Title: Using qualitative research to inform development of professional guidelines: A Case Study of the SCCM Family Centered Care guidelines

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Abstract

Objective: To explore the importance, challenges, and opportunities of using qualitative research to enhance development of clinical practice guidelines, using recent guidelines for family-centered care in the intensive care unit as an example.

Methods: In developing the SCCM guidelines for Family Centered Care in the Neonatal, Pediatric and Adult Intensive Care Unit, we developed an innovative adaptation of the GRADE approach to explicitly incorporate qualitative research. Using GRADE and the Council of Medical Specialty Societies principles, we conducted a systematic review of qualitative research to establish family-centered domains and outcomes. Thematic analyses were undertaken on study findings and used to support Population, Intervention, Comparison, Outcome (PICO) question development.

Results: We identified and employed three approaches to using qualitative research in these guidelines. First, previously published qualitative research was used to identify important domains for the PICO questions. Second, this qualitative research was used to identify and prioritize key outcomes to be evaluated. Finally, we used qualitative methods, member-checking with patients and families, to validate the process and outcome of the guideline development.

Conclusions: In this a novel report, we provide direction for standardizing the use of qualitative evidence in future guidelines. Recommendations are made to incorporate qualitative literature review and appraisal, include qualitative methodologists in guideline taskforce teams, and develop training for evaluation of qualitative research into guideline development procedures. Effective methods of involving patients and families as members of guideline development represent opportunities for future work.

Introduction

The descriptive, exploratory findings of qualitative research bring much to our understanding about behaviors and experiences of individuals and social groups, [1] especially in situations where little is known.[2] Whilst the contribution of qualitative research to the science of health care continues to be defined and evaluated,[3,4] the potential for qualitative research to inform clinical knowledge and practice is recognized in the specialty of critical care.[5,6] Use of qualitative research to inform professional guidelines has also been explored.[7,8] Although, to date, this has mainly looked at 'which' qualitative studies have been used in professional guidelines, rather than critique of 'how and when' qualitative research can be used in guideline development processes.

In this paper, we explore the contribution that qualitative research can make to the development of critical care professional guidelines. We use the processes and methodology of the recently updated Family-Centered Care (FCC) guidelines as a case study. We describe the lessons learnt from our experience are shared, and recommendations for future guideline development.

Overview of the FCC guidelines project

The recent guidelines for Family Centered Care in the Neonatal, Pediatric and Adult Intensive Care Unit (ICU)[9] were developed through the American College of Critical Care/Society of Critical Care Medicine (ACCM/SCCM). Council of Medical Specialty Societies (CMSS) guidelines for guideline development were followed.[10] At the beginning of the project, operational definitions of 'family-centered care' and 'family' were developed through review of literature and policy documents and agreed on by all members of the guideline taskforce and by a sample of ICU survivors and family members. Review of qualitative research that explored FCC in the ICU was then conducted to identify key domains of FCC. Thematic analyses of qualitative findings were undertaken. Findings were used to develop core areas of the guidelines and inform components of population, intervention, comparison and outcomes (PICO) questions. A systematic review of quantitative research was then conducted using the PICO questions. GRADE methodology was used to appraise the quantitative research and to make guideline recommendations.[11,12,13] Full details of the project and the FCC guidelines recommendations are published elsewhere.[9] All authors of this paper were members of the FCC guidelines task force.

Methodology for using qualitative research in the FCC guidelines

In the past, ACCM/SCCM guideline groups would commence guideline development by writing PICO questions based upon the perspectives and clinical experience of the expert writing panel. In

developing the FCC guidelines, we utilized a novel approach that incorporated qualitative research in several different ways.

Descriptive, exploratory and explanatory qualitative research on FCC in the ICU was identified and reviewed over a six-month period. We posited that the qualitative literature would be rich with descriptions of important FCC concepts stemming from the perspective of patients, families, and clinicians (physicians, nurses and others), and that these would inform guidelines development. With recognized challenges in accurately retrieving qualitative research,[14,15,16,17] empirically-tested search filters[18,19] with high sensitivity (92%) and specificity (92%)[20] for qualitative research were applied to the databases searched. Searches were limited to English language publications between 1994-2014. All neonatal, pediatric and adult populations were included. Full details of the search strategy and data management processes are available.[9]

To analyze the identified qualitative research, an evidence-analysis tool was developed using recognized qualitative research constructs previously published.[21,22,,23] Three experts in qualitative research and qualitative data analysis reviewed the tool (Table 1) prior to use. Written and verbal guidance was developed for the guideline taskforce about how to use the evidence-analysis tool. Each taskforce reviewer received between eight to ten papers. Once all reviews were complete, appraisal sheets were checked by the taskforce team leaders. Key findings from individual studies were subjected to constant comparison and thematic analysis. Common themes were identified and discussed amongst the guideline taskforce and validated by patients and families engaged in the study.

