

The Concept of Vulnerability in Mental Health Research: A Mixed Methods Study on Researcher Perspectives

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Corinne Lajoie^{1,2}, Jelena Poleksic^{1,3,4}, Dearbhail Bracken-Roche¹,
Mary Ellen MacDonald^{5,6}, and Eric Racine^{1,5,7} 

Abstract

The concept of vulnerability plays a central role in research ethics in signaling that certain research participants warrant more careful consideration because their risk of harm is heightened due to their participation in research. Despite scholarly debates, the descriptive and normative meanings ascribed to the concept have remained disengaged from the perspective of users of the concept and those concerned by its use. In this study, we report a survey- and interview-based investigation of mental health researcher perspectives on vulnerability. We found that autonomy-based understandings of vulnerability were predominant but that other understandings coexisted, reflecting considerable pluralism. A wide range of challenges were associated with this concept, and further training was recommended by researchers.

Keywords

vulnerability, bioethics, mental health, pragmatism, feminism, researchers, survey, interviews

Background

The notion of vulnerability has played a central role in research ethics since the publication of the Belmont Report in 1979. The notion was first introduced to identify a need for protections for participants who are more at risk of being subjected to unethical conduct, such as “the sick, the old, the retarded or mentally ill, children, prisoners, the impoverished, and those whom life has neglected or betrayed” (The National Commission for the Protection of Human Subjects of Biomedical and Behavioral Research, 1979). It underscores the importance of the principle of respect for persons in research ethics and identifies individuals or groups whose participation in research warrants more careful consideration. Accordingly, the notion of vulnerability may serve to identify participants with a higher possibility of exposure to risk and an increased susceptibility to harm, or participants lacking the ability to safeguard their own interests (e.g., because of impaired decision-making or disempowering social positioning).

However, the literature on vulnerability, more generally, and research ethics guidelines about vulnerability, more specifically, both display considerable confusion on the question of what makes an individual or a group vulnerable, and what an assessment of vulnerability might entail for researchers and research ethics oversight. Tensions have surfaced in the academic literature regarding the validity of individual versus relational accounts of vulnerability (Luna,

2009). The literature also discusses whether vulnerability is only explainable in terms of impaired autonomy (Bell et al., 2014; Kipnis, 2003), or if it also identifies other kinds of concerns related to fairness, justice, and power asymmetries (Bell et al., 2014). A recent review of major research ethics policies illustrates this conceptual confusion regarding understandings and applications of the concept of vulnerability (Bracken-Roche et al., 2017). This review revealed that only three out of 11 policies offered any definition of the concept of vulnerability. In addition, these policies identified more than 50 distinct groups of individuals as vulnerable based on a number of different concerns. When combined, these observations suggest that certain groups are identified as essentially vulnerable without this essentializing diagnosis being supported by a clear argument nor by sufficient evidence. The implications associated with

¹Institut de recherches cliniques de Montréal, Québec, Canada

²The Pennsylvania State University, University Park, USA

³Schulich School of Medicine & Dentistry, London, Ontario, Canada

⁴Western University, London, Ontario, Canada

⁵McGill University, Montréal, Québec, Canada

⁶McGill University Health Centre, Montréal, Québec, Canada

⁷Université de Montréal, Québec, Canada

Corresponding Author:

Eric Racine, Pragmatic Health Ethics Research Unit, Institut de recherches cliniques de Montréal, 110 Avenue des Pins Ouest, Montréal, Québec, Canada H2W 1R7.
Email: eric.racine@ircm.qc.ca

vulnerability also vary considerably across these policies and involve (a) restrictions for research with vulnerable groups or individuals (e.g., research carried out with vulnerable participants should be responsive to the needs, conditions, or priorities of the vulnerable group involved) and (b) the need for special protections and obligations (e.g., greater level of attention and consideration, research ethics board (REB) composition, assessing harms, risks, and benefits, recruitment practices, process of informed consent, debriefing). In view of this variability and of the lack of conceptual clarity surrounding the notion of vulnerability, it is not surprising that the concept has been faulted for its vagueness and inapplicability (Schroeder & Gefenas, 2009). When it serves to identify specific groups and individuals as vulnerable without a clear sense of what this notion means and what normative obligations it implies, the notion offers little practical guidance to REBs and researchers reviewing and conducting research.

In response to these concerns, and because vulnerability operates as a key concept in research ethics, several scholars have developed proposals for better identifying types of vulnerability (Kipnis, 2003), accounting for intersecting layers of vulnerability (Luna, 2009), and addressing ethical concerns captured by principles of autonomy and justice (Nickel, 2006). For example, Hurst (2008) has provided a functional definition where the term stands for “an identifiably increased likelihood of incurring additional or greater wrong.” She also proposes to ask whether concerns for vulnerability make a difference for the evaluation of key ethics criteria (Emmanuel et al., 2000). This functional account of vulnerability gives us a better sense of how the concept can be used. Yet, it stills falls short of specifying the particular reasons that might lead to an increased likelihood of incurring an additional or greater wrong. Hurst’s account also lacks resources to validate triggers of concern for vulnerability (as we might expect that group attributions of vulnerability can generate false positives) and does not specify what kinds of responses would be necessary to tackle these concerns. Racine and Bracken-Roche (2019) address some of these issues in a more recent integrative-functional account of vulnerability. Drawing on a pragmatic theoretical approach, this account proposes to envision the concept of vulnerability as a practical tool allowing researchers and those responsible for research ethics oversight to identify, validate, and respond to concerns for participant vulnerability (Racine & Bracken-Roche, 2019). Although promising, this account currently relies on a preliminary theoretical proposal and warrants inclusion of the perspectives of stakeholders immediately involved in research (i.e., researchers and research participants). Importantly, the integrative-functional account suggests that concerns for vulnerability need to engage those actively involved in a given situation. This step is crucial given the possible conceptual enrichment generated by

stakeholder understanding of ethics concepts (Racine et al., 2019; Racine et al., 2017).

In light of the gaps identified in the literature on vulnerability and the need for better-informed research ethics guidelines and policies, our objective with this study was to elucidate what the concept of vulnerability means for mental health researchers (and research participants, as will be reported in a separate, forthcoming paper). We focused on the mental health research community because of the important concerns expressed about the inappropriate labeling of mental health research participants as inherently vulnerable without due attention being given to these claims (Bell et al., 2014), as well as to verify the validity of an overwhelming focus on autonomy, consent, and decision-making capacity in discussions of vulnerability in mental health research participants (Bracken-Roche et al., 2016). To our knowledge, no such study had been undertaken at the time and only a few such studies have been published (Sengupta et al., 2010).

Method

This study proceeded in two steps. First, we collected data via an online survey designed by the research team to examine mental health researchers’ perspectives on the meaning of the concept of “vulnerability” in research ethics, as well as on whether people with mental health conditions represent a vulnerable population and why. Then, we conducted one-on-one in-depth qualitative interviews with some of the researchers who had taken part in the survey. Survey and interview participants are referred to as SPs and IPs, respectively. The general term “participants” refers to both groups.

