FRONTIERS IN CARDIOVASCULAR OUALITY AND OUTCOMES

Qualitative Methodology in Cardiovascular Outcomes Research

A Contemporary Look

ABSTRACT: Qualitative research offers unique opportunities to contribute to cardiovascular outcomes research. Despite the growth in qualitative research over the last decade, outcomes investigators in cardiology still have relatively little guidance on when and how best to implement these methods in their investigations, leaving the full potential of these methods unrealized. We offer a contemporary look at qualitative methods, including publication trends of qualitative studies in cardiology journals from 1998 to 2018, novel emerging data collection and analytic methods, and current use and examples of cardiovascular outcomes research that apply qualitative methods such as user-centered design, preimplementation evaluation, implementation evaluation, effectiveness evaluation, and policy analysis.

utcomes research seeks to inform health and healthcare decisions at the individual, system, and policy levels by taking into account patients' experiences, preferences, and values in the context of complex healthcare settings. Studies examine cost-effectiveness, health status, disease burden, and clinical outcomes to improve health interventions and care delivery.^{1,2} There is increasing recognition that many aspects of these complex questions cannot be answered exclusively with quantitative methods.³ Accordingly, qualitative research continues to gain interest among outcomes researchers. Qualitative research is a form of scientific inquiry that spans different disciplines, fields, and subject matter and comprises many varied approaches.^{4,5} These methods are used to understand complex social processes, capture essential aspects of a phenomenon from the perspective of study participants, and uncover beliefs, values, and motivations that underlie individual health behaviors.^{5–7}

Notably, policy organizations, funding agencies, healthcare systems, and providers are increasingly focused on understanding patient and family-centered outcomes. The Patient-Centered Outcomes Research Institute was created in 2010 to focus on improving the quality of relevance of evidence available to help patients, families, clinicians, employers, insurers, and policy-makers make better-informed health decisions.⁸ Since 2012, Patient-Centered Outcomes Research Institute has funded hundreds of studies, with several of the initial studies incorporating qualitative methodologies.⁹ Exemplars in cardiovascular outcomes research include user-centered design, preimplementation evaluation, implementation evaluation, effectiveness evaluation, understanding disparities, and policy analysis. Despite the growth in qualitative research over the last decade, outcomes investigators in cardiology still have relatively little guidance on when and how best to implement Colleen K. McIlvennan, DNP, ANP Megan A. Morris, PhD, MPH Timothy C. Guetterman, PhD, MA Daniel D. Matlock, MD, MPH Leslie Curry, PhD, MPH

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qualitative research

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these methods in their investigations, leaving the full potential of these methods unrealized.

A review published in *Circulation* in 2009 described the types of questions for which qualitative approaches are most helpful, summarized primary principles and practices in qualitative methods, and synthesized standards for ensuring rigor and enhancing credibility of qualitative research.¹⁰ Herein, we offer a contemporary look at qualitative methods, including the frequency of qualitative studies in cardiology journals, current examples of cardiovascular outcomes research that use qualitative methods, and novel, newly emerging data collection and analytic methods. Our aim is to complement the comprehensive 2009 article with current information, further describing the potential role qualitative methods can play in cardiovascular outcomes research.

TRENDS IN QUALITATIVE RESEARCH IN CARDIOVASCULAR JOURNALS

To gain an understanding of the current state of published gualitative research in cardiovascular research, we performed a review of publications trends from 1998 through 2018 on PubMed.gov. According to 2017 SCImago Journal Rank, the top 30 cardiovascular journals were included in the search. We also included the top 3 cardiovascular nursing journals (ranked 102, 134, and 142 by SCImago Journal Rank indicator) as nursing journals tend to publish gualitative research more frequently. SCImago Journal Rank indicator is an alternative to impact factor and is a measure of scientific influence of scholarly journals that accounts for both the number of citations and the importance or prestige of the journals.¹¹ Inclusion criteria were research papers (not methods or opinions) and published in English. Mixed-methods papers were included as qualitative papers in the final analysis because they include a qualitative component by definition.

In PubMed, the advanced search strategy function was used with each journal name searched along with the following terms with and without parentheses: qualitative research, interview, focus group, grounded theory, phenomenology, content analysis, constant comparison, ethnography, and discourse analysis. All search results and abstracts were reviewed (or full paper if no abstract available) to ensure the article met inclusion criteria and was truly qualitative research in the way we intended.

Of 33 identified cardiovascular journals, 15 journals published a qualitative study from 1998 to 2018 for a total of 365 studies (Table 1). The 3 cardiovascular nursing journals published over three-quarters of articles (n=283, 78%). Five of the cardiovascular journals

only published one qualitative research study over the time period. The greatest number of gualitative studies published in one year was 34 in 2013; however, there has been an upward trend since 1998 in publications (Figure). The data suggest that high-impact cardiovascular journals are publishing more qualitative research studies than they were previously. The majority of cardiovascular qualitative studies are published in nursing journals. Qualitative methods remain a small minority in the cardiovascular literature for a variety of potential reasons including continuing skepticism about the relevance of gualitative findings, confusion or disagreement regarding standards for rigor in qualitative research, and lack of substantive training in the methodology for investigators and reviewers. A final potential factor is that, despite a modest increase in awards over the past 2 decades through organizations such as Patient-Centered Outcomes Research Institute, federal funding mechanisms for gualitative research remain proportionally low relative to overall research budgets.¹²

CURRENT USE OF QUALITATIVE METHODS

Qualitative research has evolved substantially over the past several decades. While core principles and practices remain, researchers have explored new ways in which to apply an increasingly diverse array of qualitative methods. The growth of areas such as implementation science and patient-reported outcomes has spurred interest, as well as the broader evolution of multidisciplinary research teams that include gualitative methods expertise. Qualitative methods can be considered when the research aim is one or more of the following: to investigate complex phenomena that are difficult to measure quantitatively, to generate data necessary for a comprehensive understanding of a problem, to aid in the rigorous development of quantitative measurement processes or instruments, or to study under-researched populations that are smaller and have unique experiences. Here, we provide illustrative examples to demonstrate the range of gualitative methods used in current empirical cardiovascular outcomes research literature.

