Deferred Consent for Randomized Controlled Trials in Emergency Care Settings

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abstract

BACKGROUND: There is limited experience in using deferred consent for studies involving children, which was legalized in the United Kingdom in 2008. We aimed to inform future studies by evaluating consent rates and reasons for nonconsent in a large randomized controlled trial in pediatric intensive care.

METHODS: In the CATCH trial, eligible children from 14 PICUs in England and Wales were randomly assigned to 3 types of central venous catheters. To avoid delay in treatment, children admitted on an emergency basis were first randomly assigned to a trial central venous catheter, and we deferred seeking consent to use already collected data and blood samples until after stabilization.

RESULTS: Consent was obtained for 984/1358 (72%) of children admitted on an emergency basis. Failure to obtain consent resulted mainly from a lack of opportunity (early discharge or transfer) for survivors and difficulties in seeking consent for children who died. For admissions where there was an opportunity to approach (n = 1298), inclusion rates differed according to survival status: 93/984 (9%) of consented patients died, compared with 58/314 (18%) of nonconsented patients. For children admitted on an emergency basis whose families were approached, 984/1178 (84%) provided deferred consent (n = 15 sites), compared with 441/641 (69%) of children admitted on an elective basis who were approached for prospective consent (n = 9 sites).

CONCLUSIONS: Design of emergency randomized controlled trials should balance the potential burden that seeking consent in difficult situations may cause against risk of bias by disproportionately excluding children who die or are transferred. Ethics committees could consider approving the use of already collected data when best efforts to obtain deferred consent are unsuccessful.

WHAT'S KNOWN ON THIS SUBJECT: Deferral of consent avoids delaying emergency interventions while ensuring consent to ongoing participation and use of data. Deferred consent is particularly important for enabling trials in pediatric settings, where many medicines and devices are unlicensed and untested for use.

WHAT THIS STUDY ADDS: Approaches for seeking deferred consent should balance the potential burden of obtaining consent against risk of bias due to outcome-related attrition. Ethics committees could consider approving data use when best efforts to obtain deferred consent are met with no response.

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Many medicines and devices used in pediatric practice are unlicensed and untested for use in children.[1,2] Children are not little adults, and evidence in adults cannot always be safely extrapolated to children.[3,4] This discrepancy has led to a growing recognition of the need to increase the number and quality of pediatric trials to improve the evidence base and the need for practical, appropriate, and clear information for children and families participating in studies.[5–8] In emergency pediatric settings specifically, there is a conflict between the requirement for prospective informed consent, which may not be practicable in emergencies, and the need for better evidence. First, there is uncertainty about the validity of informed consent obtained in such a stressful environment. Parents in this situation may not be able to absorb the information given to them or make a fully informed decision about consent.[9] Second, the need to start treatment without delay means that there is often no time for the consent process.[10] The requirement for informed consent before intervention could therefore compromise patient care, particularly in circumstances when a parent or legal guardian is not present when a child is admitted.

Deferral of consent to participation in a study avoids delaying emergency interventions while ensuring consent to ongoing participation and use of data.[11] Legislation introduced in the United Kingdom in 2008 allows the use of deferred consent for studies involving children provided that treatment is urgently needed, urgent action is needed for the purposes of the trial, it is not reasonably practicable to obtain consent prospectively, and an ethics committee has given approval to the procedure under which the action is taken.[12,13] However, there is a lack of evidence for the acceptability, design, and conduct of deferred consent in children, particularly relating to complex situations such as the death of a child.

The aim of the CATCH trial (www.catchtrial.org.uk) was to determine the clinical value and cost-effectiveness of 3 types of central venous catheters (CVCs) for preventing bloodstream infection. CVCs are widely used for patients of all ages to provide venous access for blood sampling and administer life-saving medicines. Importantly, all of the CATCH CVC types were used in routine practice before the trial, but evidence was lacking on their effectiveness for children.[14] Deferred consent in CATCH enabled the participation of children admitted on an emergency basis. CATCH was one of the first UK studies to use deferred consent in children, and ethics committee decisions (Box 1) were based on opinion because there was a lack of evidence about potential biases caused by exclusion of nonconsenting participants.[15–18] We aimed to inform future decisions on the use of deferred consent in children by evaluating rates of deferred and prospective consent and reasons for nonconsent for emergency and elective admissions in the CATCH trial.

