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Title

Lessons Learned Establishing the Palliative Care Research Cooperative's Qualitative Data Repository

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Abstract

Data sharing is increasingly an expectation in health research ~~since~~as part of a general move toward more open sciences. In the United States, in~~I~~ –particular, the implementation of the 2023 National Institutes of Health Data Management and Sharing Policy~~. Qualitative~~ has made it clear that qualitative studies are not exempt from this data sharing requirement. Recognizing this trend, the Palliative Care Research Cooperative Group (PCRC) realized the value of creating a de-identified qualitative data repository to complement its existing de-identified quantitative data repository. The PCRC Data Informatics and Statistics Core leadership partnered with the Qualitative Data Repository (QDR) to ~~develop guidelines for depositing and sharing qualitative data, creating~~establish the first serious illness and palliative care qualitative data repository in the U.S. We describe the processes used to develop this repository, called the PCRC-QDR, as well as our outreach and education among the palliative care researcher community, which le~~a~~d to the first ten projects to share the data ~~contained~~ in the new repository~~, as well as lessons learned.~~. Specifically, we discuss ~~options~~how we co-designed the PCRC-QDR and created tailored guidelines for ~~data~~

depositing and sharing, qualitative data depending on the original research context, establishing uniform expectations for key components of relevant documentation, and the use of suitable access controls for sensitive data. We also describe how PCRC was able to leverage its existing community to recruit and guide early depositors and outline lessons learned in evaluating the experience. This work advances the establishment of best practices in qualitative data sharing.

Key Message: The article describes the process of developing the first data repository of qualitative research in palliative and serious illness care. Our experience shows that ethical sharing of qualitative data from palliative-care research is possible but requires careful consideration throughout the research process.

Key Words: qualitative data; data sharing; open science; data repository; ~~Palliative Care~~palliative care

Running Title: The PCRC~~'s~~ Qualitative Data Repository

Introduction

The National Institutes of Health (NIH) Data Management and Sharing policy took effect on January 25, 2023. The goal of this U.S. federal policy is to increase the pace of biomedical research and ultimately improve the health and wellbeing of individuals and communities. As part of this policy, NIH-funded investigators and institutions are required to follow established standards for managing and sharing research data, including creating data management and sharing plans (DMSP~~PS~~s) that outline how data will be collected, organized, and shared during and after a study. These plans must accompany all NIH grant applications, and it is expected that appropriate sharing of data will be maximized for NIH-funded and supported studies and contracts that generate scientific data, including from qualitative research. NIH expects investigators and institutions to budget for and comply with their approved data management plans.(1)

This is the first new policy of its kind since 2003 and is a laudable step as avoidable waste in production of research evidence has been widely recognized. One estimate is that 85% of research dollars do not translate into intended public health impact.(2) This waste is worsened by not sharing research and scientific data. ~~Data sharing~~Data sharing after the end of a project can multiply the benefits of research in several ways. First, it provides an opportunity to generate new evidence and ask new questions of existing evidence through data re-use and synthesis~~.~~ both by the original researchers and by others outside of the research team. This can increase the impact of the ~~original~~initial data collection and allow more effective reappraisal of published work.(3) Shared data facilitates research transparency and verification, which both enhance the robustness of scientific results and trust in their accuracy. Shared data also permits more effective pedagogy, exposing students to realistic data in the classroom. Not least – and

particularly relevant for studies from the vulnerable participants typically involved in PCRC-type research – sharing qualitative data can also bring about ethical benefits to populations and communities that are the subject of study~~,~~ by allowing researchers to avoid unnecessary repeated intrusion and study burden if data on pertinent questions have already been collected by others.

While the scientific community generally recognizes the importance of sharing empirical data, debate continues about best practices for ensuring that data, including qualitative data, are shared in a responsible and ethical manner.(4–9) Concerns about sharing of qualitative data include: protecting the privacy and confidentiality of research participants, especially vulnerable or protected groups such as children~~, persons from Tribal communities,~~ or those with rare or stigmatized conditions; the complexity of the data compared to quantitative data; and being able to de-identify, curate, and share qualitative data in a way that is meaningful and useful to other researchers~~.~~ (i.e., epistemological disconnect (10, 11)). Practical concerns include lack of standard criteria, time, and resources to de-identify the data, and identifying suitable platforms or data repositories. ~~Establishment of best practices to address these challenges is ongoing.~~

Consequently, shared qualitative research data are scarce. A recent ten-year review found only seventy-one studies that reported secondary analysis of qualitative data published in a wide range of social and health-related peer-reviewed journals.(10) This limited amount of qualitative data sharing is concerning because ~~of the bias that can be introduced into~~ the evidence generated may lack ~~base when~~ rich descriptions of a ~~person~~person's or a family's lived experience and contextual considerations ~~are missing~~. Without parity between quantitative and qualitative data sharing, potential methodological bias in favor of quantitative data and subsequent results will impact what evidence is available to answer questions and, ultimately, impact care of seriously ill people, their families, and their communities. In addition, collecting qualitative data often is

labor-intensive, so not reusing these data is a missed opportunity.(12) In contrast, quantitative data are regularly used for secondary analyses by researchers other than the primary collectors that are useful in answering research questions that differ from the original study questions. (e.g., 13–17) This more frequent secondary analysis of quantitative but not qualitative data may lead to a preponderance of publication of only quantitatively-~~–~~based findings. The scarcity of qualitative data sharing is also concerning because it creates a barrier to the secondary data use of multi- and mixed-methods and hybrid implementation designs, which are increasingly common in NIH-funded and other health research for their ~~likelihood of~~promise of more far-reaching knowledge creation.

