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Commentary on the current Guidelines in Psychopharmacotherapy

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Introduction

Psychiatry is frequently perceived as a 'soft' science and treatment of mental illness can be mis-perceived as not focused nor specific, thus allegedly not effective.

In the last decades, the need to standardize different therapeutic approaches and to reduce incorrect practices has encouraged the development of guidelines to advise on the treatment, management and assessment of psychiatric disorder [1].

Publication of evidence-based practice guidelines supports the recognition of the scientific approaches of psychiatric treatment and improves health care delivery by decreasing inappropriate variation in clinical interventions [2].

Implementation of these guidelines accelerates both the acquisition and the dissemination of new scientific in-depth knowledge, as clinicians and researchers are better able to identify similar illnesses and compare findings. At the same time, compliance to practice guidelines can increase the comparability of treatment approaches and stimulate more effective research [3].

While playing an important role to assist clinicians in their decision-making, treatment guidelines suffer for a number of limitations. Some psychiatrists claim that the use of guidelines would contribute to a culture of "cook-book medicine"; others are concerned about the lack of implementation strategies and the risks of potential escalation of malpractice litigations.

Moreover, there is also an objective gap in research base (especially for long-term treatments and patients with comorbid conditions) that creates further complexity when providing recommendation under clinical consensus [4].

Clinical guidelines can be defined as "systematically developed statements to assist practitioners and patient decisions about appropriate health care for specific clinical circumstances" [5].

Internationally they have been developed by professional associations, by government agencies, by insurance companies and other third party payers, and by providers of care.

In scientific literature, guidelines that meet the 5 following specific criteria are identified as "good" guidelines. In detail, it occurs when the guidelines:

- are developed by physicians in active clinical practice;
- integrate relevant research and clinical expertise;
- describe specific treatment approaches, including indicators, efficacy, safety and alternative treatment strategies;
- are reviewed and revised at regular intervals not longer than 5 years;
- after approval, are widely disseminated.

Notwithstanding recent developments, there are difficulties in clinical application. Only a few studies analyze the applicability and the implementation of treatment guidelines in psychiatry.

The guidelines, according to the latest medical culture, provide recommendations based on scientific evidence and standards of good clinical practice useful for guiding and supporting the decisions of all professionals working in the various medical specialties, including psychiatry.

However, it is necessary to keep in mind that the guidelines are not rigid and rigorous protocols to be applied indiscriminately but it is necessary to take

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into account the clinical characteristics of the individual patient, as well as his expectations regarding treatments and preferences motivated also by ethical aspects.
Another important aspect is that most of the real-world patients are characterized by multi-morbidity and the balance between risk and benefit of planned care is often unpredictable due to the fact that efficacy tests derive from studies carried out on selected patient groups that often they do not take into consideration patients suffering from multiple pathologies.
Despite this premise, one cannot deny the great positive impact that the development of guidelines based on scientific evidence has made for medicine.
It is not possible to establish a ranking of importance or completeness with respect to the various guidelines present in psychiatry to date. Some of the most well known and widely accepted guidelines, taken into account by psychiatrists in daily clinical practice are listed in Table I.
Specifically, the CANMAT previously published treatment guidelines for bipolar disorder in 2005, along with international commentaries and subsequent updates in 2007, 2009, and 2013. The last two updates were published in collaboration with the *International Society for Bipolar Disorders* (ISBD). The main objective of these publications was to synthesize the wealth of evidence on the efficacy, safety, and tolerability of the range of interventions available for this complex and varied illness, with the goal of providing clear, easy to use recommendations for clinicians to improve outcomes in their patients. The 2018 CANMAT and ISBD Bipolar Treatment Guidelines represent the significant advances in the field since the last full edition was published in 2005, including updates to diagnosis and management as well as new research into pharmacological and psychological treatments.
These advances have been translated into clear and easy to use recommendations for first, second, and third line treatments, with consideration given to levels of evidence for efficacy, clinical support based on experience, and consensus ratings of safety, tolerability, and treatment-emergent switch risk.
A hierarchical rankings were created for first and second-line treatments recommended for acute mania, acute depression, and maintenance treatment in bipolar I disorder. This hierarchy will further assist clinicians in making evidence-based treatment decisions.
In addition to addressing issues in bipolar I disorder, these guidelines also provide an overview of, and recommendations for, clinical management of bipolar II disorder, as well as advice on specific populations, such as women at various stages of the reproductive cycle, children and adolescents, and older adults. There are also discussions on the impact of specific psychiatric and medical comorbidities such as substance use, anxiety, and metabolic disorders. Finally, an overview of issues related to safety and monitoring is provided.
Psychiatry is a discipline that deals with the dimensions of human suffering and positions itself between psychology, sociology and biology. The psychiatrist therefore needs to have robust guidelines available that can support clinical decisions in the real world.
As a good practice, all the guidelines mentioned above should be uniform and precise. However, it seems that there are many differences when all the guidelines are compared.
According to the Guideline International Network [11], founded in 2002, high quality guidelines are defined in compliance with fundamental requirements and involve various phases, each of which can be managed with different degrees of methodological rigor:
• composition of the development group of the guideline

