


The Process and Impact of Stakeholder Engagement in Developing a Pediatric Intensive Care Unit Communication and Decision-Making Intervention

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Kelly N Michelson, MD, MPH^{1,2,3}, Joel Frader, MD, MA^{2,4,5},
Lauren Sorce, RN, MSN, CPNP-AC/PC⁶, Marla L Clayman, PhD, MPH⁷,
Stephen D Persell, MD, MPH⁸, Patricia Fragen, BA⁹, Jody D Ciolino, PhD¹⁰,
Laura C Campbell, BS¹, Melanie Arenson, BA^{1,11}, Danica Y Aniciete, MS¹,
Melanie L Brown, MD, MSE¹², Farah N Ali, MD, MS^{2,13,14},
and Douglas White, MD, MAS¹⁵; The Navigate Study Investigators

Abstract

Stakeholder-developed interventions are needed to support pediatric intensive care unit (PICU) communication and decision-making. Few publications delineate methods and outcomes of stakeholder engagement in research. We describe the process and impact of stakeholder engagement on developing a PICU communication and decision-making support intervention. We also describe the resultant intervention. Stakeholders included parents of PICU patients, healthcare team members (HTMs), and research experts. Through a year-long iterative process, we involved 96 stakeholders in 25 meetings and 26 focus groups or interviews. Stakeholders adapted an adult navigator model by identifying core intervention elements and then determining how to operationalize those core elements in pediatrics. The stakeholder input led to PICU-specific refinements, such as supporting transitions after PICU discharge and including ancillary tools. The resultant intervention includes navigator involvement with parents and HTMs and navigator-guided use of ancillary tools. Subsequent research will test the feasibility and efficacy of our intervention.

Keywords

stakeholder engagement, pediatric intensive care unit, patient navigator, communication, decision making

¹ Division of Pediatric Critical Care Medicine, Ann & Robert H. Lurie Children's Hospital of Chicago, Chicago, IL, USA

² Department of Pediatrics, Feinberg School of Medicine, Northwestern University, Chicago, IL, USA

³ Center for Bioethics and Medical Humanities, Northwestern University, Chicago, IL, USA

⁴ Division of Academic General Pediatrics and Primary Care, Ann & Robert H. Lurie Children's Hospital of Chicago, Chicago, IL, USA

⁵ Program in Medical Humanities and Bioethics, Northwestern University Feinberg School of Medicine, Chicago, IL, USA

⁶ Department of Nursing, Ann & Robert H. Lurie Children's Hospital of Chicago, Chicago, IL, USA

⁷ Health and Social Development, American Institutes for Research, Chicago, IL, USA

⁸ Division of General Internal Medicine and Geriatrics, Department of Medicine, Center for Primary Care Innovation, Institute for Public Health and Medicine, Northwestern University Feinberg School of Medicine, Chicago, IL, USA

⁹ Normal Moments, Inc, Naperville, IL, USA

¹⁰ Division of Biostatistics, Department of Preventive Medicine, Northwestern University Feinberg School of Medicine, Chicago, IL, USA

¹¹ University of California San Francisco, San Francisco, CA, USA

¹² The University of Chicago Comer Children's Hospital, Chicago, IL, USA

¹³ Division of Kidney Diseases, Ann & Robert H. Lurie Children's Hospital of Chicago, Chicago, IL, USA

¹⁴ Baxter Healthcare, Deerfield, IL, USA

¹⁵ Program in Ethics and Decision Making in Critical Illness, Department of Critical Care Medicine, University of Pittsburgh School of Medicine, Pittsburgh, PA, USA

Corresponding Author:

Kelly N Michelson, MD, MPH, Ann & Robert H. Lurie Children's Hospital of Chicago, 225 E. Chicago Avenue, Box 73, Chicago, IL 60611, USA.
Email: kmichelson@luriechildrens.org



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Introduction

Clinicians and families make complicated medical decisions for pediatric intensive care unit (PICU) patients (1,2). In some cases, decisions have life-altering implications, such as whether to place a tracheostomy tube, participate in research, or withdraw life-sustaining therapies (3-5). Research demonstrates that high-quality communication positively impacts decision-making for families (6,7).

Despite the importance of high-quality clinician–family communication, few formally developed and tested interventions exist to support parental decision-making in the PICU (5,8). Moreover, there is growing emphasis on the importance of engaging key stakeholders in research, including intervention development (9,10). However, few data describe methods for and outcomes of stakeholder engagement in research (11-14). Thus, there is a need for a PICU-specific communication and decision-making intervention. There is also a need for literature describing stakeholder engagement in developing interventions.

In this article, we describe the process and impact of engaging stakeholders to develop a PICU-specific communication and decision-making intervention. We also describe the resultant intervention. Subsequently, we will test our intervention in the clinical setting.

Methods

Intervention Development Process Overview

With few models for engaging stakeholders in intervention development (15), we developed a process (Figure 1) combining qualitative methodology and community-based participatory research principles. Qualitative research uses experiential data to describe a phenomenon (16). Community-based participatory research engages those affected by an issue to effect change and has been useful for intervention development (17). For us, the “community” equates to stakeholders: parents of PICU patients, healthcare team members (HTMs) caring for PICU patients, and clinical research experts. We involved stakeholders as research team members (research stakeholders) and as participants (community stakeholders) in focus groups (FGs) and interviews (Is).

Composition of Research Stakeholders

Our research stakeholders included 3 groups: (1) parents, (2) HTMs, and (3) research experts (researchers). We included 7 parents of 6 children (cared for at 3 different ICUs) with diverse medical problems including cancer, complex chronic illnesses, gastrointestinal disorders, and neurologic/neuromuscular disorders. Four parents had a child who died prior to this project. The 11-member HTM group included PICU and subspecialty physicians, as well as a PICU bedside nurse, advanced practice nurse (APN), social worker, chaplain, and hospital bereavement program representative.

