Chapter 5
Establishing Normative Validity for Scientific Psychiatric Nosology: The Significance of Integrating Patient Perspectives

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Introduction

The potential for patients to contribute to a scientific psychiatric nosology is further reaching than is commonly recognized. It extends all the way into the heart of the science of nosology, into the establishment of scientific validity. This assertion may appear strange in view of the fact that the neo-Kraepelinian notion of validity, so influential in contemporary psychiatric nosology, was felt to place the issue of validity, at last, on a firm empirical scientific footing. But it would be a mistake to equate an empirical footing with a transcendence of normative questions about the right way to proceed. It is not a matter of nosology either being empirical or normative. Instead nosology entails a mixture of the descriptive and the prescriptive. When carefully examined, it becomes apparent that neo-Kraepelinian notions of validity are underdetermined by empirical truth claims and must be supplemented by normative claims about what nosology ought to accomplish. When the normative assumptions that guide neo-Kraepelinian nosology are made explicit it becomes equally apparent that there are alternative ways of conceptualizing nosology that are commensurate with the empirical data. Normative elements are not an extra-scientific appendage of nosology. There is simply a normative dimension to the science of nosology. The normative dimension of science often makes scientists uncomfortable because it entails evaluative elements. Positivist equations of the evaluative with the subjective and the arbitrary are still very influential in scientific circles, and scientists are used to justifying empirical truth claims about the world, not normative truth claims about the right way to proceed. The philosophical work of Jurgen Habermas is a helpful antidote here because, counter to a stance of value skepticism or relativism, Habermas maintains that normative judgments about the

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J. Paris and J. Phillips (eds.), *Making the DSM-5: Concepts and Controversies*,
DOI 10.1007/978-1-4614-6504-1_5,

right way to proceed are susceptible to falsifiable validity claims. Habermas establishes a procedural notion of normative validity that would safeguard the normative issues in nosology from being resolved in an arbitrary or coercive manner. This procedural notion of normative validity points toward the depth of importance of patient participation for the science of nosology. The fact that normative issues form an essential part of nosology means that we should remain skeptical toward any claims for the validity of the science that ignore the normative dimension of the science while attending solely to empirical issues.

Channels for public input were made available during the development of the Diagnostic and Statistical Manual of Mental Disorders 5 (DSM-5). Input came from patients, family members of patients, patient advocacy groups as well as other stakeholders. Leadership of the DSM-5 revision process cited numerous positives that resulted from patient contributions including prevention of the use of pejorative terms and the prevention of unintended consequences such as increasing stigma and interfering with access to care [1]. The level of patient contribution to the DSM-5 can be seen as the culmination of a growing trend in the most recent formulations of the DSM toward greater democratization and transparency in the process of development. But the development of the DSM-5 was also guided by a self-conscious drive toward developing diagnoses with greater validity [2]. The DSM-5 leadership adopted a largely neo-Kraepelinian conception of validity that has been a guiding force for psychiatric nosology since the development of DSM-III [3]. This conception of validity is contestable and, as it currently stands, actually acts to conceal the depth of potential benefit from patient participation in the development of psychiatric nosology. In order to understand this we must retrace the logic of neo-Kraepelinian and to some extinct Kraepelinian conceptions of valid diagnostic constructs.

The Atheoretical Theory of the Neo-Kraepelinians

The term “neo-Kraepelinian” refers to a school of thought emanating from a group of psychiatrists at Washington University in the late 1960s and early 1970s. The namesake of this school was Emil Kraepelin, a preeminent psychiatrist whose theories were immensely influential at the beginning of the twentieth century. The neo-Kraepelinian school of thought was critical of the psychoanalytic influence on psychiatry and wanted to move psychiatry toward a medical model with a greater emphasis on biology [4]. An important aspect of the neo-Kraepelinian turn was a return to an emphasis on clinical description. Kraepelin was renowned for his careful empirical work in the description of the signs and symptoms of mental illness. Organizing nosology on the basis of a description of signs and symptoms without specific reference to etiology in DSM-III could be seen as a neo-Kraepelinian turn in psychiatric nosology. It certainly marked a significant conceptual shift from the organizing principles of DSM-II where psychoanalytically oriented conceptions of etiology were contained within the definitions of mental disorders [5]. The neo-Kraepelinian conception of validity was spearheaded by Robins and Guze prior to

