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Clinical paper

Community consultation in the pediatric intensive care unit for an exception from informed consent Trial: A survey of patient caregivers

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Abstract

Aim: To explore perspectives of families in the pediatric intensive care unit (PICU) about an emergency interventional trial on peri-arrest bolus epinephrine for acute hypotension using Exception From Informed Consent (EFIC).

Methods: We performed face-to-face interviews with families whose children were hospitalized in the PICU. A research team member provided an educational presentation about the planned trial and administered a survey with open- and closed-ended items. Analyses included descriptive statistics for quantitative data and thematic analysis for qualitative data.

Results: Sixty-seven participants contributed to 60 survey responses (53 individuals and 7 families for whom 2 family members participated). Most participants answered favorably toward the planned trial: 55/58 (95%) reported that the trial seemed "somewhat" or "very important"; 52/57 (91%) felt the use of EFIC was "somewhat" or "completely acceptable"; and 43/58 (74%) said they would be "somewhat" or "very likely" to allow their child to participate. Five themes emerged supporting participation in the planned trial: 1) trust in the clinical team; 2) familiarity with the study intervention (epinephrine); 3) study protocol being similar to standard care; 4) informed consent during an emergency was not feasible; and 5) importance of research. Barriers to potential participation included requests for additional time to decide about participating and misconceptions about study elements, especially eligibility.

Conclusions: Families of PICU patients generally supported plans for an emergency interventional trial using EFIC. Future inpatient EFIC studies may benefit from highlighting the themes identified here in their educational materials.

Keywords: Exception from informed consent, Pediatric ICU, Family perspectives, Peri-arrest bolus epinephrine

Introduction

The Exception From Informed Consent (EFIC) regulations were adopted by the United States Food and Drug Administration (FDA) in 1996 to facilitate research of treatments needed in life-threatening medical emergencies during which informed consent is not feasible.[1] EFIC regulations balance the need for emergency interventional research with the protection of vulnerable patient populations by placing additional responsibilities on the researchers, including a process called "community consultation" (CC), which provides "the opportunity for discussions with, and soliciting opinions from, the community ... from which the study subjects will be drawn."[2] However, there are currently no standardized methods to fulfill these requirements, and published reports of CC activities reveal variable approaches.[3]

A recent scoping review by Dickert et al.[3] noted an overrepresentation of quantitative data related to CC activities but a paucity of published qualitative data. Qualitative research in this area is impor-

Abbreviations: EFIC, exception from informed consent, FDA, Food and Drug Administration, CC, community consultation, PICU, pediatric intensive care unit, EPI Dose, Epinephrine in the Pediatric Intensive Care Unit: A Dose-Eect Trial

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tant to understand the perspectives of potential EFIC study participants (or family members) and to guide future CC efforts. Therefore, we conducted an in-person structured interview study to explore the perspectives of the families whose children were admitted to pediatric intensive care units (PICU) about a planned clinical trial using EFIC. We aimed to gain insights on how they viewed the study's importance, acceptability of using EFIC and their likelihood of participation.

Methods

Planned trial

Epinephrine in the Pediatric Intensive Care Unit: A Dose-Effect Trial (EPI Dose) is a single-center, prospective, randomized, double-blind, dose–effect trial comparing two initial doses of peri-arrest bolus epinephrine (PBE) for acute, life-threatening hypotension in the PICU (NCT05327556). Currently, there are no standardized PBE dosing guidelines for this practice, and pediatric intensivists worldwide have reported significant variation in initial dosing strategies.[4] The two doses to be used in the EPI Dose Trial are within the recommended dose range at our institution.[5] At the time of writing, the EPI Dose protocol has been approved by our Institutional Review Board (IRB-P00035730) and been issued Investigational New Drug status from the FDA, which is required for all studies utilizing EFIC.

The trial screening process includes an in-person visit or phone call from the research staff to the legally authorized representative (typically a parent) for all eligible patients admitted to the PICU. Research staff will briefly describe the study and provide educational resources about the trial, as well as provide the opportunity to opt out of future participation, if desired.

Development of CC materials

We developed a scripted verbal presentation, educational flier and survey to solicit feedback from PICU patients and families at Boston Children's Hospital (Supplemental File 1 and 2).

