05 - Using the CDDR in research

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Clinical Descriptions and Diagnostic Requirements for ICD-11 Mental, Behavioural or Neurodevelopmental Disorders of engagement, diagnosis, evaluation and treatment selection, and addresses the following areas: • cultural variation in prevalence and symptoms of disorders; • information about social contexts and sociocultural mechanisms that may account for this variation; and • descriptions of cultural concepts of distress (e.g. idioms, causal explanations) that are relevant to diagnosis and treatment decisions, prioritizing cultural variations that may be associated with national or ethnocultural background (60,61). The resulting guidance aims to assist the clinician in making informed decisions likely to foster more contextually applicable patient-centred care that is sensitive to the cultural and social milieu of the clinical encounter. For example, the section on culture-related features of the CDDR for panic disorder indicates that the symptom presentation of panic attacks may vary across cultures, and describes several notable cultural concepts of distress that link panic, fear or anxiety to cultural attributions regarding specific social and environmental influences. Understanding these attributions can assist in differential diagnosis and can also clarify whether panic attacks should be considered expected or unexpected (as is required for a diagnosis of panic disorder) given the environmental circumstances. The development of the CDDR incorporated cultural considerations in several other ways. First, global applicability of diagnostic material was identified early on as an overarching objective of the CDDR, and the development process was led and guided by experts and clinicians representing all major global areas. The Advisory Group, the FSCG and all working groups included members with diverse geographical and linguistic backgrounds, many of whom had direct experience working in low-resource contexts and within various cultures. The design and implementation of ICD-11 field studies also adhered to the principle of enhancing the global and cultural applicability of the CDDR by engaging thousands of clinicians from around the world in a comprehensive research programme to assess the reliability, clinical utility and global applicability of the requirements. For example, the formative studies that helped to shape the architecture and linear structure of the CDDR involved clinicians from over 40 countries and were conducted in multiple languages. The evaluative case-controlled studies engaged clinicians in large-scale, multilingual studies related to major diagnostic areas of the CDDR. The clinicians who participated in the case-controlled studies were members of the Global Clinical Practice Network (62), which now includes more than 18 000 mental health professionals from over 160 countries, and was established by WHO for the purposes of assisting in the development of ICD-11 by its members

participating in internet-based field studies. Similarly, clinic-based field studies testing the implementation of the CDDR with real patients took place in over 25 study sites in 14 culturally, linguistically and geographically diverse countries. Hundreds of clinicians in these countries provided feedback directly on the CDDR to help enhance its reliability and utility in culturally diverse global settings. Using the CDDR in research In addition to the ICD-10 CDDG, the WHO Department of Mental Health and Substance Use published The ICD-10 classification of mental and behavioural disorders: diagnostic criteria for research (DCR) (63) as a companion document. The DCR presented fully operationalized criteria for ICD-10 mental disorder entities, specifically intended for use in research. These criteria were designed to replace the “diagnostic guidelines” portion of the corresponding category in the CDDG, which tended to be more flexible and less fully operationalized. The core criteriabased approach taken in the DCR was therefore much more compatible with the approach of

13 DSM-IV (51), although substantial differences between the two systems remained (64). However, almost no research using the ICD-10 DCR appears to have been published. The greater standardization and the provision of a broader and more systematic range of clinically relevant information in the ICD-11 CDDR compared to the ICD-10 CDDG (16) was designed to make the CDDR more useful in clinical decision-making, and therefore also in education and training. The extremely high ratings of the clinical utility of the CDDR, particularly in international clinic-based field studies with real patients (19,48) suggest that this objective was achieved. Moreover, the solid reliability results from the ICD-11 field studies (18,48) indicate that the CDDR would be satisfactory for use in certain kinds of research projects – for example, projects focused on individuals with particular diagnoses as these are assigned in health-care settings (e.g. patients diagnosed with recurrent depressive disorder receiving services at a particular facility). However, in other types of research projects, in which obtaining reproducible and precise psychiatric diagnoses is more important, standardized diagnostic assessment procedures are necessary. This is meant to control variability inherent in diagnostic processes that rely on the interviewer’s diagnostic interviewing skills (different interviewers may ask different questions to assess the same clinical phenomena) and clinical judgement (different interviewers may arrive at different diagnostic conclusions). For example, studies of the efficacy of treatments for particular disorders require consistency in diagnostic procedures to ensure that the population being studied has been assigned the diagnosis for which the treatment is intended according to consistent and explicit diagnostic rules to reduce random diagnostic heterogeneity. Similarly, epidemiological studies that utilize lay (i.e. not clinically trained) interviewers to apply the ICD-11 CDDR require pre-scripted questions and strict decision rules because they cannot rely on the clinical expertise of the interviewer to make judgements about which features are present. For these reasons, several WHO-sponsored diagnostic instruments are being developed to facilitate the application of the ICD-11 CDDR in particular research settings. The Structured Clinical Interview for ICD-11 (SCII-11) is a semi-structured diagnostic interview that requires experience in clinical interviewing on the part of the interviewer. The SCII-11 is designed to be used in conjunction with the CDDR, and provides a standardized set of questions to assist researchers to elicit the information needed to conduct a differential diagnosis in the context of research studies. It will also be useful for training purposes and in clinical settings. The development of the SCII-11 required extensive decisions about operationalizing the CDDR so that they can be more reliably applied in research settings. The SCII-11 operationalized the CDDR in two different ways: by substituting more precise diagnostic thresholds and by the choice of wording of corresponding interview questions. The CDDR