Table I. The most common international guidelines in psychiatry.

APA Guidelines *American Psychiatry Association* [6]	USA	Probably the most famous guidelines in Psychiatry as they also come from the association that deals with the management of the DSM-V diagnostic manual
NICE Guidelines *National Institute of Health and Care Excellence* [7]	UK	It has acquired a certain international authority, also as a model for the development of clinical guidelines not only psychiatric, based on evidence, literature analysis and cost/effectiveness evaluation. The NICE publishes guidelines in four areas of health: health technology (drugs and therapeutic procedures), clinical practice (appropriateness of the treatment of people with specific pathologies), prevention of diseases and occupational medicine
RANZCP Guidelines *The Royal Australian and New Zealand College of Psychiatrists* [8]	Australia	It is a mine of information not only on the most up-to-date and clear guidelines of psychiatry but also on many other current topics related to psychiatry (legislation, ethics, neuro-science, innovative and alternative treatments etc.). RANZCP addresses all diseases of both adult and adolescent patients and childhood
Maudsley Guidelines [9]	UK	The 10th edition of the *Maudsley Prescribing Guidelines* fully updates the 9th edition and includes new sections offering guidance on, for example, the use of psychotropic drugs in atrial fibrillation, alternative routes for antidepressant administration and the covert administration of medicines
CANMAT Guidelines *Canadian treatment guidelines and Canadian Network for Mood and Anxiety Disorders* [10]	CANADA	It focuses on mood and anxiety disorders, provides up-to-date scientific information, treatment guidelines and educational opportunities for physicians, as well as clear and helpful information on symptoms and treatments for patients and their families. CANMAT conducts research on the clinical management of diseases, pharmacological and psychotherapeutic treatments and biomarkers of mood disorders

that should include several relevant stakeholders (professionals, health professionals, methodologists, subject matter experts and patients);
- decision-making process used to reach consensus among the members of the group and, if applicable, for approval by sponsors. This process should be defined before starting the development of the guidelines;
- conflicts of interest of any type to be disclosed and potentially addressed;
- scope and objectives of the guideline to be clarified;
- methods to be stated;
- review of scientific evidence evaluated and identified with systematic methods;
- guideline recommendations to be formulated clearly and based on evidence relating to benefits, risks and, if possible, costs;
- rating of evidences and recommendations: to classify and communicate both the quality and reliability of evidence, to assess the strength of clinical recommendations;
- peer review and stakeholder consultation;
- validity and updating of the guidelines;
- financing and sponsorship.

Results

Translating scientific evidence into daily practice is complex. First of all there is inconsistent use of terminology, which contributes to difficulties in replicating and understanding the association between intervention and outcomes [12]. It was noted that while in some areas, the recommendations provided by the guidelines appear to be fairly uniform (eg Valproate in the case of acute management of mixed episodes, use of antidepressants and duration of long-term antipsychotic treatment), in other areas, they differed widely (recommendations on psychosocial management and duration of acute treatment of the mood episode).

The primary aim of clinical guidelines is to provide the best practice treatment, i.e. to increase the quality of care available to patients [4].

From patients and families perspectives, accepted guidelines can be considered an information tool that opens to a higher level of disclosure. Once informed about recommended best practices about treatment alternatives, under some circumstances, they have the chance to participate in implementation decisions as well.

