



# Master of Public Health

Master de Santé Publique

## **Assessing diagnostic imaging appropriateness: a mixed perspective on how the use of diagnostic imaging is currently managed.**

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## TABLE OF CONTENTS

ACKNOWLEDGEMENT .....	1
ACRONYMS AND ABBREVIATIONS .....	3
ABSTRACT .....	4
1 INTRODUCTION .....	5
1.1 Research question: .....	8
1.2 Analytical Framework.....	8
1.3 Research design .....	10
2 METHODS .....	11
2.1 Scoping review .....	11
2.2 Semi structured interviews .....	13
2.3 Ethical considerations .....	15
3 RESULTS .....	16
Section 1: Scoping review.....	16
Section 2: Qualitative study.....	19
4 DISCUSSION.....	23
5 CONCLUSION .....	29
REFERENCES .....	30
LIST OF APPENDICES .....	35
RÉSUMÉ .....	52

## ACRONYMS AND ABBREVIATIONS

CT	Computed Tomography
MRI	Magnetic Resonance Imaging
NM	Nuclear Medicine
PET	Positron Emission Tomography
SPECT	Single-Photon Emission Computerized Tomography
US	United States
EU	European Union
TA	Technology assessment
IOM	The Institute of Medicine
CRD	Centre for Reviews and Dissemination
INAHTA	International Network of Agencies for Health Technology Assessment database
CRD	Centre for Reviews and Dissemination
ACR	American College of Radiology
ESR	European Society of Radiology
CDSS	Clinical decision support systems
CMS	Center for Medicare and Medicaid Services
AdHopHTA	Adopting Hospital-Based Health Technology Assessments
SR	Systematic Review
RCT	Randomized Controlled Trial
OS	Observational Study
CER	Comparative Effectiveness Research
HTA	Health Technology Assessment
CADTH	The Canadian Agency for Drugs and Technologies in Health
QPP	Quality Payment Program
AUC	Appropriateness Use Criteria

## **ABSTRACT**

**Background:** We are currently in a dichotomous era where on the one hand high-cost diagnostic imaging is critical in the management of public health strategies such as early diagnosis in cancer and cardiovascular disease, but on the other hand we live in a system with deficiencies of financial and human resources that intentionally affect public health. Hence the interest of this report in how the appropriateness of the use of high-cost diagnostic imaging is assessed.

**Methods:** A scoping review was performed to provide an overview of the existing literature on the assessment of the appropriateness of diagnostic imaging. In addition, semi-structured interviews were conducted with diagnostic imaging experts from the medical imaging industry to capture their views on the subject. Content analysis was used to describe common themes.

**Results:** Considering the process a patient goes through during their imaging journey, at the ordering stage (pre-analytical) 2 systematic reviews (SR), 2 randomized controlled trials (RCT) and 5 observational studies (OS) were found; at the stage of patient interaction with the radiology area (analytical) there are 55 qualitative studies including patient experience and safety (38%), radiology service workflow (24%), radiologist experience (21%) and diagnostic technology performance (17%); and at the stage of decision making based on the results of the imaging exam (post-analytical) there are 9 Health Technology Assessments (46% CT; 27% MRI; 18% PET-CT; 9% CTCA), 8 RCT and 1 OS were found. Experts' opinions have corroborated some of the complexity and current practice in the evaluation of medical imaging in the care continuum.

**Conclusion:** There is a high degree of dispersion of information on the impact of diagnostic imaging. Efforts are needed to bring this information together and view the impact holistically in order to define the value of diagnostic imaging and provide the best diagnosis, treatment and patient experience.

**Keywords:** Diagnostic imaging, appropriateness criteria, imaging process

## 1 INTRODUCTION

In line with most public health objectives, the aim of all radiological methods is to lower the mortality and morbidity of individual diseases and thus elongate a patient's quality of life. (1) Radiological methods based on ionizing radiation are used to create images, both structural and physiological (X-ray, Computed Tomography (CT) and Magnetic Resonance Imaging (MRI)), or functional (Ultrasound, Nuclear Medicine (NM), Positron Emission Tomography (PET) and Single-Photon Emission Computerized Tomography (SPECT)). (2) Imaging technology is an essential component of the care pathway, adding value at every stage where it is used. (3) It contributes to better, more accurate diagnoses from the outset and, through ongoing monitoring and measuring, allows for improved care decisions and more effective treatments and outcomes. (4)

However, there have been growing concerns that the sharp increase in the high-cost diagnostic imaging testing consisting in CT, MRI, NM, and PET, does not necessarily correspond proportionately to improved patient outcomes. (2) (5) (6). If prescription of diagnostic imaging can help get the correct diagnosis of a patient's health problem and informs subsequent decisions about care, (7) in some cases, diagnostic imaging prescriptions are inappropriate. Estimates of inappropriate imaging are reported to amount to up to 30%, or even up to 77% for certain applications. (8) In a recent publication on 26 low-value medical procedures, 12 involved medical imaging among several categories: diagnostic, preventive and preoperative testing. (9) In an analysis of outpatient referrals for CT and MRI using on evidence-based appropriateness criteria from a radiology benefit management company, 35% of referrals for MRI of the spine and 37% for MRI of the shoulder were considered inappropriate. (10) In this manner, the associated costs implied are also a critical concern for the finite healthcare budgets of most health systems. The landmark 2017 OECD report on "Wasteful Spending in Health" presented alarming data on inappropriate care and wasted resources. The report stressed that a significant amount of health spending is "at best ineffective and at worst wasteful". Furthermore, a study in the Netherlands estimated that 20% of expenditures on acute care could be avoided by reducing overuse, increasing the integration of care, and involving patients in care decisions. (11) Estimations of wasted healthcare resources range from a conservative 10% (12) up to 34% in the United States (US). (13) (14) (15) Similarly, evidence from various European Union (EU) countries suggests that up to one-fifth of health spending is wasteful and could be reallocated for better use, with as much as 9.6% of European GDP directed to health care. (16) (17) The situation has been further exacerbated by COVID-19, where radiology departments are

challenged to combine examinations and procedures for patients with cancer, heart disease and other conditions, while continuing to provide critical care to COVID-19 patients, and often without clinical substantiation, causing collateral damage from induced radiation. (18)

### **What is involved in measuring appropriateness in diagnostic imaging?**

The most widely used definition of appropriate care was probably developed by Brook and colleagues at the RAND Corporation: *“The indication to perform a medical procedure is appropriate when the expected health benefit (ie, increased life expectancy, relief of pain, reduction in anxiety, improved functional capacity) exceeds the expected negative consequences by a sufficiently wide margin that the procedure is worth doing.”* (19) (20) (21)

Mayo and Munk (2010) (22) argued that appropriate diagnostic imaging exams are those deemed “acceptable, suitable, or correct for a given clinical scenario or circumstance”. (23) Furthermore, The American College of Cardiology Foundation points out that an imaging test’s appropriateness must include test performance characteristics for a clinical indication, the potential negative consequences of imaging, an understanding of the implicit impact of cost on clinical decision making. (24) (25)

The complexity of assessing diagnostic imaging appropriateness has been pointed out in the literature. Deinum et al (2018) (26), noted that evaluating imaging technologies is more complex than evaluating treatments, where their ultimate impact on patient outcomes depends on the effect of the clinical intervention selected from the information provided by diagnostic imaging, so there is a direct relationship between surrogate outcomes (e.g., bone mass levels) and final outcomes (e.g., clinical morbidity, functional status, quality of life, and mortality). Conversely, for diagnostic imaging there is not a direct relationship between their use and final patient outcomes. Therefore, one challenge for assessing diagnostic imaging technologies is the need to evaluate the technology in the context of its effect on the pathway of care, which makes the assessment more complex. Scott IA et al (2015) (27) points out that the science of measuring overuse in imaging diagnostic is in its infancy. The majority of measures are constrained by the lack of systematic collection of granular clinical data at the level of individual patient care that captures the indications for the intervention (why was it given?) and the views and preferences of patients (was there a strong patient preference to receive it?). Such nuanced data are necessary in deciding when the same service is high value in one patient but low value in another.