METHODS

CATCH is the largest individual-level randomized controlled trial in pediatric intensive care and enrolled children from 15 sites across 12 National Health Service Trusts between 2010 and 2012. Children were randomly assigned to either standard, heparin-bonded, or antibiotic-impregnated CVCs. For elective admissions, written informed consent was obtained prospectively. Children admitted on an emergency basis who needed a CVC immediately were first randomly assigned to a trial CVC to avoid any delay in treatment. Deferred consent was obtained once the child was stabilized, ideally within 48 hours of CVC insertion. Because the intervention had already been delivered, deferred consent was sought only for the use of routinely recorded clinical data and 0.5 mL of blood collected whenever a blood culture was clinically necessary.

For emergency admissions, data on eligibility, randomization, and consent were routinely recorded by CATCH research nurses on case report forms (CRFs). For elective admissions, screening data were collected at 9 Trusts (at the remaining 9 Trusts), there were no elective admissions, or data were collected only on those with consent). Refusals to consent were categorized on the CRFs as "No reason provided," "Enrolled in another trial," or "Other." We later created broad categories from free text recorded in the "Other" category.

Inclusion rates were evaluated as the percentage of children whose parents

BOX 1 ETHICS COMMITTEE DECISIONS FOR DEFERRED CONSENT

1. For bereaved parents, the patient information sheet should be given as soon as possible, but timing for the approach for consent could be decided by the clinician.
2. For children for whom no consent was provided, data already recorded should not be analyzed and no further data should be collected.
3. For children who were randomized but discharged or transferred prior to consent being obtained, families need *not* be approached for deferred consent, considering the anxiety this may cause and the fact that all children had received a treatment already used in standard practice. (An approach for consent was not made, and trial data already collected could not be analyzed, as specified in decision 2.)

TABLE 1 Children Admitted for an Emergency and Randomly Assigned in CATCH (n = 15 sites): Reasons for Failure to Approach for Consent

	Reason for Failure to Approach	*N* (%)
No opportunity to approach	Transferred to nonparticipating hospital	60 (33)
Decision that approach not required	Child discharged before consent was attempted	59 (33)
	Parents not present on ward	6 (3)
	CVC insertion not attempted	5 (3)
	Double randomization	4 (2)
Decision that approach not appropriate	Social/language issues[a]	32 (18)
	Not approached after death of child in PICU	12 (7)
	Other reasons	2 (1)
		N = 180

[a] Includes 2 children who died in PICU.

were approached for consent, excluding those admitted when there was no opportunity to approach (children who were randomly assigned to a trial CVC by the retrieval team but then transferred to a nonparticipating PICU). Inclusion rates therefore reflect access to families and clinician decisions on approaching. Consent rates were evaluated as the percentage of approached children for whom consent was obtained, and they reflect parental responses to approaches for consent. We separately evaluated inclusion and deferred consent rates in children who died in the PICU.

The Research Ethics Committee for South West England approved the CATCH study protocol.

RESULTS

A total of 1859 children were included in CATCH, 1358 (73%) of whom were admitted on an emergency basis.

Inclusion Rates

Families were approached for deferred consent for 1178/1358 (87%) of emergency admissions. The remaining 180 (13%) could not be included in trial analysis. Failure to approach was caused by lack of opportunity for 60/180 (33%) of children who were randomly assigned to a trial CVC by the retrieval team but then transferred to a nonparticipating PICU.

For the remaining 120 admissions, a decision was made by the research nurse or clinician to not approach (Table 1). The reasons for this decision were related to ethics committee decisions on the requirement to follow up for consent (eg, for children who were discharged before an approach was attempted; see Box 1) or were made because it was thought that an approach would not be appropriate. The "Social/language issues" category included cases where families did not speak adequate English or where social services were involved because of child protection concerns. The "Other reasons" category included cases where the research nurses decided that the parents were "not in the right state of mind" or that it "would be inappropriate to speak with family about participating" (quotes from free text).

Inclusion rates differed according to whether the child died or survived (Fig 1). Of the consented children included in the trial analysis, 93/984 (9%; 95% confidence interval [CI], 8%–12%) died, compared with 58/314 (18%; 95% CI, 14%–24%) of the nonconsented children whose data were excluded from analysis.

Consent Rates

Consent rates were higher for emergency compared with elective admissions. Prospective consent was provided for 441/641 (69%) of children approached after elective admissions (n = 9 sites with available data), and deferred consent was provided for 984/1178 (84%) of children approached after emergency admissions (n = 15 sites). A number of families (n = 17) did not respond when contacted for deferred consent, all of whom had experienced the death of their child. Deferred consent was refused for 26 children who died and 151 children who survived.

