany, quality assurance in mental healthcare is regulated in the German Social Code Book and the current focus is on developing and establishing quality indicators for mental healthcare [23,33]. In Italy, a quality assurance program is effective, which deals with the accreditation

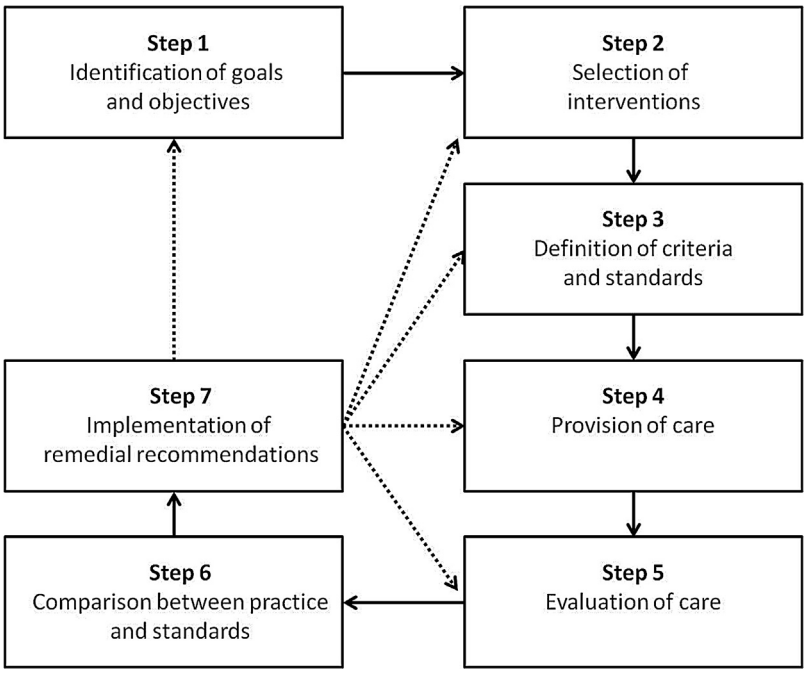

Fig. 2. Steps in quality assurance in mental healthcare. Solid arrows indicate the sequence of steps and dotted arrows the feedback onto the process steps after implementation of remedial actions taken in quality assurance.
Modified after [123].

of mental health services [79]. In the framework of the National Clinical Audit and Patient Outcomes Programme, several reports have been published dealing with mental healthcare. These address National Health Service audits by the Royal College of Psychiatrists on dementia care, schizophrenia care, prescribing practices and memory clinics audits (http://www.rcpsych.ac.uk/workinpsychiatry/qualityimprovement/nationalclinicalaudits.aspx). Beyond these, we found only one set of more recent recommendations developed for mental healthcare services in Western Australia in 2011 (http://www.mentalhealth.wa.gov.au/Libraries/pdf_docs/WA_QA_Framework_Final_Report_11_October_2011_FINAL_2.sflb.ashx).

1.2. Aims of the EPA Guidance on Quality Assurance in Mental Healthcare

The main purpose of this EPA Guidance on Quality Assurance in Mental Healthcare is to develop recommendations to advance quality assurance in mental healthcare in Europe founded on a scientific evidence base obtained from a systematic literature review of studies on quality assurance in mental healthcare. It continues the development of quality assurance tools in mental healthcare initiated with the EPA Guidance on the quality of mental health services published in 2012 [25]. We focus on quality assessment tools and evaluations of mental healthcare services, since these areas are central to the quality assurance process. In order to provide guidance recommendations for all European mental healthcare systems, we concentrated on recommendations with a high probability of efficacy as shown in randomized controlled trials, and chose studies which were not only pertinent to locally, regionally or nationally relevant mental healthcare services structures or processes, but had a high likelihood to be used throughout Europe.

2. Methods

2.1. Guidance development process

To identify the evidence base for this guidance, we performed a systematic literature review. We searched the databases Medline (Pubmed), Scopus and DIMDI (German Institute of Medical Documentation and Information). The latter database includes the databases Embase, Global Health, Social SciSearch, Sci Search and PsychInfo. The time limit in these searches was from 2004 to 2014 in order to focus on recent evidence and to limit the retrievals to a manageable number of publications for the structured review process. The search terms were "mental health care" and "quality assurance". Table 1 provides the details of this step including the number of documents retrieved.

The inclusion criteria for the further analysis were:

- studies related to quality assurance in mental health care (original studies and reviews);
- studies of relevance to the European mental health care situation;
- publication in English or German.

The exclusion criteria were:

- lack of original or review data, like publications dealing only with a study protocol;
- letters, editorials and personal opinion papers;
- data from non-European study with lack of transferability to the European mental health care situation;
- evaluation of a special care segment with lack of transferability to the European mental health care situation;
- case reports;
- studies related to a purely forensic context;
- studies related solely to children and adolescents;
- cost-analysis studies without more general aspects of mental healthcare quality assurance.

Two EPA Guidance authors (B.J. and J.Z.) independently reviewed all retrieved documents. Discrepancies between the raters were resolved by discussion and structured evidence evaluation tables were generated for all studies obtained as full texts. The flow of articles through this process is detailed in Fig. 3.

Evidence evaluation tables adapted from SIGN50 (Scottish Intercollegiate Guidelines Network) and NICE (National Institute of Clinical Excellence, UK) templates were generated for studies evaluated as full text articles, since we used evidence from original studies and reviews, for which suggestions for evidence evaluation were available in these systems [27]. These searches led to recommendations in the fields of physical healthcare of patients with mental disorders, benchmarking, quality indicators, and the use of routine data, referrer assessments, and patient and family assessments for quality assurance purposes. Following this process, the authors found that important fields of quality assurance had not been covered by the results of this systematic literature review and decided to additionally hand search the literature to identify further areas, which included guideline implementation, content of care monitoring, therapeutic drug monitoring, polypharmacy, coercive measures, outcome and needs assessments, monitoring of suicidal ideation, critical incident monitoring and reporting, implementation of general hospital standards in mental healthcare, and providing adequately trained staff in mental healthcare. For this purpose, these keywords in combination with "mental health" for literature searches were used using only the Medline database (no time or language limits) in December 2014 and further documents were added found in the literature lists of these documents or in related documents of these articles provided by the Medline database. Recommendations were developed by the authors of this manuscript (including representatives of patients and families; see [114]) and reviewed by the EPA Guidance Committee and the EPA Board. Two additional aspects (mental healthcare for immigrants and parity of mental and physical health funding) were added following the review. A revised version of the

Table 1
Search terms and syntax of the systematic literature search as performed in June 2014.

Database	Search terms, syntax and search strategy	Number of retrieved documents
SCOPUS	(TITLE-ABSTR-KEY [mental health care] AND KEY [quality assurance]) AND PUBYEAR > 2003	188
Medline (Pubmed)	(TI-ABSTR) mental health care AND (MESH) quality assurance AND PY = 2004–2014	270
DIMDI	(TI) mental health care AND (KEY) quality assurance AND PY = 2004 to 2014	64

Searches were performed using titles and texts of documents and were performed as a mixed strategy of Medical Subject Heading term search and Title-Abstract-Key search. There was no restriction as to country of origin of the study, but languages were limited to English and German.

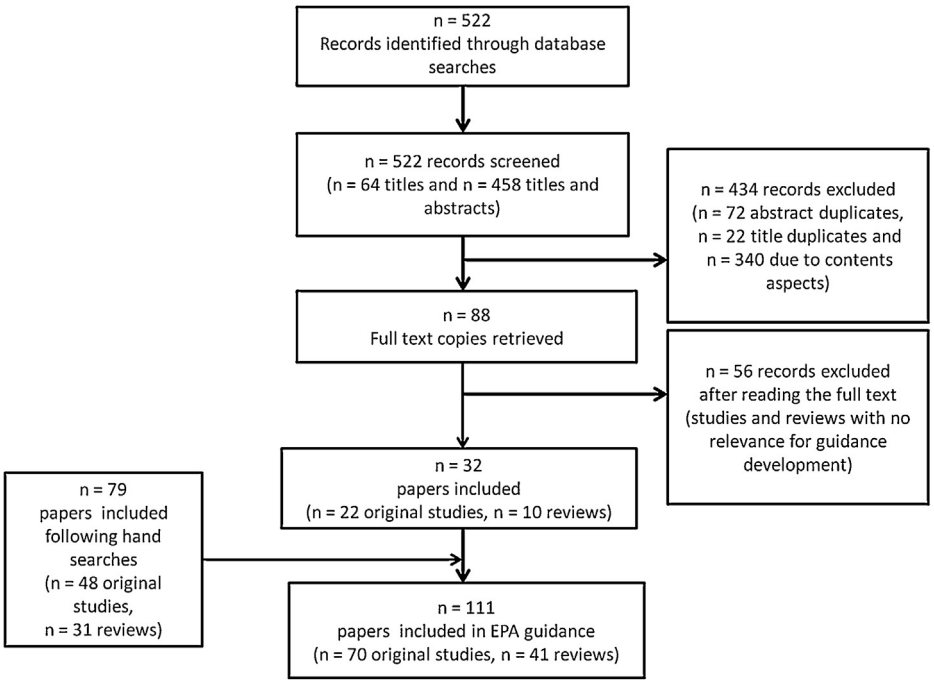

Fig. 3. Flow of studies retrieved in the systematic literature search with the algorithm detailed in Table 1.

manuscript was then circulated by email to the authors for final approval.

2.2. Evidence and recommendation grading

The evidence rating of each study and the grading of recommendations followed the previous EPA Guidance procedures as described previously (Tables 2 and 3, abbreviated after [27]).

3. Results

3.1. Summary of evidence assessments

The evidence assessment for all included studies and reviews is detailed in Tables 4–6.

These tables also indicate which references were used for which recommendation. The following sections list the areas of quality

Table 2
Grading of evidence from quantitative studies, qualitative studies and reviews.

Study type	Features of qualitative research	Features of quantitative studies	Features of reviews
Level I Generalizable studies	Sampling focused by theory and the literature, extended as a result of analysis to capture diversity of experience. Analytic procedures comprehensive and clear. Results can be generalized to settings or stakeholder groups other than those reported in the study	Randomized controlled trials. Surveys sampling a large and representative group of persons from the general population or from a large range of service settings. Analytic procedures comprehensive and clear usually including multivariate analyses or statistical modeling. Results can be generalized to settings or stakeholder groups other than those reported in the study	Systematic reviews or meta-analyses
Level II Conceptual studies	Theoretical concepts guide sample selection, based on analysis of literature. May be limited to one group about which little is known or a number of important subgroups. Conceptual analysis recognizes diversity in participants' views	Uncontrolled, blinded clinical trials. Surveys sampling a restricted group of persons or a limited number of service providers or settings. May be limited to one group about which little is known or a number of important subgroups. Analytic procedures comprehensive and clear. Results have limited generalizability	Unsystematic reviews with a low degree of selection bias employing clearly defined search strategies
Level III Descriptive studies	Sample selected to illustrate practical rather than theoretical issues. Record a range of illustrative quotes including themes from the accounts of "many", "most", or "some" study participants	Open, uncontrolled clinical trials. Description of treatment as usual. Survey sampling not representative since it was selected from a single specialized setting or a small group of persons. Mainly records experiences and uses only a limited range of analytical procedures, like descriptive statistics. Results have limited generalizabiltiy	Unsystematic reviews with a high degree of selection bias due to undefined or poorly defined search strategies
Level IV Single case study	Provides rich data on the views or experiences of one person. Can provide insight in unexplored contexts	Case studies. Provides survey data on the views or experiences of a few individuals in a single setting. Can provide insight in unexplored contexts. Results cannot be generalized	Editorials

Modified after [27].

Table 3
Grading of recommendations derived from quantitative studies, qualitative studies and reviews.

Recommendation grade	Description
A	At least one study or review rated as I and directly applicable to the target population; or A body of evidence consisting principally of studies and/or reviews rated as I, directly applicable to the target population, and demonstrating overall consistency of results
B	A body of evidence including studies and/or reviews rated as II, directly applicable to the target population, and demonstrating overall consistency of results; or Extrapolated evidence from studies and/or reviews rated as I or II
C	A body of evidence including studies and/or reviews rated as II–III, directly applicable to the target population and demonstrating overall consistency of results; or Extrapolated evidence from studies and/or reviews rated as II–III
D	Evidence level III or IV; or Extrapolated evidence from studies and/or rated as III or IV; or Expert consensus

Modified after [27].