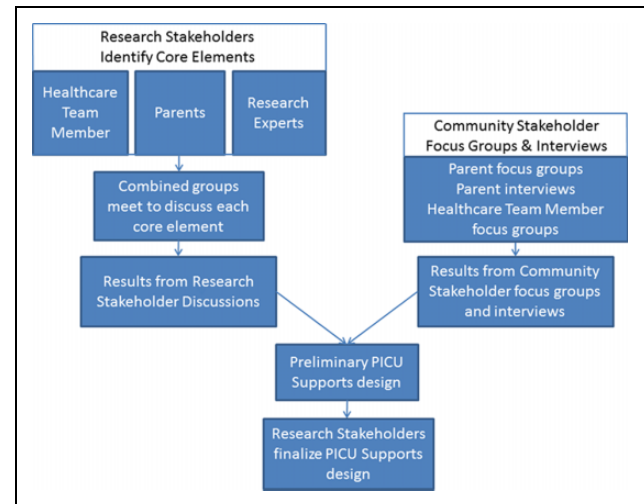


Figure 1. Intervention development process. PICU indicates pediatric intensive care unit

Healthcare team members worked at the same institution. The 9-member researcher group included experts in palliative care, decision-making, communication, statistics, clinical research, adult intensive care, and a parent. The researchers represented 3 institutions. Acting as a liaison, 1 parent participated in the parent group and researcher group and 1 nurse participated in the HTM group and researcher group. The research stakeholders were 83% (24/29) women and 83% white.

Define Intervention Core Elements

We started with an adult intensive care unit navigator-based model called Four Supports (18). We chose this model because other settings have successfully used navigators (19-21) and because our work identified potential benefits to having a point person akin to a navigator (3).

The 3 research stakeholder groups met separately to identify desirable core intervention elements. We then brought the 3 research stakeholder groups together to discuss each element, obtaining additional suggestions via e-mail. This process involved 25 meetings over 12 months. Two authors (K.N.M. and L.C.C.) summarized the meeting input based on the review of the meeting notes and e-mails. Because we did not record meetings, results about meeting content are presented qualitatively.

Community Stakeholder Input via FGs/Is

The hospital institutional review board approved the FG/I component. After obtaining written consent, we conducted FGs/Is with additional parents and HTMs, the community stakeholders. We organized FGs into categories: bereaved parents, nonbereaved parents, PICU physicians, subspecialty attending physicians, APNs, PICU bedside nurses, social workers, chaplains, and other team members (eg, case

managers). We avoided interdisciplinary FGs because we felt that mixing groups might inhibit conversations. For example, a nurse might be reluctant to comment on physician practices with physicians present.

We identified English-speaking parent FG/I participants through medical record review, identifying English-speaking parents of PICU patients admitted within the previous 6 months to 3 years and with a PICU admission of >3 days. Two study team members (the principal investigator and hospital bereavement program director) reviewed the list of eligible bereaved parents to exclude parents experiencing complicated grief. We sent letters to 90 parents, then made phone calls to nonresponders 2 weeks later. Research stakeholders identified additional parent participants by distributing brochures to parents they knew who met our eligibility criteria. English-speaking parents unable to participate in a FG due to scheduling or transportation barriers participated in an interview (conducted at the hospital or by phone). To recruit Spanish-speaking parent participants, we identified and requested study participation from Spanish-speaking parents of current PICU patients. We chose this approach to maximize Spanish-speaking parent recruitment, which in our experience is more difficult after a child's PICU discharge. Spanish-speaking parent interviews were conducted in Spanish at the hospital.

We invited HTMs by e-mail or at staff meetings to participate in FGs conducted at the hospital. The FG/I moderators (a healthcare communication researcher, a sociologist, and a Spanish-speaking social worker with qualitative research experience) used a semi-structured discussion guide. No moderators provided clinical care to the children of participating parents or worked with participating HTMs. The guide prompted moderators to ask about PICU communication, mechanisms to improve PICU communication, comments (positive or negative) about having a navigator to support PICU communication, and characteristics of an ideal navigator (see Appendix A). Following FGs/Is, participants completed a survey requesting demographic information.

Focus Group/Interview Data Analysis

We audio recorded FGs/Is and transcribed recordings verbatim. Focus groups/interviews conducted in Spanish were transcribed, translated, and reviewed by the Spanish-speaking moderator for accuracy. We used a qualitative data analysis program, Dedoose (Dedoose version 5.2.0, 2014; SocioCultural Research Consultants, LLC [www.dedoose.com], Los Angeles, California). We analyzed qualitative data using directed content (22). We identified excerpts (blocks of text with similar content) and assigned excerpts to 3 content areas: (1) PICU communication patterns, barriers, and facilitators (not discussed in this report), (2) input on intervention design, and (3) navigator characteristics. Two people read 2 conference transcripts and created unique lists of codes and then narrowed the code list by eliminating

redundancy and combining similar codes. The revised code list was then used to code 2 other transcripts, creating new codes as necessary. This process was repeated until no new codes were identified, creating a final coding dictionary. Finally, the 2 coders independently assigned codes to each excerpt. Disagreements were resolved by consensus until achieving 100% agreement. We assigned codes to broad categories based on group consensus. We used descriptive statistics for all quantitative data using Excel (Microsoft Office 2010, version 14.0.7116.5000)

Research Stakeholders Finalized the Intervention Design

The principal investigator preliminarily described the intervention by combining input from the community stakeholders and research stakeholders. The research stakeholders reviewed, amended, and finalized the intervention.