The treatment of mental illnesses has grown very rapidly and in order to accept guidelines as reliable, clinicians need to review the extent and the nature of evidences related to the various interventions in the cure of the specific psychiatric disorders. Consequently, guidelines effectiveness ranks in accordance to the level of clinical confidence in the recommendation (weights of relevance) and the nature of supporting evidence (code of reference).

Guidelines also represent a relevant educational instrument; by leveraging on their comprehensive nature and the extensive, coded reference sections, they support clinical reasoning, literature search and provide data and analysis with easy and quick availability.

Although guidelines may be intended as a chance to bridge the gap between clinical research and evidence-based practice, they are not universally welcome. Many attitudinal and behavioral barriers prevent physicians from adopting them.

First of all, it is clear that comprehensive and relatively lengthy guidelines are not easily used in busy practices. It is often also a matter of attitude because there is no tradition in psychiatry of following clinical guidelines and, as a new approach, it requires great adaptation that sometimes is agreed upon after discussion of different psychiatric schools of thought and theories. Traditional treatment approaches can be questioned in the light of presented evidence and this can be addressed as a barrier [13].

Perception of appropriate guidelines and implementation strategies are also crucially important in order to build up the accepted consensus on reliable updated recommendations as well as to avoid oversimplification of complex clinical questions. In this latter case, known as the “reductionist approach to medical care”, clinicians refuse to practice “cook-book” medication to preserve their judgmental autonomy against excessive standardisation and trivialization of care [2].

Another limitation that can affect the guidelines development is the gap in research base because of the undeniable complexity of psychiatric disorders: a majority of patients who suffer from mental illness present comorbid conditions and experience them in the long-term. These factors take time for properly addressing the state of knowledge and the adequate tools for the evaluation of the care.

Moreover, it has been seen that the identified barriers to, and facilitators of, the implementation of guidelines could be classified into three major categories: (a) organizational resources; (b) health care professionals’ individual characteristics; and (c) perception of guidelines and implementation strategies [2].

In detail, the first category related to organizational resources involves:
- in terms of barriers, the risks of experiencing a lack of trust in the guidelines’ recommendations and an environment not supportive to clinical guidelines due to several reasons (e.g. no agreement on need to use clinical guidelines, lack of time influence of prior experiences, lack of organizational strategy and skills, resistance to multi-disciplinary team, etc.). Furthermore, financial concerns on cost control and standardization of care might threaten the doctor or therapeutic-patient relationship;
- in terms of facilitators, multi-disciplinary implementation team with clear roles, awareness of clinic attitudes and actions, feedback on performance and quality indicators.

With reference to health care professionals’ individual characteristics, as mentioned above, personal behaviours and attitudes can significantly affect the approach to guidelines in favour or in opposition to them. Positive beliefs regarding evidence-based treatments and new actions, and high levels of practitioner’s awareness support the definition and implementation processes of guidelines, while the lack of knowledge, skills and motivation, the fear of loss of autonomy and of standardised care, together with insufficient dedicated time and specialised training create a hostile environment for their development.

Promotion of learning culture, definition of precise roles,

awareness of clinic actions and effective team working in applying recommendations uphold positive perception of guidelines and implementation strategies, as well as easy access to tools and clinical scales.
On the contrary, the lack of familiarity and overwhelming amount of medical research, doubtful credibility of the recommendations and uncertain reliability of the sources are perceived as barriers to these strategies [1]. "Missing" recommendations, a lack of addressing issues believed to be important for clinical practice and for patients or a failure to internalize guidelines into clinical routines are also hurdles that influence the providers' willingness to accept guidelines [14].
The psychiatrist should base his work on solid scientific and clinical grounds. Diagnosis and therapy suggested by manuals and treaties of psychiatry with national and international diffusion, attention to the guidelines and protocols recognized by scientific societies are factual data justifying good clinical practice.
However, the principles of good clinical practice must be contextualised in that specific psychiatrist, with those specific clinical experiences and training, with that particular patient, in that specific psychopathological and psychosocial context in which the fact occurred.
This need, however, must not underestimate the limits of the guidelines and must lead the specialist to a critical acceptance of them in everyday clinical practice.
The guidelines are constructed with a methodology that takes little account of the opinions of experts in daily practice; they are linked to specific schools of thought that are not always shared; refer to ideally selected patients in ideal care settings for hotel, social and pharmacological assistance; they do not take into account the complex patients present in daily practice; they can be influenced by economic-managerial-insurance order priorities; they are different in the indications between them; often they change their principles over time; they can be used for a defensive psychiatry that does not privilege the patient's benefit [15].

