The Role of Decision Impact Studies in Genomic Medicine in Cancer Care: A Scoping Review and Bibliometric Analysis Protocol

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Protocol

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Abstract

Background

Decision impact studies have become increasingly prevalent in oncology in recent years, particularly in breast cancer prognostic research. Such studies, which aim to evaluate the impact of a test on clinical decision-making, appear to be a new form of knowledge with the potential to impact clinical practice and regulatory decision-making in genomic medicine. Yet their origins, intended purpose and usage have not yet been explored. The objectives of this review are to identify and characterize decision impact studies in genomic medicine in cancer care. This review is comprised of two parts. First, we will conduct a scoping review to catalogue the characteristics of decision impact studies. The scoping review will be followed by a bibliometric analysis to understand the role of actors and institutions in the production and dissemination of this new knowledge, by identifying influential articles, authors, global research trends and collaboration networks.

Methods

We will conduct a scoping review and a bibliometric analysis of the scoping review results. The search will include four databases, Medline, Embase, Scopus and Web of Science, using a comprehensive search strategy developed through a preliminary review of the literature. Arksey & O'Malley's scoping review methodology, with updates by Levac et al. will be used, and the review will be reported following the PRISMA-ScR checklist. The FT Model will be used to collect and analyze data on clinical utility of decision impact studies. Our bibliometric analysis, using Bibliometrix software, will elucidate the evolution of these studies and provide data on the trends, influences and networks emerging in the field.

Discussion

This review will be a first step in understanding the evolution and uses of these studies and their potential influence on the integration of emerging genomic technologies into clinical practice. By exploring their origin and evolution across space and time, this study will equip future research to investigate the role of these studies in decision-making for regulatory processes, including market access and public and private coverage decision-making.

Systematic review registration: Open Science Framework osf.io/hm3jr

Background

Decision impact studies propose to evaluate the impact of a test on clinical decision-making. Emerging in the last ten years, decision impact studies (DIS) appear to be a new form of knowledge with particular relevance to decision making in genomic medicine. Though new, DIS have already been referenced in numerous international health technology assessments [1–4] and used in funding decisions for collectively financed health services. Understanding the origin and evolution of these studies is a critical

first step to exploring their integration into regulatory decision-making, including market access and coverage.

We conducted a preliminary search of the literature to gain insight into the research, reviews and critical appraisals of this type of study. An initial search of Medline and Embase for the term “decision impact study” found studies that used the term as a methodology or referenced other “decision impact studies”. The search located a systematic review and meta-analysis of the decision impact of a 21-gene assay used for breast cancer prognostics. These results would indicate that this term is related to a distinct style of research, but no methodology or explanatory literature was found. A more extensive search returned a significant number of studies that reported on the impact of a genomic test on decision-making but did not use the exact term. These results illuminate an area of research that is currently understudied and confirmed the need for a more comprehensive and rigorous examination of the literature.

There is a growing literature on the production and authorization of knowledge in regulatory processes [5–7]. Scientific knowledge is critical in regulatory processes, which are inherently knowledge intensive. New technologies have uncertain properties and effects, which regulatory agencies aim to adjudicate. Previous research has interrogated the relationships between researchers and industry and the production of evidence for regulatory and commercial success in areas of genomic medicine [5, 8–12], but the purpose and role of decision impact studies has yet to be explored. As new types of evidence are developed and disseminated, it is the responsibility of researchers to interrogate these sources of knowledge, to understand their place within regulatory processes and evidence-based medicine.

