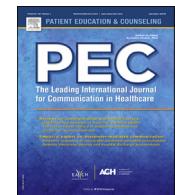




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### Review article

## Strategies to facilitate shared decision-making about pediatric oncology clinical trial enrollment: A systematic review

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### ABSTRACT

**Objective:** We conducted a systematic review to identify the strategies that have been recommended in the literature to facilitate shared decision-making regarding enrolment in pediatric oncology clinical trials.

**Methods:** We searched seven databases for peer-reviewed literature, published 1990–2017. Of 924 articles identified, 17 studies were eligible for the review. We assessed study quality using the 'Mixed-Methods Appraisal Tool'. We coded the results and discussions of papers line-by-line using nVivo software. We categorized strategies thematically.

**Results:** Five main themes emerged: 1) decision-making as a process, 2) individuality of the process; 3) information provision, 4) the role of communication, or 5) decision and psychosocial support. Families should have adequate time to make a decision. HCPs should elicit parents' and patients' preferences for level of information and decision involvement. Information should be clear and provided in multiple modalities. Articles also recommended providing training for healthcare professionals and access to psychosocial support for families.

**Conclusion:** High quality, individually-tailored information, open communication and psychosocial support appear vital in supporting decision-making regarding enrollment in clinical trials. These data will usefully inform future decision-making interventions/tools to support families making clinical trial decisions.

**Practice implications:** A solid evidence-base for effective strategies which facilitate shared decision-making is needed.

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### Contents

1. Introduction .....	00
2. Methods .....	00
2.1. Database search procedure .....	00
2.2. Study selection .....	00
2.3. Quality assessment .....	00

**Abbreviations:** CINAHL, cumulative index of nursing and allied health literature; EMBASE, Excerpta Medica database; HCP, healthcare professional; MMAT, mixed-methods appraisal tool; PRISMA, Preferred Reporting Items for Systematic Reviews and Meta-Analyses; SDM, shared decision-making.

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2.4.	Data extraction and synthesis .....	00
3.	Results .....	00
3.1.	Study characteristics .....	00
3.2.	Methodological rigor .....	00
3.3.	Strategies to facilitate SDM in pediatric oncology clinical trial enrolment	00
3.3.1.	Theme 1: decision making as a process (n = 11 articles) .....	00
3.3.2.	Theme 2: individuality of the process (n = 15 articles) .....	00
3.3.3.	Theme 3: information provision (n = 17 articles) .....	00
3.3.4.	Theme 4: the role of communication (n = 15 articles) .....	00
3.3.5.	Theme 5: decision and psychosocial support (n = 14 articles) .....	00
4.	Discussion and conclusion .....	00
4.1.	Discussion .....	00
4.2.	Strengths and limitations .....	00
4.3.	Practice implications .....	00
4.4.	Conclusion .....	00
	Summary .....	00
	Funding Source .....	00
	Financial disclosure .....	00
	Conflict of interest .....	00
	Contributions .....	00
	References .....	00

## 1. Introduction

In pediatric oncology, many families are faced with a decision about whether or not to enroll their child in a clinical trial. Across the United States and Australia, approximately 60% of young people with cancer are treated on a clinical trial protocol [1,2]. Phase 1 and 2 trials (also known as early phase trials) are designed to evaluate a new treatment to determine safety and efficacy. Phase 1 and 2 trials are considered experimental, and are not expected to result in a cure. Patients offered experimental trials have usually failed standard treatment or there may not be a standard treatment available. If treatments are proven safe and efficacious in an early phase trial, the treatment is evaluated in a Phase 3 trial which compare the new treatment with the current standard treatment. Phase 3 trials usually involve randomisation to determine whether the new treatment or standard treatment is better [3].

Parents can find the decision to enroll difficult [4], especially if offered an early phase clinical trial, which have been referred to as one of the most difficult decisions a parent of a child with cancer will make [5]. Families can feel overwhelmed with the amount of information provided, and may not fully comprehend what has been said or provided to them [6,7].

In clinical trial decisions, shared decision making (SDM) may be most appropriate given that sometimes there is no single 'correct' decision [8]. In pediatric oncology, SDM often occurs between the healthcare professional (HCP) and parents. When SDM extends to include the young patient, this results in a triadic relationship between the patient, parent and their HCP. Determining when and how to include the child based on their level of maturity and preferences is a key challenge [9]. SDM in pediatric oncology may extend to a quadratic relationship if parents do not agree, or if additional HCPs are involved [10]. Although decision-making preferences may vary between and within families, as well as across decisions, SDM is becoming increasingly valued by parents and HCPs [11], with a recent review showing that SDM appears to be a preferred model of decision-making for many families coping with a pediatric cancer [12].

Given the complexity of clinical trial decision making, there is a need for rapid development and implementation of interventions to better accommodate SDM preferences for parents and young people (where appropriate) [13]. However, effective SDM interventions need to be developed in accordance with available evidence and recommendations in the field. We therefore systematically examined the results and discussions of all

qualitative, quantitative and mixed-methods studies that evaluated SDM in the context of pediatric oncology clinical trials. We then synthesized all strategies recommended in the literature to facilitate SDM regarding clinical trial enrolment for children with cancer. We included studies of parents', patients' and/or HCPs perspectives to gain a more comprehensive understanding of best practice clinical trial delivery.

## 2. Methods

### 2.1. Database search procedure

We conducted a systematic review following the Preferred Reporting Items for Systematic Reviews and Meta-Analyses (PRISMA) statement [14]. Two authors (ER, JF) developed the search strategy based on key articles in the field. The search strategy underwent review by all authors. We searched four databases (PsychInfo, Medline, EMBASE and CINAHL), limited to human studies published in English between January 1990–August 2017. Two authors (ER, CS) searched two grey literature databases (OpenGrey and Grey Literature Report), and reference lists of eligible articles (detailed search strategy in [Appendix A](#)). Two authors (ER, CS) also searched Google Scholar as it may provide good international coverage of the literature in pediatric oncology [15].

### 2.2. Study selection

Two authors (ER, CS) screened abstracts and included qualitative, quantitative and mixed-methods studies that focused specifically on the decision-making process for clinical trial enrolment or informed consent process for clinical trials. We included studies that focused on improving the informed consent process given that true consent involves supporting the patient/family to make an informed choice through SDM [16]. While communication and information comprehension play a large role in decision-making, this review focuses on strategies specifically to facilitate the decision making process or improve the consent process for clinical trials. We included original articles if they focused specifically on the SDM process within pediatric oncology (e.g. factors or barriers to SDM, preferences for decisional involvement in SDM). We excluded narrative and systematic reviews. We excluded cancer survivors (defined as 5 years post-diagnosis) to limit any potential recall limitations. We developed

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