Published qualitative research used in the FCC guidelines development

864 studies were identified that focused on family and clinician perspectives of FCC in ICU (Table 2). After elimination of duplicates, single case studies, narrative reviews of the literature, and abstracts, 228 qualitative studies were available for review. These studies described patient/family perspectives (n=133) or clinician perspectives (n=118) on aspects of FCC. Twenty-three of these studies explored FCC from multiple perspectives, that is from the perspective of clinicians, patients and family members. Twelve meta-syntheses were also considered and the references searched to find additional studies).

The qualitative studies were conducted across diverse ICU populations, for example: patient, family, nurses, physicians, and settings in neonatal, pediatric, and adult ICUs. These studies used a

range of qualitative methodologies, qualitative data collection methods and analytic approaches. This gave us confidence that family and clinicians perspectives of FCC had received wide and diverse exploration (Table 3). The eighteen initial developed sub-themes (Table 4) were synthesized to five over-arching themes within the qualitative literature.

Findings from this qualitative research analysis were used at certain points in the FCC guideline development (Figure 1). Specifically, we incorporated qualitative data in the key areas of: 1) review of qualitative research to inform development of the PICO domains; 2) review of qualitative research to inform selection and prioritization of PICO outcomes; and 3) use of qualitative methods to provide member checking of the results of the guideline development process from patients and family members.

Review of qualitative research to inform development of PICO domains

Review of the qualitative research brought considerable detail and nuanced understanding about the concept and key domains of FCC early on in the guideline project. A key issue raised by patients and families in the qualitative research was the importance of clinician support to help them become a family unit (in the case of an infant in ICU), or maintain the family unit (for older patients) while enduring the exposure to critical illness;[24,25] this area was not identified in the clinician literature. Qualitative studies also identified how patients and families reported that conflict between clinicians reduced their ability to cope with critical illness and delayed psychological healing.[26,27] In contrast, clinicians described being stressed when interacting with the families of critically ill patients and needing help to manage family emotions.[28] In this way, review of the qualitative studies informed taskforce thinking about FCC constructs and consequences, and helped define the process and outcomes of FCC at the project outset.

Sub-themes and themes developed from the qualitative evidence-appraisals and coding lists helped frame PICO questions used for the quantitative research review. For example, qualitative research had been conducted on open visiting hours, sibling/child visitation, family presence on rounds, and family presence during resuscitation. The theme that was developed from these findings led to the development of the PICO domain 'Family presence in the ICU'. The influence of these areas of qualitative research are seen in the following PICO questions from this domain:

- In the critical care environment, does **open family presence** at the bedside (also called open visiting) affect family satisfaction?

- Does **family presence during interdisciplinary team rounds** improve family psychological symptoms, family trust in clinicians, family satisfaction with and preferences for care or communication, family or clinician conflict, degree of shared decision-making, and family knowledge?
- Does **family presence during resuscitation** affect: family psychological symptoms, caregiver burden, family trust in clinicians, family satisfaction with care, family satisfaction with communication, family or clinician conflict?

The five PICO domains used for the guidelines were based on the final synthesized themes from the qualitative literature (family presence in the intensive care, family support, communication with family members, use of specific consultations and intensive care team members, and operational and environmental issues).

Review of qualitative research to inform selection of PICO outcomes

Findings from the qualitative review informed thinking about potential PICO outcomes. For example, studies that explored use of ICU diaries, family meetings and nursing communication qualitatively reported how these affected satisfaction with care,[29,30,31,32] emotional preparedness for events in ICU, and trust in clinicians.[33,34] This raised the importance of using measures of family satisfaction with care, family stress, family self-efficacy, and family trust in clinicians. Similarly, qualitative findings from studies focusing on family presence during resuscitation,[35,36,37,38,39,40] informed thinking about potential quantitative measures, such as family psychological symptoms, caregiver burden, family satisfaction with communication, and family-clinician conflict.