~~While secondary data analysis of quantitative data is increasingly recognized and encouraged across disciplines, secondary data analysis of qualitative data has met criticism and concerns regarding potential methodological and ethical problems.[11,12] For example, researchers have expressed concern about potential re-identification of participants, potential epistemological disconnect, and potential inability for secondary reviewers to understand the context within which the original data were collected.[11,12]~~

Specifically, qualitative studies make substantial contributions to scientific inquiry in end-of-life and palliative care, which fundamentally deals with personal, existential, spiritual, and experiential aspects of the human condition and yield valuable insights that cannot be gleaned from quantitative data alone.(18–21) To this end, and in response to requests from its members, Palliative Care Research Cooperative Group (PCRC) leaders decided to develop a qualitative data repository ~~in~~focused on palliative care research. The purpose of this paper is to describe the processes and lessons learned from developing the first qualitative data repository in palliative care in the United States (U.S.). Our goal is to contribute to the development of best practices in

capturing and sharing qualitative research data, particularly in light of the new NIH data sharing policy and ~~the need to advance palliative care and serious illness research~~in the hope of advancing palliative care and serious illness research in ~~a new way~~new ways. In ~~both~~ the description of our repository co-design ~~and initial deposit recruitment steps,~~ as well as in the concrete examples from the first PCRC-QDR deposits, we present a clear model for how the challenges raised above can be ~~overcome~~addressed so that ~~and~~ more qualitative data can be shared appropriately, ethically, and sustainably.

The Palliative Care Research Cooperative Group (PCRC) and Initial Repository Activity

Funded through a cooperative agreement with the NINR, the PCRC was the first nationwide palliative care cooperative group in the U.S.(22) A central aspect of the PCRC's mission was to leverage cooperative group structure and function to support palliative care investigators through pilot grants and unified data infrastructure based on common data elements and data sharing standards, within the bounds of regulatory requirements.

The PCRC initially created a de-identified data repository (DiDR) for quantitative data. (23) ~~Hosted by its Data Informatics and Statistics Core (DISC), use~~Use of ~~repository~~that repository's data ~~required~~requires an easy-to-use form to request data and access related study materials for secondary analysis from the consortium's Data Informatics and Statistics Core (DISC), which hosts the DiDR. This repository provided an important foundation and precedent for conceptualizing a qualitative data repository.

Processes of building a qualitative data repository

The PCRC DISC expanded its data repositories with the goal of developing the first qualitative data repository in palliative care in the U.S. The goals were to: 1) accelerate science through sharing and secondary use of qualitative, multi-, and multi- and mixed-method research data; and 2) bring more methodological balance and diversity by leveraging the potential of qualitative and mixed methods to shaping our body of knowledge for the benefit of patients, families, and societies.

~~[11,12]To~~To address ethical, methodological, and safety concerns, we formed an advisory committee of qualitative researchers and experts across a range of qualitative and multi- and mixed- methods who were known internationally for expertise in qualitative and mixed methods methods as evidenced through their publications, grant funding, teaching portfolios, and mentee scholarship. Led by DISC co-lead (primary author, S.H.M.), the committee engaged in several meetings to discuss feasibility, acceptability, ethical, legal, practical, and fiscal considerations of sharing qualitative data. A review of the literature on the state of qualitative data repositories and use of shared qualitative data informed the committee's discourse.

Committee members completed an original survey to explore the idea of developing a qualitative data repository in the field, as well as potential benefits and challenges. The general benefits of data sharing recognized by the committee included: knowledge generation; no added cost of study administration and data collection; maximization of outputs of research funded by public dollars; transparency and trust in the research process; greater visibility, impact, and collaboration; and compliance with funding agencies with an increasing emphasis on data sharing. Specific to palliative care, the committee considered potential benefits for maximizing the impact of data generated from patients and families during vulnerable stages in their lives and minimizing additional burden on research participants if a research question may be

meaningfully addressed using secondary data analysis. The committee also considered the challenges of data sharing, such as ensuring that ~~those who did the~~ secondary analyses acknowledg~~ed~~ how the data were context-bound, ensuring privacy and confidentiality when samples may contain individuals with rare diseases, and ~~ensuring that the~~whether and how investigators who ~~did~~ undertook ~~the~~ intensive primary data collection could control what secondary questions were asked of the data they coll~~e~~~~t~~cted. ~~-~~Thus, the committee was supportive of creating a qualitative data repository in palliative care and turned its attention to investigating related resources.

