ORIGINAL RESEARCH

Patient-centred outcomes of imaging tests: recommendations for patients, clinicians and researchers

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ABSTRACT

Background Imaging tests are one of the most frequently used diagnostic modalities in healthcare, but the benefits of their direct impacts on clinical decision-making have been countered by concerns that they can be overused. Assessing the relative value of imaging tests has largely focused on measures of test accuracy, which overlooks more comprehensive benefits and risks of imaging tests, particularly their impact on patient-centred outcomes (PCOs). We present the findings of the Patient Reported Outcomes of Diagnostics (PROD) research study in response to a methodological gap in the area of diagnostic test comparative effectiveness research.

Methods Over a 3-year period, the PROD Study engaged with multiple stakeholders to identify existing conceptual models related to PCOs for imaging testing, conducted primary research and evidence synthesis, and developed consensus recommendations to describe and categorise PCOs related to imaging testing.

Results The PROD framework categorises PCOs from imaging studies within four main domains: information or knowledge yielded, physical impact, emotional outcomes and test burden. PCOs interact with each other and influence effects across domains, and can be modified by factors related to the patient, clinical situation, healthcare team and the testing environment.

Conclusions Using PCOs to inform healthcare decision-making will require ways of collating and presenting information on PCOs in ways that can inform patient–provider decision-making, and developing methods to determine the relative importance of outcomes (including test accuracy) to one another.

INTRODUCTION

Multiple frameworks have been developed to evaluate diagnostic tests, which typically include generating evidence across phases of technical efficacy, test accuracy, diagnostic efficacy, therapeutic efficacy, patient outcome and societal aspects.[1–4] While test accuracy plays a pivotal role for clinical outcomes and regulatory approval, there have been repeated demands for more comprehensive methods to evaluate the benefits and risks of diagnostic tests in terms of patient-centred outcomes (PCOs).[5]

The concept that tests can impact patient well-being, in addition to 'clinical' outcomes,[6] has mainly been explored in the context of impacts of false positive screening test results.[7–9] There have been few attempts to systematically determine which PCOs are important to patients undergoing testing, nor the extent to which these outcomes are shared across different types of tests, and how these outcomes can be used as part of shared decision-making. Patient-centred care is based on the understanding that PCOs include topics that patients themselves identify as important,[10] which in turn can be used to drive service improvements by comparing performance on outcome metrics that matter to patients.[11,12] While this concept has been applied to comparative effectiveness research of interventions, it has rarely been applied to diagnostic tests.[5]

The Patient Reported Outcomes of Diagnostics (PROD) Study[13] aimed to develop consensus-based recommendations to guide methods for incorporating PCOs within comparative effectiveness research of diagnostic tests. We focused on imaging testing, given that this is one of the most frequently used modalities of testing in healthcare, yet faces concerns of overuse and rising costs.[9,14,15] We used primary research, evidence syntheses and input from multiple stakeholders to describe and categorise PCOs from imaging tests with a goal of informing clinical care, research and policy.

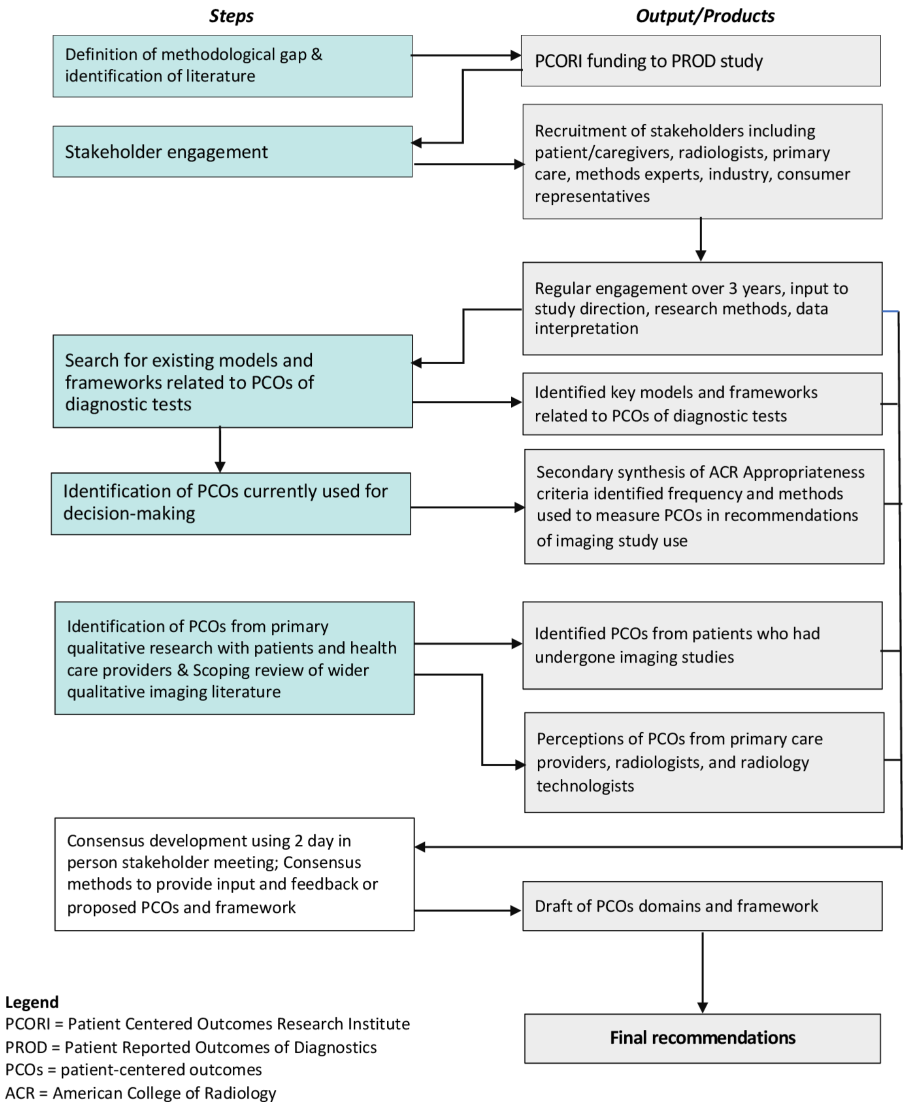

Figure 1 Data sources and methods used to develop final recommendations. Note: This figure was created by the authors and no persmission is required.

METHODS

Overview of approach

Our approach was based on the multistep processes used to develop consensus methods and research reporting guidelines.[12 16–18] Over a 3-year period, we: (1) confirmed the methodology gap and identified relevant conceptual models and frameworks, (2) recruited and engaged stakeholders, (3) identified PCOs currently used in clinical recommendations for imaging testing, (4) conducted qualitative research with patients and healthcare providers to identify PCOs, (5) conducted a scoping review of PCOs from existing qualitative literature, and (6) developed consensus-based recommendations on PCOs of imaging testing (figure 1).[19] We considered that consensus methods provided two advantages over other methods (such as Delphi or nominal group technique): first, allowing synthesis of the best available information; and second, allowing a process of consensus and validation between key stakeholders.[20]

Confirmation of methodology gap and identification of relevant conceptual models and frameworks

We used an iterative process to identify published literature that had attempted to address the methodological gap, including an extensive search of existing research on diagnostic test evaluation and imaging tests specifically. This was used to provide additional justification for the proposed research and identify any additional evaluation frameworks for diagnostic tests, conceptual models outlining the range of PCOs that may occur with testing, and literature specific to PCOs from imaging tests. We used a non-systematic scan of the literature search, including existing systematic reviews,[1–8] input from methods experts and focused hand-searching.

Stakeholder recruitment and engagement

We adopted the Six-Stage Model for Patient-Centered Outcomes Research and Comparative Effectiveness Research to guide stakeholder engagement.[21] Stakeholders were selected from the following: (1) patients and patient advocates with support from a patient advisory network (http://becertain.org/partnerships/patient-advisory-network); (2) primary care clinicians and radiology staff from the Washington, Wyoming, Alaska, Montana and Idaho Practice and Research Network; (3) the American College of Radiology (ACR); (4) consumer advocates; (5) imaging industry and (6) diagnostic methods experts. Recruitment was based on a combination of outreach through national, regional and local organisations. The stakeholders guided research direction, informed data collection instruments, interpreted findings and contributed to research outputs.[22 23] Additionally, stakeholders attended a 2-day meeting to develop the final recommendations.

Identification of PCOs currently used in clinical recommendations

In order to identify the frequency and type of PCOs reported in studies of imaging testing that are used to inform clinical recommendations, we conducted a secondary analysis of studies included in the ACR's Diagnostic Imaging Appropriateness Criteria which are used by referring physicians and radiologists to guide imaging test decisions and are incorporated into clinical decision support mechanisms. We used a broad definition of PCOs used by Patient Centered Outcomes Research Institute (PCORI) and modified by other researchers in this field.[5 6 24] We searched for PCOs reported in articles published across all clinical areas relevant to the PROD Study (ie, excluding paediatric and obstetric imaging, interventional radiology), and used systematic methods to extract and synthesise data.[25 26]

Qualitative research with patients and healthcare providers to identify PCOs

We conducted semistructured interviews with 45 patients who had undergone imaging studies across a variety of conditions and imaging modalities, 16 primary care providers, and 16 radiologists and radiology technologists to seek their experiences and perceptions of PCOs.[25 27] Patients and clinicians were recruited from primary care clinical sites and radiology offices affiliated with the Washington, Wyoming, Alaska and Montana Practice and Research Network (WPRN). This research also aimed to identify factors that could influence the perceived importance of these outcomes for patients.[28]

Scoping review of PCOs from existing qualitative literature

A scoping review of qualitative studies reporting PCOs from imaging studies was used to broaden the evidence base of PCOs beyond those identified from our primary research. We searched for studies reporting PCOs across multiple imaging modalities and clinical settings. The review aimed to identify relevant studies that had explored patients' emotions, knowledge, and physical preferences in relation to imaging tests either before, during, or after imaging testing. The scoping review, described in full in online supplemental appendix 1, identified and synthesised qualitative research that had reported PCOs from any type of imaging modality, clinical setting and patient group.[29–31]

Development of consensus-based recommendation on PCOs for imaging testing

At the end of the 3-year period, 28 stakeholders (online supplemental appendix 2) participated in a 2-day meeting held in Seattle, Washington, which aimed to define and categorise PCOs related to imaging testing, and provide recommendations for next steps needed to implement PCOs in decision-making. We followed the five key elements of consensus methods as outlined by Black *et al*.[32] (1) Approach to the task: the open-ended study goals were chosen to avoid influencing judgement or selectivity of the stakeholders, and our process included research evidence, experience of consumers (in this case, patients/caregivers) and clinical expertise (in this case, the primary care, radiologists and other stakeholders).[33] (2) Participant selection: one of the most important components of our consensus method was engaging multiple stakeholders, as described above, representing different potential viewpoints and expertise on PCOs. We considered this would provide a range of values, beliefs and experiences.[20] (3) Presentation of scientific data: we used the regular stakeholder meetings to engage stakeholders across the entire lifespan of this research. This included direct involvement with developing the primary research studies, input to findings from the primary research (including as coauthors), and presenting emerging descriptions and details of PCOs as they emerged. (4) Structure of the interaction: stakeholder meetings were facilitated by research staff with experience in patient engagement and occurred approximately quarterly teleconference for the initial study period of 2 ½ years. We held additional meetings only attended by patients and caregivers, with the same frequency over this period, to allow their voices to be fully heard. (5) Method of synthesising data: we aimed to achieve conclusions regarding the definition and categorisation of PCOs using a reflexive and iterative process.[34] Over the initial 2 ½ years of the research period, we synthesised findings from the emerging research at quarterly stakeholder meetings, developing and publishing in peer-reviewed literature the emerging findings. The 2-day in-person conference aimed to debate and review proposed final definitions and categorisation of PCOs, and provide recommendations for next steps needed to implement PCOs in decision-making. We did not intend to use this meeting to eliminate or rank importance of PCOs. Prior to the meeting, stakeholders received preparatory material including descriptions of PCOs that had emerged during the previous 2 ½ years, and lay summaries of additional publications. During the meeting, the research team presented the draft materials and used small group breakout sessions, to seek input on both the clarity of these definitions and whether any PCOs had been overlooked or missed out. We also used small groups to attempt to identify the best way to categorise the PCOs. Following the meeting, multiple written drafts of the consensus recommendations were distributed to stakeholders, and agreement was reached on the final document from all stakeholders.