This has led several authors to emphasize that current measurements contain a great deal of bias and inaccurate information that is detrimental to how interventions are being created by federal agencies and medical associations to combat this problem. Mayo et al (2010) (22), in its report —Towards Clarity: What does "Inappropriate Imaging" really mean?—, questions the percentage of inappropriate use of CT scans that has been published in different official reports in Canada, compared to the rates in the US. The author discusses the great difficulty in categorising CT scans that include questionable clinical utility, where anatomical changes are unlikely or imaging results will not affect clinical management, in this case, the definition of "inappropriate" will be very context-specific and emphasizes that misinterpreting what is truly inappropriate and thus miscounting the extent of inappropriate scans could lead to poor decisions regarding resource allocation for imaging modalities. The best way to reduce the size of this questionable diagnostic utility category of "inappropriate" CT scans is through physician education, screening of consultation requests and implementation of medical imaging guidelines describing clinical scenarios and suggested imaging strategies. (28) (29) Furthermore, Murphy et al (2010) (30), reported that appropriateness ratings for nearly 29 percent of patients with indications for cardiac CT procedures could not be determined, while in another, up to 46 percent of patients with indications for coronary CT angiography could not be assigned appropriateness ratings. The validity of this statistic has been questioned, yet the true proportion is unknown. (23) (31) There is currently a wide variety of evidence reported on the causes, effects and possible solutions to the problem of inappropriate use of high-cost diagnostic imaging. (32)

Authors have written about the complexity of viewing health problems from a system thinking perspective, that is, viewing the different factors that influence patient care in a holistic way, looking not only at the silos of medical care for each of the specialties but in a comprehensive way looking at the entire spectrum of the care pathway that patients require. (21) (26) (27) (33) (34) This research offers a holistic view of how to assess the impact of diagnostic imaging technologies. By reviewing existing the literature and discussing with subject matter experts challenges associated with diagnostic imaging appropriateness assessment; ambition is to bring insights with healthcare managers at different level (policy makers, regulators, providers) to support advances in the assessment of the adequate use of these technologies and hence ensure they can be used at their full value-adding potential.



### 1.1 Research question:

The main goal of this research is to provide readers with an overview of where and how the use of diagnostic imaging is currently assessed and analyze what frameworks and instruments are being used. For that, the main research question addressed in this report is:

1. What criteria or frameworks have been studied to evaluate the appropriate use of diagnostic imaging in the care continuum?

Secondary questions will be covered:

- 1.1 How many non-empirical studies have been published since January 2010 on the efficient or appropriate use of Diagnostic Imaging?
- 1.2 Which clinical areas and imaging modalities have been most assessed?
- 1.3 What national-level initiatives are in place to promote appropriateness?
- 1.4 What hospital-level assessment tools are being used to measure appropriateness?

### 1.2 Analytical Framework

There has been found several approaches on how to assess the appropriate use of medical imaging, each one seeking to address some aspect of their technical performance, diagnostic efficacy, and clinical effectiveness. One of the approaches that is frequently mentioned is the technology assessment (TA) hierarchy, developed by Fryback and Thornbury in 1991 (35). This “TA hierarchy” framework is composed by six-levels: (L1) Technical efficacy; (L2) Diagnostic accuracy efficacy; (L3) Diagnostic thinking efficacy; (L4) Therapeutic efficacy; (L5) Patient outcomes efficacy; (L6) Societal efficacy (*APPENDIX 1, figure a*). Siström et al (2009) (21) developed a thorough explanation of the description of the TA hierarchy framework. According to the author, the first of these dimensions starts with the physical performance of diagnostic equipment and proceeds to a rather abstract concept of societal effectiveness. A point not often emphasized is that actual clinical decisions about diagnostic imaging are made at levels 5 and 6 of the hierarchy. Even if only studies at levels 1–3 are available, the practitioner must decide each case at level 5 (expected outcome). Policy makers and health care executives are working at level 6, by definition, when they make decisions about capacity planning, utilization management, and reimbursement. Although this framework was also named by Fryback and Thornbury as the “imaging process”, most healthcare researchers have used the “TA hierarchy” as a concept title, thus making it popular by this name, however, some authors like Seidel et al (2016) (36) has brought up the “imaging process” concept again in his article “The Evidence Value Matrix for Diagnostic Imaging”. The author connects the idea that the “imaging process”,

(which involves an imaging device such as a CT that records an image) is embedded in a larger “clinical process” (whereby a clinician makes a diagnosis and treatment decision). That clinical process, in turn, is part of the wider health care system whose goal is to improve patient outcomes and reduce costs. The impact of the imaging process on the clinical process and the health care system is described as “value”. In other words, the value of an imaging device is defined by what it is worth in terms of improving diagnosis, treatment decisions, patient outcomes, and health care costs. Furthermore, building on Fryback and Thornbury model, Gazelle et al (2011) (37) created a new framework 20 years later to provide guidance for assessing the value of diagnostic imaging from a payer perspective. The framework includes the size of the at-risk population, the anticipated clinical benefits, and the potential economic impact (*APPENDIX 1, figure b*).

While these frameworks provide a way to evaluate the value of diagnostic imaging by categorizing the impact according to their study rubric (Technical efficacy, Diagnostic accuracy efficacy, Diagnostic thinking efficacy, etc), there are other "end-to-end" frameworks that intuitively take into account the process that patients have to go through to obtain their diagnosis based on image analysis. In 2015, The Institute of Medicine (IOM) in the US, through its report "Improving Diagnosis" (38), developed an exhaustive work on "diagnostic error". An important aspect about this report, is that the authors make reference to the "brain-to-brain turnaround time loop", which has been used for the last 40 years as a framework to explain the “diagnostic process” for laboratory medicine. (39) (40) (41) The model can be translated in the diagnostic imaging within its five phases (*APPENDIX 1, figure c*): 1) a pre-pre-analytic phase, which involves the selection and ordering of medical imaging; 2) a pre-analytic phase (preparing the patient for imaging); 3) an analytic phase (image acquisition and analysis); 4) a post-analytic phase (the imaging results are interpreted and reported to the ordering clinician or the patient); and 5) a post-post-analytic phase (the integration of results into the patient context and further action). (42) (43) The relevant differences between the diagnostic imaging and laboratory medicine processes include the nature of the examination and the methods and technology used to interpret the results. (38) Other authors have followed this type of framework to analyze and understand how to create value by taking a holistic view of the diagnostic process. Larson et al (2017) (44) explored the role of radiology in the diagnostic process, focusing on key concepts of information and communication, as well as key interpersonal interactions of teamwork, collaboration, and collegiality. Lastly, more recently, as part of the book "Philosophy of Advanced Imaging", Lalumera et al (2020) (45) reported a complete outline on the

appropriate use of diagnostic imaging that can be evaluated in each of the stages of the "diagnostic process" (APPENDIX 1, figure c).

The "brain-to-brain turnaround time loop" framework (figure 1) reported by IOM (38) was used to analyze the data from the scoping review. This model outlines the importance in regards of the patient pathway and its interaction with the diagnostics process, thus, this framework can be translated in diagnostic imaging by the following themes represented by the questions: Did the patient receive appropriate care?; Was the study the patient received optimized according to the clinical presentation?; Was the patient's disease process changed because of it? These themes were chosen by the author to present the finding to make it easy for the reader to navigate in the result.

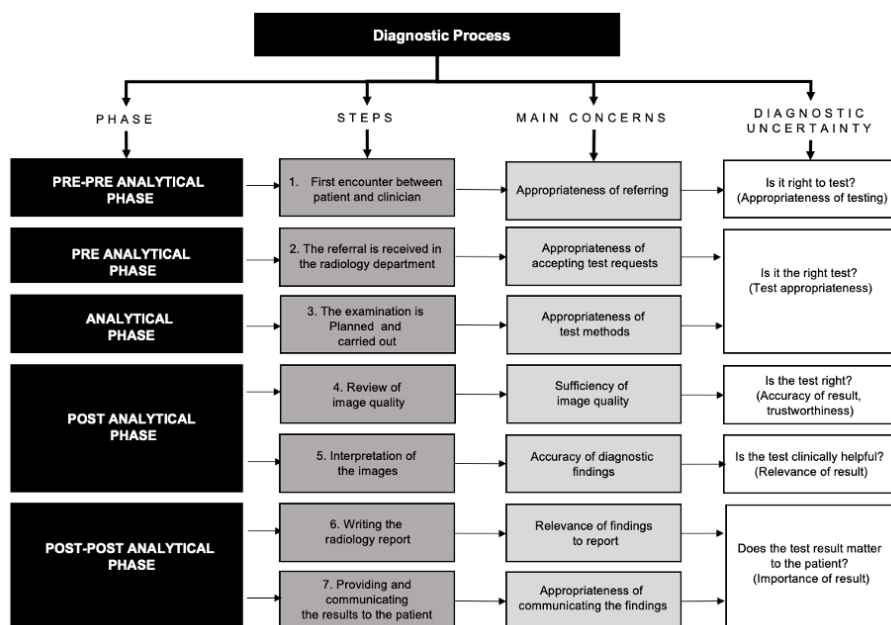


Figure 1. Brain-to-brain turnaround time loop process

### 1.3 Research design

This study is an exploratory research (46) and the design includes a mixed method approach. One definition of mixed method relates to a “research in which the investigator collects and analyzes data, integrates the findings, and draws inferences using both primary and secondary data in a single study or program of inquiry”. (47) (48) In this report, the research included a scoping review to obtain a systematic overview of the existing literature and semi-structured interviews to analyze actual practice in the field. Data was collected between August 2021 to October 2021.

