



Factors That Impact Hospital-Specific Enrollment Rates for a Neonatal Clinical Trial: *An Analysis of the HEAL Study*

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Appendix A. Study Survey

Definitions

Site = Hospital in which NICU patients were recruited for HEAL

Recruitment = The process of tracking, approaching, enrolling, consenting, and providing follow-up related to study participation; includes both those who enroll and those who do not

Enrollment = A portion of recruitment involving pragmatics of a participant joining research

Consent = A portion of recruitment involving the regulatory required processes of informed consent for research participation

Scale to use for most questions:

B					B				
Strongly Disagree	Disagree	Neither Agree or Disagree	Agree	Strongly Agree					

A. HEAL site characteristics

1. Study site name:
2. Name of person completing this form:
3. Is this site:
 - A. an academic medical center: a hospital that is organizationally and administratively integrated with a medical school
 - B. a community hospital
4. Is this site:
 - A. a free-standing children's hospital: **not housed** within a larger hospital that caters to adults
 - B. an attached children's hospital **housed** within a larger hospital that caters to adults
 - C. a NICU located within an adult hospital that is not part of a children's hospital
5. How many NICU beds is this site licensed for?
6. What level NICU?
 - A. III
 - B. IV
7. Does this site have a "NeuroNICU" unit?
 - A. Yes
 - B. No
8. If yes, please describe.
9. Please select the proportion that best reflects the patient mix of all NICU admissions at this site.
 - A. All outborn
 - B. Mostly outborn
 - C. About equally inborn and outborn
 - D. Mostly inborn
 - E. All inborn

B. Personnel

10. At our site, we missed potential participants due to study personnel issues such as someone being out on leave or vacation:
 - A. Never
 - B. Very Rarely
 - C. Rarely
 - D. Occasionally
 - E. Frequently
 - F. Very Frequently
11. At our site, when a key person performing recruitment was out on leave, on vacation, or away for another reason, there was another person easily available to recruit in their place:
 - A. Never
 - B. Very Rarely

- C. Rarely
 - D. Occasionally
 - E. Frequently
 - F. Very Frequently
12. At our site, there were formal meetings related to recruitment for HEAL led by the site PI:
- A. Never
 - B. 1-3 times per year
 - C. 4-6 times per year
 - D. 7 or more times per year
13. At our site, there was a person (whether or not directly involved in the study) in a leadership position (e.g., division chief, department chair, medical director) who championed the HEAL study.
- A. Strongly disagree
 - B. Disagree
 - C. Neither agree or disagree
 - D. Agree
 - E. Strongly agree
14. Describe this person's position and what they did for study.
15. Who was/were the primary person/s who performed the day-to-day tasks necessary for keeping the HEAL study going? (OK to pick more than 1)
- A. A. Site PI
 - B. B. Research coordinator
 - C. C. Other (please list)

C. Process

16. IRB approach to consent (choose all that apply):
- A. Allowed to consent by phone
 - B. Allowed to obtain signatures remotely (e.g., photocopy with follow-up in-person signature was sufficient)
 - C. Required in-person signature prior to enrollment
- 16A. Please tell me more about how consent requirements may have affected recruitment.
17. If chose A above: how frequently was consent obtained for study participation over the phone?
- A. Never
 - B. Very Rarely
 - C. Rarely
 - D. Occasionally
 - E. Frequently
 - F. Very Frequently
18. In what languages were you able to obtain consent? (choose all that apply):
- A. English
 - B. Spanish

C. Other—describe process

19. Who was authorized to obtain consent for the HEAL study at this site? (can choose multiple)
- A. Study PI
 - B. Any study physician
 - C. Any physician
 - D. Research Coordinator
 - E. Research nurse
 - F. Study NNP or PA
 - G. Other: (please specify)
20. Did the IRB require that a clinical team member approach the family before the research team could approach?
- A. Yes
 - B. No
21. What date was the protocol for HEAL initially submitted to the IRB at this site?
22. At this site, IRB rules and/or restrictions negatively impacted HEAL enrollment.
- A. Strongly disagree
 - B. Disagree
 - C. Neither agree or disagree
 - D. Agree* (*please describe below)
 - E. Strongly agree* (*please describe below)
23. Please tell me more about how IRB practices and restrictions affected study recruitment.

