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Defining the concept of mental dysregulation in patients requiring ambulance and/or emergency department care: protocol for a Delphi consensus study

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ABSTRACT

Introduction From the patient and staff perspective, care delivery for patients experiencing a mental health problem in ambulance and emergency department (ED) settings is challenging. There is no uniform and internationally accepted concept to reflect people with a mental health problem who require emergency care, be it for, or as a result of, a mental health or physical health problem. On initial presentation to the emergency service provider (ambulance or ED), the cause of their healthcare condition/s (mental health and/or physical health) is often initially unknown. Due to this (1) the prevalence and range of underlying causes (mental and/or physical) of the patients presenting condition is unknown; (2) misattribution of physical symptoms to a mental health problem can occur and (3) diagnosis and treatment of the initial somatic complaint and cause(s) of the mental/physical health problem may be hindered.
This study will name and define a new concept: 'mental dysregulation' in the context of ambulance and ED settings.

Methods and analysis A Delphi study, informed by a rapid literature review, will be undertaken. For the literature review, a steering group (ie, persons with lived experience, ED and mental health clinicians, academics) will systematically search the literature to provide a working definition of the concept: mental dysregulation. Based on this review, statements will be generated regarding (1) the definition of the concept; (2) possible causes of mental dysregulation and (3) observable behaviours associated with mental dysregulation. These statements will be rated in three Delphi rounds to achieve consensus by an international expert panel (comprising persons with lived experience, clinicians and academics).

Ethics and dissemination This study has been approved by the Medical Ethical Committee of the University of Applied Sciences Utrecht (reference number: 258-000-2023_Geurt van der Glind). Results will be disseminated via peer-reviewed journal publication(s), scientific conference(s) and to key stakeholders.

STRENGTHS AND LIMITATIONS OF THIS STUDY

⇒ The proposed study method is based on contemporary evidence that identifies quality indicators for Delphi studies in healthcare research.
⇒ Both in the steering group (responsible for defining the relevant statements and for analysing the level of consensus and remarks related to these statements) and in the Delphi panel of experts, persons with lived experience will be involved.
⇒ The Delphi panel will comprise members from relevant international stakeholder groups.
⇒ As this matter has not been raised before, there is no research base in the existing literature for the new concept of interest.
⇒ The Delphi study will be performed in English, hampering the inclusion of panel members who may have the appropriate background and/or expertise but are not fluent in English.

INTRODUCTION

The number of people living with a mental disorder has increased over recent decades.[1] According to the Organisation for Economic Co-operation and Development, one in two people experiences a mental health condition at some point in their lifetime.[2] For some people, their mental health problem and/or somatic complaint(s) may require ambulance and/or emergency department (ED) care.[3 4] Mental healthcare comprises 11% of ambulance call-outs in Scotland.[4] In Australia, people presenting to ED for a mental health problem experience worse outcomes (including longer stays in ED) compared with people presenting for other reasons.[5 6]

From the patient, ambulance and ED staff perspective, care delivery for people experiencing a mental health problem in ambulance

and ED settings is challenging.[7–9] A specific problem not isolated to the ED context, is stigma, with related negative attitudes towards people with mental health conditions.[10]

Several definitions and terms are used to describe people with mental health problems in ambulance and ED settings including patients with 'mental illness',[11] 'mental disorder'[12] or 'mental health crisis'.[8] Other reports refer to patients with a specific mental disorder or problem needing emergency care, such as patients with 'borderline personality disorders',[13] 'substance use disorders'[14] or 'suicide attempters'.[15] Other research focuses on problematic behaviour (that may or may not include people with a mental health problem) such as 'acute agitation[16]', 'acute behavioural disturbances'[17] 'violence and aggression'[18] or to a lesser extent, 'emotional dysregulation'.[19] Hence, it is apparent that there is no uniform and internationally used concept that encompasses all presenting patients with mental health and/or behavioural and/or emotional problems in need of ambulance and/or ED care. Moreover, on initial presentation to the emergency service provider (ambulance or ED), the cause of their healthcare condition/s (mental health and/or physical health) is often initially unknown.