Investigating Complex Phenomena That are Difficult to Measure Quantitatively

Metrics defining organizational performance are available, yet the mechanisms that drive these metrics (such as organizational culture and processes) can be difficult to capture quantitatively. A recent study explored how top-performing hospitals organize their resuscitation teams to achieve high survival

Table 1.	Number of Qualitative Research Publications by Journal,
1998 to 2	008

Journal Title	Qualitative Research Publications	2017 SCImago Journal Rank (SJR Indicator)	
Heart and Lung: Journal of Acute and Critical Care	110	0.757	
European Journal of Cardiovascular Nursing	100	0.945	
Journal of Cardiovascular Nursing	73	0.709	
Resuscitation	26	2.643	
Circulation. Cardiovascular Quality and Outcomes	13	2.743	
European Journal of Heart Failure	8	5.784	
Heart	8	2.853	
Journal of Heart and Lung Transplantation	7	4.592	
American Heart Journal	7	3.267	
Journal of the American Heart Association	7	2.674	
Circulation	2	8.95	
Journal of the American College of Cardiology	1	11.061	
European Heart Journal Cardiovascular Imaging	1	3.625	
Europace	1	2.748	
Stroke	1	3.529	

rates for in-hospital cardiac arrest through gualitative methods. Interviews were performed at 9 hospitals with 158 individuals across multiple disciplines. Sites were identified by risk-standardized in-hospital cardiac arrest survival to discharge rates between 2012 and 2014 and purposefully sampled to compare and contrast processes at high, middle, and lower performing sites. Resuscitation teams at top-performing hospitals demonstrated key features including dedicated or designated resuscitation teams, participation of diverse disciplines as team members during in-hospital cardiac arrest, clear roles and responsibilities of team members, realistic mock codes, and clear lines of communication, and leadership during in-hospital cardiac arrest.¹³ In the current healthcare landscape, understanding how to provide high-value care is essential; the results of this study provide recommendations that could assist individual hospitals in examining their own care processes.

Generating Data Necessary for a Comprehensive Understanding of the Problem

A recent study explored symptom perception in 36 outpatient individuals with chronic heart failure. With a longitudinal mixed methods design, researchers quantitatively measured thoracic fluid accumulation and daily reports of signs and symptoms. Semi-structured qualitative telephone interviews were performed every 2 weeks for 3 months to assess symptom identification and response patterns. Quantitatively, researchers found 44% of individuals had a symptom-hemodynamic mismatch for fluid retention. To characterize symptom perception, gualitative interviews identified 2 groups: (1) individuals who had difficulty detecting and interpreting their symptoms and (2) individuals who were able to monitor, interpret, and respond appropriately to symptoms. Individuals in the second group reported higher decision-making skills and guality of social support, yet both groups included individuals with symptom-hemodynamic mismatch and hospitalizations.¹⁴ Another study sought to gain an understanding of patient and cardiologists' perspectives about the decision-making process for implantable cardioverter defibrillators. Matlock et al¹⁵ performed semistructured, in-depth interviews with 11 cardiologists and 20 patients. The results highlighted the barriers to shared decision making when it comes to implantable cardioverter defibrillators, such as cardiologists' desire to adhere to published guidelines and patients' not understanding the risks and benefits of the device before implantation. These findings later informed the development of patient decision aids-a cornerstone of patient-centered care-for implantable cardioverter defibrillators.¹⁶

Rigorous Development of Quantitative Measurement Processes or Instruments

Qualitative methods can be useful in the development of patient-centered, quantitative instruments for outcomes research. Starting with qualitative methods helps to ensure that instruments are grounded in the views of the target audience rather than in the perspectives of researchers. For example, qualitative methods have been used in the early stages of developing patientcentered quantitative measures of health-related constructs.¹⁷ An example includes the health-related guality of life measure being developed for patients with mechanical circulatory support. To develop a psychometrically sound, patient-centered instrument measuring adjustment and health-related guality of life after mechanical circulatory support, gualitative interviews were performed with 30 patients and their caregivers. In this first phase, effects on guality of life for patients with mechanical circulatory support and their caregivers were explored, which included positive and negative outcomes.¹⁸ These findings subsequently will be used in the construction and validation of a standardized measure to assess patient adjustment and healthrelated guality of life after mechanical circulatory support implantation.



Figure. Number of qualitative research publications per year in top 30 cardiovascular journals by SCImago Journal Rank and 3 cardiovascular nursing Journals, 1998 to 2018.

Studying Unique and Under-Researched Populations

A recent qualitative study sought to describe the bereaved caregiver experience of a loved one dying with a left ventricular assist device in place. This group of individuals is small, since almost half of patients with a left ventricular assist device subsequently receive a heart transplantation.¹⁹ There is minimal research describing this experience, mostly due to difficulty locating and approaching these individuals after the death of their loved one. In addition, this experience is very unique with some patients electively deactivating their left ventricular assist device or more commonly, the device continuing to circulate blood after the patient's death. Eight bereaved caregivers were interviewed and described a complex end-of-life process as well as confusion surrounding the ethical and legally permissible care for patients dying with a left ventricular assist device.²⁰ These findings brought attention to the endof-life process with future research and initiatives now focused on improving care for these individuals.