After review of published CC survey data, authors (CER, SL, MMH, AMS) iteratively developed an initial survey following best practices of survey design.[6] We conducted cognitive interviews with 6 PICU families (not included in the final survey population results), consisting of "think-aloud" interviews and probing techniques to minimize response error and maximize clarity and comprehension of each survey question.[7] The final interviewer-administered survey included 3 closed-ended items with 5-point response options and 3 open-ended items (Supplemental File 3). The closed-ended items covered attitudes in three key domains: 1) importance of the EPI Dose Trial (1 = "not at all important," 5 = "very important"); 2) willingness to have the patient participate in the EPI Dose Study if they developed acute hypotension (1 = "very unlikely," 5 = "very likely"); and 3) acceptability of the use of EFIC (1 = "completely unacceptable," 5 = "completely acceptable"). Open-ended items invited respondents to provide overall comments, feedback on the informational flier, and suggestions to improve the team's communication about the study; however, this report focuses on the general comments and stated rationale for the participants' rating of the closed-ended items. We additionally asked for demographics of the respondent(s) and medical history of the hospitalized patient.

Participants and data collection

Families of patients receiving care in the PICU at Boston Children's Hospital were surveyed between January 28th and March 29th, 2022 to reach the target of 60 surveys. This sample size was chosen by the EPI Dose investigators and approved by the Institutional Review Board to satisfy part of the CC requirements. Screening was performed intermittently based on research staff availability to perform interviews. Families of patients who were wards of the state or had resuscitation limitation orders in place were not approached; all other families were eligible to participate in the survey contingent upon their availability (in person or by phone) and willingness to participate. Hospitalized patients over 18 years old were invited to complete the survey themselves if they were able; otherwise, one or more legally authorized representative was asked to participate and verbal consent was obtained. After thoroughly rehearsing the presentation material, a single author (SL) performed the interviews, recorded notes and entered the responses into Research Electronic Data Capture (REDCap; Vanderbilt University, Nashville, TN) within 30 minutes after each interview to ensure accuracy. Non-English-speaking families were approached with an interpreter and translated fliers.

Analysis

Descriptive statistics are presented as counts with relative frequencies, medians with interquartile ranges (IQRs).

To analyze open-ended responses, we carried out a qualitative thematic analysis.[8] Authors (CER, SL, MMH, AMS) independently reviewed all open-ended responses and created preliminary codes (Supplemental Fig. 1). These were iteratively discussed and refined. We addressed trustworthiness (validity of inferences) by having multiple meetings amongst the authors, having two non-physician researchers (SL, AMS) as part of the coding group and maintaining an audit trail to document coding decisions and interpretations of data.[9] The group met frequently to resolve any differences by consensus and to refine the code book. We then linked the codes to the data using Dedoose software.[10] After the data were coded, we reviewed the open-ended items to identify themes in the data. These were discussed and reconciled during ongoing research team meetings.

Results

A total of 67 participants contributed to 60 survey responses (53 individuals and 7 families for whom 2 participants contributed to the response). Two additional families were approached to participate but declined; 4 families could not be reached by phone; and in 5 cases, the clinical staff requested that the family not be approached during an emotionally sensitive period. The majority of survey participants were parents, including 46 (69 %) mothers and 19 (28 %) fathers (Table 1). Three respondents were unable to complete some or all of the quantitative items. The racial profile of respondents was similar to the historical racial distribution of PICU patients at our institution, with the exception of a slightly higher proportion of Hispanic/Latinx and a lower proportion of White individuals participating in the current study (Supplemental Table 1).

The majority of participants answered favorably toward the planned trial across the 3 quantitative domains, including 43/58 (74 %) said they would be "somewhat" or "very likely" to allow their child to participate in the EPI Dose Trial (Table 2). Two (3 %) chose to opt out the patient from future participation in the trial.

Table 1 – Respondent and patient characteristics by likelihood to participate in parent trial.