Health technology assessments (HTA) are important tools to assess the validity of a medical test, device or drug. HTAs establish standards and expectations for knowledge production and legitimize evidence and regulatory decisions [13–14]. Diagnostics do not directly act on health outcomes. Instead, they inform decision making about risk profiles or the use of therapeutic interventions. Efforts to measure the clinical and economic value of a test must therefore consider a “chain of evidence” linking intermediate to ultimate outcomes [15–16]. The links in this chain typically assess the analytic validity, clinical validity and clinical utility of the test or device. Clinical utility has been defined as something that improves patient outcomes and adds value to the clinical decision-making process [16]. Clinical utility is viewed as a key standard for reimbursement decision-making, but a lack of evidence and ambiguity regarding standards for the clinical utility of genomic tests has been identified in the literature [7, 14, 17–19]. As decision impact studies report on the impact of a test on decision making, these studies appear to position themselves as a form of evidence to assess clinical utility.

HTAs typically use an evaluative framework to support the assessment of the medical device, test or drug. For our review, we will leverage the FT Model [21], with Walcott et al.’s expanded categories [16] to collect and analyze data on how clinical utility is reported in DISs. This model offers the most comprehensive categorization of the components of clinical utility. The largely hierarchical and nested nature of the framework is well-suited to the context of genetics because the components of

effectiveness are specific, well defined, and linked as a chain of evidence [16]. The Model consists of six domains of efficacy, with domains 2-6 pertaining to clinical utility:

1. Technical efficacy (i.e., laboratory performance),
2. Diagnostic accuracy efficacy (i.e., clinical sensitivity and specificity),
3. Diagnostic thinking efficacy (i.e., impact on clinician's diagnostic process),
4. Therapeutic efficacy (i.e., impact on clinical management),
5. Patient outcome efficacy (i.e., patient benefit) and
6. Societal outcome efficacy (i.e., cost-benefit, cost-effectiveness, societal acceptability)

Walcott et al. (2021) found that the diagnostic thinking efficacy domain was not prevalent in the literature. The authors acknowledge the importance of measuring “the extent to which a test result helps a clinician come to a diagnosis and/or how the test results compare to a clinician's pretest estimate of the probability of disease” [16:384] and call for future work to explore measures of diagnostic thinking efficacy.

Study objectives

DIS are a new and potentially important form of evidence for assessing the clinical utility of diagnostics as part of a linked chain of evidence. Yet many questions about the evolution, organization and evidentiary role of this new form of scientific evidence are unanswered. The objective of this scoping review and bibliometric analysis (herein called our review) is to identify and categorize decision impact studies in genomic medicine to provide knowledge and context about this new form of evidence and contribute to an understanding of how these studies are situated in research, industry and clinical networks.

Methods

We will conduct a scoping review and a bibliometric analysis of the scoping review results.

Scoping review

A scoping review is a useful methodology to determine the coverage of a body of literature on a given topic and identify and analyze knowledge gaps [22]. To our knowledge, there is nothing in the current literature summarizing these studies, therefore a scoping review will examine the extent, range and nature of research activity [22]. We will use Arksey and O'Malley's rationale for scoping reviews and incorporate enhancements made to this methodology by Levac et al., [23]. The Preferred Reporting Items for Systematic Reviews and Meta-Analyses statement (PRISMA-ScR) will also be used to guide the reporting process of this review [24] and has been completed for this protocol (see additional file 1).

Bibliometric analysis

To give a more comprehensive and complete overview of the extent and complexity of the topic, we will conduct a bibliometric analysis of the scoping review results as a second step in our research study [25]. A bibliometric analysis is a type of social network analysis that can provide an overview of regional and time-based publishing trends, including research fields and keyword co-occurrence networks; influential journals, authors and collaboration networks between influential authors, countries, and institutions [25].

Identifying the research questions

Through an iterative process and based on the results of the preliminary literature review, the following research questions have been selected for this review:

RQ1: What are the characteristics of published articles of decision impact study articles?

RQ2: What areas of cancer research and geographic areas produce decision impact studies?

RQ3: How has the literature about decision impact studies developed and changed over time?

RQ4: What are the characteristics of decision impact studies?

RQ5: How do the outcomes of decision impact studies align with HTA clinical utility components (FT Model)?

