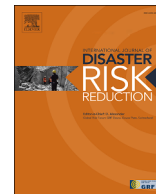


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An application example of translational science in disaster medicine: From grant to deliverables

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ABSTRACT

The Sendai Framework for Disaster Risk Reduction 2015–2030 recognizes the importance of increasing resilience to disasters, a target that the Horizon 2020 funded project Novel Integrated Toolkit for Enhanced Pre-Hospital Life Support and Triage in Challenging and Large Emergencies (NIGHTINGALE) is aiming to achieve by supporting the preparedness of first responders during sudden onset disasters (SODs) and related mass casualty incidents (MCIs) through an innovative toolkit featuring different technological solutions. This manuscript aims to describe the translational science (TS) methodology adopted to guide the development of the NIGHTINGALE toolkit. The multi-stage process featured three different scoping reviews, three Modified Delphi studies and subsequent translation of consensus statements into evidence-based tools and guidelines on triage, prehospital life support and damage control interventions, and prehospital processes during SODs and MCIs. This manuscript shows the potential of the TS methodology to translate grant requirements into deliverables based on scientific evidence and a sound research approach.

1. Introduction

The Sendai Framework for Disaster Risk Reduction 2010–2030 emphasizes boosting disaster preparedness for effective response to enhance the resilience of global communities [1]. This target has been adopted by the Horizon 2020 framework [2] to direct funding of research and innovation projects, aspiring to strengthen health system preparedness and to promote disaster-resilient societies within the European Union (EU). The EU-funded Novel Integrated Toolkit for Enhanced Pre-Hospital Life Support and Triage in Challenging and Large Emergencies (NIGHTINGALE) [3] project aims at improving disaster preparedness and response. This result will be achieved by providing technological solutions to support EU first responders (FRs), including health personnel, civil protection agen-

Abbreviations: NIGHTINGALE, Novel Integrated Toolkit for Enhanced Pre-Hospital Life Support and Triage in Challenging and Large Emergencies; FR, First Responder; PHLSDC, Prehospital Life Support and Damage Control; PHP, Pre-Hospital Processes; SOD, Sudden Onset Disaster; MCI, Mass Casualty Incident; TS, Translational Science; WG, Working Group; EMDM, European Master of Disaster Medicine; ESTES, European Society for Trauma and Emergency Surgery; WADEM, World Association for Disaster and Emergency Medicine.

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cies, fire brigades, police, search and rescue teams, and volunteers, augmenting their response capabilities during the prehospital management of sudden onset disasters (SODs) and related mass casualty incidents (MCIs). Such technological solutions, that will constitute the NIGHTINGALE toolkit, include a suite of interconnected wearable technologies, sensors and mobile applications, unmanned aerial vehicles, coordination systems facilitating real-time multi-agency crisis management operations, and artificial intelligence [3]. The necessary premise to guide and monitor the development of this toolkit is to define common denominators and devise updates of the current SODs and MCI practices among EU emergency medical and non-medical practitioners. The intrinsic and defining characteristic of SODs and MCIs is their unexpected and extensive impact resulting in large numbers of casualties exceeding resources normally available, straining and often overwhelming the local response systems [4,5]. Other than testing the health care sector and involved response agencies, SODs and MCIs pose a challenge also for the academic world, as the possibility to perform research with high level of evidence, such as randomized control trials and conventional prospective studies, is extremely rare in such unpredictable circumstances [6]. Additionally, data collection during SODs and MCIs is often fragmented and not supported by a standardized reporting methodology. This results in further challenges for research scientists who frequently prefer leaning towards retrospective survey-based methodologies and lessons learnt [6,7]. Thus, despite the fact that research in disaster medicine has progressively increased and improved throughout the years [5], there is a compelling need for evidence-based approaches to foster advances in this field of study and create new knowledge [8]. The use of translational science (TS) applied to disaster medicine research represents a promising approach to transfer evidence-based knowledge into implementations and interventions, engaging different perspectives gathered from researchers, practitioners and other stakeholders [9]. In the framework of the NIGHTINGALE project, that relies on the collaborative effort of different organizations including universities, public bodies, and private companies, this multi-step translational methodology was adopted to produce high quality deliverables following a sound scientific evidence-based approach. Indeed, to reach the abovementioned core objective of defining common denominators and provide updates in the prehospital MCI management process, the following targets have been set in line with the TS approach: a) to perform a thorough research study of the existing guidelines and widely operated protocols for MCI Triage, prehospital life support and damage control (PHLSDC) interventions, and pre-hospital processes (PHP), b) to extract evidence-based knowledge including gaps and challenges encountered by FRs in the prehospital management of SODs and MCIs, and c) to elaborate and propose recommendations [3]. The aim of this manuscript is therefore to provide a comprehensive description of the TS methodology applied in the NIGHTINGALE project to provide an answer to the T0 question “to develop, integrate, test, deploy, demonstrate and validate a Novel Integrated Toolkit for Emergency Medical Response which ensures an upgrade to MCI Triage, PHLSDC and PHP”. Results and findings of each stage of the TS methodology will be presented separately in dedicated papers.