Table 4
List of included reviews, their methods and process of analysis, the main results and comments including evidence ratings.

Reference	Method and process of analysis	Main results	Comments
Agius et al., 2005* [1]	Six experts consented recommendations based on unsystematic literature reviews	Development of 28 standards formulated as recommendations	The developed common standards may be applicable for the EPA Guidance although the strength of the reported evidence varies between the 28 standards and the cited evidence is more than 10 years old Evidence level III
Baars et al., 2010* [2]	Systematic literature review of the use and purpose of performance indicators for mental health care services	23 articles were found and indicators are described for accountability, quality improvement and performance management	Does not contain sufficient detail. May serve for providing some ideas about quality indicators Evidence level IV
Barbui et al., 2014 [5]	Cochrane systematic review	Studies on guideline implementation in schizophrenia treatment in specialist mental healthcare showed no conclusive benefits, but the evidence base and its quality was limited. Although small changes in psychiatric practice were evident following guideline implementation, uncertainty remained as to clinically meaningful and sustainable effects	Provides limited evidence for some beneficial effects of guideline implementation in schizophrenia treatment Used in recommendation 10 Evidence level I
Bernert et al., 2014 [6]	Systematic literature review of clinical practice guidelines in suicide prevention	Current guidelines address similar aspects of suicide risk assessment and management, but differ in recommendations	A lack of consensus was evident in core competencies, indicating that quality assurance needs to be based on a harmonized guidance Evidence level I–II
Coia and Glassboro, 2009* [10]	Unsystematic review of mental healthcare services in Scotland	Describes benchmarking in Scottish mental healthcare	Example of benchmarking in mental healthcare Used for recommendation 2 Evidence level II
De Hert et al., 2009 [11]	Unsystematic review of the literature and development of a position statement regarding cardiovascular disease and diabetes in people with severe mental illness	Recommendations about the type of useful clinical tests to assess the presence of cardiovascular disease and diabetes, and about the management of these risks and disorders in persons with severe mental illness	Joint position statement of the European Psychiatric Association supported by the European Association for the Study of Diabetes and the European Society of Cardiology. Comprehensive, but unsystematic literature search Used for recommendation 4 Evidence level II
De Hert et al., 2010 [12]	Unsystematic literature review and report of experiences from a Belgian mental healthcare service about the management of physical health in psychiatric settings	Description of the scope of the issue and recommendation to implement a structured and elaborate screening and monitoring protocol	Limited generalizability due to experiences from a single setting Used for recommendation 4 Evidence level III
Delaffon et al., 2012 [13]	Unsystematic literature review	Review of the evidence of the development and use cases of the Health of the Nation Outcome Scales (HoNOS)	Provides evidence on the pros and cons about using the HoNOS as outcome measures in mental healthcare Evidence level II

Table 4 (*Continued*)

Reference	Method and process of analysis	Main results	Comments
Fisher et al., 2012 [21]	Reports of quality measurement initiatives in mental healthcare collected from experts	29 programs were identified and 656 indicators could be retrieved from these programs	Indicates need for a unified scheme in light of the multitude of approaches Evidence level II
Foley, 2013 [22]	Unsystematic review	Report to the Royal College of Psychiatrists and the Centre for Mental Health (UK) about funding disparities between mental and somatic healthcare and how to address them	Evidence of disparities in the UK Used for recommendation 5 Evidence level III
Gaebel et al., 2012 [25]	Systematic literature review to identify studies important for quality assurance of mental healthcare services	Development of 30 recommendations and associated quality indicators	European Guidance developed by the European Psychiatric Association Used for recommendation 1 Evidence level I–II
Gaebel et al., 2014 [27]	Systematic literature review	Experiences of coerciveness reduced trust in mental healthcare services by patients	Guidance on trust in mental healthcare developed by the European Psychiatric Association. Monitoring of coerciveness is indicated as a quality assurance element if trust by patients in mental healthcare services is to be ascertained Used for recommendation 7 Evidence level I–II
Gallego et al., 2012 [29]	Systematic literature review	Antipsychotic polypharmacy was associated with increased rates of medication side effects and there were only moderate benefits in certain situations. It was concluded as an expert opinion that antipsychotic polypharmacy should be regarded as a last resort after monotherapy, switching and non-antipsychotic combinations have failed	Provides arguments against polypharmacy in psychotic disorders Evidence level I–II
Gaskin et al., 2007 [30]	Systematic literature review	Multiple interventions were identified which may reduce the use of seclusion in psychiatric facilities including monitoring of seclusion episodes	Quality assurance by monitoring seclusion episodes in mental healthcare is warranted Used for recommendation 6 Evidence level I–II
Haberer et al., 2013 [34]	Unsystematic literature review	Reviews new concepts of using outcome data to guide therapy by using information technology methods (“measurement-based care”)	Provides use case examples of outcome assessments as quality assurance method in mental healthcare with a focus on the use of new information technologies Evidence level II
Härter et al., 2006* [36]	Review of a German program to foster the implementation of a depression guideline	The availability of guidelines, the introduction of quality management measures, public relations activities, training and continuing medical education, health services research and monitoring could be areas of fostering improvements	This review-type study with some preliminary data shows that a structured guideline implementation process may improve the quality of depression mental health care Used for recommendation 7 Evidence level III
Hermann et al., 2006a* [37]	Unsystematic review Quality indicator suggestions were developed in a structured consensus process based on evidence reviews	Main result was the development of 12 quality indicators for benchmarking of mental health services	This study gives suggestions for quality indicators for international benchmarking of mental health care, but is limited due to the participation of only seven panelists Evidence level III
Hiemke et al., 2008 [39]	Unsystematic literature review	Relationships between blood levels of psychopharmacological agents and clinical effects and adverse drug-related events exist. These are influenced by genetic variations of enzymes involved in drug metabolism like the cytochrome P450 system	Provides evidence of the principle of the association between drug blood levels and clinical effects Used in recommendation 11 Evidence level I–II
Hiemke et al., 2010 [40]	Expert consensus, reviews of literature and guidelines	Guidelines of the international *Arbeitsgemeinschaft für Neuropsychopharmakologie und Pharmakopsychiatrie* (AGNP; Working Group on Neuropsychopharmacology and Pharmacopsychiatry)	Practical recommendations for therapeutic drug monitoring in psychiatry Used in recommendation 11 Evidence level I–II

Table 4 (*Continued*)

Reference	Method and process of analysis	Main results	Comments
Lloyd-Evans et al., 2007 [58]	Systematic literature review	25 scales of assessing content of care were identified and as no gold standard emerged, it was concluded that a multi-methods approach should be adopted	Review of methods of content of care assessment in mental healthcare Used for recommendation 8 Evidence level I–II
Lochmann van Bennekom et al., 2013 [60]	Systematic literature review	Polypharmacy with antipsychotic drugs is associated with modest clinical benefits in patients refractory to clozapine, but increased mortality, metabolic syndrome and increased health costs	Provides an argument against antipsychotic polypharmacy Evidence level I
Lord et al., 2010* [61]	Systematic review	Twenty-seven comparisons revealed inferior preventive health care for persons with mental disorders, but 10 comparisons showed better preventive health care and 24 were inconclusive findings	Shows diversity and problem areas in somatic disorders screening for persons with mental disorders Evidence level I
Mann et al., 2008 [64]	Review of methodological issues about identification and classification adverse drug events and medication errors in psychiatry	Multidimensional procedures for detecting and classifying incidents related to the medication process are recommended	Review provides evidence for the feasibility of monitoring adverse drug events and medication errors as important elements of a critical incident reporting system in psychiatry Used for recommendation 3 Evidence level II
Malone et al., 2007 [63]	Cochrane systematic review	Review of outcome studies for community mental health services indicating the range of potential outcome assessment methods	Provides evidence of the use of a range of outcome domains which may need to be assessed in quality assurance of mental healthcare Used in recommendation 16 Evidence level I
Mayer et al., 2014 [65]	Literature review	European guidance on post-graduate psychiatric training	Provides impetus for the development of harmonized psychiatry training standards in Europe Used for recommendation 7 Evidence level II–III
Qureshi et al., 2009 [76]	Systematic review of studies on the quality of referrals to psychiatric services	A successful referral is described of a complex process with a multidimensional nature, including referrer aspects (like the quality of the referral letter), patient aspects (like attrition rates) and psychiatric service aspects (like waiting times)	This review shows the multidimensional nature of a successful referral process and the paucity of studies in this area of mental healthcare Details of who selected the literature and the selection criteria following literature retrieval are not given Used in recommendation 9 Evidence level II
Scanlan, 2010 [88]	Systematic literature review	Monitoring of seclusion and restraint episodes was identified as a key component of intervention programs to reduce coercive measures in mental healthcare	Quality assurance by monitoring seclusion episodes in mental healthcare is warranted Used for recommendation 6 Evidence level I–II
Sheehan, 2009 [91]	Unsystematic literature search and opinion statements	Reviews various types of compulsory treatment types, shows lack of comparative epidemiological y data from European countries	Concludes that compulsory treatment in psychiatry remains an ethically and clinically contentious issue Evidence level III
Spaeth-Rublee et al., 2010 [95]	Systematic literature review and expert reports	Description of quality assessment programs in 12 countries including the use of quality indicators	Indicators varied widely in scope and level of developments Used in recommendation 10 Evidence level I
Spiessl and Cording, 2000 [96]	Unsystematic literature review	Details general practitioners expectations towards psychiatric services regarding communication to assure continuation of care	Aspects determining referral practice were complex and multidimensional including aspects such as waiting times, communication methods and competencies in mental healthcare Evidence level III
Steinert et al., 2010 [101]	Systematic literature search	Reviews epidemiological studies on the use of seclusion and restraint in Europe and found scarcity of data and a high degree of differences between countries	Concludes that databases are needed using comparable key indicators Evidence level I–II

Table 4 (*Continued*)

Reference	Method and process of analysis	Main results	Comments
Steinert et al., 2014 [102]	Unsystematic literature search	Reviews developments on the use of coercive interventions in mental healthcare comparing Germany and the Netherlands and shows the importance of mental health policy changes as a factor	Shows that differences between European countries exist in the use of coercive interventions in mental healthcare and that mental health policy is an important factor Evidence level III–IV
Tani et al., 2013 [105]	Systematic literature review	Paucity of data on interventions to reduce antipsychotic polypharmacy, but careful switching from polypharmacy to monotherapy was considered to be feasible in a majority of patients with schizophrenia	Provides evidence for switching from polypharmacy to monotherapy in patients with schizophrenia Used in recommendation 12 Evidence level I–II
Van Hasselt et al., 2013 [111]	Systematic review about randomized prospective studies evaluating interventions to improve somatic health in patients with severe mental illness	21 original studies were included. Evaluation was hampered by the fact that the studies used different ways of evaluation and did not use uniform outcome measures	Shows the limited number of trials and methodological problems in comparing studies with a view to identify optimal interventions Evidence level I
Wallcraft et al., 2011 [114]	Unsystematic literature review by a World Psychiatric Association Task Force on Best Practice in Working with Service Users and Carers	Literature review to identify relevant topics followed by structured stakeholder consultation to develop recommendations on best practices in working with service users and family carers. Ten recommendations were developed, including among others a recommendation that international organizations should seek the involvement of consumers and carers in their own activities, and that education, research and quality improvement require collaboration between users, carers and clinicians	These principles were implemented in the EPA guidance on quality assurance Evidence level II
Wasserman et al., 2012 [115]	Unsystematic review and development of a guidance on suicide treatment and prevention	Monitoring for risk factors for suicide is needed for the early detection of suicidal ideation	Guidance of the European Psychiatric Association for the elements of quality assurance in suicide treatment and prevention by providing recommendations for the assessment of patients with suicidal ideation Used in recommendation 13 Evidence level II
Wobrock et al., 2009* [118]	Unsystematic review about quality indicators and guideline implementation in psychiatry	Guideline implementation mostly led to moderate and temporary effects, while guideline adherence	Provides evidence for the effects of guidelines in psychiatry Evidence level II–III
Woloshynowych et al., 2005 [119]	Systematic health technology assessment report of methods of investigation and analysis of critical incidents and adverse events in healthcare including the mental healthcare sector	Six techniques were identified and had the potential to be applied to any specialty or discipline related to healthcare	Study shows a need for further evaluation studies of the risk assessment techniques currently in use. No specific information on mental healthcare, but this review supports the notion that critical incident reporting systems may be valuable tools for quality assurance in mental healthcare Used for recommendation 3 Evidence level II

Asterisks indicate reviews identified through the systematic search. All other reviews were identified by hand search.

assurance topics and how the evidence in each of these areas was used to build recommendations.