Characteristic	Overall[1]	Very or Somewhat Likely to Participate[2]	Neither Likely Nor Unlikely To Participate[2]	Very or Somewhat Unlikely to Participate[2]
Respondent Characteristics	N = 67	N = 43	N = 10	N = 5
Relationship to patient				
Father	19 (28)	8 (19)	3 (30)	2 (40)
Mother	46 (69)	35 (81)	6 (60)	3 (60)
Non-Parental LAR	1 (2)		1 (10)	
Self	1 (2)	0	0	0
Race/Ethnicity				
Asian	3 (4)	2 (5)	0	1 (20)
Black, African American or African	8 (12)	6 (14)	1 (10)	1 (20)
Hispanic/Latinx	11 (16)	5 (12)	3 (30)	1 (20)
White	41 (61)	30 (70)	5 (50)	1 (20)
Arabic or Middle Eastern	2 (3)	0	0	0
Other[3]	2 (3)	0	1 (10)	1 (20)
Preferred Language				
Arabic	2 (3)	0	0	0
English	62 (93)	42 (98)	8 (80)	5 (100)
Spanish	3 (4)	1 (2)	2 (20)	0
Religious affiliation				
Christian	31 (46)	21 (49)	5 (50)	2 (40)
Muslim	2 (3)	2 (5)	0	0
None	27 (40)	18 (42)	3 (30)	1 (20)
Other[3]	7 (10)	1 (2)	2 (20)	2 (40)
Patient Characteristics	N = 60	N = 43	N = 10	N = 5
Age (years), median (IQR)	4 (0.5, 12.5)	3.5 (0.4, 12)	2.9 (0.5, 11)	7 (5, 14)
Location				
Medical ICU	30 (50)	19 (44)	5 (50)	4 (80)
Medical/Surgical ICU	30 (50)	24 (56)	5 (50)	1 (20)
Number of chronic comorbidities[4] median (IQR)	2 (1, 3)	1 (1, 2)	2.5 (1, 4)	3 (3, 6)
Comorbidities				
Cardiac	14 (23)	10 (23)	2 (20)	2 (40)
Pulmonary	21 (35)	12 (28)	4 (40)	3 (60)
Renal	8 (13)	4 (9)	2 (20)	2 (40)
Rheumatologic/Immunologic	4 (7)	2 (5)	2 (20)	0
Neurologic	17 (28)	12 (28)	2 (20)	3 (60)
Oncologic	6 (10)	3 (7)	1 (10)	1 (20)
Hematologic	6 (10)	2 (5)	3 (30)	0
Gastrointestinal/Hepatic	21 (35)	11 (26)	4 (40)	5 (100)
Metabolic /Endocrine	6 (10)	3 (7)	2 (20)	0
Genetic abnormality	11 (18)	5 (12)	3 (30)	2 (40)
Other	14 (23)	14 (33)	3 (30)	1 (20)
None	8 (13)	6 (14)	1 (10)	0

Presented as N (%) unless otherwise noted. Totals may exceed number of participants due to multiple responses for an individual. Abbreviations: LAR, legally authorized representative; ICU, intensive care unit; IQR, interquartile range.

[1] Characteristics in the "Overall" column represent all participants including cases in which more than one respondent participated in a single interview.

[2] Counts in the final three columns represent the primary respondent only, so as to not weight the responses. Two participants were unable to respond to the question regarding likelihood of participating in the parent trial (N = 58).

[3] Includes unknown and individuals who declined to answer.

[4] Sum of organ system-based categories for which the patient was reported to have a chronic condition.

Five major themes supporting participation in the EPI Dose Trial emerged from our analysis (respondents are identified by number, R1-R60. Additional quote examples can be found in Supplemental Table 2):

1 **Trust in the clinical team to decide about study participation.**

Participants indicated that they trusted the clinical team to make the decision about the appropriateness of enrolling the patient in the EPI Dose Study during the emergency, citing physicians' clinical expertise and belief that they will do what is best for the patient."[I have] faith in [the] doctor's choice if they think enrolling in the study is safe/minimal risk. In a way, [the] doctor is making the informed consent on my behalf . . . Since we're already handing over everything to them, then this is just another decision that [we] trust [the] doctor to make." R#17.

"I don't feel that I should make the call. The MD should make the call if they are okay with a random and blind dose. I don't know

Table 2 – Responses to quantitative items.