2. Translational science

The process of translating observations performed in different settings, from laboratories to clinic and communities, into effective interventions that will ultimately improve the well-being at both the individual and population level, has been largely adopted in many medical fields [10,11]. Recently, the different stages outlined in the TS methodology have been successfully adapted and applied in disaster medicine research, aiming to produce new knowledge and to transfer evidence-based data into recommendations and guidelines, as advocated by the scientific community [8,9]. Such stages, which are not to be seen as separate blocks but rather represent a continuum in the research activity, have been analyzed and implemented in the NIGHTINGALE project to reach one of its objectives, that is to define common denominators and devise updates in the prehospital management of MCIs (Table 1.)

The first three TS phases feature a multi-stage consensus-building approach, engaging different stakeholders involved in the project. The NIGHTINGALE consortium encompasses twenty-three partners of which eight are first response organizations, including health care professionals, scientific societies, academic research centers, health care facilities, emergency medical service, fire fighters, law enforcement agencies, and from the volunteer sector, thus, representing the end-users of the final product. Furthermore, the project is supported by an external expert advisory board, grouping individuals with extensive experience in the field of SODs and MCIs, thus also comprised among the end-users' category. As a key preliminary step, end-users have been divided into three work groups (WGs) to address the three overarching topics of MCI Triage, PHLSDC, and PHP. Each WG worked under the coordination of a team leader, responsible for setting deadlines, organizing virtual meeting and ensuring the progression of the work. By design, the 3 WGs followed the same methodology for the T1 and T2 phases and adopted the same protocols to process the different subjects, thus the same studies have been replicated in parallel three times, and results have been subsequently synthesized in the T3 phase (Fig. 1).

Table 1
Description of the different step of the TS methodology adapted for the NIGHTINGALE project.

TS phase	Methodology	Description
T1	Scoping Review	Identification of current approaches and data examining MCI Triage, PHLSDC and PHP (potential for intervention)
T2	Modified Delphi	Consensus statements as a basis for the development of evidence-based tools and guidelines (translation to end-users: efficacy of the intervention)
T3	Implementation	Creation of evidence-based tools and recommendations (translation into practice)
T4	Study Outcomes	Evaluation and outcomes assessment of the tools and recommendations (translation to community)

MCI = mass casualty incidents, PHLSDC = prehospital life support and damage control, PHP = prehospital processes.