In the process of reviewing ~~the existing~~available resources, the committee researched and vetted ~~a new~~an existing repository focused on qualitative data ~~repository~~. Hosted by Syracuse University's Center for Qualitative and Multi-Methods Inquiry at the Maxwell School of Citizenship and Public Affairs and online since 2014, the Qualitative Data Repository (QDR) is the first data repository in the U.S. dedicated to archiving and sharing digital data (and accompanying documentation) generated or collected through qualitative and multi-method research in the social sciences and related disciplines~~.~~, including public health. The repository serves researchers from around the world, both as depositors and as secondary users.

The DISC co-lead (S.H.M.) met with the senior leaders of the QDR (S.K.) and learned that this fully curated domain repository could meet the PCRC's needs – robust processes and data safety – for a modest fee. Subsequent meetings occurred among the PCRC executive committee (JK, CR, KP), DISC leadership and QDR leadership to further assess the feasibility of the partnership (Box 1).

PCRC-QDR Partnership

In December 2019, the PCRC formalized a relationship with Syracuse University's Center for Qualitative and Multi-Methods Inquiry. Their QDR demonstrated a track record of diligent processes, such as working closely with investigators to consider specific considerations of their data and the people from whom ~~they~~the data were collected ~~it~~ (e.g., inclusion of full transcript versus excerpts, degree of deidentification, creation of best practices for planning for data sharing during proposal creation and language for informed consent forms, access controls in line with those provided for quantitative materials by the DiDR) in order to uphold qualitative rigor and data safety, our advisory committee's main concerns.

Among the many available data repositories, "domain repositories," which specialize in data in specific formats and/or from specific disciplines, generally provide the most sophisticated options for data sharing and are recommended as the first-best option by many journals and funders.(24) Data repositories are not centrally regulated, so identifying repositories that are trustworthy, i.e., will make data effectively findable, useable, and keep them secure for the long term, can be challenging. In the U.S., both the NIH and the White House Office of Science and Technology Policy have issued detailed catalogs of features of trustworthy repositories.(25, 26) The most widely used certification for data repositories is performed by the CoreTrustSeal, which provides peer-reviewed assessment of repositories based on sixteen key requirements and has ~~been~~to be renewed every three years to ensure continued compliance with community best practices even as those evolve.(27)

QDR has been continuously certified by CoreTrustSeal since the beginning of its existence and meets all requirements for repositories set out in federal guidelines.(28) QDR has received external funding from several organizations, including the National Science Foundation. Through its membership in the Data Preservation Alliance for the Social Sciences (Data-PASS),

QDR closely collaborates with other leading social science data archives in the U.S. (including the Inter-university Consortium for Political and Social Research [ICPSR], Harvard Dataverse, the Roper Center for Public Opinion Research, and the Odum Institute at the University of North Carolina). Additionally, Data-PASS members mutually assure continued access to data held by member institutions should one of them cease operations. However, QDR's mission is not limited to providing the infrastructure for sharing qualitative data. The development and dissemination of "guidance for managing, sharing, citing, and reusing qualitative data" is a core part of QDR's work as well, making it an ideal partner for PCRC as it both had the desired technologies in place and could lend expertise in shaping responsible policies for sharing qualitative PCRC data in particular.

Once the PCRC's relationship with the QDR was formalized, the DISC prepared detailed guidance for PCRC grantees as part of the "Resource Data Sharing Plan" on how to share qualitative data with the PCRC-QDR repository (https://palliativecareresearch.org/resources/documents).(29) Guidance included: 1) who can share data; 2) the QDR data deposit and approval process; 3) human subjects considerations; 4) qualitative data de-identification guidelines; 5) data preparation strategies to minimize loss of qualitative data and context; 6) use of access control options; 7) consent for data sharing and secondary analysis; 8) a data security statement; 9) types of data that can and cannot be shared; and 10) instructions for depositing multi- and mixed-methods data. Additionally, in consultation with QDR, DISC revised PCRC's required consent language document *(Information Sheet: Consent Form: PCRC Required Language)* to reflect language specific to sharing qualitative, multi- and mixed-methods studies. The updated language was disseminated to the then-current grantees to prevent issues with the scope of the consent for data sharing.

To ensure its long-term sustainability, QDR charges fees for individual deposits, which typically range from $250 to $2,000 (U.S. dollars), depending on required storage and curation labor. In addition, QDR offers ~~Institutional Membership~~institutional memberships at three different tiers that cover storage and curation for 5, 10, or 20 deposits of typical size each year. Data that are submitted remain indefinitely with QDR or within the bounds of the access control stipulations set by the investigator. Through such a membership agreement, PCRC covered the costs of the pilot deposits of PCRC-funded qualitative data with QDR.

