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Defining the need for analgesia in the emergency department: protocol for an international Delphi process

Barbara Scotti,[1] Anna Szczesna,[2] Christian H Nickel,[2] Bojana Degen ,[3] Olivier Hugli ,[4] Sandy Jean-Scherb,[5] Lucrezia Rovati,[6,7] Monika Kirsch,[8] Fiona C Sampson ,[9] Gernot Mayer,[10] Heike Thomys,[10] Bruno Minotti [2]

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For numbered affiliations see end of article.

Correspondence to
Dr Bruno Minotti;
bruno.minotti@usb.ch

ABSTRACT

Introduction The high prevalence of pain in the emergency department (ED) highlights the importance of accurate assessments to provide effective interventions. However, common pain scales such as the Numerical Pain Rating Scale have shown limitations in assessing analgesic requirements and adequacy. The ideal outcome for evaluating a pain scale predicting analgesic requirements would be the 'need for analgesia', for which there is no universally accepted definition. Accordingly, the primary aim of this study is to define the 'need for analgesia' using an interdisciplinary approach. The secondary aim is to define the 'adequacy of analgesia'.

Methods and analysis A two-stage modified Delphi process will be conducted by a core study group chosen for its expertise in ED pain management. A larger expert panel, identified through a comprehensive search in Scopus and CINAHL databases, will be invited to participate in the study and will be supplemented by patients recruited via international patient organisations or snowballing. In stage 1, the expert panel will complete a written survey to collect potential clinical variables for defining the 'need for analgesia' and 'adequacy of analgesia'. The core study group will elaborate on these variables. In stage 2, the same participants will use a five-point Likert scale to achieve consensus defined as ≥80% of combined agreement on the proposed variables, over a maximum of three rounds. The same process will be used to define the 'adequacy of analgesia'.

Ethics and dissemination The Ethics Committee of Northwestern and Central Switzerland exempted the project from committee approval under the Human Research Act. Written consent will be obtained from all participants. Results will be disseminated through publication in peer-reviewed journals and conferences.

STRENGTHS AND LIMITATIONS OF THIS STUDY

⇒ This study addresses the limitation of pain scales in the emergency department (ED) setting as predictors of analgesic requirement.
⇒ Defining the need and adequacy for analgesia in the ED setting might provide a valuable measurable outcome to assess the performance of current pain scales in the ED.
⇒ An interdisciplinary approach involving clinicians and patients from diverse geographic locations will ensure a wide range of perspectives and comprehensive insights into the definition of need and adequacy of analgesia.
⇒ The results will only be applicable to adults without cognitive impairments presenting to the ED.
⇒ Recognising which patients need analgesia will not provide guidance on which analgesic strategy to pursue (eg, which medication to administer).

INTRODUCTION

Pain, a common presenting symptom in the emergency department (ED), is defined as an unpleasant sensory and emotional experience.[1] Despite pain being a multidimensional experience, assessment in the ED is often performed using unidimensional pain scales, such as the Numerical Rating Scale (NRS), the Verbal Rating Scale or the Visual Analogue Scale.[2] The most frequently used criterion for therapeutic success is the reduction in the intensity of pain. However, up to 50% of ED patients in pain (and up to 35% even in an NRS range of 7 or higher) do not desire pain medications.[3] Furthermore, patients interpret pain scores differently from professionals, leading to potential mismanagement when healthcare providers rigidly follow guidelines prescribing analgesics based solely on numerical scores.[4 5] Additionally, the association between pain intensity and desire for analgesia is only moderate.[6] Accordingly, a 50% pain reduction measured using unidimensional pain scales as a standard outcome for therapeutic success has been questioned.[7] Unidimensional pain scores might not even reflect intensity.[8] One study, for example, investigated the association between the NRS and various dimensions of postoperative pain with the multidimensional affect and pain survey. The authors found that among three dimensions of the pain scale, which are somatosensory, well-being and emotional pain, only emotional pain predicted a

patient's score on the NRS.[9] Moreover, the nature of pain in the ED is notably different from pain experienced in other contexts, such as after surgery: postoperative pain occurs within a controlled environment, characterised by predictability and pain is an anticipated part of the recovery process.[10 11] Conversely, in the ED, patients suffer from acute pain which is often unpredictable and of uncertain origin, resulting in anxiety and emotions becoming interwoven with a painful experience.[12] In addition, while in the postoperative setting pre-emptive analgesia is administered, such treatment is not possible in ED patients.[13] In a laboratory study providing different thermal stimuli evoking pain, the intensity of the stimulus did not match with the reported pain perception by the subject. This suggests that pain perception itself, rather than the intensity of the pain stimulus, should be the indicator for providing analgesia.[14] Therefore, analgesics should be titrated according to the patient's comfort, and not simply until a certain level of pain on a unidimensional pain scale is reached.[15]