In some instances where we identified limited or no interventional studies that used quantitative assessment of outcomes in our systematic review, qualitative studies and assessment of qualitative outcomes after an intervention were used to inform the FCC guidelines. This was the case when exploring impact of provision of family support on family psychological symptoms. Three out of four identified intervention studies of peer-to-peer support in neonatal ICU provided qualitative description of the perceptions of health professionals[41] or mothers[42,43] regarding effects of the interventions. Findings from these studies suggested that families valued peer support interventions in neonatal ICU and this gave some support to the limited quantitative work in this area. Similar use of qualitative data[44,45] influenced the assessment of outcomes for family members of noise reduction interventions in the ICU. As per GRADE protocol, only level D (very low) quality could be assigned to these data since hypothesis testing is generally not the goal of qualitative studies. Our aim in this

approach was not to minimize the value of qualitative studies, but rather emphasize how qualitative studies can help inform and improve comprehensive guideline development.

Translating quantitative evidence about PICO outcomes into recommendations involved decisions that were similarly informed by the qualitative literature. Uncertainties about how much a particular outcome was valued, weighing the balance of desirable and undesirable effects of an intervention, or assessing costs-versus-benefit involved judgments based, in part, on qualitative data that informed recommendations where low level quantitative evidence was present. This was evident when considering family sleep space. Qualitative evidence highlighted the importance of disrupted sleep and sleep deprivation to families of critically ill patients, in combination with a desire to always be close to the ICU.[46,47] With no reported quantitative research on the effect on families of providing sleep space, a recommendation for provision of sleep space was made based on the qualitative findings.

Use of qualitative methods to provide member checking from patients and family members

Although patient involvement is suggested in the CMSS guidelines for development of clinical practice guidelines,[10] no standard exists to guide involvement of ICU survivors and family members in guideline development. In the development of the FCC guidelines, we involved a group of ICU survivors and family members to validate the domains of the PICO questions and outcome measures as relevant to patients and family members. For the FCC guidelines, former ICU patients and family members (n=27) were enrolled through Institutional Review Board (IRB) approved studies (University of Maryland IRB HP-0058018; University of California San Diego IRB 140458) as described previously,[9] using a snowball approach.[48]

Participants contributed at three time points during the guidelines development: development of operational definitions of 'family' and 'family-centered care'; consensus on the PICO domains; and rank-order of importance of PICO outcomes. Opinions and views of patients and family members were obtained via telephone interviews or via email, depending on participant preference. Whilst recommendations for the FCC guidelines arose from review of the quantitative evidence, the values and preferences expressed by patients and families were useful to endorse this evidence, especially for low or very low quality evidence. For example, the inclusion of spirituality and hope, daily communication, and participation in care were important for patients and families: these are reflected in the final FCC guidelines recommendations.

Recommendations to inform future use of qualitative research in guideline development

In our experience, review of the qualitative literature was beneficial in identifying the most important domains of FCC for development of PICO questions and prioritizing the domains of family-centered outcomes. Given the yield from our qualitative review, we recommend this approach for future guidelines. In addition, we also suggest that guideline-writing teams involve qualitative methodologists to complement the skills of the quantitative methodologists. This approach requires that qualitative review and appraisal be built into the project timeline. It is also important to incorporate the time to obtain consensus on a qualitative evidence appraisal tool, and to instruct guideline writing team members on how to appraise qualitative literature, similar to how training is required to appraise quantitative evidence using the GRADE methodology.

In the FCC guidelines, we reviewed qualitative research to inform selection and prioritization of the family-centered outcomes. We did not use qualitative research to assess efficacy of interventions, although recommendations were informed by qualitative findings. GRADE methodology offers limited guidance on incorporating qualitative data into the assessment of the certainty of evidence behind recommendations, although work is developing in this area.[49,50] Until robust guidance is developed, we would suggest that where quantitative data is weak, robust corroborating qualitative data builds confidence in the quantitative results, and can inform the guideline development process.