3.2. Using patient and family assessments for quality assurance

The involvement of patients and family carer assessments for quality assurance is part of the implementation of the World Psychiatric Association recommendations about best practices in working with service users and family carers [114]. Patient satisfaction with mental healthcare varies widely between individuals. It is very much influenced by the type of services and the individual experiences of treatment [80]. In a longitudinal study on a Norwegian psychiatric ward over more than 20 years, significant associations were evident between patient satisfaction, staff control, user involvement, practical orientation of staff and experiences of angry or aggressive behavior [78]. Although this study is limited by a low number of assessments ($n = 129$ in 11 sessions over 20 years), the significant correlations demonstrate that the treatment environment and patient satisfaction are associated (evidence level III). This finding is corroborated by a questionnaire-based study by Spiessl et al. [99] with psychiatric inpatients ($n = 496$) showing that patient satisfaction was correlated with therapy success, but also by attitudes of psychiatrists and nurses. The group has developed self-report questionnaires for different professional groups, patients and relatives [98] and tested them in 253 patients, 58 relatives and 196 mental healthcare professionals. Across these groups and in different therapeutic settings, the study showed high expectations for therapy success,

Table 5
List of included qualitative studies, their data collection methods, methods of process and analysis, population and sample collection methods, main results, and comments including evidence ratings.

Reference	Data collection	Method and process of analysis	Population and sample collection	Main results	Comments
Bramesfeld et al., 2012* [7]	Focus groups ($n = 47$; average group size 12 members)	Audio-recorded and transcribed sessions were analyzed with regard to content. After a three-step analysis, statements on the practices of cooperation in mental health care were formulated	Focus group members were representatives of a large range of different service providers (e.g., psychiatrists and representatives of social psychiatric services) in different regions (urban/rural) in East and West Germany	The analysis identified presumable factors fostering or inhibiting cooperation. It was recommended that to improve cooperation, regional and sustainable mental health networks should be systematically implemented and interdisciplinary collaboration practice should become part of the curricula of medical students and residents in psychiatry	This qualitative study provides insights into network and cooperation promotion, provides an example of potential referrers Evidence level II
Burbach, 1997 [8]	77 general practitioner referral letters to mental healthcare (out of a total of 339 referrals, of which 113 were randomly selected for analysis, of which 30 did not contain a referral letter)	Topic-focused content analysis by a single rater and matching with mental health team case assessments	West Somerset community mental health team (United Kingdom)	Diagnosis was clear in approximately 60% of referral letters, most common request was for counseling and referrals in about one fourth of the cases underestimated the severity of the mental disorder	Most referral letters were insufficiently detailed. Single rater only may have introduced some selection bias. Analysis was effective as a quality assurance project and lead to changes in case management (spending less time discussing referral letters; study summary provided to general practitioners as a feedback) Used in recommendation 9 Evidence level II
Devillé et al., 2011 [14]	8–11 experts in the field of migration and mental healthcare from 16 European countries	Delphi rounds	Members of academia, non-government organizations, policy makers and clinicians	Nine topics emerged: easy and equal access to mental healthcare, empowerment, culturally sensitive services, quality of care, communication, respect, networking, targeted outreach activities, data availability	Analyses the principles of good clinical practice in mental healthcare for migrants Used in recommendation 14 Evidence level III
Hannes et al., 2010* [35]	Five focus groups ($n = 39$, group sizes varied)	Recorded and transcribed sessions were analyzed with regard to "grounded theory approach" using the software program ATLAS-ti (5.0)	39 psychiatrists were selected on the grounds of interest in evidence-based practice, expertise with evidence-based practice, geographical region and setting (in- vs. outpatient services)	The study shows that interviews with psychiatrists yield a range of problematic areas for applicability of evidence-based practice and barriers to implementing evidence-based practice	This high-quality qualitative study provides psychiatrist-rated problem topics about the implementation of evidence-based practice with a view to assist health policy makers in identifying objectives and developing strategies to foster evidence-based practice (macro-level) Evidence level I–II
Huisman et al., 2013* [44]	Dutch healthcare system	Interviews, but further methods not given in detail	Interviews with 31 (15 psychiatrists, 1 physician, 9 mental health nurses, 6 psychologists) and 28 institution directors in which suicides had occurred, mostly from mental healthcare institutions	Most clinicians thought that supervision was helpful, but in more than half the supervision procedure added to the stress of dealing with a recent suicide	Limited generalizability Evidence level II

Table 5 (*Continued*)

Reference	Data collection	Method and process of analysis	Population and sample collection	Main results	Comments
Kluge et al., 2012 [52]	Representatives of three emergency departments, three mental health services and nine primary care services in each of the 16 participating European countries	Questionnaires, structured interviews with the topics availability of data on service use by immigrant patients, the provision of interpreting services and the number of immigrant staff members	240 interviews	Data availability needs to be improved and more consistent availability of interpretation services would be warranted	Shows areas of quality assurance of immigrant mental healthcare Used in recommendation 14 Evidence level III
McDonnell and Jones, 2010* [66]	Single National Health Service (NHS) Trust	Continuous observation and accompaniment of an initiative to implement the "Essence of care framework"	Exact numbers of participants are not given, but included staff, service users and carers at a NHS trust in Warrington, United Kingdom	The Mental Health Quality Framework Tool was introduced as a benchmarking tool for mental healthcare	Provides evidence for the feasibility and the labor intensity of implementing benchmarking in a mental healthcare setting Used for recommendation 2 Evidence level III
Sandhu et al., 2013 [87]	Analysis of semi-structured interviews with mental healthcare professionals	Open questions and case vignettes, analysis of transcripts or written protocols, content coding and categorization of responses	48 interviews in 16 countries	Describes major challenges (diagnosis, trust and risks of marginalization) as major emerging topics	Assessment of provider experiences with immigrant mental healthcare Used in recommendation 14 Evidence level III
Stockdale et al., 2011 [103]	Analysis of interviews with psychiatric hospital leaders	Structured data coding and analysis	33 psychiatry chairs, service directors or medical directors at 33 hospitals in Massachusetts and South California	Areas for improvement of communication between inpatient and outpatient mental health clinicians were local hospital communication cultures, and need for additional staff time and information	Supports the notion that communication quality assurance may be needed to identify areas of future improvements in communication between inpatient and outpatient mental healthcare services Evidence level I
Tanielian et al., 2000 [106]	Cross-sectional observational study of outpatient referral patterns	10 item self-report survey	Random sample ($n = 1481$) of psychiatrists of the American Psychiatric Association Practice Research Network	68.5% of psychiatrists reported that the communication with primary care physicians for follow-up was poor or fair, especially regarding adequacy and sufficiency of information provided back to the psychiatrist	Assessments of communication between referrers and psychiatrists may uncover problem areas of the referral process Used in recommendation 9 Evidence level I

Asterisks indicate studies identified through the systematic search. All other studies were identified by hand search.

Table 6
List of included quantitative studies, their study types, population and sample collection characteristics, main results, and comments by the guidance authors including a rating of the evidence level.

Reference	Study type	Population and sample collection	Main results	Comments
Bak and Aggernaes, 2012 [3]	Unsystematic literature review and questionnaire study	Experts in eleven European countries participated	Large variation in types and frequency of coercive measures with limited comparability between countries due to methodological differences in measuring coercive measures	Indicates a need to harmonize European definitions and modes of assessment of coercive measures for quality assurance purposes Used for recommendation 6 Evidence level II–III
Bakker et al., 2014 [4]	Community-based prospective study using the Camberwell Assessment of Needs scales	215 patient-carer dyads of patients with young onset dementia	Patients and caregivers generally agreed on the areas in which needs occurred, but some disagreement was found regarding the question whether needs could be met	Demonstrates the importance of both patient and caregiver assessments of needs Used in recommendation 17 Evidence level I
Burgess et al., 2006 [9]	Outcome assessment in mental healthcare	14,659 acute and 23,692 community episodes of mental disorders in Australia, outcome assessment with the Health of the Nation Outcome Scales	Magnitude of improvements depend on setting and episode type	An example of quality assurance in mental healthcare using standardized outcome assessments Used in recommendation 16 Evidence level I
Dlouhy, 2014 [16]	Questionnaire study	Seven Eastern European countries (Bulgaria, Czech Republic, Hungary, Moldova, Poland, Romania, Slovakia)	Large differences of mental healthcare funding between Eastern European countries were found as a ratio of total health expenditures	Provides evidence for disparities between mental and physical healthcare funding, large inter-country differences, and a low level of mental healthcare funding in Eastern European countries compared to other European countries. Questionnaires were sent to experts, but no further details were given. Authors concede that the availability and reliability of the data differed highly between the participating countries Used for recommendation 5 Evidence level II
Donath et al., 2009* [20]	Questionnaire study identifying predictors of mental health care utilization of family caregivers of dementia patients in Germany, and telephone survey of day hospital managers were interviewed regarding their quality concept	Family caregivers ($n = 404$) and 11 day hospital managers	The only significant predictor of mental healthcare utilization was the perceived need	The study indicates that caregivers' needs and expectations need to be considered in quality assurance programs Evidence level II
Gaebel et al., 2013 [26]	Study of the combined use of routine health insurance and pension insurance data for assessing utilization of mental healthcare services in Germany	9.9 million members of statutory health insurance in Germany	33% utilized healthcare for mental health reasons and most contacts occurred in non-specialist general medical services employing a multitude of individual care pathways	Indicates the usefulness of routine data analyses for quality assurance of mental healthcare systems Used for recommendation 15 Evidence level I
Gebhardt et al., 2006* [31]	Questionnaire study Evaluation of employees' expectations as well as the satisfaction of cooperation with two different hospitals in Germany	15 employees of socio-psychiatric services	Differences in the satisfaction with cooperation existed between the two hospitals The satisfaction with the cooperation between socio-psychiatric service and basic-care hospital was higher after the implementation of a psychiatric outpatient service	The survey was completed only by 15 employees, therefore the results have limited applicability to the target group of the guidance Evidence level III
Glezer et al., 2009 [32]	Medication assessment in a chart review in patients with depression in a U.S. university hospital setting	135 patients with depression	Patients were on average on two antidepressive medications	Shows high degree of antidepressive polypharmacy in depression care. Small sample size, retrospective chart review Evidence level II

Table 6 (*Continued*)

