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How have PHEIC determinations changed since the COVID-19 pandemic? A document analysis of 101 WHO International Health Regulations Emergency Committees' statements

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Abstract

Background The World Health Organization (WHO) is chiefly responsible for declaring a Public Health Emergency of International Concern (PHEIC). The WHO makes the assessment on whether to declare a formal PHEIC if the event fulfils three criteria: (i) it is an extraordinary event, (ii) is a public health risk to other States through the international spread of disease, and (iii) potentially requires a coordinated international response. There have been seven PHEIC declarations, including for the 2009 H1N1 flu pandemic, Ebola and Polio outbreaks, the COVID-19 pandemic, and most recently, the mpox outbreak. While the WHO's approach to PHEIC declarations prior to COVID-19 has been previously analyzed, there has been limited scholarly attention to how the approach has shifted since the pandemic. Given that COVID-19 constitutes the most severe pandemic in a century, this study empirically assesses how the PHEIC declaration process has been impacted by, and what has changed during and after, the COVID-19 pandemic.

Method A document analysis of 101 WHO International Health Regulations Emergency Committees' (EC) statements was undertaken with inductive thematic analysis. The thematic analysis focused on identifying common patterns in the EC statements to ascertain changes to PHEICs since COVID-19.

Results Three primary themes emerged from our analysis: (i) this work affirms previous findings that the rationale for a PHEIC declaration and the criteria used to declare PHEICs have been applied inconsistently; (ii) since the COVID-19 pandemic, there has been a greater focus in explaining and justifying the use of the three criteria for PHEIC declarations and terminations; and (iii) since the COVID-19 pandemic, there has been increased detail, discussion, and structure in IHR EC statements.

Discussion This analysis suggests that changes to the PHEIC process are needed and we present two primary recommendations: first, to create a new standardized interpretation of PHEIC criteria; and second, for the WHO EC to reaffirm its commitment to clear and transparent communications.

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Conclusion Given changes to the PHEIC declaration process following the COVID-19 pandemic, it is evident that reforms are necessary to ensure a more consistent, transparent, and effective global health response moving forward. Our recommendations, if adopted, could significantly enhance the WHO's ability to respond to future global health crises, ensuring more consistent and transparent decision-making in PHEIC declarations, and ultimately strengthening international preparedness and cooperation.

Keywords Public Health Emergency of International Concern, PHEIC, Global health, International health, Public health emergencies, Public health, Health policy, Public policy, World HealthOrganization, WHO

Background

The World Health Organization (WHO) is chiefly responsible for the coordination of the international response to public health emergencies [1, 2]. As a multilateral organization, the WHO employs a variety of binding and non-binding mechanisms, including the International Health Regulations (IHR). The IHR are binding, legally mandated rules and protocols that outline countries' rights and obligations in dealing with public health emergencies that extend beyond borders [3]. The cornerstone of the IHR is a declaration of a Public Health Emergency of International Concern (PHEIC) by the WHO, which is defined as:

> *"an extraordinary event which is determined to constitute a public health risk to other States through the international spread of disease and to potentially require a coordinated international response" [4].*

The IHR includes a variety of measures that govern how member states should report and coordinate a PHEIC with the WHO. These include specific monitoring and evaluation requirements and the reporting of any potential PHEIC within 24 hours [4]. Member states must assess several criteria when considering whether to report a possible PHEIC to the WHO: (i) is the public health impact of the event serious? (ii) is the event unusual or unexpected? (iii) is there a substantial risk for international spread? and (iv) is there a substantial risk for international travel or trade restrictions [4]?. When at least two of the above questions are answered in the affirmative, a potential PHEIC must be reported to the WHO. A PHEIC is then only invoked after an ad-hoc IHR Emergency Committee (EC) is convened, which reviews the case and provides advice and guidance to the WHO Director General, who is ultimately responsible for making the final declaration decision [5].

The WHO makes the assessment on whether to declare a formal PHEIC by considering three criteria as part of the PHEIC definition: (i) it constitutes an extraordinary event, (ii) it constitutes a public health risk to other States through international spread of disease, and (iii) it potentially requires a coordinated international response [4]. Upon invoking a PHEIC, the WHO issues guidance and Temporary Recommendations for implementation, but the final decision rests with member states regarding policy coordination, travel restrictions, public health orders, and enforcement measures [6].