CONTEMPORARY DATA COLLECTION AND ANALYTIC METHODS

In addition to more traditional forms of data collection such as in-person in-depth interviews and focus groups, the emergence of digital technology has created important opportunities for novel methods. Online focus groups and social media platforms are contemporary data collection methods that are gaining popularity in qualitative research. In addition, more rapid qualitative methods are being used to analyze data.

Online Focus Groups

Several types of online synchronous and asynchronous focus groups exist, including computer-mediated or internet-based focus groups, electronic focus groups, chat-based focus groups, or virtual panel discussion. Online focus groups offer cardiovascular outcomes researchers an alternative to in-person focus groups, especially for rare or unique conditions or populations that are geographically dispersed. Online approaches can also capture individuals who may not be open to sharing in a public forum or when leaving home is challenging or impossible. Few examples of online focus groups exist in the cardiology literature. In patients with cancer, an online focused group was conducted with gay and bisexual males diagnosed with prostate cancer.²¹ An asynchronous online focus group was conducted over a 4-week period, with 10 participants responding to a series of questions. Emergent themes included the psychosocial and physical impact of prostate cancer as well as a focus on ways to improve guality of life. The researchers concluded that these results should inform further research that focuses on the distress that accompanies the diagnosis and treatment of prostate cancer in gay and bisexual men. In this example, researchers were able to reach an understudied population through online focus groups and gain insight in to the emotional and physical impacts of the diagnosis. Although some caution that online groups have notable limitations, data from online focus groups

compared with traditional in-person focus groups suggests the approaches are broadly comparable.^{22,23}

Social Media Platforms

Social media platforms such as Facebook, Twitter, You-Tube, and Instagram, contain a vast amount of data that may be useful in addressing particular types of research questions. Such data can provide insight into daily activities, interactions, and communicative messages across comparatively large samples and can be analyzed relatively unobtrusively.²⁴ The use of social media platforms to perform qualitative research through content and thematic analyses is becoming increasingly popular. A cardiovascular research study used social media sites including Facebook, Twitter, and YouTube to characterize discussions related to left ventricular assist devices to assess the scope and guality of information available.²⁵ The analysis revealed that patients and caregivers use these sites to obtain and share information but also to seek psychosocial support. The results can be used to tailor further dissemination of health information, enhance current education related to left ventricular assist devices, and offer psychosocial support. Researchers have also used social media to explore other chronic disease processes, such as diabetes mellitus.²⁶ The 15 largest Facebook groups focused on diabetes mellitus management were identified, and thematic analysis was used to analyze 690 comments from wall posts and discussion topics from 480 unique users. The researchers found that patients, family members, and friends used Facebook to share personal experiences and information, ask questions, and receive emotional support. In addition, unsolicited sharing of diabetes mellitus management strategies was common. Less frequent were posts requesting personal information and promoting products. These data are important when seeking to understand behaviors and information access for patients with diabetes mellitus and offer support for the proposed public health benefits of social networking in the management of chronic disease.

Qualitative Comparative Analysis

In addition to these emerging methods of qualitative data collection, advances in analytic techniques also offer new possibilities for cardiovascular outcomes researchers. Qualitative comparative analysis (QCA) is an analytical method used to study complex causality.²⁷ In the field of outcomes research, this method provides the ability to identify pathways to an outcome as opposed to a list of factors that is associated with traditional thematic analysis. QCA may help identify factors that impact an outcome and provide more detailed recommendations for practice.²⁸ The method uses

boolean algebra and relies on qualitative data that is then transformed to numbers for analysis, facilitated by specific software programs. The first step of QCA is to identify an outcome of interest and a list of conditions (eg, factors) that may be associated with that outcome. Next, calibration metrics are developed, and data from the cases are transformed to numerical data.²⁷ A truth table is developed based on this data showing all possible combinations of conditions. The last steps involve arriving at pathways to the outcome. In the field of outcomes research, this method provides the ability to identify multiple potential pathways to an outcome as opposed to a list of static factors that are associated with traditional thematic analysis.

A review of the literature did not identify any published cardiovascular outcomes research that has used QCA; however, there have been a few studies in the cancer population that have used this method. A recent article explored organizational approaches at 8 hospitals that were associated with underuse of breast cancer care, defined as no radiation after lumpectomy in women <75 years or mastectomy in women ≥4 positive nodes, or no systemic therapy in women with tumors ≥1 cm.²⁹ QCA identified 3 pathways to lower rates of underuse. All hospitals with low underuse had high levels of information sharing, approaches to followup, and a patient-centered culture and one additional condition: (1) strong system support, (2) flexible and creative clinical staff, or (3) a private practice model. These QCA findings offer hospitals different pathways to achieve lower rates of underuse in breast cancer care. One possible use of QCA in the cardiovascular domain is examining factors that are evident in successful integration of palliative care specialists into outpatient cardiology practices for patients with symptomatic cardiovascular disease. Qualitative interviews with key stakeholders including clinicians, patients, and administrators would help to inform the different potential pathways to successful integration.