Role of funding source

The work was funded by the PCORI, which approved the research plan submitted by the research team, but had no input to the research methods, findings, development of consensus recommendations, nor in preparation or approval for any manuscripts submitted for publication.

Human subjects approval

All primary qualitative studies conducted by the authors, which are referenced in this manuscript, were approved by the University of Washington Division of Human Subject as documented in those publications.[25 27 28] The activities of this consensus manuscript (including scoping review and systematic review) were determined to not involve human subjects and did not require additional IRB approval.

RESULTS

Confirmation of the methodology gap and identification of relevant conceptual models and frameworks

We identified several recommendations from groups such as guideline development organisations from the USA and Europe, and the Grading of Recommentations Assessment, Development and Evaluation (GRADE) Working Group that supported a need for methods to measure the effects of tests on PCOs.[5 18 35] The need for methods to broaden the evaluation of imaging testing was identified in several publications, including limitations in reporting of imaging test research.[9 36] Several studies had suggested a range of potential PCOs from diagnostic tests, but none had defined these in a systematic way.[6–9 37] This step of the process therefore confirmed that the methods gap that PCORI had identified had not been addressed in other publications.

Identification of PCOs currently used in clinical recommendations for imaging testing

The secondary analysis of the ACR Appropriateness Criteria identified 89 eligible studies; these covered a wide range of clinical areas and imaging modalities.[26] The most frequent PCOs identified were: concerns about radiation exposure (n=37), the need for additional testing following an initial test (n=20), test complications (n=19), and indeterminate or incidental findings (n=10). Other PCOs included quality of life (n=7), physical discomfort (n=5), patient values and experiences (n=4), patient financial and time costs (n=4), psychosocial outcomes (eg, depression, anxiety, claustrophobia) (n=4) and test duration (n=2) This analysis highlighted that relatively few PCOs are included in studies that underpin this set of clinical recommendations. The outcomes identified were mainly related to immediate or short-term health complications from the test process itself, and rarely reported from patients themselves.

Qualitative research with patients and healthcare providers to identify PCOs

Analysis of interviews with 45 patients, 16 primary care providers, and 16 radiologists and radiology technologists identified four themes related to PCOs.[25 27 38] These were: (1) information or knowledge gained from the test to address patients' questions and to facilitate next steps in their healthcare; (2) physical experiences during the test procedure, such as discomfort or potential adverse effects; (3) positive and negative impacts of the testing process on patients' emotions; and (4) the direct and indirect financial burden of testing. This research also highlighted factors that might influence outcomes, such as the effectiveness and content of patient–provider communication, impact of radiology staff, and patients' previous testing experience, underlying health, level of knowledge, expectations of the imaging test, insurance status, and cultural background.

Scoping review of PCOs from existing qualitative literature

We identified 25 qualitative studies that described PCOs, mainly focusing on mammography and MRI scanning, and most related to cancer screening, conducted in multiple countries (online supplemental appendix 1). We identified PCOs in three main domains, namely: (1) knowledge or information yielded by the imaging test including the desire to know what is wrong, irrespective of the finding, and a desire to know what individuals might experience both during test preparation and the procedure itself; (2) the emotional impact of the test both during preparatory stages and during the test, and the impact of compassion and empathy from radiology staff; and (3) physical discomfort associated with the testing procedure.

Development of consensus-based recommendation on PCOs of imaging testing

The stakeholder meeting facilitated discussion and feedback on proposed PCOs, domains and

Table 1 Patient-centred outcomes within domain of information or knowledge yielded by imaging tests

Outcomes	Definition/explanation
Finding cause of symptoms	▶ Finding out what is causing symptoms ▶ With a known diagnosis, information that leads to finding out how serious it is ▶ The desire for a definitive diagnosis, to reduce uncertainty
Reducing the probability of a condition that patient worried about	▶ Excluding a serious condition based on the test results
Value of just knowing or finding out more, whatever the outcome	▶ The desire to know, to find answers or just to find out/see something in their own body
Decision-making around the information given by the test, leading to action	▶ Test results facilitating access to higher level of care or proceed with a particular treatment course
False information from test results	▶ Initial positive results leading to need for further tests (or a sequence of tests) to further confirm/rule out a condition (false positives) ▶ False reassurance from test results (false negatives)
Incidental and indeterminate findings	▶ Indeterminate or inconclusive results leading to further downstream testing ('testing cascade') in attempts to arrive at a definitive diagnosis ▶ Unexpected findings that may or may not have clinical significance, but can lead to additional testing

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recommendations. The PROD team developed a matrix which proposed PCOs occurring across a range of domains, before, during and after an imaging test. This matrix was shared with stakeholders to develop consensus regarding the full scope of potential PCOs and categorisation into potential domains. The main outcomes, described below, categorised PCOs within four domains, outlined how PCOs can potentially interact with each other and identified factors that can modify how they are experienced.

Domain 1: information or knowledge yielded by an imaging test

PCOs in this domain included test information that contributes to determining an underlying cause for patients' symptoms or concerns, or information that led to reducing the likelihood of a condition (table 1). In addition, patients described the value of knowing or seeing these results, regardless to some extent of what the imaging had revealed. Additional PCOs related to the impact of test results on decision-making, such as facilitating access to a higher level of care or a particular treatment course. There were also several negative outcomes, including: misleading information, particularly false positive tests prompting the need for additional testing to confirm/rule out a condition; inconclusive or indeterminate results that did not provide a definitive diagnosis and could lead to further testing; and unexpected or incidental findings that might or might not have clinical significance, but require additional testing or investigations with associated burdens and impact on PCOs.

Domain 2: physical effects of the test or testing process

Preparing for imaging tests was associated with specific unpleasant experiences, such as undergoing bowel preparation prior to colonography (table 2). However, more prominent outcomes were pain and physical discomfort while undergoing the imaging procedure (eg, mammography), as well as its immediate consequences. In some instances, the discomfort from an imaging modality depended on the area of the body being examined, for example, transvaginal versus abdominal ultrasound. Other physical outcomes included the effects of ionising radiation, which was mainly cited by patients undergoing frequent imaging.

Domain 3: emotional impact of the test or testing process

Tests used to evaluate new and/or concerning symptoms provided reassurance and relief when results ruled out certain conditions (table 3). Even in situations when results indicated an underlying

Table 2 Patient-centred outcomes within domain of physical outcomes from imaging tests

Outcomes	Definition/explanation
Preparation for the test	▶ Undergoing preparation such as bowel preparation, or fasting, or ensuring full bladder
Physical discomfort, tolerability during the test	▶ Pain from interventions or manipulation needed as part of testing procedure ▶ Bruising from body parts being compressed or held in certain positions
Longer term physical effects	▶ Reactions to contrast material ▶ Cumulative effects of ionising radiation

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Table 3 Patient-centred outcomes within domain of emotional outcomes from imaging tests

Outcomes	Definition/explanation
Reassurance, relief	▶ Relief or reassurance after finding symptoms not caused by serious condition
Anxiety, worry	▶ Fear or anxiety waiting for testing to be performed and in anticipation of results ▶ Stress and anxiety while waiting to get test result ▶ Distress and other negative emotional impacts when test shows a serious condition, including false positive results
Claustrophobia, embarrassment	▶ Claustrophobia, distress from imaging testing process (eg, narrowness of scanner, noise) ▶ Embarrassment or loss of modesty from exposing private body parts
Lack of control	▶ Perceived lack of control over the test ordering, its conduct and the next steps the results lead to ▶ Feeling abandoned, isolated or helpless during the imaging test itself
Decisional regret, mismatch with expectations	▶ Frustration or regret about uncertain test results leading to further testing ▶ Disappointment in test results that do not provide the information or findings expected, or that leave residual uncertainty

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condition, some patients reported feelings of relief that they had found the cause of their concerns. However, testing also produced anxiety and negative emotional outcomes that could occur before the test (anticipation anxiety), and afterwards while waiting for results, and as a result of test findings. During the imaging procedure, the physical constraints, confined spaces, noise and unfamiliarity of the procedures could lead to feelings of claustrophobia and distress, as well as embarrassment from having to undress. On some occasions, negative emotional outcomes resulted from disappointment or regret about initiating testing, from test results that did not answer concerns or revealed information that did not advance their care.

Domain 4: test burden

Outcomes related to the direct or indirect burdens of imaging tests (table 4) included financial costs to patients, but these varied with the healthcare/health insurance system. These costs were particularly noted for complex imaging (MRI, CT, etc), and in situations where an initial, less costly, imaging test revealed findings that required more complex, and more expensive, subsequent imaging. Direct costs were not always expected or considered prior to the test itself, and few patients were aware of costs. Similarly, healthcare providers recognised the importance of cost, but lacked information about actual costs. Other test burdens included time off work and travel times particularly for patients living far from imaging centres. Occasionally, the results of imaging testing led to financial benefits to patients, for example, when imaging testing revealed conditions related to occupational or other injuries.

Interactions between outcomes

In addition to the outcomes categorised within these four domains, PCOs interacted with, and influenced, outcomes in other domains. These interactions included, for example, knowledge or information provided by a test result (domain 1) influencing patients' emotions (domain 3), or, a test that is more physically unpleasant (domain 2) that provides more valuable information (domain 1) than one that is less invasive. The pattern of interactions appeared to be complex and varied with factors such as test modality and clinical situation. Recognising these interactions exist suggests that weighing of risks and benefits across domains is likely to be challenging to incorporate into research or clinical care.

Modifiers of outcomes

Multiple factors potentially impacted or modified whether or not a PCO occurred, its severity, its relative importance and its impact on the patient (table 5).[28] These ranged from the characteristics of the individual patient, the type of test they are undergoing, the clinical situation, as well as the healthcare providers involved, the physical environment of the testing suite and communication of results. Embedded within several of these modifiers was the concept of a patient's prior (pretest) probability of a particular outcome or condition.

Table 4 Patient-centred outcomes within domain of burden from imaging tests

Outcomes	Definition/explanation
Financial costs of the test	▶ Costs that the patient experiences directly or indirectly from the testing process itself ▶ Costs that arise from the clinical actions that the test leads to ▶ Potential financial benefits from workplace injuries or insurance or disability claims
Disruption to work or social life	▶ Disruption to work, school, social activities from waiting for test to be performed, and undergoing the test itself, and waiting for test results (eg, time off work)

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Table 5 Factors that may modify patient-centred outcomes (PCOs) related to imaging tests

Modifier	Definition/examples
Individual patient characteristics	▶ Sociocultural factors may impact response to multiple components of the testing process ▶ Prior experience of the test or testing process may influence knowledge and expectations of the test's purpose and acceptance of related risks ▶ Prior probability of the condition being tested for, whether actual or perceived by the patient
Test type (ie, screening, diagnostic, monitoring)	▶ Screening tests can lead to false positive results given large numbers of asymptomatic people being tested with relatively low prior probability ▶ Monitoring or surveillance for known condition (eg, cancer recurrence) can lead to anxiety in test intervals, and/or reassurance if results are negative
Clinical situation	▶ Nature of the clinical condition being evaluated and its potential significance for that person's healthcare may affect the balance of PCOs ▶ Testing in high acuity (eg, emergency department) settings may present different balance of benefits and risks (and prior probability of a given condition) compared with lower acuity (eg, primary care) setting
Clinicians and healthcare team	▶ Perception of size and importance of test benefits and risks, based on experience, relationship with patient, healthcare setting, and knowledge or perception of an individual patient's prior probability ▶ Ability (including time) to communicate indication for test is being used, relative risks and benefits ▶ Medical culture(s) may impose norms around test utilisation, acceptable levels of risk, patient expectations
Physical environment of imaging suite	▶ Location in the clinic/hospital, visual appearance can influence patient emotions around the testing process ▶ Radiology staff can modify outcomes such as emotions and physical experiences through communication, trust and empathy
Communication of test results	▶ Methods and timing of communicating results may impact the knowledge or information or emotional impact of the test

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For example, a patient with a known history of a given condition may be at higher risk of recurrence (higher prior probability), whereas an asymptomatic individual being screened for that condition would be at a lower prior probability. These prior probabilities can influence outcomes following the test result (such as greater anxiety in the emotion domain).