Reference	Study type	Population and sample collection	Main results	Comments
Großimlinghaus et al., 2013 [33]	Systematic development of quality indicators for mental healthcare	Structured evidence- and consensus-based development process including clinicians, families and patients	10 quality indicators were developed for alcohol dependence, 10 for dementia, 12 for depression and 12 for schizophrenia	Example of a combination of a structured and transparent, evidence- and consensus-based development process for mental healthcare quality indicators Used in recommendation 10 Evidence level I
Hermann et al., 2006b* [38]	Evaluation of routine data of mental healthcare utilization data	Medicare data 1994–1995	Benchmarking showed large variations of provider level performance using quality indicators	Demonstrates feasibility of benchmarking for quality assurance purposes using quality indicators Used for recommendation 2 Evidence level I
Hübner-Liebermann et al., 2005* [41]	Evaluation of routine data of the German psychiatric basic documentation system (DGPPN-BADO)	Data of 4066 inpatients consecutively admitted to the psychiatric state hospital affiliated to the University of Regensburg in 2001	An analysis of treatment pathways of patients between in- and outpatient mental healthcare services showed an increasing trend towards self-referral for inpatient psychiatric care by patients	Routine mental healthcare data supplemented by routine basis documentation data are useful for quality assurance of the care pathways between service providers especially at the in- and outpatient boundary Evidence level II
Hübner-Liebermann et al., 2008* [42]	Evaluation of routine data of the German psychiatric basic documentation system (DGPPN-BADO)	Data of 52,124 inpatients consecutively admitted to the psychiatric state hospital of the University of Regensburg (1996–2006)	Shift of diagnoses towards affective and neurotic disorders, increased rates of self-referral. No changes in outcome (Global Assessment of Functioning, Clinical Global Impression scales) inspite of increasing case numbers in the observation period	Study shows that routine data evaluation may inform about new pathways into psychiatric treatment and may yield information about treatment outcomes Evidence level II
Huisman et al., 2009* [43]	Quantitative and qualitative analyses of responses to questionnaires was used to survey 10% of the suicide cases in a Dutch notification system	505 of 5483 suicide notifications were followed up (1996–2006). 227 of these notifications had a response from the inspectorate and were analyzed	The response rate by the Dutch Health Care Inspectorate was only 37%. Younger suicide cases had higher response rates, if treatment was less than a year or when the notification was accompanied by the mental health institution's plans for improving its policies. Recommendations for the study were to place greater emphasis on addressing suicidal impulses and treating older and chronically suicidal patients soon after inpatient discharge	The study showed that the treatment status of the patient, the patient's age and time in treatment were important factors in determining if a response was generated. The study showed also that supervision in mental health care can be optimized in accordance with guidelines. However, the results are not generalizable since they pertain only to the special situation of the Dutch suicide reporting system Evidence level I
Janssen et al., 2010 [45]	Controlled trial. Effects of the introduction of a computerized guideline implementation decision support tool in schizophrenia	522 patients with schizophrenia in outpatient treatment in three German cities	A strong initial but time-limited improvement were found in the patient group whose treatment was supported by a computerized decision support system	Demonstrates modest beneficial effects of a computerized decision support system based on guideline in schizophrenia outpatient healthcare Evidence level I
Janssen et al., 2011* [46]	A short report about benchmarking results in Germany in patients with severe mental illness	1696 patients of nine psychiatric hospitals in Germany	Benchmarking of process and outcome parameters did not result in a significant improvement of quality. But in some hospitals, treatment processes were improved	The study provides an example method for quality assurance by benchmarking in psychiatry routine inpatient care Used for recommendation 2 Evidence level III
Janssen et al., 2011 [47]	Testing of a standardized assessment instrument for coercive measures in psychiatric hospitals	12 Dutch mental health institutions covering 31,594 admissions	Large variations in the type and frequency of coercive measures between the participating mental healthcare services were found	Benchmarking showed large variability of coercive measures (type, frequency) Evidence level II
Katona et al., 2014 [49]	Non-interventional retrospective-prospective parallel arm study	Antipsychotic monotherapy ($n = 5480$) vs. polypharmacy with two antipsychotic drugs ($n = 7901$). Health insurance fund data	Monotherapy was superior for second generation antipsychotics in terms of treatment discontinuation, but polypharmacy was associated with a reduced mortality and hospitalization rate	Indicates that antipsychotic polypharmacy may be warranted in special clinical situations like exacerbation of psychotic symptoms Evidence level II

Table 6 (*Continued*)

Reference	Study type	Population and sample collection	Main results	Comments
Kirschenbauer et al., 2008* [51]	Questionnaire study	677 involuntary hospitalizations in the psychiatric hospitals and departments in Frankfurt/ Main (Germany)	70% of involuntarily admitted patients did not receive any complementary psychosocial care; only 10% were examined by physicians before being transferred to hospital	Specific additional information supplementing routine data yielded results about the non-use of social psychiatric services before involuntary hospitalization in a majority of cases implemented Evidence level III
Kuosmanen et al., 2008 [53]	Register study	Register data (n = 4645 patient complaints) between 2000 and 2004 processed by the five State Provincial Offices of Finland and the National Authority for Medicolegal Affairs	45% increase of patient complaints in the Finnish mental health care service. The outcomes of the complaints showed that the number of measures taken increased from 19% of all complaints to 28%. 99% of the measures were administrative reprimands	Patient complaint systems may lead to practical consequences, although studies are lacking about the efficiency of such services for quality assurance and user satisfaction with them Evidence level II
Kurian et al., 2009 [54]	Controlled trial of the effects of the introduction of a computerized, guideline-based decision support software for depression care	4 primary care physicians, 55 patients	Better clinical improvements in patients receiving care based on computerized decision software	Demonstrates the beneficial effects of computerized guideline-based decision support software in outpatient depression care, but low number of patients Evidence level II
Lasalvia et al., 2008 [55]	Prospective 3 month-prevalence cohort study	188 patients with mental disorders assessed at baseline and at 4 years using the Camberwell Assessment of Need scale	Better staff-patient agreement on needs for care predicted better health outcomes	Agreement of patients and carers on needs is one of the factors influencing patient outcomes Evidence level I
Laursen et al., 2007 [56]	Register-based cohort study	5.5 million persons in Denmark	Excess mortality was found for patients with unipolar depressive disorder, bipolar disorder, schizoaffective disorder and schizophrenia	Study shows that quality assurance measures to assess mortality in patients with severe mental disorders is warranted. A range of possible causes was discussed and suggests that monitoring both mental health state and the somatic health state is warranted. The study also shows the utility of case registries for the use of routine care data in quality assurance Used for recommendations 4 and 15 Evidence level II
Laursen et al., 2009 [57]	Population-based cohort study with 13 year follow-up to determine rates of mortality, somatic healthcare contacts and numbers of invasive cardiac procedures in persons with severe mental disorders	4.6 million persons in Denmark 1994–2007 were assessed. While there was excess mortality due to heart diseases in those with mental disorders, their rates of heart disease-related healthcare contacts and invasive cardiac procedures was similar to the general population indicating under-treatment	Study provides epidemiological indirect evidence for under-treatment for cardiac disorders in persons with severe mental illness	Study proves association but not causality. Quality assurance is warranted to increase the rate of appropriate cardiac treatment in persons with severe mental illness Used for recommendation 4 Evidence level II
Lloyd-Evans et al., 2011 [59]	Comparative analysis of four scales to measure content of care from patient- and clinician-perspectives	Ratings from eight psychiatric inpatient services (three non-hospital crisis houses and five inpatient acute wards)	While one of the four instruments had a good inter-rater reliability (kappa = 0.71), concordance between patient- and clinician-rated scales was low, with patients usually indicating less care received than indicated by clinicians	Demonstrates that point of care assessments are needed and a multi-methods approach taking both the patient perspective and the clinician perspective are warranted Used for recommendation 8 Evidence level I
Lotz-Rambaldi et al., 2008 [62]	Questionnaire study about psychiatry specialty training in Europe	22 questionnaires from 31 national representatives involved and 424 questionnaires completed by the chief of training and the representative of trainees at the responding training centres from 22 countries	Provides evidence for the diversity of European psychiatric specialty training programs	Evidence level II

Table 6 (*Continued*)

Reference	Study type	Population and sample collection	Main results	Comments
Mojtabai et al., 2010 [68]	Analysis of annual data from the 1996–2006 U.S. national ambulatory care survey; systematic random sampling of outpatients visits during a 1-week period	13,079 psychiatric outpatient visits	Increase of the median number of prescribed medications in each visit from one to two during the reporting period	Documents increase of polypharmacy across mental disorders in outpatient settings Evidence level I
Nijman et al., 1997 [70]	Controlled study to assess the effects of interventions for preventing one type of critical incidents (patients' aggression) on a closed acute admission ward of a psychiatric hospital	Dutch psychiatric hospital, assessment of the number and severity of incidents using a standardized scale before and after implementation of an intervention for preventing aggression	No significant effects, but standardized reporting by staff of aggressive incidents on closed psychiatric wards may in itself result in a reduction of violent incidents	Study shows that reporting of critical incidents may serve as a quality assurance tool Used for recommendation 3 Evidence level II
Nock et al., 2009 [71]	Cross-national analysis of the associations among mental disorders and suicidal behavior	World Mental Health Survey	A wide range of mental disorders increased the odds of experiencing suicidal ideations	Shows the increase of suicidal ideation among persons with mental disorders Evidence level I
Nock et al., 2010 [72]	Analysis of associations between mental disorders and subsequent suicidal behavior (suicide ideation, suicide plans and suicide attempts)	National Comorbidity Survey Replication	In the United States, approximately 80% of all suicide attempters have a temporally prior mental disorder	Shows the increase of suicidal ideation among persons with mental disorders Evidence level I
Parker et al., 1996 [73]	Rating of 36 items on referrer satisfaction	Questionnaire study. Completed forms were returned by 52 general practitioners, 26 obstetricians/ gynecologists, and 55 neurologists/ other physicians (overall response rate 53%)	The most important dimensions across the groups of referrers was – following a factor analysis – "accessibility and helpfulness" followed by the quality of the report of the psychiatrist back to the referrer	Supports the notion of multidimensionality of the quality of a referral system indicating especially the importance of psychiatrist characteristics needed for referrers' satisfaction Used in recommendation 9 Evidence level I
Pitman et al., 2011 [75]	Survey questionnaire about the use of cardiovascular screening for people with mental illness. Selection of a representative cross-section of services users, community mental health center staff and primary care staff in Great Britain	The survey was completed by 227 service users, 143 primary care staff and 166 CMHT staff	Main results were the identification of obstacles to service use for cardiovascular screening and that incentives for both providers and users to improve implementation of clinical guidelines seem warranted	The study shows the lack of screening for somatic disorders in mental healthcare Evidence level II
Reininghaus et al., 2013 [77]	Analysis of the use of the Camberwell Assessment of Needs Scales (patient- and clinician-rated versions) in mental healthcare	605 patients with psychotic disorders and their clinicians	The findings support the convergent validity and predictive validity of the CANSAS (hospital days)	Validation data for quality assurance with CANSAS in mental healthcare Evidence level I
Røssberg et al., 2006* [78]	Questionnaire- based longitudinal analyses of one psychiatric ward atmosphere (1981–2000)	129 inpatients in 11 assessments in a Norwegian acute psychiatric ward	Main results were that involvement, practical orientation, angry and aggressive behavior and staff control correlated with patient satisfaction	The study shows an association between treatment experiences in inpatient psychiatric wards and treatment environment, but small numbers of assessments limit the generalizability of the results Evidence level III
Ruggeri et al., 2003 [80]	Assessment of patient satisfaction with mental health services using the Verona Service Satisfaction Scale	404 patients with schizophrenia in Germany, Italy, The Netherlands, Spain and the United Kingdom	Study showed large inter-individual variations of patient satisfaction with mental health services and a range of influencing factors like place of residence, degree of psychopathology, remaining unmet needs and numbers of hospital admissions	Empirical study demonstrating the multitude of factors influencing patient satisfaction with mental health services across Europe Evidence level II
Ruggeri et al., 2006 [81]	Assessment of patient satisfaction with emergency services using the Verona Service Satisfaction Scale	Interviews with 48 patients with schizophrenia, affective disorders or organic psychotic disorders in the United Kingdom and 40 patients in Italy	Patients with access to a well-developed community-based service and crisis intervention were more satisfied that patients with no such access	Describes a special aspect of mental healthcare services (emergency services) and how their organizational structure is related to patient satisfaction Evidence level II

Table 6 (*Continued*)