## 2 METHODS

### 2.1 Scoping review

#### 2.1.1 Sample design

The research followed Arksey and O'Malley's framework to explore the existing literature on the use of diagnostic imaging. Arksey et al (2005) (49) stated that literature reviews can be conducted methodologically in many various ways. For instance, some reviews were claiming to be meta-analyses or fully systematic, with a strong focus on quality assessment of the selected studies, whereas other literature reviews were traditional reviews or scope oriented with more focus on the research findings. This literature review was related to the scope- oriented category, so-called scoping review. This literature is focused on developing an overview on what we knew about appropriate use of diagnostic imaging. This literature review is explorative. The quality of the included studies is not discussed.

#### 2.1.2 Data collection procedures

The literature search was conducted in September 2021. The search strategy included PubMed, Science Direct (Scopus), Centre for Reviews and Dissemination (CRD) and the International Network of Agencies for Health Technology Assessment database (INAHTA). Additionally, the literature search was supplemented by hand searches ("informed electronic browsing") in search engines (i.e. google) and screening of the references cited in the documents previously identified (i.e. cross-referencing). The type of studies selected were health technology assessments, systematic and scoping reviews, observational, qualitative, ecological and quasi experimental studies.

The US and the EU were selected as the study region, as well as information published during 2010 to 2021. This was due to the increase in the use of diagnostic imaging reported in different publications, as well as the constant involvement in the topic of appropriateness through publications in high impact journals and participation in the design of public policies (6) (50) by the medical societies of these two regions, especially the American College of Radiology (ACR) in the US and the European Society of Radiology (ESR) in the EU.

The literature review was based on an approach called the "*building block*". According to Marchionini (1995) (51) this approach builds keywords and terms combined in one block. In the present study the block included related terms, for instance, ("Health Services Misuse [MAJR]")

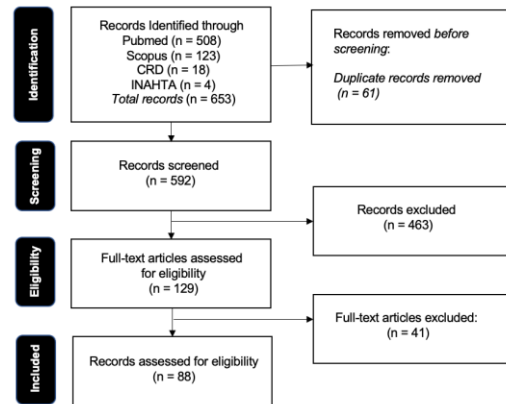
and other related terms. The search strings that were used is presented in *APPENDIX 2*.

The search process consisted of several steps, the first step included entering a search string. All items from the search were screened through titles only in the first step. Second, if a title was relevant, the abstract was read. Third, if the abstract seemed relevant for the review, the full text was read. Fourth, if the full text was relevant, the article was evaluated with respect to the study's inclusion criteria described in Table 1.

Inclusion criteria	Exclusion criteria
Studies published in English in the United States and the European Union	Papers in non-English language and other countries
Type of article: primary and secondary research or mix-methods studies, reviews, meeting reports, book chapters	Type of article: conference abstracts, letters to the editor.
Definitions and recommendations by internationally recognized evidence-generating medical associations	Definitions and recommendations by group of authors unsupported by reported evidence
Imaging modalities including CT, MRI, PET, or any combination of the aforementioned	Any other kind of imaging modalities
Studies with a research objective that explicitly explores the appropriate/inappropriate use of imaging diagnostic	Studies that include other types of diagnostics not related to imaging modalities
Publications available from 2010 to December 2021	Studies not including ethical considerations

**Table 1: Inclusion and exclusion criteria for literature review**

A total of 653 articles were identified through systematic searching in the four databases. After removal of duplicates from the 653 studies, 592 articles were identified for screening. An initial title and abstract review using the inclusion and exclusion criteria stated above resulted in the further exclusion of 463 articles. The full text of 129 articles were retrieved, of which 41 were excluded. Reasons for the exclusion of these studies included: studies that mentioned causes and factors of inappropriate use of medical imaging, but did not give a concrete definition of appropriateness; studies that combined terms such as inappropriate, misuse, overuse, underuse, but did not highlighted the difference between these terms; studies that referred to the process of pathology laboratory diagnosis, but not diagnostic imaging; studies that mentioned local programs not endorsed by a medical society or any national policy. From the remaining 88 articles the author selected relevant parts by qualitative aspects, categorized and summarized them in the present report. Figure 2 shows the selection flowchart.



**Figure 2. Flowchart of study selection**

## 2.2 Semi structured interviews

### 2.2.1 Sample design

In order to understand the level of awareness of the appropriate use of diagnostic imaging and also the applicability of the information contained in the scientific evidence in practice, through the opinions and perspectives of experts in the management of diagnostic imaging, a semi-structured interview consisting of 7 open-ended questions was conducted, following Lune and Berg (2017) (52) recommendations.

The study population included personnel working as part of the Philips company, who were responsible for areas related to diagnostic imaging on a global scale, had expertise in the subject of diagnostic imaging technologies and were involved in the communication with hospital decision makers and medical community. Participants were selected using a convenience sampling technique, defined as a non-probability sampling method in which existing subjects provide referrals to recruit samples required for a research study based on availability. (53) Likewise, snowball sampling technique was also utilized —with this technique the selection is by referral from other participants or people who know potential participants. (53) All this information was approved by the project advisors. Six initial participants were deliberately chosen by the researcher to represent individuals from different departments and with a variety of years of work experience to achieve a diversity and richness of information. Due to the COVID-19 situation, these sampling methods were adopted for their accessibility and feasibility; however, only two participants took part in the exercise, as the rest of the participants decided to postpone or cancel their participation.

The participant demographics including professional background, position, department and years of experience are presented in Table 2. Code numbers were assigned to participants in order to ensure confidentiality instead of their names in data analysis. The study's purpose was fully explained to the participants and oral consent was obtained before beginning the interview by the development of a research instrument (*APPENDIX 3*).

CODE	PROFESSIONAL BACKGROUND	POSITION	DEPARTMENT	YEARS OF EXPERIENCE
P1	Sonographer	KOL Engagement Leader	Precision Diagnosis Marketing Strategic Clinical	+20
P2	Radiologist	Medical Officer Precision Diagnosis	Precision Diagnosis Scientific Office	+30

**Table 2: Participant Demographics**

### *2.2.1 Data collection procedures*

The semi-structured interviews took place during the month of October 2021. A semi-structured interview guide, was created to gain insights from the participants who were invited. The interviews lasted between 30 – 50 minutes. The themes and questions addressed were the following:

**Theme 1 (T1):** The importance and vision of the medical imaging industry in the proper use of diagnostic imaging

T1-Q1: Can you elaborate on the industry's perspective regarding the overuse of diagnostic imaging?

T1-Q2: Can you describe the priority clinical areas and diagnostic imaging modalities in this problem?

T1-Q3: Where in the “diagnostic process” does industry have an opportunity to generate solutions?

**Theme 2 (T2):** Interaction with decision making and generation of evidence-based information

T2-Q1: Can you elaborate on how systematic evaluations can enhance the appropriate use of diagnostic imaging? — What is the role of the industry?

T2-Q2: How can Comparative Effectiveness Research (CER) and Health Technology Assessments (HTA) implemented at the hospital-level provide support to hospital/radiology managers in the proper management of diagnostic imaging? — What is the role of the industry?

T2-Q3: Coordination and alignment between the medical community and industry

**Theme 3 (T3):** Coordination and alignment between the medical community and industry

T3-Q1: Can you detail current priority programmes aimed at promoting the appropriate use of diagnostic imaging in the US and EU? — What is the role of industry?

T3-Q2: Are there any barriers in the US and the EU to the adoption of these programs in the Radiology community?

### *2.2.2 Data analyses for interviews*

The study was descriptive, and all data were collected across participants through semi-structured interviews via videoconference through the Microsoft Teams ® software, which were recorded with sound and video through an app called Photo Booth. Then the data were transcribed and analyzed by the interviewer. All interviews were in English. Each respondent was addressed with a different ID number. Content analysis was used. Content analysis is a method for analyzing written, verbal or visual communication messages, additionally, it allows the researcher to test theoretical issues to enhance understanding of the data (deductive method). (54) (55) The interviews were compared with existing codes to identify similarities and differences as well as frequency and correspondence. Later the codes were grouped into categories.

The content analyses were used in three steps. First, the participants' responses were divided and sorted into domains or topic areas that were already existing and that were relevant to the aim and research questions. Then, core ideas, which was a summary of what was said was constructed within each domain for each individual case for comparison. That was the codifying process, where the author arranged things in a systematic order, to make something part of a system or classification, for categorization. In the last stage, the categories were developed to describe the common themes which had been reflecting in the core ideas within domains across cases. As have been shown in the literature, themes are the outcomes of coding (*APPENDIX 4*). (56) (57)

### *2.3 Ethical considerations*

Within all research, ethical considerations must be thorough and transparent. Ethical considerations for researchers must include the presence and transparency of ethics approval, funding and conflicts of interest, as well as discussion of relationships with participants and



possible personal subjectivity and bias within the study. (58) (59) For the literature review, no summary scores were calculated for included studies, instead, ethical considerations, such as the ones previously mentioned, were considered as part of the inclusion criteria. Moreover, for the qualitative research, anonymity, confidentiality and informed consent was taken into account. (60)

### **3 RESULTS**

In order to structure the evidence on what we know about the appropriate use of diagnostic imaging (Section 1), the analysis of the information is shown below in three subsections. In a first subsection, we elaborate on the type and amount of evidence that exists within the diagnostic process, in the following two subsections, the instruments and programs related to the appropriate and efficient use of diagnostic imaging are presented. In Section 2, we analyze the information gathered from experts in the field.