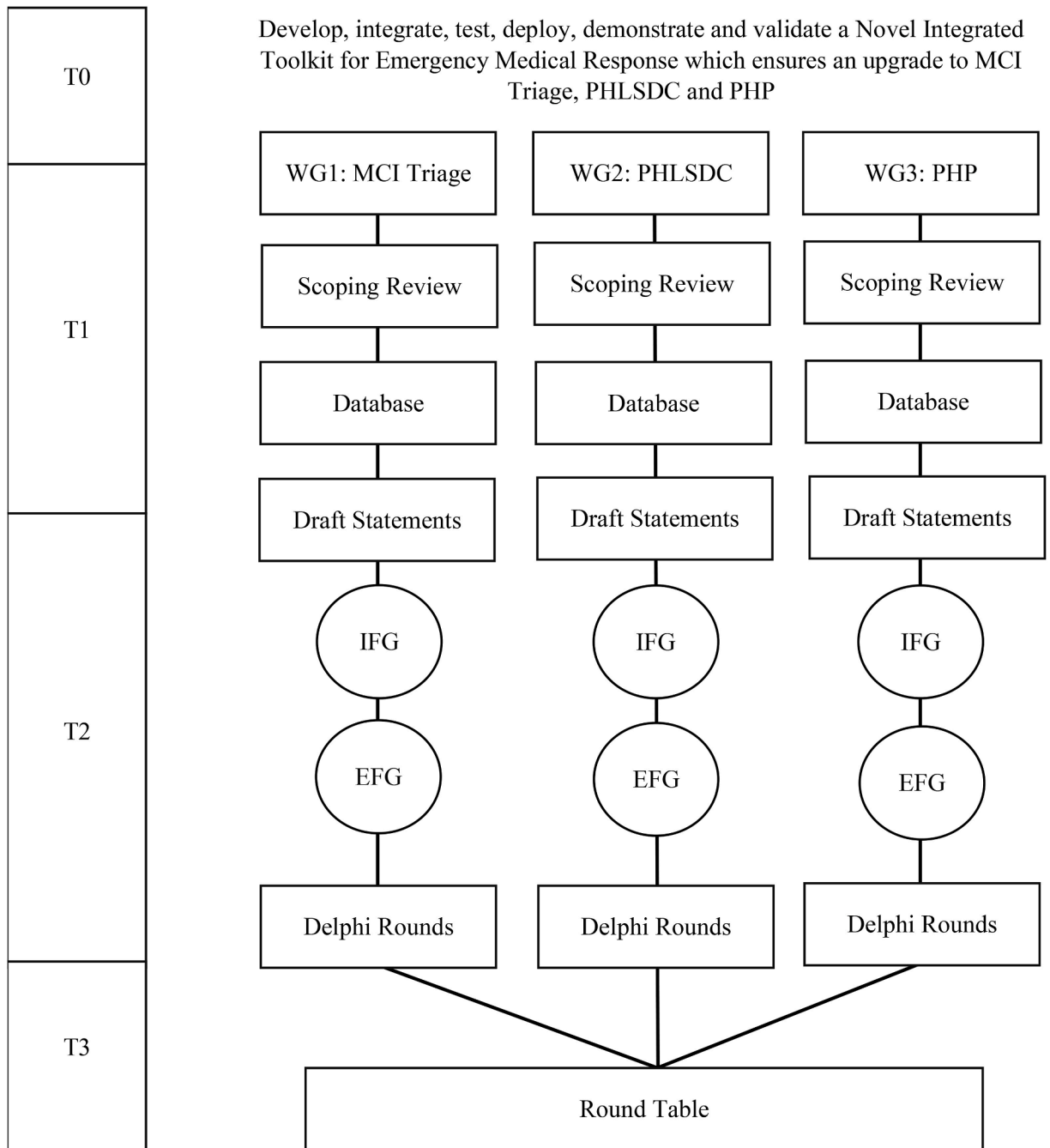


Fig. 1. Schematic reproduction of the Translational Science phases from T0 to T3 applied to the NIGHTINGALE project
 EFG = external focus group; IFG = internal focus group; MCI = mass casualty incident; PHLSDC = prehospital life support and damage control; PHP = prehospital processes;; WG = work group.