DISCUSSION

The Institute of Medicine highlighted that patient-centred practices are needed to address the psychological and social dimensions of patients' healthcare concerns, in order to close quality gaps in healthcare.[39 40] This study provides the first comprehensive attempt to define PCOs of imaging tests. We found that PCOs from imaging tests can be categorised into four domains: (1) information or knowledge yielded, (2) physical effects, (3) emotional outcomes and (4) test burden. We also noted that PCOs interact and influence each other in ways that are complex. Moreover, PCOs are not experienced identically; instead, they are influenced by factors related to the patient, the clinical environment and the physical environment of the test.

Our research advances an earlier concept that tests have more than 'medical value'.[6 7 41 42] While certain outcomes related to testing have been previously described, for example, emotional distress from false positive screening tests,[43–45] a clear description and categorisation of PCOs related to imaging tests have largely been overlooked.[4647]

A strength of our recommendations is that they were informed by a wide body of primary and secondary research, and relied also on extensive input from a range of stakeholders, and are applicable to imaging testing generally, rather than one type of test (eg, screening) or a single imaging modality. We used consensus methods, following key steps that have been recommended for this type of process.[32] Furthermore, a key area of guidance from our stakeholders was to focus on PCOs more directly related to the test and the testing process itself, rather than less direct (or indirect) impacts of the test on 'downstream' clinical management decisions and outcomes. We acknowledge there is limited literature to evaluate the validity, reliability and rigour of consensus methods,[32] but we believe the methods used fulfil the criteria proposed by Hasson *et al*, namely credibility, applicability, auditability and confirmability.[48] We used a process of prolonged engagement, with ongoing reflection of research findings both from research conducted by our team as well as wider literature, and based draft PCOs on evidence, and iterated on these over a period of 3 years including teleconference and a face-to-face conference with a heterogeneous group of stakeholders, representing patient, caregiver, clinician, researcher and industry perspectives. However, we acknowledge that there may now be value in further research to prioritise or rank the PCOs that we have described, using methods such as Delphi or nominal group technique.

The current focus on accuracy in evaluating imaging tests (and diagnostic tests in general) risks ignoring outcomes that may be meaningful from patients' perspectives; it is the balance of outcomes

Box 1 Next steps needed to advance the use of patient-centred outcomes (PCOs) for imaging testing

Measurement

⇒ Validated measurement instruments for the full range of PCOs.

⇒ Outcomes collected from patients themselves.

Relative importance of outcomes

⇒ Methods to rank the importance of individual PCOs, and to balance positive (beneficial) and negative (harmful) outcomes, considering their severity, impact, timing of outcome.

Reporting

⇒ Expanded standards for reporting PCOs in evaluation of imaging tests.

Impacting care

⇒ Information on PCOs that can be collected and meaningfully shared with patients and the healthcare team to inform decision-making.

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that are important to patients, their caregivers and clinicians.[49] However, patients and their clinicians currently lack information to make reasoned choices on the benefits and harms of diagnostic tests.[50] Incorporating PCOs into diagnostic test evaluations has implications for guideline developers and policymakers. Measures of patient satisfaction typically focus on patient experience of services provided, overlooking PCOs. Fulfilling outcomes that are important to patients may lead to greater satisfaction. This can only be achieved for diagnostic testing if the outcomes that are important to patients are known and can be measured.[25 51 52] Regulatory approval of new tests also focuses on test accuracy, although there is growing interest by the US Food and Drug Administration to consider additional impacts of tests in such decisions.

In order to advance the use of PCOs in research and implementation of imaging testing, we propose several next steps (box 1). First, validated measurement instruments exist for only some PCOs we identified, and few outcomes are collected using information from patients; there is a need to develop instruments to measure the range of outcomes we describe.[53] This may be challenging when measuring the value of information (knowledge) from patients' perspectives, and in considering the implications of the modifying factors we identified. Second, we need to determine the relative importance of outcomes to each other (and particularly to test accuracy). Evaluating risks and benefits of a given test is likely to vary with the severity, prominence or impact of the PCO related to that test. Balancing beneficial and harmful, as well as short-term and long-term impacts, may require more quantitative or discrete choice methods.[54] Third, improved reporting of PCOs by extending current reporting standards for diagnostic accuracy studies[55] could facilitate reporting of additional test outcomes.

Finally, measuring PCOs is of little value if it fails to inform healthcare decision-making and quality of care.[51] If the outcomes of imaging testing that are important to patients are known and can be measured, attempts to achieve these outcomes may lead to greater engagement with subsequent clinical management.[51 52] Currently, however, for most tests and testing situations, patients, caregivers and providers lack information on PCOs. Efforts will be needed to collect information of PCOs and present this in ways that can be used to guide decision-making.[35 56] We anticipate that this expansion of methods for test evaluation will stimulate new standards for research, reporting and use of PCOs, across the wider field of diagnostic testing beyond imaging tests.

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Appendix 1: Methods and findings from scoping review of qualitative literature regarding patients' preferences in relation to imaging tests

Aim of the scoping review

Evaluation of imaging tests has been primarily concerned with demonstrating their ability to correctly 'rule in' or 'rule out' a diagnosis, and studies comparing test accuracy are used to guide regulatory approval and clinical adoption[1-4]. In order to describe more fully the range of patient-centered outcomes (PCOs) that are important to patients undergoing imaging studies we conducted a scoping review of qualitative research that described patients' experiences of imaging testing, to provide further evidence on the PCOs that had been identified by our primary qualitative research.[5 6] Our overarching research question was to describe adult patients' emotional, knowledge, and physical experiences and outcomes occurring before, during, or after undergoing imaging testing for any reason and any medical condition. We also sought to understand why these preferences were important to patients.

Methods used for scoping review

We followed Arksey and O'Malley's methodological framework for scoping reviews, supplemented by more recent recommendations and reported in line with the scoping review extension to PRISMA [7-9]. A protocol was developed and refined based on input from the Patient-centered Research for standards of Outcomes in Diagnostic testing (PROD) stakeholder group consisting of clinicians, methodological experts and patient representatives, convened to provide input to the PROD research program.

Search strategy

We developed a list of preliminary search terms related to the following overarching PCO themes identified from primary research conducted for the PROD study as well as additional literature on PCOs related to diagnostic tests: emotional reactions, physical effects, and the knowledge/information gained from imaging testing [6], this was facilitated by an Information Specialist and identification of keywords used in titles and abstracts of relevant articles known to the authors. Search terms were then mapped onto the relevant domains of the SPIDER framework for qualitative evidence synthesis (Sample, Phenomenon of Interest, Design, Evaluation, Research type) [10] to build a search strategy. The SPIDER tool was chosen as the domains allowed construction of an inclusive yet efficient search strategy. The search strategy was iteratively tested to determine the optimal search and the included terms and domains refined until agreement on the final strategy was reached between two authors (VH, MT). We searched a single bibliographic database searched (PubMed). Filters were applied for date range

(01/01/2003 through 06/28/2018), English language, and human subjects. (see terms available from authors).

Study selection

The final search results were imported into EndNote and duplicate articles removed. Titles and abstracts were screened for eligibility by one reviewer (VH); articles deemed potentially relevant were reviewed by a second reviewer (MT) and discussed for final determination of inclusion. Studies of original research conducted within the last 15 years were eligible for inclusion if they solicited patients' and/or caregivers' lived experiences of imaging testing. Caregivers' perspectives were included due to the integral role they have advocating, supporting and coordinating patients' healthcare. To capture narratives representative of the spectrum of patients undergoing imaging tests in routine practice, studies of patients with cognitive or physical disabilities were included. We limited study settings to high income countries (as defined by the OECD). We excluded neonatal, pediatric, or adolescent imaging studies, and interventional radiologic procedures to align with the PROD study aims. 'Snowballing' was used to identify additional studies from references of relevant full texts and any systematic reviews identified.

Data abstraction

An electronic data-abstraction spreadsheet was used to abstract data on author, country, population, setting, number of participants, imaging modality and purpose, and data collection methods/qualitative approach. One reviewer (VH) extracted the data of which 20% was checked by a second reviewer (MT). Qualitative data was charted against *a priori* PCO domains of 'emotion', 'knowledge' and 'physical'; excerpts consisted of participant quotes (with relevant participant descriptors where reported), and verbatim interpretation of the original data.

Collating, summarizing and reporting results

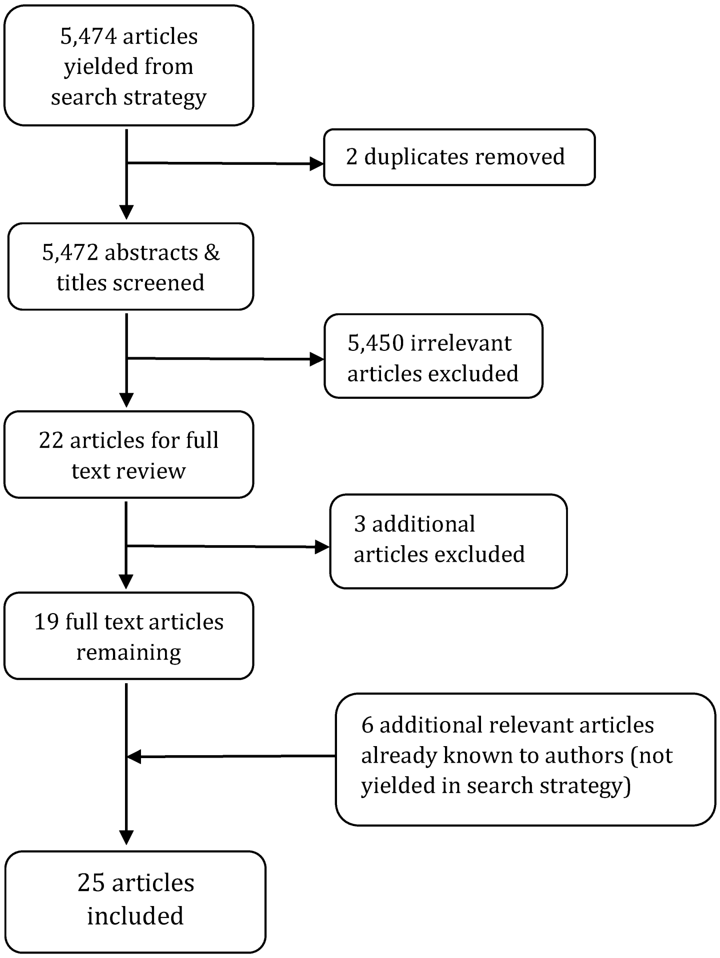
We used framework synthesis to synthesize results, which is appropriate when using a pre-existing 'framework' underpinned by previous research, and for conceptualizing the range of ideas (i.e. PCOs) being explored [11]. Data analysis was led by one reviewer (VH) and began by reviewing the included articles to become familiar with the findings. The same author re-read the articles in-depth, highlighting and making annotations against words, sentences and sections of text (participant quotes and authors' interpretation) that related to emotion, knowledge/information gain, and physical aspects of imaging testing. New PCOs within each of the pre-established domains were allowed to emerge from the coded data, forming subthemes. Themes were discussed with two reviewers (MZS, MT) and consensus reached. During this process, we reflected on any impacts that our own preconceptions and interests could have had on data interpretation. To ensure balanced interpretation and presentation, findings were reviewed by stakeholders. The organization and analysis of qualitative data was facilitated by NVivo.

Results

Study selection

The search identified 5,472 articles, after removing duplicates, which were screened to identify 22 potentially includable articles. Following full text review, 19 qualified for inclusion in this review. A further 6 relevant articles were identified from snowballing, providing a total of 25 articles included in this review (**Figure**).