#### ***Section 1: Scoping review***

Following the analytical framework, 9 studies were found (2 systematic reviews, 2 randomized controlled trials and 5 observational studies) in regards of the evaluation of the pre-analytical phase, including the variation in utilization considered as appropriate, semi-appropriate, and inappropriate medical imaging prescriptions. Most the of this literature evaluate the use of clinical decision support systems (CDSS) — CDSS is a broad term that refers to any form of automated real-time feedback in response to data entered by a clinician. With regards to imaging order entry, the purpose of CDSS is to assist a referring physician in selecting the most appropriate imaging study. (61) (62) Secondly, 55 studies were found as part of the factors that fulfill the analytic phase within the analytical framework. The proportions of studies considering these factors were presented as follows: Patient experience and safety (38%), Radiology service workflow (24%), Radiologist experience and safety (21%) and Diagnostic Technology performance (17%). These studies relied largely on qualitative studies design including surveys and semi-structured interviews. Lastly, for the post-analytic stage, 18 studies were found evaluating the clinical management of patients and their results based on decision making through medical imaging, as well as comparisons of treatments including and excluding certain strategies contemplating medical imaging. For this phase, 9 health technology assessments (46% were studies evaluating CT, 27% for MRI, 18% for PET-CT and 9% for CTCA); 8

randomized controlled trials and 1 retrospective cased control study were found. Overall, the calendar year of 2015 and 2021 have been the years where the most studies have been published, mostly focused on MRI, followed by CT and CTCA. The United States, UK and Austria have been the countries that have generated the most evidence in the last ten years (Figure 3-a). Additionally, imaging modalities with an impact on neuroradiology have been the most evaluated, followed by cardiology and traumatology (Figure 3-b). APPENDIX 5 shows all studies included in this analysis.

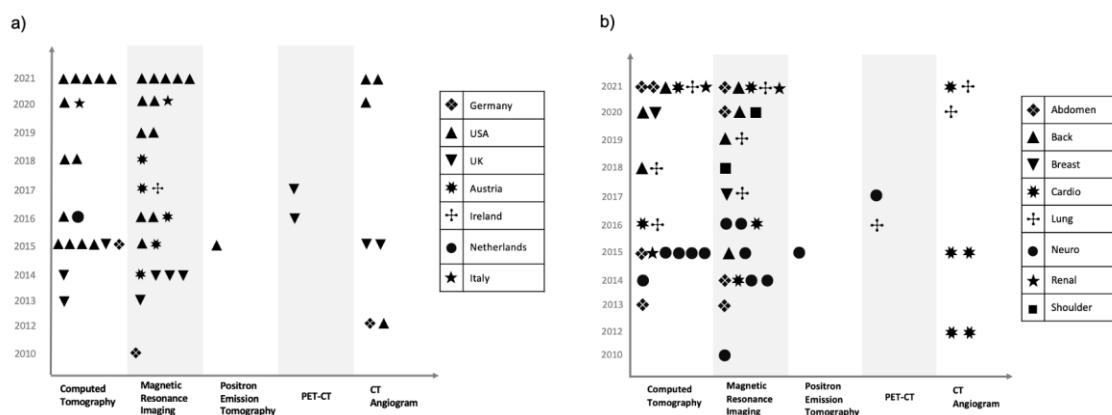


Figure 3. a) Year and country of study by imaging modality; b) Year and type of organ studied by imaging modality

### National-level initiatives in place to promote appropriateness

Public and private organizations and governments have increasingly focused on quality improvement, including the development of performance measures in medicine. (63) (64) With appropriate benchmarks, performance measures allow health care practitioners to identify areas within their practices that could be improved. (65) Although authors evaluating the various programmes to encourage efficiency and appropriate use of diagnostic imaging are scarce, recently, Steinwald et al (2021) (66) from the USC-Brookings Schaeffer Initiative for Health Policy in the United States, reported a comprehensive evaluation of the positive and negative effects of the application of various programs implemented by the Center for Medicare and Medicaid Services (CMS) in relation to the appropriate and efficient use of diagnostic imaging. On the European side, the European Society of Radiology (ESR) (5) (67), is the author of publications bringing together the experience and practice of European countries. In 2015, the ESR published a summary of the most important aspects of the European Directive 2013/59/Euratom, (67) emphasizing the safety standards for protection against the dangers

from exposure to ionising radiation, the need for justification of medical exposure (appropriateness), the requirements concerning patient information, among other topics. Likewise, in 2016, the ESR carried out an extensive international review on the use of imaging referral guidelines and the clinical decision support system by the radiology community. (5) Figure 4 shows the programs being carried out in the US and EU. Despite being programs that have been implemented since the beginning of this decade, information regarding their evaluation is scarce, however, information on their characteristics and scope can be found in numerous publications.

Region, name	Organizing group, start year	Concrete objectives	Measurement approaches	Priority areas
USA, Appropriate Use Criteria	American College of Radiology (ACR), Started in 2020	Intended to define “when to do” and “how often to do” a given test in the context of an individual patient, the health care environment, and a physician’s judgment.	<ul style="list-style-type: none"> <li>• Median Score 7-9: Appropriate Care;</li> <li>• Median Score 4-6: May Be Appropriate Care</li> <li>• Median Score 1-3: Rarely Appropriate Care</li> </ul>	<ul style="list-style-type: none"> <li>• Coronary artery disease; pulmonary embolism; Headache (traumatic and nontraumatic); Hip pain; Low back pain; Shoulder pain (to include suspected rotator cuff injury); Cancer of the lung (primary or metastatic, suspected or diagnosed); Cervical or neck pain</li> </ul>
USA, Medicare Access and CHIP Reauthorization Act (MACRA)	Center of Medicare Service (CMS), Started in 2017	Reward high-value, high-quality Medicare clinicians with payment increases - while at the same time reducing payments to those clinicians who aren’t meeting performance standards.	Merit-Based Incentive Payment System (MIPS): <ul style="list-style-type: none"> <li>• Quality; Cost; Clinical practice improvement; EHR use.</li> </ul> Advanced Alternative Payment Models (AAPM): <ul style="list-style-type: none"> <li>• High-quality; Cost-efficient care</li> </ul>	CMS is publicly reporting 480 clinician MIPS quality measures as star ratings in the Provider Data Catalog (PDC), 19 of them being related to Radiology practice
USA, Hospital Value-based purchasing programme	Center of Medicare Service (CMS), Started in 2013	<ul style="list-style-type: none"> <li>• Eliminating or reducing adverse events (healthcare errors resulting in patient harm).</li> <li>• Adopting evidence-based care standards and protocols in order to obtain the best outcomes for Medicare patients.</li> <li>• Incentivizing hospitals to improve patient experience.</li> <li>• Increasing the transparency of care quality for consumers, clinicians, and others.</li> <li>• Recognizing hospitals that provide high-quality care at a lower cost to Medicare</li> </ul>	<ul style="list-style-type: none"> <li>• Mortality and complications</li> <li>• Healthcare-associated infections</li> <li>• Patient safety</li> <li>• Patient experience</li> <li>• Efficiency and cost reduction</li> </ul>	Outpatient Imaging Efficiency (OIE-2022): <ul style="list-style-type: none"> <li>• MRI Lumbar Spine for Low Back Pain</li> <li>• Abdomen CT</li> <li>• Cardiac Imaging</li> <li>• Head CT or MRI Scan for Stroke</li> </ul>
EU, ESR iGuide	European Society of Radiology (ESR), Started in 2011	To ensure referrers and patients benefit from the best possible guidance for appropriate imaging	<ul style="list-style-type: none"> <li>• Median Score 7-9: Appropriate Care</li> <li>• Median Score 4-6: May Be Appropriate Care</li> <li>• Median Score 1-3: Rarely Appropriate Care<sup>15</sup></li> </ul>	<ul style="list-style-type: none"> <li>• Breast Imaging; Cardiac Imaging; Gastrointestinal Imaging; Musculoskeletal Imaging; Neurologic Imaging; Paediatric Imaging; Thoracic Imaging; Urologic Imaging; Vascular Imaging; Women’s Imaging</li> </ul>
EU, Eurosafe Imaging	European Society of Radiology (ESR), Started in 2014	<ul style="list-style-type: none"> <li>• Promoting appropriateness in radiological imaging</li> <li>• Maintaining radiation doses within DRLs</li> <li>• Promoting the use of up-to-date equipment</li> <li>• Using the ‘as low as reasonably achievable’ principle to further reduce doses while maintaining image quality</li> <li>• Improving communication with patients</li> </ul>	Clinical audit is now required under the Euratom Directive and is therefore mandatory: <ul style="list-style-type: none"> <li>• Is your service safe?</li> <li>• Is your service responsive?</li> <li>• Is your service caring?</li> <li>• Is your service effective?</li> <li>• Is your service well led?</li> </ul>	<ul style="list-style-type: none"> <li>• Diagnostic radiological imaging</li> <li>• Nuclear medicine</li> <li>• Radiotherapy</li> </ul>