As there is no uniform concept used for patients with mental health problems and/or problematic behaviours in the ambulance and ED context, in addition to the already mentioned problem of stigma, several problems may occur:

First, the prevalence of this group of patients in ambulance and ED care is unknown. Fulbrook and Lawrence surveyed an Australian ED including 681 ED patients of whom 251 (36.9%, 95% CI 33.2% to 40.5%) may have had an actual mental health disorder,[20] based on the K10, a validated mental health screener.[21] In discussing their findings, the authors argued the 36.9% prevalence was likely to be an underestimation of the true prevalence.[20] A national study in the USA analysed 100.9 million ED-visits in the period 2007–2016. Of these, 8.4 million (8.3%) were related to a psychiatric and/or substance use disorder, with an increase from 6.6% to 10.9% (p<0.001) over the 10-year study period of the proportion of ED visits for mental health diagnoses.[22] The differences in prevalence/proportion between these studies indicate that, without a clear definition, accurate numbers of patients with mental health problems that require emergency care are difficult to capture. Furthermore, the use of primary mental health diagnoses only in reporting limits other important concomitant considerations including somatic complaints for which emergency care may be indicated. Adding to this complexity is that comorbid, underlying or triggering mental health problems are not always screened for or documented.[23]

The second problem arising from not having a uniform concept is diagnostic overshadowing, defined as 'a multidimensional experience of interconnecting factors including systematic healthcare system issues, health professionals limited mental health knowledge and skills, stigmatic attitudes and mental health consumers miscommunicating their physical healthcare needs.[24] Patients with psychiatric disorders may well experience several problems related to diagnostic overshadowing, including both misdiagnoses and delay of treatment due to factors related to their mental illness.[25–27]

The third problem is that the extent to which other underlying factors such as anxiety, panic[28] or somatic problems such as delirium caused by neurological problems/trauma/infections[29] impact on the ambulance/ED presentation are often unknown. Furthermore, the emotional dysregulation or disruptive behaviour may interfere with the timely diagnosis and treatment of underlying causes.

These complex problems highlight the need for further efforts to enhance processes and systems that can reduce the chance of misinterpretation and support best care and best outcomes for people presenting to ambulance and/or EDs. A well-defined concept that includes consideration of mental health problems, problematic behaviours and causes, and somatic complaints within the ambulance and ED care context is warranted. As, to our knowledge, no such concept exists, a preliminary working term, mental dysregulation, is used in this protocol. In the Delphi study, the definitive name of this concept, together with a description of the concept, causes and related observable behaviours are part of the consensus process.

AIM

The aim of this study is to name and define the concept of mental dysregulation in such a way that monitoring, developing and guiding care delivery, education, policy and research regarding patients experiencing mental dysregulation who require ambulance and/or ED care can be facilitated. The objective of this study is to use a Delphi process to reach expert consensus on name and definition of mental dysregulation.

METHODS AND ANALYSIS

Patient and public involvement

The importance of the involvement of patients or people with lived experience (within the problem area domain) is increasingly regarded as important in healthcare,[30] mental health[31] and emergency care[32] research. Therefore, three persons with lived experience (PWLE)[10] were involved in the development of this study protocol. Full details of PWLE involvement in this protocol are reported in table 1 in accordance with the Guidance for Reporting Involvement of Patients and the Public (2nd version) - Short Form (GRIPP2-SF) checklist.[33] For the Delphi study, the consensus procedure will not start until at least four PWLEs (preferably coming from more than one country) are part of the expert group, and have commented on the literature review results and proposed set of statements for Delphi round 1.

Table 1 Patient and public involvement (PPI) in this Delphi study protocol, informed by GRIPP2-SF reporting guidelines[33]

Section and topic	Item
1: Aim Report the aim of the study	To develop a protocol for a Delphi consensus study on mental dysregulation in the ambulance and ED setting, with the aim of defining the concept of mental dysregulation in such a way that monitoring, developing and guiding care delivery, education, policy and research regarding patients experiencing mental dysregulation who require ambulance and/or ED care can be facilitated. Integral to this specific aim, we collaborated with three people with lived experience as research partners in the development of the Delphi consensus study protocol.
2: Methods Provide a clear description of the methods used for PPI in the study	Three PWLE of mental health problems and experiences in ambulance and ED care were invited to join the research team as a partner for this Delphi consensus study protocol. They were involved in contributing ideas and insights which informed this study protocol, identifying areas of concern from a patient perspective and checking comprehension of the draft manuscript.
3: Results Outcomes: Report the results of PPI in the study, including both positive and negative outcomes	As this paper reflects a study protocol, no results are available. The PWLE representatives in this Delphi protocol contributed by: ► Considering and advising on the need for the proposed Delphi study to obtain clarity for the concept of mental dysregulation, reflecting on their own experience and tacit knowledge. ► Highlighting potential benefits/concerns. ► Providing constructive feedback.
4: Discussion Outcomes: Comment on the extent to which PPI influenced the study overall. Describe positive and negative effects	As this paper reflects a Delphi-study protocol, there is no discrete discussion section.