Results

Core Elements Identified by Research Stakeholders

The core intervention elements of navigator activities identified by the research stakeholders included initial meetings with HTMs and parents, daily meetings ("check-ins") with HTMs and parents, family meetings, and end-of-stay activities.

Everyone indicated that the intervention should be individualized to parents' needs and support communication among HTMs, not just communication between parents and HTMs. The groups felt the intervention should focus on parents but include relevant family members. Thus, hereafter, we use the term parents to describe 1 parent, both parents, and/or other family members.

Some HTMs, particularly social workers and chaplains, expressed concern about overlap with services by existing HTMs. To avoid duplicating or compromising existing support systems, people suggested that the navigator meets with the patient's HTMs prior to meetings with parents. After each meeting with the parents, the navigator should report relevant components of their discussion with the HTMs.

The research stakeholders felt regular family meetings could improve communication, if parents desire such meetings. Some stakeholders felt that having regular family meetings could normalize the experience, as opposed to relegating family meetings to emotionally charged discussions occurring during acute crises and/or when clinicians deliver bad news or discuss difficult decisions.

Research stakeholders, particularly parents, identified transitions out of the PICU as challenging, specifically transfers to a non-PICU hospital bed, discharges from the PICU to another facility or home, or when the child dies. Stakeholders felt the navigator could support such transitions by preparing parents for their next situation, ensuring parental

understanding about subsequent medical care and having postdischarge contact with parents. Developing a checklist for end-of-life care and providing bereavement support were discussed.

Finally, parent stakeholders suggested that parents receive written information about people's roles (eg, what a resident does), difficult medical terms, and therapies encountered in the PICU (eg, ventilators). Some stakeholders suggested that a list of questions might help parents consider what to ask HTMs.

Input From Community Stakeholder FGs/Is

We conducted 2 parent FGs, 1 included parents of living children (n = 3) and 1 included parents of deceased children (n = 4). Sixteen parents participated in interviews. The parents' children had neurologic disorders (n = 9), cancer/tumors (n = 4), respiratory disorders (n = 4), musculoskeletal disorders (n = 1), cardiovascular anomalies (n = 2), sepsis (n = 2), and liver disease (n = 1). Fifty-two HTMs participated in 8 FGs (Table 1). Three parents and 3 HTMs did not complete surveys. The FGs included a social worker and chaplain who were also part of the research stakeholders because they provided unique PICU expertise and experience. Comments about our proposed intervention fell into 2 categories: intervention design (Table 2) and navigator characteristics (Table 3).

Input on Intervention Design

All respondents, except Spanish-speaking parents, described benefits to assigning families a support person when discussing the navigator role. English- and Spanish-speaking parents focused on how the navigator could serve as a liaison between HTMs and parents, support understanding, and advocate for parents. Healthcare team member comments focused not only on how the navigator could serve as a liaison and advocate but also on how the navigator could organize and facilitate discussions. Parents proposed having regular family meetings.

In addition to the navigator, stakeholders suggested other resources or tools. Parents (particularly English-speaking parents) and HTMs (except physicians) felt a handbook with information about the PICU could help parents. Some parents, a physician, and a nurse suggested that a "sign-in log" might help parents track who comes and goes from their child's room.

Most HTM-voiced concerns about having a navigator indicated worry that the navigator's role could overlap with that of existing HTMs. Parents did not express this concern. Another concern expressed by HTMs and parents was that this position could be too much work for a single person.

Navigator Characteristics

All stakeholders talked about personality traits that would enhance the navigator's ability to provide emotional support.

Table 1. Demographics of the Community Stakeholders (Focus Group/Interview Participants).

	Parent Stakeholders (n = 20), n (%) ^a	HTM Stakeholders (n = 49), n (%) ^b
Age, mean (median, range) in years	38 (39, 26-53)	42 (39, 25-70)
Sex		
Female	18 (90%)	45 (92%)
Male	2 (10%)	4 (8%)
Relationship to the patient		
Biological parent	19 (95%)	NA
Adoptive parent	1 (5%)	NA
Race		
White	13 (65%)	42 (86%)
American Indian/Alaskan Native	2 (10%)	0 (0)
Asian	0 (0)	3 (6%)
Black/African American	2 (10%)	1 (2%)
Other	3 (15%)	2 (4%)
Not reported	0 (0)	1 (2%)
Ethnicity		
Not Hispanic	13 (65%)	45 (92%)
Hispanic	7 (35%)	1 (2%)
Did not report	0 (0)	3 (6%)
Education		
Elementary school	1 (5%)	NA
High school	7 (35%)	NA
College	5 (20%)	NA
Postgraduate	6 (30%)	NA
Other ^c	1 (5%)	NA
Marital status		
Single	1 (5%)	NA
Married/living as married couple	17 (85%)	NA
Separated/divorced	2 (10%)	NA
Position in the hospital		
Chaplains	NA	6 (12%)
Social workers	NA	6 (12%)
APN	NA	5 (10%)
PICU attending	NA	6 (12%)
Subspecialty attending	NA	8 (16%)
Fellow	NA	5 (10%)
PICU bedside nurse	NA	8 (16%)
Multidiscipline team member ^d	NA	5 (10%)
Years in position		
1 to 5 years	NA	20 (40%)
5 to 10 years	NA	15 (31%)
>20 years	NA	13 (26%)

Abbreviations: APN, advanced practice nurse; HTM, healthcare team member; NA, not applicable; PICU, pediatric intensive care unit.

^aMissing data from 3 parents.

^bMissing data from 3 HTMs.

^cReported as vocational.

^dIncludes case managers, speech and music therapists, and child-life specialists.