Access to the repository was made available via the PCRC DISC website. All PCRC-affiliated investigators were sent an email inviting them to share qualitative datasets and recommending that they create a new project in QDR using the link on the DISC website using non-identifiable materials or study documentation only (e.g., an interview guide) (https://palliativecareresearch.org/corescenters/data-informatics-and-statistics-core-disc~~.~~). ~~After this step, researchers~~After a researcher initiated a deposit in this manner – which ten teams did as part of this pilot effort – they were contacted by the QDR team for a consultation on the specifics of the actual data from a given project and provided with customized guidance about how to proceed. During this step, any exceptions to data sharing were reviewed. While the NIH policy on data sharing emphasizes the importance of promoting open data access in research endeavors, the policy also recognizes circumstances where data may not be shared or ~~necessitates~~where specific conditions for limited sharing might be necessary, for example, based on commitments made in the original informed consent. ~~One particular scenario is when research involves data owned by Indigenous communities or Tribes. In such cases, the principles of data sovereignty and cultural considerations are crucial factors to be considered.~~

In all cases, researchers were encouraged to include documentary materials such as study information sheets, recruitment materials, and interview or focus group guides~~.~~, as well as provide as much contextual metadata for the study (e.g., dates of data collection, geographic area, any related publications based on the data). Data from PCRC-funded deposits fell into two categories of studies. In one category, data sharing was clearly specified in the study's informed consent and study information sheets. For these studies, full, de-identified data are shared in the QDR.(30) In the other category, informed consent assured participants that none of their information would be shared beyond the study team, such that deposited, even de-identified, data would have violated these agreements. In these cases, researchers deposited aggregate data. Examples include aggregate participant sociodemographic details, or a codebook of all code labels generated during data analysis, together with definitions and selected sample quotes.(31) Such aggregate data ~~offers~~offer little opportunity for direct data re-use, but ~~it does~~they do provide additional transparency about analysis and use, increasing overall research transparency.

Researchers were responsible for de-identifying deposited transcripts using guidelines provided by QDR (https://qdr.syr.edu/guidance/human-participants/deidentification). De-identification using these guidelines went significantly further than removal of HIPAA-protected identifiers by also considering indirect identifiers such as profession or years of employment that could be used to re-identify participants using publicly available databases. Additionally, QDR curators (as part of the repository's standard processes) individually reviewed all de-identified transcripts and flagged additional elements that presented potential disclosure risks ~~for depositors, who~~. Depositors then further redacted transcripts where needed.

Despite the significant care used to ensure the confidentiality of participants, de-identification of data can never be entirely guaranteed. Given the sensitive content of much of the interview data, access to most transcripts in the PCRC collection on QDR is under "controlled access~~"~~," in which access to data requires an application and a research plan by the requesting researcher, whose identity and affiliation are then verified by QDR. In addition, the researcher signs a comprehensive use agreement for the data that stipulates, among other things, that all data must be fully removed from the requesting investigator's storage after project completion. As necessary, QDR is able to impose additional access controls for data. Given the thorough de-identification of all data deposited by PCRC-funded researchers, no additional controls were necessary. In a handful of cases, depositing researchers and QDR determined that standard access conditions are sufficient, typically in cases where either only aggregate data or interview notes were shared.(32) The DISC and QDR provide consultation for any questions related to the deposit or de-identifying qualitative data.

For multi- and mixed-method studies funded through PCRC, quantitative materials were deposited with DiDR and qualitative materials with QDR. The qualitative data are linked in the respective project metadata, so researchers can easily find and request access to both (see 33, 34 for an example). For studies deposited after the end of the PCRC grant period, QDR is, with rare ~~exception~~exceptions, able to archive all data resulting from multi-methods research, providing metadata, curation, and access controls suitable for both qualitative and quantitative components. We summarize our developmental process in Box F1.

Lessons Learned

The current PCRC-QDR collection contains data from ten studies that range from qualitative and mixed-methods investigations of psychosocial and symptom distress interventions, to ethical challenges in palliative care research, advanced care planning among adults with serious illness, experience of de-escalating medications on hospice, and family perceptions of unplanned ICU admissions for seriously ill adult, as well as barriers to palliative care utilization among adolescents and young adults living in poverty (Table 1). The PCRC qualitative data will remain housed at the Qualitative Data Repository (https://data.qdr.syr.edu/dataverse/pcrc) as part of the PCRC's plan for its sustainable products and services. The data already deposited will be hosted indefinitely based on the earlier 2019 contract with QDR. PCRC investigators ending their studies in the future may continue sharing their data.