Identifying relevant studies

We will conduct a comprehensive search of 4 databases, Medline, Embase, Scopus, and Web of Science including publications from inception of the databases. Due to resource constraints, only English language studies will be included. All publication types in these databases, e.g., reviews, conference abstracts, research studies will be included, and no study designs will be excluded. The rationale to include conference abstracts is to track origins and growth of these studies. As we are exploring the production and validation process of this new form of knowledge, this review will only include publications listed in the selected databases and not include gray literature.

Search strategy

We have developed two search strategies to identify decision impact studies in the literature. For the primary search we will use a broad search strategy to identify decision impact studies in genomic medicine in cancer care. Currently there are numerous different names and phrases used to describe “genomic testing” in cancer and this heterogeneity and lack of overarching taxonomy makes this type of search challenging. Therefore, we conducted a review of the literature and collected 47 terms, and from this list we developed a search strategy containing 28 search terms to capture genomic testing. In addition, we will include the names of 17 commercial assays. These terms, along with terms identified in our preliminary search to denote characteristics of a decision impact study, will be used for the primary search. Table 1 illustrates the search terms for the primary database search.

Table 1
Terms for primary database search

Topic	Search terms
Test/tool/assay	((("21-gene" or "70-gene" or "80-gene" or "recurrence score" or "50-gene" or molecular* or "genetic* profil*" or genomic* or ("tumour* sequenc*" or "tumor* sequenc*") or ("tumour* profil*" or "tumor* profil*") or "gene-expression" or (multi-gene* or multigene*) or multi-analyte* or "next generation" or "whole-genom*" or whole-exom* or transcriptomic* or biomarker*) adj2 (Diagnostic* or assay* or test* or profil* or technolog* or sequenc* or panel* or signature* or classifier* or prognostic*)) or (Mammaprint or endopredict or "endo predict" or prosigna or MammoStrat or Oncotype or "Breast cancer index" or BCI or IHC4* or "genomic grade test" or "Radiotype Dx" or "AIR-CIS" or "UroVysion FISH" or Cologuard or "Lung RS" or "MyPRS Plus" or ResponseDX or "FoundationOne CDx" or Percepta)
Action	(test* or assess* or recommend*) and (reduc* or unnecessary or decreas* or chang* or impact* or avoid* or minimiz* or "less likely" or "benefit") and (decide* or decision* or recommend*) and (adjuvant or "treatment recommendation*" or "treatment decision*" or "therapy change*" or "therapy recommendation*" or "treatment selection" or referral* or evaluation*)
	"Clinical utility" and ((individual* or direct* or guide* or tailor* or target*) and (therap* or treatment*)) or ((treatment* or therap*) and (selection* or management*)) or (actionable or prognostic* or decision* or reduc* or unnecessar*)
Area	cancer* or neoplasm*

As we are interested in the publication of decision impact studies and the origin and evolution of these type of studies broadly, we will search for items that use the exact phrase ("decision impact stud*" or "decision impact analys*" or "decision-making impact" or "decision making impact" or "decision impact") without limitation of the other search terms. This secondary search will identify articles that use this term in any area of research, topic or publication and will potentially illustrate the breadth and scope of these studies and provide data within which we will be able to contextualize decision impact studies and their role in evidence production. The results of the two searches will follow the same process, but the screening and data collection will be conducted separately. As we do not know at this time what type of study will be identified in the second search, we anticipate we will need to modify the data collection sheet for these results.

Study selection

Database search results will be imported into Covidence, a Cochrane technology platform, (www.covidence.org) for screening. The title and abstract screening process will be conducted by the full research team. Two reviewers (GP and HV) will screen all title/abstracts. As stated above, the title and abstract screen and full-text review for the two searches will be conducted separately. The title and abstract screening will be piloted with 25 articles for each search and results will be discussed and resolved with the research team. Full-text review for both searches will be conducted by two reviewers (GP and HV) with the third reviewer (FM) checking a random 10% sample of articles to ensure reliability. Discrepancies will be discussed and resolved collaboratively. For the results of the primary database

search, articles will be excluded if they are not human, not healthcare, not genomic medicine or not cancer focused.