Reference	Study type	Population and sample collection	Main results	Comments
Ruggeri et al., 2007 [82]	Assessment of the relationship between satisfaction with psychiatric care mental health indicators, including socio-demographic, clinical and service intervention variables	356 patients in community mental health services in Italy	Overall satisfaction was medium-high, while patients with longer duration of service contact and higher disability were the most dissatisfied	Routine assessments of service satisfaction provided insights into quality assurance of community mental health service as regards their strengths and weaknesses Evidence level II
Ruggeri et al., 2008 [83]	Development and implementation of guideline-based quality indicators for schizophrenia treatment	19 Italian mental health services	Some areas of discrepancies between routine care and guideline-principles were identified	Demonstrates the usability of quality indicators in the quality assurance of guideline implementation Evidence level I
Salvador-Carulla et al., 2007* [84]	Benchmarking of mental health services in Spain	12 regional mental health services	One service was identified as a benchmark standard	Example of the use of benchmarking in mental healthcare Used for recommendation 2 Evidence level II
Salvi et al., 2005 [85]	Factor analysis of the Health of the Nation Outcome Scale (HoNOS) and the Camberwell Assessment of Needs Scale (CANSAS)	264 patients newly admitted to mental healthcare services in the United Kingdom with completed assessments of both scales	Both scales can be used to obtain a detailed characterization of clinical and social needs of the patient. Compared with HoNOS, the CANSAS provides extra information about met patient needs	The use of both scales will provide a more comprehensive picture of outcomes than using only a single scale. Limited generalizability due to a small number of patients and only consideration of newly admitted patients Evidence level II
Sánchez et al., 2006 [86]	Report on experiences of introducing the European Foundation for Quality Management (EFQM) model as a quality assessment framework	31 health organizations in Basque County, Spain, including mental health institutions	Scores for most of the EFQM criteria improved during a process of four EFQM cycles. Provision of sufficient resources and long-term engagement in the EFQM process were important factors of success	Results for mental health institutions are limited to patient satisfaction data from one year since psychiatric organizations only started using consumer surveys very late. The study shows the feasibility of implementing the EFQM model in healthcare including psychiatric services Evidence level III
Schmid et al., 2006 [89]	Questionnaire study	25 psychiatrists and 8 psychologists completed the questionnaire and treated 390 patients in general psychiatry	The weekly time spent with relatives is significantly lower (6.5 minutes) than the German official calculations demand (11.9 minutes). There was an average of 76.2 minutes per week for a therapist to spent time with relatives	Study indicates the importance to include the analysis of contact times with relatives of patients with mental disorders in quality assurance. The study was only performed at a single psychiatric hospital, which limits the generalizability of the results Evidence level III
Schmidt-Kraepelin et al., 2013 [90]	Medication assessment in a representative sample of patients with schizophrenia	638 inpatients with schizophrenia	44% of patients had more than one antipsychotic drug	Shows a high rate of polypharmacy among inpatients with schizophrenia. Limited generalizability due to single setting only Evidence level II
Slade et al., 1999 [92]	Parallel use of the Camberwell Assessment of Needs (CANSAS) questionnaire in mental healthcare and the Health of the Nation Outcome Scale (HoNOS)	382 patients with mental disorders in the United Kingdom	Both scales differ in the domains they assess: HoNOS can track changes in social functioning and appears less useful for treatment planning. CANSAS can indicate useful times for treatment commencement	Evidence to use both scales in parallel as they assess different domains of mental healthcare Evidence level II
Slade et al., 2004 [93]	Use of the Camberwell Assessment of Needs Scale and the Lancashire Quality of Life Profile to investigate the relationship between meeting needs and quality of life	1-year follow-up study was achieved in 121 patients in community mental healthcare in Italy	Inverse relationship between quality of life and unmet needs	Demonstrates that unmet needs are associated with reduced quality of life in community mental healthcare Evidence level II

Table 6 (*Continued*)

Reference	Study type	Population and sample collection	Main results	Comments
Slade et al., 2005 [94]	Use of the Camberwell Assessment of Needs questionnaire in mental healthcare	101 patients using adult mental healthcare services in the United Kingdom	Regression model of results showed inverse relations between levels of needs and quality of life	Provides a rationale for including needs assessment in quality assurance of mental healthcare Used in recommendation 17 Evidence level II
Spiessl et al., 2006* [98]	Development of a patient and relatives questionnaire to evaluate patient expectations and satisfaction in psychiatric hospitals. Following qualitative content analyses of interviews with inpatients, relatives, general practitioners, psychiatrists and staff members of social psychiatric services a self-report questionnaire was developed	598 persons (n = 344 inpatients of psychiatric hospitals, n = 58 relatives, n = 156 general practitioners and psychiatrists, n = 40 employees of socio-psychiatric services) completed the questionnaire	The results of the questionnaire show that the expectations towards inpatient mental health care differ between the user and staff groups	Draws attention to include patient satisfaction with experienced services and assessments of the needs of patients in quality assurance Evidence level II
Spiessl et al., 2009* [99]	Self-report questionnaire to evaluate patient' satisfaction. The questionnaire was developed after qualitative content analyses of interviews with 38 patients	Inpatients (n = 366) of the psychiatric hospital in Regensburg and of the psychiatric ward in a hospital in Darmstadt (n = 130)	The satisfaction of inpatients mainly depended on treatment success, doctors' and nurses' attention to patients' and inpatients' participation in treatment decision	Multidimensionality of the concept of patient satisfaction in quality assurance is demonstrated by this study. Limited generalizability due to only two settings in which assessments were performed Evidence level II
Spiessl et al., 2004* [97]	Following a qualitative interview phase, a 41 Item questionnaire was developed to cover satisfaction and expectations of inpatients' relatives	The questionnaire was sent to n = 139 relatives. It was completed by n = 58 relatives (response rate 41.7%)	Discrepancies between expectations and satisfaction of relatives were found especially regarding psychotherapy, information to relatives regarding therapies, medication, side effects and progress of treatment, and the clarity of the explanations. Relatives demanded more support and information about reintegration after inpatient care	The study points out that the collaboration with family caregivers has to be intensified and personalized, as well as optimized according to the relative's needs Evidence level III
Steinert et al., 2010* [100]	Assessment of clinical outcome by patients and doctors using standardized rating scales (clinical global impression and patient global impression)	3957 simultaneous patient and doctor assessments in German in- and outpatient mental healthcare (out of 5625 patients, i.e., 70.3% rate of simultaneous assessments)	Patient- and clinician-rated outcomes were similar in about 50% of cases, while in approximately 25% of cases patients rated their outcome better or less favourable than the treating clinicians	Concurrent use of the same scale by patients and doctors may reveal discrepancies of assessments by both groups Limited practicability (70% of cases were rated) Evidence level II
Sullivan et al., 2006 [104]	Routine data analysis	Emergency visits for diabetes (n = 4275)	Persons with diabetes and co-occurring mental illness were less likely than those without mental illness to be hospitalized after an emergency department visit (odds ratio .55)	Provides evidence for disparities of somatic healthcare for diabetes among persons with and without a mental disorder Evidence level I
Thornicroft and Slade, 2014 [107]	Unsystematic review and opinion paper	Development of a taxonomy of eight domains of outcome assessments in mental healthcare	Domains include the target population, the scientific stage of development of the outcome domain, the kind of outcome domain, the level of assessment, the use of recovery as an outcome concept, the perspectives to be considered, a focus on strengths or deficits, and whether invariant or personalized measures be preferred	Provides a taxonomy of outcome assessments indicating the complexity of quality assurance using outcome measures Evidence level III–IV
Vallejo et al., 2007 [108]	Report on experiences of introducing the European Foundation for Quality Management (EFQM) model as a quality assessment framework	Acute psychiatric ward of a university general hospital	Most of the EFQM principles could be implemented and was helpful for identifying areas of potential optimization of the mental healthcare service, with some improvements in staff communication and involvement	Proof of principle study for the implementation of the principles of the EFQM model in a psychiatric ward. Limited generalizability due to the single setting Used for recommendation 1 Evidence level III

Table 6 (*Continued*)

Reference	Study type	Population and sample collection	Main results	Comments
Van Dijk et al., 2014 [109]	Controlled study	Anxiety treatment guideline implementation vs. guideline dissemination in specialized mental healthcare settings	Systematic guideline implementation resulted in earlier clinical benefits and shorter treatment times	Controlled clinical trial showing benefits of guideline implementation in mental healthcare of patients with anxiety disorders Used in recommendation 10 Evidence level I
Van Weeghel et al., 2011* [112]	Standardized interview instrument and structured group sessions to assess the effects of the introduction of guidelines	Average of 38 community patients with schizophrenia participated in each of eight regions in the Netherlands	Availability of the entire range of care elements of schizophrenia guidelines increased, and slight improvements of patient satisfaction occurred	Standardized interview instruments can be helpful for service monitoring and development, but generalizability needs to be demonstrated Evidence level II
Van Winkel et al., 2006 [113]	Full laboratory screening	415 persons with schizophrenia	6.3% met criteria for diabetes and a 2-step method of screening using an oral glucose tolerance test resulted in improved screening sensitivity	The study suggests a high incidence of diabetes among those with schizophrenia and that a 2-step screening method for diabetes is warranted in persons with schizophrenia Used for recommendation 4 Evidence level I
Wells et al., 2005* [116]	A screening interview and a telephone interview were used at baseline. The follow-up surveys were mailed questionnaires. In a randomized controlled trial, the study compared the effects of usual care with the effects of a complex quality improvement program addressing medication management or psychotherapy management by evidence-based recommendations	604 patients with depressive disorder and sub-threshold depression participated. (usual care $n=161$, medications quality improvement $n=211$, psychotherapy quality improvement $n=232$)	Quality improvement interventions improved 57 months-outcomes (probable depression, unmet need, or both)	Generalizability to the European situation is questionable, but study provides proof of principle from a controlled clinical trial for the efficacy of complex quality improvement interventions in long-term follow Evidence level I
Wiersma et al., 2009 [117]	Study on the sensitivity to change of the Camberwell Assessments of Needs scale (CANSAS), patient- and clinician-rated assessments	294 patients with schizophrenia in four European countries	Unmet needs decreased significantly over time. Sensitivity to change of unmet needs was high: about two third of all unmet needs made a transition to no or met need, and more than half of all unmet needs at follow-up were new. Agreement between patient and clinician on unmet needs at baseline as well as follow-up was rather low	Provides transnational evidence of the sensitivity to change of the CANSAS scale Used in recommendation 17 Evidence level I
World Health Organisation, 2008 [121]	Review of the percentage of funding allocated for mental health services compared to total health budget	Survey of the WHO Europe region countries	Funding allocated to mental healthcare compared to total health budgets or expenditures varied greatly between the European countries (2.0–13.8%)	Study shows large differences of mental healthcare spending compared to the spending for physical disorders in the different European countries. Study also discusses limitations of comparing different mental healthcare systems and the funding systems Used for recommendation 5 Evidence level II
Wright and Parker, 1998 [124]	Pilot study on the implementation of an incident monitoring service in psychiatric inpatient services	Eight psychiatric inpatient services	Development of a unified incident reporting system for use by psychiatric clinicians	Limited generalizability due to age of the study and the limitation to participants from Australia and New Zealand, but demonstrates feasibility of implementing critical incident reporting systems in mental healthcare services Used for recommendation 3 Evidence level III

Asterisks indicate studies identified through the systematic search. All other studies were identified by hand search.

respect for human rights and patient autonomy, friendliness of staff members, clean facilities and effective treatment. The strength of this study is that several mental healthcare settings and different groups (patients, relatives and professionals) were studied (evidence level II).

An Italian Study – the South-Verona Outcome Project – analysed in 356 patients across three subsequent waves the relationship between satisfaction with psychiatric care and a number of well-established mental health indicators, including socio-demographic, clinical and service intervention variables. Overall satisfaction was medium-high, while patients with longer duration of service contact and higher disability were the most dissatisfied. The study showed that repeated routine assessments of service satisfaction provided insights into quality assurance of community mental health service as regards their strengths and weaknesses [82]. Another study compared satisfaction with response to emergencies in community mental health services in South-Verona and London [81]. The findings suggest that users of a service with a well-developed community-oriented approach and with crisis intervention outside the hospital setting are more satisfied with the emergency interventions than users of a mental health service relying mostly on hospital facilities during emergencies.

For quality assurance in this area of mental healthcare, it would be necessary to not only assess patient satisfaction, but to also give patients an easy and effective way to communicate dissatisfaction. A Finnish study analyzed five years (2000–2004) of patient complaints ($n = 4645$) showing that mental healthcare in Finland had the smallest increase of complaints among all medical specialties, but the increase was still statistically significant (45%; [53]). In 19% (2000) to 28% (2004) of complaints, corrective measures were taken, mainly as administrative reprimands. This study shows that such patient complaint systems may lead to practical consequences, although studies are lacking about the efficiency of such services for quality assurance and user satisfaction with them. Of note, there are also interrelationships between trust by patients in mental healthcare services and similar factors as those identified in the previously mentioned studies regarding patient satisfaction. A previous EPA Guidance has developed separate recommendations regarding improvements of trust by patients and the public in mental healthcare services [27].