Since the IHR was finalized in 2005, there have been seven PHEIC declarations, including for the 2009 H1N1 flu pandemic, Ebola and Polio outbreaks, the COVID-19 pandemic, and most recently, the mpox outbreak. The WHO's approach to each of these PHEIC declarations has been discussed and debated extensively by global health policy researchers over the last two decades, with criticisms leveled at their inconsistent application of Temporary Recommendations, slow and/or inadequate responses, and unequal treatment of member states regarding a declaration [7–11]. The West Africa Ebola PHEIC from 2014 to 2016 epitomized the problems with the IHR and PHEIC process, leading to substantial criticism and calls for reform [12–14]. Other notable examples include criticisms of inaction with the 2013 MERS outbreak [15]—and subsequent question around the lack of a PHEIC declaration—and the slow declaration of the COVID-19 PHEIC [7–14]. Although reforms were made to ensure better surveillance practices and operational readiness, these reforms did not resolve the longstanding problems with the PHEIC declaration process [13]. As well, others have argued that the PHEIC process itself has been so highly politicized that EC decisions are clearly driven by factors beyond the criteria outlined in the IHR [15]. As a result, significant debate continues around the most notable criticism identified in research, which has been the inconsistent, selective, and arbitrary application of the PHEIC criteria, particularly when justifying a decision as to whether to declare a PHEIC [16–19].

Previous research has analyzed the evolution of PHEIC declarations over several years [12, 16, 17, 20]. Mullen et al. and Worsnop et al. each conducted analyses of WHO PHEIC declarations and Temporary Recommendations through WHO EC statements, issued after each meeting of the EC. Mullen et al. analyzed 66 EC statements from the 2009 H1N1 pandemic to the early days of the COVID-19 pandemic to assess which of the IHR criteria were used to contribute to a PHEIC declaration justification and the language used to explain decisions, finding that the EC often failed to describe and justify which of the criteria had been satisfied. Worsnop et al. conducted

a comparative analysis of the WHO Temporary Recommendations, reviewing specifically the range of international travel and trade measures declared during PHEICs [16]. They reviewed all EC statements from April 2009–April 2023. Worsnop et al. found that the Temporary Recommendations issued in EC statements during PHEICs were often difficult to interpret and relate back to the IHR obligations [16]. Both studies similarly concluded that WHO EC decisions and justifications are often vague, applied inconsistently, and lack clarity.

Although Mullen et al. assessed the evolution of PHEIC EC declarations, given their study timeline they were not able to analyze how the PHEIC process changed during or since the COVID-19 pandemic, including the recent mpox PHEIC. This suggests an important gap in the literature. Therefore, our analysis is also particularly topical given the 2024 agreement on a package of critical amendments to the International Health Regulations (2005) (IHR) by the World Health Assembly. The recent changes to the IHR, including a new designation of a "pandemic emergency" label, are informed by lessons from recent health crises and have the potential to significantly influence future PHEIC declarations and global health responses [21].

This study thus builds on previous analyses of PHEICs before COVID-19 while extending the analysis further to the entirety of the COVID-19 and 2022–2023 mpox PHEICs to illuminate any shifts. Building from this analysis, we then propose changes for consideration to the PHEIC process and discuss the potential impact of recent IHR amendments on future responses to global health emergencies.

Methods

Data sources

The WHO IHR EC issues statements after each meeting during discussions around potential and declared PHEICs [5]. Statements include information related to the consideration, declaration, maintenance, and termination of a PHEIC and therefore offer a valuable data source to analyze the WHO's decision-making processes.

The decision to focus this document analysis on EC official statements is because EC official statements provide a consistent basis from which to conduct a document analysis to allow for observing common themes around the WHO's response to declared and potential PHEIC, including outlining any Temporary Recommendations. This approach contrasts with an analysis of EC press conferences which commonly, but not always, follow EC meetings and would require controlling for the unpredictability of information resulting from journalists' questions. EC statements are publicly available and are posted online by the WHO after each IHR EC meeting [5]. As such, we did not seek ethical clearance to undertake this study.

We also want to emphasize that we are not questioning the technical expertise and care of those drafting the Public Health Emergency of International Concern (PHEIC) declarations. Rather, EC statements provide a glimpse into other factors that may be at play, including influence of the local and international political contexts that have shaped both the decision to issue certain declarations and the manner in which they are framed.