the publication of DSM-III. Their seminal paper on diagnostic validity published in 1970 [6] pioneered the use of external validators as a means of establishing the validity of a diagnostic construct. Specifically Robins and Guze stated that a diagnostic construct should be validated by family studies, course of illness, clinical description, laboratory studies, and differential diagnosis. External validators afford evidence that diagnostic constructs provide relevant information not already contained in the definition of the diagnostic construct. As such they could be interpreted as providing evidence of the pragmatic value of the diagnostic construct. But, there is good reason to question the adoption of a "validity through pragmatic value" stance on the part of the neo-Kraepelinians. It was perhaps the move away from psychoanalytic theory that motivated Robins and Guze [6] to announce that their concept of validity was not based upon "a priori principles." But it would be more accurate to state that their notion of validity is based upon different a priori principles than those of psychoanalysis and, it should be noted, different a priori principles than those of pragmatism.

There is a productive tradition within medicine of moving from the description of a characteristic pattern of signs and symptoms in the form of a syndrome to the eventual discovery of the etiology of the syndrome. When the etiology is discovered the syndrome attains the status of a disease entity. The term "disease" is, of course, also used within medicine to refer to illnesses where there is no knowledge of etiology. But there is reason to believe that this historical notion of the syndrome as a stepping stone on the way to disease is theoretically operational in the thinking of the neo-Kraepelinians and compatible with the thinking of Kraepelin himself. Kraepelin, in his 1899 textbook, asserted his belief that "cases arising from the same causes would always have to present the same symptoms and the same post-mortem result" [7]. If this holds true then the characteristic patterns of signs and symptoms described by a syndrome could be seen as mapping onto or representing characteristic biological changes which in turn represent genetic sources of etiology. In this light, the external validators developed by Robins and Guze take on a different form of significance than evidence of pragmatic value. They can be seen as evidence that the syndrome described is "valid" in the sense that it represents a characteristic biological change in the brain with a genetic etiology at root. As noted earlier, Robins and Guze elaborated five external validators: family studies of heredity, clinical description, clinical course, differential diagnosis, and lab studies. Robins and Guze made it clear that a diagnostic construct could only be considered "fully validated" [6] if all five validators apply. If a construct represented a disease in the Kraepelinian sense of a biologically determined syndrome with an underlying genetic etiology then we would indeed expect all five validators to line up on that particular construct.

Neo-Kraepelinians Compton and Guze were quite explicit that the notion of validity first elaborated by Robins and Guze was part and parcel of a "medical model" of psychiatry that could be differentiated from a biopsychosocial model, for example, because, "the brain and how brain mechanisms are related to functional impairment would be considered the first goal of medical-model psychiatry" [8]. Yet they continued to regard themselves as working on the basis of observation

alone without any theoretical assumptions, leading to the seemingly self contradictory statement, "The medical model is without a priori theory, but does consider brain mechanisms to be a priority" [8]. It could be that the belief that mental syndromes map seamlessly onto specific biological abnormalities is not regarded by neo-Kraepelinians as a theoretical assumption that can be called into question because it is held as a matter of faith that this is the nature of "reality." Theoretical assumptions cannot be called into question if they entail an unreflective commitment to an implicit ontology. This seems to have been confirmed by Kendell and Jablensky [9] when they referred to Kraepelin as a "disease realist," where a *real* disease is one in which we understand the causal mechanisms behind the signs and symptoms and validity can be considered synonymous with "delineating a specific, necessary, and sufficient biological mechanism" [9]. Kendell and Jablensky readily acknowledged the implicit "disease entity" assumption at play in the work of Robins and Guze. It should be noted that Robert Spitzer, the chief architect of DSM-III, protested against accusations that the DSM favored a biological perspective. He held that the descriptive approach of the DSM facilitated etiological pluralism. He further stated external validators were evidence of the usefulness of a diagnostic construct (as opposed to evidence that it represented an underlying biological entity or mechanism). He specifically used the term "clinical utility (validity)" [5], implying that validity and clinical utility are synonymous. Kendell and Jablensky were highly critical of Spitzer's pragmatic definition of validity stating that valid diagnoses must be clearly differentiated from diagnoses that merely have utility. For Kendell and Jablensky syndromes may be considered valid only insofar as there is evidence that "natural boundaries" [9] exist between them. In stark contrast to Spitzer's identification of validity and pragmatic utility, Kendell and Jablensky identify the pragmatic with the arbitrary, asserting that in the absence of natural boundaries, boundaries must "be decided arbitrarily on pragmatic grounds" [9].