Natural Language Processing

One area that has emerged as a potential solution for analyzing large amounts of text data with a qualitative approach is natural language processing. Natural language processing is a sub-field of artificial intelligence that leverages computer algorithms to understand, interpret, and manipulate human language.³⁰ Researchers use several different methods, such as searching for text that has semantically similar meaning using an existing database—WordNet—that carefully maps word relationships.³¹ Essentially, natural language processing looks for clusters of text with similar meaning and returns an appropriate label for those clusters. Additional techniques, such as sentiment analysis can capture context and emotion. In a recent study, traditional qualitative text analysis, natural language processing analysis, and an augmented approach that combines qualitative and natural language processing methods were compared.³² Ultimately, an augmented approach proved to be most comprehensive, with natural language processing providing a foundation to code all data while adding only minimal time to the analysis and to provide a validity check of qualitative findings. Meanwhile, traditional qualitative text analysis provided important details and context. Further development and refinement of natural language processing and other technologically focused methods are needed though it shows promise when hand coding a large data set is not feasible.³³

Rapid Qualitative Methods

Qualitative methods play a major role in outcomes research, yet one of the most common criticisms is the amount of time it takes to perform a research study from start to finish. There has been increased focus on rapid qualitative methods, including rapid analysis techniques. While the use of rapid analysis techniques have been compared with traditional qualitative analysis techniques, it remains unknown exactly how much time is saved or if findings differ from traditional qualitative methods. Some detail may be lost in the rapid analysis processes; however, certain time-sensitive or novel research questions may benefit from a more rapid process.^{34,35}

One method, the rapid assessment process, is described as qualitative inquiry using triangulation, iterative data analysis and additional data collection to quickly develop preliminary understanding of a situation.³⁶ Rapid assessment focuses on data reduction and analysis in a team-based setting. A study of black and Latino men with diabetes mellitus was performed to understand how sex influences health behaviors.³⁷ Three focus groups were conducted and transcribed. Tables were created to organize the data. Researchers reduced the data to shorten and focus the tables on the aim of the study and thus identify common topics both within and across groups. The themes identified led researchers to conclude that sex values and beliefs may have implications on health behaviors in men with diabetes mellitus.

Another example is the use of mind mapping as a visual tool for engaging users during focus groups and analysis of qualitative data. In one example, 5 focus groups were conducted to gain insight into patient experiences of support services for people who misuse alcohol. A researcher created a mind map on a flip-chart during an audio-recorded focus group with users of the services, alcohol service providers, and others who were current or past alcohol misusers.³⁵ The structure of the map mirrored the interview questions used

by the facilitator, such as suggestions for improvements in current services and ideas for new prevention services. Participants were able to comment on the evolving mind map and were encouraged to correct any misinterpretations. Detailed field notes were taken. After the focus group, researchers listened to recordings of the discussion, consulted the field notes and made revisions to the mind map. The mind map was then sent to participants for member checking. The end result was a more rapid process of analysis, and a visual representation of the results that were used to enhance support services provided.

While these methods show promise, it remains unknown if they truly save time compared to more traditional methods or if findings differ.

ENSURING RIGOR OF QUALITATIVE RESEARCH

Despite the integration of qualitative methods in biomedical and outcomes research, as well as a vast body of literature defining principles and practices of these methods, questions about scientific rigor may persist. Concerns include the potential for researcher bias, a lack of reproducibility, and limited generalizability of findings.³⁸ Much like validity and reliability are evaluated in quantitative methods, trustworthiness in qualitative research is a term used to ensure studies are ethical, fair, and represent participants' experiences and perceptions accurately. It also confirms that researchers conform to standards for acceptable and competent conduct. The 4 criteria for trustworthiness include credibility, transferability, dependability, and confirmability (Table 2). Several specific techniques are recognized by gualitative experts to ensure trustworthiness of gualitative research. These include strategies for study design, data collection, analysis, and reporting. Experts caution that the rote use of these techniques does not necessarily confer rigor and that principles and assumptions of gualitative research design and analysis must be applied consistently.39-41

A number of useful guidelines exist for standardizing the reporting of qualitative research, thus setting standards for what a rigorous qualitative research study should entail. The Consolidated Criteria for Reporting Qualitative Research is a 32-item checklist that was published in 2007 aimed to standardize the reporting of interview and focus group research.⁴² Based on a comprehensive review of existing checklists, the Consolidated Criteria for Reporting Qualitative Research checklist includes 3 domains: research team and reflexivity, study design, and analysis and findings. Another guideline is the Standards for Reporting Qualitative Research published in 2014.⁴³ This checklist consists of 21 items and was developed after a comprehensive

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Qualitative Criterion	Definition	Techniques to Ensure Rigor in Qualitative Research	Related Concept in Quantitative Research	
Credibility	The confidence that is placed in the truth of the research findings; whether the research findings are plausible, drawn from original data, and correctly interprets participants' views	Member checking	Internal validity	
		Triangulation		
		Prolonged and varied engagement		
		Field notes		
Transferability	Degree to which themes or research protocols can be transferred or generalized to other settings, contexts, or populations	Audit trail	External validity	
		Purposive sampling		
		Thorough description of sample, environment, and research process		
Dependability Degree to which the researchers account for and		Audit trail	Reliability	
	the changing contexts and circumstances during the study	Use of multiple coders		
		Multidisciplinary research team		
Confirmability	Degree to which the results can be confirmed or corroborated by other researchers	Audit trail	Objectivity	
		Field notes		

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Audit trail: A transparent description of the research steps taken from the start of a research project to the development and reporting of findings. It may include examples of the coding process, descriptions, and rationale for development of codes.