Figure. Flow of included studies



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Characteristics of included studies

Data on a total of 656 patients and 23 caregivers were included in the 25 studies, with the overall sample being predominantly women (78%) (**Table 1**). Included articles were conducted in the United States (9), United Kingdom (8), Sweden (3), New Zealand (2), Australia (1), Germany (1), and Spain (1). Imaging tests included mammography (10), MRI (4), PET/(CT) (2), CT (2), SPECT-CT (1), CT colonography (1), CCTA (1), two were of multiple imaging modalities, and in one study the imaging test was not clearly reported. The target conditions and/or outcomes reported in the included studies were breast cancer (7), oropharynx/oral cancer (1), lung and/or colorectal cancer (3), inflammatory arthritis (1), coronary artery disease (1), multiple sclerosis (1), false-positive test results (2), incidental/indeterminate findings (3), Alzheimer's Disease (1), and was unclear or not reported (5). In studies where both patient and staff views are presented, only the patient views are extracted.

Table 1. Characteristics of Included Studies

Author, year (country)	Population	Gender; race/ethnic composition	Imaging modality	Purpose	Target condition / outcome	Data collection method
Andersson et al., 2017 (Sweden) [12]	Patients with confirmed head and neck cancer (n=9)	7 men, 2 female (aged 48-75 years); not reported	F-FDG PET/CT with fixation mask	Staging and radiation treatment planning	Oropharynx or oral cancer	Conversational interviews within 1 week of imaging
Bourke et al., 2017 (New Zealand)[13]	Patients with confirmed or suspected inflammatory arthritis with peripheral joint imaging test in preceding 6 weeks (n=33)	17 female, aged 25-83 years , 70% New Zealand, 12% New Zealand Maori	Conventional radiology, Ultrasound, MRI, CT	Diagnosis and management	Inflammatory arthritis (included rheumatoid, psoriatic, gout and undifferentiated inflammatory arthritis)	Semi-structured interviews within 6 weeks of imaging
Bond et al., 2015 (UK)[14]	Asymptomatic women who had experienced false-positive mammogram (n=21)	21 female aged 42-69 years; not reported	Mammogram	Screening	Breast cancer	Semi-structured interviews held between 0.5 and 12 years since false-positive mammogram
Brand et al. 2014 (Germany) [15]	Multiple Sclerosis patients with relapsing-remitting course (n=5)	All female aged 22-48 years; not reported	MRI	Management	Multiple Sclerosis	Semi-structured interviews
Carlsson et al. 2013 (Sweden)[16]	Patients undergoing variety of imaging examinations (e.g. brain, spine, pelvis, and hip) (n=10)	5 male, 5 female aged 21-70 years; not reported	MRI	Diagnosis	Unclear	Semi-structured interviews
Devcich et al. 2013 (New	Non-acute cardiac patients attending	Not reported (aged 39-71 years)	CCTA	Diagnosis	Coronary artery disease	Semi-structured interviews

Zealand)[17]	heart clinic (n=13)					conducted immediately following CCTA but prior to diagnosis, and immediately after communication of test results during cardiology consultation
Engelman et al., 2005 (USA)[18]	Women who underwent a mammogram within the previous 3 years with no history of cancer (n=103)	103 female aged 40-83 years; 53% Hispanic, 15% Black, 32% Non-Hispanic White	Mammogram	Screening	Not reported	Focus groups conducted in rural and urban communities
Engelman et a., 2012 (USA)[19]	Women with no prior history of breast cancer with mammogram during the 36 months prior to focus groups (n=88)	All female aged 40-82 years; 55% Hispanic, 45% Non-Hispanic White	Mammography	Screening	Breast cancer	Focus groups stratified by racial/ethnic groups: Hispanic and non-Hispanic white women
Evans et al., 2017 (UK) [20]	Patients participating in trials investigating value of WB-MRI for accelerating cancer treatment (n=51)	31 male, 20 female aged 40-89 years; not reported	Whole Body-MRI	Staging	Lung and colorectal cancer	Face to face and telephone interviews within 63 days of test
Grill et al., 2017 (USA)[21]	Patients (n=10) and caregivers (n=23) for whom option of amyloid imaging had been discussed	*Patients:* 4 female aged52-83 years; 8 white, 2 Latino *Caregivers:* 14 female aged 38-89 years; 19 white, 3 Latino	PET	Diagnosis	Alzheimer's Disease	Telephone interviews including open-ended questions with patients (and caregivers) who did and did not complete the scan
Hafeez et al., 2012 (UK)[22]	Patients referred for conventional colonoscopy invited to undergo MR colonography 2 hours prior (n=18)	11 male, 8 female median age of 40.5 years; not reported	MR Colonography	Diagnosis	Inflammatory bowel disease and suspected colon cancer	Semi-structured interviews
Lown et al. 2009 (USA)[23]	Women who had a diagnostic mammogram within previous 12 months (n=13)	All female with a mean age of 54 years; all white	Mammogram	Diagnosis	Breast cancer	Focus groups
Lumbreras et al. 2017 (Spain)[24]	Participants identified from a population survey with experience of imaging in previous 12months (n=20)	8 male, 12 female aged 18-90 years; not reported	X-ray CT MRI Mammography Ultrasound	Unclear	Unclear	Focus groups
Mathers et al.,	Women aged 42-63	All female; not	Mammography	Diagnosis	Breast cancer and	Semi-structured

2013 (UK)[25]	years with diagnosis of cancer or attending for further investigations of breast abnormalities previously detected (n=16)	reported			previously detected breast abnormalities	interviews first conducted 1 to 23 years after original diagnosis. Additional interviews conducted for those attending subsequent breast imaging
Nightingale et al., 2012 (UK)[26]	Cardiac patients attending cardiac imaging (n=22)	13 female, 9 male with a mean age of 63.9 years; not reported	SPECT-CT	Unclear	Unclear	Semi-structured interviews conducted before and after imaging on the day of SPECT-CT procedure
Poulos et al., 2005 (Australia)[27]	Women attending breast screening programs (n=12)	All female	Mammography	Screening	Breast cancer	Not reported
Slatore et al. 2013 (USA)[28]	Asymptomatic veterans with incidentally detected pulmonary nodules planning to obtain follow-up imaging (n=19)	18 male with a mean age of 66 years; 17 white	Unclear	Unclear	Incidental pulmonary nodules	Interviews conducted mean of 154 days after nodule detection
Sullivan et al. 2015 (USA)[29]	Veterans with an incidentally detected pulmonary nodule (n=17)	16 male with a mean age of 64 years; 14 white	CT	Surveillance	Incidental pulmonary nodules	Interviews conducted after first and second annual follow-up CT scan
Thomson et al. 2015 (USA)[30]	Women with confirmed false positive screening mammogram result with no personal history of cancer undergoing secondary imaging testing (n=40)	All female aged 40-68 years; 45% African American.	Mammogram	Screening	Breast cancer	Semi-structured interview
Tornqvist et al., 2006 (Sweden)[31]	Patients who did and did not complete different MRI scans (e.g. brain, spine, abdomen, wrist) because of varying levels of anxiety about the test (n=19)	12 female, 7 male aged 22-73 years; not reported	MRI	Unclear	Unclear	Conversational interviews with patients who did and did not complete the scan
Truesdale-Kennedy et al., 2010 (UK)[32]	Women with borderline to moderate intellectual disabilities undergoing breast screening in	All female aged 31-69 years	Mammography	Screening	Breast cancer	Focus groups using a semi-structured topic guide

	previous 12months (n=19)					
von Wagner et al., 2009[a] (UK)[33]	Symptomatic patients who had recently undergone CT colonography, barium enema or colonoscopy (n=49)	35 female, 14 male aged 57-92 years; not reported	CT Colonography	Diagnosis	Colorectal cancer	Semi-structured interviews conducted within 3 months of CT colonography, colonoscopy, or barium enema
Whelehan et al., 2016 (UK)[34]	Women with satisfactory and unsatisfactory experiences of breast screening programs (n=22)	All female (aged 28-56 years); 20 White British/Scottish, 1 African, 1 Afro-Caribbean	Mammography	Screening	Breast cancer	Semi-structured in-depth face-to-face or telephone interviews within 6 weeks of test (3 interviews were conducted >3 years after screen)
Wiener et al. 2012 (USA)[35]	Patients undergoing surveillance of an indeterminate nodule identified during workup of a pulmonary symptom or an incidental finding during workup of a non-pulmonary symptom (n=22)	86% female with a mean age of 60.7 years; 77% white, 18% black, 4.5% Hispanic	CT	Surveillance	Indeterminate pulmonary nodules	Focus groups
Wilkinson et al., 2011 (USA)[36]	Women with intellectual disabilities (n=27)	All female aged 27-69 years; 24 white, 3 black	Mammography	Screening	Breast cancer	Semi-structured interviews

Abbreviations: OP = outpatients, CT = computerized tomography, MRI= magnetic resonance imaging, SPECT-CT = single photon emission computed tomography, CCTA = coronary computed tomography angiography, PET = positron emission tomography, FDG-PET = fluorodeoxyglucose-positron emission tomography.

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KNOWLEDGE OUTCOMES

Desire to know what is wrong

Knowing *what* is wrong was important to the majority of (symptomatic) patients undergoing MRI (e.g. for staging of lung and colorectal cancer), PET (e.g. for suspected Alzheimer's) and SPECT-CT (for conditions including multiple sclerosis and disc herniation), whereas knowing *if* something is wrong was important among patients under surveillance for incidental findings (e.g. pulmonary nodules) (**Table 2**).[12,13,15,20,21,26,29,31,35] Although patients, irrespective of imaging test, were fearful of a positive result such as tests showing recurrence or metastasis, most wanted a definitive diagnosis so they could either pursue the care needed to help them manage their condition, or make future social and health care plans.[12,21]

Patients and caregivers (sometimes with a mixed understanding of what a test could reliably rule-out),[35] viewed information yielded from imaging tests as a stepping stone towards obtaining a resolution.[16 20 21] Overall, this desire for knowledge was often reported to motivate patients to have an imaging test - only a small number were reported to decline (one example was the use of PET for Alzheimer's[21] because they felt test results (whether positive or negative) would have little impact on their overall management plan or prognosis.[21] Getting a definitive diagnosis brought relief to many symptomatic patients, irrespective of the results. On the other hand, feelings of surprise or shock were reported among a small number of symptomatic patients who had not considered a serious illness as a possibility, and anxiety in those with indeterminate results. Furthermore, those with incidental findings experienced anxiety from not knowing whether the finding (e.g. a lung nodule) was malignant, or might eventually become malignant.[35]

Desire to know what to expect

Patients ranged from feeling well informed about what they might expect while preparing for the test or during the test itself (WB-MRI, colorectal cancer),[13] to feeling insufficiently prepared.[20 36] Specifically, they wanted information about any potential sensory (e.g. what they might feel when injected with contrast material) or physical experiences of the test (e.g. narrowness of the imaging machine, noises they would hear, or discomfort they could expect to experience).[36] This information was typically desired ahead of the procedure to help them prepare for the experience,[20] or manage underlying anxieties, or to reconcile what they had learned from friends or relatives who had undergone the test and/or internet searches. During the procedure, patients highlighted the importance of repetition of the instructions so they knew what to expect at each step. This made patients feel more in control of their own emotions, and made the test feel less intimidating.[19]

Desire to know the possible harms of the test

Overall, patients' views were mixed regarding possible harms associated with imaging tests. Some were aware of the potential for adverse reactions from intravenous contrast material and concern about (accumulated) radiation exposure from (repeated) advanced imaging modalities (e.g. CT, MRI).[24] Patients generally believed risks had not been adequately explained[26] or where they had been, they struggled to understand what had been communicated to them due to use of medical jargon.[24 26] Consequently, they expressed desire for clear and concise information about possible harms. Although lack of knowledge concerned some patients who wanted to be informed about the risks of tests, notably radiation exposure;[17 24 26] they believed the benefits typically outweighed the risks and were unconcerned or dismissed any possible harms and informational needs.[24]

Rapid feedback of results

A desire for rapid feedback of imaging results was prominent among the majority of patients who underwent a range of imaging studies (CT, MRI, MR colonography and mammogram). The anticipation of receiving potentially life-altering information was difficult to manage for many. They felt anxious and 'in limbo', reluctant to make important life decisions or plans in case of bad news when those plans might have to be abandoned. Most were symptomatic and were waiting for a diagnosis (of bowel disease, multiple sclerosis, breast cancer) and expressed dissatisfaction or distress with the length of time taken for results to be released or reported to them (between 3 days and 5 weeks, reported in one study).[25] A few patients believed the time it took to receive results was inversely proportional to the gravity of those results and so were reassured (falsely) by slower communication of results.[28] Patients experiencing an exacerbation of a known disease (of inflammatory bowel disease [22] were less anxious about waiting for results. However, for most patients alleviating anxiety over the possibility of cancer (or its recurrence), patients (symptomatic, without a diagnosis) wanted results issued on the same day as the test, regardless of whether findings were positive or negative.[16 20] Preferences for method of result communication varied; some preferred notification in person or over the telephone,[28] others were satisfied with written communication if it enabled results to be issued more promptly.