Those characteristics included: supportive, empathetic, calm, objective, assertive, organized, and respected. Everyone indicated that she/he should be able to communicate medical terminology in lay language. All groups except Spanish-speaking parents described that she/he should be able to mediate conflict. Having the ability to engage people

Table 2. Input on Intervention Design and Exemplar Quotes From Focus Groups and Interviews.

Category	Code	Exemplar Quote	Number/Percentage of Excerpts ^a					
			Physician	RN	Psyc	ParentE	ParentS	All
Navigator role	One person for the family	"And given that you're in a brand new situation, having 1 person who really understood your case..."—ParentE	N = 22 4, 18.2%	N = 33 12, 36.4%	N = 17 3, 17.6%	N = 120 34, 28.3%	N = 14 0, 0%	N = 206 53, 25.7%
	Liaison between HTM and family	"But I think what I see them doing is being like the liaison between the medical team and the family services team."—Multidisciplinary group	10, 45.5%	15, 45.5%	11, 64.7%	57, 47.5%	5, 35.7%	98, 47.6%
	Support understanding	"I would appreciate it if a navigator could ask me if I understand what's going on? If I have any questions? Is there anybody who she can bring in to talk with me?"—ParentE	4, 18.2%	8, 24.2%	2, 11.8%	33, 27.5%	8, 57.1%	55, 26.7%
	Organize and facilitate discussions	"I think when we have really difficult cases come in the PICU or maybe not everyone sees eye-to-eye on managing, someone who could come help and even just facilitate those discussions to be a more a discussion that's more productive."—APN	9, 40.9%	12, 36.4%	8, 47.1%	23, 19.2%	3, 21.4%	55, 26.7%
	Advocate and support for the family	"Yes, it would have been very helpful to have kind of a care conference or something at the beginning."—ParentE "And I think the navigator being able to sit down with a parent and say, 'Okay, let me know where your thoughts are and what you're thinking and what you're concerned about so I can make sure it gets addressed or explain to you this is what's going on.'"—ParentE	6, 27.3%	15, 45.5%	3, 17.6%	37, 30.8%	3, 21.4%	64, 31.1%
Resources	Guide/handbook	"I think if there was a way to educate parents or even if there's a patient's/parent's guide 101 and how to talk to your child's doctor."—ParentE	N = 1 0, 0%	N = 2 2, 100%	N = 3 2, 66.7%	N = 30 20, 66.7%	N = 2 2, 100%	N = 38 26, 68.4%
	Sign-in/communication log	"So if volunteers come, if a service comes... And not that it's any formal sign-in but it's just like, oh, I can see that they came today and notices."—Multidisciplinary group	1, 100%	0, 0.0%	1, 33.3%	13, 43.3%	0, 0%	15, 39.5%
Concerns	Overlap with other services	"I mean I think that's useful. I'm not sure how it would fit in... I just don't—I feel like that would be in some ways a redundant person in the ICU."—Subspecialty attending	N = 14 11, 78.6%	N = 3 2, 66.7%	N = 15 13, 86.7%	N = 10 0, 0%	N = 0 0, 0%	N = 42 26, 61.9%
	Too much for 1 person	"Seems like it would be a lot of work for 1 person."—Bedside nurse	3, 21.4%	1, 33.3%	3, 20%	10, 100%	0, 0%	17, 40.5%

Abbreviations: APN, advanced practice nurse; HTM, healthcare team member; ParentE, English-speaking parent; ParentS, Spanish-speaking parent; PICU, pediatric intensive care unit; Psyc, psychosocial; RN, bedside nurse. ^aIndicates the number of excerpts (block of text with similar content) based on the stakeholder group. The numbers in the shaded rows represent the number of excerpts assigned to each category. The numbers in rows without shading represent the number of excerpts assigned to each code. Percentages indicates the percent of excerpts assigned to a code within each category. The sum of percentages for a particular category may be >100 because some excerpts were associated with more than one code.

Table 3. Input on Navigator Characteristics and Exemplar Quotes From Focus Groups and Interviews.

Category	Code	Exemplar Quote	Number/Percentage of Excerpts ^a					
			Physician	APN/RN	Psycoc	ParentE	ParentS	All
Personality	Emotional support components	“They have to be so nonthreatening. Because so many parents would feel . . . intimidated . . . that person has to be so approachable. Really have that empathy . . .”—ParentE	N = 8 8, 100%	N = 2 2, 100%	N = 4 4, 100%	N = 5 5, 100%	N = 6 6, 100%	N = 25 25, 100%
			N = 16 5, 31.3%	N = 18 7, 38.9%	N = 20 6, 30.0%	N = 29 6, 20.7%	N = 9 1, 11.1%	N = 92 25, 27.2%
Skills	Able to communicate medical terminology in lay language Able to facilitate discussions and be a mediator Culturally competent/diverse	“Being able to communicate the actual medical terminology and jargon which might bring up questions among the family, you need somebody to be knowledgeable.”—Multidisciplinary group “So she would kind of get to know the family a little bit beforehand and then go in and ask those questions that the family wasn’t able to think of at the time.”—APN “I think that cultural diversity is probably important too, because different cultures are going to approach child illness in different ways than you know.”—ParentE “Well, I think someone who speaks the same language.” ParentS	2, 12.5%	11, 61.1%	7, 35.0%	8, 27.6%	0, 0%	28, 30.4%
			13, 81.3%	3, 16.7%	12, 60.0%	17, 58.6%	8, 88.9%	53, 57.6%
Background	Medical	“Because if you’re going to bring somebody in who’s going to be navigating this family through the process, I truly believe you need either a physician or fellow or something to that caliber that’s going to bring something to the table.”—Multidisciplinary group “Maybe that’s somebody in social work, the social work department. Maybe that’s somebody from the family life department that would kind of know the ins and the outs.”—ParentE	N = 13 5, 38.5%	N = 10 6, 60.0%	N = 13 4, 30.8%	N = 24 10, 41.7%	N = 4 3, 75.0%	N = 64 28, 43.8%
			3, 23.1%	3, 30.0%	2, 15.4%	5, 20.8	1, 25.0%	14, 21.9%
	Both	“I think you need both, because a lot of the things, like with the example [he] was saying, that was medical knowledge of what was going on with the patient—the very sick girl who had had the sibling die. Social work and chaplaincy were very important, but they wouldn’t have gotten over this hurdle of trying to explain all the medical details that the mother and sister wanted.”—Attending	5, 38.5%	1, 10.0%	7, 53.8%	9, 37.5%	0, 0%	22, 34.4%