ED, emergency department; GRIPP2-SF, Guidance for Reporting Involvement of Patients and the Public (2nd version) - Short Form; PWLE, persons with lived experience.

Design

The Delphi method will be used to guide this study. The Delphi method uses the collective opinion of heterogeneous 'experts' to seek consensus on a certain subject.[34] A steering group (comprised ambulance/ED nurses, physicians, PWLE, academics) will guide the undertaking of the Delphi study. The steering group (chaired by WHWH) will meet regularly (every 2 months) via MS TEAMS, to provide input and feedback on the process, including participation in the rapid literature review, pilot testing the Delphi survey (for face and content validity), support advertisement for panel recruitment, advise of question refinement and participate in dissemination of study findings.

While several guidelines and reviews exist to inform the undertaking and/or reporting of Delphi studies,[34–36] we will use the approach from Nasa *et al*[34] which comprises nine points embedded within four steps: (1) problem area, (2) panel members, (3) Delphi rounds and (4) closing criteria (see table 2).

Step 1: problem area

A rapid literature review will be undertaken to identify and summarise the available literature regarding definitions, causes, behaviours of ambulance/ED presentation for people presenting with mental/emotional/somatic complaints. The review will be used to provide a working definition of the concept 'mental dysregulation', and inform initial statements used for the Delphi. Rapid literature reviews still comprise a clear research question, search protocol, process of study selection and data extraction, however, the simplified procedures can enable the review to be completed in a shorter timeframe than a systematic literature review.[37] The questions informing the rapid review are: (1) what are the concepts used in scientific peer reviewed literature for people presenting to ambulance/ED with mental/emotional/behavioural problems?; (2) what are the causes of these problems?; (3) how are these concepts and causes defined? and (4) what instruments are used to screen/diagnose problems and causes?

In our rapid review, an iterative approach will be applied where the databases of Medline, CINAHL and PsycINFO will be searched using keywords and their combination relating to the population (eg, people presenting to the ED with: mental health problems; mental illness; mental health disorder; psychiatric disorder; substance use disorder; borderline personality disorder; suicide attempt; self-injury); context (eg, ED, emergency room, A&E, accident and emergency, ambulance) and concept (eg, psychological distress; mental distress; anxiety; pain; delirium; disruptive behaviour; problematic behaviour; aggression; violence; emotional dysregulation). A librarian will be involved to assist in creating the search strategy and performing the search. Articles published in English between January 2013 and September 2023 will be included. Titles and abstracts of retrieved articles

Table 2 Steps and points for Delphi studies[34] how applied to our study, with anticipated time frames

Step	Point	Application to this study	Anticipated time frame
Step 1: Problem area	Systematic identification of problem area.	Rapid literature review undertaken to summarise available literature; Initial set of statements prepared for Delphi questionnaire and pilot tested.	Start January 2024 End May 2024
Step 2: Panel members	Selection based on objective and a predefined criteria.	Expert panel members (PWLE, HCPs, academics) invited through personal contacts, professional organisations and social networks.	Start March 2024 End May 2024
Step 3: Delphi rounds	1. Anonymity of panellists and responses 2. Controlled feedback 3. Iterative rounds	eDelphi used with panel members responses remaining anonymous; Controlled feedback to each member providing a summary of overall trend, group trend and their response; Three Delphi rounds planned.	Start May 2024, End November 2024
Step 4: Closing criteria	1. Consensus criteria 2. Analysis of consensus 3. Closing criteria defined a priori 4. Stability of results	Consensus criteria: when ≥75% of panel members rate the statement as 'strongly agree' or 'agree'; Descriptive statistics used for analysis of consensus; Stability assessed (if >2 rounds): consensus if SD≤1 for an item.	Start May 2024 End December 2024

HCPs, healthcare professionals; PWLE, persons with lived experience.