2.1. T1: scoping review

The need to perform a literature review stemmed from the limited published evidence produced by systematic reviews, TS or other scientific processes supporting consistent MCI Triage, PHLSDC interventions, and PHP response policies and guidelines. Existing practice greatly varies between nations, states, institutions (medical and non-medical), and settings (e.g., conflict zones and humanitarian crisis), and this variance is further confounded by a lack of ethical consistency in and standardization of key performance indicators, terminology, education and training, validation and verification of evolving technology. As such, to identify and map the available evidence, we chose to perform a scoping review, an approach that allowed the identification of key concepts, key characteristics and current approaches in MCI management and provided a database of MCI triage, PHLSDC and PHP themes and subthemes.

The T1 PRISMA scoping review phase started in November 2021 and ended in January 2022. The 3 WGs followed the same study protocol using a set of core search term and inclusion and exclusion criteria specific for NIGHTINGALE, then adding search term and inclusion and exclusion criteria specific for each WG (MCI Triage, PHLSDC, PHP). The research was performed under the direction of a medical informaticist and identified search results were screened by title and abstract. Articles that met inclusion criteria underwent review of the full text according to the PRISMA flowchart. Any disagreement between researchers screening the title and abstract or full text review phase was settled by consensus. Articles that were included after this step proceeded to the data extraction phase utilizing the database created for each WG with themes and subthemes specific for each WG, developed according to NIGHTINGALE objectives (Table 2). Such data and information included statements, figures, graphs and tables deemed as important to address the subject matter. At the end of the process, each WG created a set of draft modified Delphi statements based on the databases mentioned above.

2.2. T2: Modified Delphi

In the T2 stage, we performed a modified Delphi study, which consisted of engaging different perspectives and determining expert group consensus through an iterative process of repeated rounds of voting. In contrast to the traditional Delphi method based on the collection of quantitative or qualitative data from experts [12], in our modified Delphi study, data retrieved from the T1 scoping review was discussed in different focus groups. In our context, the use of a modified Delphi technique created several advantages, including the possibility to provide guidance to experts and guarantee the focus of the study, the possibility to clarify any redundancy or

Table 2
Topics, themes and subthemes of the scoping review database.

Topic	Themes	Subthemes
Triage	Education	Just in time, initial curriculum, maintenance curriculum
	Simulation Training	Tabletop, full scale exercise, virtual Reality, Computerized
	Patient's History	Mechanism of Injury, Time since injury, Warm-ischemia time Exposure to environment time, Comorbidity, Medications, Allergies, Bystander information/intervention
	Physical examination	Initial cursory, Primary, Secondary
	Equipment	Cardiac monitor, Pulse oximeter, BP cuff, Advanced monitoring (cardiac output), Sensors (wristband, etc.), Ultrasound,
	Patient Tracking	Triage tag, RFID, arm bands, wristbands, other
	Patient record	Electronic, paper, phone, radio
	Re assessment	Warm ischemia, tourniquet time, compartment syndrome, time on backboard, response to IV fluids, response to medications, new complaints
	Outcomes of decisions	Treatment prioritization Evacuation prioritization
	Reporting withing the transfer of care	Electronic, paper, phone, radio
PHLSDC	Education	Just in time, initial curriculum, maintenance curriculum
	Simulation Training	Tabletop, full scale exercise, virtual Reality, Computerized
	Patient's History	Mechanism of Injury, Time since injury, Warm-ischemia time Exposure to environment time, Comorbidity, Medications, Allergies, Bystander information/intervention
	Physical examination	Initial cursory, Primary, Secondary
	Equipment to perform LSDC	Airway adjuncts, needle decompression, stop the bleeding, IV fluids, decontaminating, antidotes, splinting, spine motion restriction
	Equipment	Cardiac monitor, Pulse oximeter, BP cuff, Advanced monitoring (cardiac output), Sensors (wristband, etc.), Ultrasound, Splinting, Bandages, Spine motion restrictions, Medications, other
	Patient record	Electronic, paper, phone, radio
	Re assessment	Warm ischemia, tourniquet time, compartment syndrome, time on backboard, response to IV fluids, response to medications, new complaints
	Outcomes of decisions	Treatment prioritization Evacuation prioritization
	Reporting withing the transfer of care	Electronic, paper, phone, radio
PHP	Education	Just in time, initial curriculum, maintenance curriculum
	Terminology of MCI Processes	Incident management system, Incident command system, Mass Casualty response
	Policy/Planning framework	Government, Non-governmental, vulnerable populations
	First Responders	Volunteers' management/activation/notification
	Activation(Incident notification	Government request, organization activation, bystander information/intervention, staff call, surge plan
	Command system/Authority	Government, non-governmental
	Resource augmentation/ allocation	Logistics, field medical post, mass fatality management, family reunification, telemedicine
	Safety	Decontamination, PPE
	Casualty distribution	Real time, coordinated/planned, patient tracking, distribution matrix
	Communication/Situational awareness	Artificial intelligence, electronic, radio, phone
	Reporting/Documentation	Electronic, paper, phone, radio
Recovery/staff care	Mental health, debriefing, patient experience, staff welfare	