The use of multidimensional pain scales in the ED has been suggested to improve understanding of how to manage pain appropriately.[16] However, there is a paucity of data investigating the utility of such multidimensional pain scales in the ED.[17] Only the Brief Pain Inventory Short Form, a multidimensional pain scale, originally developed for patients with cancer, has been tested for feasibility in an ED population.[18] Furthermore, it is unclear how such pain scales should be used to guide analgesia in patients in acute pain. In the postoperative setting, for example, the Clinically Aligned Pain Assessment (CAPA) tool was developed and introduced.[19] The CAPA instrument consists of a non-scripted conversation addressing comfort, change of pain over time, pain control, physical functioning and sleep. Even though this tool replaced the NRS in two hospitals,[20] cross-sectoral validation appears impossible as there is no reproducible scoring system.

Despite the opioid crisis and the risk of overtreatment or addiction,[21–24] oligoanalgesia remains a problem in the ED.[25–27] One potential solution to improve pain management could be to address the current lack of a consensus regarding the adequacy of analgesia, considering the multidimensional nature of pain.[28 29] To develop and validate new, possibly multidimensional tools for pain assessment in the ED, a measurable outcome reflecting patients' needs is required. The sensitivity of a pain scale that best represents clinical improvement lies in its ability to effectively detect changes in pain levels, reflecting the impact of treatment.[30 31] In contrast, the sensitivity of a diagnostic tool is the ability to detect the identification of a patient with a disease, that is, people needing analgesia. To date, to our surprise, there seems to be no commonly accepted definition of 'need for analgesia' for ED patients with painful conditions. Furthermore, the threshold for severe pain in unidimensional assessment scores varies across studies, ranging from 6 to 8 (on an 11-point unidimensional pain scale).[32–34] In addition, there is no consensus on 'adequacy' (eg, when the patient feels comfortable). For example, despite some studies suggesting a pain score of less than 4/10 as pain relief,[35] it has been observed that nearly 20% of patients within this pain range still desire pain medication.[3]

The primary aim of this study is to develop a definition of 'need for analgesia' by an interdisciplinary team of expert clinicians in the field of emergency medicine as well as patients and their representatives. Second, we aim to define 'adequacy of analgesia'. The overarching objective is to define a measurable outcome to develop a pain assessment and management tool for ED patients in acute pain.

METHODS AND ANALYSIS

This protocol was submitted prior to the start of the study. This study will follow the proposed recommendations for the definition of outcome measures in clinical trials by using a Delphi procedure, as described by Sinha *et al*,[36] and the OMERACT initiative.[37] Additionally, we will incorporate Guidance for Reporting Involvement of Patients and the Public.[38]

Rationale to choose a Delphi procedure

Pain is a subjective, multidimensional experience that cannot be objectively measured by simple tools.[39] Consequently, the definition of the 'need for analgesia' as a measurable outcome in the context of pain management must be established using clinical variables. The utilisation of a Delphi method will enable us to explore and reach a consensus on these clinical variables among geographically distant participants, including both providers' and patients' diverse perspectives, cultures and gender. It is crucial to involve patients in this research, as their participation is essential for accurately measuring pain, which is inherently a subjective outcome, particularly within the ED setting.[40] We selected a modified Delphi Method over other consensus methods such as the nominal group technique because it allows for a greater degree of anonymity among participants, encouraging honest and open contributions while mitigating the impact of dominant voices. Furthermore, the Delphi allows for the involvement of a larger and geographically diverse group of experts, enriching the consensus-building process. Finally, it will enable a broader initial stage with open-ended questions, followed by a second stage with consensus rounds.