Use of qualitative methods to provide member checking from patients and family members was valuable in the development of this guideline. Direct feedback solicited from patient and family members generated qualitative evidence to support guideline processes and outcomes. Although the most effective method of involving patients and families in guideline development has yet to be determined, we would suggest that future guideline groups recruit patient and family members as full participants on guideline development groups. The best way to educate and support patient and family members for being involved in the guideline development process is not clear and represents an opportunity for future work. Their contribution can provide a valuable "service-user" perspective for a wide range of issues including: defining the guideline scope; prioritizing the PICO questions; selecting and prioritizing the outcomes; and ensuring that important consumer values and preferences are incorporated.

Conclusions

We have reported on the novel use of qualitative methods to enhance development of a clinical practice guideline, using the SCCM Family Centered Care Guidelines as an example. We identified and incorporated three specific approaches for using qualitative methods, including using qualitative research to inform development of the PICO question domains, using qualitative research to inform selection and prioritization of the outcomes, and using qualitative methods to provide member checking of the results of the guideline development. Inclusion of patient or family members as representatives on guideline development group is a fourth method that should be considered, although future work is needed to identify effective ways to enable full patient and family participation. In outlining our experiences, this paper offers direction about how qualitative research can inform future guidelines.

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Table 1: Areas of appraisal in qualitative evidence with examples of potential responses.

Population: patient, family, staff, physician, patient and family, staff and physicians, all, other
Age Group: neonatal, pediatric, adult, mixed
Methodology: grounded theory, discourse analysis, ethnography, phenomenology, phenomenography, content analysis, descriptive, case study, biography, historical, meta-synthesis, narrative analysis, general qualitative methods, not disclosed, other
Sampling Method: purposive, convenience, snowball, not declared, other
Data Collection Method: face-to-face, telephone, email, other
Transferability/Scale of Population: single center, multicenter one country, multicenter international, other
Research Design and Methodology Consistent with Aim: yes, no
Ethics review or IRB approval declared?: yes, no
Member Checking/Participant Feedback?: yes, no, n/a (chart review, mail, email)
Coding/Analysis method described?: yes, no
Depth of reporting?: Direct quotes provided to confirm themes, direct quotes not provided, n/a chart review, n/a survey did not include open ended questions
Sample size methodology reported: yes, no
Consistency: data matches conclusions, data does not match conclusions
Paraphrased Results: free text response
Major themes (aspects of FCC addressed): free text response

Table 2: Search results of family-centered care in ICU qualitative papers (n=864) identified prior to removal of duplicates.

Context / setting	Family-centered care	Qualitative	Database & date run	# results
"Intensive Care Units"[Mesh]OR "Critical Care"[Mesh] OR "Critical Care Nursing"[Mesh] OR "intensive care" OR "critical care"	Family-centered care	"Qualitative Research"[Mesh] OR (qualitative OR descriptive OR observational OR focus group OR survey OR case study OR phenomenolog* OR lived experience OR narrative OR interview* OR grounded theory)	PubMed 12/18/2013	114
intensive care OR critical care	Family centered care OR family centred care OR family-centered OR family-centred	(MH "Qualitative Studies") OR (qualitative OR descriptive OR observational OR focus group OR survey OR case study OR phenomenolog* OR lived experience OR narrative OR interview* OR grounded theory)	CINAHL 12/18/2013	240
intensive care OR critical care	Family centered care OR family centred care OR family-centered OR family-centred	qualitative OR descriptive OR observational OR focus group OR survey OR case study OR phenomenolog* OR lived experience OR	Web of Science 12/18/2013	510

Context / setting	Family-centered care	Qualitative	Database & date run	# results
		narrative OR interview* OR grounded theory		

Table 3: Selected methodological features from qualitative studies appraised for family-centered care guidelines

Methodology	Participants	Data collection method And/or type of approach/sampling	Data analysis
grounded theory	patients/families	Data collection:	Thematic analysis
discourse analysis	clinicians (physicians,	Interviews	Content analysis
ethnography	nurses, others)	Focus groups	Axial coding
phenomenology	both	face-to-face	Open
phenomenography		telephone	Theoretical
content analysis		mail	Taxonomic
descriptive		email	Other
case study		chart review	Not declared
biography			
historical		Sampling method:	
meta-synthesis		purposive	
narrative analysis		convenience	
general qualitative		consecutive	
methods		snowball	
not disclosed		not declared	
other		other	