Member checking: Sharing of the research findings with the research participants to determine accuracy and authenticity of the work. It can be performed during the interview process, at the conclusion of the study, or both.

Triangulation: The use of multiple methods or data sources to develop a comprehensive understanding of a phenomenon. There are 4 types: method triangulation, investigator triangulation, theory triangulation, and data source triangulation.

review of the literature and input from external reviewers. The Enhancing the Quality and Transparency of Health Research Network has approved Consolidated Criteria for Reporting Qualitative Research and Standards for Reporting Qualitative Research as qualitative reporting guidelines.⁴⁴ In addition, these standards have been adopted by some scientific journals as a standard when submitting qualitative research; however, guidelines should be used with judgment and integrity, with the primary aim of reporting rigorous qualitative research and are not a substitute for judging for the quality of the study.⁴¹

Applications of Qualitative Methodology in Cardiovascular Outcomes Research

Qualitative research, either as an independent study or within the context of a mixed methods study, offers unique opportunities to contribute to the empirical literature on key aspects of cardiovascular outcomes research. The following examples illustrate the use of these approaches in selected areas of cardiovascular outcomes research, including user-centered design, preimplementation evaluation, implementation evaluation, effectiveness evaluation, understanding disparities, and policy analysis.

User-Centered Design

The iterative approach in user-centered design can be valuable in developing interventions that are feasible and applicable to the intended recipient. Although widely used in the development of products, services, and systems, user-centered design is only recently being applied to health care interventions.⁴⁵ Qualitative approaches are ideal when seeking to understand patient, caregiver, clinician, and system needs. A series of studies aimed to understand the decision-making processes for patients, caregivers, and mechanical circulatory support coordinators when considering destination therapy left ventricular assist devices.^{46–48} Semistructured qualitative interviews were performed with 22 patients, 17 caregivers, and 18 mechanical circulatory support coordinators. Emotion, complexity, burden, and realistic expectations were among the factors identified as important in the decision-making process. The findings were used to develop a decision support tool for patients and caregivers considering a left ventricular assist devices.^{46–48} Iterative development of the decision aids was performed, with feedback from end-users including patients, caregivers, and members of the healthcare team.⁴⁹ To ensure dependability, a detailed audit trail of changes throughout the user-centered design was maintained.

Preimplementation Evaluation

Identifying barriers and facilitators to change is an important preliminary step to inform intervention design. Potential barriers and facilitators within programs, organizations, or healthcare systems can often best be identified using qualitative methods. As part of a larger study to evaluate the implementation of a multifaceted strategy for stroke assessment, Hamilton⁵⁰

performed a mixed methods study to assess the facilitators and barriers to this change. Semi-structured interviews with 20 staff members and 6 patients recently discharged were performed. Focus groups were also conducted. The Team Climate Inventory guestionnaire was sent to 206 staff members, with 148 responses. The qualitative and quantitative data revealed several facilitators to change such as positive work environments, positive examples of past organizational change, and organizational commitment to education as well as several barriers to change such as weak team climate in some teams, negative examples of past organizational change, and varying structure in current assessment practices. The results informed a combined strategy to implement change consisting of the use of leadership, education, and evidence-based guidelines for assessment. Another study aimed to evaluate factors influencing cardiologists' perspective about pharmacogenomic testing in clinical practice to inform future pharmacogenomic interventions.⁵¹ Sixteen cardiologists were interviewed, and 6 themes were identified: cardiologists' knowledge and needs, perceived clinical validity and utility of pharmacogenomic testing, dissemination and management of pharmacogenomic results, patient-related considerations and incidental findings. Most cardiologists cited lack of evidence as a major barrier to use in cardiovascular medicine.

Implementation Evaluation

A major focus of the current healthcare landscape is implementation science—the study of methods to promote the integration of research findings and evidence into policy and practice.⁵² Qualitative methods are used to assess implementation evaluation in a study by Kim et al.⁵³ A longitudinal qualitative study was performed at 21 hospitals to assess barriers and facilitators of implementation of targeted temperature management after cardiac arrest. Forty interviews and 2 focus groups conducted over a one-year period revealed 3 major themes: (1) healthcare professionals' perceptions of the guidelines and protocols, (2) interdisciplinary and interprofessional collaboration, and (3) organizational resources. Targeted interventions and resources based on these themes were proposed as potential solutions.

Effectiveness (or Lack Thereof) Evaluation

Translation of evidence-based practices in to clinical care is a major focus of outcomes and effectiveness research. For example, a group of researchers performed a 2-year mixed methods study at 10 hospitals aimed at assessing the integration of pharmacists into quality-improvement initiatives focus on patients hospitalized with acute myocardial infarction.⁵⁴ In-depth interviews and ethnographic observations of key staff were performed, in addition to guantitative data collection including adoption of 5 evidence-based strategies associated with reducing risk-standardized mortality rates for acute myocardial infarction, changes in 5 key domains of organizational culture, and risk-standardized mortality rates for acute myocardial infarction. The results of the study showed a significant increase in mean number of evidence-based strategies used per hospital (2.4 at baseline to 3.9 at 24 months, P=0.02). Innovative approaches for integrating pharmacists included information technology solutions, targeted rounding on patients, medication-bridging programs, and education of patients. These findings support the need for generating novel, feasible solutions to ensure evidence-based care, and can be used to inform future pharmacy initiatives focused on evidencebased strategies in hospitalized patients.

