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Authors

Phillips, Charles A
Barakat, Lamia P
Pollock, Brad H
et al.

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Implementation science in pediatric oncology: a narrative review and future directions

Charles A. Phillips, MD, MSHP, MBMI[1,2,3], **Lamia P. Barakat, PhD**[1,2], **Brad H. Pollock, PhD, MPH**[4,5], **L. Charles Bailey, MD, PhD**[1,2,3], **Rinad S. Beidas, PhD**[6,7,8,9]

[1]Division of Oncology, the Children's Hospital of Philadelphia, Philadelphia, PA, United States

[2]Department of Pediatrics, Perelman School of Medicine at the University of Pennsylvania, Philadelphia, PA, United States

[3]Department of Biomedical and Health Informatics, the Children's Hospital of Philadelphia, Philadelphia, PA, United States

[4]Department of Public Health Sciences, School of Medicine, University of California, Davis, CA, United States

[5]University of California Davis Comprehensive Cancer Center, Sacramento, CA, United States

[6]Department of Psychiatry, Perelman School of Medicine at the University of Pennsylvania, Philadelphia, PA, United States

[7]Department of Medical Ethics and Health Policy, Perelman School of Medicine at the University of Pennsylvania, Philadelphia, PA, United States

[8]Department of Medicine, Perelman School of Medicine at the University of Pennsylvania, Philadelphia, PA, United States

[9]Penn Implementation Science Center at the Leonard Davis Institute (PISCE@LDI), University of Pennsylvania, Philadelphia, PA, United States

Abstract

Implementation science (IS) has garnered attention within oncology and most prior IS work has focused on adult, not pediatric, oncology. This narrative review broadly characterizes IS for pediatric oncology. It includes studies through 2020 using the following search terms in PubMed, Ovid Medline, and Cochrane: "implementation science," "pediatric," "childhood," "cancer," and "oncology." Systematic review was not performed due to the limited number of heterogeneous studies. Of 216 articles initially reviewed, nine were selected as specific to IS and pediatric oncology. All nine examined oncologic supportive care, cancer prevention, or cancer control.

Corresponding author: Charles A. Phillips, MD, MSHP, MBMI, Division of Oncology, The Children's Hospital of Philadelphia, Roberts Center for Pediatric Research, 2716 South Street, 11th Floor, Office 11392, Philadelphia, PA 19146, Phone: 267-496-0161, phillipsc2@chop.edu.

Conflict of Interest

Rinad Beidas receives royalties from Oxford University Press P50 CA244690-01 (Beidas, Bekelman, Schnoll); has provided consultation to the Camden Coalition of Healthcare Providers; and serves on the scientific advisory committee for Optum Behavioral Health.

Charles Phillips is a consultant for Merck.

The supportive care focus is potentially due to the presence of cooperative study groups such as the Children's Oncology Group, which efficiently drive cancer-directed therapy changes through clinical trials. Future IS within pediatric oncology should embrace this ecosystem and focus on cancer control interventions which benefit patients across multiple cancer types and patients treated outside cooperative group studies.

Keywords

pediatric oncology; pediatric cancer; implementation science; supportive care

Introduction

Over the past decade, implementation science (IS), or the scientific study of methods to increase the uptake of evidence-based practices into routine care,[1] has gained momentum as a field and is being applied in a number of areas including oncology.[2–4] Implementation science is important for pediatric oncology because it informs delivery of evidence-based care and addresses key facets of care delivery including healthcare structures, patient and provider behaviors, health disparities and patient outcomes.[2] In this article, we present a narrative review of prior implementation research within pediatric oncology, focusing on the application of IS principles and calling for a pragmatic research agenda. We will highlight the unique facets of the pediatric oncology ecosystem which influence implementation including the significant presence of pediatric cancer research consortia and their predominant role in both developing the evidence-base and setting practice standards for pediatric oncology.