Figure 4. National programs implemented to enhance effectiveness and appropriateness in diagnostic imaging

### Hospital-level assessment tools to measure appropriateness

Value of healthcare interventions often needs to be assessed locally. (68) (69) The potential of healthcare interventions assessments at a hospital level is to identify and adapt national evidence-based guidelines and systematic reviews for the local setting, create local evidence-based guidelines in the absence of national guidelines, use local data to help define problems and implement evidence into practice through quality-improvement initiatives. (68) (70) No studies have been found that evaluate the applicability of these instruments in the field of diagnostic imaging, nor have they included performance at the hospital level in any of the

diagnostic process sections. However, several authors such as Palozzi et al (2019) (33) and Sampietro-Colom et al (2016) (71) referred to these instruments as promising solutions to achieve the maximum efficiency required at the hospital level. Figure 5 shows the most common hospital-level assessment instruments in the literature. It is important to mention that although the trend is to analyze information on the use of medical technologies at a more personalized level, the assessment instruments at the national level are the spearhead for determining national priorities in terms of the need for and introduction of new medical technologies. On the US side, efforts to encourage the use of Value Assessment Committees (72) and Hospital-Based Evidence Practice Centers (73) through Comparative Effectiveness Research (CER) (74) have been on the healthcare agenda in the process of searching for and designing strategies for value creation. However, the applicability of evaluation instruments in medical imaging is still far from what a standardized framework, replicated by several hospitals, can achieve. On the other hand, in the European Union, the use of Health Technology Assessment (75) is becoming more and more important, recently the Adopting Hospital-Based Health Technology Assessments (AdHopHTA) (76) project was developed with the intention of knowing what information is the most useful to add value to the knowledge of hospital managers (77), however, no cases related to the use of medical imaging have been reported so far.

Region	Level	Evaluation agency	Model, year	Special feature
EU	National	<b>EUneHTA</b> : European Network for Health Technology Assessment	HTA Core (2004)	Main components: 1) Methodological guidance to assist in answering the research questions; 2) Reporting structure for presenting findings 3) Standardised set of HTA questions within a hierarchical structure. Recently developed spin-off models: REA (Rapid Effectiveness Assessment—2015) & National Assessments
EU	Hospital	<b>AdHopHTA</b> , Adopting hospital based health technology assessment in EU	Hospital-Based HTA (2007-2013)	Based on the HTA Core Model but with additional insights from Hospital Managers. Political & Strategic perspective as a complement.
USA	National	<b>PCOR</b> , Patient-Centered Outcomes Research	Comparative Effectiveness Research (2010)	Compares interventions commonly used in actual practice in terms of their medical outcomes, most desirably in real-world clinical settings. Economic input is not a strong feature.
USA	Hospital	<b>EPC</b> , Evidence Based Practice Centers	Hospital-CER (2002)	Considered the hospital-based models for CERs, they investigate quality improvement opportunities and implement system-wide care pathways. Hospitals incentives are aligned to establish EPCs.
USA	Hospital	<b>VAC</b> , Value Assessment Committees	"EPC" like (2013)	Making value-driven purchasing decisions is at its core. Factors included are clinical outcome, product quality, benchmarking and financial analysis. While the FDA gives permission to sell the tech, VACs find a reason to buy it. Mostly focused on PPIs; a.k.a Tech Assessments, Executive Medical Device & Product, Commodity Committees.
USA	Hospital	<b>AdvaMed</b> , Advanced Medical Technology Association	"HTA" like (2017)	Includes a set of 12 principles/domains as evaluation categories. Additionally, It includes four broad categories of "value drivers" to be incorporated in the assessment process.
USA	Hospital	<b>BRC</b> , Benefit-Risk Criteria	Technology Assessment (TA) Hierarchy Criteria (2012)	Its aim is to identify benefits and risks and characterizing their magnitude, probability and duration; the aggregate effect of harmful events, uncertainty, disease characterization and patient tolerance.
USA	Hospital	<b>CMS</b> , Inpatient/Outpatient Quality Reporting	Balanced Score Card (2005)	Is intended to equip consumers with quality of care information to make more informed decisions about health care options. Results are reported on the Hospital Compare website.
USA	Hospital	<b>ICER</b> , Institute for Clinical & Economic Review	Health Economic eval: CEA, CBA, CUA, BIA (2006)	Evaluates the clinical and economic value of medical tests. Develop "long-term value for money" and "short-term affordability."
USA	Hospital	<b>ISPOR STF</b> , The Professional Society for HEOR	Health Economic eval: CEA, CBA, CUA, BIA (2015-2016)	Developed a set of recommendations for value frameworks. CEA is at its core. It recommends the utilization of multi-criteria decision analysis (MCDA).

Figure 5. Flowchart of study selection

## Section 2: Qualitative study

Participants exclaimed precise points on the available evidence regarding the appropriate use of diagnostic imaging and what is currently practiced in the clinic. To further understand this topic

with the help of the participants, three themes were created: Vision of the medical imaging industry in the appropriate use of diagnostic imaging; interaction with decision making and generation of evidence-based information; and coordination and alignment between the medical community and industry. The three themes are described below using representative verbatim from the participants labeled with their code (P1-P2).

### **Vision of the medical imaging industry on the appropriate use of diagnostic imaging**

Recognition of the accelerated and disproportionate increase in the use of high-cost diagnostic imaging was recognized as a widely discussed issue in the medical community and industry. Inappropriate and inefficient use has been a key factor in this trend, common factors such as lack of regulation in the excessive use, financial incentives with particular interests, the human judgment with intrinsic and extrinsic motivations on the part of health professionals have been the most mentioned.

*(P1): People can use very poor CT or MRI scanners and get a very poor-quality image, make a judgement based on that image and build the same as if it's PET or a photon counting machine. There's no differential reimbursement based on quality; even with technologies that give more definitive answers that remove the need for secondary exams, the current reimbursement climate continues to reimburse people for exams that were not needed, because people didn't take advantage of the technology that's available in the first place.*

An important aspect of the trend in the increase in the use of medical imaging, participants mentioned that this behavior is contrary to popular belief in the medical community, assuming that the era of disproportionate increase has been on the decline over the last five years. P1 mentioned that in addition to the current increase in common modalities, new trends have recently emerged in the use of new modalities as efficient alternatives to other modalities that have been used as standard of care for years:

*(P1): CT has exploded, MRI continues to grow, ultrasound has exploded, PET scanning has exploded, and nuclear scanning that is not PET scanning, has finally started to decrease. With the emergence of cardiac CT, it has become the predominant imaging study of choice. And so much so that the payers in North America have recognized that and started to stop paying for other things that were much more expensive and turns out were less useful than coronary CTA.*

The participants envision taking exemplary practices from different regions of the world as an example in order to make the most of them and adapt them to the local context.

*(P2): I think that there is a large potential to get the European experience of the only utilization of ultrasound in particular. So, in the United States, there's a lot of utilization of MRI and CT, because those are more common. However, ultrasound It's more portable and cheaper procedure to perform, and in Europe, it's being done much cheaper or so much more commonly, and I think that where I'm seeing the shift is with a portable equipment or point-of-care ultrasound, we're seeing the increase in utilization of the ultrasound at the point of care for the clinicians.*

An important point to note is the applicability and practicality of data analysis along the care continuum, the exercise of which could reveal how much value the use of diagnostic imaging provides to a certain time of patients. Nevertheless, there are still a few challenges to make this possible.

*(P2): I think we are practically very far from having that complete care cycle view. So, we have the data, if you look at the data as the video stream of the patient journey, we have the snapshots of some of the episodes, but we do not have it all and by putting together those snapshots, we are saying that, okay, this is your journey, it's not necessarily that we might have a very good insight into particular segment of it, then we might have a huge gap because of the interoperability deficiencies.*

### **Interaction with decision making and generation of evidence-based information**

The participants expressed the importance of the use of evaluation tools for measuring the value of diagnostic imaging equipment. The best represented tool was ROI (return of investment), taken into account for the acquisition of new medical equipment in hospitals and the assessment of the range of reimbursement to public health insurers.

*(P2): ROI calculators-like tools, from North America perspective are being created in Philips based on the reimbursement codes and time which is spent by customer or by patient.*

Likewise, the importance of having visible and real-time information on the performance of the radiology area was described in order to make better decisions regarding patient care and functional and operational performance of the diagnostic imaging equipment for appropriate use.