Abbreviations: APN, advanced practice nurse; ParentE, English-speaking parent; ParentS, Spanish-speaking parent; PICU, pediatric intensive care unit; Psycoc, psychosocial; RN, bedside nurse. ^aIndicates the number of excerpts (block of text with similar content) based on the stakeholder group. The numbers in the shaded rows represent the number of excerpts assigned to each category. The numbers in rows without shading represent the number of excerpts assigned to each code. Percentages indicates the percent of excerpts assigned to a code within each category. The sum of percentages for a particular category may be >100 because some excerpts were associated with more than one code.

Table 4. PICU Supports Navigator Activities.

Navigator Activity	Description
Initial visit with the HTMs	<ul style="list-style-type: none"> • Elicits team perception of the patient's clinical situation and parent's needs • Provide relevant feedback to healthcare team after meeting the family
Initial visit with the parents	<ul style="list-style-type: none"> • Explain the navigator's role and the components of PICU Supports • Begin to establish a relationship/rapport • Provide emotional support and empathy • Elicit parent's understanding of their child's medical situation (diagnosis, prognosis, treatment plan). • Elicit family's questions and concerns • Understand the patient as a person • Orient the parents to the PICU • Plan for next steps
Weekday visits with HTMs	<ul style="list-style-type: none"> • Elicits team perception of the patient's clinical situation and parent's needs • Inquire about how the navigator could help the healthcare team during visits with the parents • Provide relevant feedback to healthcare team after meeting the family
Weekday visits with parents	<ul style="list-style-type: none"> • Provide emotional support • Assess parents understanding of the patient's medical situation • Elicit and attend to concerns/questions/practical needs • Assess communication between family and healthcare team and assist if needed • Utilize ancillary tools as needed by the parents
Coordination of family meetings	<ul style="list-style-type: none"> • Meet with parents before the family meeting <ul style="list-style-type: none"> ○ Identify topic areas and questions of interest to the parents (utilize question prompt list if needed) ○ Determine who the parents would like in attendance at the meeting • Meet with the healthcare team before the meeting <ul style="list-style-type: none"> ○ Identify clinician goals for the meeting ○ Inform the healthcare team about the parents' goals/questions ○ Identify a conference leader • Participate in family meeting <ul style="list-style-type: none"> ○ Provide emotional support to parents ○ Help parents ask questions/encourage participation ○ Listen for and address misunderstandings ○ Ensure discussion of plan for next steps ○ Keep notes for the parents • Meet with parents after the meeting <ul style="list-style-type: none"> ○ Provide emotional support and express empathy ○ Help parents synthesize key information from the clinician ○ Elicit concerns and questions ○ Listen for key misunderstandings ○ Identify persistent or new questions ○ Give parents written notes • Meet with healthcare team after the meeting <ul style="list-style-type: none"> ○ Provide update about what happened when talking with the parents after the meeting ○ Inquire how the navigator can further help the healthcare team ○ Plan for next meeting
Support for transitions out of the PICU	<ul style="list-style-type: none"> • For dying patients, utilize the end-of-life care checklist • For patients being transferred to a non-PICU bed or being discharged to home or another facility <ul style="list-style-type: none"> ○ Prepare parents for their next situation ○ Ensure parents' understanding about medical care and follow-up once leaving the PICU ○ Facilitate communication with the next healthcare team or non-PICU care providers about relevant issues to the parents ○ Provide parents with relevant informational resources and/or education materials
Post-PICU discharge check-in	<ul style="list-style-type: none"> • For patients transferred to a non-PICU bed, check-in with the parents in person • For patients discharged to home or a chronic care facility or for patients who have died, check-in with parents via the phone • Provide emotional support • Elicit and attend to concerns/questions/practical needs • Inform the new healthcare team (if still an inpatient) of ongoing parental concerns and goals • Provide follow-up to outpatient healthcare team (eg, primary medical physician or subspecialty physician) when appropriate

Abbreviations: HTMs, healthcare team members; PICU, pediatric intensive care unit

Table 5. PICU Supports Ancillary Tools.

Ancillary Tool	Description
PICU handbook	A book (written by the parent advisors, HTM advisors, and research advisors) with information about how the PICU runs, medical terms, machines and procedures, and how parents can support themselves and their family while their child is in the PICU.
Diary	A place for parents to keep a diary of events and goals for their child. The diary is meant for parent use and not to be reviewed by others unless that is the parent’s choice.
Question prompt list	A list of questions covering issues relevant to parents of children in the PICU. The list is meant to help parents think about questions they might want to ask the healthcare team.
Provider information sheet	Written information, compiled by the navigator and given to healthcare team members, about the parents’ psychosocial issues, concerns, needs, or goals. This tool is not part of the patient’s medical record.
Bedside communication log	A log where HTMs (other than PICU physicians, nurses, and APNs) write their name and service so parents know which HTMs have visited.
End-of-life care checklist	A list of activities or options that should be offered to families of dying children that the navigator would ensure gets addressed.
Bereavement packet	A packet of written information to support parental and family bereavement for those whose child dies.
Ancillary information	Additional informational resources (eg, websites, written materials) relevant to the patient’s medical situation

Abbreviations: APN, advanced practice nurse; HTMs, healthcare team members; PICU, pediatric intensive care unit.