The diagnostic constructs contained heretofore in the DSM have not been validated in the sense delineated by Robins and Guze, a fact readily recognized by the DSM-5 leadership [3]. But, this fact has not been interpreted by the DSM-5 leadership as reason to call the neo-Kraepelinian concept of validity into question. Instead there appears to be ample evidence that neo-Kraepelinian theoretical commitments remain largely intact. We could imagine ourselves to be reading one of Kraepelin's texts when Regier declares that the DSM-5 objective of facilitating "research exploring the etiology and pathophysiology of mental disorders" is tantamount to "a renewed focus on the validity of diagnoses" [2]. When *diverse* (emphasis mine) topics in depression research are noted to include "preclinical animal models, genetics, pathophysiology, functional imaging, clinical treatment, epidemiology, prevention, medical comorbidity, and public health implications" [2], I think it is fair to conclude that the medical model extolled by Compton and Guze has remained very much at work in the development of DSM-5. The psychosocial aspects of illness are largely marginalized and diversity within the biological sciences appears to be all the diversity that is needed.

The Pragmatic Turn

Neo-Kraepelinian thinking may equate the pragmatic with the arbitrary but it is possible to invert this logic and call into question the pragmatic value of maintaining neo-Kraepelinian theoretical assumptions. Karl Jaspers [10] wrote in 1913 with skepticism about Kraepelin's assumption that psychological forms would map seamlessly onto cerebral pathology which would map seamlessly onto specific genetic etiologies. This skepticism was founded not only on the historical failure to discern specific etiologies for specific patterns of psychopathology, but also on the realization that in the case of syphilis, where the specific etiology of psychopathology is known, a great diversity of symptomatic presentations results. Jaspers proposed "ideal types" [10] as an alternative means of categorizing mental disorder. As opposed to conceiving of a syndrome as representing a concrete thing or essential process, ideal types are seen to abstract a few salient features from the myriad of empirical data available on the basis of pragmatic interests. The use of ideal types in nosology has contemporary advocates [11, 12], and Peter Zachar [13] has delineated a practical kind model for classification that has much in common with the notion of ideal types. This model emphasizes that those decisions about where to draw the conceptual lines in nosology will change depending upon our pragmatic interests. It is important to note that the discovery of a singular determining etiology for a mental disorder would likely have tremendous pragmatic value, not only prognostically but quite possibly leading to the development of therapeutic interventions. As such, "real diseases" in the traditional sense advocated by neo-Kraepelinians may certainly be accommodated by a practical kind model. Jaspers [10], for example, noted that even in the absence of "real diseases" working scientifically as if there were mental diseases could yield pragmatically useful information. But Jaspers found the disease model neither necessary nor sufficient and therefore advocated a plurality of approaches to study the complex subject of psychopathology. Because a practical kinds model does not have a theoretical/ontological commitment to the traditional disease concept it can entertain different manners of conceptualizing disorder and call into question the pragmatic value of insisting upon a disease model if and when that seems to lead us further and further afield from matters with clinical relevance. A pragmatic approach transcends the mindset that illness is either entirely a biological matter or not biological at all. As such it can incorporate relevant contributions not only from the biological and social sciences but from philosophy and the humanities as well [14].