Table 2: Knowledge outcomes: themes and illustrative quotes

Desire to know what is wrong	*"But from a standpoint of managing her care and figuring out how best to take care of her with her symptoms, I feel like the scan was really positive in that it let me know she probably couldn't go home and live by herself again and that I would really need to take her care in a direction that none of us anticipated or could have predicted"* [21] *"These loud noises really paled into significance because in my body now I've got a nasty little house guest, which has now stayed, not welcome, I'm going to get rid. And this is part of the mechanism to get rid […]. And these are the pictures that would help me get that done"* [12]
Desire to know what to expect	*"if you're informed and you know what to expect then it's not so scary"*[19]
Desire to know the possible harms of the	*"I always wonder how much radiation I am going to receive because I have never studied it and no-one has ever told me."*[24]

test	*"There's a lot of strange fears about radiation and it's gone crazy"*[13] *"If the physician thinks I need the test to improve the management of my disease, I consider that the benefit/risk balance is in my favor"*[24]
Faster feedback of results	*"Waiting for the results is absolute hell"* [25] *"No test results yet. I am just hoping they didn't find anything and there is another avenue that I might go down. I am dreading it might be cancer"* [20]

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EMOTIONAL OUTCOMES

Desire for compassion and empathy from radiography staff

Patients identified that compassion and empathy from radiography staff, both before in the preparation and during imaging, as influencers of their experience of imaging, particularly when undergoing screening mammography.[27 34 36] Although some appreciated a depersonalized approach by staff as one way to mitigate embarrassment, others felt that a 'clinical' demeanor or perceived lack of interest by staff could be distressing.[25] Given anxiety about the (anticipated or previously experienced) discomfort of the mammogram, the possibility of a diagnosis of breast cancer diagnosis, and vulnerability from being physically exposed, patients wanted radiography staff to demonstrate sensitivity in the manner in which they gave verbal guidance and physical assistance (during breast positioning);[23 32 34] and cultural awareness of their modesty. Although patients infrequently reported terminating the procedure as a result of the demeanor of staff[20] their manner contributed to them feeling reluctant to participate in future screening programs[36] whereas compassion and empathy helped patients to endure any discomfort and pain associated with the imaging test.[34]

Desire for reassurance that they 'are not alone'

Patients wanted to know that they were not alone in what they viewed as the unfamiliar and lonely environment of some imaging modalities, and were reassured by physical presence and/or verbal interaction with staff [20 26]. This was frequently identified as important to patients during MRI, CT and PET imaging procedures, where feelings of isolation, abandonment and helplessness dominated.[12 20 26] Whilst physical proximity of staff typically provided patients with the most reassurance, communication through the intercom (and trust that staff would respond to calls for help) was also helpful in making patients feel secure during image acquisition.[16 20 26] The emotional comfort of knowing staff were close by was sometimes enough to influence whether the procedure was prolonged or prematurely terminated.[26 31]

Table 3: Emotional outcomes: themes and illustrative quotes

Desire for compassion and empathy from radiography staff	*""It's like they're handling a lump of meat. Sort of throwing it on a slab and doing something to it. That how I think I would feel if I had large breasts"* [27] *"I just felt she didn't seem interested, you were just another number. It was quite uncomfortable and she just kept saying 'If you don't stand right, you will have to come back again'"* [25] *"She was very comforting the whole time. Very good she was. You feel a bit vulnerable"* [31]
Desire for reassurance that they 'are not alone'	*"Have they forgotten me? I can't take it…it's getting worse and worse"* [16] *"[it] just made me feel a bit confident that you wasn't on your own, you know?"* [20]

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PHYSICAL OUTCOMES

Comfort of the imaging environment

Patients' perceptions and experiences of the imaging environment for mammography, MRI, WB-MRI, and PET/CT varied widely from being acceptable to provoking negative feelings.[20 31] Prior to the test, factors such as the location of the imaging suite itself could provoke negative feelings (e.g. imaging suite location in the hospital basement perceived to be close to the mortuary; the observed narrowness of the MRI scanner which eliciting worry about claustrophobia (particularly among patients who had experienced this before),[20 31] and the *'sterile'*, '*mechanical'* or *'impersonal'* physicality of the imaging device (e.g. the breast plates of mammogram) which prompted anxiety as patients imagined their breasts being flattened, contributed to these perceptions.

During imaging patients likened the narrowness of the scanner as like being on a sunbed, in a space shuttle or entombed, and the loud hammering noises at unpredictable intervals during data acquisition sometimes posed a threat to patient's self-control.[16] This sometimes resulted in interruption, or, in occasional cases termination of the scan when patients were unable to control their emotional reactions.[20 31]

Not all patients experienced such negative feelings; some felt no threat to self-control and were able to control their reactions to the imaging environment and completed the test with little effort, although neither prior imaging test experience or social background consistently helped patients prepare or navigate their emotional responses to imaging.[16] Having music in the scan room,[16] comfortable ambient temperature[26] and a mirror in MRI scanners allowing patients to see out of the tunnel were identified as important for reducing anxiety during procedures, particularly amongst patients struggling with self-control.

Comfort of the imaging procedures

Most patients reported some degree of physical discomfort with mammography, SPECT-CT and CT colonography testing. The unpleasant experiences included: being put in awkward positions and breast compression (mammogram),[19 34] lying still for prolonged periods of time during data acquisition (WB-MRI, SPECT-CT),[12 22] use of gas/water enemas to distend the colon (CT colonography) leading to feelings of tenesmus[22 37] and the fixation mask to ensure correct head and neck positioning during scanning (PET/CT).

However, patients held mixed views with regards to the perceived severity of the discomfort, with some describing sensations as discomfort.[34 37] In contrast, others very clearly articulated pain [37] Regardless of the perceived intensity of the discomfort experienced, sensations were typically reported as transient. The level of discomfort was exacerbated for patients with pre-existing musculoskeletal problems.[20] Patients appreciated when staff paid attention to positioning them comfortably, and stimuli such as a TV to distract them,[20] suggesting this was important to help patients manage the discomfort.

Table 4: Physical outcomes: themes and illustrative quotes

Comfort of the imaging environment	*I'm not claustrophobic that (enclosed space) doesn't frighten me*" versus: *"when I saw the small tunnel I thought, shall I go in there, and then I felt panic."*[31] "*That was one of the worst ones that I've had to go through with the noise…I felt like something was going to fall off and hit me."*[20] *"It doesn't bother me. I've worked in pipes and tunnels and all sorts of places."*[20] and *"so – I've been lying under huge filters where you couldn't take a deep breath without feeling your chest against the wall, and that worked all right. But now, it was a feeling of panic."*[16]

Comfort of the imaging procedures	*"it's not a painful painful, but it's just tender"* (mammogram) [34] and *"I felt very bloated at one time and it was slightly painful. It was as comfortable as anything like that could be. I did experience some pain in the beginning"* [37] *''Lying in same position for an extensive time period and not being able to move is very uncomfortable and in addition there is some weight on your back for the scan, which gets unbearable after approximately 20 min. There should be something in the room for distraction during scan, something like a TV even without the sound as you have to hear the breathing instruction as well.'* [20]

Note: This table was created by the authors and no permission is required

Summary of key findings from scoping review

Patient-centered outcomes identified

Based on the qualitative research identified in this scoping review across a wide range of imaging modalities, patient groups and clinical areas we identified multiple outcomes within domains we had identified a priori, namely the information or knowledge yielded by a test, the emotional impact of the test, and effects on physical symptoms patients may experience during or after the test. Outcomes within each of these domains were both positive (beneficial), and others negative (harmful). For example, knowing the result of an imaging test might provide explanation for symptoms a patient is experiencing, yet may also yield inconclusive or incorrect results. The emotional impact of a test might lead to peace of mind or reassurance, or, provoke more anxiety or distress. In contrast, the physical effects of the test, or preparing for a test were usually reported as negative effects, such as pain or discomfort from the procedure, or concern about longer term effects such as radiation exposure.

Factors identified that can influence test experience and outcomes

Findings from this review also provides evidence for multiple factors that could influence the test experience. These included moderating factors which are conditions that influence an outcome (its presence or absence), and mediating factors which explain how or why this relationship might exist.[38] For example, clinical staff frequently appeared to moderate several PCOs experienced by patients; this effect was mediated by their demeanor and communication about what patients would expect during the procedure. A further moderator appeared to be patients' level of self-activation from prior imaging test experience, or the level of preparedness; this mediated effects on outcomes such as anxiety or anticipated level of pain. Finally, the physical design and location of the imaging testing suite acted as a moderator, for example through causing more distress and anxiety due to a tight or enclosed space, or the physical location of the imaging office in basement locations.

Strengths and weaknesses of the review method used

Consolidating findings from multiple primary studies allows deeper and more transferable insights about a phenomenon that is often not possible from a single study. This type of synthesis of qualitative research has gained popularity in recent years as an evidence-based method for informing patient-centered healthcare. We followed scoping review methods, including using two reviewers to identify eligible studies, snowballing techniques, and approaching the identification of themes. We feel that this technique was ideal, as it allowed a broader review of a wide body of literature using a rigorous approach.

A potential weakness of this review where we emphasized breadth over depth, is that we may have missed some relevant primary literature. The primary literature we identified focused heavily on the period of time during or shortly after testing, and we identified little research on longer term outcomes. Short term negative experiences during a procedure (e.g. pain) may become less important over time, although there is some evidence that at least some negative experiences (e.g., distress from false positive mammogram results) can lead to longer term anxiety and changes in screening behavior. In addition, we did not identify literature on the outcomes and experiences of patients who had declined testing. A further limitation is that we did not conduct independent abstraction of data or coding to check reliability, nor did we conduct critical appraisal of the primary studies identified (consistent with methods for scoping reviews). Qualitative research is an ideal method to identify outcomes of importance to patients, but does not allow us to weight or rank these outcomes, nor are we able to determine their overall importance to the patient, compared to other parts of their health care journey. We focused on adults (and excluded studies on pregnant women) and acknowledge that the experiences and outcomes of pregnant women, teenager and children might differ from those of adults. Limitations in the primary evidence that we identified for this scoping review may have overlooked PCOs related to certain imaging modalities, clinical situations, or patient populations, particularly where there have been fewer qualitative studies. This may limit the generalizability of our findings.

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Appendix 2: Stakeholder List

Barbara Berney: (Patient & Consumer Advocate) – Co-Founder and President of the Vision Surgery Rehab Network, NFP

Becky Haines: (Radiology-American College of Radiology) – Senior Director, Press & Imaging 3.0, American College of Radiology

Bernhard Weigl: (Non-Governmental Organization) – Principal Investigator, Bill and Melinda Gates Foundation.

Beverly Green: (Methodologist) – Associate Investigator, Kaiser Permanente Washington Health Research Institute, Seattle.