Survey

Developing the survey. We developed an online survey (deigned in SurveyMonkey) based on a previous analysis of the concept of vulnerability in research ethics literature and guidelines (Bracken-Roche et al., 2017; Racine & Bracken-Roche, 2019) as well as the materials developed for a pioneering study of HIV/AIDS researchers’ perspectives on vulnerability (Sengupta et al., 2010). Dillman’s (2007) tailored Design Method also inspired our development of the survey. The questions sought to elicit participants’ spontaneous views and reporting of related strategies to manage vulnerability in their research and their perspectives on the vulnerability of people with mental health conditions.

We circulated a draft of this survey to colleagues with expertise in survey design and research ethics to ensure readability and ease of understanding. Two members of the research team (D.B.-R. and E.R.) revised the survey based on this feedback. We circulated a subsequent version to colleagues with expertise in mental health research and ethics (E.R. and M.E.M.) for feedback on its exhaustiveness. We

asked those consulted whether they felt that some elements were missing and whether some of the questions needed to be eliminated. Two members of the research team (D.B.-R. and E.R.) revised the survey after this second round of feedback. Finally, we circulated the survey for feedback to experts in mental health research to ensure the quality of its content, ease of understanding and accessibility for mental health researchers who do not necessarily have expertise in ethics or research ethics. Pretesting followed a technique known as cognitive interviewing (Forsyth & Lessler, 1991), in which survey respondents are asked to think aloud as they go through the draft questionnaire and tell the interviewer everything that they are thinking. To obtain as broad a response as possible, we conducted pretest interviews with five English-speaking and four French-speaking researchers from a diverse set of mental health disciplines, including neuroscience, anthropology, psychology, psychiatry, nursing, and social work. As a result, we made some changes to the survey. A native French speaker in the research team translated the final version of the survey to French and another verified the translation.

Survey structure. The survey consisted of 27 questions (including short answers and multiple-choice formats) and took approximately 25 min to complete. Questions 3 to 10 collected demographic and background information about participants (e.g., age, sex, current position, area of research, and years of experience). Questions 11 to 15 asked SPs to reflect on definitions of vulnerability for persons with mental health conditions. For example, we asked SPs how they would define the concept of participant vulnerability and its implications for research and research ethics. Questions 16 to 21 introduced the *Diagnostic and Statistical Manual of Mental Disorders*' (5th ed.; *DSM-5*; American Psychiatric Association, 2013) use of severity ratings (mild, moderate, severe) to capture gradients of mental illness, which are also used more broadly. We asked SPs to reflect on the connection of these gradients to vulnerability in research participants. Questions 21 to 27 covered general issues associated with vulnerability in research, including aspects of the research process that might raise concerns, relations with REBs, and strategies to address and counter vulnerability.

We provided comment boxes for specific questions. SPs could use comment boxes to specify their research positions, themes of research, experience with REB and ethics approval, and gender identity, in the event that these were not captured by our multiple-choice options. We also invited SPs to provide follow-up explanations and/or full-text responses in comment boxes to questions regarding (a) definitions of the concept of participant vulnerability in mental health research ethics; (b) opinions regarding whether persons experiencing mental health conditions should also be thought of as vulnerable in research; (c) aspects of participant vulnerability that our questions might have missed; (d) opinions regarding the

implications of mild, moderate, and severe mental health conditions; (e) opinions on how the concept of participant vulnerability affects their research with persons experiencing mental health conditions; (f) experiences dealing with REBs and their concerns about participant vulnerability; and (g) opinions regarding research stages in which researchers think that the potential vulnerability of persons with mental health conditions is a concern.

Recruitment. We recruited SPs using both convenience sampling and snowball recruitment strategies, using a combination of extensive online searches on relevant professional websites and the websites of Canadian universities and research centers and input from members of the research team and colleagues working in the area of mental health research. We also contacted institutions to invite them to distribute the survey to their members. We identified additional SPs through searches of publicly available information (e.g., successful Canadian Institute of Health Research [CIHR] funding applications) and word of mouth. We sent more than 400 emails to institutions, individual researchers, and departments. We also encouraged participants to forward the invitation and survey link to interested individuals within their networks. We recruited 130 survey participants.

Data analysis

Quantitative. A research assistant extracted all quantitative and qualitative data into a spreadsheet in preparation for analysis. The responses of 50 (40 English, 10 French) SPs were excluded from the quantitative analysis because they only responded to the questions collecting demographic and background information (Q3-10) and did not respond to any question beyond that point, thus providing significantly incomplete data. The sample thus counted 80 SPs. A statistician working closely with the research team produced basic descriptive statistics on the multiple-choice format survey questions.

Qualitative data. Qualitative data were extracted (by J.P.) along with the questions they were associated with, to understand them in context. We then elaborated a coding guide based on our preliminary analysis of these data. Two members of our research team (J.P. and C.L.) consulted on the elaboration of this coding guide. The codes captured (a) general issues in mental health research and (b) views, opinions, perspectives, and concerns with the application and use of the notion of vulnerability in mental health research. We used the MAXQDA qualitative data analysis software to code all qualitative answers of the survey based on our coding guide.

Demographic overview of survey participants. In all, 72.6% ($n = 58$ participants) responded in English and 27.5% ($n = 22$

participants) responded in French. Of these participants, 62.5% identified as female, 31.3% ($n = 25$ participants) identified as male, 5% preferred not to answer, and 1.3% preferred to self-describe but provided no specification as to how they identified. The median age was 41.5, the mean 43.8, and the minimum and maximum age of respondents 22 and 73, respectively.

The highest reported education levels of respondents were, in order, PhDs (48.8%), master's degrees (22.5%), doctoral degrees in medicine or dentistry (15%), bachelor's degrees (12.5%), and university certificates (1.3%). Most SPs had 1 to 5 years of experience in research (35%), while the others reported more than 25 years (18.8%), 21 to 25 years (10%), 16 to 20 years (7.5%), 11 to 15 years (8.4%), 6 to 10 years (10%), 6 months to a year (5%), and less than 6 months (5%). SPs were either principal researchers or coinvestigators (58.8%), student researchers or postdoctoral fellows (28.7%), or research staff (12.5%). In addition to these responses, some specified that they were retired researchers (2.5%), psychiatrists (1.3%), or that they were CQI (continuous quality improvement) project leads and clinical staff members whose patients might participate in research studies (1.3%). We asked SPs to describe their main area of research according to one of the four research themes defined by the CIHR ("The Power of Health Research," 2017) or as "other." SPs could select more than one option. Seventy percent identified their research as clinical research; 30% as health services research; 30% as social, cultural, environmental, and population health research; 13.8% as biomedical research; and 10.5% as another type of research.¹

We asked SPs to describe the institution where they most often sought research ethics approval with REBs or research ethics committees (RECs). SPs chose between an institution that did not specialize in mental health and addictions research and has moderate experience in this area (48.8%), an institution that specializes in mental health and addictions research (32.5%), and an institution that does not specialize in mental health and addictions research and has little experience in this area (7.5%). Ten percent (10%) selected the option "unsure/not applicable," and 1.3% selected "other."