Generation and inclusion of the outcome measures for the Delphi survey

The Delphi process will follow a two-stage procedure. In stage 1, the expert panel and the core study group, along with a pool of individual patients, will complete a written online survey to collect potential clinical variables. Subsequently, the core study group will evaluate and categorise these variables. In stage 2, the expert panel and the core study group will vote on the identified clinical variables to reach consensus. The inclusion of the core study group in the Delphi process will allow us to ensure that their

expertise in the study objectives is fully available. To mitigate potential bias arising from their participation, all voting will be anonymised. Accordingly, all inputs from the core study group will not be identified to each other and will be weighted equally, like those from all other panel participants. The inclusion of a diverse group of experts and patients ensures that multiple perspectives are reflected in the final variable set, diluting the potential overrepresentation of the core study group's views.

Stage 1: collection of clinical variables

The aim of stage 1 is to collect clinical variables as potential outcome measurements to define 'need for analgesia' and 'adequacy of analgesia'. We will approach a multidisciplinary and international expert team comprised of selected physicians, nurses and patients. They will be asked to respond to the following questions:

For adult patients without cognitive impairments presenting to the ED,

a. "Based on your experience, which clinical variables should define the need for analgesia?"
b. "Which parameters should define adequacy of analgesia?"
c. "What are the challenges encountered when assessing patient's pain?"

To explain the aim of this survey and introduce the questions, a shorter version of this protocol will be sent to the participants (online supplemental appendix 1). The first two questions are directly related to the potential clinical variables. The final open-ended question will encourage brainstorming, potentially leading to the generation of additional clinical variables. We have chosen to begin with open-ended questions to prevent potential bias from the researchers' perspective. This way, we will avoid imposing any preconceived notions onto participants. This difference from conventional practices, often reliant on predetermined lists, aims to prevent bias towards researchers' preferences, ensuring a focus on outcomes that represent all stakeholders' perspectives and priorities.[37]

The core study group will analyse the survey anonymised answers and collaborate to discuss and exclude clinical variables that do not meet the criteria (screening):

- Answers (a) and (b): clinical variables that cannot be measured (neither objectively nor subjectively) will be excluded.
- Duplicates will be excluded or merged as appropriate.

If a unanimous agreement is reached among all core study groups that a clinical variable should be discarded, it will be removed from the list. However, in case of disagreement, the clinical variables will be retained. The core study group will use the answers (c) to eventually generate additional clinical variables to include in the survey in stage 2.

Stage 2: consensus procedure

This stage aims to reach a consensus on the generated list of clinical variables to define 'need for analgesia' and 'adequacy of analgesia'. The same expert panel from stage 1, including the core study group, will evaluate the importance of each clinical variable using a 5-point Likert scale, with 1 being strongly disagree, 2 disagree, 3 undecided, 4 agree and 5 strongly agree. Delphi rounds will be repeated until data saturation is achieved, indicating consensus among experts, with at least 80% of respondents voting 'agree' or 'strongly agree' for each clinical variable. However, to allow sufficient time to clarify the most important variables while maintaining sustained engagement from the expert panel, we will plan a maximum of three rounds in this stage. The core study group will meet virtually after each round to review the results. Variables that achieve consensus will be validated and thus excluded from subsequent rounds. Variables lacking consensus will be further reviewed if they receive diverse expert opinions, strong support from some panellists or are close to the consensus threshold. In such cases, non-consensus may result from unclear wording or missing information. The core study group will assess these variables for clarity and rationale, refine their definition if needed and/or provide additional information before forwarding them to the next round. Otherwise, a list of removed variables with a rationale for their exclusion will be provided in the next round. In each round, participants will have the possibility to provide free-text comments, enabling the refinement and potential incorporation of new clinical variables. New proposed variables will be assessed by the core study group and, if deemed appropriate, forwarded to the next round. General comments will be reviewed to potentially reformulate existing variables without consensus that are advancing to the next round. The distribution of votes among participants in each round for scored clinical variables will be anonymised.

Selection of participants

Core study group

Prioritisation of individuals for core study group selection was based on their track record and their expressed interest in the field of pain in the ED setting. The core study group consists of 12 members, 8 women and 4 men, including patient representatives to ensure comprehensive representation. Members of the core study group are all authors of this protocol and include individuals affiliated with EDs, nursing sciences, psychology and pain medicine holding various roles. This group consists of participants from 4 countries and 10 institutions.