Understanding Health and Healthcare Disparities

Disentangling the potential sources of documented disparities in access to and outcomes of cardiac care has been identified as a priority. Engagement in self-care can improve outcomes; however, little is known about self-care practices in black patients with heart failure. Dickson et al⁵⁵ performed a mixed-methods study with 30 black patients with heart failure to assess cultural beliefs, social support, and beliefs about self-care. Indepth interviews and standardized instruments measuring self-care and social-support were used for data collection. Overall, self-care was poor in this group and was influenced by factors such as spirituality, cultural beliefs, dietary preferences, and the belief that heart failure was inevitable or related to stress. Culturally sensitive interventions are needed and can be grounded in the findings presented.

Policy

Qualitative methods can be used to inform and evaluate policy. The Hospital Readmissions Reduction Program, a Medicare value-based purchasing program that reduces payments to hospitals with excess readmissions, was enacted in 2012.⁵⁶ Brewster et al⁵⁷ sought to understand how hospitals improved readmission rates and evaluate whether changes to clinical and organizational practices differed from hospitals whose readmission rates increased. A qualitative study of 82 hospital staff at 10 hospitals, a combination high-performing and low-performing organizations, was conducted. Several organizational practices were identified in highperforming hospitals that enhanced the effectiveness of readmission reduction strategies, including collaboration across hospital departments, sharing data with post-acute providers, engagement in trial and error learning, and emphasized patient-focused outcomes of readmissions. These findings provided insight into how hospitals addressed the Hospital Readmission Reduction Program and offered organizational approaches to improve readmission rates.

CONCLUSIONS

Qualitative research offers unique opportunities to contribute to cardiovascular outcomes research. The use of qualitative methodology has evolved in exciting ways, and researchers have become more sophisticated and creative in the application of gualitative methods. Many opportunities exist for developing new and adaptable ways to conduct and apply gualitative methods. Technology offers tremendous potential, with innovative methods of data collection through images and videos as well as capitalizing on the plethora of text data in online forums, electronic medical records, and text messaging. Contemporary data collection methods and use in areas such as user-centered design, preimplementation evaluation, implementation evaluation, effectiveness evaluation, and policy analysis are emerging. High-impact cardiovascular journals are publishing more qualitative research studies than they were previously; however, the method remains underused. We encourage investigators to consider adding gualitative methods expertise to their teams and to consider the full potential of these methods to address complex questions in cardiovascular outcomes research.

ARTICLE INFORMATION

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Disclosures

None.

REFERENCES

- 1. Jefford M, Stockler MR, Tattersall MH. Outcomes research: what is it and why does it matter? *Intern Med J.* 2003;33:110–118.
- Krumholz HM. Outcomes research: myths and realities. Circ Cardiovasc Qual Outcomes. 2009;2:1–3. doi: 10.1161/CIRCOUTCOMES.108.844035
- Krumholz HM, Bradley EH, Curry LA. Promoting publication of rigorous qualitative research. *Circ Cardiovasc Qual Outcomes*. 2013;6:133–134. doi: 10.1161/CIRCOUTCOMES.113.000186