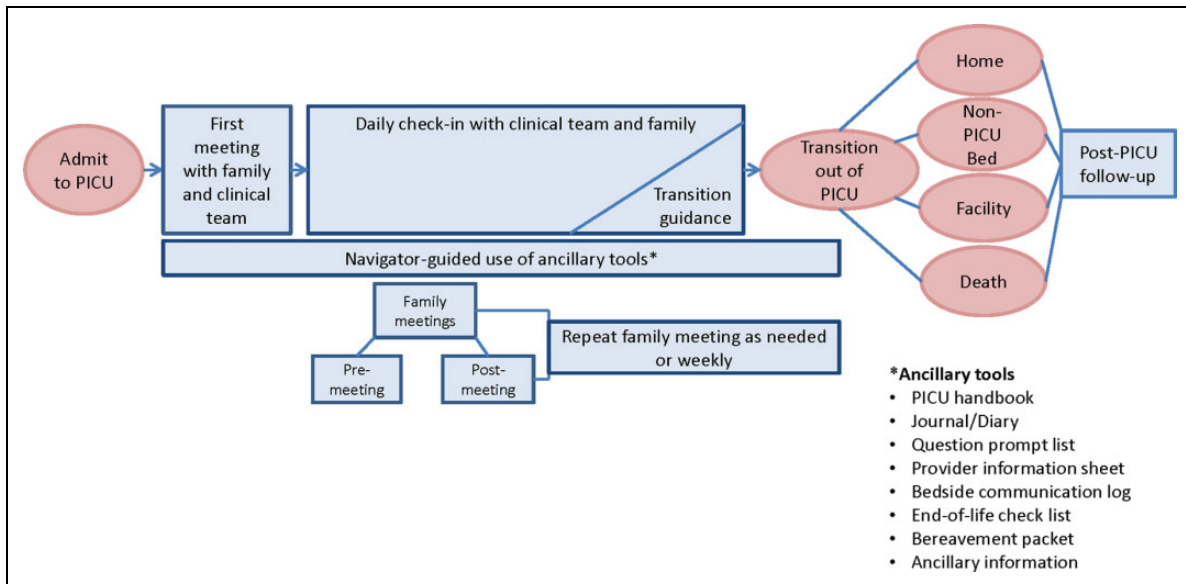


Figure 2. The PICU Supports design. Navigator activities are noted in blue. PICU indicates pediatric intensive care unit.

from diverse cultural backgrounds was a major focus of conversation related to navigator skills. Spanish-speaking parents recommended having Spanish-speaking navigators and/or high-quality, available interpreters. Input on the navigator’s preferred background varied with 43.8% of comments, indicating he/she have a medical background (like a nurse), 21.9% a psychosocial background (like a social worker or chaplain), and 34.4% both a medical and psychosocial background.

Final Intervention Design

Research stakeholders named the intervention “PICU Supports.” Reflecting stakeholder input, PICU Supports seeks to provide emotional, communication, decision-making,

information, and transition (ie, transitions out of the PICU or death) support. PICU Supports includes navigator activities (Table 4) and ancillary tools (Table 5), delivered based on individual needs/desires. PICU Supports is meant to augment existing HTMs or processes as needed (Figure 2).

Discussion

We describe a process for engaging stakeholders in intervention development. Stakeholder input added elements to our intervention (PICU Supports) including attention to transitions out of the PICU and tools such as the PICU handbook, a question prompt list, a place for journaling, and a mechanism for tracking HTMs involved in patient care. These elements

might not have been included in PICU Supports without stakeholder input.

The need to address transitions out of the PICU was only partially addressed by the adult model which focused on end-of-life care. While PICU Supports addresses the challenges faced by parents of dying children, it also addresses the discharge needs of surviving children. The need for this expanded focus may reflect differences in mortality rates between adult ICUs (as high as 33%) versus PICUs (typically less than 7%; 23,24). It could also reflect the need for healthcare systems to address post-ICU syndrome, a documented problem for which organized treatment options are lacking (25). Regardless, stakeholder input directed its inclusion in PICU Supports.

The inclusion of ancillary tools is another stakeholder-driven distinguishing feature of PICU Supports. Variations in these tools have been studied in other settings. For example, researchers have shown the benefits of educational brochures and diaries for surrogates in the ICU (26,27). We included these elements because stakeholders identified them as potentially beneficial.

Stakeholder concerns also influenced the design of PICU Supports. As a result of worries about overlap with the roles of existing HTMs, stakeholders designed PICU Supports to function as an adjunct to ongoing resources with the navigator integrated into the medical team. To enhance navigator-medical team integration, PICU Supports has many contact points between the navigator and the medical team including before and after daily family discussions and organized family meetings and through the use of the provider information sheet (Table 5).

Challenges we encountered highlight some limitations. Scheduling parent FGs was difficult. Resultant smaller FGs leave the possibility that the conversations might have been more robust had we organized larger groups. We also had difficulty recruiting culturally diverse stakeholders and fathers; most stakeholders were white and most parents women. Thus, our intervention may not reflect needs of underrepresented groups. Also, finding resolution is difficult when stakeholders disagree. For example, there was no consensus about the navigator's background. Finally, stakeholder input resulted in a complex intervention, raising questions about implementation feasibility.

This work, therefore, represents a first step. A subsequent pilot implementation study is needed to address unanswered questions such as what would be the ideal navigator background; whether or not to include all intervention components described here; which families should receive PICU Supports; how much time effort/cost PICU Supports requires; if a navigator should be available on weekends and evenings; and how to provide ancillary materials (eg, via the Internet).