Data collection and extraction

The data collection worksheet will be designed iteratively. It will be piloted with 5 studies that meet the eligibility criteria and revised based on the results. The data collected for the scoping review relate to the nature and characteristics of the studies and the data collected for the bibliometric analysis relate to the nature of publication, author details and geographic and affiliations. As described above, data collection for the two searches will be processed separately and we anticipate we will need to modify the data collection worksheet depending on the type of studies identified in the second search.

A component of our data analysis will be guided by the FT Model [21], with expanded thematic categories [16]. We will utilize the domains of the FT Model that demonstrate clinical utility to collect data pertaining to decision-making, treatment plans, patient and societal outcomes. Table 2 below details the research questions, data to be extracted, coding examples and stage of the review.

Table 2
Overview of the data extraction and coding table

Research Question	Data to be extracted	Coding examples	Scoping Review or Bibliometric Analysis
RQ1: What are the characteristics of decision impact study articles?	Type of literature	e.g., empirical, meta-analysis	SR
	Use the term "Decision impact study" or "Decision impact analysis"	Y/N	SR
	Total uses of term "decision impact"	#	SR
	How/where is the term used in article?	Title, abstract, keyword, body	SR
	Keywords	list	BA
	Co-occurrence of keywords	#	BA
RQ2: What types of cancer research and geographic areas use decision impact studies?	Type of cancer	e.g., breast, colon, lung	SR
	Geographic location of study	Country	BA
RQ3: How has the literature about decision impact studies developed and changed over time?	Year of publication	Year	BA
	Journal or conference	J or C	BA
	Journal published in	Name	BA
	Journal impact	Impact #	BA
	Conference presented at	Name	BA
	Authors	Names	BA
	Authors in common with other included studies	Names	BA
	Corresponding author's country	Country	BA
	Author's affiliation	Organization	BA
	Disclosure of interest/ conflict of interest	Author, disclosure	BA

Research Question	Data to be extracted	Coding examples	Scoping Review or Bibliometric Analysis
	Study funding	Source	
	Author funding (e.g., honorarium, employment, compensation)	Author, funding type, funding source	BA
	Citations	#	BA
RQ4: What are the characteristics of decision impact studies?	Objective of the study	State objective	SR
	Study design	Observational, Randomized experimental, non-randomized experimental	SR
	Data collection method	Retrospective, Prospective, Prospective and retrospective	SR
	Number of participants	#	SR
	Population	e.g., women with ER+, HER2-, breast cancer	SR
	Outcome measures	State outcome measures	SR
	Decision-maker	Provider or (molecular) tumour board (MTB)	SR
RQ5: How do the outcomes of DIS align with HTA clinical utility components? (from FT Model [21])	Level 3: Diagnostic Thinking Efficacy		
	Impact on Diagnostic Process	% Patients in which testing was identified as useful	SR
		% Patients that received a modified diagnosis or prognostic assessment based on genetic test results	SR
	Level 4: Therapeutic Efficacy		
	Impact on Clinical Recommendation(s)	Change in clinical recommendations	SR
	Impact on Intervention(s)	Change in intervention	SR
	Prevention and Treatment Optimization Outcomes	Net % reduction in unnecessary adjuvant chemotherapy usage	SR

Research Question	Data to be extracted	Coding examples	Scoping Review or Bibliometric Analysis
	Level 5: Patient Outcome Efficacy		
	Health-related	General: clinical response rate, life years gained, adverse event rate	SR
		Cancer-related: disease-free interval, disease recurrence rate, remission rate	SR
		QOL-related: Quality of life years (QALY)	SR
		Psychological: Cancer Worry Scale, Decisional Conflict Scale	SR
	Level 6: Societal Outcome Efficacy		
	Cost of Testing	Cost per patient, cost per patient/progression free survival week	SR
	Cost-Effectiveness	Cost per QALY gained, incremental cost effectiveness ratio (ICER), willingness to pay per QALY gained, PPV needed to achieve cost-effectiveness	SR
	Cost Savings	Mean annualized savings rate, net savings rate, average cost savings per patient	SR