This analysis reviews WHO IHR EC official statements from the first statement in April 2009 through to November 2023. This analysis excludes the most recent EC statements of the IHR Emergency Committee for the ongoing Polio epidemic and the resurgent mpox PHEIC in 2024, given that these events occurred after the point when analysis was conducted. There were a total of 101 WHO EC statements during this period included in this study—all publicly available online on the WHO's website [22].

Ten PHEIC ECs, including those declared and not declared a PHEIC, were included in this analysis as outlined in Table 1. Seven of these PHEIC ECs led to a PHEIC declaration, which are noted with an asterisk in the table.

Document analysis

We employed qualitative document analysis to provide a systematic procedure for reviewing and evaluating documents—in this case the WHO EC statements. Document

Table 1 PHEIC ECs selected for analysis across each period

	Potential and declared PHEIC ECs before COVID-19	Potential and declared PHEIC ECs since COVID-19
PHEIC ECs selected	• Influenza Pandemic (H1N1), 2009–2010* • Middle East Respiratory Syndrome Coronavirus (MERS), 2013–2015 • Poliovirus (Polio), 2014–present* • Ebola Virus Disease in West Africa, 2014–2016* • Zika Virus, 2016* • Yellow Fever, 2016 • Ebola Virus Disease in the Democratic Republic of the Congo, Equateur, 2018 • Ebola Virus Disease in the Democratic Republic of the Congo, Kivu and Ituri, 2018–2020*	• The COVID-19 PHEIC, 2020–2023* • mpox, 2022–2023*

* PHEIC ECs that led to a PHEIC declaration

Table 2 Inductive codes generated per PHEIC

PHEIC	Codes generated*
Influenza Pandemic (H1N1), 2009–2010	surveillance, human-to-human transmission, no travel/trade restrictions, more information needed, unpredictable, extraordinary event
Middle East Respiratory Syndrome Coronavirus (MERS), 2013–2015	surveillance, human-to-human transmission, no travel/trade restrictions, more information needed, healthcare settings, whole-of-government response
Poliovirus IHR Emergency Committee, 2014–present	surveillance, human-to-human transmission, no travel/trade restrictions, more information needed, healthcare settings, extraordinary, severe, international spread, global risk, fragile state
Ebola Virus Disease in West Africa, 2014–2016	surveillance, human-to-human transmission, no travel/trade restrictions, more information needed, healthcare settings, severe, international spread, global risk, fragile state, quarantine, travel ban, political recommendations, extraordinary event
Zika Virus, 2016	surveillance, research, no travel/trade restrictions, geographic spread, more information needed, gaps in knowledge, accommodation of gatherings/events, Olympics, long-term management
Yellow Fever, 2016	surveillance, no travel/trade restrictions, serious, control measures, regional transmission, vaccine, prevention
Ebola Virus Disease in the Democratic Republic of the Congo, Equateur, 2018	surveillance, no travel/trade restrictions, serious, healthcare settings, severe, regional spread
Ebola Virus Disease in the Democratic Republic of the Congo, Kivu and Ituri, 2018	surveillance, no travel/trade restrictions, serious, healthcare settings, severe, regional and international spread, fear-based response, human-to-human transmission, more information needed, fragile state, humanitarian response, attention-grabbing, extraordinary event
COVID-19 PHEIC, 2020–2023	surveillance, serious, healthcare settings, severe, clinical discussion, international spread, unknowns, misinformation/disinformation, human-to-human transmission, more information needed, inequality/inequity, vaccine equity, virus evolution, global attention, limit travel/trade restrictions, risk management, public gatherings, politicization, self-criticism
mpox, 2022–2023	surveillance, low severity, international spread, unknowns, misinformation/disinformation, human-to-human transmission, more information needed, research gaps, divergent views/assessment, clinical information, deliberations, self-criticism

* Please note that terms utilized in respective documents are presented here, rather than synonymous or like terms

analysis has been shown to be a useful research tool to understand policy content and processes and discourse "across time and geographies" as demonstrated by Dalglish et al. [23]. This method has been commonly used to yield significant and substantive findings in health policy research [23], such as by Mullen et al. [17] and Worsnop et al. [16]. We aimed to build on these scholars' research with a more comprehensive and recent compilation of data using similar methods. A document analysis approach also provided an opportunity to review the content and rhetorical style used by the WHO to communicate about the state of declared and potential PHEICs, which is important information relayed to the world to inform public health measures.