We asked SPs about their own experience with the process of ethics approval. They could select more than one option. In all, 76.3% had prepared their own research ethics application, 72.5% had undertaken formal training in research ethics, 70% had contributed to the preparation of ethics applications submitted by other researchers, 28.7% had sat on REBs or RECs, 7.5% felt that this question did not apply to their situation, and 2.5% selected other options (i.e., conducting research on research ethics and conducting research that did not require formal ethics approval).

Interviews

Developing the interview grid. We drafted the interview grid to reflect key areas explored by the survey that could

benefit from more in-depth perspectives. Accordingly, all steps undertaken to validate the survey content fed into the development of the interview grid. Furthermore, a parallel ongoing study on participant perspectives on vulnerability (not reported in this manuscript) informed the construction of the interview grid for researchers to ensure eventual cross-talk. The interview grid was refined iteratively to accommodate the progression of the study and included three sections. The first part of the final interview structure focused on identifying the general context and challenges of ethics in mental health. The second part addressed the notion of vulnerability itself and followed-up on questions from the survey (e.g., regarding definitions, justifications, challenges in interpretation and application). A third part captured any other insights and recommendations the participants wanted to share in the context of this study. A native French speaker in the research team translated the final version of the interview grid to French and another verified the translation.

Interview structure. We divided the interview into three parts. The first part concerned the general context and challenges of ethics in mental health. We asked IPs how they viewed ethics and ethical challenges in mental health. We also asked for examples of ethical challenges they might have encountered. The second part of the interview directly concerned the concept of vulnerability and raised issues elicited by the survey (regarding, for example, definitions, justifications, and challenges in interpretation and application). We asked IPs how they would define vulnerability, whether they had encountered this notion before, and whether or not they felt that it was useful to guide ethical research. We also asked IPs about the relationship between vulnerability and levels of mental illness. The third part opened up the conversation to capture any insights and recommendations that IPs wanted to share, as well as expectations for mental health research.

Recruitment. We recruited IPs through the online survey described above. SPs had the opportunity to signal their interest in follow-up, one-on-one interviews at the end of the survey. Of the 130 SPs, 16 initially manifested interest in participating in individual interviews by answering positively to a question to this effect. The researchers who expressed interest were invited to participate in the individual interviews by email and were provided with a separate consent form. Seven accepted our invitation and participated in individual in-depth interviews. The remaining nine did not participate in the interviews, either because they were going through personal issues ($n = 1$ participant) or because they did not respond to our email and follow-up requests ($n = 8$ participants).

Data collection. Two members of our research team (C.L. and J.P.) conducted the phone interviews, in French and in English. The interviews lasted between 30 min and 1 hr.

The interview audio files were transcribed verbatim by a professional transcription company. We did not collect any systematic demographic information about IPs.

Data analysis. We used thematic analysis and rich coding methods to code the interviews. Rich coding implies non-mutual exclusiveness of the application of coding categories, that is, the same content could be coded for two or more content themes it contained. A member of the research team (C.L.) familiarized herself with the transcripts twice with annotations and proposed a first coding grid. Two members of our research team (C.L. and J.P.) used this grid to code a sample of two interviews. We then used consensus agreement to compare the coding of these samples and henceforth refine the coding grid. Most disagreements were based on understandings of codes that presented significant overlap. The researchers (C.L. and J.P.) discussed their coding strategies and decisions and came to an agreement on all segments. We rescinded codes that were repetitive. A member of the research team (C.L.) then proceeded to recode all (seven) interviews.

A member of the research team (E.R.) with experience in bioethics and qualitative research revised the coding and coding grid and offered feedback. As a result, the coding grid was divided between (a) general concerns regarding mental health experiences and mental health research (e.g., concerning inclusion and exclusion of participants, or informed consent procedures) and (b) answers *directly* concerned with the notion of vulnerability (e.g., its application in research and challenges to this application, sources of vulnerability, definitions of vulnerability and variability in vulnerability). This shift allowed us to frame these answers in terms of their relevance for a rich understanding of the notion of vulnerability in mental health research ethics. Although there are generally key ethical issues in mental health research, which our coding also highlighted, they are not a central focus of this article.

Results

Because we recruited participants for individual interviews in the pool of participants from the national survey, we combined the results of the interviews (IPs) with the responses from the national survey (SPs). We divided the data in five sections: (a) assessing vulnerability in mental health research, (b) defining vulnerability, (c) consequences of vulnerability, (d) using the notion of vulnerability in mental health research, and (e) recommendations and needs for best practices and policies in mental health research.

Assessing Vulnerability in Mental Health Research

When SPs were asked if they thought that people with mental health conditions should always be considered vulnerable

in the context of research, 57.5% of thought that they should not, 22.5% thought that they should, and 20% were not sure. SPs were also asked whether the concept of participant vulnerability affected their research with persons experiencing mental health conditions. Seventy-one percent stated that it affected their research, 15% that it did not, 13% were not sure, and 1% did not answer. Forty-eight percent of SPs reported that REBs had raised concerns about participants' vulnerability when reviewing their research on persons with mental health conditions. Thirty-three percent said they had never encountered these concerns, 12% were not sure, and 7% did not answer.

We asked the following question to SPs regarding mild, moderate, and severe mental health conditions: In your opinion, which of the following statements are true for persons experiencing (*mild, moderate, or severe*) mental health conditions? SPs could select more than one option. Table 1 compares their answers to these questions.

Concerns about participant vulnerability can arise regarding different aspects of the research process. We presented SPs with a list of stages involved in the design and conduct of research and asked them to select the stages in which they thought that the potential vulnerability of persons with mental health conditions was of concern, based on their experience. They could select more than one option. Table 2 compares their answers to these questions.