Implementation science seeks to understand how interventions work in real-world settings and test approaches to improve their uptake and use.[5, 6] It also includes de-implementation of ineffective practices.[7] Implementation science is complementary to, but distinct from, clinical efficacy and effectiveness research[8, 9] because of its focus on outcomes which characterize the implementation itself, rather than the intervention being implemented.[10] Key features of IS include an emphasis on theories, models, and frameworks to understand the context in which interventions and processes are translated from research into practice and a requirement that the intervention to be implemented is efficacious, effective, and sustainable.[8, 11, 12] For situations with limited evidence, effectiveness-implementation hybrid designs can assess both effectiveness and implementation research questions simultaneously.[13]

Within oncology, the majority of implementation research has focused on adult oncology with considerable infrastructure that has been built in cancer control research and an emerging cancer care delivery research portfolio supported by the National Cancer Institute (NCI) [https://cancercontrol.cancer.gov/IS/index.html]. This infrastructure includes the Implementation Science Centers in Cancer Control (ISC3) Program which supports the implementation of evidence-based cancer control interventions. Funding has been provided for IS within oncology through the NCI's Cancer Moonshot initiative as the

Moonshot's Blue Ribbon Panel identified the implementation of evidence-based approaches as a priorty.[14] This funding is largely focused on adult centers.

Work complementary to implementation is being performed in both adult and pediatric populations by the NCI Community Oncology Research Program (NCORP) with a strong focus on cancer care delivery research (CCDR). CCDR emphasizes how care delivery structures and processes, as well as provider and patient behaviors, impact equitable cancer care access, quality, cost, and health outcomes.[2] Many of the same cancer care delivery concerns in adult oncology are relevant to pediatric oncology. However, limited prior work has addressed IS for pediatric oncology. This narrative review seeks to characterize IS in pediatric oncology and inform next steps in applying this approach to pediatric oncology research.

Methods

A systematic search of the databases PubMed, Ovid Medline, and Cochrane with key search words "implementation science," "pediatric," "childhood," "cancer," and "oncology" was performed by author (CP) for articles published prior to January 2021. Additional relevant articles were selected if they were listed in the references of the identified articles or were known to the authors. Individual manuscripts were reviewed at the title, abstract, or full text level. Articles were included if they were written in English and germane to both implementation science and caring for pediatric oncology patients. More granular target characteristics were not included in an effort to emphasize specificity. Manuscripts that obviously did not apply from the title were excluded (example, "The Quality of Care for Australian Children with Autism Spectrum Disorders"). Abstracts for all remaining manuscripts were reviewed. If the abstract was ambiguous for inclusion or clearly applied to both pediatric oncology and IS, the full manuscript was reviewed. A second reviewer (RB) reviewed a random subset of six manuscripts selected for abstract review to ensure general agreement. The articles were categorized *a priori* into groups based on subject matter such as "cancer prevention" in the case of human papilloma virus vaccination or "supportive care" for a manuscript detailing the application of the Psychosocial Standards of Care in pediatric oncology.

During the literature review, it became clear that a limited number of manuscripts would meet our inclusion criteria. Therefore, this narrative review is very broad due to insufficient IS focus on a single area of pediatric oncology. This wide scope, in combination with the very limited number of pediatric oncology IS publications, precluded the completion of a systematic review.

Results

The PRISMA flow diagram is shown (Figure). The initial search resulted in 214 unique manuscripts. Two additional titles were identified. The 216 titles were reviewed. Manuscripts that did not pertain to pediatrics, oncology or implementation science were excluded. Thirty-seven abstracts were reviewed and of these, twelve full-text articles were selected. Three of these were subsequently excluded due to not focusing on pediatric

oncology (1), not focusing on implementation (1) and not applicable to patient care (1). For the random subset of six articles selected for dual review, there was 83% agreement on articles to review the full text (5/6) and 100% agreement for articles for final inclusion/exclusion (6/6). After exclusions were applied, nine studies formed the basis of the review (Table).[15–23]

All nine papers focused on oncologic supportive care or cancer prevention. Implementation studies focusing on psychosocial supportive care were the most common (5/9, 56%) followed by studies about cancer prevention (human papilloma virus vaccination) in pediatric clinics (2/9, 22%). Approximately 67% (6/9) of the studies directly involved oncology providers with the other studies located in the primary care (2/9, 22%) or emergency room setting (1/9, 11%). None of the studies focused on direct delivery of chemotherapy or other cancer-directed treatment.