Approach to coding

We employed an inductive coding strategy to undertake thematic analysis [22]. Inductive coding entails a ground-up approach to derive codes from the data and was selected because this study is exploratory in nature [24]. Our aim was to be open to what emerged from the data, in contrast to deductive coding using a preset coding framework [25]. Each document was carefully read and coded manually in Microsoft Word by K.H. and codes we deemed relevant are presented in Table 2. Codes were first reviewed by K.H. to identify common analytical themes that help answer the research question. These themes were agreed upon by the full authorship team for which the findings are based on.

Results

This analysis led to three concrete thematic findings. First, this work affirms previous research findings that the rationale for a PHEIC declaration and the criteria used to declare PHEICs have been applied inconsistently. Second, since the COVID-19 pandemic, there has been a greater focus in explaining and justifying the use of the three criteria for PHEIC declarations and terminations. And third, since the COVID-19 pandemic, there has been increased detail, discussion, and structure in IHR EC statements.

Inconsistency of rationale for declaring PHEICs

The 2009 H1N1 pandemic marked the first initiation of the WHO EC and PHEIC process under the new IHR. The H1N1 EC declared a PHEIC on 25 April 2009 at the first meeting [26]. This decision to declare a PHEIC was made despite stated informational gaps and a need for more information to assess the epidemiological conditions of the virus's spread. Further, a PHEIC was declared even though the EC had not made a determination of raising the H1N1's now defunct pandemic level system from phase 3 (which only suggested sustained animal-human transmission) to phase 4 (human-human transmission) [27]. This contrasts with EC deliberations around the 2013–2015 MERS outbreak, which did not result in a PHEIC declaration [28]. One key rationale put forward in defence of not declaring a PHEIC for MERS was that human-to-human transmission had not been

established [29], in addition to noting that outbreaks seemed to be confined largely to healthcare settings [30]. By contrast, despite finding that human-to-human transmission was occurring, the COVID-19 EC did not initially declare a PHEIC [31]. One week later, the EC declared COVID-19 a PHEIC, noting in their statement that a significant number of additional cases in other countries led to the decision [32].

Another rationale cited for a PHEIC declaration was the observance of international or geographical spread, which was stated as a reason for declaring the 2014–2015 Ebola outbreak a PHEIC [33]. Similarly, the 2016 Zika outbreak led to a PHEIC decalaration after clusters were detected in different regions, including Brazil and French Polynesia [34]. This denoted a risk of "geographic spread" and that it was because of "considerable gaps in knowledge" that the EC justified its PHEIC declaration [35]. By contrast, during the second Ebola outbreak (2018–2020) in the Democratic Republic of the Congo, the EC decided *against* a PHEIC declaration during the first three meetings, despite acknowledging that cases in neighbouring Uganda "constitute international spread of disease" and that there was a "very high risk of regional spread" to other countries [36, 37]. However, only a month later in its fourth meeting the Ebola EC concluded that the outbreak did meet the conditions of a PHEIC [38]. The main stated justification was a confirmed first case in the city of Goma *within the DRC*, which members noted as a city of two million "and the gateway to the rest of the DRC and the world" [38]. EC Members also indicated that there was not enough global attention on the outbreak, so a PHEIC would allow the world "to take notice and redouble our efforts", a consideration that is not part of the PHEIC criteria, nor identified as a justification in other cases prior to COVID-19 [38].

A final inconsistency came in the use of the word "extraordinary" as an assessment for a PHEIC declaration. For instance, the EC justified its declaration of H1N1 as a PHEIC with no explicit mention of its "extraordinary" status. Yet in the EC's justification for declaring H1N1 no longer a PHEIC, they justified their decision based on H1N1 "no longer represent[ing] an extraordinary event" [39]. In contrast, in the initial EC meetings for the Ebola outbreak (2018–2020), the EC pointedly declined to declare a PHEIC saying that "while the outbreak is an extraordinary event, with risk of international spread" the response would not be "enhanced by formal Temporary Recommendations under the IHR [37]. This rationale therefore clearly contradicted the "extraordinary" criterion used for H1N1 and other cases [37]. We see this inconsistency too with the COVID-19 PHEIC, where the EC again makes no mention of an "extraordinary" status in declaring a PHEIC but decided to terminate expressing that COVID-19 "is no longer an unusual or unexpected event" in assessing its "extraordinary" status [40].