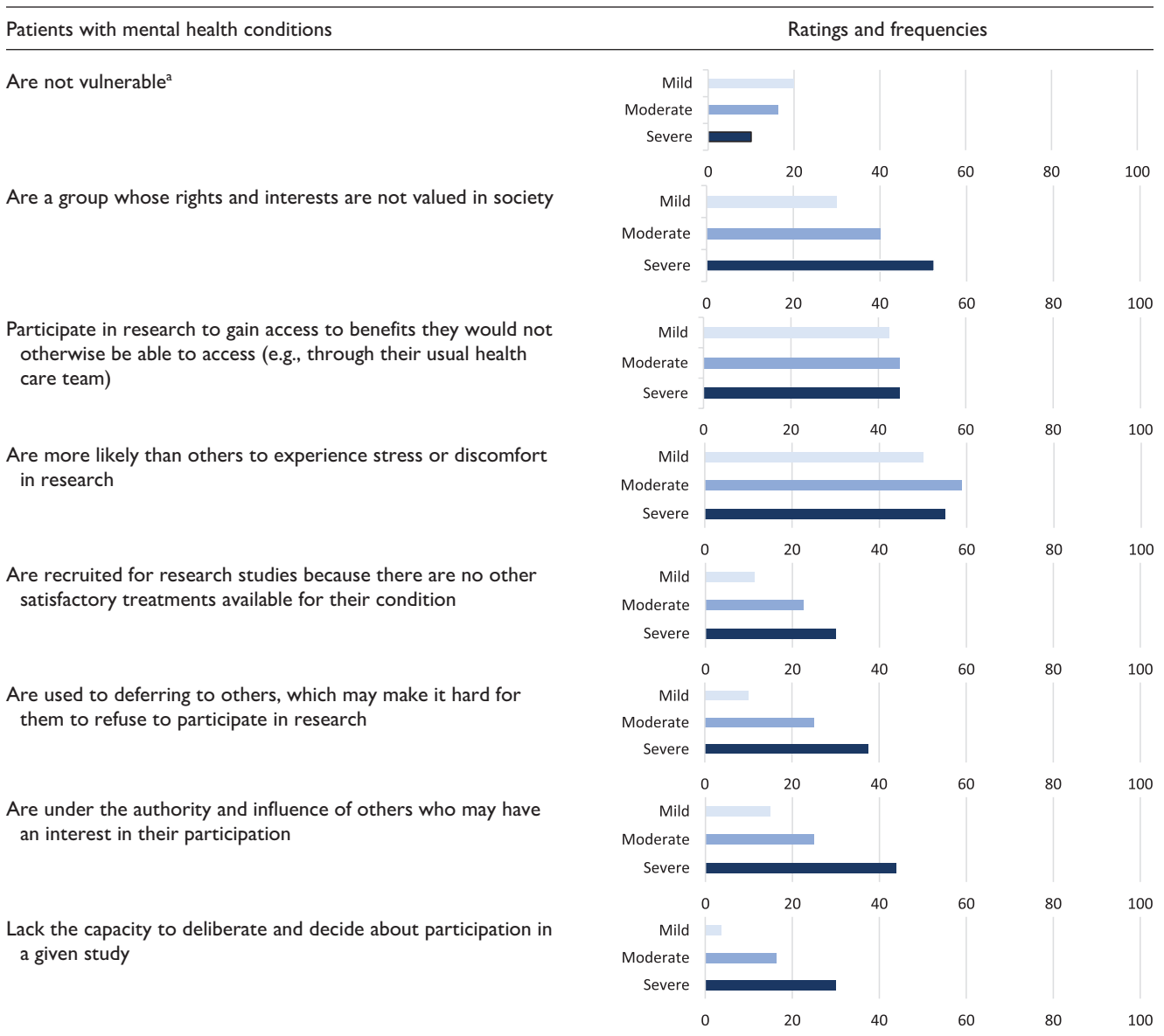
Defining the Notion of Vulnerability

We asked SPs to consider potential aspects of participant vulnerability that they would include in a definition of this concept in mental health research. Table 3 compares their answers to this question.

Participants (IPs and SPs) also identified many different and wide-ranging sources that they considered to augment or generate vulnerability in research participants. These included the following: financial insecurity and lack of resources, legal issues and criminalization, difficulties accessing care and treatment, addiction, medical comorbidities, illiteracy, varying cognitive and decision-making abilities, stigma, isolation, marginalization, lack of peer support, age, and various vulnerabilities created by research contexts (e.g., the label of vulnerability itself, exclusion from research, susceptibility to coercion and abuse). These various sources did not necessarily manifest in isolation. Instead, IP suggested that they are often co-occurring and support each other in creating areas of vulnerability.

Variability of vulnerability. Many participants suggested that each experience of vulnerability is uniquely different. This view is compatible with one IP's claim that the definition of vulnerability is "dynamic" and "fluid" (IP3). Similarly, one IP suggested that evaluations of vulnerability should be "multidimensional" (IP7) and include consideration of diverse criteria in "some kind of general vulnerability

Table I. Perceived Impacts of Mild, Moderate, and Severe Mental Health Conditions on Different Aspects of Vulnerability Based on Percentage of Respondents.



^aDue to a mistake in the elaboration of the French version of the survey, we did not present French survey participants with the option “are not vulnerable” for this question. The option was however listed in the English survey, and 46.6% of the English respondents ($n = 27$) selected this option. Given this mistake, 20% of the total number of survey participants selected Option I “are not vulnerable.”

index” (IP7), rather than be the product of a unilateral assessment. Participants however recognized that these types of assessments are very complex.

Several ideas regarding the variability of vulnerability as it applies to participants living with mental health conditions were shared by IPs, such as (a) all research participants can be vulnerable, (b) all participants with mental health conditions are not necessarily vulnerable and/or more vulnerable than research participants without mental health conditions, (c) there are different levels of vulnerability (within the same participant and across participants),

and (d) participants with mental health conditions are vulnerable research participants. Some participants (SPs and IPs) rejected the assumption that all participants living with mental health conditions were vulnerable (a problematic assertion we deliberately formulated in the interviews and in the survey to provoke reactions), while others questioned the idea that these participants could be described as experiencing no vulnerability *at all*. Rather than a binary between vulnerable and nonvulnerable participants, researchers shared their preference for a “continuum” or “gradient” (IP6) of vulnerability. Most participants

Table 2. Concerns About Vulnerability With Respect to Different Stages in the Research Process Based on Percentage of Respondents.

Concern	Frequency
<i>Obtaining informed consent</i> from participants experiencing mental health conditions (e.g., planning the process of consent, creating the consent form, executing informed consent conservations).	78.8%
<i>Assessing risks and benefits</i> for participants experiencing mental health conditions (e.g., types of risks and benefits expected, likelihood of those risks and benefits).	71.3%
<i>Deciding which subpopulations will be included (or excluded)</i> in research (e.g., severity of condition of participants, comorbidities of participants).	66.3%
<i>Recruitment strategies and practices</i> for participants experiencing mental health conditions (e.g., prescreening, pool of participants to recruit from, strategies used for recruitment).	66.3%
<i>Designing research protocols</i> (e.g., selecting methods, measurement tools, and research settings) that include participants with mental health conditions.	61.3%
<i>Retention of participants</i> experiencing mental health conditions in research studies (e.g., follow-up procedures, favoring participation in all study procedures).	60%
<i>Debriefing practices</i> for sharing results with participants experiencing mental health conditions (e.g., type of information offered to participants).	56.3%
<i>Compensating persons</i> experiencing mental health conditions for their research participation (e.g., types of incentives offered, amount of incentives offered).	55%
<i>Other</i>	6.3%

Note. These answer choices were generated based on a preliminary review of the literature and of research ethics policies (Bracken-Roche et al., 2017).

expressed feeling more comfortable speaking about a variable gradation and provided various explanations for what distinguishes these gradients (see below). Overall, participants tended to agree about the existence of fine-grained variations in experiences of vulnerability both among groups of individuals living with mental health conditions, across diagnoses, and within individuals themselves.

We presented participants with a scale inspired by the DSM-5 distinguishing between mild, moderate, and severe levels of mental health conditions (see Table 1) to evaluate whether and/or how they believed that participant vulnerability varied across it. When we asked them other questions that referenced this scale, some felt comfortable with these distinctions, while others questioned the ability to perceive and

Table 3. Agreement With Definitional Attributes of Vulnerability Based on Percentage of Respondents.