Discussion

Standard clinical practice is usually guided by clinical guidelines. A good guide should be able to identify the Diagnosis, the evaluation strategy and the choice of the treatment, allowing to evaluate the benefits, risks and costs of the alternative decisions and presenting concise and updated recommendations. The guidelines should be able to guarantee the best clinical standards for doctors. However, they are often not read or followed because of poor quality or obstacles due to lack of agreement or ambiguity.
It was also noted that most of the guidelines provide more detailed recommendations in the field of pharmacotherapy, while dealing in general with psychosocial management.
An ideal guideline should derive from a complete literature review and should explicitly evaluate the quality of support research studies and the methods used to summarize the evidence. This guideline should provide recommendations for the management of pharmacological treatment, but also for evaluation and psychosocial interventions during the acute and maintenance stages of the disease [16].
There is therefore a need for internationally acceptable and culturally fair recommendations to be developed and then set the framework for further development on a national or local basis. International organizations such as the WPA or WHO may help formulate a unified guideline, which may then be modified to meet national or local needs.

Conflict of interests

The authors declare that there is no conflict of interests.

References

1 Forsner T, Wistedt AA, Brommels M, et al. *An approach to measure compliance to clinical guidelines in psychiatric care.* BMC Psychiatry 2008;8:64.
2 Forsner T, Hansson J, Brommels M, et al. *Implementing clinical guidelines in psychiatry: a qualitative study of perceived facilitators and barriers.* BMC Psychiatry 2010;10:8.
3 Weinmann S, Koesters M, Becker T. *Effects of implementation of psychiatric guidelines on provider performance and patient outcome: systematic review.* Acta Psychiatr Scand 2007;115:420-33.
4 Qaseem A, Forland F, Macbeth F, et al; Board of Trustees of the Guidelines International Network. *Guidelines International Network: toward international standards for clinical practice guidelines*. Ann Intern Med 2012;156:525-31.
5 Field MJ, Lohr KN. *Guidelines for Clinical Practice: from Development To Use.* Washington (DC): National Academy Press (US) 1992.
6 Practice Guideline 2006; American Psychiatric Association. http://www.psych.org/mainmenu/psychiatricpractice/practice- guidelines 1.aspx.
7 National Institute for Health & Clinical Excellence. *NICE guidelines for Mental Health & Behavioral conditions.* 2010. http://guidance.nice.org.uk/Topic/MentalHealthBehavioural.
8 Galletly C, Castle D, Dark F, et al. *Royal Australian and New Zealand College of Psychiatrists clinical practice guidelines for the management of schizophrenia and related disorders*. Aust N Z J Psychiatry 2016;50:410-72.
9 Taylor D, Paton C, and Kapur S. *The Maudsley prescribing guidelines*. London, UK: Informa Healthcare 2009, 10th edition.
10 Yatham LN, Kennedy SH, O'donovan C, et al. *Canadian Network for Mood and Anxiety Treatments (CANMAT) guidelines for the management of patients with bipolar disorder: update 2007.* Bipolar Disorders 2006;8:721-39.
11 Guidelines International Network. Disponibile su: www.g-i-n.net.
12 Michie S, Fixsen D, Grimshaw J, et al. *Specifying and reporting complex behaviour change interventions: the need for a scientific method.* Implementation Sci 2009;4:40.
13 Mcintyre JS. *Usefulness and limitations of treatment guidelines in psychiatry mental health policy paper*. World Psychiatry 2002;1.
14 Shiffman RN, Shekelle P, Overhage JM, et al. *Standardized reporting of clinical practice guidelines: a proposal from the Conference on Guideline Standardization*. Ann Intern Med 2003;139:493-8.
15 Nivoli G, Lorettu L, Carpiniello B, et al. *Charges and convictions of psychiatrists for the violent behavior of the patient: psychiatric-forensic remarks*. Riv Psichiatr 2017;52:101-8.
16 Grimshaw JM, Thomas RE, MacLennan G, et al. *Effectiveness and efficiency of guideline dissemination and implementation strategies*. Health Technol Assess 2004;8:3-4.