Other limitations are noteworthy. We did not record research stakeholder meetings and thus only present qualitative information about those discussions. Focus group HTMs came from the same institution, although research

stakeholders and community stakeholders included HTMs from other institutions and parents of children admitted to other PICUs. We cannot account for recall or recruiting bias. We did not analyze information conveyed in FGs/Is via body language or intonation. Finally, stakeholder input reflects a limited "pool" of knowledge/experience. We may have missed key stakeholders (eg, hospital administrators) or neglected important approaches to improve communication and decision-making.

Conclusion

Stakeholder input impacted the design of PICU Supports. Engaging stakeholders with varied backgrounds was challenging, identifying the need for innovation in recruiting stakeholders from diverse populations. Future work is needed to determine the implementation feasibility and impact of PICU Supports.

Appendix A

Focus Group/Interview Guide

- Goal:* Introductions from participants and description of background and experience in the pediatric intensive care unit (PICU).
Prompt: Please share with the group something about yourself and your experience in the PICU.
- Goal:* Obtain information about experience in the PICU related to communication to identify how communication works well and opportunities for improvement.
Prompt: We are trying to create a program to help improve communication in the PICU. In order to do that, we are interested in learning about your experiences in the PICU. We know that communication can often be memorable either because things happen really well or because things happen poorly. We would like to know what is/was memorable to you about communication in the PICU, both in terms of things that go/went well and things that do not/did not go well.
- Goal:* Elicit input about how to improve communication in the PICU.
Prompt: As we mentioned, we plan to develop a program to improve communication in the PICU. When you hear that, what kinds of things do you think we need to include in our program in order to improve communication in the PICU?
- Goal:* Elicit input about how a navigator might support PICU communication.
Prompt: There is a program that has been used in adult intensive care units to improve communication. In that program, a navigator was introduced to the care team to improve communication. The navigator is a person who is there solely to support families and improve communication in the PICU. We would like

to create a similar program. How do you think a navigator could help support families and improve communication in the PICU?

5. *Goal:* Obtain input about who (ie, a person with what type of background) should take on the role of the navigator.

Prompt: What kind of background/training should the navigator have? Who should the navigator for our program be?

Authors' Note

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References

1. Van Cleave AC, Roosen-Runge MU, Miller AB, et al. Quality of communication in interpreted versus noninterpreted PICU family meetings. *Crit Care Med.* 2014;42(6):1507-17.
2. October TW, Watson AC, Hinds PS. Characteristics of family conferences at the bedside versus the conference room in pediatric critical care. *Pediatr Crit Care Med.* 2013;14(3): e135-42.
3. Michelson KN, Patel R, Haber-Barker N, Emanuel L, Frader J. End-of-life care decisions in the PICU: roles professionals play. *Pediatr Crit Care Med.* 2013;14(1): e34-44.
4. Slosky LE, Stern M, Burke NL, Siminoff LA. Decision making in the PICU: an examination of factors influencing participation decisions in phase III randomized clinical trials. *Int J Pediatr.* 2014;2014:1-6.
5. Mello MM, Burns JP, Truog RD, et al. Decision making and satisfaction with care in the pediatric intensive care unit: findings from a controlled clinical trial. *Pediatr Crit Care Med.* 2004;5(1):40-7.
6. Davidson JE, Powers K, Hedayat KM, et al; American College of Critical Care Medicine Task Force 2004-2005, Society of Critical Care Medicine. Clinical practice guidelines for support of the family in the patient-centered intensive care unit: Amer- ican College of Critical Care Medicine Task Force 2004-2005. *Crit Care Med.* 2007;35(2):605-22.
7. Schaefer KG, Block SD. Physician communication with fam- ilies in the ICU: evidence-based strategies for improvement. *Curr Opin Crit Care.* 2009;15(6):569-77.
8. Boyle DK, Miller PA, Forbes-Thompson SA. Communica- tion and end-of-life care in the intensive care unit: patient, family, and clinician outcomes. *Crit Care Nurs Q.* 2005; 28(4):302-16.
9. Williams SS, Esposito D, Rich EC. Patients and clinicians as stakeholders in comparative effectiveness research: multiple perspectives and evolving roles. *J Comp Eff Res.* 2014;3(6): 573-5.
10. Cluzeau F, Wedzicha JA, Kelson M, et al; ATS/ERS Ad Hoc Committee on Integrating and Coordinating Efforts in COPD Guideline Development. Stakeholder involvement: how to do it right: article 9 in integrating and coordinating efforts in COPD guideline development. An official ATS/ERS workshop report. *Proc Am Thorac Soc.* 2012;9(5):269-73.
11. Gagnon MP, Desmartis M, Lepage-Savary D, et al. Introducing patients' and the public's perspectives to health technology assessment: a systematic review of international experiences. *Int J Technol Assess Health Care.* 2011;27(1):31-42.
12. Guise JM, O'Haire C, McPheeters M, et al. A practice-based tool for engaging stakeholders in future research: a synthesis of current practices. *J Clin Epidemiol.* 2013;66(6):666-74.
13. Staniszewska S, Brett J, Mockford C, Barber R. The GRIPP checklist: strengthening the quality of patient and public invol- vement reporting in research. *Int J Technol Assess Health Care.* 2011;27(4):391-9.
14. Staniszewska S, Denegri S. Patient and public involvement in research: future challenges. *Evid Based Nurs.* 2013;16(3):69.
15. Mallery C, Ganachari D, Fernandez J, Smeeding L, Robinson S, Moon M. Innovative Methods in Stakeholder Engagement: An Environmental Scan. Prepared by the American Institutes for Research under contract No. HHS A 290 2010 0005 C. AHRQ Publication NO. 12-EHC097-EF. Rockville, MD: Agency for Healthcare Research and Quality; 2012. [https:// www.effectivehealthcare.ahrq.gov/tasks/sites/ehc/assets/File/ CF_Innovation-in-Stakeholder-Engagement_LiteratureRe view.pdf](https://www.effectivehealthcare.ahrq.gov/tasks/sites/ehc/assets/File/CF_Innovation-in-Stakeholder-Engagement_LiteratureReview.pdf). Accessed December 21, 2016.
16. Giacomini MK, Cook DJ. Users' guides to the medical litera- ture: XXIII. Qualitative research in health care A. Are the results of the study valid? Evidence-Based Medicine Working Group. *JAMA.* 2000;284(3):357-62.
17. Wallerstein N, Duran B. Community-based participatory research contributions to intervention research: the intersection of science and practice to improve health equity. *Am J Public Health.* 2010;100(suppl 1): S40-6.
18. White DB, Cua SM, Walk R, et al. Nurse-led intervention to improve surrogate decision making for patients with advanced critical illness. *Am J Crit Care.* 2012;21(6):396-409.