will be screened for eligibility by one reviewer, while two reviewers will screen potentially relevant full-text articles. Disagreements will be resolved by a third reviewer. Prior to screening, a pilot of 30–50 abstracts and 5–10 full texts will be undertaken by the reviewers to test the review form and calibrate.[38] Articles will be excluded if they are abstract, theses, not focused on ambulance or ED, or not focused on the review question. A Preferred Reporting Items for Systematic reviews and Meta-Analyses (PRISMA) diagram[39] will be used to display the results of the search. Data will be extracted from included articles by one reviewer, checked by another and will include: country, setting, concepts used for mental/emotional/behavioural problems in patients presenting to ambulance/ED, causes of these problems, definitions used to describe these concepts, instruments used to screen/diagnose problems and causes. No quality assessment of included articles will be undertaken because the purpose of the review is the scope of the available evidence, rather than evaluate specific effects of an intervention.[40] Moreover, it is not anticipated to include every concept, every definition, every used instrument that is mentioned in the search results. A narrative knowledge synthesis will be used to report the results of included studies and discuss reasons for differences among studies.[40] Results from the review will be communicated among participating panel members, submitted to be published in a journal and presented at various forums.

The review will be used to generate statements for round 1 of the Delphi questionnaire regarding: (1) the definition of the concept, (2) possible causes of mental dysregulation and (3) observable behaviours associated with mental dysregulation. Members of the steering group will be invited to pilot test the Delphi questionnaire. Specifically, from the statements generated, they will be asked to comment on face and content validity and score each item on a 7-point scale the relevance of each item with items scoring at the mean or higher included, an approach used elsewhere.[41]

Step 2: panel members

Our Delphi panel members will comprise a heterogeneous group of 'experts' to garner a broad perspective and generalisation of consensus.[34] While 'experts' can be variably defined in Delphi studies,[35] our experts will comprise: (1) PWLEs, (2) ambulance and ED healthcare professionals (HCPs) and (3) emergency care academics; from varying international acute healthcare contexts (ambulance/ED). Criteria for PWLE include: aged ≥18 years, be able to provide informed consent to participate and have received care from ambulance and or ED HCP for a within the past 5 years for a mental/emotional/somatic complaint. Criteria for ambulance and ED HCPs include: aged ≥18 years, hold a professional registration and provide direct patient care or are a manager within ambulance or ED service and have at least 2 years of experience within ambulance/ED care area. Criteria for emergency care academics include: aged ≥18 years, hold at least a master's degree and have led/been an investigator on a study undertaken within the past 2 years in the field

of mental dysregulation in the ambulance or ED setting. Panel members who are both HCP and academic will be asked to participate as an academic. All panel members must be fluent in reading, understanding and writing in English.

There is no set size for Delphi expert panels, however, 39 is average in emergency nursing Delphi studies[35] and 10–100 is typical in healthcare research.[34] Given the diverse groups of experts in our Delphi study, as suggested elsewhere,[41 42] we aim to have 10–18 panel members from each of the three subgroups identified (PWLEs/HCPs/academics) and thus a minimum of 30 participants overall. It has been reported that the more participants, the higher reliability of the consensus.[41 43] We will strive for equal representation across the groups of panel members, which consequently guides the number of panel members. Therefore, we aim to include 3–5 panel members per group, per country.

Potential panel members will be recruited via the following routes: personal networks of the steering group; purposive personalised approach using publicly available email address of academics who have published at least one paper in the area of interest; via steering group members LinkedIn/X (formerly known as Twitter) profile; steering group member affiliate newsletter(s); national colleges or international associations of relevant HCPs (ie, ambulance/paramedics/ED physicians/ED nurses) and consumer organisations. (Inter)National organisations and associations will be asked to recruit a heterogeneous representation of their membership. A study advertisement poster or email will provide a brief description of the Delphi study and if interested the potential participant can connect to a link to read the study information sheet and then, if agreeing, progress to complete the questionnaire. Completing the questionnaire will indicate implied consent (as will be advised in the study information sheet). Other detail in the study information sheet will include the aim and scope of the study, the methods used for this study, data storage and security, and participants rights. Participation is voluntary and participants can withdraw from the study at any time. The questionnaire will be distributed and stored using Crowdtech,[44] a secure platform for managing online surveys for which the University of Applied Sciences, Utrecht, the Netherlands has a formal agreement. An individual participant number will be generated for each panel member to enable individual results to be provided in subsequent rounds.