Attribute	Frequency
A participant's inability to provide voluntary informed consent to participate in research	82.5%
A participant's inability to protect their own interests in research	71.3%
A participant having a higher chance of being harmed (physically, psychologically, socially, or otherwise) in research	62.5%
A participant having a higher chance of being exposed to the risks and burdens of research without having adequate benefits in return for their participation	57.5%

Note. These options were generated based on options commonly discussed in the literature.

categorize nuances between different levels of illness. Some loosely correlated variations between diagnoses with variations between levels of vulnerability, while others were more wary of these types of associations. A person's level of vulnerability could depend on stages of remission, levels of experienced stigma, needs for help, and/or current situation and state of being. Moreover, some individuals might not have a diagnosis and/or identify as living with mental health conditions, yet experience some level of vulnerability in research. On the contrary, many individuals living with mental health issues and/or a diagnosis are integrated in their environment and relatively stable and cannot (or should not) be readily identified as vulnerable individuals. These variations in levels and sources of vulnerability signaled the possibility of developing ways to address and counter the vulnerability of research participants (e.g., by sharing power with participants or developing similar strategies). Interestingly, IPs also mentioned the vulnerability of researchers themselves when outlining their understanding of vulnerability in research. They spoke of the challenge of exposing themselves to difficult and emotional situations and of lacking tools to deal with the traumatic life narratives of research participants.

Consequences of Vulnerability

Stigma and vulnerability. As much as the label of vulnerability employed in research ethics aims to protect individuals living in a "social structure that makes them vulnerable" (IP5), some participants raised the concern that the attribution of the label of vulnerability is itself stigmatizing and "diminishes the power of a person by categorizing them . . . with this label" (IP5). Accordingly, the label of vulnerability could function as a source of stigma and compound the existing stigmatization and/or marginalization of individuals living with mental health conditions.

Power differentials and vulnerability. IPs described research settings as a nexus of intersecting power relationships (e.g., relationships between participants and researchers or between participants and clinicians). They situated participants as “always in a relation of power, in the face of a researcher” (IP2), notably in view of the potential blurring of boundaries between research and clinical settings and roles. Clinicians, nurses, psychiatrists, and therapists were described as potentially helpful in identifying participants and facilitating various steps of the research process, but the question of their involvement was contentious. Some raised the concern that participants might conflate or confuse the roles of clinicians and researchers if these roles were not clearly distinguished, or if they were not distinguished at all in practice (e.g., in the case of a researcher who is also a participant’s medical doctor). One IP thus advocated for “an absolute separation” (IP1) between clinical and research activity, all the while acknowledging that it was “very difficult to achieve on a practical level” (IP1). Participants might feel compelled to participate in a specific research project because they worry that their refusal would affect their quality of care or access to services. Conversely, they might choose to participate with the expectation that they will access care that they cannot otherwise access. This is particularly salient for participants with mental health conditions who have previously experienced difficulties accessing treatment, help, or resources, or who have tried many options but are still suffering and have become “desperate for help” (IP4).

Beyond the blurring of research and clinical activities, similar power differentials could be at play between researchers and research participants. Coercion can happen very indirectly, given the influence and authority attributed to the perception of “someone in a white coat or with a title” (IP7). Other motives, such as financial compensation, might also function as a “perverse incentive” (IP7). In addition, common power differentials, such as those occurring across gender and racial lines, also exist in research contexts. Countering power imbalances might be one way of redressing some of these structural inequities. One IP suggested that sharing power with participants is an important way to address their vulnerability. Propositions for such “practices of empowerment” (IP5) included involving participants as much as possible in the research process. For another IP, participants nevertheless maintained some level of power in knowing that they could withdraw at any given time from research projects in which researchers had invested time and resources.

Autonomy, consent, and vulnerability. Many participants linked concerns for vulnerability with the ability to provide informed consent (or lack thereof). Participants emphasized the importance of verifying that research participants are both able to consent and are not coerced to do so, particularly in the case of severely mentally ill participants.

They expressed concern over the fact that the ability of participants living with mental health conditions to provide informed consent could be altered and emphasized the importance of informing participants of their rights and options while minimizing coercion. IP’s suggested that this could include (a) soliciting the assistance of clinical teams to select participants who are able to consent, (b) making sure that participants can adequately read and comprehend consent forms (and are not pretending that they can read for fear of being judged, for example), (c) addressing participants’ questions and concerns, and (d) clarifying they “have nothing to gain or to lose by participating in the research” (IP1) when this research is not related to clinical or psychiatric treatment.

Using the Notion of Vulnerability in Mental Health Research

Familiarity of researchers with notion of vulnerability. IPs who were familiar with the notion of vulnerability had encountered it either through ethics training (e.g., mandatory course work), involvement in REBs, or research and/or clinical experience. Most IPs had some level of familiarity with the notion of vulnerability. One IP mentioned that she had never seen the notion defined, but observed that her research coordinator in charge of REB applications might have.

Utility of notion of vulnerability in guiding researchers. There was no consensus between IPs on the usefulness of the notion of vulnerability in its current formulation in research ethics policies. Some agreed that it was useful, inasmuch as it serves to draw attention to the potential need for specific protections and accommodations in research for individuals living with mental health conditions, thus changing how they do research and inviting caution. Others were more ambivalent and hesitated between its usefulness and its inadequacy to protect research participants. One IP described it as a “useful starting point” (IP7), but pointed to the need for a better understanding of its implications and to the general lack of guidance on its application in the context of mental health research.

Possible challenges to application of notion of vulnerability in mental health research. IPs identified many potential challenges, risks, and concerns related to the application of the notion of vulnerability in mental health research. Many of these challenges are captured by concerns over the lack of flexibility afforded by an imprecise notion of vulnerability, the lack of guidance on its definition and application, the risk of going too far with protections, and the risk of adding a burden or of generating potential stigma and/or discomfort for researchers and research participants. Overall, IPs identified various ways in which this concept and its application could be challenging, such as the following.

Risk of going too far with protections. There is a tension between the desire to protect research participants and the implementation of severe and/or paternalistic measures (e.g., systematically assuming worst-case scenarios, REBs doubting the “competence” of researchers, perpetuating stereotypes about individuals with mental health conditions). Some REBs might impose protections that researchers judge as unnecessary or as going a “bit further than they actually should” (IP6). For example, one IP pointed out that it is a participant’s right to decide to seek participation if they personally feel that they can benefit from it and that they should not be kept from participating simply because this potential benefit is an incentive.

Risk of overusing the notion. Because the notion of vulnerability is widely used, it threatens to become more and more “hackneyed” or “overused” (IP2) and lose its relevance. The notion of vulnerability is “a double-edged sword” (IP2): If the label of vulnerability is used too widely, “every research project becomes a research project with vulnerable participants” (IP2), because all research participants can be considered vulnerable in some way. IPs questioned whether the notion of vulnerability would still fulfill its purpose if it became too general.

Risk of prioritizing group definitions over individual experiences. Group-based approaches might not adequately or completely map onto individual experiences. IPs described encountering individual participants with complex life stories and experiences, while REBs needed to “balance the rights and the needs of a whole group” (IP3). One IP suggested that this gap might explain why these boards adopt a more conservative approach.