intentionally avoid artificially precise duration and symptom cutoffs, allowing clinicians more flexibility for clinical judgement. The SCII-11 modifies some of the CDDR items, substituting more precise thresholds. For example, the ICD-11 CDDR for panic disorder define a panic attack as follows: “Panic attacks are discrete episodes of intense fear or apprehension also characterized by the rapid and concurrent onset of several characteristic symptoms. These symptoms may include, but are not limited to, the following…” The SCII-11 has modified this item, substituting the word “several” with “at least three”. Similarly, the CDDR incorporate many broadly defined diagnostic constructs that could be assessed in different ways. Rather than relying on the interviewer to decide the best way to assess them, the SCII-11 operationalizes diagnostic constructs through the specificity and wording of corresponding interview questions. For example, the CDDR for schizophrenia require the presence of at least two items from a list of seven, most of the time for a period of 1 month, with one of the seven being “persistent delusions (e.g. grandiose delusions, delusions of reference, persecutory delusions)”. Since there is no single question that can satisfactorily cover every type of delusion, the SCII-11 divides the assessment of delusions into separate questions corresponding to specific types of delusions (e.g. delusions of reference, persecutory delusions, Introduction

Clinical Descriptions and Diagnostic Requirements for ICD-11 Mental, Behavioural or Neurodevelopmental Disorders grandiose delusions, delusions of guilt, somatic delusions). Given that it is a semi-structured rather than a fully structured interview, the interviewing clinician also has the option of following up on particular responses or asking additional questions in order to assess the relevant phenomena fully. WHO plans to make available a list of the operational decisions implemented in the SCII-11 as a resource in the development of other instruments to encourage greater cross-instrument agreement. In addition, WHO is developing a fully structured diagnostic interview to be used in epidemiological studies and in other situations in which the SCII-11 is not feasible owing to time constraints or because it is not feasible to use trained clinicians as interviewers. The Flexible Interview for ICD-11 (FLII-11) covers common and high-burden mental disorders, but is less comprehensive than the SCII-11. It is based on the algorithms and operationalizations developed for the SCII-11 but consists entirely of closed-ended (primarily yes/no questions), and is designed for use by lay interviewers with a limited amount of training. It will also be available for electronic administration as an open-access tool for WHO member states. The Schedules for Clinical Assessment in Neuropsychiatry (SCAN) (65,66) is a semi-structured clinical interview used by trained clinicians to assess and diagnose mental disorders among adults, originally developed as a part of a joint project of WHO and the United States National Institute of Mental Health. The SCAN comprises a set of instruments, supported by manuals, and was originally developed around the Present State Examination, which assesses a wide range of symptoms likely to be manifested during a psychotic episode. The SCAN is designed to yield both ICD and DSM diagnoses, and has been translated into more than 35 languages. It requires extensive training by an approved training centre to administer. Its approach is different from that of the SCII-11, which attempts to assess the diagnostic requirements of mental disorders more directly via direct self-report of their essential features. Version 3 of the SCAN is currently being developed and will be fully compatible with the ICD-11. It will refer to the SCII-11 operationalizations in the formulation of its diagnostic algorithms, although its assessment methodology will remain distinct. In addition, instruments focused on particular diagnoses as formulated in ICD-11 are being developed by WHO as well as by researchers external to WHO. For example, WHO is supporting the development of screening and diagnostic tools for gaming disorder (67). Instruments not sponsored by WHO include several measures of personality disorder severity and trait domains based on ICD-11

developed by different research groups (68–71). A self-report measure of ICD-11 post-traumatic stress disorder and complex post-traumatic stress disorder has been validated (72) and translated into over 25 languages. A scale designed to assess ICD-11 compulsive sexual behaviour disorder has been developed and validated (73), and will be made available in up to 30 languages as part of a large international research project (74). Ultimately, the use of the ICD-11 classification of mental, behavioural and neurodevelopmental disorders in research will depend on the development of validated measures for specific purposes, as illustrated by these examples, rather than on the development of a separate classification intended for research use.

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