Shifts since COVID-19: justifying the three criteria

Most statements before and during COVID-19 did not outline justifications for meeting the three criteria for declaring, continuing, or terminating a PHEIC. In the instances where the three criteria were referenced, this was often done implicitly and without clear explanation of how the criterion was fulfilled. References to one or two of the criteria were evident at times, such as the risk of international spread and the urgent need for international coordination (e.g., Zika [41], H1N1 [26], Ebola Virus Disease in the Democratic Republic of the Congo (Kivu and Ituri) [38], COVID-19 [32]).

EC statements for the COVID-19 PHEIC continued this selective discussion of the three criteria. At the fourteenth COVID-19 EC meeting, the EC maintained the PHEIC, citing high transmission rates and that it was necessary to "maintain global attention to COVID-19" [42]. This is a consideration that, as observed in past EC statements, does not explicitly meet one of the three PHEIC criteria.When the EC met to terminate the COVID-19 PHEIC in May 2023, the committee noted that deaths and hospitalizations had reduced while noting the three PHEIC criteria for the first time during this PHEIC [40].

The mpox PHEIC was the first instance of a clear and substantive deliberation about all three criteria used to declare a PHEIC and discussion on how committee members reached such a decision [43]. Unlike previous PHEICs, there was clear and explicit reference and justification to meeting the three criteria. Throughout the discussion of the three criteria at the first mpox EC meeting, the committee referenced few hospitalizations and severe cases but noted that transmission was occurring in countries without previous mpox outbreaks [44]. This led to a divergence in opinions from the EC, with the committee ultimately recommending that mpox did not constitute a PHEIC based on the criteria [44]. However, the WHO Director-General made a different assessment and ultimately, using his final authority, decided that the three criteria had been met to make a PHEIC declaration at the second meeting [43]. This represented the first time that the Director-General overruled an EC committee surrounding a PHEIC declaration.

Despite the explicit references to the three criteria, when the mpox PHEIC was declared terminated in May 2023, a similarly explicit discussion about the three criteria was absent. Instead, the justification for termination centred on substantially lower cases and the EC's view that it was time to transition mpox to long-term management [45]. As we have seen with other PHEICs, the termination may imply that the three criteria were

no longer met. Despite this, there remained substantial discussion about how the current epidemiological situation informed the committee's decision to terminate in the deliberative session, which was not seen for previous PHEICs.

Increased detail, discussion, and structure in EC statements

The EC statements before the COVID-19 pandemic varied greatly in their length, scope, and detail. Those in early PHEICs were often much shorter and lacked any epidemiological discussion or deliberation. Since the first statement in 2009, statements have generally become progressively longer, from 217 words during the 2009 H1N1 PHEIC [26] to 3500 words for the last Polio PHEIC EC statement reviewed in 2023 [46]. EC statements before the COVID-19 pandemic averaged 1020 words while statements since the COVID-19 pandemic have averaged 2992 words.

Before COVID-19, a few statements did provide discussion on the basic epidemiological situation in the country—providing information on case numbers, or more rarely transmission rates, and projected spread—though this was mostly for the Ebola (2018) EC statements. Most EC statements before COVID-19 did not present substantive clinical data (e.g., incubation periods and R_0) to contextualize the situation or PHEIC declaration decisions. The lack of substantive epidemiological discussion in some EC statements may justifiably be due to the state of a PHEIC, where cases and/or transmission rates have remained stagnant and/or are genuinely not noteworthy. However, across the last nineteen years, with each new PHEIC, there generally appears to be more clinical discussion included as part of EC statements, with a more pronounced shift in 2020 with the COVID-19 pandemic.

Temporary Recommendations also varied significantly, with only three generalized recommendations issued for the 2009 H1N1 pandemic, whereas the Ebola outbreaks received more targeted, specific recommendations to each country or region. Given that each PHEIC is unique with different factors and considerations, it would be appropriate that there is variability in the content of statements and the recommendations provided. The lack of consistency, however, sometimes produced odd recommendations, such as with the Ebola outbreak (2014), where recommendations delved into explicit advice on political leadership. In one statement, the EC advised that "the head of state should continue to address the nation" and that the ministers of health should be the point person to handle outbreaks [47]. Such recommendations were not featured in any other PHEIC EC statements.

EC statements became far more detailed with the COVID-19 PHEIC on a variety of issues, reflecting the evolving nature of the pandemic, focus on continued international coordination, a global vaccine rollout, and ongoing attention to best public health practices. One addition catalyzed by the COVID-19 pandemic was that EC statements regularly included the inclusion of ethics rules and the declaration of conflicts of interest. This trend continued during the mpox EC statements.