Lack of consensus and conceptual clarity about definition. There seems to be no consensus across committees and researchers and within research groups and committees about the definition of the concept of vulnerability. One IP found that our use of this concept in the title of the project and in the interview questions was itself “perplexing” (IP1), as they did not feel that the notion was clear from the outset.

Diagnosis, mental illness, and/or capacities are unknown or nonevaluated. First, the cognitive capacities of participants are not systematically assessed prior to their participation in research. Second, participants living with mental health conditions might not have a diagnosis. Third, participants with or without a diagnosis might judge this information irrelevant to the project that they are participating in and/or choose not to disclose it to the researcher. Finally, the vulnerability of some participants might disclose itself to researchers through the research process, while other participants might discover their own mental health challenges during the course of participation. As such, “if [researchers] are not totally confident that [they are] doing

a valid and reliable assessment” (IP7) of a participant’s mental health, criteria of inclusion and exclusion will not be entirely rigorous.

Lack of training and guidance on application. There is a lack of ethics training on participant vulnerability in research and an absence of clear guidelines and parameters on the application of the notion of vulnerability. IPs expressed the need for more guidance on the circumstances in which the notion of vulnerability should be applied in ways that benefit the population that is being studied (IP7).

Variability in levels of vulnerability and application. This challenge relates to the aforementioned variability in levels of vulnerability (see “Defining the Notion of Vulnerability” section). For IPs, the experience of vulnerability varied across and within individuals, groups, diagnoses, and periods of life, thus making unilateral assessments of vulnerability extremely complex. Moreover, IPs suggested that the application of the notion of vulnerability in research ethics also varied across and within ethics committees, research teams, and research contexts. They were wary of blanket statements in the application of the concept and favored instead a case-by-case approach.

Gaps between theory and practice. Potential gaps between the theoretical understanding of the concept of vulnerability and its application in real-life situations and research contexts plague the application of the concept. One IP suggested that much as one cannot do surgery from having studied human anatomy in a laboratory, ethics training cannot anticipate the complexities of actual fieldwork.

Risk of systematic exclusion. Restrictions resulting from the application of the notion of vulnerability might systematically exclude groups and individuals from the production of new knowledge. Their experience would not be represented and taken into account “in treatment development or an understanding of different constructs” (IP7).

Risk of making participants uncomfortable. In some cases, the use of the term “vulnerable” to describe individuals living with mental health conditions “could get kind of dicey” (IP4). One IP said she did not know if participants with mental health conditions would appreciate “[being] called victims or sufferers” (IP4).

Risk of adding a burden on research(ers). Research that involves too much “jumping through [the] hoops” (IP1, IP7) or constraints described as “a real pain in the neck” (IP1) might discourage researchers and hinder the development of important research. The burden of ethics review should be “reasonable” (IP1) and balanced between protections for participants and the development of new knowledge.

Risk of adding a burden or stigma on participants. IPs felt that being identified as vulnerable in research contexts could become burdensome for research participants. One IP suggested that researchers should take in charge the potential complications and added responsibilities that arise from this identification. Instead, the onus of reducing and managing vulnerability is sometimes on participants themselves rather than being shared with researchers. A narrow focus on the vulnerability of research participants in the presentation of the project might also discourage participants from pursuing participation. Participants living with mental health conditions who participate in studies might find some protections excessive and/or intrusive (e.g., follow-up phone calls to assess suicidal ideation). In addition, the application of the notion of vulnerability might compound the stigma experienced by individuals living with mental health conditions by generating additional stigma.

Risk of changing the focus of the project. A project might involve participants living with mental health conditions without that being the central focus of the project (e.g., a project involving participants living with psychological distress but addressing another topic). An overly narrow focus on vulnerability might result in the project being presented and structured in a different way by researchers; one IP wondered whether potential participants might be lost as a result and identified this issue as a major concern for mental health research.

Recommendations and Needs for Best Practices and Policies in Mental Health Research

IPs discussed the importance of providing better and more ethics training to researchers and of providing funding for this training, to encourage shifts in perceptions of the research ethics process and in research practices more generally. This type of training should train researchers on their responsibility in this role, rather than only on ethics concepts. The current state of ethics training and lack of interest of student researchers in ethics training itself generated concerns among IPs. IPs also expressed a need for explicit policies and protocols to evaluate and address participant vulnerability and a better definition and collective understanding of the concept of vulnerability.

IPs stressed the importance of collaborations, better communication, and structures of support between researchers with experience in mental health research, REBs, and research participants. Strategies in view of this end could include creating new research tools (e.g., a guidebook of recommendations for mental health research). IPs discussed the relevance of offering mental health researchers processes of consultation with ethicists and of creating possibilities for supervision with researchers familiar with vulnerabilities that can be associated with mental health. In

addition, some IPs suggested adopting collaborative or participatory research methods to ensure sharing power with participants.

One IP explained that while she understands the role of REBs and their obligations toward participants, she fears that they might not sufficiently trust the abilities and competence of researchers working in the field of mental health research. She acknowledged the complexity of finding a balance between both, but stated that it was important. Another IP suggested that both mental health researchers and REBs have a relevant expertise: the former through experiential knowledge gained working with a specific population group, the latter with conditions for ethical research and promoting participant well-being. These complementary sources of knowledge require more sharing of expertise between these parties.

The great variability of mental illness and vulnerability also requires flexibility and understanding on the part of researchers and REBs. As previously discussed, some IPs were wary that excessive demands and surveillance (e.g., requiring researchers to emphasize potential harms over the benefits of participation in research) might discourage both researchers and participants from participating in or conducting research. They recommended shifts in the attitudes of REBs toward mental health research. One IP suggested that it was essential to evaluate projects presenting significantly different levels of risk (e.g., an interview-based qualitative study and a pharmaceutical trial) differently and that ethics committees should have requirements and ethical standards tailored to these differences.

IPs were also aware of the important responsibilities entrusted in them by their role as researchers and acknowledged that their attitudes play a key role in establishing a climate of respect. Researchers have an important responsibility and duty to accommodate and respect their participants, particularly in the face of potential vulnerabilities, so that vulnerability is not to be considered the “responsibility” or “burden” of participants. Accommodations, safeguards, and protections for vulnerable participants suggested by IPs included (a) providing participants with consent forms in advance (e.g., for participants with severe anxiety), (b) doing an “emotion check” during and after the interview to assess how the participant is feeling, (c) prioritizing face-to-face interviews for difficult topics if that is the option that participants prefer, (d) putting less emphasis on potentially undesirable effects and/or more emphasis on potential benefits, (e) offering community or peer support resources in mental health to participants who require them, (f) training of research staff, (g) increased awareness and caution, (h) debriefing with participants after interviews, (i) adapting the structure of interviews to participant needs, (j) employing alternative recruitment strategies to meet the needs of participants (unspecified), and (k) having emergency or crisis protocols.