Tracking of potential participants

24. At this site, how did research team become aware of potential HEAL participants? (please select as many as apply)
- A. An automated system upon NICU admission
 - B. Manually identified by research team (specify whom of: research coordinator, study physician, other?)
 - C. Medical team notified research team (specify whom of: admitting physician, NICU fellow, NICU resident, NICU APP, neurology attending, neurology fellow, neurology resident, neurology APP, clerk/unit coordinator, transport team, other)
 - D. Any other relevant processes not described above?
25. At this site, we had a system to identify potential participants that worked well.
- A. Strongly disagree
 - B. Disagree
 - C. Neither agree or disagree
 - D. Agree
 - E. Strongly agree
26. Why do you think this system worked or didn't work well?

27. At this site, what percentage of eligible patients do you think were missed due to failure to identify a patient that would have been eligible?
- A. <1%
 - B. 1-5%
 - C. 5-10%
 - D. 10-25%
 - E. >25%

Coverage system for obtaining consent

28. How did clinical team members know who was on call for HEAL at this site?
- A. It was always the same person
 - B. There was an on-call schedule that was either posted somewhere easy to find, or communicated regularly to the team
 - C. There was an on-call schedule that was posted somewhere but it was not easy to find
 - D. There was an on-call schedule but it is not posted anywhere
 - E. It was not necessary to know, there was just one phone number or pager to call that connected you to the appropriate person
 - F. Other, please describe
29. For this site, there was a well-functioning back-up system if on call person was unavailable for some reason.
- A. Strongly disagree
 - B. Disagree
 - C. Neither agree or disagree
 - D. Agree
 - E. Strongly agree
30. At this site, there was always someone available to enroll for HEAL.
- A. Strongly disagree
 - B. Disagree
 - C. Neither agree or disagree
 - D. Agree
 - E. Strongly agree
31. At this site, we had difficulty with having adequate staff to enroll on nights.
- A. Strongly disagree
 - B. Disagree
 - C. Neither agree or disagree
 - D. Agree
 - E. Strongly agree
32. At this site, we had difficulty with having adequate staff to enroll on weekends.
- A. Strongly disagree
 - B. Disagree
 - C. Neither agree or disagree
 - D. Agree
 - E. Strongly agree

33. At this site, we had difficulty with having adequate staff to enroll on holidays.
- A. Strongly disagree
 - B. Disagree
 - C. Neither agree or disagree
 - D. Agree
 - E. Strongly agree

First contact with family

34. At this site, a member of the research team routinely made contact with each family before the consent conversation (including any of: speaking by phone, introducing themselves, introducing the study, explaining that they'd be approaching for consent later, or any other reason).
- A. Strongly disagree
 - B. Disagree
 - C. Neither agree or disagree
 - D. Agree
 - E. Strongly agree
35. Please describe the typical approach for initially contacting the family (e.g., in person vs. phone; one vs. multiple conversations).
36. How did you determine a good time to approach family for HEAL consent? (can choose multiple)
- A. Ask the bedside nurse before approaching
 - B. Ask the attending physician before approaching
 - C. Ask a resident or fellow before approaching
 - D. Ask a nurse practitioner or physician assistant before approaching
 - E. Look in the chart to get a sense of how baby was doing and what else might be going on
 - F. Other, please describe
37. At our site, the person approaching the family for consent usually spoke directly with the attending physician caring for the baby prior to approaching a family for enrollment in HEAL.
- A. Strongly disagree
 - B. Disagree
 - C. Neither agree or disagree
 - D. Agree
 - E. Strongly agree
38. At this site, the study team often felt resistance from the clinical team regarding approaching a family for HEAL enrollment.
- A. Strongly disagree
 - B. Disagree
 - C. Neither agree or disagree
 - D. Agree
 - E. Strongly agree

39. Please describe resistance from clinical team in approaching for HEAL, including from whom (nurse, NNP, PA, fellow, resident, attending, other).