Delphi panel (experts)

Potential participants for the study were first identified through a comprehensive search using Scopus and CINAHL (Nursing and Allied Health Literature) databases, focusing on emergency pain assessment-related topics primarily through titles. By employing these search strategies, we aimed to capture a diverse range of literature relevant to our study objective and target audience, encompassing both large-scale medical research indexed in Scopus and specialised nursing and psychological

literature available in CINAHL. Queries were conducted on 27 December 2023 in Scopus and in CINAHL, using the specific keyword tailored for title and abstract in each database. These keywords included variation of pain, emergency and terms related to assessment or scale:

- TITLE (pain* AND emergency AND (assessment* OR scale*))
- TITLE (pain* AND emergency)
- TITLE (pain* AND (assessment* OR scale*))
- TITLE-ABSTRACT (pain * AND emergency AND (assessment* OR scale*))

A total of 19 079 documents were identified in Scopus and a total of 10 312 were identified in CINAHL. The retrieved documents were exported to CSV (Scopus) and RIS (CINAHL). After converting the RIS file to CSV with Zotero (V.6.0.30, Corporation for Digital Scholarship, Vienna, Virginia, USA), both files were imported to a Microsoft Excel (Microsoft 365, V.2302, Microsoft, Redmond, Washington, USA) sheet. Author(s), document title, citation count, document type and correspondence address were extracted (if available). Duplicates of DOI and Title were removed. Corresponding author (Scopus) and first/last author (CINAHL) were extracted with the following functions: "TEXT TO COLUMNS", "TEXTBEFORE" and "TEXTAFTER" (using punctuation as limiters). Duplicates were removed using the corresponding Excel function, and manual checks for author last names were performed for further deduplication. This process resulted in a list of 22 402 authors. Using the 'COUNTIF' function, we determined the number of titles per author and established a minimum threshold of relevance, with a cut-off of ≥3 articles. After deduplication, we identified 990 candidates from 58 countries. Candidates' professional backgrounds and email addresses, if not present, were manually retrieved. Finally, 57 candidates were excluded due to non-clinical background (except public health) and an additional 26 were excluded due to an unsuccessful email address retrieval. A manual check was conducted to verify the relevance of published articles to the topic of acute pain in the ED. Authors whose publications focused on unrelated topics such as chest pain, postoperative pain or chronic pain were excluded. This process resulted in the elimination of 113 candidates who did not meet the criteria for relevance to the topic. The remaining experts underwent a deduplication process, where double sources and exemplary appearances in multiple queries were addressed, resulting in a pool of 553 candidates (figure 1). This cohort underwent a ranking process based on the following criteria. First, the number of articles with titles and abstracts containing the keywords "pain", "emergency" and "assessment or scale" was considered. Second, the number of titles with