Further, COVID-19 EC statements were the first to note apprehension in justification for and against making PHEIC declarations based on the current process. The COVID-19 EC for the first time noted the "restrictive and binary nature" of the PHEIC declaration, adding to existing criticisms of the PHEIC process [31]. The mpox PHEIC included internal criticisms of the PHEIC process discussed at the third meeting, with some arguing that the criteria were not "adequate" to make an informed decision around a PHEIC declaration [48].

Finally, mpox EC statements became more structured and organized, with a section dedicated to a substantive epidemiological presentation that outlined cases, R_0 transmission rates, and incubation periods. The Temporary Recommendations were also laid out in a more structured way, with the use of consistent designations when recommendations were "modified" or "extended" [48]. The new "deliberative session" section of the statements started in the latter half of the COVID-19 PHEIC and continued with more detail during the mpox PHEIC.

Discussion

This analysis reaffirms and expands upon existing critiques of the PHEIC declaration process. It supports and builds on Mullen et al.'s analysis of EC statements pre-COVID-19, which highlighted key inconsistencies, such as the ambiguous application of the PHEIC definition of "extraordinary," the inconsistent justification for "international spread," and the selective use of "human-to-human transmission" as a determining factor for declaration [17]. Worsnop et al. similarly identified "inconsistencies" and a "lack of clarity" in their analysis of the trade and travel Temporary Recommendations within the EC statements, which they called on the WHO to address [16]. Some of the additional findings buttressing Mullen et al. and Wornsop et al. in this paper includes the presence of political leadership advice in some PHEIC EC statements during the Ebola PHEIC in West Africa (2014–2016), which was not the case for other PHEICs. Another notable addition to the critique is the consideration of global attention on an outbreak's PHEIC status, a factor that is not part of the official PHEIC criteria, and yet has been used as justification to either declare or continue a PHEIC declaration multiple times [38, 42].

Yet our study furthers this analysis by demonstrating that since the COVID-19 PHEIC, EC statements have undergone gradual internal changes to address concerns related to PHEIC declaration inconsistency, more clearly outlining and justifying the existing three criteria. We

saw that the mpox PHEIC was the first time the EC provided a clear and substantive deliberation about all three criteria and how committee members came to a decision on a declaration. By looking at the entirety of the COVID-19 PHEIC and the mpox (2022–2024) PHEIC, a clear shift is visible in how the WHO EC approaches and handles the PHEIC process. The new "deliberative session" sections speak to a change in approach from the WHO ECs, where there is a recognition that more information, transparency, and justification is needed to explain PHEIC EC decisions.

To that end, this analysis finds that the COVID-19 and mpox PHEICs allowed for witnessing internal debates and divides from EC members for the first time. Such debates included discussing the value of the current PHEIC declaration assessment and process. For example, with the mpox PHEIC, divisions on a PHEIC declaration are laid out openly. This kind of transparency also lends itself to ethical considerations being included in EC statements which started during the COVID-19 PHEIC, outlining that members did not have conflicts of interest that may cloud their judgement in WHO decisions.

Along with changes to the EC statement structure themselves, the WHO appears to be forming the basis for what can be a more objective and consistent approach going forward, which the next section details.

Policy recommendations

Since the COVID-19 pandemic, the WHO has been working on systematic reforms to its response to global public health emergencies. In December 2021, the 194 WHO member states agreed to begin negotiations to create a new pandemic agreement alongside amendments to the IHR [6]. By June 2024, a package of amendments to the IHR was agreed to while negotiations continue to finalize a new pandemic agreement [6]. These amendments will come into force starting in September 2025 [49] and create the following changes:

(1) "introducing a definition of a pandemic emergency to trigger more effective international collaboration in response to events that are at risk of becoming, or have become, a pandemic.
(2) a commitment to solidarity and equity on strengthening access to medical products and financing.
(3) establishment of the States Parties Committee to facilitate the effective implementation of the amended Regulations.
(4) creation of National IHR Authorities to improve coordination of implementation of the Regulations within and among countries" [21].