The PCRC DISC team identified three key lessons learned about timely data sharing, which we hope researchers planning to share their future qualitative research data will note~~heed~~: 1) adequate planning and budgeting for data sharing should be considered during proposal creation (e.g., resources needed to de-identify qualitative data); 2) appropriate language should be incorporated into consent and assent documents to allow storing and sharing of qualitative data and/or storing or sharing data outside one's institution; and 3) attention to concerns about re-identification of participants is needed, both to protect participants (e.g., individuals with rare disorders) and enhance trust of qualitative researchers in the deposit process. Although the concern about re-identification of participants is widely cited among qualitative researchers generally, upon review, we did not find this to be a significant concern for most PCRC studies. Experienced QDR curators reviewed all deposited transcripts for potentially disclosive information, both in the form of "direct identifiers~~",~~" (i.e., names, addresses, etc~~.~~) and "indirect

identifiers", " (i.e., contextual details that could be used to identify participants.). Most transcripts deposited as part of PCRC are rich in clinical detail but contain little information that would be traceable to individual participants. To the extent such information is present, it is concentrated in a few sections of the transcript and can be easily redacted or masked. by aggregation. If this concern arose in review, the PCRC-QDR allowed sharing of data in aggregate forms (e.g., codes and aggregate findings that pose no risk of re-identification of individual participants).

Based on these lessons, we urge researchers planning to conduct qualitative, multi-, or mixed-method research to allocate sufficient resources in the primary grant budget to support data repository-related activities, e.g., research staff time for manual de-identification of the data, as well as for any data deposit processes and fees. We also strongly recommend that researchers consult with the QDR while developing their grant proposals both to estimate costs and delineate study-specific procedures. QDR consultation may be again appropriate when submitting IRB applications, as accurateexplicit data-sharing language in the consent can help ensure the investigator's ability to add to the data repository. Contrary to many researchers' expectations, several studies suggest that participants in qualitative research tend to favor sharing data with other researchers and are rarely discouraged from participation by the inclusion of data sharing as an option in informed consent.(8, 35) Researchers' and participants' confidence in data sharing may be improved by meticulously managing and keeping memos, notes, and methodological decisions, and by documenting guidelines that provide careful description of their de-identification process. See Table 21 for an overview of lessons learned and strategies for depositing qualitative data.

Future Directions

~~The current PCRC-QDR databasecollection contains data from ten studies that range from qualitative and mixed-methods investigations of psychosocial and symptom distress interventions, to ethical challenges in palliative care research, advanced care planning among adults with serious illness, experience of de-escalating medications on hospice, and family perceptions of unplanned ICU admissions for seriously ill adult, as well as barriers to palliative care utilization among adolescents and young adults living in poverty (Table 2). The PCRC qualitative data will remain housed at Syracuse Universitythe Qualitative Data Repository () as part of the PCRC's plan for its sustainable products and services. The data already deposited will be hosted indefinitely based on anthe earlier 2019 contract with the QDR. PCRC investigators ending their studies after this datein the future may continue sharing their data.~~

Our partnership in this work has also brought new questions and areas of inquiry to light. First~~or example~~, it is important to learn what children and adolescents who assent to research think about the potential to share their data and creating mechanisms to document their assent. This input is particularly important given that only one of the deposited studies includes the experiences of adolescents and young adults and can be one way to advance science of pediatric palliative care by creating space for voices of those who receive pediatric palliative and end-of-life care. Second~~Also~~, it will be important to understand if a multiplicity of voices and perspectives are shared through data sharing and how to ensure such diversity is brought forth. ~~Finally~~Third, as the utilization of secondary data continues to grow, it is imperative for researchers to consider its alignment with methodological progressions. A crucial forthcoming step in methodological advancement involves devising robust strategies for the curation, deposition, and storage of linked data derived from multi- and mixed-methods studies. Related to this enhanced focus on better defined data management, which is planned in advance and aims

tofor maximizicng appropriate data sharing, we also want to highlightcall attention to the need for researchers to seek institutional support from various relevant entities. On the one hand, bBudget requests from funders should dedicate resources needed for data management during the course of a project and for data sharing after to happen after. On the other, and to cComplementarily, that, expertise from data librarians, information technology departments, and the curation team at QDR should be sought- throughout a study, in order to make ensure that the practical application of planned steps occursis taken in agreement with local institutional policies, as well as QDR's policies and expectations.

Finally, it will be important to advance the discussion on the poignant particular considerations that must be kept in mind when considering trelated to the sharing of data from people or communities whose data may require additional protections, such as research participants from Indigenous or Tribal communities (see also ongoing work at QDR on this topic https://sites.uw.edu/dsissresearch/), individuals with rare diseases,, or those living with substance use disorder.(4, 5) For example, QDR's collaborative work, in response to the imperative for Indigenous data governance and sovereignty, aims to establish ethical guidelines for the care and stewardship of digital Indigenous data within research data services. These guidelines have been responsibly derived from case studies of Indigenous scholarship conducted by Indigenous researchers, incorporating relevant expertise. The focus of the work has been on three main areas: 1) a careful assessment of whether to accept deposits of Indigenous data, ensuring that data were collected with proper consent and respect for Indigenous communities' values, and ensuring that depositors have the authority to make the data available to others; 2) proper representation and context for Indigenous data, considering the historical misrepresentation of Indigenous culture; and 3) prioritizing Indigenous sovereignty and

~~incorporating access controls that meet the needs and preferences of Indigenous communities. This approach ensures the proper care and preservation of Indigenous data while upholding the principles of Indigenous data sovereignty.~~ With the standing NIH Data Management and Sharing policy, we strongly encourage palliative care researchers at large who employ qualitative, multi- and mixed-methods studies to continue use of the robust QDR infrastructure and specifically the PCRC-QDR collection for implementing their data sharing plans.