Implementation studies typically involve multiple sites or providers and the majority of the studies involved multiple sites (7/9, 78%). The other studies involved multiple providers and healthcare staff within a single site. Six of the included studies had a component of planning for implementation or contextual inquiry (i.e., in depth qualitative work) and reflected the early stages of implementation work. The most common implementation framework used was the Consolidated Framework For Implementation Research (CFIR)[24] which was explicitly referenced by two of the studies. A third study used the Interactive Systems Framework for Dissemination and Implementation. However, most of the studies did not specifically address a framework.

Discussion

This review revealed a limited number of early IS studies within pediatric oncology which highlight a focus on supportive care and cancer prevention. Not only did this review find few examples of IS in pediatric oncology, but also that IS for pediatric oncology appears underdeveloped. Despite the fact that implementation science is heavily reliant on theories and frameworks, most of the studies in this review did not explicitly reference either. Additionally, the majority of the studies reviewed focused on the planning phases of IS which suggests immaturity. It is unclear if this work will generate additional, more mature IS studies. Given that implementation science is an emerging discipline and all nine studies are from within the past decade, it may be that follow up studies are forthcoming.

Beyond IS's recent emergence, the biggest reason for relatively lower IS uptake in pediatric oncology compared to other fields is likely due to the unique facets of the cooperative group trial infrastructure for pediatric oncology. For reasons detailed below, IS has the potential to move forward and improve care for pediatric cancer patients by addressing study questions for patients treated outside of clinical trials and by enhancing adoption of cancer control and supportive care interventions into practice.

When considering the implementation of cancer interventions for pediatric patients, the importance of large multi-institutional collaborative research consortia such as the National Cancer Institute-sponsored Children's Oncology Group (COG) for developing

cancer-directed therapy, must be accounted for. COG, one of several NCI Clinical Trials Network (NCTN) groups, is the only one dedicated to child and adolescent oncology. In the United States, over 90% of pediatric cancer patients are treated at a COG center.[25] When a trial is available, approximately 60% of children with cancer in the United States are enrolled in a COG study.[25] Primarily, these are treatment protocols that include biobanking, chemotherapy and radiation therapy. New COG studies and COG protocol amendments instantly change therapy for a substantial number of pediatric oncology patients in North America. For example, a recently completed COG study in standard (prognosis) risk acute lymphoblastic leukemia (ALL), published its results for maintenance chemotherapy to the COG website as a memo on May 10, 2019. A mere five months later, on October 28, 2019, the subsequent standard risk ALL study was amended to reflect these new findings and alter the treatment with the most up-to date-standard. In another example, retrospective review of outcome data from COG trials showed important outcomes for central nervous system (CNS) in two patients. These data were presented as an abstract in May 2014 and was later published in 2017.[26] At that time a phase III trial was open and an amendment to the protocol, prompted by data from these two patients published in May 2016, resulted in an instant change in the therapeutic regimen. While the published evidence-to-practice gap for healthcare in general is 17 years,[27] these examples show that COG drove the gap down to 5–24 months. This significant achievement lowers the potential magnitude of benefit that could be derived from traditional implementation science applications in pediatric cancer therapeutic research. There simply is not much of an evidence-to-practice gap to narrow in these instances of widespread cooperative group trials with timely and effective central governance. This is a unique contextual factor for pediatric oncology.

It is not surprising then that the historical emphasis of pediatric oncology IS has been on cancer prevention, cancer control and supportive care. These studies serve to highlight that the rapid translation of new cancer-directed therapy changes from evidence generation into COG institution clinical practice which leverages the NCTN protocol infrastructure still leaves relevant implementation science questions. Important questions include: what kind of care do patients receive who are not treated on a therapeutic research protocol, or who are not treated at COG-affiliated institutions? Do patients, particularly vulnerable and diverse patient populations, receive evidence-based treatment regimens and are the treatment regimens administered in the way they were intended (i.e., fidelity)? Is the implementation of advances equitable? This is a particularly important area of inquiry because for at least one COG trial, non-Hispanic Black patients, infants, and patients from zip codes with a lower proportion of poverty were less likely to enroll in the COG trial.[28]

With the proliferation of research networks such as the Pediatric Health Information System (PHIS) and PEDSnet, the infrastructure to address these pragmatic, “real world” questions will be available. PHIS has been utilized to conduct pediatric oncology research outside the clinical trials infrastructure to address topics such as racial inequities[29] and off-study immunotherapy use.[30] Patients with leukemia and lymphoma have accurately been identified within PEDSnet.[31] However, the hospitals participating in both PHIS and PEDSnet tend to be large academic centers and do not include many community hospitals. More work is needed to assess the “real-world” outcomes for pediatric oncology patients treated off-study.