Brian Do: (Patient & Consumer Advocate) – UW Undergraduate, Department of Human Centered Design and Engineering

Danielle Lavallee: (Health Services Researcher) – Research Associate Professor, Division of General Surgery, School of Medicine, University of Washington

David Kurth: (Radiology- American College of Radiology) - Senior Director, Practice Parameters and Appropriateness Criteria, American College of Radiology

Eunice Kim: (Student Researcher – Health Economics and Outcomes) – Doctor of Pharmacy student, University of Washington

Fiona Walter: (Methodologist) - Primary Care Cancer Research, Department of Public Health and Primary Care, School of Clinical Medicine, University of Cambridge, England

Gianna (Gigi) McMillan: (Patient & Consumer Advocate) – Graduate Program Coordinator, Bioethics Institute, Loyola Marymount University

Jerry Jarvik: (Radiologist/Health Services Researcher) – Radiologist, Adjunct Professor, Pharmacy and Orthopedics & Sports Medicine; Co-Director, Comparative Effectiveness, Cost and Outcomes Research Center

Karen Wernli: (Methodologist) – Associate Investigator, Kaiser Permanente Washington Health Research Institute, Seattle

Katherine Carter: (Radiology-Industry) – Regional Research Manager, West USA, GE Healthcare

Lisa Freeman: (Patient & Consumer Advocate) – Executive Director, Connecticut Center for Patient Safety

Matt Reilly: (Radiology-Industry) – Director, Clinical Research, Philips Healthcare

Matthew Thompson: (PROD PI/Primary Care/ Health Services Researcher) – Family Physician,; Helen D. Cohen Endowed Professor and Vice Chair for Research, Family Medicine, University of Washington

Monica Zigman Suchsland: (Research Scientist) – Family Medicine; Research and Sports Medicine Sections, School of Medicine, University of Washington

Pat Vigil: (Primary Care) –Family Physician, Central Washington Family Medicine Residency Program, Yakima, WA

Patty Spears: (Patient & Consumer Advocate) - Co-Chair of the Susan G. Komen Advocates in Science Steering Committee, and a Komen Scholar

Phil Posner: (Patient & Consumer Advocate) – Patient representative for the Food and Drug Administration, Department of Defense (CDMRP), PCORI Ambassador; Chair, WMATA Accessibility Advisory Committee; and volunteer with the National Capital MS Society

Robert Dubbs: (Patient & Consumer Advocate) – Retired, Healthcare Business, and Finance Attorney

Roger Chou: (Methodologist) – Professor, Medical Informatics and Clinical Epidemiology, School of Medicine, Oregon Health & Science University

Sally Lord: (Methodologist) – Head of Epidemiology and Medical Statistics, Notre Dame, and Senior Research Fellow of the National Health and Medical Research Council (NHMRC) Clinical Trials Centre in the University of Sydney, Australia

Steven Findlay: (Patient & Consumer Advocate) – Enterprising health policy analyst, advocate, communicator and writer/editor

Tom Trikalinos: (Methodologist) – Director, Center or Evidence-based Medicine (CEBM) at Brown University

Victoria Hardy: (Research Scientist) – Department of Family Medicine Research, School of Medicine, University of Washington

William Woodhouse: (Primary Care) – Family Physician and Clinical Professor, Department of Family Medicine, Idaho State University

Ying Zhang: (Primary Care) –Family Physician; and Assistant Professor, School of Medicine, University of Washington

Appendix 1: Methods and findings from scoping review of qualitative literature regarding patients' preferences in relation to imaging tests

Aim of the scoping review

Evaluation of imaging tests has been primarily concerned with demonstrating their ability to correctly 'rule in' or 'rule out' a diagnosis, and studies comparing test accuracy are used to guide regulatory approval and clinical adoption[1-4]. In order to describe more fully the range of patient-centered outcomes (PCOs) that are important to patients undergoing imaging studies we conducted a scoping review of qualitative research that described patients' experiences of imaging testing, to provide further evidence on the PCOs that had been identified by our primary qualitative research.[5 6] Our overarching research question was to describe adult patients' emotional, knowledge, and physical experiences and outcomes occurring before, during, or after undergoing imaging testing for any reason and any medical condition. We also sought to understand why these preferences were important to patients.

Methods used for scoping review

We followed Arksey and O'Malley's methodological framework for scoping reviews, supplemented by more recent recommendations and reported in line with the scoping review extension to PRISMA [7-9]. A protocol was developed and refined based on input from the Patient-centered Research for standards of Outcomes in Diagnostic testing (PROD) stakeholder group consisting of clinicians, methodological experts and patient representatives, convened to provide input to the PROD research program.

Search strategy

We developed a list of preliminary search terms related to the following overarching PCO themes identified from primary research conducted for the PROD study as well as additional literature on PCOs related to diagnostic tests: emotional reactions, physical effects, and the knowledge/information gained from imaging testing [6], this was facilitated by an Information Specialist and identification of keywords used in titles and abstracts of relevant articles known to the authors. Search terms were then mapped onto the relevant domains of the SPIDER framework for qualitative evidence synthesis (Sample, Phenomenon of Interest, Design, Evaluation, Research type) [10] to build a search strategy. The SPIDER tool was chosen as the domains allowed construction of an inclusive yet efficient search strategy. The search strategy was iteratively tested to determine the optimal search and the included terms and domains refined until agreement on the final strategy was reached between two authors (VH, MT). We searched a single bibliographic database searched (PubMed). Filters were applied for date range

(01/01/2003 through 06/28/2018), English language, and human subjects. (see terms available from authors).

Study selection

The final search results were imported into EndNote and duplicate articles removed. Titles and abstracts were screened for eligibility by one reviewer (VH); articles deemed potentially relevant were reviewed by a second reviewer (MT) and discussed for final determination of inclusion. Studies of original research conducted within the last 15 years were eligible for inclusion if they solicited patients' and/or caregivers' lived experiences of imaging testing. Caregivers' perspectives were included due to the integral role they have advocating, supporting and coordinating patients' healthcare. To capture narratives representative of the spectrum of patients undergoing imaging tests in routine practice, studies of patients with cognitive or physical disabilities were included. We limited study settings to high income countries (as defined by the OECD). We excluded neonatal, pediatric, or adolescent imaging studies, and interventional radiologic procedures to align with the PROD study aims. 'Snowballing' was used to identify additional studies from references of relevant full texts and any systematic reviews identified.

Data abstraction

An electronic data-abstraction spreadsheet was used to abstract data on author, country, population, setting, number of participants, imaging modality and purpose, and data collection methods/qualitative approach. One reviewer (VH) extracted the data of which 20% was checked by a second reviewer (MT). Qualitative data was charted against *a priori* PCO domains of 'emotion', 'knowledge' and 'physical'; excerpts consisted of participant quotes (with relevant participant descriptors where reported), and verbatim interpretation of the original data.

Collating, summarizing and reporting results

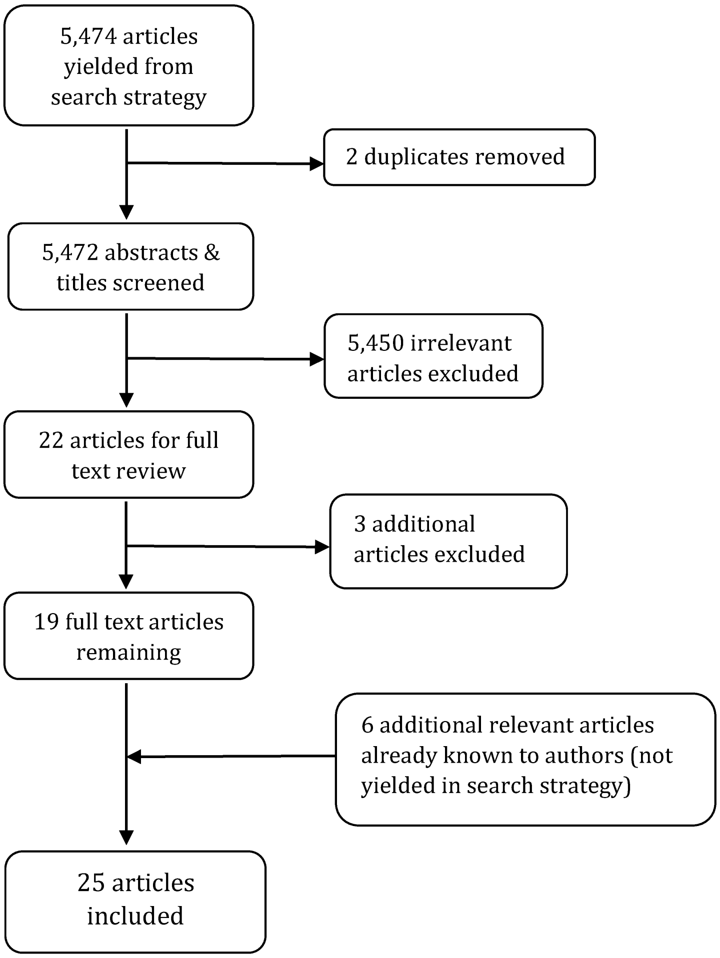
We used framework synthesis to synthesize results, which is appropriate when using a pre-existing 'framework' underpinned by previous research, and for conceptualizing the range of ideas (i.e. PCOs) being explored [11]. Data analysis was led by one reviewer (VH) and began by reviewing the included articles to become familiar with the findings. The same author re-read the articles in-depth, highlighting and making annotations against words, sentences and sections of text (participant quotes and authors' interpretation) that related to emotion, knowledge/information gain, and physical aspects of imaging testing. New PCOs within each of the pre-established domains were allowed to emerge from the coded data, forming subthemes. Themes were discussed with two reviewers (MZS, MT) and consensus reached. During this process, we reflected on any impacts that our own preconceptions and interests could have had on data interpretation. To ensure balanced interpretation and presentation, findings were reviewed by stakeholders. The organization and analysis of qualitative data was facilitated by NVivo.

Results

Study selection

The search identified 5,472 articles, after removing duplicates, which were screened to identify 22 potentially includable articles. Following full text review, 19 qualified for inclusion in this review. A further 6 relevant articles were identified from snowballing, providing a total of 25 articles included in this review (**Figure**).

Figure. Flow of included studies



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Characteristics of included studies

Data on a total of 656 patients and 23 caregivers were included in the 25 studies, with the overall sample being predominantly women (78%) (**Table 1**). Included articles were conducted in the United States (9), United Kingdom (8), Sweden (3), New Zealand (2), Australia (1), Germany (1), and Spain (1). Imaging tests included mammography (10), MRI (4), PET/(CT) (2), CT (2), SPECT-CT (1), CT colonography (1), CCTA (1), two were of multiple imaging modalities, and in one study the imaging test was not clearly reported. The target conditions and/or outcomes reported in the included studies were breast cancer (7), oropharynx/oral cancer (1), lung and/or colorectal cancer (3), inflammatory arthritis (1), coronary artery disease (1), multiple sclerosis (1), false-positive test results (2), incidental/indeterminate findings (3), Alzheimer's Disease (1), and was unclear or not reported (5). In studies where both patient and staff views are presented, only the patient views are extracted.

Table 1. Characteristics of Included Studies

Author, year (country)	Population	Gender; race/ethnic composition	Imaging modality	Purpose	Target condition / outcome	Data collection method
Andersson et al., 2017 (Sweden) [12]	Patients with confirmed head and neck cancer (n=9)	7 men, 2 female (aged 48-75 years); not reported	F-FDG PET/CT with fixation mask	Staging and radiation treatment planning	Oropharynx or oral cancer	Conversational interviews within 1 week of imaging
Bourke et al., 2017 (New Zealand)[13]	Patients with confirmed or suspected inflammatory arthritis with peripheral joint imaging test in preceding 6 weeks (n=33)	17 female, aged 25-83 years , 70% New Zealand, 12% New Zealand Maori	Conventional radiology, Ultrasound, MRI, CT	Diagnosis and management	Inflammatory arthritis (included rheumatoid, psoriatic, gout and undifferentiated inflammatory arthritis)	Semi-structured interviews within 6 weeks of imaging
Bond et al., 2015 (UK)[14]	Asymptomatic women who had experienced false-positive mammogram (n=21)	21 female aged 42-69 years; not reported	Mammogram	Screening	Breast cancer	Semi-structured interviews held between 0.5 and 12 years since false-positive mammogram
Brand et al. 2014 (Germany) [15]	Multiple Sclerosis patients with relapsing-remitting course (n=5)	All female aged 22-48 years; not reported	MRI	Management	Multiple Sclerosis	Semi-structured interviews
Carlsson et al. 2013 (Sweden)[16]	Patients undergoing variety of imaging examinations (e.g. brain, spine, pelvis, and hip) (n=10)	5 male, 5 female aged 21-70 years; not reported	MRI	Diagnosis	Unclear	Semi-structured interviews
Devcich et al. 2013 (New	Non-acute cardiac patients attending	Not reported (aged 39-71 years)	CCTA	Diagnosis	Coronary artery disease	Semi-structured interviews