Item Domain	Likert Scale				
Importance of EPI Dose Trial (N = 58)	Very Important	Somewhat Important	Neither Important Nor Unimportant	Slightly Important	Not at all Important
	47 (81)	8 (14)	2 (3)	1 (2)	0
Acceptability of EFIC in EPI Dose Trial (N = 57)	Completely Acceptable	Somewhat Acceptable	Neither Acceptable nor Unacceptable	Somewhat Unacceptable	Completely Unacceptable
	50 (88)	2 (4)	4 (7)	1 (2)	0
Likelihood of participating in EPI Dose Trial (N = 58)	Very Likely	Somewhat Likely	Neither Likely Nor Unlikely	Somewhat Unlikely	Very Unlikely
	37 (63)	6 (10)	10 (17)	3 (5)	2 (3)

Presented as N (%) unless otherwise noted. Abbreviations: EFIC, exception from informed consent.

enough about [the] medical aspect, [and I] don't want to tell [the doctor] how to do their job... [I'm] okay with it if the [doctor] is okay with it. [I] would not opt out." R#57.

2 **Familiarity with epinephrine.**
Several families also shared that their willingness to participate had to do with the fact that they were already familiar with epinephrine.

"[I] had experience with [my] child going into anaphylactic shock requiring epinephrine in the hospital. If [another] family had no experience [with] epinephrine, then [they] may not understand that it is an emergency." R#31.

3 **Similarity of study protocol to current standard of clinical care.**
Many respondents stated they were willing to participate in the EPI Dose Trial because it compares two doses of the same medication, and epinephrine would be given for the clinical situation regardless of the trial. Some stated that they felt reassured that either dose would help the patient while others felt that receiving one of the two standard care doses was less risky than a study examining a "new" medication.

"Since [he/she] would receive [epinephrine] anyways, might as well be a part of the study ... As long as the medication is normally given, and it's just the amount that's different, that's okay." R#5.

4 **Recognition that informed consent during the hypotensive emergency did not seem feasible.**
Many respondents acknowledged the idea that obtaining informed consent was not realistic during an emergency and thus agreed with the rationale for the study team approaching families ahead of time. Some cited practical reasons including prioritizing treating the patient or not being able to "do the paperwork" during an emergency; others voiced concerns about the families' emotional state during the stressful situation.

"Good that [you] talk [to families] before the emergency because there is just not enough time during the emergency and [the] family [is not in the] right headspace." R#16.
"In an emergency, fix it first and then talk later." R#28.

5 **Acknowledgement of the importance of research.**
Overall, participants stated that they valued research, both in general and specific to the clinical scenario described in the EPI Dose Study. Some voiced a desire to "give back" while others felt that this research may be important for them and others in the future.

"Since this is a research hospital, [research] feels like an opportunity to give back." R#46.

Other themes denoted barriers to potential participation:

1. **Need for more time to decide.**
Some participants requested more time to decide if they would be willing to participate in the EPI Dose Study. Many felt they needed to "do their own research," while others felt they needed to consult with other members of their clinical team or another family member.

"I would need more time to review information and discuss with [my spouse] about likelihood of participating." R#55.

2. **Misconceptions about logistical aspects of the study, including eligibility.**
One of the most common misconceptions about the EPI Dose study design was thinking that the trial was not applicable to patients who had never had prior blood pressure issues or those who have chronic hypertension (in clinical practice, any patient with life-threatening acute hypotension may receive epinephrine regardless of their prior medical history). More general inquiries included questions about the side effects of epinephrine and the typical clinical care for acute hypotension.

"[I don't] think [this] study is applicable to [my] child [because he has] chronic hypertension, so [I] would consider opting out." R#7.

Discussion

In this face-to-face interview study we elicited perspectives of caregivers of PICU patients toward a planned emergency interventional

trial using EFIC using both quantitative and qualitative survey items. Most respondents answered favorably toward the planned EPI Dose trial in terms of importance, use of EFIC and their willingness to have their child participate in the EPI Dose Trial. Prominent reasons for families' comfort with participating in the EPI Dose Trial were that they 1) had trust in the clinical team to determine the safety of enrollment; 2) had a sense of familiarity with epinephrine for other emergencies; 3) viewed the nature of the EPI Dose Trial as being similar to standard care for the medical emergency; 4) felt that informed consent during a hypotensive emergency did not seem feasible; and 5) felt the research was important. Themes expressing barriers to potential participation included requests for additional time to decide about participating and misconceptions about study elements, especially eligibility.