Discussion

This study elicited the perspectives of researchers about vulnerability in mental health research. Our analysis provides a preliminary account of some ways in which researchers perceive, understand, explain, and employ this notion in the context of research. Through a national survey, we found that respondents differed in their views on selected aspects of vulnerability with respect to mild, moderate, and severe mental health conditions (Table 1); that concerns related to vulnerability surfaced at different stages of the research process (Table 2); and that many respondents agreed with common definitional attributes of vulnerability, especially consent-based views (see Table 3). A series of qualitative interviews allowed us to explore the themes generated by the quantitative data in more detail. Through one-on-one interviews with mental health researchers, our data provided insight into the perspectives of researchers on potential sources of vulnerability, as well as its consequences on stigma, power differentials in research settings, and the autonomy and ability of participants to provide informed consent. Across our results, we also collected data about the variability of vulnerability and potential risks, challenges, and concerns associated with its application in mental health research settings. Finally, researchers formulated recommendations and expressed needs for better research practices and policies in mental health research as well as greater training about vulnerability. The limitations of this study include relatively low levels of participation due to extensive challenges in recruitment in spite of significant effort and the limited theoretical knowledge of some researchers regarding mental health research ethics. Understanding in greater depth why participation was low would be instrumental for future similarly-minded research investigating practical implications of research ethics policy. We here discuss our results in light of issues related to (a) the importance of user perspectives on the concept of vulnerability and (b) a contextual and multidimensional account of vulnerability.

User Perspectives on the Concept of Vulnerability: Including the Perspectives of Research Participants

Our survey data clearly reflect a preference for a consent- and autonomy-focused view of vulnerability and indicate that concerns for ability to consent are greater than other concerns raised by SPs. For example, the two main definitional attributes of vulnerability identified by SPs were (a) the inability to provide informed consent and (b) the inability to protect their own interests in research. Elsewhere in the quantitative results, we find that the two stages at which most researchers think that the vulnerability of individuals living with mental health conditions can arise are (a) the

process of obtaining informed consent and (b) the process of assessing risks and benefits. Although these concerns are also predominant in the literature on vulnerability (Bell et al., 2014; Kipnis, 2001, 2003), their scope appears limited and the full breadth of potential moral concerns expressed by the concept of vulnerability does not seem to be as clearly integrated by researchers. This understanding of vulnerability as being mostly about issues of consent may be discrepant with participants' insight that vulnerability is inherently contextual, relational, and generated by disempowering situations, rather than being strictly a property of individuals. Overall, the perspectives of researchers reflect the complex issues presented by the notion of vulnerability in the literature and speak to the lack of clarity and consensus about its purpose and the issues it seeks to redress. These perspectives, however, have not been validated through consultation of mental health research participants themselves. Of interest with respect to the inclusion of more stakeholder perspectives are researchers' concerns that the label of vulnerability might bring stigma on individuals living with mental health conditions, a point made elsewhere in literature (Bracken-Roche et al., 2016). Other participants worried about the unevenly distributed burden of concern for vulnerability and signaled the possibility that it might fall too heavily on the shoulders of their research participants. However, researchers did not explicitly specify having heard this directly from research participants themselves. Accordingly, we think that the perspectives of research participants living with mental health conditions should be solicited to inquire into their perception of the research process and the vocabulary of vulnerability. The inclusion of the voices of stakeholders involved as participants in mental health research would contribute to these discussions of vulnerability an account that is reflective of their experiences and perspectives. Our study on research participant perspectives, conducted in parallel with this study, seeks to address this need.

Within an instrumentalist account of ethics theory concepts, principles, and understandings, it is absolutely crucial for a tool to adequately reflect the perspectives of stakeholders using it and concerned by its use (Racine et al., 2017). One potential strategy to ensure that ethics concepts and principles do not alienate the experiences that they intend to capture and become what Fiester (2015) has described as weapons against the vulnerable is the adoption of a collaborative framework including participants living with mental health conditions, mental health researchers, and REBs. Consistent with this proposal, in our study, some participants expressed their dissatisfaction with the current structure of evaluation of research projects (e.g., its lack of nuance and flexibility). Researchers discussed the importance of bridging different sources of knowledge and expertise and encouraged structures favoring communication and collaboration between different stakeholders (e.g., researchers, REBs, and

research participants), but they did not specify how this kind of collaboration would be different from the current state of research. These are key issues for mental health research and the evaluation of research projects, as scholars and agencies attempt to develop practices and guidelines that make room for the experiential knowledge of mental health research participants. Participants' calls for better training on the ethics of mental health research, for clear policies and protocols, and for a better general understanding of what is meant by participant vulnerability, can also be folded into these broader discussions about collaborative research.

The Practical Complexity of a Contextual and Multidimensional Account of Vulnerability

Many scholars have criticized blanket notions of vulnerability that target specific groups and that are too sweeping to be meaningful for researchers and their participants (Levine et al., 2004) and have raised the concern that the concept is both widely employed and extremely vague. These accounts reflect questions and concerns raised by participants when discussing challenges to the application of the notion of vulnerability in mental health research. A key issue that emerges from our study is the complexity and variability of the notion of vulnerability used in mental health research contexts as experienced by researchers. Participants stressed the importance of recognizing that vulnerability is inherently contextual, multidimensional, variable, and "messy." In this sense, their perspectives reflect the ambiguities encountered in research ethics policies and resonate with the academic literature proposing more relational and contextual accounts of vulnerability (Bell et al., 2014; Luna, 2009; Mackenzie et al., 2013). An important concern with the traditional "labeling" approach to vulnerability is the stigma it brings on vulnerable populations as "[lists] and group descriptions can [lead] to the essentialization of vulnerability for group members" (Racine & Bracken-Roche, 2019). For example, a "labeling" approach to vulnerability contributes to identifying participants with mental health issues as inherently vulnerable and can lead to systematic exclusion from research, stereotyping biases, or discrimination. Although it is important that concern for human vulnerability remains a central aspect of research ethics, many authors support a shift from a categorical labeling of specific groups (e.g., individuals living with mental health conditions), toward a more nuanced functional and relational account of the various asymmetries that emerge in the context of research to create situations of vulnerability. This shift is consistent with recent feminist work conceptualizing both autonomy and vulnerability as socially constituted capacities, and supporting more nuanced and context-sensitive evaluations of the normative obligations arising from vulnerability (Mackenzie & Stoljar, 2000).

The practical complexity of a truly contextual and multidimensional account of vulnerability however raises key questions for mental health research and research ethics: What kinds of practical tools and strategies for intervention are required to anticipate, identify, and assess potential participant vulnerabilities? If a unilateral account of vulnerability does not hold valid across different groups, diagnoses, contexts, and individuals, how should researchers and REBs address concerns for vulnerability? The possible challenges of the application of the concept of vulnerability to mental health research highlighted by IPs in this study clearly point to this challenge. Without a clear framework to envision and assess the implications of concerns for vulnerability, the risks of generating undesired effects and of stigmatizing, excluding or burdening disenfranchised populations, or issues of conceptual confusion and gaps between theoretical and practical understandings, can all plague mental health research evaluation and practice.