The scientific work of Kenneth Kendler has emphasized that in addition to biological factors, psychological, social, and cultural factors can be seen to have an impact on the development of psychopathology. These factors do not work in isolation or in a simple linear, additive manner. Instead they influence each other in a complex manner that belies a simplistic singularly determining etiology story for mental disorder. For example a genetic disposition to alcoholism may be modified by the cultural acceptability of alcohol use, policies of taxation, or simply by witnessing the horrible toll that alcoholism exacted on one's parents [15]. Clinically, are we going to conclude that alcoholism is not a "real" medical problem because biological approaches only tell part of the story? The mindset that holds that mental disorders

are all biological or not biological at all simply does not put us in the best position to understand the complex phenomena that fall under the rubric of mental disorder. Kendler [16] underscores that alcoholism is not an exception in this regard. In general, psychiatric disorders lend themselves to explanatory pluralism. This pluralism stands as a stark alternative to seeing nosology as the neo-Kraepelinians did. At the time of the advent of DSM-III there seemed to be essentially a choice between psychoanalytic mechanistic forms of explanation or biological mechanistic forms of explanation [5]. The picture that emerges from Kendler's work is that biological approaches to understanding mental disorder have limited explanatory power and we are in a better position to understand mental disorders if we take a pluralistic approach.

Schaffner [17] noted that genetic determination of behavior appears to be an oversimplification even in the simplest behaviors exemplified by the simplest forms of organisms. In Schaffner's studies of nematode behavior, genetic behavioral dispositions unfolded differently in different environmental contexts. As such it should not come as a surprise that the diagnostic construct for schizophrenia that is best validated by course of illness is a narrower construct than that best validated by family history [18]. A broader definition of schizophrenia includes what the narrow definition would exclude and define as different disorders, schizotypal personality, and the affective psychoses for example. The broader definition is better able to accommodate a genetic disposition that can unfold in a different manner depending upon environmental contingencies. The narrow definition has more specific prognostic ramifications. The fact that different validators point toward different constructs makes neither the narrow diagnostic construct nor the broad diagnostic construct valid by the standards of Robins and Guze. It is important to note the different potential theoretical responses to empirical evidence of the lack of neo-Kraepelinian validity in the current DSM nosology. One can reject entirely the value of syndromal medicine for nosology and instead pursue a neuro-circuitry first and foremost strategy. This appears to be the guiding supposition of the Research Domain Criteria (RDoC) project being funded by the National Institute of Mental Health [19]. One can attempt to reform syndromal nosology in a more dimensional direction in order to better reflect the underlying biological etiology. This appears to be the strategy of the DSM-5 leadership [3]. Thinkers with a pragmatic orientation can assert that no one diagnostic construct can be all things to all people, and accordingly conclude that the hegemony of any singular system of nosology is unjustified. Instead they call for a more pluralistic approach to nosology [20]. Indeed, it is possible to endorse both the RDoC and the DSM approaches as pragmatically "valid," the DSM approach having greater clinical utility but the RDoC having potential value for scientific research regarding etiology.

The Normative Turn

The potential for multiple theoretical responses to what is recognized as the same empirical fact underscores the evaluative dimension of the science of nosology. Kenneth Kendler [18] emphasized the normative issues involved in the science of

nosology that are not simply resolved by the collection of data. Which theoretical assumptions should we adopt, which explanations should take priority, which validators have more practical importance? The notion of a *valid* diagnostic construct entails multiple evaluative judgments of salience. Evaluative issues were always present in neo-Kraepelinian nosology but they remained implicit. With the pragmatic turn evaluative issues become explicit and therefore visibly contestable. Because the pragmatic turn clarifies the evaluative dimensions of the science of nosology it puts us in position to examine the ethical dimensions of the science of nosology. Are the normative judgments that are being rendered ethically justifiable? The philosophical work of Jurgen Habermas on discourse ethics is helpful here because in addition to recognizing falsifiable validity claims about empirical aspects of the world, Habermas holds that the resolution of normative issues are also subject to falsifiable validity claims. Habermas's theoretical work is diverse and complex and an extensive examination of his ideas is well beyond the scope of this chapter. Nonetheless a brief excursion into Habermas's ideas is justified because he clarifies a position that stands in opposition to the belief that the resolution of value judgments is hopelessly subjective, arbitrary, and irrational. Habermas's philosophical ideas remain relatively unfamiliar to American thinkers, but they stand in a neo-Kantian tradition that is compatible with the traditional precepts of medical ethics. In addition, Habermas establishes normative validity through a process that is analogous in many ways to the process the influential philosopher of science Helen Longino devised to justify scientific claims to objectivity. As such the ideas employed by Habermas in his theory of normative validity should be relatively accessible to a broad audience.