The WHO states that these amendments will improve global preparedness and responses to public health emergencies, doing so in part through the creation of a new "pandemic emergency" designation that now serves as "the highest level of global alert". While these amendments are a positive step forward, they fall short of addressing long-standing criticisms of the PHEIC process. In the following section, we accordingly present two recommendations that address the issues outlined in this analysis and align with those identified by other researchers [16–18, 20]. These recommendations are to: (i) create a new standardized interpretation of PHEIC criteria, and (ii) engage in clear and transparent communication. We also discuss any intersection of the IHR reforms with these recommendations. These recommendations serve as broad, practical guidance to the WHO EC which can implement them through the current PHEIC criteria and 2024 amendments outlined in the now updated IHR. Though, we also offer more specific suggested changes that would require additional IHR amendments for consideration.

Create a new standardized interpretation of PHEIC criteria

The first recommendation addresses the inconsistency in the interpretation and application of criteria that leads to a declaration, continuation, or termination of a PHEIC. As this study and others have demonstrated, ECs have often "vague" and "inconsistent" interpretations of what constitutes a PHEIC, with a lack of justification provided in their statements as to which criteria have been satisfied and how [17, 18]. Given the scale of inconsistencies over the last nineteen years, this is an issue that should be concretely addressed.

As an initial step, a new standardized approach must clearly identify which criteria are strictly subject to consideration, rather than the current approach, which oscillates between the three criteria in the IHR—which includes the consideration of an event being "extraordinary"—and the additional considerations sometimes invoked such as whether the event is "unusual or unexpected". With the introduction of the new pandemic emergency definition, we now have two PHEIC tiers. One possible approach could be to integrate the "unusual or unexpected" consideration for regular PHEICs to denote a lower level of concern, while the assessment of a pandemic emergency can now be reserved for cases that are truly "extraordinary". Such an assessment in our view would be for truly historical pandemics such as the 2009 H1N1 PHEIC and the COVID-19 PHEIC. However, given this would change the language of the formalized criteria, this would likely require additional changes to the IHR to be agreed upon by member states.

Next, the interpretation of those criteria must be consistently assessed. For example, when looking at criteria

two: "a public health risk to other States through the international spread of disease", we might assess whether there is geographical spread of a virus across countries or continents to denote meeting this criterion. Of course, each public health emergency will have different considerations at play, but a level of standardization can provide clarity to governments and populations that have criticized this process in the past. Clarifying which criteria are followed and what type of evidence is considered for each event will help instil confidence in PHEIC decisions and lessen accusations of bias or accidental inconsistency, such as experienced during the Ebola (2018) outbreak and MERS (2013–2015) [17, 50].

The 2024 reforms unfortunately do not touch on this issue, with the new "pandemic emergency" designation serving to address long-standing criticisms around the binary nature of the PHEIC process [20, 51]. However, the four-part criteria that is now included in this definition may cause additional problems. There appears to be some overlap with the existing PHEIC declaration criteria, namely with point (i) of the pandemic emergency definition asking if there "has, or is at high risk of having, wide geographical spread to and within multiple States" compared to criteria (ii) of the PHEIC criteria which asks if it is "a public health risk to other States through the international spread of disease" [5, 21]. As we have seen in this study, it will be critical for the WHO to clarify these two criteria and implement a clear, standardized interpretation and application of the criteria when making a pandemic emergency designation. Otherwise, current issues with the PHEIC declaration process will simply become far more pronounced, making this change entirely unhelpful.

Engage in clear and transparent communication

Second, the WHO ECs should continue with a new approach and commitment to transparency, which, as other scholars have noted, has been sorely lacking in the past [9, 52]. Further, greater transparency on the decision-making process would be welcome. As Eccleston-Turner & Wenham (2021) and others discuss, it has not been historically clear what the decision making process is at the ECs (e.g., do decisions operate on consensus or require unanimity? How are disagreements resolved?) [18]. There is also little public information on how votes are taken in the EC, though in the past they have indicated that votes are indeed part of the process [52]. Making these procedural details known would further instil confidence in WHO PHEIC decisions.

The EC statements have gone through significant changes over the last nineteen years. It is commendable to witness—as we have seen with the COVID-19 and mpox PHEIC—EC statements provide far more detail with robust epidemiological information and transparent commentary on the committee's deliberations. Clear and transparent communication is critical to effectively informing the public on the risks and responses to public health emergencies. For example, many outside of the global public health community are not familiar with the term 'PHEIC', with the more informal term 'pandemic' usually used instead [19]. It is therefore welcome to see the new 2024 "pandemic emergency" designation from a communications standpoint, which is easy and clear to understand. Continuing to simplify language might help with more effectively communicating to the public the urgency, severity, and/or importance of PHEIC assessments, determinations, and recommendations.