Racine and Bracken-Roche's integrative-functional account of vulnerability moves away from an essentializing view of vulnerability or a group-based approach and proposes a first possible way of validating or (invalidating) concerns for vulnerability and then operationalizing a response to genuine concerns. In a similar vein, Luna (2018) distinguishes between "conceptual" and "practical" problems and spheres of discussion generated by the notion of vulnerability and suggests that while the concern over conceptual issues is valid (i.e., a vacuous use, essentializing, or stereotyping effects and uses), "the concept is still very relevant from a practical sphere." Consistent with feminist theories, the integrative-functional account conceptualizes vulnerability as a context-specific feature dependent on "interpersonal and social relationships or economic, legal and political structures" (Mackenzie et al., 2013) and stresses complex relational histories over unilateral dyadic interactions between researchers and research participants. Vulnerability is defined not as an intrinsic property but as "a situation in which a research participant has an identifiably increased likelihood of incurring additional or greater harm or wrong because of relation asymmetries in the research context" (Racine & Bracken-Roche, 2019; Mackenzie et al., 2013). The causes of these relation asymmetries loom large and include various contextual elements related to the research setting (e.g., research design, interpersonal dynamics, cultural preferences). The particularity of the integrative-functional account, however, and what it can bring to our discussion and the concerns of researchers, is its ability to operationalize ethical concerns for vulnerability and "[lend] itself to a process through which vulnerability can be identified and addressed" (Racine & Bracken-Roche, 2019). Although this framework does not constitute in itself a blueprint for ethical research, the steps it outlines represent important

moments in the assessment of participant vulnerability. On this view, the concept of vulnerability functions as a key analytic tool aimed at concrete and practical changes. In short, both Luna's feminist and Racine and Bracken-Roche's pragmatist accounts point to the complexity and importance of a nuanced, contextual analysis of vulnerability and focus on issues raised by its practical application in real-life research settings and research evaluation processes. If the concept of vulnerability is anything like a tool for mental health research, its users need to be able to wield it and feel like it is useful for conducting ethical research.

Best Practices

Given the potential issues associated with the use of the notion of vulnerability in mental health research ethics, we recommend that discussions about the vulnerability of research participants involve members of the target research group. The inclusion of the voices of these stakeholders is necessary in developing richer and more nuanced accounts of vulnerability that are reflective of the experiences and perspectives of the people it seeks to protect.

Considering the results of this study, ethics guidance should aim for flexible, multidimensional, and contextual understandings of participant vulnerability and gain insight from recent calls in the academic literature for layered and relational accounts of vulnerability. This requires moving away from legalistic trends in research ethics and adopting pragmatic and context-sensitive approaches to mental health research practice and oversight.

Research Agenda

The perspectives of researchers on ethics review and research ethics need to be further investigated and contrasted with the perspectives of other important stakeholder groups. For example, we found that researchers worry about the potential harms and discomfort generated by the notion of vulnerability for research participants. Further research into the perspectives of mental health research participants is needed to follow up on the results of this study and evaluate the relevance and use of the notion of vulnerability in the context of mental health research.

The integrative-functional account of vulnerability (and similar calls for a practical account of the term) appears promising and helpful in addressing some of the shortcomings and limitations of essentializing views and uses of vulnerability, but still requires testing and further validation in real-life settings. Such testing would need to track the potential challenges, risks, and concerns related to the application of the notion of vulnerability raised by researchers in this study, including concerns about overusing the notion, adopting paternalistic or stigmatizing attitudes toward individuals living with mental health conditions, or

making the research process burdensome for researchers and participants.

Educational Implications

This study identified key challenges with the notion of vulnerability in mental health research, notably its sweeping and generalized use, as well as lack of consensus about its meaning. This has implications for ethics training on participant vulnerability and research ethics policies. Academic training on mental health research should take these conclusions into account and ensure that researchers become familiar with the issues associated with the notion of vulnerability.

We encourage the development of additional practical (vs. theoretical) training on participant vulnerability for mental health researchers. In addition, we encourage a shift toward the operationalization of concerns for vulnerability and the creation of research tools geared toward this aim (e.g., collaborative frameworks between participants, REB's and researchers, mentoring programs for mental health researchers, guidebook of practical recommendations).

Conclusion

Our empirical study of the concept of vulnerability sought to examine the ways in which mental health researchers understand and problematize the use, meaning, and application of this concept in mental health research. Although concerns for participant vulnerability have been a central element of research ethics at least since the publication of the Belmont Report, inconsistencies and disagreements over the use of the concept of vulnerability remain a key challenge for research practice and evaluation. Our study revealed that researchers understand vulnerability as a complex and inherently variable concept springing from a variety of sources and arising at different stages of the research process. They identified a series of potential challenges to its application, ranging from risks of stigmatization or discrimination against participants living with mental health conditions, to lack of training, guidance, and agreement on the use of this concept and the obligations that arise from it, and risks of overusing the notion and going too far with protections. Our discussion pointed to the urgent need for more user perspectives, particularly those of research participants, to verify and validate concerns about the concept of vulnerability raised in the academic literature and in this study. Ultimately, our analysis of the concept of vulnerability points to the potential limitations and shortcomings of its application, and to the importance of generating a clearer and more practical understanding of this key ethics concept in mental health research and the value of feminist and pragmatist theories therein.

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ORCID iD

Eric Racine  <https://orcid.org/0000-0001-8306-551X>

Note

1. These included basic research, social research, qualitative mental health research, quality improvement projects, medical education, quality-of-life studies of persons with serious mental health conditions and acquired brain injury, and studies about the correlation of personality factors, organizational politics, and gender with career success.

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Author Biographies

Corinne Lajoie is an associate member of the Pragmatic Health Ethics Research Unit and a PhD student in philosophy at The Pennsylvania State University. She was a research coordinator at the Pragmatic Health Ethics Research Unit at the time of this study. Currently, her research explores the intersections between critical phenomenology, mad and disability studies, and feminist ethics.

Jelena Poleksic is a medical student at the Schulich School of Medicine & Dentistry, Western University. She received her MSc in global health from McMaster University. She developed an interest in the concept of vulnerability in mental health research ethics during her previous role of Research Coordinator with the Pragmatic Health Ethics Research Unit.

Dearbhail Bracken-Roche is a bioethicist currently working as a health researcher and strategist in the private industry. She holds an MSc in biomedical ethics from McGill University and was previously a research coordinator at the Pragmatic Health Ethics Research

Unit where her research focused on unpacking and understanding the concept of vulnerability in mental health research ethics.

Mary Ellen Macdonald, PhD, is a medical anthropologist, currently associate professor in the Division of Oral Health and Society in the Faculty of Dentistry at McGill University. Her research program focuses on the health of vulnerable populations in Canada, looking across three main domains: oral health, Indigenous health, and palliative care. A central focus of her research program is on the ways the social, the cultural, and the political intersect to both produce and respond to particular forms of vulnerability within Canadian society.

Eric Racine is the Director of the Pragmatic Health Ethics Research Unit at the Institut de recherches cliniques de Montréal (IRCM) since 2006 and full research professor at IRCM and Université de Montréal with additional appointments at McGill University. Inspired by philosophical pragmatism, his research aims to bring to the forefront the lived experience of ethically problematic situations by patients and stakeholders and to then resolve them collaboratively through deliberative and evidence-informed processes.