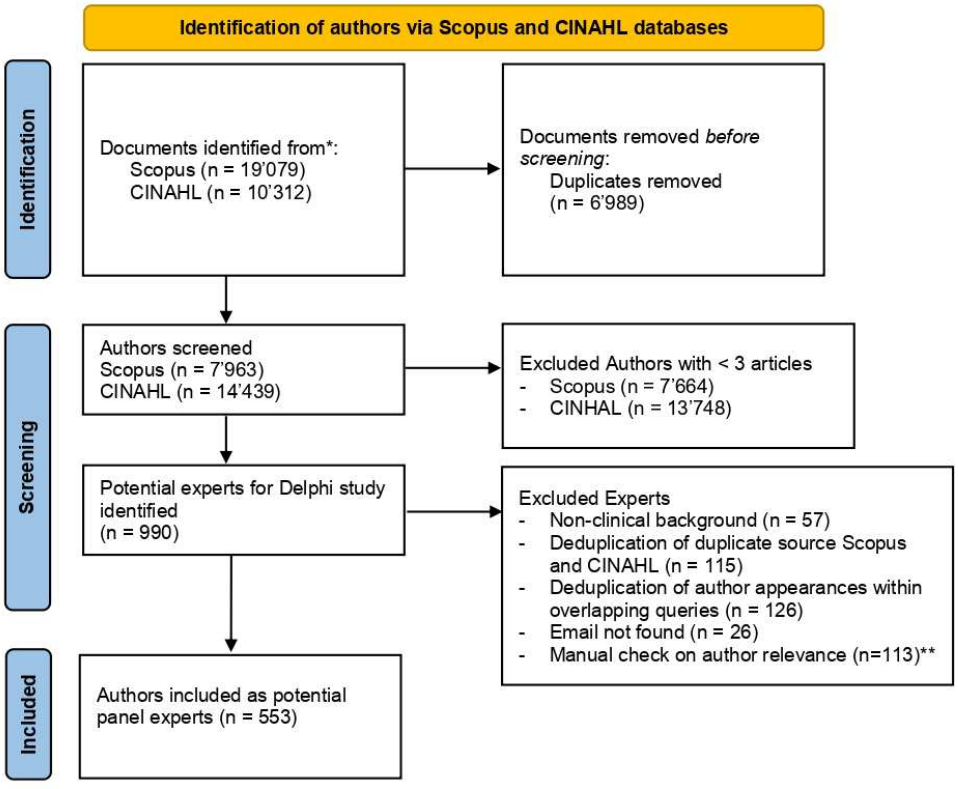

Figure 1 Flow chart defining the expert panel. *Following queries conducted on 27 December 2023: TITLE (pain* AND emergency AND (assessment* OR scale*)); TITLE (pain* AND emergency); TITLE (pain* AND (assessment* OR scale*)); TITLE-ABSTRACT (pain* AND emergency AND (assessment* OR scale*)). NOTE: using the specific keywords for TITLE and ABSTRACT in the respective databases. **Candidates focusing solely on chest pain, postoperative pain or chronic pain were excluded from the study.

"pain" and "emergency". Third, the number of titles with "pain" and "assessment or scale". Authors were finally prioritised based on the highest citation count and the relevance of their professional background. The complete authors' list with rankings is available as online supplemental appendix 2. Considering into account an anticipated response rate of at least 30% and an estimated dropout rate of 20%,[41 42] we will reach out to the first 300 candidates to achieve our target population of 100 individuals. Stakeholders will receive an invitation via email, as described in online supplemental appendix 1. When participants agree to participate, they will be asked to provide informed consent and then automatically directed to the survey. There will be no financial compensation for the panellists. However, to encourage engagement and participation, we will send three reminder emails at 1-week intervals before each round during both stages, as well as provide regular study updates after each meeting of the core study group. Additionally, all participants will be given the opportunity to be identified as collaborative authors of the study.

Patients' involvement

Two patient representatives from the European Patients' Academy on Therapeutic Innovation in Switzerland (EUPATI CH) were recruited during the planning phase of this study. As all other members of the core study group, they will participate in all stages of the Delphi process, including the discussion between rounds. In stage 1, we will also include a maximum of 50 additional patients identified through national or international patient organisations found online to maximise the diversity of the potential variables (invitation as online supplemental appendix 3). To reach a more diverse population, we will also recruit patients via the snowball sampling procedure as underrepresented groups may not be part of national patient advocacy panels. Patients selected for this study will have to meet the following criteria: having at least one experience with acute pain in the ED, preferably within the last 2 years, being comfortable using computers for online surveys and having a proficient understanding of English, as the survey will be administered in English. While this may still limit the diversity of patient perspectives, it would allow the participation of patients with recent experiences of acute pain who are willing to share their insights and thoughts on the 'need for analgesia' they may have had. In stage 2, patient experts from the core study group and a maximum of eight additional patient representatives selected through a snowball sampling method will be included. The rationale for including patient representatives in the consensus rounds (stage 2) is to ensure a broader representation of patient perspectives with a minimal number of individuals. To maintain balance within the expert panel, we have arbitrarily chosen not to exceed 10% representation from patient representatives (and not to include individual patients).