Zealand)[17]	heart clinic (n=13)					conducted immediately following CCTA but prior to diagnosis, and immediately after communication of test results during cardiology consultation
Engelman et al., 2005 (USA)[18]	Women who underwent a mammogram within the previous 3 years with no history of cancer (n=103)	103 female aged 40-83 years; 53% Hispanic, 15% Black, 32% Non-Hispanic White	Mammogram	Screening	Not reported	Focus groups conducted in rural and urban communities
Engelman et a., 2012 (USA)[19]	Women with no prior history of breast cancer with mammogram during the 36 months prior to focus groups (n=88)	All female aged 40-82 years; 55% Hispanic, 45% Non-Hispanic White	Mammography	Screening	Breast cancer	Focus groups stratified by racial/ethnic groups: Hispanic and non-Hispanic white women
Evans et al., 2017 (UK) [20]	Patients participating in trials investigating value of WB-MRI for accelerating cancer treatment (n=51)	31 male, 20 female aged 40-89 years; not reported	Whole Body-MRI	Staging	Lung and colorectal cancer	Face to face and telephone interviews within 63 days of test
Grill et al., 2017 (USA)[21]	Patients (n=10) and caregivers (n=23) for whom option of amyloid imaging had been discussed	*Patients:* 4 female aged52-83 years; 8 white, 2 Latino *Caregivers:* 14 female aged 38-89 years; 19 white, 3 Latino	PET	Diagnosis	Alzheimer’s Disease	Telephone interviews including open-ended questions with patients (and caregivers) who did and did not complete the scan
Hafeez et al., 2012 (UK)[22]	Patients referred for conventional colonoscopy invited to undergo MR colonography 2 hours prior (n=18)	11 male, 8 female median age of 40.5 years; not reported	MR Colonography	Diagnosis	Inflammatory bowel disease and suspected colon cancer	Semi-structured interviews
Lown et al. 2009 (USA)[23]	Women who had a diagnostic mammogram within previous 12 months (n=13)	All female with a mean age of 54 years; all white	Mammogram	Diagnosis	Breast cancer	Focus groups
Lumbreras et al. 2017 (Spain)[24]	Participants identified from a population survey with experience of imaging in previous 12months (n=20)	8 male, 12 female aged 18-90 years; not reported	X-ray CT MRI Mammography Ultrasound	Unclear	Unclear	Focus groups
Mathers et al.,	Women aged 42-63	All female; not	Mammography	Diagnosis	Breast cancer and	Semi-structured

2013 (UK)[25]	years with diagnosis of cancer or attending for further investigations of breast abnormalities previously detected (n=16)	reported			previously detected breast abnormalities	interviews first conducted 1 to 23 years after original diagnosis. Additional interviews conducted for those attending subsequent breast imaging
Nightingale et al., 2012 (UK)[26]	Cardiac patients attending cardiac imaging (n=22)	13 female, 9 male with a mean age of 63.9 years; not reported	SPECT-CT	Unclear	Unclear	Semi-structured interviews conducted before and after imaging on the day of SPECT-CT procedure
Poulos et al., 2005 (Australia)[27]	Women attending breast screening programs (n=12)	All female	Mammography	Screening	Breast cancer	Not reported
Slatore et al. 2013 (USA)[28]	Asymptomatic veterans with incidentally detected pulmonary nodules planning to obtain follow-up imaging (n=19)	18 male with a mean age of 66 years; 17 white	Unclear	Unclear	Incidental pulmonary nodules	Interviews conducted mean of 154 days after nodule detection
Sullivan et al. 2015 (USA)[29]	Veterans with an incidentally detected pulmonary nodule (n=17)	16 male with a mean age of 64 years; 14 white	CT	Surveillance	Incidental pulmonary nodules	Interviews conducted after first and second annual follow-up CT scan
Thomson et al. 2015 (USA)[30]	Women with confirmed false positive screening mammogram result with no personal history of cancer undergoing secondary imaging testing (n=40)	All female aged 40-68 years; 45% African American.	Mammogram	Screening	Breast cancer	Semi-structured interview
Tornqvist et al., 2006 (Sweden)[31]	Patients who did and did not complete different MRI scans (e.g. brain, spine, abdomen, wrist) because of varying levels of anxiety about the test (n=19)	12 female, 7 male aged 22-73 years; not reported	MRI	Unclear	Unclear	Conversational interviews with patients who did and did not complete the scan
Truesdale-Kennedy et al., 2010 (UK)[32]	Women with borderline to moderate intellectual disabilities undergoing breast screening in	All female aged 31-69 years	Mammography	Screening	Breast cancer	Focus groups using a semi-structured topic guide

	previous 12months (n=19)					
von Wagner et al., 2009^{a} (UK)[33]	Symptomatic patients who had recently undergone CT colonography, barium enema or colonoscopy (n=49)	35 female, 14 male aged 57-92 years; not reported	CT Colonography	Diagnosis	Colorectal cancer	Semi-structured interviews conducted within 3 months of CT colonography, colonoscopy, or barium enema
Whelehan et al., 2016 (UK)[34]	Women with satisfactory and unsatisfactory experiences of breast screening programs (n=22)	All female (aged 28-56 years); 20 White British/Scottish, 1 African, 1 Afro-Caribbean	Mammography	Screening	Breast cancer	Semi-structured in-depth face-to-face or telephone interviews within 6 weeks of test (3 interviews were conducted >3 years after screen)
Wiener et al. 2012 (USA)[35]	Patients undergoing surveillance of an indeterminate nodule identified during workup of a pulmonary symptom or an incidental finding during workup of a non-pulmonary symptom (n=22)	86% female with a mean age of 60.7 years; 77% white, 18% black, 4.5% Hispanic	CT	Surveillance	Indeterminate pulmonary nodules	Focus groups
Wilkinson et al., 2011 (USA)[36]	Women with intellectual disabilities (n=27)	All female aged 27-69 years; 24 white, 3 black	Mammography	Screening	Breast cancer	Semi-structured interviews

Abbreviations: OP = outpatients, CT = computerized tomography, MRI= magnetic resonance imaging, SPECT-CT = single photon emission computed tomography, CCTA = coronary computed tomography angiography, PET = positron emission tomography, FDG-PET = fluorodeoxyglucose-positron emission tomography.

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KNOWLEDGE OUTCOMES

Desire to know what is wrong

Knowing *what* is wrong was important to the majority of (symptomatic) patients undergoing MRI (e.g. for staging of lung and colorectal cancer), PET (e.g. for suspected Alzheimer's) and SPECT-CT (for conditions including multiple sclerosis and disc herniation), whereas knowing *if* something is wrong was important among patients under surveillance for incidental findings (e.g. pulmonary nodules) (**Table 2**). [12 13 15 20 21 26 29 31 35] Although patients, irrespective of imaging test, were fearful of a positive result such as tests showing recurrence or metastasis, most wanted a definitive diagnosis so they could either pursue the care needed to help them manage their condition, or make future social and health care plans.[12 21]

Patients and caregivers (sometimes with a mixed understanding of what a test could reliably rule-out),[35] viewed information yielded from imaging tests as a stepping stone towards obtaining a resolution.[16 20 21] Overall, this desire for knowledge was often reported to motivate patients to have an imaging test - only a small number were reported to decline (one example was the use of PET for Alzheimer's[21] because they felt test results (whether positive or negative) would have little impact on their overall management plan or prognosis.[21] Getting a definitive diagnosis brought relief to many symptomatic patients, irrespective of the results. On the other hand, feelings of surprise or shock were reported among a small number of symptomatic patients who had not considered a serious illness as a possibility, and anxiety in those with indeterminate results. Furthermore, those with incidental findings experienced anxiety from not knowing whether the finding (e.g. a lung nodule) was malignant, or might eventually become malignant.[35]

Desire to know what to expect

Patients ranged from feeling well informed about what they might expect while preparing for the test or during the test itself (WB-MRI, colorectal cancer),[13] to feeling insufficiently prepared.[20 36] Specifically, they wanted information about any potential sensory (e.g. what they might feel when injected with contrast material) or physical experiences of the test (e.g. narrowness of the imaging machine, noises they would hear, or discomfort they could expect to experience).[36] This information was typically desired ahead of the procedure to help them prepare for the experience,[20] or manage underlying anxieties, or to reconcile what they had learned from friends or relatives who had undergone the test and/or internet searches. During the procedure, patients highlighted the importance of repetition of the instructions so they knew what to expect at each step. This made patients feel more in control of their own emotions, and made the test feel less intimidating.[19]

Desire to know the possible harms of the test

Overall, patients' views were mixed regarding possible harms associated with imaging tests. Some were aware of the potential for adverse reactions from intravenous contrast material and concern about (accumulated) radiation exposure from (repeated) advanced imaging modalities (e.g. CT, MRI).[24] Patients generally believed risks had not been adequately explained[26] or where they had been, they struggled to understand what had been communicated to them due to use of medical jargon.[24 26] Consequently, they expressed desire for clear and concise information about possible harms. Although lack of knowledge concerned some patients who wanted to be informed about the risks of tests, notably radiation exposure;[17 24 26] they believed the benefits typically outweighed the risks and were unconcerned or dismissed any possible harms and informational needs.[24]

Rapid feedback of results

A desire for rapid feedback of imaging results was prominent among the majority of patients who underwent a range of imaging studies (CT, MRI, MR colonography and mammogram). The anticipation of receiving potentially life-altering information was difficult to manage for many. They felt anxious and 'in limbo', reluctant to make important life decisions or plans in case of bad news when those plans might have to be abandoned. Most were symptomatic and were waiting for a diagnosis (of bowel disease, multiple sclerosis, breast cancer) and expressed dissatisfaction or distress with the length of time taken for results to be released or reported to them (between 3 days and 5 weeks, reported in one study).[25] A few patients believed the time it took to receive results was inversely proportional to the gravity of those results and so were reassured (falsely) by slower communication of results.[28] Patients experiencing an exacerbation of a known disease (of inflammatory bowel disease [22] were less anxious about waiting for results. However, for most patients alleviating anxiety over the possibility of cancer (or its recurrence), patients (symptomatic, without a diagnosis) wanted results issued on the same day as the test, regardless of whether findings were positive or negative.[16 20] Preferences for method of result communication varied; some preferred notification in person or over the telephone,[28] others were satisfied with written communication if it enabled results to be issued more promptly.

Table 2: Knowledge outcomes: themes and illustrative quotes

Desire to know what is wrong	*"But from a standpoint of managing her care and figuring out how best to take care of her with her symptoms, I feel like the scan was really positive in that it let me know she probably couldn't go home and live by herself again and that I would really need to take her care in a direction that none of us anticipated or could have predicted"* [21] *"These loud noises really paled into significance because in my body now I've got a nasty little house guest, which has now stayed, not welcome, I'm going to get rid. And this is part of the mechanism to get rid […]. And these are the pictures that would help me get that done"* [12]
Desire to know what to expect	*"if you're informed and you know what to expect then it's not so scary"*[19]
Desire to know the possible harms of the	*"I always wonder how much radiation I am going to receive because I have never studied it and no-one has ever told me."*[24]

test	*"There's a lot of strange fears about radiation and it's gone crazy"*[13] *"If the physician thinks I need the test to improve the management of my disease, I consider that the benefit/risk balance is in my favor"*[24]
Faster feedback of results	*"Waiting for the results is absolute hell"* [25] *"No test results yet. I am just hoping they didn't find anything and there is another avenue that I might go down. I am dreading it might be cancer"* [20]

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EMOTIONAL OUTCOMES

Desire for compassion and empathy from radiography staff

Patients identified that compassion and empathy from radiography staff, both before in the preparation and during imaging, as influencers of their experience of imaging, particularly when undergoing screening mammography.[27 34 36] Although some appreciated a depersonalized approach by staff as one way to mitigate embarrassment, others felt that a 'clinical' demeanor or perceived lack of interest by staff could be distressing.[25] Given anxiety about the (anticipated or previously experienced) discomfort of the mammogram, the possibility of a diagnosis of breast cancer diagnosis, and vulnerability from being physically exposed, patients wanted radiography staff to demonstrate sensitivity in the manner in which they gave verbal guidance and physical assistance (during breast positioning);[23 32 34] and cultural awareness of their modesty. Although patients infrequently reported terminating the procedure as a result of the demeanor of staff[20] their manner contributed to them feeling reluctant to participate in future screening programs[36] whereas compassion and empathy helped patients to endure any discomfort and pain associated with the imaging test.[34]