Analysing the data

For the scoping review, the data will be collected and entered into an Excel spreadsheet for analysis and reporting. Descriptive statistics will be used to categorise and summarize the data. Categorisation will be completed by two members of the research team (GP and HV), with discrepancies resolved independently by a third reviewer (FM). All members of the research team will review the final summary of findings. The FT Model [21] with expanded thematic categories [16] will be used to categorize the clinical utility of the included studies. Aligning with scoping review methodology, the focus of this review is to identify and characterize decision impact studies and the quality of the studies will not be assessed. For the bibliometric analysis we will use Bibliometrix software to analyze the bibliometric data in the included studies. This analysis will be completed by two members of the research team (GP and HV). We will create a time map distribution of the literature and produce descriptive statistics and/or network visualizations for publication dates, publishing countries, impact (Impact Factor, CiteScore, and EigenFactor Score), citation count, keyword co-occurrences, coauthorships, funding, and collaboration networks for authors, institutions and countries. In addition, we plan to create hierarchical clusters based on the relevance of the words in the titles and keywords.

Discussion

The field of genomic medicine in cancer care is rapidly advancing. Decision impact studies are an emerging form of knowledge with a potential to inform the adoption and use of genomic tests in cancer care. To date, however, little is known about how this new form of knowledge has evolved, is organized, or structured to inform assessments of clinical utility. This review is the first step in developing this important body of knowledge. Understanding how these studies are motivated, developed and used to guide decision-making in cancer care is critical to understand their role in evidence-based regulatory and funding decision-making.

The scoping review methodology brings rigour and breadth to this task, enabling a comprehensive capture and analysis of the literature. Bibliometrics methods are an important source of complementary insight, supporting an understanding of the evolution and distribution of the actor networks that have developed this body of knowledge. There will, however, be a few limitations to this review. Due to resource limitations, we will only include English language articles and, as previously mentioned, the current heterogeneity of the terminology used to describe genomic tests may mean that the search criteria do not capture all studies on the topic.

Implications for research, policy and practice

Clinical practice, funding and market access are critical areas of healthcare that require complex decision-making. Understanding the origins, motivations and intended purposes of this new form of knowledge is critical to situating it in the context of its decision-making and regulatory role. This scoping review and bibliometric analysis will provide an in-depth synthesis of the research field to-date on decision impact studies. By making the knowledge production process explicit this review can add valuable insights to evidence-informed decision-making processes.

We anticipate the findings of this review will identify important research data to support future investigations. In our subsequent study we will leverage the knowledge gained from this review to further understanding of how decision impact studies are being used in decision-making at various levels including clinical practice, clinical practice guidelines, health technology assessment, market access regulation and funding decision-making in cancer care.

Abbreviations

PRISMA-ScR: The Preferred Reporting Items for Systematic Reviews and Meta-Analyses statement; EBM: Evidence-based medicine; EIDM: Evidence informed decision making; RCT: Randomised control trial; HTA: Health technology assessment; CPG: Clinical practice guideline; NIPT: Non-invasive prenatal testing

Declarations

Ethics Approval: Not applicable.

Consent for publication: Not applicable.

Availability of data and materials: The data supporting this article are included within the article and its additional files.

Additional file 1: PRISMA-ScR Checklist. Completed PRISMA-ScR Checklist indicating page number in manuscript of relevant content.

Competing interests: The authors declare that they have no competing interests.

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Authors' contributions: GP and FM conceived and designed the study. GP drafted the manuscript. FM provided critical commentary on the manuscript. Both authors read and approved the final manuscript.

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