- Denzin NK, Lincoln YS. The SAGE Handbook of Qualitative Research. Thousand Oaks, Calif.: Sage Publications; 2017.
- 5. Sandelowski M. Using qualitative research. *Qual Health Res.* 2004;14:1366–1386. doi: 10.1177/1049732304269672
- Creswell JW, Poth CN. Qualitative Inquiry and Research Design: Choosing Among Five Approaches. Thousand Oaks, Calif.: Sage Publications; 2016.
- Sandelowski M. "To be of use": enhancing the utility of qualitative research. Nurs Outlook. 1997;45:125–132.
- Patient Centered Outcomes Research Institute (PCORI). 2019. https:// www.pcori.org. Accessed January 29, 2019.
- 9. Vandermause R, Barg FK, Esmail L, Edmundson L, Girard S, Perfetti AR. qualitative methods in patient-centered outcomes research. *Qual Health Res.* 2017;27:434–442. doi: 10.1177/1049732316668298
- Curry LA, Nembhard IM, Bradley EH. Qualitative and mixed methods provide unique contributions to outcomes research. *Circulation*. 2009;119:1442–1452. doi: 10.1161/CIRCULATIONAHA.107.742775
- 11. Scimago Journal and Country Rank. 2019. https://www.scimagojr.com. Accessed January 24, 2019.
- Coyle CE, Schulman-Green D, Feder S, Toraman S, Prust ML, Plano Clark VL, Curry L. Federal funding for mixed methods research in the health sciences in the United States: recent trends. *Journal of Mixed Methods Research*. 2018;12:305–324.
- Nallamothu BK, Guetterman TC, Harrod M, Kellenberg JE, Lehrich JL, Kronick SL, Krein SL, Iwashyna TJ, Saint S, Chan PS. How Do Resuscitation Teams at Top-Performing Hospitals for In-Hospital Cardiac Arrest Succeed? A Qualitative Study. *Circulation*. 2018;138:154–163. doi: 10.1161/CIRCULATIONAHA.118.033674
- Riegel B, Dickson VV, Lee CS, Daus M, Hill J, Irani E, Lee S, Wald JW, Moelter ST, Rathman L, Streur M, Baah FO, Ruppert L, Schwartz DR, Bove A. A mixed methods study of symptom perception in patients with chronic heart failure. *Heart Lung.* 2018;47:107–114. doi: 10.1016/j.hrtlng.2017.11.002
- Matlock DD, Nowels CT, Masoudi FA, Sauer WH, Bekelman DB, Main DS, Kutner JS. Patient and cardiologist perceptions on decision making for implantable cardioverter-defibrillators: a qualitative study. *Pacing Clin Electrophysiol.* 2011;34:1634–1644. doi: 10.1111/j.1540-8159.2011.03237.x
- Implantable Cardioverter Defibrillator (ICD). Colorado Program for Patient Centered Decisions. 2019. www.patientdecisionaid.org/ICD. Accessed February 2, 2019.
- Krause N. The use of qualitative methods to improve quantitative measures of health-related constructs. *Med Care.* 2006;44(11 suppl 3):S34– S38. doi: 10.1097/01.mlr.0000245429.98384.23
- Magasi S, Buono S, Yancy CW, Ramirez RD, Grady KL. Preparedness and mutuality affect quality of life for patients with mechanical circulatory support and their caregivers. *Circ Cardiovasc Qual Outcomes*. 2019;12:e004414. doi: 10.1161/CIRCOUTCOMES.117.004414
- Kormos RL, Cowger J, Pagani FD, Teuteberg JJ, Goldstein DJ, Jacobs JP, Higgins RS, Stevenson LW, Stehlik J, Atluri P, Grady KL, Kirklin JK. The society of thoracic surgeons intermacs database annual report: evolving indications, outcomes, and scientific partnerships. J Heart Lung Transplant. 2019;38:114–126. doi: 10.1016/j.healun.2018.11.013
- Mclivennan CK, Jones J, Allen LA, Swetz KM, Nowels C, Matlock DD. bereaved caregiver perspectives on the end-of-life experience of patients with a left ventricular assist device. *JAMA Intern Med.* 2016;176:534– 539. doi: 10.1001/jamainternmed.2015.8528
- Thomas C, Wootten A, Robinson P. The experiences of gay and bisexual men diagnosed with prostate cancer: results from an online focus group. *Eur J Cancer Care (Engl).* 2013;22:522–529. doi: 10.1111/ecc.12058
- Underhill C, Olmsted MG. An experimental comparison of computer-mediated and face-to-face focus groups. *Social Science Computer Review*. 2003;21:506–512.
- Rupert DJ, Poehlman JA, Hayes JJ, Ray SE, Moultrie RR. virtual versus inperson focus groups: comparison of costs, recruitment, and participant logistics. J Med Internet Res. 2017;19:e80. doi: 10.2196/jmir.6980
- Paulus TM, Wise AF. Looking for insight, transformation, and learning in online talk. New York: Routledge; 2019.
- Kostick KM, Blumenthal-Barby JS, Wilhelms LA, Delgado ED, Bruce CR. Content analysis of social media related to left ventricular assist devices. *Circ Cardiovasc Qual Outcomes*. 2015;8:517–523. doi: 10.1161/ CIRCOUTCOMES.115.002032
- Greene JA, Choudhry NK, Kilabuk E, Shrank WH. Online social networking by patients with diabetes: a qualitative evaluation of communication with Facebook. J Gen Intern Med. 2011;26:287–292. doi: 10.1007/s11606-010-1526-3

- Rihoux B, Ragin CC. Configurational comparative methods: Qualitative Comparative Analysis (QCA) and related techniques. Thousand Oaks, Calif.: SAGE Publications; 2009.
- McAlearney AS, Walker D, Moss AD, Bickell NA. using qualitative comparative analysis of key informant interviews in health services research: enhancing a study of adjuvant therapy use in breast cancer care. *Med Care.* 2016;54:400–405. doi: 10.1097/MLR.00000000000503
- Bickell NA, Moss AD, Castaldi M, Shah A, Sickles A, Pappas P, Lewis T, Kemeny M, Arora S, Schleicher L, Fei K, Franco R, McAlearney AS. organizational factors affect safety-net hospitals' breast cancer treatment rates. *Health Serv Res.* 2017;52:2137–2155. doi: 10.1111/1475-6773.12605
- Chowdhury GG. Natural language processing. Annu Rev Inform Sci Technol. 2003;37:51–89.
- 31. Miller GA. WordNet: a lexical database for English. *Commun ACM*. 1995;38:39–41.
- Guetterman TC, Chang T, DeJonckheere M, Basu T, Scruggs E, Vydiswaran VGV. Augmenting qualitative text analysis with natural language processing: methodological study. *JMed Internet Res.* 2018;20:e231. doi: 10.2196/jmir.9702
- Lauer C, Brumberger E, Beveridge A. Hand collecting and coding versus data-driven methods in technical and professional communication research. *IEEE Transactions on Professional Communication*. 2018;61: 389–408.
- 34. Taylor B, Henshall C, Kenyon S, Litchfield I, Greenfield S. Can rapid approaches to qualitative analysis deliver timely, valid findings to clinical leaders? A mixed methods study comparing rapid and thematic analysis. BMJ Open. 2018;8:e019993. doi: 10.1136/bmjopen-2017-019993
- 35. Burgess-Allen J, Owen-Smith V. Using mind mapping techniques for rapid qualitative data analysis in public participation processes. *Health Expect*. 2010;13:406–415. doi: 10.1111/j.1369-7625.2010.00594.x
- 36. Beebe J. Rapid Assessment Process: An Introduction. Rowman & Littlefield Pub Incorporated; 2001.
- Hawkins J, Watkins DC, Kieffer E, Spencer M, Piatt G, Nicklett EJ, Lebron A, Espitia N, Palmisano G. an exploratory study of the impact of gender on health behavior among African American and Latino Men with type 2 diabetes. *Am J Mens Health.* 2017;11:344–356. doi: 10.1177/1557988316681125
- Sandelowski M. Rigor or rigor mortis: the problem of rigor in qualitative research revisited. ANS Adv Nurs Sci. 1993;16:1–8.
- Bradley EH, Curry LA, Devers KJ. Qualitative data analysis for health services research: developing taxonomy, themes, and theory. *Health Serv Res.* 2007;42:1758–1772. doi: 10.1111/j.1475-6773.2006.00684.x
- Hannes K, Heyvaert M, Slegers K, Vandenbrande S, Van Nuland M. Exploring the Ppotential for a consolidated standard for reporting guidelines for qualitative research: an argument delphi approach. *Int J Qual Methods*. 2015;14:1609406915611528.
- Barbour RS. Checklists for improving rigour in qualitative research: a case of the tail wagging the dog? *BMJ.* 2001;322:1115–1117. doi: 10.1136/bmj.322.7294.1115
- Tong A, Sainsbury P, Craig J. Consolidated criteria for reporting qualitative research (COREQ): a 32-item checklist for interviews and focus groups. *Int J Qual Health Care.* 2007;19:349–357. doi: 10.1093/ intqhc/mzm042
- O'Brien BC, Harris IB, Beckman TJ, Reed DA, Cook DA. Standards for reporting qualitative research: a synthesis of recommendations. Acad Med. 2014;89:1245–1251. doi: 10.1097/ACM.00000000000388