D. Challenging situations/barriers

40. What recruitment challenges came up during the HEAL study?

41. How far were individuals involved in enrollment/consenting (e.g., researcher coordinators, research physicians) located from the NICU on weekdays? (examples: in the unit, in the same building, a 2 min walk down the hall, a 15 min drive away, taking call from home).

41A. How far were individuals involved in enrollment/consenting (e.g., researcher coordinators, research physicians) located from the NICU on weekends, nights, and holidays? (examples: in the unit, in the same building, a 2 min walk down the hall, a 15 min drive away, taking call from home).

42. At our site, distance between the location of those consenting and the NICU negatively affected recruitment for HEAL.

- A. Strongly disagree
- B. Disagree
- C. Neither agree or disagree
- D. Agree
- E. Strongly agree

43. At our site, potential participants are hesitant to enroll in research.

- A. Strongly disagree
- B. Disagree
- C. Neither agree or disagree
- D. Agree
- E. Strongly agree

44. Why do you think this may be true?

45. At our site, potential participants are willing to enroll in research.

- A. Strongly disagree
- B. Disagree
- C. Neither agree or disagree
- D. Agree
- E. Strongly agree

46. Why do you think this may be true?

47. Please describe any specific steps or adaptations to overcome the challenges or impediments of recruitment for HEAL that were made at this site.

48. Which elements of your site's recruitment processes worked especially well in contributing to the success of patient recruitment at your site? Feel free to share any thoughts you have regarding what worked well.

49. Please share 1-2 lessons that you learned during the 3 years of HEAL recruitment at your site, regarding how to optimize recruitment processes for neonatal treatment trials. We would appreciate any advice or observations you can share, whether big or small.

50. Would you modify any of your site's recruitment practices next time you are involved in a neonatal treatment trial? If so, how?

Research team

51. Who was able to get consent for HEAL at your site (choose all that apply)?
- A. NICU attending
 - B. NICU fellow
 - C. Pediatric resident
 - D. APP/PA/NP
 - E. Neurology attending
 - F. Neurology fellow
 - G. Neurology resident
 - H. Research coordinator
 - I. Other, please describe
52. How many individuals who were able to get consent for HEAL at your site? (give a number)
53. How did this actually occur logistically (e.g., was there a single or small group of high performers? Was it evenly split among a larger group?)
54. Describe the team involved with tracking of potential participants (e.g., numbers of individuals, their roles).

QUESTIONS FOR:

a) HEAL SITE PI,

b) PRIMARY HEAL RESEARCH COORDINATOR,

c) Individual who did the most consenting at each site

Please state the extent to which you agree with the following statements:

63. It is likely that EPO will ultimately be shown to be effective as a neuroprotection for term infants with HIE.
- A. Strongly agree
 - B. Agree
 - C. Neither agree nor disagree
 - D. Disagree
 - E. Strongly disagree
64. I would encourage a close friend or family member to enroll their infant in the HEAL study.
- A. Strongly agree
 - B. Agree
 - C. Neither agree nor disagree
 - D. Disagree
 - E. Strongly disagree
65. Prior to HEAL, for how many clinical trials were you part of the team enrolling people?
- a. No experience
 - b. 1-2 times

- c. 3-5 times
 - d. 6 or more
66. Prior to HEAL, what role did you serve enrolling people in clinical trials (choose as many as appropriate)?
- a. None
 - b. Research coordinator for clinical trial
 - c. Site-PI for clinical trial
 - d. Lead PI for clinical trial
 - e. Enrolling families for clinical trials lead by colleagues
 - f. Other, please describe
67. Describe your roles at work outside of HEAL (examples may include: medical director of NICU, NICU attending, division faculty, clinical nurse, clinical APP, NICU fellow, pediatric resident, working on other clinical trial, working on bench research, leading a research lab, serving on IRB, etc.).