Reasons for refusal differed slightly between elective and emergency admissions. For elective compared with emergency admissions, consent was more likely to be refused because the parent was too distressed, wanted the standard treatment, or stated that there was too much information to take in, but refusals were less likely to be caused by the perceived burden on the child (Table 2). The "Burden on child" category included parental concerns about extra blood samples or the child's health status ("blood" was explicitly mentioned in more than half of these responses). The "Parent distressed" category included instances in which the parents were overwhelmed by the situation and stated that they were too upset to take in any information, discuss the trial, or make decisions. The "No reason provided" category was derived directly from the CRF and may have included instances where the parent provided no reason or where the research nurse did not record a reason. None of the reasons provided mentioned study design or the nature of deferred consent, and no reports of parental dissatisfaction with the consent process were received.

Deferred consent rates were lower for children who died in the PICU: Consent was provided for 93/136

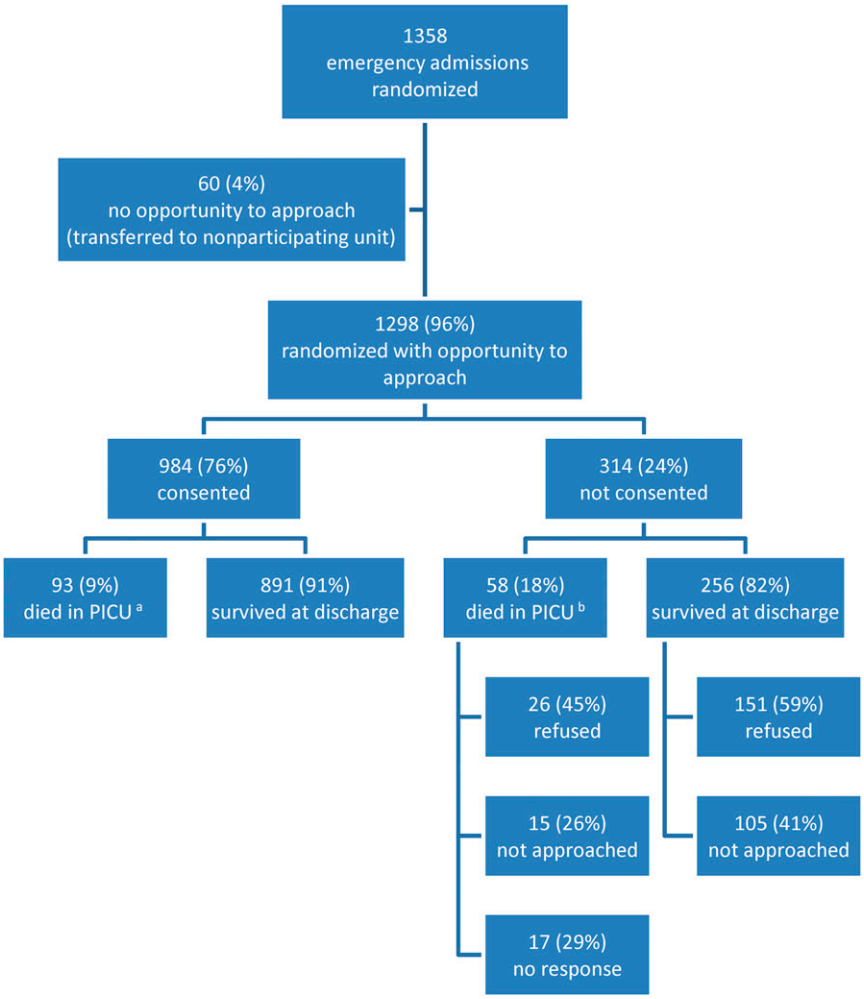

FIGURE 1
Children admitted on an emergency basis and randomly assigned to CATCH (n = 15 sites): inclusion rates by survival status at discharge. [a]9 and [b]43 families approached after the death of their child.

(68%; 95% CI, 55%–84%) of children admitted on an emergency basis who died in the PICU and whose families were approached, compared with 891/1042 (86%; 95% CI, 80%–91%) who survived. For families who were approached for consent after the death of their child in the PICU, rates were particularly low, with deferred consent being provided for only 9 (17%) of the 52 approached at this time.