Conclusion

Leveraging the benefits of depositing qualitative data, while simultaneously mitigating the risks, has been an important goal of the PCRC-QDR partnership. We have made an important contribution that will continue to advance the science of palliative care and enhance clinical application. We believe we have also made a methodological contribution in starting the conversation of data sharing in palliative care research (and beyond) and developing a resource and a publicly available set of models for other researchers. We recognize the additional work involved during grant and IRB proposal writing, yet we believe that thoughtful upstream consideration of downstream data uses will advance knowledge, enhance equity for early career researchers and students to learn from the stories of participants and with all investigators, and amplify the stories of participants to improve the human condition. Further research about best practices in qualitative data sharing and other stakeholder perspectives on the potential benefits and risks will be important to advance this conversation and inform science and regulatory policy.

Disclosure/Conflict of Interest

Meghani was the co-lead of the Data Informatics and Statistics Core of the Palliative Care Research Cooperative Group. Harrison received a Pilot award from the PCRC Group, funded by the National Institute of Nursing Research. Karcher and Kirilova are employed by the Qualitative Data Repository, whose work is described in this manuscript. All other authors declare no conflicts of interest related to this manuscript.

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Box 1. Process of Developing a Qualitative Repository in EOLPC

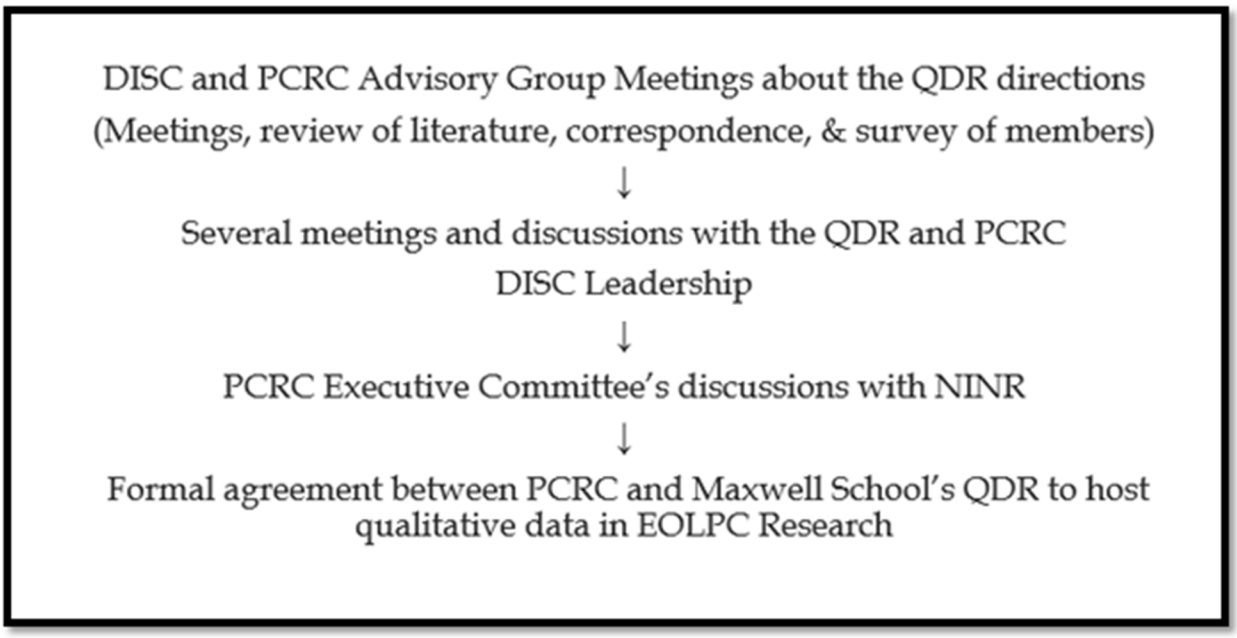

Table 1. Deposited Qualitative Datasets in PCRC-QDR ~~EOLPC~~ and Make Data Count (MDC) Utilization Metrics (as of May 2024)[1]