Implementation science's role for supportive care in pediatric oncology has already gained traction and was the most common domain focus of published IS studies. Within supportive care, over half of the studies included pertained to psychosocial supportive care and psychosocial researchers are playing a leading role in IS for pediatric oncology. Fifteen evidence-based standards exist for psychosocial care for children with cancer and their families.[32] These standards include, but are not limited to, routine systematic assessments of patient and family member psychosocial health needs, access to psychosocial interventions, survivorship care, and assessment of financial toxicity.[32] The most recent literature is adamant that implementation needs to have a role in delivering equitable, evidence-based psychosocial interventions to patients and tools to guide implementation of psychosocial care standards have been published.[22, 23]

Similar to the psychosocial community, the survivorship community has been vocal in advocating for IS to help deliver optimal care to long term survivors.[33] For studies ranging from medication adherence to palliative care delivery to transitioning to adult providers as a childhood cancer survivor, IS principles can be useful in contextualizing the healthcare environment and addressing barriers and facilitators to care delivery.[34]

The focus on improving adoption of proven, evidenced-based psychosocial interventions for pediatric cancer patients highlights another area where IS could improve cancer care delivery: sustainability. Hybrid implementation studies measure patient-level health outcomes in addition to implementation outcomes.[13] If future trials incorporate implementation outcomes from the outset, it will be much easier to deploy the intervention broadly after the trial is complete and sustain the benefits. A hypothetical example where a hybrid study may be relevant would be to determine the best way to address manufacturing and logistical considerations for a study testing the efficacy of chimeric-antigen receptor (CAR) T-cell immune therapy for patients who live a significant distance away from the clinical trial center.

One important consideration is whether supportive care advances are translated into patient care as rapidly as cancer-directed therapies. For example, a landmark COG-sponsored study was published in 2018 regarding levofloxacin prophylaxis in relapsed leukemia and bone marrow transplant.[35] Will this study translate into changes in levofloxacin prophylaxis in the pediatric oncology community as rapidly as cancer-directed therapy findings from COG trials? Does the culture of cancer-directed therapy protocol adherence have a positive or negative impact on implementation of evidence generated by supportive care studies that are not explicitly referenced for the current treatment protocol? These are examples of the types of questions that implementation science can, and should, address for pediatric oncology.

Conclusions

Implementation science has garnered attention within the oncology community and to date, little IS work has focused on pediatric oncology. Within pediatric oncology, the role of implementation science will be heavily influenced by the large research consortia like the COG. IS has the potential to inform and improve care for pediatric cancer patients not by trying to speed cancer-directed therapy interventions, but rather by focusing on questions not

addressed by the remarkable clinical trial infrastructure. This focus includes health equity, assessing interventions for patients treated off study, assessing implementation for evidence-based cancer control and supportive care interventions, and speeding implementation of new interventions by incorporating hybrid trial designs for select studies.

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Abbreviations Table Key:

CHOP	Children's Hospital of Philadelphia
IQR	Interquartile range

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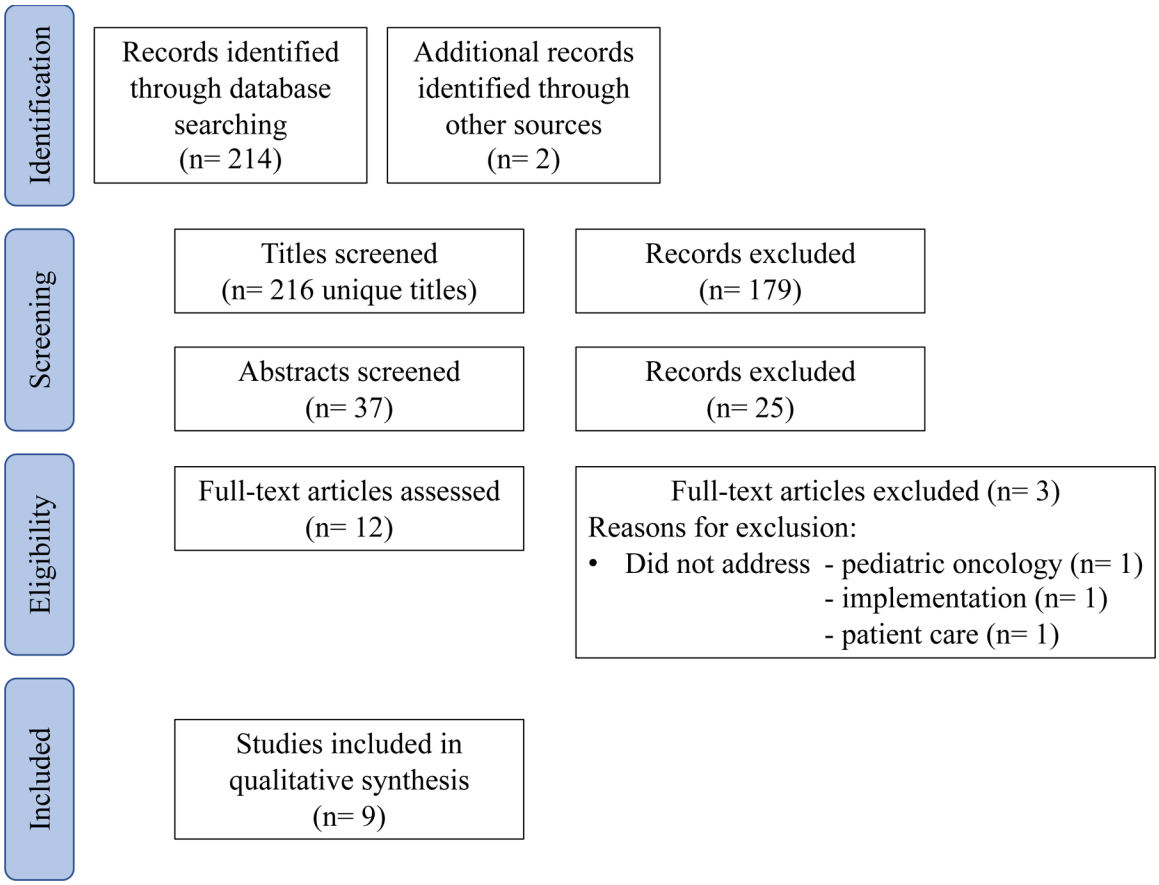

Figure. PRISMA diagram

The PRISMA diagram shows the manuscripts reviewed and stages of exclusion. Two hundred fifteen unique articles were assessed with nine included in the final review. A subset of manuscripts were reviewed by two authors and there was 83% agreement on articles to review the full text (5/6) and 100% agreement for articles for final inclusion or exclusion (6/6).

Table.

Pediatric oncology implementation science studies

Study	Publication year	Pediatric oncology domain	Pediatric oncology subdomain	Implementation setting
Cohen et al.[15]	2016	Infection prevention	Febrile neutropenia	Emergency department
Garbutt et al.[16] *	2018	Cancer prevention	Pediatric HPV programs	Primary care - multisite
Hockenberry et al.[17]	2012	Supportive care	Procedural sedation for intrathecal chemotherapy	Oncology sedation unit
Kazak et al.[18]	2017	Supportive care	Psychosocial standards of care	Oncology departments - multisite
Scialla et al.[19]	2017	Supportive care	Psychosocial standards of care	Oncology departments - multisite
Scialla et al.[20]	2018	Supportive care	Psychosocial standards of care	Oncology departments - multisite
Walker et al.[21] *	2019	Cancer prevention	Pediatric HPV programs	Primary care - multisite
Wiener et al.[22]	2020	Supportive care	Psychosocial standards of care	Oncology departments - multisite
Kazak et al.[23] *	2020	Supportive care	Psychosocial standards of care	Oncology departments - multisite

HPV: human papilloma virus

* Used an implementation science framework in the methods for the study; Garbutt and Walker manuscripts used the Consolidated Framework For Implementation Research (CFIR) while the Kazak manuscript used the Interactive Systems Framework for Dissemination and Implementation