Details on the approaches made to bereaved families (eg, by letter or phone or in person) are not available, but the median time to consent for families whose child had died was 1329 hours (interquartile range 84–4376 hours), or ~55 days. For families who were approached while their child survived, just over half (52%) of those who consented did so within 48 hours of randomization (as recommended in the protocol), and the median time to consent was 46 hours (interquartile range 22–94 hours).

TABLE 2 Reasons for Nonconsent to CATCH for Emergency (n = 15 Sites) and Elective Admissions (n = 9 Sites) Who Were Approached

	No Consent Obtained	Emergency Admissions (%)	Elective Admissions (%)
No reason provided	No reason provided (child survived)	88 (45)	88 (44)
	No reason provided (child died in PICU)	26 (13)	0
	No response (child died in PICU)	17 (9)	0
Reason provided	Burden on child	26 (13)	8 (4)
	Parent distressed or too much information	15 (8)	59 (30)
	Not supportive of research generally	11 (6)	14 (7)
	Social or language reasons	8 (4)	3 (2)
	Enrolment in another trial	3 (2)	4 (2)
	Parent wanted standard treatment	0	24 (12)
		N = 194	N = 200

No bereaved families gave a reason for not providing consent.

DISCUSSION

Deferred consent was obtained for 84% of families who were approached, indicating that deferred consent was an effective strategy for recruiting to CATCH in the high-stress environment of the PICU. Without deferred consent, CATCH would not have been able to recruit emergency admissions; the time and funding needed to reach the target sample size would have increased, and results may not have been generalizable or convincing to clinicians working in the emergency setting. Our evaluation of reasons for nonconsent was limited by the quality of available screening data; there were many cases where no reason was provided for declining to consent, and there was no detailed record of approaches made to families. However, our results are consistent with other evidence indicating the acceptability of deferred consent to parents and to practitioners with experience of the process.[13,19,20]

The higher consent rate for emergency compared with elective admissions may reflect a greater capacity for informed decision-making when parents were approached after the medical emergency had taken place, in a potentially less stressful environment. For elective admissions, parents may have felt responsible for

deciding on a possible change in treatment. Previous evidence from parents indicates that being asked to make choices and to listen to information adds to the stressful environment of the pediatric setting.[20,21] This difference was reflected in the large proportion of parents of children admitted on an elective basis feeling too distressed and overwhelmed to engage with CATCH while having to focus on the impending surgical intervention. On the other hand, consent for emergency admissions was sought for use of data already collected and follow-up data collection only, because the intervention had already taken place. However, a substantial proportion of families refused deferred consent because of the perceived burden on the child. Ongoing research (the CONNECT study) is investigating more closely the experiences of parents recruited to CATCH and may help explain why deferred consent rates were not even higher.[15]

A major concern relating to deferred consent in CATCH is that inclusion of children in analysis was related to the child's outcome. In CATCH, 13% of patients admitted on an emergency basis were not approached for deferred consent, mainly because many were discharged or transferred before the approach could be made. The ethics committee decision to not approach for consent in this situation may have been inappropriate because it could have led to biased attrition. Even more concerning is that children who died were underrepresented in the trial data, because inclusion rates were lower in this group. This discrepancy has implications for the generalizability of trial results to children who are at high risk of adverse outcomes. Furthermore, any associations between adverse outcomes (that were excluded from analysis because of biased attrition) and treatment arm could seriously compromise results. Study design and ethical considerations should be equally prioritized, because there are ethical implications of imposing restrictions that may prevent the research question being answered reliably.

There is a lack of consensus on the most appropriate way to approach bereaved parents for deferred consent, and additional research is needed to identify, evaluate, and train practitioners on the most appropriate strategies.[19,22] In CATCH, decisions on timing of approach for consent after bereavement depended on the circumstances around the death and how well the team knew the family. Up to 2 telephone or mail reminders were sent to those who did not respond. We do not know how the 17 families who did not respond to approaches for consent after the death of their child would have responded to a different form of approach. However, a number of parents did provide consent weeks after the death of their child, demonstrating a wish for their child's involvement in the trial despite how upsetting it must have been to receive the trial information initially.[22] Ethics committee decisions should balance the potential benefits of "chasing" consent decisions with the burden on both bereaved families and research nurses, who are under pressure to minimize data loss due to nonconsent while being mindful of families' traumatic situations.[23] Our results demonstrate that ethics committee decisions resulted in biased exclusion of children who died, and implications for the validity of research due to outcome-related attrition must be considered carefully.