Title/ Date Available	Principal Investigator	Project Description (Provided by PI)	MDC* Metrics
Anticoagulation Therapy on Discharge to Hospice Care (January 19, 2021)	Furuno, Jon	The goal of this qualitative study was to better understand antithrombotic decision making on discharge to hospice care. This study was part of a larger mixed-methods study which examined the frequency and indication for antithrombotic prescriptions on discharge to hospice care. We recruited physicians who recently (<1 week) discharged a patient to hospice care between July 2015-March 2016. Potential participating physicians were identified prospectively using discharge disposition data from the Department of Care Management. Within one week of the discharge date, we identified and emailed discharging physicians and invited them to participate in the study. In order to capture variation in the perspectives and opinions regarding prescribing antithrombotic therapy on discharge to hospice, we are purposefully sampled three different physician groups: 1) those that continued antithrombotic therapy, 2) those that discontinued antithrombotic therapy, and 3) those that de-escalated antithrombotic therapy (e.g., warfarin to aspirin) on discharge to hospice care.	3,558 Views 64 Downloads
Barriers to Hospice and Palliative Care Utilization Among Adolescent and Young Adult Cancer Patients Living in Poverty (April 22, 2021)	Mack, Jennifer	Adolescents and young adults (AYAs; aged 15-39 years) with cancer frequently receive intensive measures at the end of life (EOL), but the perspectives of AYAs and their family members on barriers to optimal EOL care are not well understood. We conducted qualitative interviews with 28 bereaved caregivers of AYAs with cancer who died in 2013 through 2016 after receiving treatment at 1 of 3 sites. Interviews focused on ways that EOL care could have better met	6,197 Views 624 Downloads

		the needs of the AYAs. Content analysis was performed to identify relevant themes.	
Unplanned Admission to the ICU: A Qualitative Study Examining Family Member Experiences (July 12, 2021)	Jennerich, Ann	The project seeks to create knowledge about family members' experiences during hospital stays complicated by a patient's unplanned admission to the ICU. Qualitative data were collected from semi-structured interviews with families of patients who were transferred from acute care to the ICU after a clinical deterioration. All participants were recruited from a level-1 trauma center in Seattle, WA, where patients could be transferred to the following ICU services: medical, cardiac, surgical/trauma, or neurocritical care. Eligible family members were 18 years of age and English-speaking. They were identified by screening each ICU census for patients who were transferred from acute care to the ICU, excluding patients whose acute care or ICU stay was <24 hours. Family members were approached at the patient's bedside, and written informed consent was obtained. Consent for medical record review was provided by patients when they retained decision-making capacity or legal-next-of-kin when they did not.	4,313 Views 465 Downloads
Advance Care Planning in Hospice Organizations: A Qualitative Pilot Study (Nov 10, 2021)	Harrison, Krista.	In 2016, we conducted a qualitative, descriptive multisite study of the practices, attitudes, and measurement of the ways in which clinicians elicit goals and values for hospice care, the provision of that care, and changes in these practices over time. At the time the study was initiated, no data existed on hospice staff members' perceptions of Advance Care Planning (ACP), their ACP practices, and their measurement of ACP, making it essential to use a flexible methodology for the formative research. We selected a case study approach with qualitative methods, as appropriate for exploratory research questions related to processes and 'how' and 'why' questions not previously addressed in the literature. The study uses multiple data types – interviews and documents– to triangulate and gain a detailed understanding of process and address the research aims.	5,619 Views 442 Downloads

Understanding advance care planning in patients and care partners living with Parkinson's disease (April 19, 2022)	Lum, Hillary.	Advance care planning is a core quality measure in caring for individuals with Parkinson disease (PD) and there are no best practice standards for how to incorporate ACP into PD care. This study describes patient and care partner perspectives on ACP to inform a patient- and care partner-centered framework for clinical care.	1,434 Views 257 Downloads
Ethical Challenges When Engaging Patients and Families in End-of-Life and Palliative Care Research". (June 28, 2022)	DeCamp, Matthew	Delivering high quality, patient- and family-centered care depends upon high quality end-of-life and palliative care (EOLPC) research. Engaging patients and families as advisors, partners, or co-investigators throughout the research lifecycle is widely regarded as critical to ensuring high quality research. Engagement is not only an ethical obligation, it also raises ethical challenges of its own. We conducted a qualitative study to understand ethical challenges and potential solutions when engaging patients and families in EOLPC research. We recruited and interviewed 20 clinical investigators and 22 patients or family caregivers through the Palliative Care Research Cooperative Group (PCRC). Interview transcripts were analyzed using constructivist grounded theory methodology. Analysis sought to identify ethical challenges and potential solutions, as well as to synthesize findings into practical recommendations tailored to engaging patients and families in EOLPC research.	928 Views 66 Downloads
Pilot Testing a Virtual Reality Protocol for Improving Pain and Pain-Related Distress in Patients with Advanced Stage Colorectal Cancer (Sep 29, 2022)	Kelleher, Sarah	This study was done to test the feasibility, acceptability, safety, and impact of exposing patients to a single 30-minute virtual reality underwater/sea environment (called VR Blue) for reducing pain and pain-related symptoms in patients with advanced stage colorectal cancer. VR Blue is an immersive computer-generated environment featuring calming scenic graphics and relaxing nature music, which has been shown to increase tolerance for thermal pain stimuli in healthy participants in prior research. All participants were patients with stage IV colorectal cancer. The purpose of this VR Blue intervention was to reduce pain and pain-related symptoms	481 Views 123 Downloads