Delphi data collection, analysis and software

The Delphi survey will be digitalised using the Research Electronic Data Capture (REDCap V.14.0.16, Vanderbilt University) platform, a web-based, secure application to support data capture. Participants will receive the online survey links, with monitoring for opening and three reminders to complete the questionnaire, to achieve the target population of 100 individuals. Responses will be extracted from REDCap, anonymised and analysed in Microsoft Excel. The data will be stored on the Basel University system accessible only to the study team. We will report descriptive statistics pertaining to the participants involved in the Delphi process. The results from the list of potential clinical variables generated for stage 2 from Delphi will be shown to the participants. In stage 2, a new REDCap link will be sent to the expert panel for each round of the Delphi process. Each link will remain active for a maximum of 4 weeks to ensure timely responses and efficient progress. The survey period is expected to last 3 months for stage 1, and up to 1 month per round for stage 2, with a maximum of 3 months for stage 2. The expert panel will have this period to provide their feedback and evaluations on the clinical variables. The results of the consensus analysis obtained from the expert panel's responses will be presented.

Ethics and dissemination

A clarification of competence by the Ethics Committee of Northwestern and Central Switzerland showed that the project does not fall within the scope of the Human Research Act, in accordance with Art 2. The project, therefore, does not require approval from the Ethics committee. The results will be disseminated in a peer-reviewed journal, at conference presentations and in abstracts for congresses.

DISCUSSION

The coexistence of oligoanalgesia and pain overtreatment (eg, with opioids) in the ED presents a significant challenge. Accordingly, the aim of pain assessment in this setting should be to effectively distinguish between patients who require analgesia and those who do not. This will require a definition of who needs analgesia, which does not currently exist and is therefore the objective of this study.

This modified Delphi study presents some key strengths. The international core study group represents diverse professional backgrounds, including patient representatives, ensuring broad subject matter expertise from diverse perspectives. The expert panel was systematically selected based on specific keywords in their publication track record within this research area. The two-stage design allowed for an initial unconditioned brainstorming, followed by a structured consensus process. This study

has three main limitations. (1) Diversity cannot be fully guaranteed, though the strategy for recruiting the expert panel was designed to ensure the highest level of expertise in pain assessment within the ED setting. (2) The core study group might have some influence on the selection and categorisation of the variables through their participation in the consensus process, although blinding of respondents' identities and response equal weight limit this potential bias. (3) The definition of need for analgesia will be limited to adult patients without cognitive impairment.

This project started in June 2024 by inviting the selected potential panellists to participate in the study and is currently in its final phases. Since the ultimate objective of this study is to develop a new tool for assessing pain in the ED, the established definition of 'need for analgesia' must be translated into a measurable outcome for validation. As this definition will likely involve multiple variables, the weight of each variable should be addressed in the future, as well as the sequence in which these variables will be evaluated (eg, within an algorithm). A comparison with current assessments, such as the NRS, along with factors like the amount of administered analgesia and patient satisfaction, would provide valuable insights, helping to determine the potential benefits of such a tool in the future.

Author affiliations
[1]Department of Internal Medicine and Emergency, Luzerner Kantonsspital Sursee, Sursee, Switzerland
[2]Emergency Department, University Hospital Basel, Basel, Switzerland
[3]Department of Clinical Psychology and Psychotherapy, Faculty of Psychology, University of Basel, Basel, Switzerland
[4]Emergency Department, University Hospital of Lausanne, Lausanne, Switzerland
[5]Department of Pain Medicine, Lausanne University Hospital, Lausanne, Switzerland
[6]Department of Emergency Medicine, ASST Grande Ospedale Metropolitano Niguarda, Milano, Italy
[7]School of Medicine and Surgery, University Milano-Bicocca, Milan, Italy
[8]Applied Health and Nursing Sciences, Duale Hochschule Baden Wurttemberg, Karlsruhe, Germany
[9]School of Health and Related Research, The University of Sheffield, Sheffield, UK
[10]European Patient's Academy on Therapeutic Innovation Switzerland, Zürich, Switzerland

X Fiona C Sampson @fcsampson

Contributors BS: investigation, data curation, writing original draft and visualisation. AS: investigation, review. CHN: conceptualisation, resources, review and supervision. LR: methodology and software, review. FCS: review. OH: review. BD: review. SJ-S: review. MK: review. GM: review. HT: review. BM: conceptualisation, resources, writing, review, supervision and project administration (guarantor for the study).

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ORCID iDs
Bojana Degen http://orcid.org/0009-0008-7263-7509
Olivier Hugli http://orcid.org/0000-0003-2312-1625
Fiona C Sampson http://orcid.org/0000-0003-2321-0302
Bruno Minotti http://orcid.org/0000-0002-4820-9968

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