BP = blood pressure; IV = intravenous; PPE = personal protective equipment; RFID = Radio Frequency Identification.

problems regarding comprehension, grammar or syntax of each statement produced by the WGs, and the possibility to quickly refine solid and evidence-based statements within the NIGHTINGALE consortium, thus including all relevant stakeholders and end-users of the project. Starting from January 2022, the three set of draft statements were presented to 3 different internal focus groups (IFGs), led by each specific WG and comprised of NIGHTINGALE end-users, including partners and external expert. During each IFGs, draft statements were reviewed with the responsibility to make them clear, concise and consistent to the overall aim of the project. To remove bias from the statement creation process, 3 external focus groups (EFGs) comprised of experts not engaged in the NIGHTINGALE project were held in February and March 2022, to openly discuss the presented statements to assure that each were clear and concise to be presented to the modified Delphi panel. Final statements were then forwarded to the modified Delphi study specific to that WG. Administration and analysis of the 3 modified Delphi studies was performed using Stat59 (STAT59 Services Ltd; Edmonton, Alberta, Canada). Delphi experts recruited included operational FRs, academic researchers identified among the authors of included papers, alumni of the European Master of Disaster Medicine (EMDM) and members of the professional scientific societies, the European Society for Trauma and Emergency Surgery (ESTES) and the World Association for Disaster and Emergency Medicine (WADEM) as experts in the field of either triage, PHLSDC and PHP in SODs and MCIs. Experts participated in three modified Delphi rounds, in which they were asked to rank the statements using a seven-point linear numeric scale and to review their choice if consensus was not reached in the first round. Formal feedback of group ratings was shared with experts during the second and third round to re-consider their vote until consensus was reached.

2.3. T3: implementation

In the T3 stage, statements that attained consensus at the end of the 3 Delphi rounds were presented to the NIGHTINGALE end-users in a round table held on the April 25, 2022 during the ESTES Congress in Oslo, Norway. The overall aim of the meeting was to translate the statements into practice, producing recommendations and exploring ways of applying them in SODs and MCIs settings. To achieve the abovementioned objective, the twenty end-users participating to the event were assigned to a specific group in charge of discussing the statements according to themes and subthemes (Table 3).

Specifically, the three different group discussions revolved around the same subthemes listed in Table 3 but applied to three different levels of control (strategic, operational, and tactical), represented by the three overarching themes of health authority, operations and technology. Each group was tasked to translate the statements into a series of recommendations on policy, education and training activities and practical guidelines clear enough to function as measurable denominators, thus meeting one of the core objectives of the NIGHTINGALE project, and to serve as a base for the implementation of the novel toolkit for emergency response. At the end of the one-day discussion, the list of recommendations produced was presented in a plenary meeting to the NIGHTINGALE consortium, which included also technical partners in charge of developing the novel toolkit. The results achieved with the T3 stage will provide a foundation for all the core objectives enlisted in the NIGHTINGALE grant agreement. Once integrated with the outputs of other parallel project tasks, such as the definition of end-user needs and requirements as well as criteria and parameters for technology to assist the continuum of care from the initial assessment of the injured person through repeated assessments, treatment in a resource scarce environment, and priority transportation to definitive care, the operational guidelines produced will guide technical partners in developing each component of the NIGHTINGALE toolkit.