		such as tension and distress and enhance patients' abilities to cope with pain. We also wanted to better understand patients' experiences, preferences, thoughts, and feelings about the virtual reality experience to optimize VR Blue for future study.	
Conquer Fear SUPPORT: A Psychosocial Intervention in Patients with Advanced Cancer	Reb, Anne	Approximately 49% of cancer survivors overall and up to 70% of vulnerable groups experience moderate to high levels of fear of cancer progression or recurrence (FOP). Recent data suggest that FOP is an even more pressing concern in advanced cancer. Patients with FOP have intrusive thoughts about cancer, unhelpful coping behaviors, and difficulty making future plans. Although some degree of FOP is normal, excessive levels adversely affect quality of life and health care costs. The purpose of this study was to assess the feasibility, acceptability, and preliminary effects of a nurse-led intervention for managing FOP in patients with advanced gynecologic or lung cancer. The intervention was adapted from an intervention called "Conquer Fear," which has shown to have efficacy in a large RCT of patients with breast, colorectal, and melanoma cancer treated with curative intent.	443 Views 82 Downloads
Building Evidence for a Concurrent Hospice and Dialysis Program for Terminal Patients with End-Stage Renal Disease (ESRD) 06/27/2023	Schell, Jane & Ernecoff, Natalie.	The shared data consist of 39 de-identified interview transcripts and a number of documentation files contextualizing the process of data collection and analysis, namely the three consent templates (used for clinicians/administrators, caregivers and patients, respectively), the four interview guides (for the same participant groups, plus another one for program administrators), and the final version of the codebook developed. The data file names reflect the type of participant of each by letter ("A" for administrators, "P" for patients and caregivers, "C" for clinicians).	243 Views 65 Downloads

Experiences of Serious Illness Conversations (SICs) to Drive Health Equity in Serious Illness Care (07/ 28/2023)	Izumi, Seiko.	The primary purpose of this study is to describe the experience with and perception about serious illness conversations (SICs) from the perspective of patients from underserved minoritized groups. Secondary goal is to identify structure and contents that make SICs accessible and acceptable by patients from underserved minoritized groups.	317 Views 74 Downloads

Table 2. Lessons Learned and Associated Strategies for Depositing Qualitative Data

Lessons Learned	**Associated Strategies**
Planning and Budgeting Adequate planning and budgeting for data sharing should be considered during proposal creation.	• Allocate sufficient resources in the primary grant budget to support data repository-related activities, such as research staff time for manual de-identification of the data, as well as for any data deposit processes and fees. • Consult with the QDR while developing their grant proposals both to estimate costs and delineate procedures.
IRB and Informed Consent and Pediatric Assent Appropriate language should be incorporated into consent and assent documents to allow storing and sharing of qualitative data and/or storing or sharing data outside their institution.	• Consult with the QDR to delineate procedures of de-identification and accurate language for IRB applications and consent and assent forms. • Consult QDR when submitting IRB applications for accurate language that can be included in consent and assent forms to streamline acquiring permissions needed from participants to add their data to the repository. • Check with your institutional review board for specific language requirements for broad and responsible data sharing (e.g., deposit in one of the NIH-supported data repositories).
HIPAA and De-Identification Attention to concerns about re-identification of participants is needed, both to protect	• Meticulous data management, including keeping memos, notes, and audit trail of methodological decisions. • Document guidelines for and careful description of de-dentification process. • In the case of rare diseases, consider sharing aggregate data to describe sample or sharing particular sections of transcript text that do not contain information about the disease, but describe

participants (e.g., individuals with rare disorders) and enhance trust of qualitative researchers in the depository process.	the phenomenon under investigation (e.g., a parent may share the story of learning a child's diagnosis with a rare disease in one section of a transcript, but in another share descriptions of the central phenomenon under investigation, impact of the child's hospitalization on the family unit, in another section).
Other Ethical and Legal Considerations	• Obtain certificate of confidentiality or comparable documents based on country of residence (e.g., applying for certificate of confidentiality for research in tribal areas/territories).[a] • Ensure proper care and preservation of data from vulnerable and protected groups ~~Indigenous data while upholding the principles of Indigenous data sovereignty.~~[24~~24~~]
Re-Use and Partnership with Secondary User Considerations[11~~11~~]	• Employ clear definition of secondary qualitative analysis and ensure all participating investigators are aligned. • Consider whether new research question is sufficiently different than the original research question but related and can be answered by the data. • Delineate involvement, if at all, of original investigator and relationship to secondary investigators. • Ensure ethics approval for secondary analyses is included in subsequent manuscript. • Consider including original research team members as part of the secondary analysis team to ensure fit of secondary analysis question and original research question and to provide insight into original study context.

[a]This is a requirement for U.S.-based research.