The group of relatives and other persons close to patients with mental disorders has quality expectations just as the patients and this is a major determinant of mental healthcare utilization, as a study by Donath et al. [20] showed. The study used a questionnaire to assess the opinions of 404 care-providing family members of dementia patients. The quality expectations mainly related to the qualifications of mental health personnel in day care and the quality of the therapeutic interventions. A similar study in a general psychiatric hospital setting using questionnaires for 32 relatives also showed the importance of high-quality treatment, thorough information about procedures, assurance of the provision of psychotherapy, and measures of empowerment of patients [97]. These studies are limited in their generalizability due to the fact that they were performed at single sites. The study by Spiessl et al. only had a small number of participants (evidence level II–III). These studies indicate that the incorporation of the expectations of the opinions of family members of the mentally ill is warranted in the quality assurance of mental healthcare, because it may provide information about expectations and experiences not otherwise available in the process of quality assurance. Another study in Germany used a questionnaire to assess whether psychologists and psychiatrists of a mental healthcare inpatient service allocated the time indicated by the Psychiatry Personnel Act to collaboration with relatives of inpatients with mental disorders [89]. The study showed that the required time periods were not met, indicating another piece of evidence for the need to include collaboration with relatives of the mentally ill in the EPA Guidance recommendations, although studies from other countries are lacking and the study was only performed at a single psychiatric hospital, which limits the generalizability of the results (evidence level III). We have formulated this in recommendations 8, 16 and 17, which recommend to include patient- and caregiver views when assessing the contents and outcomes of mental healthcare.

3.3. Using referrer assessments of the referral process between inpatient and outpatient mental healthcare services for quality assurance of mental healthcare

In a recent review, Qurishi et al. identified only few studies on criteria for good referral systems in psychiatry [76]. Among the relevant criteria, communication aspects between referrers and psychiatrists take centerstage, in that the referral letters often lack necessary details and in that the necessary bidirectionality of the information flow is often hampered ([8,73,96,103,106], evidence level I–III). This applies both to general practitioners and outpatient psychiatrists as referrers. In a smaller study, Gebhardt et al. [31] assessed the experiences with cooperation by 15 employees of social psychiatric services (evidence level III), showing that this may identify areas of expectations of potential referrers. In a qualitative study using a focus group approach, Bramesfeld et al. [7] addressed the opinions of 47 participants representing a large range of different mental healthcare service providers as to perceived barriers in mental healthcare across disciplines, services and service sectors in Germany. Although selection bias may have played a role and the number of groups of participants from different service providers was low, the study gives some indications on presumable factors fostering or inhibiting improvements of cooperation among mental healthcare service providers including potential referrers. The main recommendation was to systematically implement regional and sustainable mental health networks and to introduce interdisciplinary collaboration into the curricula of medical students and residents in psychiatry. Taken together, the results from these studies indicate that it is warranted to include referrer assessments and assessments of the quality of the referral process in quality assurance in mental healthcare, that sustainable networks of cooperation are necessary, and that interdisciplinary cooperation needs to be considered in specialty training curricula of all professions involved in mental healthcare. Accordingly, recommendation 9 also deals with the need to implement quality assurance of the referral process.

3.4. Using routine data for quality assurance in mental healthcare

For quality assurance purposes, routine data provide the opportunity to assess the quality of structures, processes and outcomes only in a limited fashion. This is due to the organizational non-availability of data, incompleteness of data sets and lack of assessment of outcome data for the inclusion in routine data, but they may be of use as quality indicators and outcome may be the most important area of the assessment of quality assurance and quality improvement [24]. Besides this, it is expected that there are wide variations of the type, quality and accessibility of routine data in the different European countries, but systematic surveys about these issues are lacking. Supplementation of routine data with specific additional care data for quality assurance purposes would be expected to be necessary to assess specific mental healthcare questions, like in involuntary hospitalizations, in which a German study showed that specific additional information yielded important results about the non-use of social psychiatric services before involuntary hospitalization in a majority of cases [51]. In another

study, benchmarking of mental healthcare processes and outcomes in a German association of psychiatric hospitals also necessitated the use of specific additional survey instruments besides routine data [46]. The results were variable between the participating departments. For quality assurance on the meso- to macro-level, another study analyzed treatment pathways of patients between in- and outpatient mental healthcare services including an increasing trend towards self-referral for inpatient psychiatric care by patients [41,42]. In another study using routine data from statutory health insurance companies, Gaebel et al. [26] showed the multitude of service pathways for mental healthcare patients. Both studies showed that there were complex associations between type of service use, outcomes and mental disorder types. Taken together, these studies indicate that a recommendation to use routine data for mental healthcare research is warranted with a view to identify care pathways and how these influence the help-seeking behavior of patients and their families. Case registries are important elements of routine data collections and may yield important quality assurance information (see, for example, [56]). We have accordingly formulated recommendation 15 to use routine data in quality assurance whenever possible.

3.5. Using quality indicators for quality assurance in mental healthcare

Baars et al. [2] performed a systematic review of performance indicators in mental health care and identified 30 studies, but did not provide details about the indicators. Based on their findings, the authors developed a conceptual framework for the classification of performance indicators and a model for the use of information gained from performance measurements. However, these models are not based on studies, so that their evidence level is IV and they do not result in recommendations for the EPA guidance. An overarching issue to improve the processes, structures and outcomes of mental healthcare by means of quality assurance would be the introduction of quality indicators based on evidence-based guidelines and their implementation for all of these areas. While we could not identify any studies assessing the question whether the introduction of quality indicators in mental healthcare leads to the expected improvements, there are now studies showing the systematic development of such indicators in mental healthcare [33,37,95], and their implementation to assess guideline fidelity and serving benchmarking purposes [83]. A global survey identified more than 600 quality assurance measures in mental healthcare ([21], evidence level II). A recommendation is warranted to initiate studies to evaluate the feasibility of quality indicator implementation and their efficacy in assuring the quality of mental healthcare, especially in conjunction with guideline implementation (included in recommendation 10 dealing with the implementation of guidelines).

3.6. Using benchmarking for quality assurance in mental healthcare

Benchmarking using routine data has been used for quality assurance purposes in mental healthcare in England, Scotland, Germany, Spain and the United States ([10,38,46,66,84]; evidence level I–III). Such assessments showed large variations on the provider level regarding the kind of benchmarking. These studies demonstrated the feasibility of benchmarking for quality assurance of mental healthcare, although it proved to be a labor-intensive process. Further studies are needed to show how such data are used for adapting mental healthcare processes to needs, but a recommendation is warranted to use benchmarking for quality assurance in mental healthcare (recommendation 2).

3.7. Screening for physical disorders in patients with mental disorders

An important aspect of mental disorders is the increased rate of somatic disorders in patients with mental disorders, which is associated with excess mortality [56,57] and insufficient rates of somatic healthcare provided to those with severe mental disorders [57,104]. A systematic review showed that the numbers of randomized controlled trials to evaluate interventions to improve somatic health in severe mental illness was limited, indicating a need for further controlled studies to identify the optimal interventions [111]. Previous reviews had shown that the quality of the preventive and screening services for somatic disorders received by patients with mental illness was often lower, but occasionally superior to that received by persons with no mental disorder [61]. Especially the increased risk of cardiovascular diseases is well established in people with mental disorders, with relative risk (RR) increases in the range of 1.3–1.9 based on register studies [28]. Pitman et al. [75] performed a questionnaire survey of 227 mental health service users, 166 community mental health staff and 143 primary care staff about perceived obstacles to service use of cardiovascular screening in people with severe mental illness in England. The strengths of the study are the large number of participants and the balanced selection of participants both from rural and urban areas. While the majority of participants agreed with the need for heart checks and the majority of users had received screening tests for cardiovascular disorders in the previous year, health promotion advice had only been received by 20–50% of service users. There was also a discrepancy between the interest of service users in this topic and their willingness to attend the offered programs. Taken together, the survey shows that there is still a gap in cardiovascular screening and the implementation of prevention programs, so that a recommendation is warranted to include such measures in the EPA Guidance for quality assurance recommendations (evidence level II). Therefore, reviews recommend to implement multidisciplinary assessments of mental and physical conditions in psychiatric settings [12] with a special emphasis on diabetes and other metabolic abnormalities in patients with schizophrenia and schizoaffective disorders [113], and cardiovascular disorders in people with severe mental illnesses [11]. Based on this evidence, it is recommended to implement structures of multidisciplinary assessment of physical conditions in psychiatric settings (recommendation 4). An additional factor would be the parity of funding of mental and physical health, which may also serve to provide quality assurance for the "quality of esteem" of mental as compared to somatic healthcare. In the UK, an analysis by the Royal College of Psychiatrists showed that mental disorders accounted for 28% of the morbidity of the population, but that expenditures for mental health services was only 13% of total expenditures of the National Health System [22]. A recent study showed that expenditures in Eastern European countries as part of the total health expenditure was especially low: the average for the WHO European region was 6.3% and 2.5–8.0% in Eastern European countries [16]. A similar study by the WHO had also shown that the Eastern European countries were mostly beneath the European average for mental healthcare spending as a ratio of total healthcare spending [121]. Taken together, these figures indicate that there is currently no parity between the funding for mental and physical health, and that large differences exist between the European countries as to the degree of disparity of funding. Therefore, a recommendation was warranted on the macro-level to address the issue of parity of funding (recommendation 5).

3.8. Guideline development and implementation

As a further more general process recommendation, the implementation of guidelines may be useful in quality assurance

in mental healthcare. A Cochrane review recently investigated whether there was evidence that schizophrenia guidelines had any impact on provider performance or patient outcomes [5]. Only five studies were found and due to methodological heterogeneity, a meta-analysis was only possible for the question for antipsychotic drug therapy. Although small changes in psychiatric practice were found, uncertainty remained as to whether clinically meaningful effects of treatment guidelines on patient outcomes occurred and how to best implement guidelines for maximal benefit. In anxiety disorders, guideline implementation led to shorter treatment times [109]. Other studies indicate that comprehensive, service-specific interventions and guideline implementation improve the quality of mental healthcare [116,118]. Against the background of this limited and inconclusive evidence, it is recommendable to use guideline recommendations for quality assurance in mental healthcare (recommendation 10). Note that such guidelines should not only cover psycho-pharmacotherapy, but also the "talking" aspects of psychosocial interventions used in mental healthcare. As regards assessment instruments to be used in the quality assurance of guideline implementation, we identified an Italian study using quality indicators to assure guideline implementation in mental healthcare [83] and a Dutch study using a specifically developed instrument (QUARTS, Quality Assessment of Regional Treatment Systems for Schizophrenia; [112]). The instrument consists of two questionnaires about schizophrenia care including the major interventions recommended in the Dutch schizophrenia guideline and a second questionnaire about patient and carer satisfaction. They are employed in structured group sessions of mental health professionals, patients with schizophrenia, family members and representatives of community organizations. The study showed improvements in all studied eight regions of the Netherlands of the availability of care elements following the introduction of the multidisciplinary schizophrenia guidelines [110,112]. This shows that the instrument is sensitive to change and feasible, but further studies with other diagnostic groups and in other countries would be necessary to increase the generalizability of the findings.

Using a qualitative study design, Hannes et al. [35] explored barriers to the implementation of evidence-based practices in psychiatry. Five focus groups with a total of 39 Belgian psychiatrists were performed following purposeful sampling of participants with an interest or expertise in evidence-based practice, and from a range of geographical regions and settings (in- and outpatient care). The interviews showed that a range of problematic areas and barriers for the implementation of evidence-based practices was mentioned. Five clusters of problem areas emerged: Characteristics of patients, characteristics of evidence, characteristics of psychiatry, characteristics of the commercial partners (which means, among other issues, attempts to influence psychiatrists' decisions) and characteristics of government. Although the study provides a good level of evidence especially due to its sampling procedure (evidence level I–II), the complexity and number of identified problem areas precludes using these results for a specific EPA Guidance recommendation. However, based on this study, it can be recommended to consider all these problem areas in future studies aimed at increasing the implementation of evidence-based practices in psychiatry. This notion is supported by a review by Härter et al. [36], who reviewed a German program to foster the implementation of a depression guideline and showed that the availability of guidelines, the introduction of quality management measures, public relations activities, training and continuing medical education, health services research and monitoring could be areas of fostering improvements. Another useful approach may be to use guideline-based computerized decision support systems, whose application showed some modest benefits in schizophrenia and depression healthcare [45,54] and guideline-based quality indicators (see Section 3.4). A recommendation was thus formulated to use the established national guidelines and quality indicators for quality assurance (recommendation 10).