*(P1): Whether we are required to do so is a separate question whether we should absolutely. When we deliver equipment, we should have built into that equipment software or bundled in a program that on an ongoing dashboard way reveals how one is performing on the ROI for having spent this money. That reveals whether studies were done when they didn't give an answer that had anything to do with the clinical question, or that ended up requiring another study afterwards because they didn't answer the question. And then somehow, we have to look back and say, did we order the wrong study? Was it an inappropriate study?*

However, the use of systemic medical technology assessments was not part of the routine management of the participants.

*(P2): This is something where I'm just surprised because we are conducting key opinion leader meetings at C suite level where I'm clinician myself, I have colleagues who are working at the hospitals, I have colleagues who are former radiology directors, etc. And I've just been feeling absolutely out of tune. So, thank you so much for bringing it to my attention. I'll ask around, but I'm not familiar.*

### **Coordination and alignment between the medical community and industry**

Regarding the applicability of the policies designed to encourage the appropriate use of diagnostic imaging, the most pointed out was the Appropriateness Use Criteria by the American College of Radiology under the mandatory call by the Center of Medicare and Medicaid Services. One of the most important challenges emphasized is teamwork on the part of health professionals involved in diagnostic imaging.

*(P1): The appropriateness criteria is not going to be implemented on their own. Most radiologists are vaguely aware of it, but radiologists are not allowed to order studies. So, it has to be the clinician that orders the appropriate or inappropriate study.*

An important part of the decision-making process is the ethical component that involves raising awareness about the appropriate use of technologies for the benefit of all health care stakeholder.

*(P1): I think it's not necessarily the responsibility in terms of legal responsibility. I'm not even sure about ethical responsibility or moral responsibility. I think it's the right thing to do. I think it's what in the longer run would benefit Philips tremendously with their customers to provide that service on every piece of equipment that a customer purchases.*

On the other hand, it has been also mentioned that it is imperative the type of information you are working with to provide feedback on the use of the technology.

*(P2): We talk a lot with our campaign leaders with the ethical use of data and also with the data credibility. I think that the data which we possess is not necessarily objectively represented. So, that brings us to that conundrum of ethics, so first of all medical ethics, representational data, objectivity of data, and data rights.*

## **4 DISCUSSION**

### **Scoping review**

The results suggested that there is a greater concentration in the evaluation of diagnostic imaging performance on the activities undertaken in the radiology area, those related to patient scheduling, equipment performance, radiologist productivity, image quality, etc. In the framework developed by Lalumera et al (2021) (45) this stage is composed by different sections aimed at asking the following questions: is it the right test? (test appropriateness); is the test right? (accuracy of results, trustworthiness); is the test clinically helpful (relevance of results). It is interesting to note that more than 70% of these evaluations are qualitative studies, mostly including surveys and interviews with radiology staff, and also including the patient's experience of the visit during the examination. The second type of evaluations most present in the literature were those related to the comparison of treatments based on the results of medical imaging tests, as well as comparisons between treatments that used diagnostic imaging as support and treatments that did not. At this stage the ordering clinician, sometimes in consultation with radiologists, incorporates the test results into the clinical context of the patient, considers the likelihood of a particular diagnosis in light of the test results, and considers the harms and



benefits of future testing and treatment given the newly acquired information. Possible factors contributing to failure at this stage include incorrect interpretation of the test result by the ordering clinician or radiologist and failure of the ordering clinician to act on the test results: e.g., failure to order a follow-up test or to provide treatment consistent with the test results (38). Of the eighteen studies consulted, the Health Technology Assessment developed by Halligan et al (2015) (78) on computed tomographic colonography compared with colonoscopy or barium enema for diagnosis of colorectal cancer in older symptomatic patients in the UK, stands out the most, including all the assessment components suggested by Fryback and Thornbury (1991) (35) in its Technology Hierarchy (TA). (35) Finally, evaluations related to the appropriate prescription and ordering of imaging diagnostics were the least present in the literature. This stage has been identified as a key point of vulnerability in the work-up process due to the large number and variety of tests available, which makes it difficult for non-specialist clinicians to accurately select the correct test or series of tests. (38) The information reported on this stage in the present review is in line with other recently published studies. The rapid response report on "Clinical Decision Support Systems for Appropriate Medical Imaging: Clinical Evidence and Cost-Effectiveness" produced by The Canadian Agency for Drugs and Technologies in Health (CADTH) in 2019, (79) highlights the low availability in the literature on the evaluation of computerized decision support systems, including only two randomized controlled studies and about 3 to 14 low-quality "before and after" studies, noting also that it found no cost-effectiveness studies. Moreover, Goldzweig et al (2015), (80) presented a systematic review and meta-analysis, reporting similar results in terms of the number of studies present in the literature up to 2015, including 3 randomized trials, 7 time series studies, 13 pre-post studies that evaluated the effect of CDSS on the ordering of diagnostic radiological tests in adults and none cost-effectiveness studies.

The overall findings of this scoping review indicated that the way in which the impact of diagnostic imaging is currently assessed across the care continuum is merely representative of how healthcare in general is assessed in a siloed fashion, significantly excluding the holistic view that would allow us to see the problem in an inclusive and systematic way. As pointed out by Narayan et al (2015) (81) in a systematic review on quality measurements in radiology, finding that more than 70% of indicators available today are those related to process and structure metrics, meaning by process metrics those that are related to services provided in health care settings and whether or not these services were appropriate care for a given condition (eg, universal protocol followed, appropriateness criteria), and structure metrics are

more into quality measures that focus on relatively fixed practice characteristics, such as equipment, qualifications of facilities and staff members, and practice or hospital volume. Comparatively to outcomes metrics, related to assess the consequences of the health care received (mortality, cancer diagnoses, correct or incorrect diagnoses), the present scoping review showed similar results.

Therefore, the author suggests that more studies be conducted that take into account the impact of utilization on the entire diagnostic process, although the challenge is to find a way to link one stage to another, having a view of all these components can give us a better idea on how to have a more efficient and appropriate use of diagnostic imaging. Analyzing, understanding and categorizing the evidence in light of the different diagnostic imaging assessment frameworks can provide a clear picture of where in the continuum of care more assessment and therefore more action steps are required, moreover, reporting and documenting this information in the various hospital-wide instruments can substantially help decision-makers to provide better services and increase how patients are being treated in their imaging test journey.

### **Semi-structure interviews**

Evidence on what is effective, and under what circumstances, is often lacking, poorly communicated to decision makers, or inadequately applied, and despite significant expenditures on health care, these investments have not translated to better utilization in healthcare services. (82) One of the reasons this is happening, according to Buxbaum in the report "Tackling Low-Value Care: A New "Top Five" for Purchaser Action" published in Health Affairs in 2017, (83) is because in many respects, public and private healthcare purchasers, as well as the medical imaging industry, have been absent from the movement to eliminate low-value care. For example, despite the hard work of several campaigns on the appropriate use of diagnostic imaging such as Choosing Wisely and hundreds of related effort guidelines, (28) awareness of the initiative remains limited and low-value care persists at unacceptably high rates. Thus, new efforts are urgently needed to translate research and guidelines into action.

The level of resilience of some healthcare systems allows for new ways of managing how resources are used and financed. In the case of healthcare systems within the European Union, initiatives based on regulating the appropriate use of medical services through changes in the

reimbursement scheme or the design of incentives for medical personnel who are part of the patient's healthcare management are not yet fully feasible. On the other hand, in the United States, initiatives of this type have been implemented over the last ten years, although it has not been enough, there is an imperative to finance and measure health outcomes based on metrics that contemplate a comprehensive vision of what it means to have good health and to provide treatments that increase the quality of life. Without the existence of a system that rewards quality and avoids in some way using health services just because they are accessible and can provide more information without some objective, the equation that represents high value health care will be truncated and the costs will always outweigh the outcomes that the health system craves. Another very interesting perspective that should be taken into account is the understanding of the diagnostic process, the components of which it is made up and the role that the different stakeholders have in trying to provide tools to make it more efficient and achieve results in accordance with the level of quality required. For this, the availability of information is of utmost importance, but not without overlooking the possible risks and costs that this may cause, since patients are the most vulnerable when handling this type of information, and at the end of the day, without a fair and appropriate regulation, the use of this tool may be counterproductive and result in non-beneficial decisions. From this, we can see how the industry plays a fundamental role in obtaining, analyzing, and creating initiatives through the information collected in the care continuum and also the clarification of the efficiency that some imaging modalities can provide based on the clinical variation that exists in each patient. This corresponds with the finding obtained in obtaining the vision and perspective on the current use of medical imaging by the interviewees. The suggested theme was: *Vision of the medical imaging industry in the appropriate use of diagnostic imaging.*