Establishing clear and transparent communication is a subjective measure and will, in part, depend on the actions and cooperation of member states. Geopolitical realities, especially with more hostile attitudes towards the WHO by some countries, may make it difficult to reach consensus. However, if there is one overarching public health lesson from the COVID-19 pandemic, it is the critical nature of transparency and clear communication to maintaining the trust of people during a pandemic emergency. COVID-19 served to elevate global attention around pandemic declarations, increasing demand for information and scrutiny of the WHO's decisions. The WHO has already shown that changes, such as providing more information and being transparent about processes, can be implemented, and it is likely that member states, pressured by their citizens, will demand further transparency from the WHO's decisions going forward. The WHO would be well advised to continue such an approach as it seeks to rebuild confidence with member states and prepare for future PHEICs or pandemic emergencies.

Limitations

This study utilizes the document analysis approach to provide an in-depth and comprehensive overview of the PHEIC declaration process through EC statements, providing a consistent basis from which to assess changes before and since COVID-19. However, as this study relies solely on publicly available WHO IHR EC statements, internal deliberations excluded from these texts are not reflected in this analysis. It is possible that inconsistencies or a lack of deliberation noted in PHEICs before COVID-19 may, in part, be due to the limited public information analyzed. There remains other sources of information, such as public commentary from EC members themselves regarding debates around the PHEIC process or more systematic reviews of scholarly research around PHEICs, that might inform and add to the findings in this study [9, 53]. However, as this study and previous research has outlined, relying on publicly available EC statements provides a consistent source of primary

research that spans the entirety of the IHR's existence. Further, publicly available information has provided a relatively accurate understanding of how PHEIC declarations have been made [16, 17]. This analysis could be further strengthened by accessing other sources of information from the WHO, such as internal documents or memos, and further assessing why these changes happened, which we recommend for future studies.

Conclusion

This study reaffirms that the rationale for declaring PHEICs has been inconsistent, lacking both clarity and a standardized justification for declaration. However, during COVID-19, we began to see statements providing more detail into deliberations with insights into the epidemiological deliberation and divisions within ECs having been apparent. Finally, in the latter half of the COVID-19 PHEIC, the WHO began discussing the three PHEIC criteria more concretely. This approach was further refined during the mpox PHEIC, where the WHO provided a detailed, point-by-point rationale for meeting the criteria.

Observing that there has been an evolving approach to declaring a PHEIC both during and since COVID-19—as observed in this study—we argue that the COVID-19 pandemic provided an inflection point for serious reflection and change [54]. This is demonstrated by the WHO's work on a new pandemic accord and agreed upon amendments to the IHR that partially address this study's concerns. There remains, however, a clear window of opportunity for substantive change [55, 56]. The findings in this paper reinforce the work of previous scholars in identifying the long-standing nature of this problem and highlighting the necessity for reform as we prepare for the inevitable next PHEIC. We strongly suggest that the WHO capitalize on this opportunity and work with member states to fully implement our two recommendations for revising the PHEIC process. Given existing criticism of the role that politics plays in the PHEIC declaration process, there remains a need to limit opportunities for politicization [15]. Our hope is that by providing a technical solution through our recommendations to the longstanding issues with the PHEIC process, we limit the debate on the PHEIC process to constructive conversations about how to deal with public health emergencies instead of debating perceptions of favouritism, unequal treatment, or neglect, as has happened for previous PHEICs. A standard interpretation and application of the criteria would help remove the subjectivity that leads to such problems.

Actioning these recommendations in our view is a global public health imperative. It is worth underscoring that the inconsistency in the WHO's decision-making process for PHEIC declarations has profound real-world implications. These declarations shape global responses to health emergencies, influencing the allocation of resources, international coordination, and ultimately, public health outcomes. The COVID-19 pandemic highlighted the critical importance of clear and transparent public health communication, without which the legitimacy of public health officials and institutions like the WHO are undermined and exploited. Given the stakes involved, ensuring greater clarity, consistency, and transparency in the criteria and processes for declaring a PHEIC has enormous consequences for the lives and well-being of people worldwide, particularly those most vulnerable to the impacts of global health crises.

Abbreviations

EC	IHR Emergency Committee
IHR	International Health Regulations
PHEIC	Public Health Emergency of International Concern
WHO	World Health Organization

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Author contributions

KH conducted the analysis and drafted the manuscript. MA and DEK contributed to manuscript development. All authors approved the final manuscript.

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