3.9. Outcome monitoring

An important aspect of quality assurance in mental healthcare is the monitoring of the outcomes. Such an approach is now part of new concepts using outcome data to guide therapy by using information technology methods ("measurement-based care", reviewed by [34]). Thornicroft and Slade [107] provided a conceptual taxonomy of outcome assessments indicating the complexity of quality assurance using outcome measures, and including needs assessments as outcome assessments, because mental healthcare should result in reduced needs. Another aspect may be the agreement between clinical staff members and patients in the assessment of needs, which makes a contribution in predicting patient outcomes [55]. Using the same scales for patient and doctor assessements of clinical outcome showed that agreement was obtained in approximately 50%, while there were divergent assessments in the other 50% [100]. In practice, outcome assessments in mental healthcare may involve a wide range of outcome areas including, but not limited to, death rates, utilization rates of different types of mental healthcare services, symptom severity, social functioning and patient satisfaction as indicators of quality of life (see, for example, the Cochrane review on the efficiency of community mental health services by Malone et al. [63]). Standardized outcome measures can be used on national levels to assure the quality of mental healthcare, as has been shown by a large Australian study [9]. For each of these domains of outcome assessments, a variety of scales or questionnaires is available and it would be recommended to use scales validated for the specific countries. While some of these measures like death rates or service use data could be obtained from routine data, their accessibility is often limited due to national personal data protection regulations. Similarly, scales of symptom severity are often used in hospital databases, but may not be available in a usable format.

Alternatively or supplementing the available data sources, combined outcome scales may be used. An example is the "Health of the Nation Outcome Scale", which was developed by the Royal College of Psychiatrists and is used routinely in the United Kingdom, and for which three versions (for child and adolescent psychiatry, adult psychiatry, and geriatric psychiatry) are available ([13]; evidence level II). Validation in other countries than the United Kingdom is limited and its practicability has been discussed critically. In summary, it is recommended to use outcome assessments for quality assurance of mental healthcare, but the selection of which domains should be assessed with which scales would be up to the individual European countries and would be dependent on data availability (recommendation 16).

High-quality studies have shown that outcome measurements alone focusing on the domains listed above have limited value for guiding individual patient treatment selection processes, but need to be supplemented by scales assessing remaining individual patient treatment needs ([85,92]; evidence level II). This will contribute to the quality assurance in mental healthcare outcome assessments as it will draw attention to areas of patient needs not identified or not met in routine care. Needs assessments are correlated with the quality of life of patients with mental disorders [93,94] and are highly sensitive to changes in mental healthcare practices ([117]; evidence level I).

Therefore, it is recommended to supplement standard outcome assessments with an assessment of patient needs (recommendation 17). For this purpose, several scales are available and it may be

recommended to use a standardized scale like the Camberwell Assessment of Needs scale or other scales validated in individual countries. Both patient- and clinician-rated versions are available and factor analyses showed that items of these two versions loaded on a common factor of unmet needs with both convergent and predictive value (for hospital days) ([77]; evidence level I). Caregiver assessment of needs will usefully complement the patient-rated needs, as was shown in dementia patients [4]. Note that we use a recommendation for standardized needs assessments among the outcome measures of quality assurance for mental healthcare, as one of the desired outcomes of mental healthcare is to match the patient needs with the achieved outcomes, which should lead to low scores on need assessment scales [77].

3.10. Content of care monitoring at the point of care

Mental health quality assurance is only possible if the processes of care taking place in mental health services are known in sufficient details. Therefore, close to the point of care, i.e., on the level of individual mental healthcare services locally, it is necessary to assess the "content of care" using standardized scales, of which several are available which use patient, family or clinician information sources ([58,59]; evidence level I–II). Usually, patients indicate that they have received less care than clinicians indicate. Methodologically, these scales show little correlation among each other and while studies determining which is the best scale regarding psychometric are warranted, it is recommended to choose several scales which cover both the patient perspective and the clinician perspective, and which have been validated for the respective service type if possible and use it consistently over longer periods of time for quality assurance purposes and to check if services comply with national standards of mental healthcare, for example with those described in national disorder-specific treatment guidelines (recommendation 8).

3.11. Therapeutic drug monitoring

Among the process quality assurance measures in mental healthcare, one of the most tested is therapeutic drug monitoring and consensus guidelines are available for therapeutic drug monitoring in psychiatry [40]. It is part of the point of care monitoring approach and it is based on the assumption that there is a relationship between blood levels and clinical effects (both therapeutic and adverse) [39]. Therapeutic drug monitoring following the published consensus guidelines is therefore recommended as a quality assurance of the process of psycho-pharmacotherapy (recommendation 11).

3.12. Polypharmacy

In the process of psycho-pharmacotherapy, a trend of recent years is an increase of polypharmacy, [32,68,90]. Polypharmacy is associated with increased side effects and should remain a last resort following failure of monotherapy [29], although polypharmacy may be warranted in special clinical situations [49]. There is no evidence for cost-effectiveness [60]. Therefore, it is warranted to include a recommendation to avoid polypharmacy in the psycho-pharmaco-therapy of mental disorders (evidence level I–II). Careful switching from poly- to monopharmacy seems to be warranted following a recent review (evidence level I–II; [105]), but evidence in this area of research is still scarce (recommendation 12).

3.13. Monitoring of coercive measures

Compulsory treatment in psychiatry is an ethically and clinically contentious issue [91] and experiences of coercion diminish patients' trust in mental healthcare services [27]. The quality of mental healthcare should be targeted to reduce coercive measures as much as possible. In Europe, there are huge differences between countries and within countries in the rate of coercive measures like seclusion and restraint in psychiatric hospitals [3,47,101]. Also, practices may change with changes in jurisdiction or mental health policy [102]. Interventions are available for reducing the use of seclusion and restraint, for example, increased staff-to-patient ratios, psychiatric emergency response teams, staff education and monitoring of seclusion episodes [30,88]. Thus, it is recommended to implement such structures, which may reduce the risk of coercive measures in mental healthcare and to harmonize the ways of how coercive measures are defined and assessed in Europe (recommendation 6).

3.14. Monitoring of suicidal intention and ideation

Large epidemiological studies have shown that mental disorders are among the strongest predictors of suicide attempts [71,72]. Therefore, monitoring suicidal ideation (intentions) and behavior (suicidal attempts, gestures, planning) is an important element in the prevention of suicides in mental healthcare. A recent review came to the conclusion that current guidelines address similar aspects of suicide risk assessment and management, but differ in recommendations [6]. Therefore, it is recommended to implement the EPA Guidance on suicide treatment and prevention for quality assurance purposes unless a binding national guideline is available ([115]; recommendation 13). Two studies addressed the effects of the Dutch supervision system for suicides of mental health care users introduced in 1984. These studies showed that there was ambivalence by healthcare providers about this system, which was reformed in 2011 [43,44]. Although the results of these studies show that many factors come into play when such reporting procedures are introduced, we refrain from generating guidance recommendations based on these studies since they do not seem to be generalizable to the situation in other European countries given the background of a country-specific audit system. Still, there is a need to address the quality assurance of suicide prediction and suicide prevention, but no studies are yet available providing evidence about effective measures of quality assurance.

3.15. Critical incident monitoring and reporting

A major topic is the quality assurance of critical incident monitoring and reporting. This includes the establishment of a critical incident reporting system as a structural requirement to monitor the occurrence of such critical incidents. As a rule, such systems operate on the basis of anonymous reports of critical incidents. While we found a number of examples for such monitoring systems in mental healthcare, we could not find studies on their effectiveness in assuring the quality of mental healthcare. An Australian study had shown that critical incident monitoring as an instrument of quality assurance in psychiatric inpatient services revealed a small number of incident types (adverse outcomes and "near misses"; [124]). A single Dutch study indicated that standardized reporting by staff of aggressive incidents on closed psychiatric wards might in itself result in a reduction of such incidences [70]. An unsystematic review showed that monitoring adverse drug events and medication errors in psychiatry was an important element of strategies to contain the risk associated with these factors [64]. A systematic review came to the conclusion that more research was needed to formally evaluate the outcomes of the implementation of risk monitoring systems and their effectiveness [119]. We still deemed it necessary to recommend the implementation of anonymous critical incident

reporting systems for quality assurance purposes (recommendation 3).

3.16. Implementation of general standards in mental healthcare

Agius et al. [1] developed a set of 28 standards for the management of patients with common mental illnesses in primary care. However, the process of standard development is not transparent. The evidence for these recommendations is intermediate and an update and review of the standards would be necessary to ascertain that the currently available evidence still supports them. Also, there is lack of transparency of the evidence retrieval and evidence evaluation processes of this study. The unsystematic way of evidence evaluation and standard development lead to an evidence level of IV. We therefore decided not to include these standards in the EPA Guidance on quality assurance, but they can be recommended as a source of potential future standards for outpatient mental healthcare. For assuring the general quality of mental healthcare services structures and processes, various forms of quality management certification systems are used. Spanish studies showed that quality assurance as with the excellence model of the European Foundation for Quality Management (EFQM) could be implemented and had positive effects on staff communication [86,108]. The Royal College of Psychiatrists uses a standards-based accreditation program (AIMS) for similar purposes. The previous European Guidance on the quality of mental health services provided additional evidence-based suggestions for quality assurance [25]. Both the physical and the psychosocial quality and aesthetics of the mental healthcare facilities come into play here. Therefore, it is recommended to use nationally established accreditation and certification standards to assure the structural quality of mental healthcare services (recommendation 1). Note that these systems usually are not confined to the quality assurance of structures, but also include recommendations for process quality assurance. If no national standards are available, it is recommendable to consider their development and establishment.

3.17. Mental healthcare for migrants

An increasing part of the European population has a background of migration from other countries inside and outside Europe. A qualitative study among European mental healthcare professionals showed that three challenges were experienced: complications with diagnosis, difficulty in developing trust, and increased risks of marginalization [87]. There is a relatively broad consensus among experts about the major principles of good practice for mental healthcare of immigrants in Europe [14]. A qualitative study showed that there is a need to improve the availability of data on immigrant mental healthcare in Europe and to provide more consistent access to interpreting services [52]. Quality assurance of mental health care for immigrants and refugees should therefore include equal access to services, culturally sensitive care in mainstream services, provision of interpreting (when needed) and building professional collaborative relations with immigrant communities (meso- and micro-level; recommendation 14; [14,52,87]).

3.18. Providing an adequately trained mental healthcare staff

A structural prerequisite for quality assurance is the provision of adequately trained medical and nursing staff, who is taking part in programs of continuing education. Although we did not identify formal studies in this area, a recommendation is warranted to ascertain a high degree of professional standards and certifications where demanded by national applicable laws. Previous reviews have shown that providing well trained clinical staff is an important element of fostering trust by patients with mental disorders [27] and that providing materials of continuing medical education may support guideline implementation [36]. Specialty programs in Europe vary widely [62]. The European Psychiatric Association has addressed this issue in its Guidance on post-graduate psychiatric training (evidence level II–III; [65]). The Section of Psychiatry of the Union of European Medical Specialties (UEMS) has developed a formal qualification profile of psychiatrists, which may serve as a guideline for the quality assurance of national psychiatric specialty, for example through structured audits (http://uemspsychiatry.org/wp-content/uploads/2013/09/2009-Oct-EFCP.pdf; last accessed December 27, 2014). For assuring the quality of local specialty training programs, the UEMS has also provided an assessment scheme, which is, for example, used by the German national psychiatric associations for voluntary audits of specialty training programs in psychiatry (http://uemspsychiatry.org/wp-content/uploads/2013/09/schemeAssess.pdf; last accessed December 27, 2014). For continuing medical education of board certified psychiatrists, there is currently no overview of the requirements in the different European countries. Germany and Hungary, for example, have introduced compulsory CME for all medical specialties and the need to acquire 250 CME points within five years. The UEMS has provided a report on the framework of CME and its quality assurance, for example by certification of CME activities (http://uemspsychiatry.org/wp-content/uploads/2013/09/CME.pdf; last accessed December 27, 2014). Taken together, a recommendation was formulated to address the quality assurance of specialty training programs for all professions involved in mental healthcare (recommendation 7).

4. Recommendations

The following recommendations start with recommendations about structures followed by recommendations about processes and then outcomes. For each recommendation, it is indicated whether it is on the macro-level (whole national health system), the meso-level (health care provider level up to a regional level) or the micro-level (individual patient care level).

4.1. Structure recommendations

4.1.1. Recommendation 1

The European Psychiatric Association considers (Grade of recommendation: B) that nationally established accreditation standards should be followed in mental healthcare services to assure a sufficient structural quality is provided (macro- and meso-level recommendation; Section 3.16; evidence grade I–III; [25,108]). If no such standards are available in individual countries, initiatives to develop and implement them are warranted.