2.4. T4: study outcome

The T4 phase of the NIGHTINGALE project will focus on the evaluation of the NIGHTINGALE toolkit components in relation to identified outcomes and key performance indicators. To achieve this objective, different testing strategies, from laboratory testing to table-top, functional and full scale-exercise, will be adopted to allow for a thorough analysis of the toolkit. In parallel, the NIGHTINGALE consortium plans to engage different stakeholders and EU policy makers to translate the recommendations produced through the multi-stage consensus building approach described in this paper into policy.

3. Discussion and conclusion

The paper describes the application of the TS methodology to the Horizon 2020 NIGHTINGALE project, that aims to optimize current procedures and to enhance the operational capacities of FRs in MCIs [3]. While currently scientists struggle to perform sound research and achieve evidence-based results in the field of SODs and MCIs, the TS approach applied to disaster medicine proved to be a structured and effective process able to translate observations gathered by multiple stakeholders into improvements [9]. In our context, the different TS stages allowed to translate the NIGHTINGALE grant requirements of identifying common denominators and devise updates in the current prehospital MCI practice into research-based recommendations and tools, that will be summarized in the projects' deliverable. While the presentation of such results is out of the scope of this paper, we believe that the description of this

Table 3

Overarching topics used in the T1-Scoping Review and T2-Modified Delphi Study and their translation into themes and subthemes for the T3-Implementation phase.

T1 and T2 overarching topics	T3 themes	T3 subthemes
<ul style="list-style-type: none"> ● MCI Triage ● PHLSDC ● PHP 	Health Authority Operations Technology	Education and training, competences, regulations, ethics, triage, logistics, coordination, command and control, transportation, vitals, technological equipment

novel approach in the field of disaster medicine could assist scientists in their effort of producing robust research outputs. Therefore, the paper focuses on thoroughly detailing the methodology adopted in the different stages, in the attempt to use the NIGHTINGALE project as a valuable example that could be generalized and adopted in other projects. Indeed, the choice of performing three scoping reviews to map current available knowledge in the field of MCI management was of value, considering that the subject material is extremely diverse in knowledge and publications, and different operational and academic disciplines contribute to the disaster management practice [13]. Therefore, in our specific context, the identification of sources and references on MCI Triage, PHLSDC interventions, PHP allowed to summarize current knowledge and practices, while the subsequent data extraction laid the groundwork for the development of three initial sets of statements. Once refined through specific FGs, statements have then been submitted to experts through a modified Delphi process, the method of choice to reach expert consensus on pre-selected items drawn from the literature, to support and inform practice [9,14]. This approach provided solid grounding for the following implementation phase, a dedicated workshop that aimed to produce a series of pragmatic recommendations. In compliance with the NIGHTINGALE objectives, these recommendations will guide the use of state-of-the art technologies (such as wearables, artificial intelligence, drones and other verified means) in order to minimize morbidity and mortality of the injured, upgrade the evaluation of victims and affected population, and enable priority transportation from the scene to the definitive site of care. Overall, results of the application of the TS approach to the project should be interpreted in light of some limitations, primarily pertaining to the different type of studies adopted in the TS stages (scoping review and modified Delphi study). While these results and corresponding limitations will be reported separately in dedicated manuscripts, it is worth mentioning that the two main factors that could have impacted the research outputs are related to: a) the data extraction process, which though intended to be encompassing may not have detected pertinent material, and b) the selection of experts, that was limited based on their domain of expertise and geographic distribution. Nonetheless, we believe that this manuscript contributes to show the potential of the TS methodology applied to the disaster medicine field, especially when adopted in the framework of grant-funded research and innovation projects, to produce high quality deliverables based on a sound scientific approach.

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Declaration of competing interest

The authors declare that they have no known competing financial interests or personal relationships that could have appeared to influence the work reported in this paper.

Data availability

No data was used for the research described in the article.

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