In relation to decision making and evaluation of the impact of health services based on information collected at the local level, it is a topic that is still in its infancy, but has a high potential to develop in the coming years. In the European Union region, the role of Health Technology Assessment agencies has been fundamental in understanding the requirements of the population and the health system to meet their needs. Although the focus of these agencies is at the national level, there has been a great deal of interest in the last ten years in developing assessments at the hospital level. The Adopting Hospital-Based Health Technology Assessment (AdHopHTA) project that emerged during 2012 is a clear example of this. Although, as mentioned by Palozzi et al (2009) (33) and Deinum et al (2017), the applicability of the results has been somewhat slow, the intention and willingness on the part of regulatory

agencies remains constant in order to replicate success stories in different hospitals throughout the region. In the case of the United States, although there is no national coordinating body, there are several initiatives from different fronts. Although the priorities on what and how to measure differ somewhat from the European Union perspective, they share a very similar objective, which is to ensure that medical services and technologies deliver the greatest possible value by meeting the expectations of all stakeholders and focusing on patient outcomes. The suggested theme was: *Interaction with decision making and generation of evidence-based information*

Regarding the various programs designed by medical societies and national agencies and their interaction with the industry, the interviewees were optimistic and empathetic about what is currently being done. The role of the radiologist plays an important, but at the same time indirect, role in the patient's passage through the radiology area. There is a vacuum effect, where the referring clinician, who is the main author of the decision about ordering a new imaging exam, requests information regarding the results of that exam, and based on that, assigns the treatment trajectory to the patient, leaving the radiologist only as an intermediary without being able to have direct interaction in the patient's treatment design, in the best of cases, the referring clinician works together with the radiologist, however, this happens rarely. It is this direct interaction that makes programs such as the Appropriateness Use Criteria, established by the American College of Radiology in 2012 in the US and the European Society of Radiology in 2019 in the EU, to be implemented partially, since even having available different tools to make an appropriate medical image ordering, there are many variables and factors for which this type of programs will have objection at the time of use: clinical variability of the patient that leads to a decision different from what is recommended by clinical guidelines, financial incentive to perform a second examination, among others.

On the other hand, programs that attempt to measure medical practice with indicators related to the level of quality provided to the patient, such as those integrated in the Quality Payment Program (QPP) in 2015 by the Center of Medicare and Medicaid Services in the United States, can serve as a milestone in the provision of high quality services with measurement of results based on improvements in patient outcomes. However, there is still uncertainty as to whether these types of initiatives will encourage more reporting on quality improvement and in the end the results will not demonstrate the quality of care provided, but rather how well providers were complying with the reporting requirements of the program.

By understanding the functioning and impact of these programs, the industry will be able to integrate their knowledge and skills to complement the efforts. The interaction that diagnostic imaging equipment has should serve more than just delivering the desired results, adding value to the patient care chain by analyzing information gathered along the way and providing recommendations for better patient treatment design, hence the importance of the industry's parallel efforts at the clinical, health policy, reimbursement, market access and technology demand levels. The suggested theme was: *Coordination and alignment between the medical community and industry.*

#### *4.2 Strength and limitations of the study*

A scoping review is a form of research that maps the relevant literature in the field of interest to address research gaps. (49) Unlike the systematic review, which aims to provide answers to specific questions, a scoping review is less likely to attempt to address very specific research questions. In addition, the nature of the scoping review is to focus on breadth, rather than depth. (49) Therefore, it is beneficial to the objective of the present study because the objective included such a broad term that can be represented in the entire diagnostic process, which as we have seen in this report, is dependent on the time and phase in which the patient is on his or her way to obtaining a medical imaging exam. However, this target is not specific, so it is an appropriate method to adopt.

This was the first known scoping review that synthesized the literature in a systematic way regarding the appropriate use of diagnostic imaging taking into account the different stages of the diagnostic imaging process. In a nuanced manner, the potential problems of the present study were the scarce evidence regarding the evaluation of the utilization of diagnostic imaging by analyzing the entire episode of care taking into account clinical scenarios, imaging modality and patient specificity. This limited the scope of the study to maintaining a general overview of diagnostic imaging and did not allow focusing on a specific imaging modality. Further, this study was limited by the geolocation search filter, although it focused on finding data only from the United States and the European Union region due to issues pointed out during the study, a complementary review to the present one would be required taking into account countries that have registered an increase in diagnostic imaging in recent years in a similar fashion and that are making efforts to combat its overuse, in these regions it may be possible that there are initiatives related to investigate what evidence exists on the impact of diagnostic imaging in the entire care continuum.

The qualitative study could be promising to support or verify previous research and current practice if it had a high participation rate including not only professionals with expertise in the clinical perspective, but also those in conversation with medical associations and public agents, as this would help to reach saturation of responses, as well as it could be a promotion to generate new theories based on a solid analysis process. Therefore, more interviews should be conducted in the future to explore the fact. To understand the matter of these findings, the author presented the data and then linked it to a core of concepts and social cognitive theory. Then later, some citations from some previous relevant studies were compared to the results of this study.

#### *4.2 Possible implications of the work*

This research is important to understand how the impact of the use of diagnostic imaging on the patient is evaluated. Qualitative research is important to know how much of the evidence reported in the literature is not only being applied, but also how much knowledge regarding its results and its existence exists in common practice. The closest we have come are the reviews included in the Health Technology Assessments, however, there is still very little work related to diagnostic imaging. Thus, this review can be key for developing recommendations and policies.

## **5 CONCLUSION**

Regarding the scoping review, there is more evidence on the interaction between the radiology area, including the existing technology, the radiologist's work and the patient's experience at the time of having a diagnostic imaging exam, however, evidence regarding the adequate or inadequate prescription through the use of clinical decision support systems, and evidence regarding the effectiveness of certain treatments that are prescribed based on the results of diagnostic imaging is scarce. The gap is clear in the body of research due to the low number of identified studies. Therefore, the author recommends that future research should be conducted considering the impact in the episodes of care. As for the qualitative study, the approach is appropriate for the knowledge-gap analysis intended in this study, but it is necessary to include more variety of perspectives from stakeholders to obtain more comprehensive information. Therefore, future studies related to these subjects are highly recommended.

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## **LIST OF APPENDICES**

APPENDIX 1 : Value assessment frameworks for Diagnostic Imaging

APPENDIX 2 : Search strategy

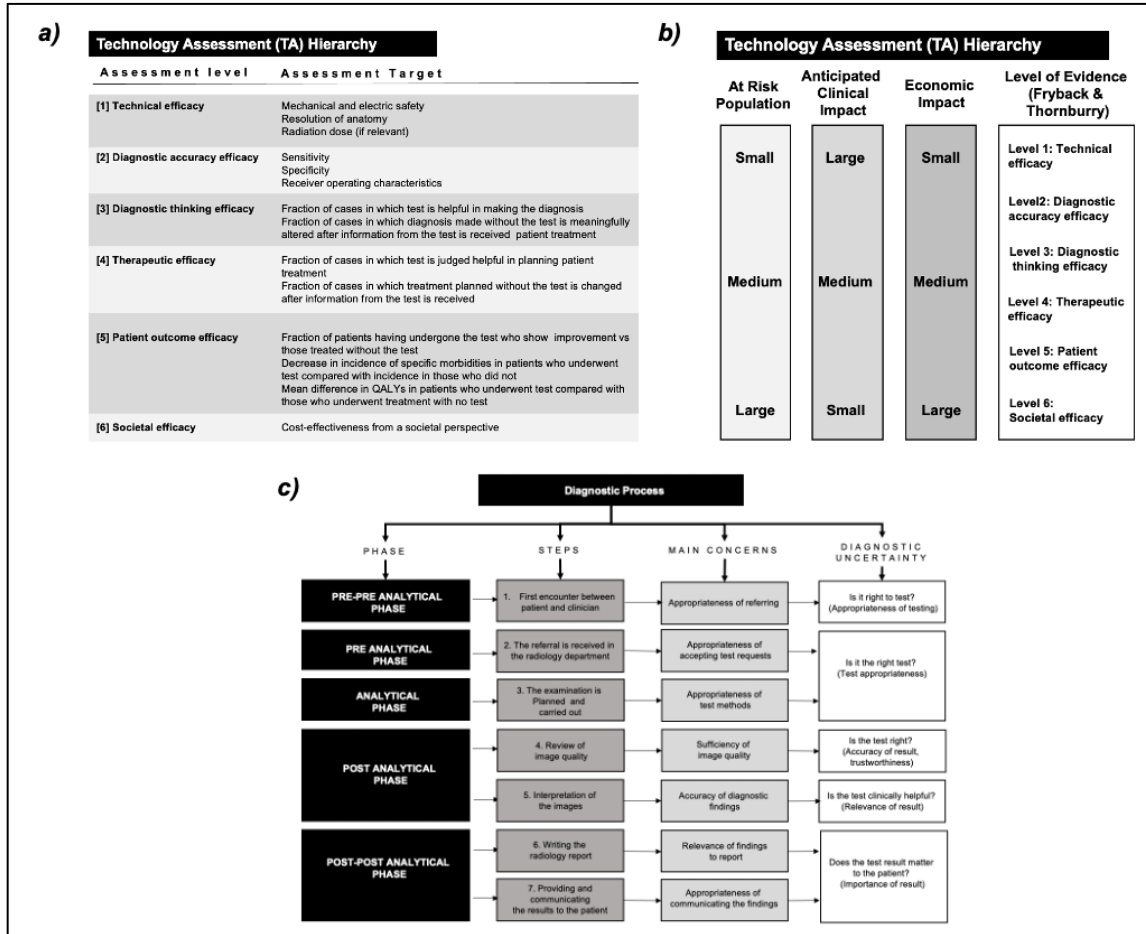
APPENDIX 3 : Research instrument

APPENDIX 4 : Qualitative analysis

APPENDIX 5 : Studies analyzed according to the diagnostic imaging phase

# APPENDIX 1

Value assessment frameworks for Diagnostic Imaging: a) "Imaging process" diagram; b) "Imaging process" diagram adjusted by Gazelle et al; c) "Diagnostic imaging" including data from IOM, 2015 report and Lalumera et al, 2020