Table 4: Themes developed from appraisal of qualitative research

| Patient Family Themes	Clinician Themes
Communication	Communication
Presence	Presence
Relationship-based care	Relationship-based care
Adaptation/Sensemaking	Adaptation/Sensemaking
Operational/Organizational	Operational/Organizational
End of life	End of life
Environment	Environment
Individualized care	Individualized care
Maintaining Family Integrity	Staff Consequences
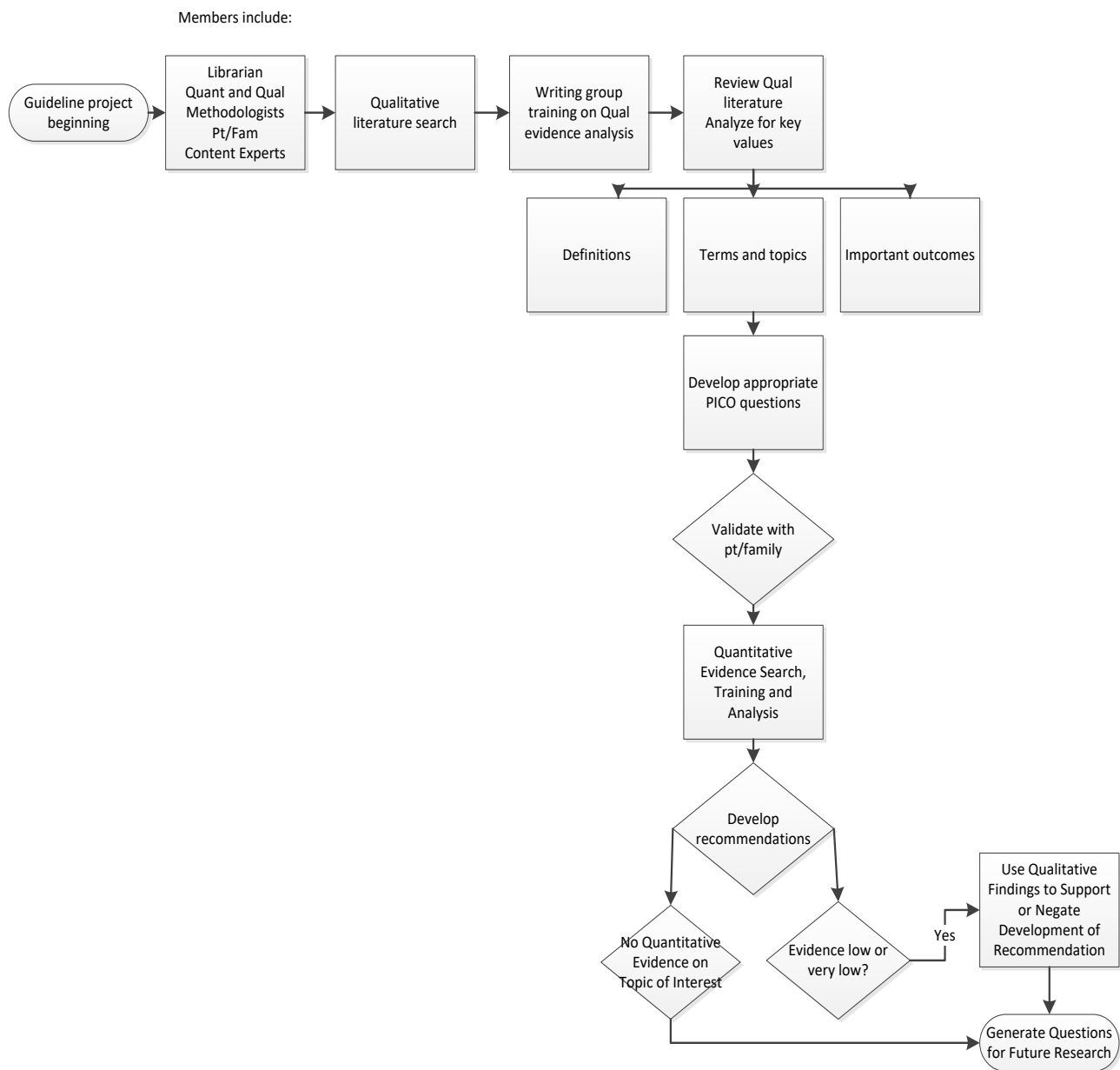
Figure 1: Process of Guidelines Development

Key: Quant - Quantative; qual - qualiatative; pt – patient; fam – family