Habermas is "neo-Kantian" in the sense that he adopts the Kantian premise that moral values should be differentiated from other ethical values on the basis of their universal significance [21]. While there may be a plurality of ethical views of "the good life," there is a universal moral imperative to respect a person's capacity to reason and develop a notion of the good life [22]. Kant formalized the moral imperative to universally respect free and equal moral persons with his categorical imperative to treat all people as ends in themselves and never merely as a means to fulfill another person's needs [23]. Habermas adopts Kant's moral imperative for universal respect for persons and notes accordingly that institutional norms should be acceptable to all the people affected by those institutions. Habermas states that "valid norms must deserve recognition by all concerned" [24] and formalizes this in a principle of universalization. For every valid norm: "All affected can accept the consequences and the side effects its general observance can be expected to have for the satisfaction of everyone's interests" [24].

But, Habermas is critical of Kant's and much later John Rawls's [25] attempts to monologically justify the universalizability of a norm on the basis of a thought experiment. It simply places too much burden on one thinker to determine that a norm is acceptable to all affected parties. Instead Habermas invokes the importance of an inclusive deliberative democratic process as a means of establishing/confirming this acceptability. Habermas posits a discourse principle where: "Only those norms can claim to be valid that meet (or could meet) with the approval of all affected in their capacity as participants in a practical discourse" [24].

Habermas is, of course, aware that empirical cases of consensus may very well be invalid if, for example, they are secured through coercive acts of manipulation. Habermas introduces rules of argumentation in order to minimize coercion in discourse:

> Every subject with the competence to speak and act is allowed to take part in a discourse.
> Everyone is allowed to question any assertion whatever.
> Everyone is allowed to introduce any assertion whatever into the discourse.
> Everyone is allowed to express his attitudes, desires, and needs [24].

Helen Longino [26] has noted the strong parallels in Habermas's procedural approach to securing normative validity with her own procedural approach to securing objective knowledge in the sciences. For Longino objectivity in science hinges upon four criteria:

> There must be recognized avenues for the criticism of evidence, of methods, and of assumptions and reasoning;
> There must exist shared standards that critics can invoke;
> The community as a whole must be responsive to such criticism;
> Intellectual authority must be shared equally among qualified practitioners [26].

The reason for the similarity in approach is that both thinkers are trying to minimize coercive practices so that the persuasive force of the better argument is the only force at play. This holds true whether the discourse involves empirical assertions or normative assertions.

To some extent Kant's categorical imperative to treat people as ends in themselves has already been institutionalized in the practice of medicine. The categorical imperative grounds the moral significance of the principle of autonomy guiding the practice of informed consent in medicine [27]. Much ado is often made in medical ethics of the conflicting demands of principles of autonomy which underscore the importance of treating a person as self-determined and principles of beneficence that demand physicians act in the best interests of their patients. But, the truth is respect for autonomy typically furthers the interest in beneficence. The moral significance of beneficence is underscored by the vulnerability created by illness and the imbalance of power seen in the clinical encounter. The principle of autonomy clarifies that in order to act in the best interests of a patient medical knowledge must be applied in a manner that accords with the patient's conception of their best interests [28]. The practice of informed consent is a further means of ensuring that the vulnerability and imbalance of power created by illness does not prevent beneficent medical practice. If medical knowledge were a value-neutral matter then the normative issues involved would be exhausted by the consensual application of that knowledge in the clinical encounter. But, as we have seen from our exploration of the theoretical issues at stake in nosology, the development of medical knowledge is far from value-neutral. Edmund Pellegrino and David Thomasma [29] have noted that medicine is a profession insofar as physicians profess knowledge of *value* to their patients. "Practical" interests are in the eye of the beholder. Medical knowledge has the potential to be developed according to practical interests, for example guild or industrial interests, which diverge from patient interests. If medical

knowledge were developed according to guild interests as opposed to patient interests, the knowledge could be empirically valid and of practical value, yet the knowledge would be unjust and therefore normatively invalid. This underscores the fact that practice of informed consent at the bedside may be necessary but it is not sufficient to ensure patient autonomy. The consensual application of unjust knowledge hardly secures patient autonomy.