One approach in the situation where best efforts to obtain consent are met with no response would be to seek ethics approval for use of trial data already collected or for linkage to routinely collected health care data for these patients (eg, for safety analyses). If this had been allowed for the 17 nonresponders in CATCH, there would have been less risk of bias due to underrepresentation of deaths. There are strong ethical and safety arguments that the advantages of using data without consent in these situations outweighs any harms relating to a lack of consent.[13,24,25]

Regulatory and management barriers to comparing standard treatments are well recognized: "The clinician who is convinced that a certain treatment works will almost never find an ethicist in his path, whereas his colleague who wonders and doubts and wants to learn will stumble over piles of them."[26] Informed consent is not required for treatment with nonvalidated therapies that are currently used in practice but for which there is a lack of evidence on benefits and risks. The CVCs used in CATCH were all already in use in practice before the trial, and selection of CVC type for children attending non-CATCH sites depended on the individual PICU practice and did not involve discussion with parents.[27] Although some argue that consent is always necessary to promote respect for patients and their right of self-determination, others suggest that consent under these circumstances might not be necessary at all, because the alternative to randomization is a clinician decision that is not based on evidence.[24,28,29] In this minimal-risk situation, patients who are randomly assigned are at no higher risk that those who are not, and they might even benefit from participation in the trial itself.[30,31] Waiver of informed consent is currently used under certain restrictions in the United States (http://www.hhs.gov/ohrp/policy/faq/informed-consent/may-requirement-for-obtaining-informed-consent-be-waived.html), but is not currently used in the United Kingdom.[32]

CONCLUSIONS

When deciding on the most appropriate process for consent in the pediatric emergency setting,

researchers and ethics committees should consider not only the standard requirements for fully informed consent but also the potential burden on parents, the timing of the recruitment discussion, and means of approach.[33] Research has shown how parents' provision of deferred consent depends on many things, including the trial type, perceived safety of the intervention, and the nature and route of administration of the intervention.[19] Our experience with CATCH highlights a need to evaluate approaches for seeking deferred consent, particularly from bereaved parents, and additional in-depth research should be incorporated into the design of trials involving more invasive interventions. As the number of randomized controlled trials using deferred consent in children increases, additional research on approaches for consent in emergency settings should be embedded into trial designs.

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ABBREVIATIONS

CI: confidence interval
CRFs: case report forms
CVC: central venous catheter
RCT: randomized controlled trial

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REFERENCES

1. Cuzzolin L, Atzei A, Fanos V. Off-label and unlicensed prescribing for newborns and children in different settings: a review of the literature and a consideration about drug safety. *Expert Opin Drug Saf*. 2006;5(5):703–718
2. National Audit Office. Safety, quality, efficacy: regulating medicines in the UK. London, England: The Stationery Office; 2003. Available at: www.audace.org/Vet_folder/UK/0203255.pdf. Accessed September 16, 2014
3. Bellis JR, Kirkham JJ, Thiesen S, et al. Adverse drug reactions and off-label and unlicensed medicines in children: a nested case–control study of inpatients in a pediatric hospital. *BMC Med*. 2013;11:238
4. Mason J, Pirmohamed M, Nunn T. Off-label and unlicensed medicine use and adverse drug reactions in children: a narrative review of the literature. *Eur J Clin Pharmacol*. 2012;68(1):21–28
5. Junker A, Klassen T. Improving standards for paediatric clinical trials. *Paediatr Child Health*. 2011;16(9):539–540
6. Stephenson T. The medicines for children agenda in the UK. *Br J Clin Pharmacol*. 2006;61(6):716–719
7. Hartling L, Wittmeier KDM, Caldwell P, et al; StaR Child Health Group. StaR child health: developing evidence-based guidance for the design, conduct, and reporting of pediatric trials. *Pediatrics*. 2012;129(suppl 3):S112–S117
8. van Stuijvenberg M, Suur MH, de Vos S, et al. Informed consent, parental awareness, and reasons for participating in a randomised controlled study. *Arch Dis Child*. 1998;79(2):120–125
9. Li FX, Nah SA, Low Y. Informed consent for emergency surgery—how much do parents truly remember? *J Pediatr Surg*. 2014;49(5):795–797
10. Roberts I, Prieto-Merino D, Shakur H, Chalmers I, Nicholl J. Effect of consent rituals on mortality in emergency care research. *Lancet*. 2011;377(9771):1071–1072
11. Brierley J, Larcher V. Emergency research in children: options for ethical recruitment. *J Med Ethics*. 2011;37(7):429–432
12. The medicines for human use (clinical trials) and blood safety and quality (amendment) regulations no. 941. 2008. Available at: www.legislation.gov.uk/uksi/2008/941/contents/made. Accessed September 16, 2014
13. Gamble C, Nadel S, Snape D, et al. What parents of children who have received

emergency care think about deferring consent in randomised trials of emergency treatments: postal survey. *PLoS One*. 2012;7(5):e35982