Desire for reassurance that they 'are not alone'

Patients wanted to know that they were not alone in what they viewed as the unfamiliar and lonely environment of some imaging modalities, and were reassured by physical presence and/or verbal interaction with staff [20 26]. This was frequently identified as important to patients during MRI, CT and PET imaging procedures, where feelings of isolation, abandonment and helplessness dominated.[12 20 26] Whilst physical proximity of staff typically provided patients with the most reassurance, communication through the intercom (and trust that staff would respond to calls for help) was also helpful in making patients feel secure during image acquisition.[16 20 26] The emotional comfort of knowing staff were close by was sometimes enough to influence whether the procedure was prolonged or prematurely terminated.[26 31]

Table 3: Emotional outcomes: themes and illustrative quotes

Desire for compassion and empathy from radiography staff	*""It's like they're handling a lump of meat. Sort of throwing it on a slab and doing something to it. That how I think I would feel if I had large breasts"* [27] *"I just felt she didn't seem interested, you were just another number. It was quite uncomfortable and she just kept saying 'If you don't stand right, you will have to come back again'"* [25] *"She was very comforting the whole time. Very good she was. You feel a bit vulnerable"* [31]
Desire for reassurance that they 'are not alone'	*"Have they forgotten me? I can't take it…it's getting worse and worse"* [16] *"[it] just made me feel a bit confident that you wasn't on your own, you know?"* [20]

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PHYSICAL OUTCOMES

Comfort of the imaging environment

Patients' perceptions and experiences of the imaging environment for mammography, MRI, WB-MRI, and PET/CT varied widely from being acceptable to provoking negative feelings.[20 31] Prior to the test, factors such as the location of the imaging suite itself could provoke negative feelings (e.g. imaging suite location in the hospital basement perceived to be close to the mortuary; the observed narrowness of the MRI scanner which eliciting worry about claustrophobia (particularly among patients who had experienced this before),[20 31] and the *'sterile'*, '*mechanical'* or *'impersonal'* physicality of the imaging device (e.g. the breast plates of mammogram) which prompted anxiety as patients imagined their breasts being flattened, contributed to these perceptions.

During imaging patients likened the narrowness of the scanner as like being on a sunbed, in a space shuttle or entombed, and the loud hammering noises at unpredictable intervals during data acquisition sometimes posed a threat to patient's self-control.[16] This sometimes resulted in interruption, or, in occasional cases termination of the scan when patients were unable to control their emotional reactions.[20 31]

Not all patients experienced such negative feelings; some felt no threat to self-control and were able to control their reactions to the imaging environment and completed the test with little effort, although neither prior imaging test experience or social background consistently helped patients prepare or navigate their emotional responses to imaging.[16] Having music in the scan room,[16] comfortable ambient temperature[26] and a mirror in MRI scanners allowing patients to see out of the tunnel were identified as important for reducing anxiety during procedures, particularly amongst patients struggling with self-control.

Comfort of the imaging procedures

Most patients reported some degree of physical discomfort with mammography, SPECT-CT and CT colonography testing. The unpleasant experiences included: being put in awkward positions and breast compression (mammogram),[19 34] lying still for prolonged periods of time during data acquisition (WB-MRI, SPECT-CT),[12 22] use of gas/water enemas to distend the colon (CT colonography) leading to feelings of tenesmus[22 37] and the fixation mask to ensure correct head and neck positioning during scanning (PET/CT).

However, patients held mixed views with regards to the perceived severity of the discomfort, with some describing sensations as discomfort.[34 37] In contrast, others very clearly articulated pain [37] Regardless of the perceived intensity of the discomfort experienced, sensations were typically reported as transient. The level of discomfort was exacerbated for patients with pre-existing musculoskeletal problems.[20] Patients appreciated when staff paid attention to positioning them comfortably, and stimuli such as a TV to distract them,[20] suggesting this was important to help patients manage the discomfort.

Table 4: Physical outcomes: themes and illustrative quotes

Comfort of the imaging environment	*I'm not claustrophobic that (enclosed space) doesn't frighten me*" versus: *"when I saw the small tunnel I thought, shall I go in there, and then I felt panic."*[31] *"That was one of the worst ones that I've had to go through with the noise…I felt like something was going to fall off and hit me."*[20] *"It doesn't bother me. I've worked in pipes and tunnels and all sorts of places."*[20] and *"so – I've been lying under huge filters where you couldn't take a deep breath without feeling your chest against the wall, and that worked all right. But now, it was a feeling of panic."*[16]

Comfort of the imaging procedures	*"it's not a painful painful, but it's just tender"* (mammogram) [34] and *"I felt very bloated at one time and it was slightly painful. It was as comfortable as anything like that could be. I did experience some pain in the beginning"* [37] *''Lying in same position for an extensive time period and not being able to move is very uncomfortable and in addition there is some weight on your back for the scan, which gets unbearable after approximately 20 min. There should be something in the room for distraction during scan, something like a TV even without the sound as you have to hear the breathing instruction as well.'* [20]

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Summary of key findings from scoping review

Patient-centered outcomes identified

Based on the qualitative research identified in this scoping review across a wide range of imaging modalities, patient groups and clinical areas we identified multiple outcomes within domains we had identified a priori, namely the information or knowledge yielded by a test, the emotional impact of the test, and effects on physical symptoms patients may experience during or after the test. Outcomes within each of these domains were both positive (beneficial), and others negative (harmful). For example, knowing the result of an imaging test might provide explanation for symptoms a patient is experiencing, yet may also yield inconclusive or incorrect results. The emotional impact of a test might lead to peace of mind or reassurance, or, provoke more anxiety or distress. In contrast, the physical effects of the test, or preparing for a test were usually reported as negative effects, such as pain or discomfort from the procedure, or concern about longer term effects such as radiation exposure.

Factors identified that can influence test experience and outcomes

Findings from this review also provides evidence for multiple factors that could influence the test experience. These included moderating factors which are conditions that influence an outcome (its presence or absence), and mediating factors which explain how or why this relationship might exist.[38] For example, clinical staff frequently appeared to moderate several PCOs experienced by patients; this effect was mediated by their demeanor and communication about what patients would expect during the procedure. A further moderator appeared to be patients' level of self-activation from prior imaging test experience, or the level of preparedness; this mediated effects on outcomes such as anxiety or anticipated level of pain. Finally, the physical design and location of the imaging testing suite acted as a moderator, for example through causing more distress and anxiety due to a tight or enclosed space, or the physical location of the imaging office in basement locations.

Strengths and weaknesses of the review method used

Consolidating findings from multiple primary studies allows deeper and more transferable insights about a phenomenon that is often not possible from a single study. This type of synthesis of qualitative research has gained popularity in recent years as an evidence-based method for informing patient-centered healthcare. We followed scoping review methods, including using two reviewers to identify eligible studies, snowballing techniques, and approaching the identification of themes. We feel that this technique was ideal, as it allowed a broader review of a wide body of literature using a rigorous approach.

A potential weakness of this review where we emphasized breadth over depth, is that we may have missed some relevant primary literature. The primary literature we identified focused heavily on the period of time during or shortly after testing, and we identified little research on longer term outcomes. Short term negative experiences during a procedure (e.g. pain) may become less important over time, although there is some evidence that at least some negative experiences (e.g., distress from false positive mammogram results) can lead to longer term anxiety and changes in screening behavior. In addition, we did not identify literature on the outcomes and experiences of patients who had declined testing. A further limitation is that we did not conduct independent abstraction of data or coding to check reliability, nor did we conduct critical appraisal of the primary studies identified (consistent with methods for scoping reviews). Qualitative research is an ideal method to identify outcomes of importance to patients, but does not allow us to weight or rank these outcomes, nor are we able to determine their overall importance to the patient, compared to other parts of their health care journey. We focused on adults (and excluded studies on pregnant women) and acknowledge that the experiences and outcomes of pregnant women, teenager and children might differ from those of adults. Limitations in the primary evidence that we identified for this scoping review may have overlooked PCOs related to certain imaging modalities, clinical situations, or patient populations, particularly where there have been fewer qualitative studies. This may limit the generalizability of our findings.

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Appendix 2: Stakeholder List

Barbara Berney: (Patient & Consumer Advocate) – Co-Founder and President of the Vision Surgery Rehab Network, NFP

Becky Haines: (Radiology-American College of Radiology) – Senior Director, Press & Imaging 3.0, American College of Radiology

Bernhard Weigl: (Non-Governmental Organization) – Principal Investigator, Bill and Melinda Gates Foundation.

Beverly Green: (Methodologist) – Associate Investigator, Kaiser Permanente Washington Health Research Institute, Seattle.

Brian Do: (Patient & Consumer Advocate) – UW Undergraduate, Department of Human Centered Design and Engineering

Danielle Lavallee: (Health Services Researcher) – Research Associate Professor, Division of General Surgery, School of Medicine, University of Washington

David Kurth: (Radiology- American College of Radiology) - Senior Director, Practice Parameters and Appropriateness Criteria, American College of Radiology

Eunice Kim: (Student Researcher – Health Economics and Outcomes) – Doctor of Pharmacy student, University of Washington

Fiona Walter: (Methodologist) - Primary Care Cancer Research, Department of Public Health and Primary Care, School of Clinical Medicine, University of Cambridge, England

Gianna (Gigi) McMillan: (Patient & Consumer Advocate) – Graduate Program Coordinator, Bioethics Institute, Loyola Marymount University

Jerry Jarvik: (Radiologist/Health Services Researcher) – Radiologist, Adjunct Professor, Pharmacy and Orthopedics & Sports Medicine; Co-Director, Comparative Effectiveness, Cost and Outcomes Research Center

Karen Wernli: (Methodologist) – Associate Investigator, Kaiser Permanente Washington Health Research Institute, Seattle

Katherine Carter: (Radiology-Industry) – Regional Research Manager, West USA, GE Healthcare

Lisa Freeman: (Patient & Consumer Advocate) – Executive Director, Connecticut Center for Patient Safety

Matt Reilly: (Radiology-Industry) – Director, Clinical Research, Philips Healthcare

Matthew Thompson: (PROD PI/Primary Care/ Health Services Researcher) – Family Physician,; Helen D. Cohen Endowed Professor and Vice Chair for Research, Family Medicine, University of Washington

Monica Zigman Suchsland: (Research Scientist) – Family Medicine; Research and Sports Medicine Sections, School of Medicine, University of Washington

Pat Vigil: (Primary Care) –Family Physician, Central Washington Family Medicine Residency Program, Yakima, WA

Patty Spears: (Patient & Consumer Advocate) - Co-Chair of the Susan G. Komen Advocates in Science Steering Committee, and a Komen Scholar

Phil Posner: (Patient & Consumer Advocate) – Patient representative for the Food and Drug Administration, Department of Defense (CDMRP), PCORI Ambassador; Chair, WMATA Accessibility Advisory Committee; and volunteer with the National Capital MS Society

Robert Dubbs: (Patient & Consumer Advocate) – Retired, Healthcare Business, and Finance Attorney

Roger Chou: (Methodologist) – Professor, Medical Informatics and Clinical Epidemiology, School of Medicine, Oregon Health & Science University

Sally Lord: (Methodologist) – Head of Epidemiology and Medical Statistics, Notre Dame, and Senior Research Fellow of the National Health and Medical Research Council (NHMRC) Clinical Trials Centre in the University of Sydney, Australia

Steven Findlay: (Patient & Consumer Advocate) – Enterprising health policy analyst, advocate, communicator and writer/editor

Tom Trikalinos: (Methodologist) – Director, Center or Evidence-based Medicine (CEBM) at Brown University

Victoria Hardy: (Research Scientist) – Department of Family Medicine Research, School of Medicine, University of Washington

William Woodhouse: (Primary Care) – Family Physician and Clinical Professor, Department of Family Medicine, Idaho State University

Ying Zhang: (Primary Care) –Family Physician; and Assistant Professor, School of Medicine, University of Washington