19. Feinberg AW. Questions & answers. What are geriatric care managers? *Health News*. 2004;10(2):16.
20. Williams V, Smith A, Chapman L, Oliver D. Community matrons—an exploratory study of patients' views and experiences. *J Adv Nurs*. 2011;67(1):86-93.
21. Yamokoski AD, Hazen RA, Kodish ED. Anticipatory guidance to improve informed consent: a new application of the concept. *J Pediatr Oncol Nurs*. 2008;25(1):34-43.
22. Hsieh HF, Shannon SE. Three approaches to qualitative content analysis. *Qual Health Res*. 2005;15(9):1277-88.
23. Williams TA, Dobb GJ, Finn JC, Webb SA. Long-term survival from intensive care: a review. *Intensive Care Med*. 2005;31(10):1306-15.
24. Marcin JP, Song J, Leigh JP. The impact of pediatric intensive care unit volume on mortality: a hierarchical instrumental variable analysis. *Pediatr Crit Care Med*. 2005;6(2):136-41.
25. Needham DM, Davidson J, Cohen H, et al. Improving long-term outcomes after discharge from intensive care unit: report from a stakeholders' conference. *Crit Care Med*. 2012;40(2):502-9.
26. Azoulay E, Pochard F, Chevret S, et al. Impact of a family information leaflet on effectiveness of information provided to family members of intensive care unit patients: a multicenter, prospective, randomized, controlled trial. *Am J Respir Crit Care Med*. 2002;165(4):438-42.
27. Ewens BA, Hendricks JM, Sundin D. The use, prevalence and potential benefits of a diary as a therapeutic intervention/tool to aid recovery following critical illness in intensive care: a literature review. *J Clin Nurs*. 2015;24(9-10):1406-25.

Author Biographies

Kelly N. Michelson, MD, MPH, is an associate professor of Pediatrics, Julia and David Uihlein professor in Bioethics and Medical Humanities, and Director of the Center for Bioethics and Medical Humanities at Northwestern University Feinberg School of Medicine. She is also an attending physician in the pediatric intensive care unit at Ann & Robert H. Lurie Children's Hospital of Chicago.

Joel Frader, MD, MA, is a Todd Davis professor of Academic General Pediatrics and professor of Bioethics and Medical Humanities at Northwestern University Feinberg School of Medicine. He is also the Director of the Bridges Pediatric Palliative Care Team at Ann & Robert H. Lurie Children's Hospital of Chicago.

Lauren Sorce, RN, MSN, CPNP-AC/PC, is a pediatric critical care nurse practitioner and an advance practice nurse manager in the Division of Pediatric Critical Care at Ann & Robert H. Lurie Children's Hospital of Chicago. She is also the associate director for nursing research.

Marla L. Clayman, PhD, MPH, is a senior researcher at American Institutes for Research. She is also an adjunct professor at Northwestern University Feinberg School of Medicine.

Stephen D. Persell, MD, MPH, is associate professor of Medicine and Director of the Center for Primary Care Innovation within the Institute for Public Health and Medicine at Northwestern University Feinberg School of Medicine. He is also the Director of Quality Improvement in the Division of General Internal Medicine and Geriatrics at Northwestern University.

Patricia Fragen, BA, is the founder and president of Normal Moments, Inc. Normal Moments is a non-for-profit organization devoted to supporting parents with critically ill children in the home, in the hospital, and via web resources so that they can spend as much time as possible sharing normal moments with their children.

Jody D. Ciolino, PhD, is assistant professor in the Biostatistics Collaboration Center and Department of Preventive Medicine at Northwestern University Feinberg School of Medicine.

Laura C. Campbell, BS, is a clinical research coordinator at Ann & Robert H. Lurie Children's Hospital of Chicago.

Melanie Arenson, BA, is a clinical research associate at Ann & Robert H. Lurie Children's Hospital of Chicago.

Danica Y. Anciete, MS, is a clinical research associate and clinical navigator at Ann & Robert H. Lurie Children's Hospital of Chicago.

Melanie L. Brown, MD, MSE, is associate professor in the Department of Pediatrics at the University of Chicago & Biologic Sciences. She is also the Director of the Pediatric Comfort Team at the University of Chicago Medicine Comer Children's Hospital.

Farah N. Ali, MD, MS, is the Medical Director for Renal Medical Affairs in the United States at Baxter Healthcare.

Douglas White, MD, MAS, is the UPMC Endowed Chair for Ethics in Critical Care Medicine and Associate Professor of Critical Care Medicine at the University of Pittsburgh Medical Center. He is also the Director for the Program on Ethics and Decision Making in Critical Illness at the University of Pittsburgh Medical Center.