14. Wang H, Huang T, Jing J, et al. Effectiveness of different central venous catheters for catheter-related infections: a network meta-analysis. *J Hosp Infect*. 2010;76(1):1–11
15. Woolfall K, Frith L, Gamble C, Young B. How experience makes a difference: practitioners' views on the use of deferred consent in paediatric and neonatal emergency care trials. *BMC Med Ethics*. 2013;14:45
16. Maitland K, Molyneux S, Boga M, Kiguli S, Lang T. Use of deferred consent for severely ill children in a multi-centre phase III trial. *Trials*. 2011;12:90
17. Gamble C, Woolfall K, Williamson P, Appleton R, Young B. New European Union regulation of clinical trials is conflicting on deferred consent in emergency situations. *BMJ*. 2013;346:f667
18. McIntyre J, Robertson S, Norris E, et al. Safety and efficacy of buccal midazolam versus rectal diazepam for emergency treatment of seizures in children: a randomised controlled trial. *Lancet*. 2005;366(9481):205–210
19. 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(5):e005045
20. Molyneux S, Njue M, Boga M, et al. "The words will pass with the blowing wind": staff and parent views of the deferred consent process, with prior assent, used in an emergency fluids trial in two African hospitals. *PLoS One*. 2013;8(2):e54894
21. Cameron MA, Marsillio LE, Cushman LF, Morris MC. Parents' perspectives on the consent approach for minimal-risk research involving children. *IRB*. 2011;33(6):6–13
22. Snowdon C, Brocklehurst P, Tasker R, Ward Platt M, Harvey S, Elbourne D. Death, Bereavement and Randomised Controlled Trials (BRACELET): a methodological study of policy and practice in neonatal and paediatric intensive care trials. *Health Technol Assess*. 2014;18(42):1–410
23. Shilling V, Williamson PR, Hickey H, et al. Communication about children's clinical trials as observed and experienced: qualitative study of parents and practitioners. *PLoS One*. 2011;6(7):e21604
24. Parvizi J, Chakravarty R, Og B, Rodriguez-Paez A. Informed consent: is it always necessary? *Injury*. 2008;39(6):651–655
25. Jansen TC, Kompanje EJ, Druml C, Menon DK, Wiedermann CJ, Bakker J. Deferred consent in emergency intensive care research: what if the patient dies early? Use the data or not? *Intensive Care Med*. 2007;33(5):894–900
26. Medical ethics: should medicine turn the other cheek? *Lancet*. 1990;336(8719):846–847
27. Harron K, Ramachandra G, Mok Q, Gilbert R; CATCH team. Consistency between guidelines and reported practice for reducing the risk of catheter-related infection in British paediatric intensive care units. *Intensive Care Med*. 2011;37(10):1641–1647
28. Luce JM. Is the concept of informed consent applicable to clinical research involving critically ill patients? *Crit Care Med*. 2003;31(3 suppl):S153–S160
29. Truog RD, Robinson W, Randolph A, Morris A. Is informed consent always necessary for randomized, controlled trials? *N Engl J Med*. 1999;340(10):804–807
30. Vist GE, Bryant D, Somerville L, Birminghem T, Oxman AD. Outcomes of patients who participate in randomized controlled trials compared to similar patients receiving similar interventions who do not participate. *Cochrane Database Syst Rev*. 2008; (3):MR000009
31. Wallenstein MB. The trouble with informed consent. *Arch Dis Child Fetal Neonatal Ed*. 2014;99(3):F251
32. Shah AN, Sugarman J. Protecting research subjects under the waiver of informed consent for emergency research: experiences with efforts to inform the community. *Ann Emerg Med*. 2003;41(1):72–78
33. Davies H, Shakur H, Padkin A, Roberts I, Slowther AM, Perkins GD. Guide to the design and review of emergency research when it is proposed that consent and consultation be waived. *Emerg Med J*. 2014;31(10):794–795

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