The 74 % rate of family-stated likelihood of approval for the respondents' child to participate in the EPI Dose Trial is similar to the rates of acceptance for personal enrollment amongst individuals surveyed as part of CC activities for other EFIC trials, which ranged from 64 % to 85 %.[3,11,12] In a recent systematic review of CC survey data from the FDA, Feldman et al. found that the rate of personal approval (i.e., the respondent reported likelihood of being enrolled themselves without informed consent) was higher than the rate of respondents endorsing the enrollment of a family member without informed consent (73.0 % vs 68.8 %, respectively; $p < 0.001$). This finding may be partially explained by the hypothesis that people prefer not to make decisions on behalf of others.[12,13] It is notable that of the 27 EFIC trials included in this review, only 2 were performed in primarily pediatric populations. This raises the question of whether acceptance rates of pediatric EFIC trials would more closely resemble those of personal acceptance of EFIC enrollment or that of enrollment of a family member. Given the unique parent–child dyad in which the parent is typically the primary decision-maker for the child, we speculate that a parent may be more accepting of EFIC for their child as opposed to another adult family member who would otherwise have their own autonomy.

In the qualitative analysis, two themes emerged that, to our knowledge, have not been previously reported and may be informative for future EFIC trials. First, we found that many respondents expressed trust in the clinical team to decide whether or not to enroll their child in the EPI Dose Trial during the medical emergency. Though previous work has described trust in researchers as contributing to positive attitudes toward EFIC,[13] trust in the medical team has not been reported. We believe this likely relates the fact that the EPI Dose Trial is an inpatient study in which families have already entrusted the medical team to care for their child. As the inpatient setting is unique amongst EFIC trials (which have historically been dominated by the pre-hospital and emergency room settings), the concept of trust in the medical team may not have been pertinent until now. Future inpatient EFIC trials may benefit from emphasizing the physicians' ability to determine the safety of enrollment in the moment, if applicable. The second unique theme that emerged was personal familiarity with the test article, in this case, epinephrine. Though this theme may only be limited to certain studies, the concept may still be used to help families understand and relate to interventions in future EFIC trials.

The remaining three themes supporting participation are consistent with prior qualitative work in countries with regulations for emergency trials similar to EFIC, including "Deferred Consent" in Europe. In a series of interviews and focus groups in the United Kingdom, Woolfall et al. similarly demonstrated that many families valued research, acknowledged that in-depth discussions of research could not be performed during a medical emergency and that they were more comfortable if the test article(s) in the associated trial were considered standard of care.[14,15]

Themes denoting barriers to participation offer insights for how to best educate families during public disclosure. For example, some families who said they were unlikely to participate cited the fact that their child had chronic hypertension and mistakenly assumed that they would be unlikely to develop acute hypotension to be eligible for the planned trial. This led us to train our research staff to provide education and emphasis on the fact that even chronically hypertensive patients could still develop hypotension in the setting of critical illness. There were also requests for more time to decide about opting out, which we addressed by amending the protocol to allow for follow-up visits from our research staff. More importantly, because our screening model requires a brief discussion with the patients' families prior to being identified as eligible, this theme emphasizes the importance of providing sufficient information at the time of the initial contact in order to maximize the window for enrollment prior to the development of hypotension.

This study has some limitations. First, we could not control nor assess for responder bias which likely swayed toward more positive attitudes about research, given the participants were amenable to participating in the current survey research study. Conversely, parents who were strongly biased against research could have chosen to respond in order to assure that their voices were heard. Second, survey participants may have responded more positively to the in-person interviewer, who was known to be associated with the EPI Dose Trial. Others may have been biased due to familiarity with the primary investigator (CER) from routine clinical care in the PICU. Additionally, it remains unclear if the attitudes reported from this quaternary care research hospital would be generalizable to other hospital settings. Finally, our findings may not be generalizable to non-English-speaking families given this group represented only a small minority of respondents.

Conclusions

Families generally supported plans for an emergency interventional trial using EFIC in the PICU, with similar acceptance rates to those reported in other EFIC trials. Themes supporting participation included 1) trust in the clinical team; 2) familiarity with the study intervention; 3) study protocol being similar to standard care; 4) informed consent during an emergency was not feasible; and 5) importance of research. Future inpatient EFIC studies may benefit from highlighting these aspects in their educational materials, if applicable. Similarly, the barriers to potential participation we elicited (requests for additional time to decide about participating and misconceptions about study eligibility) reinforce the importance of thoughtful development of educational materials for future inpatient EFIC trials to maximize enrollment.