Step 3: Delphi rounds

Participation in the three Delphi rounds will be anonymous, to minimise dominance and group conformity.[34] Three Delphi rounds are typical in emergency nursing studies.[35] Expert panel members will be asked to score their agreement of each statement using a 7-point Likert scale, where 1=strongly disagree and 7=strongly agree. Participants will also be asked if they agree with the wording of the items (yes/no/do not know); and to add suggestions for improving the wording of each statement, if required. For each round, participants will be asked to respond within 2 weeks. A reminder will be sent to non-responders after 1 week.

At the end of each round, data will be analysed using descriptive statistics (frequency, percentages, median/mean, SD/IQR) and improvements/wording changes summarised. These results will be discussed among the steering group, the Delphi questionnaire revised accordingly, and then the results (along with the revised Delphi questionnaire) will be presented in aggregate form back to expert panel members in an easy-to-understand format.[34] The purpose of this controlled feedback is to give insight to the individual member about their response, the trend overall and for their subgroup (PWLE/HCP/academic). If applicable, a summary of comments and suggestions may be provided.

Step 4: closing criteria

While various meanings of consensus exist,[34] and agreement level between 70% and 80% is widely embraced and acknowledged as thorough[45] in our study, consensus on the term, definition, description, causes and observable behaviours of 'mental dysregulation' will be considered to have been reached after three rounds (or before) when >75% agreement (ie, rating statements as either 'fully agree' or 'agree') is reached. The higher the score, the better the consensus among the group for the item. If consensus is reached on items they will not be dropped for the subsequent round. If >50% of panel members rate a statement with 1 (strongly disagree) or 2 (disagree), without providing sufficient suggestions for adjustment of the statement, the statement will be dropped.

We will make an effort to assess the stability/consistency of responses between successive rounds (if more than two rounds occur), as recommended by Nasa *et al*.[34] SPSS V. 29.0 will be used to assess stability using SD test. As guided by a previous Delphi study,[46] if SD≤1 for an item, this will indicate consensus.

Data storage and security

Our data management plan considers three types of data: informed consent data, personal data and research data. These data will be collected and stored within the Crowdtech server as part of the Delphi process. The informed consent data (ie, approval on participation/being informed on the results of the study; willing to participate in additional research related to the topic of interest; approval on use of the email address), and a key document which lists and links the participants email address and study number, will be extracted from Crowdtech, and stored in a separate secure digital data safe. The personal data (ie, panel members answers to characteristics questions, country, PWLE status/function, years of expertise) and research data (ie, responses to the statements and, if applicable, suggestions for improvement/adjustment of the statements) will be extracted from Crowdtech and stored in Research Drive. Both the digital data safe and the

Research Drive are provided via the University of Applied Sciences, Utrecht, the Netherlands. The provision of the study information letter, informed consent procedure and data storage complies with European Privacy and Good Clinical Practice in research guidelines.[47] Data will be retained for 10 years from study completion and then destroyed.

Data subject rights

Panel members have the right to stop participation without expressing the reason for this. Completed surveys and personal data will be removed on request, as long as reports on a Delphi round have not been generated. Once data are used for subsequent Delphi rounds and reports, the data will not be removed, as they are part of the calculations used for reporting level of agreement.

Language

The panel experts will receive the initial information, statements and feedback in English. Once the Delphi process defines the concept and its elements, the steering group and their research teams from non-English speaking countries will provide translations of the newly defined concept. This will be done using a back and forward translation process with native-speaking experts on the topic to ensure accuracy and cultural relevance.

ETHICS AND DISSEMINATION

This study was approved by the Ethical Commission-Health Domain (ECO-GD) of the University of Applied Sciences, Utrecht, the Netherlands (reference number: 258-000-2023_Geurt van der Glind). Results will be disseminated via peer-reviewed journal publication(s), at scientific conference(s) and to key stakeholders.

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Contributors GVdG, NG, FES, RM, JC and WHWH developed the initial protocol: research questions, introduction and methods. BS, LW, EC, EH, DB, LS and MvV commented on the manuscript and rewrote sections of the manuscript. All authors documented their approval of the final version of the review protocol before submission. As senior researcher and project leader WHWH is the guarantor of the study and of this study protocol.

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Competing interests EC declared to have received payment from Boehringer Ingelheim in October 2022 for acting as member of the suicide advisory board.

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