Transcribing the notion of autonomy to the institutional level entails developing institutional norms that accommodate the diversity of people affected by the institution. Accordingly Habermas notes that in order to live autonomously the private autonomy employed in individual encounters must be complemented by a public autonomy, self-determination of the institutional norms that affect us [30]. It may seem strange at first to classify nosology as an institutional norm, but there can be little debate about the immense public impact of decisions institutionalized in the DSM. These impacts are, of course, felt in terms of forensic issues and insurance reimbursement. But, truthfully, the DSM does a great deal to structure the very nature of the clinical encounter between patient and clinician. The philosopher of science Philip Kitcher [31] has noted more generally that the public impact of science entails a moral prerogative to develop science according to the interests of the citizens impacted by that science. Incorporating patients into the process of developing nosology is a means of assuring that their needs and interests are being addressed. As Sadler and Fulford [32] have noted the potential for patient contributions here is not limited to monitoring for stigmatizing language. It extends all the way down to determining the boundaries between normalcy and disorder. While patients are the preeminent stakeholders in terms of the institutional impact of nosology they have traditionally been the most marginalized in terms of impact upon development of the science. Normative validity entails a more significant role for patients in the development of nosology.

For theoretical purposes it is possible to neatly separate the logic of empirical validity claims from the logic of normative validity claims. In reality, in the practice of science normative and empirical issues are thoroughly intertwined throughout the process. The challenge of integrating patients into the scientific process is that patient needs and interests must be interpreted in the context of scientific contingencies. Nonetheless, the practice of informed consent has already established patients' ability to competently determine their own needs and interests in the context of scientific knowledge. The challenge in shifting to establishing public autonomy as opposed to private autonomy is that the clarification of an individual's interests and needs are not sufficient. As Habermas [33] notes, "Only *generalizable* value-orientations, which all participants (and all those affected) can accept with good reasons as appropriate for regulating the subject matter at hand, and which can thereby acquire binding normative force, pass this threshold." Pioneering work in "user-led research" has begun to explore the process of integrating patient values into the scientific process [34–37]. The complex mixture of epistemic and evaluative elements in the development of nosology underscores the value of integrating scientists who have experienced illness first hand into the process [38].

Concluding Remarks

Elizabeth H. Flanagan, Larry Davidson, and John S. Strauss [39, 40] have emphasized that patient descriptions of illness experiences are an important scientific resource that has been largely neglected in the development of psychiatric nosology to date. Bruce Cuthbert and Thomas Insel [41] are skeptical about the value of this approach because they don't feel that it will help solve the major problems besetting nosology today. They delineate these problems as heterogeneity of the disorders, excessive comorbidity, and the increasingly frequent use of Not Otherwise Specified (NOS) diagnoses. They go on to assert that the neuro-circuitry first and foremost approach of the RDoC project is in a better position to solve these problems. But whether or not comorbidity and heterogeneity really are the foremost problems besetting nosology today is not an empirical question but rather an evaluative and normative question. A syndromal approach to diagnosis is not valuable to medicine solely as a temporary stand-in until a biological etiology is discovered. It is valuable to medicine because it keeps medicine attuned to symptoms that cause distress and therefore to matters of relevance to patients. The fear that the neuro-circuitry first approach of RDoC runs the risk of losing touch with the matters of most relevance to patients is only underscored by a quick dismissal of the value of scientific research into the salient features of illness experience. The leadership of the DSM-5 confidently declared, "Mental disorder syndromes will eventually be redefined to reflect more useful diagnostic categories ('to carve nature at its joints') as well as dimensional discontinuities between disorders and clear thresholds between pathology and normality" [3]. But this assertion stands in stark contrast to the difficulties encountered in categorizing autism, for example, and discriminating between valued aspects of identity and unwanted sources of suffering. The relative value of research into illness experience, and the biological, psychological, and social factors that affect that illness experience are all normative questions. It is not clear that the marginalization of psychosocial research within the science of nosology is justifiable. But, what is clear is that the valid resolution of these normative questions hinges upon a fair process and that a fair process does entail the integration of patient perspectives.

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