4.1.2. Recommendation 2

The European Psychiatric Association considers (Grade of recommendation: B) that benchmarking between mental healthcare services of structures, processes and outcomes is useful to foster quality assurance (meso-level recommendation; Section 3.6; evidence grade I–III; [10,38,46,66,84]).

4.1.3. Recommendation 3

The European Psychiatric Association considers (Grade of recommendation: C) that critical incident reporting systems allowing reporting of critical incidents by anonymous carers are useful to assure the quality of mental healthcare services especially regarding medication errors in psychiatry (meso-level recommendation; Section 3.15; evidence grade II–III; [64,70,119,124]).

4.1.4. Recommendation 4

The European Psychiatric Association considers (Grade of recommendation: B) that structures of multidisciplinary assessments of physical conditions of patients with severe mental illnesses are useful to detect somatic disorders and assure the quality of general healthcare in psychiatric settings (meso-level recommendation; Section 3.7; evidence grade I–III; [11,12,56,57,113]).

4.1.5. Recommendation 5

The European Psychiatric Association considers (Grade of recommendation: C) that national healthcare budgets should have a parity of funds for mental and physical healthcare (macro-level recommendation; Section 3.7; evidence grade II–III; [16,22,121]).

4.1.6. Recommendation 6

The European Psychiatric Association considers (Grade of recommendation: B) that structures need to be established in psychiatric wards, which contain or reduce the use of coercive measures, and that European harmonized definitions and assessment methods for coercive measures need to be developed (meso- and micro-level; Section 3.13; evidence level I–III; [3,30,88]).

4.1.7. Recommendation 7

The European Psychiatric Association considers (Grade of recommendation: C) that quality assurance in mental healthcare needs to include boards to assess the degree of professional qualification and assure continuing education for those working in mental healthcare using national standards (macro-level; Section 3.18; evidence level I–III; [27,36]). This includes all professions working in mental healthcare. Quality assurance of the professional qualification of psychiatrists needs to include national quality assurance of the specialty training programs and continuing medical education activities by certifying such programs and activities on the basis of the standards developed by the Union of European Medical Specialties and by following the European Guidance on post-graduate training in psychiatry developed by the European Psychiatric Association (macro-level; Section 3.18; evidence level II–III; [65]).

4.2. Process recommendations

4.2.1. Recommendation 8

The European Psychiatric Association considers (Grade of Recommendation: B) that quality assurance in mental healthcare needs to include assessments of the contents of mental healthcare at the points of care using standardized patient-, family- or clinician-rated assessment instruments (micro-level; Section 3.10; evidence level I–II; [58,59]). These provide the necessary data to assure that the contents of the care provided in individual health services match those outlined in national guidelines.

4.2.2. Recommendation 9

The European Psychiatric Association considers (Grade of Recommendation: B) that sustainable networks of collaboration need to be established between general healthcare and mental healthcare, that interdisciplinary collaboration needs to be part of professional training curricula, and that quality assurance of the referral process between referrers (usually general practitioners) and psychiatrists is warranted and needs to include assessments of the quality of referrers' information for psychiatrists in referrals, the feedback by psychiatrists to referrers and the follow-up of psychiatrists' recommendations by referrers (micro-level; Section 3.3 and Section 3.8; evidence level I–II; [8,73,76,106]).

4.2.3. Recommendation 10

The European Psychiatric Association considers (Grade of recommendation: A) that quality assurance in mental healthcare can be fostered by using established national guidelines and quality indicators for the diagnosis and treatment of specific mental disorders (meso-level; Section 3.5; evidence level I; [5,33,95,109]).

4.2.4. Recommendation 11

The European Psychiatric Association considers (Grade of recommendation: A) that therapeutic drug monitoring following established guidelines is warranted as a means to assure the quality of pharmacotherapy in mental healthcare (micro-level; Section 3.11; evidence level I–II; [39,40]).

4.2.5. Recommendation 12

The European Psychiatric Association considers (Grade of Recommendation: A) that quality assurance of psycho-pharmacotherapy should include an assessment of the option to reduce polypharmacy by carefully switching to monotherapy (micro-level; Section 3.12; evidence level I–II; [105]).

4.2.6. Recommendation 13

The European Psychiatric Association considers (Grade of recommendation: B) that the use of the EPA Guidance on Suicide Treatment and Prevention is warranted to assure the quality of the monitoring of suicidal ideation and behavior in mental healthcare (micro-level; Section 3.14; evidence level II; [115]).

4.2.7. Recommendation 14

The European Psychiatric Association suggests (Grade of recommendation: C) that quality assurance of mental health care for immigrants and refugees should include equal access to services, culturally sensitive care in mainstream services, provision of interpreting (when needed) and building professional collaborative relations with immigrant communities (meso- and micro-level; Section 3.17; evidence level III; [14,52,87]).

4.2.8. Recommendation 15

The European Psychiatric Association suggests (Grade of recommendation: B) to use routine data for quality assurance if these are available whenever possible, as they represent actual service use data and show patient care pathways in the mental healthcare system (macro- and meso-level; Section 3.4; evidence level I–II; [26,56]).

4.3. Outcome recommendations

4.3.1. Recommendation 16

The European Psychiatric Association considers (Grade of recommendation: A) that quality assurance in mental healthcare should include outcome assessments, which may include – but may not be limited to – the domains of mortality rates, healthcare services utilization rates, symptom severity, social functioning, and patient or caregiver satisfaction, using scales and questionnaires validated in each country (macro-, meso- and micro-level; Section 3.9; evidence level I; [9,63]).

4.3.2. Recommendation 17

The European Psychiatric Association considers (Grade of recommendation: B) that quality assurance in mental healthcare should include needs assessments, which may apply patient-, family/caregiver- or clinician-rated versions of standardized scales and questionnaires validated in each country (micro-level; Section 3.9; evidence level I–II; [4,94,117]).

5. Discussion

The EPA Guidance on Quality Assurance provides seventeen recommendations. Earlier reviews on quality assurance in mental

health services had concluded that effective quality assurance in mental healthcare was difficult given the team approach to treatment, a lack of consensus about outcome assessment, and the necessary tracking of patients receiving multiple types of services in multiple settings [48]. As Donabedian put it in 1996 [19]: "Even rarer than well-designed studies of single interventions are assessments of variants of such methods. Rarer still, to the point of nonexistence, are studies that set out to test competing, theory-based strategies of quality assurance." Donabedian extended this view to the "foregone conclusion" that "every reasonably established method in the armamentarium of quality assurance has been shown to work in some situations." It is important to recognize the great diversity of cultural and economic influences, which are affecting mental health practice in the different European countries. What is still lacking today is a comprehensive assessment of systems-related quality assurance measures in international studies. These would be highly warranted with a view to improve the evidence base of the EPA Guidance on Quality Assurance recommendations in the future and to support the implementation of the WHO Global and European Mental Health Action Plans. Another important aspect is the harmonization of the definition of other important terms used in quality assurance in the databases used for assessing quality indicators, like "engagement", "recovery" or "intervention fidelity" [50]. Furthermore, the use of data obtained in mental healthcare is often limited by availability or incompleteness of data, or because quality indicator definitions lead to a demand for data not routinely available. Quality assurance therefore needs to be put to empirical studies with control and intervention groups, a type of study which we found too rarely. Another key aspect is the feasibility of the proposed quality assurance tests. We formulated the recommendations of this guidance in such a way that they will hopefully be feasible in all European countries.

The strengths of the recommendations are that they are evidence-based, graded regarding the level of strength of the recommendations, and validated through expert review involving clinical experts and representatives of both patients and family organizations. Additional strengths of this EPA Guidance are its systematic approach to evidence retrieval and evaluation, the provision of practical recommendations, and the overview, which it provides over the field. It addresses all levels of mental healthcare services (macro-, meso-, and micro-level), but the retrieved evidence base was focused on studies in local or at best regional contexts. Therefore, most recommendations are at the meso-level. Furthermore, most studies addressed process and outcome measurements. Most recommendations therefore deal with such recommendations. The evidence base for most recommendations is medium, and an important aspect is the use of qualitative studies, for which we have used standardized evidence-grading criteria. We think that while qualitative studies have inherent weaknesses compared to controlled, randomized trials of quality assurance interventions, the qualitative studies provide an opportunity for areas of quality assurance not suitable for controlled trials.

Some limitations of this guidance need to be addressed. A lack of evidence from controlled intervention studies is a limitation of the quality assurance field in mental healthcare. A further limitation is the high degree of variation of the diverse European mental healthcare services, which limits the generalizability of the study results. Furthermore, the systematic literature search may have overlooked important studies. We have addressed this issue by identifying reviews in the field, by adding a topic-oriented not fully systematic literature search, and employing a broad review by a high number of experts. Constraining the languages of the search to English and German may have excluded studies in other European languages. The 10-year retrieval period also was short and we found additional studies also from the period before through the topic-guided hand searches. This leads to the limitation that the process of evidence search was only partly systematic, since the systematic search did not yield evidence in important areas of quality assurance of mental healthcare, indicating that either the authors of relevant additional publications used for this guidance did not use the term "quality assurance" or the editors of databases did not link such research studies with the term "quality assurance". This leads to the limitation that the term "quality assurance" has a range of conceptualizations in the literature. We aimed at compensating these limitations by providing information on the definition of quality assurance, and by combining a systematic literature search with a not fully systematic, topic-based literature search and a broad expert consultation process. Another important issue is that some recommendations address inpatient treatment only, while others refer to both inpatient and outpatient treatment and further stakeholders (general practitioners, relatives, other caregivers). This raises the issue of how the relevant data may be gathered in practice. The need arises to develop cross-sectoral approaches to data collection and evaluation when implementing these recommendations. Future studies should address the development and use of unified definitions and implementation of quality assurance for mental healthcare with a view to compare the efficiency and effectiveness of the various mental healthcare systems in Europe.

Disclosure of interest

W. Gaebel is President of the European Psychiatric Association (EPA), Chair of the EPA Guidance Committee and Chair of the World Psychiatric Association Section on Quality Assurance. He is the co-chair of the steering committee for the development of the DGPPN guideline on schizophrenia, and Vice President and member of the guideline commission of the Association of the Scientific Medical Societies in Germany. He has received support for symposia from Janssen-Cilag, Sanofi-Aventis Germany, Lilly Germany, and Servier Germany. He is a member of the faculty of the Lundbeck International Neuroscience Foundation.

I. Großimlinghaus is a member of the coordination group for the development of the DGPPN guideline on schizophrenia.

R. Heun is a member of the EPA Guidance Committee.

B. Janssen is a member of the coordination group for the development of the DGPPN guideline on schizophrenia and a member of the World Psychiatric Association Section on Quality Assurance.

B. Johnson is President of the European Federation of Associations of Families of People with Mental Illness (EUFAMI) and declares that he has no conflicts of interest concerning this article.

M. Muijen contributes as a WHO staff member and not on behalf of WHO as an organization.

P. Montellano declares that he has the following affiliations on a volunteer basis: Global Alliance of Mental Illness Advocacy Networks-Europe (GAMIAN Europe) – President; European Brain Council (EBC) – Vice President; EUTIMIA – European Alliance Against Depression Portugal – Vice President; Expert Platform focused on Depression – Vice Chair; International Bipolar Foundation (USA) – Member of the Advisory Board; EUPATI (European Patients' Academy on Therapeutic Innovation) – Member of the Ethic Panel; EU Joint Action on Mental Health and Wellbeing – Member of the Advisory Board.

W. Rössler received during the last three years lecture fees from Eli Lilly Suisse, Janssen-Cilag, Interpharma, FOMF (Forum für medizinische Fortbildung), Med-Update and SVA (Sozialversicherungsanstalt Schweiz). He is the director of ZInEP, a comprehensive

mental health services research program sponsored by a private foundation. He was on the Advisory Board of I3G (Institut für Innovation und Integration) and IVP Networks. He is also a member of the Board of the European Psychiatric Association.

G. Thornicroft co-chairs the guideline development group of the WHO mhGAP intervention guide.

J. Zielasek has received congress travel support from the German Association for Psychiatry, Psychotherapy and Psychosomatics (DGPPN) and is a member of the coordination group for the development of the DGPPN guideline on schizophrenia.

P. Munk-Jorgensen, T. Kurimay and M. Ruggeri declare that they have no conflicts of interest concerning this article.

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