- Enhancing the Quality and Transparency of Health Research (EQUATOR Network). 2019. http://www.equator-network.org. Accessed March 14, 2019.
- 45. Witteman HO, Chipenda Dansokho S, Colquhoun H, Fagerlin A, Giguere AMC, Glouberman S, Haslett L, Hoffman A, Ivers NM, Légaré F, Légaré J, Levin CA, Lopez K, Montori VM, Renaud JS, Sparling K, Stacey D, Volk RJ. twelve lessons learned for effective research partnerships between patients, caregivers, clinicians, academic researchers, and other stakeholders. J Gen Intern Med. 2018;33:558–562. doi: 10.1007/s11606-017-4269-6
- McIlvennan CK, Allen LA, Nowels C, Brieke A, Cleveland JC, Matlock DD. Decision making for destination therapy left ventricular assist devices: "there was no choice" versus "I thought about it an awful lot". *Circ Cardiovasc Qual Outcomes.* 2014;7:374–380. doi: 10.1161/CIRCOUTCOMES. 113.000729
- Mclivennan CK, Jones J, Allen LA, Lindenfeld J, Swetz KM, Nowels C, Matlock DD. Decision-making for destination therapy left ventricular assist devices: implications for caregivers. *Circ Cardiovasc Qual Outcomes*. 2015;8:172–178. doi: 10.1161/CIRCOUTCOMES.114.001276
- McIlvennan CK, Matlock DD, Narayan MP, Nowels C, Thompson JS, Cannon A, Bradley WJ, Allen LA. Perspectives from mechanical circulatory support coordinators on the pre-implantation decision process for destination therapy left ventricular assist devices. *Heart Lung.* 2015;44:219– 224. doi: 10.1016/j.hrtlng.2015.01.012
- Thompson JS, Matlock DD, McIlvennan CK, Jenkins AR, Allen LA. Development of a decision aid for patients with advanced heart failure considering a destination therapy left ventricular assist device. JACC Heart Fail. 2015;3:965–976. doi: 10.1016/j.jchf.2015.09.007
- Hamilton S, McLaren S, Mulhall A. Assessing organisational readiness for change: use of diagnostic analysis prior to the implementation of a multidisciplinary assessment for acute stroke care. *Implement Sci.* 2007;2:21. doi: 10.1186/1748-5908-2-21
- Deininger KM, Page RL II, Lee YM, Kauffman YS, Johnson SG, Oreschak K, Aquilante CL. Non-interventional cardiologists' perspectives on the role of pharmacogenomic testing in cardiovascular medicine. *Per Med.* 2019;16:123–132. doi: 10.2217/pme-2018-0099
- Brownson RC, Colditz GA, Proctor EK. Dissemination and Implementation Research in Health: Translating Science to Practice. New York: Oxford University Press; 2012.
- Kim YM, Lee SJ, Jo SJ, Park KN. Implementation of the guidelines for targeted temperature management after cardiac arrest: a longitudinal qualitative study of barriers and facilitators perceived by hospital resuscitation champions. *BMJ Open.* 2016;6:e009261. doi: 10.1136/bmjopen-2015-009261
- Curry LA, Brault MA, Cherlin E, Smith M. Promoting integration of pharmacy expertise in care of hospitalized patients with acute myocardial infarction. *Am J Health Syst Pharm.* 2018;75:962–972. doi: 10.2146/ajhp170727
- Dickson VV, McCarthy MM, Howe A, Schipper J, Katz SM. Sociocultural influences on heart failure self-care among an ethnic minority black population. J Cardiovasc Nurs. 2013;28:111–118. doi: 10.1097/JCN. 0b013e31823db328
- Mcllvennan CK, Eapen ZJ, Allen LA. Hospital readmissions reduction program. *Circulation*. 2015;131:1796–1803. doi: 10.1161/CIRCULATIONAHA. 114.010270
- Brewster AL, Cherlin EJ, Ndumele CD, Collins D, Burgess JF, Charns MP, Bradley EH, Curry LA. What Works in Readmissions Reduction: How Hospitals Improve Performance. *Med Care.* 2016;54:600–607. doi: 10.1097/MLR.00000000000530