CRediT authorship contribution statement

Catherine E. Ross: Conceptualization, Methodology, Formal analysis, Investigation, Writing – original draft, Project administration, Funding acquisition. **Sonja Lehmann:** Conceptualization, Methodology, Data curation, Formal analysis, Investigation, Writing – review &

editing, Project administration. **Margaret M. Hayes:** Conceptualization, Methodology, Formal analysis, Writing – review & editing. **Jolin B. Yamin:** Methodology, Writing – review & editing, Project administration. **Robert A. Berg:** Conceptualization, Writing – review & editing, Supervision. **Monica E. Kleinman:** Conceptualization, Writing – review & editing, Supervision. **Michael W. Donnino:** Conceptualization, Writing – review & editing, Supervision. **Amy M. Sullivan:** Conceptualization, Methodology, Validation, Formal analysis, Writing – review & editing, Supervision.

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Appendix A. Supplementary material

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REFERENCES

1. U.S. Food and Drug Administration. 21 CFR 50.24. Exception from informed consent requirements for emergency research. Federal Register. 1996;61:51528.
2. U.S. Department of Health and Human Services, Food and Drug Administration, Office of Good Clinical Practice, Center for Drug Evaluation and Research, Center for Biologics Evaluation and Research, Center for Devices and Radiological Health. Guidance for Institutional Review Boards, Clinical Investigators, and Sponsors: Exception from Informed Consent Requirements for Emergency Research. 2013; https://www.fda.gov/downloads/Regulatoryinformation/Guidances/UCM249673.pdf.
3. Dickert NW, Metz K, Fetters MD, et al. Meeting unique requirements: Community consultation and public disclosure for research in emergency setting using exception from informed consent. Acad Emerg Med 2021;28:1183–94.
4. Ross CE, Hayes MM, Kleinman ME, Donnino MW, Sullivan AM. Peri-arrest bolus epinephrine practices amongst pediatric resuscitation experts. Resusc Plus 2022;9 100200.
5. Ross CE, Asaro LA, Wypij D, Holland CC, Donnino MW, Kleinman ME. Physiologic response to pre-arrest bolus dilute epinephrine in the pediatric intensive care unit. Resuscitation 2018;126:137–42.
6. Artino Jr AR, La Rochelle JS, Dezee KJ, Gehlbach H. Developing questionnaires for educational research: AMEE Guide No. 87. Medical Teacher 2014;36:463–74.
7. Willis GB. Cognitive Interviewing: A "How To" Guide. Meeting of the American Statistical Association 1999.
8. Kiger ME, Varpio L. Thematic analysis of qualitative data: AMEE Guide No. 131. Medical Teacher 2020;42:846–54.
9. Shenton AK. Strategies for ensuring trustworthiness in qualitative research projects. Educ Information 2004;22:63–75.
10. Dedoose: web application for managing, analyzing, and presenting qualitative and mixed method research data. 9.0.54 ed. Los Angeles, CA: SocioCultural Research Consultants, LLC; 2022.
11. Feldman WB, Hey SP, Franklin JM, Kesselheim AS. Public Approval of Exception From Informed Consent in Emergency Clinical Trials. JAMA Network Open 2019;2:e197591.
12. Fehr AE, Pentz RD, Dickert NW. Learning from experience: a systematic review of community consultation acceptance data. Ann Emerg Med 2015;65. 162-71.e3.
13. Dickert NW, Mah VA, Baren JM, et al. Enrollment in research under exception from informed consent: the Patients' Experiences in Emergency Research (PEER) study. Resuscitation 2013;84:1416–21.
14. Woolfall K, Young B, Frith L, et al. Doing challenging research studies in a patient-centred way: a qualitative study to inform a randomised controlled trial in the paediatric emergency care setting. BMJ Open. 2014;4:e005045.
15. Woolfall K, Frith L, Gamble C, Gilbert R, Mok Q, Young B. How parents and practitioners experience research without prior consent (deferred consent) for emergency research involving children with life threatening conditions: a mixed method study. BMJ Open 2015;5:e008522.