## APPENDIX 2

### Search strategy

<b>Pubmed</b>
15.09.2021
127 hits
("Health Services Misuse"[MAJR] OR "Medical Overuse/statistics and numerical data"[MeSH] OR "Medical Overuse/prevention and control"[MAJR] OR "Unnecessary Procedures/statistics and numerical data"[MAJR] OR "Unnecessary Procedures"[MeSH]) AND (“appropriate use criteria” OR appropriate OR appropriateness OR appropriate use OR inappropriate use OR inappropriateness OR inappropriate OR misuse OR overuse OR overutilization OR overdiagnosis OR unnecessary) AND ("Evidence-Based Medicine"[MAJR] OR "Guideline Adherence"[MeSH] OR "Practice Guidelines as Topic"[MeSH]) AND ("Diagnostic Imaging/standards"[MeSH] OR "Diagnostic Imaging/statistics and numerical data"[MAJR] OR "Diagnostic Imaging"[MeSH] OR "Radiology/trends"[MAJR] OR "Radiology"[MAJR]) AND (criteria OR definition OR taxonomy)
<b>CRD Database</b>
15.09.2021
15 hits
("Medical Overuse" OR "Unnecessary Procedures") AND (Appropriate OR appropriateness OR appropriate use OR inappropriate use OR inappropriateness OR inappropriate OR misuse OR overuse OR overutilization OR overdiagnosis OR unnecessary) AND ("Guideline Adherence") [Mesh] AND ("Diagnostic Imaging" ) [Mesh] AND (criteria OR definition OR taxonomy)
<b>Scopus</b>
15.09.2021
123 hits

ABS ("Diagnostic Imaging")  
AND  
("Health Services Misuse" OR "Medical Overuse" OR "Unnecessary Procedures")  
AND KEY  
(Appropriate OR appropriateness OR appropriate use OR inappropriate use OR  
inappropriateness OR inappropriate OR misuse OR overuse OR overutilization OR  
overdiagnosis OR unnecessary)  
AND  
("Evidence-Based Medicine" OR "Guideline Adherence" OR "Practice Guidelines as  
Topic")  
AND  
(criteria OR definition OR taxonomy)

**INHTA**


15.09.2021

4 hits

(Appropriate OR appropriateness OR appropriate use OR inappropriate use OR  
inappropriateness OR inappropriate OR misuse OR overuse OR overutilization OR  
overdiagnosis OR unnecessary)  
AND  
("Guideline Adherence" OR "Practice Guidelines as Topic")  
AND  
("Diagnostic Imaging")[Mesh]  
AND  
(criteria OR definition OR taxonomy)

## APPENDIX 3

### Research Instrument



**Participation in Semi-Structured Interview**

**Study Title:** Assessing appropriateness: How hospital-level assessments can adapt to improve the evaluation of Diagnostic imaging?

**Research Type:** Master's thesis for the degree of Master in Public Health, Health Policy and Management.


**Research Design:** Mix-methods research with exploratory approach — Semi-structured interview (primary research) and Literature review (secondary research).

<b>MPH student:</b> Adan Osuna French School of Public Health (EHESP) 20 avenue George Sand 93210 La Plaine St Denis, France Telephone: +33 0749697132 Email: adan.osunaaragon@eleve.ehesp.fr	<b>Philips advisor:</b> Bodo Wiegand Head of Market Access and Reimbursement CoE Medical Strategy & Innovation Email: bodo.wiegand@philips.com
<b>EHESP advisor:</b> PhD Pierre-Yves Brossard Institute of Management, EHESP 20 avenue George Sand 93210 La Plaine St Denis, France Email: pierre-yves.brossard@ehesp.fr	<b>Philips advisor:</b> Lucy McDonough Director Market Access and Reimbursement, North America Email: lucy.mcdonough@philips.com

**Introduction**  
You are invited to participate in a master thesis research directed by Mr. Adan Osuna, being part of the Master in Public Health program of the French School of Public Health (EHESP). Taking part in this research is completely voluntary; you may withdraw from the research at any time. The research description is described below. You should discuss any questions or concerns you have about this research with Mr. Adan Osuna or Lucy McDonough (contact information can be found above).

**What the research is about**  
Mr. Adan is conducting a review of the evidence trying to provide a holistic view of how to evaluate the impact of diagnostic imaging technologies. Part of this research includes understanding and aligning the current evidence reported in the scientific literature with the opinions and experiences of experts in the management of diagnostic imaging technologies.

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Mr. Adan will be the local contact for this research project, and will be conducting the interviews.

The main research question of this work is:

1. **What is the current management on the appropriate use of high-cost diagnostic imaging (DI) at national and hospital level in the United States (US) and the European Union (EU)?**

supported by the following questions:

- 1.1 What appropriateness criteria has been examined within the DI care continuum?
- 1.2 What hospital-level assessment models could be adopted for DI utilization management?
- 1.3 What national programs are currently implemented to promote the appropriateness and efficiency of DI?


**How the study is done**  
You are asked to participate in a one-on-one interview in which you will be asked to share your opinion and knowledge on the current management of imaging technologies. The interview guide can be found in Attachment #1 for more information. The interview will last between 40 and 60 minutes and will be conducted using a digital tool that allows videoconferencing. Your explicit permission to record the interview will be requested.

**Confidentiality and anonymity**  
Your privacy will be maintained throughout this study and at its completion, and your identity will not be shared. Only your academic degree, years of experience, position in the company, and the geographic area you are in charge of will be shared. Video and audio recordings will be retained for 6 months after publication. Video and audio files, transcripts, consent forms, notes and raw data will be stored on a password protected computer. You may ask questions at any time during your participation in this research study. If you have any questions about your rights as a research participant or about the conduct of this research work, you may contact the direct advisors associated with this research.

**Consent**  
By accepting participating in this interview, you are confirming:

- You have read the information about the research.
- You have been able to ask questions about this research.
- You are satisfied with the answers to all your questions.

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- You understand what the study is about and what is being asked of you.
- You understand that you are free to withdraw from the study at any time, without having to give a reason, and that doing so will not adversely affect you now or in the future.
- You have the opportunity to review the transcripts and remove any information you do not wish to include in the study.

If accept participation in this interview you do not give up your legal rights and you do not release the investigator from his or her professional responsibilities.

**Yours sincerely**

**Adan Osuna  
Market Access & Reimbursement CoE, PD Intern  
French School of Public Health (EHESP)**

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**APPENDIX 4**  
*Qualitative analysis*

Category/Content	Code	Description	Participant's comment
<p><b>Vision of the medical imaging industry in the appropriate use of diagnostic imaging</b></p>	<p><b>Appropriateness problem</b></p>	<p>Current management and perception of the problem</p>	<p>P1. CT has exploded, MRI continues to grow. ultrasound has exploded. PET scanning has exploded. And nuclear scanning that is not PET scanning, has finally started to decrease. With the emergence of cardiac CT, cardiac CT has become the predominant imaging study of choice. And so much so that the payers in North America have recognized that and stopped, started to stop paying for other things that were much more expensive and turns out were less useful than coronary CTA. So nuclear cardiology, which has been an office based practice in North America that feeds cardiologists is down over the last 10 years is down over 55% . It was just published one survey about that just two days ago, I think was published showing that that kind of work, which is high cost, and although it's valuable is no more valuable than the lower cost CT and it's more radiation than CT.</p> <p>P1. Number one, the system in North America doesn't pay based on quality. So people can use very poor CT or MRI scanners and get a very poor quality image. make a judgement based on that image and build the same as if it's PET or a photon counting machine. There's no differential reimbursement based on quality. Number two, even with technologies that give more definitive answers that remove the need for secondary exams, the current reimbursement climate continues to reimburse people for exams that were not needed, because people didn't take advantage of the technology that's available in the first place.</p> <p>P1. Philips, as the company put both feet in on spectral CT, which answers many questions definitively, but if people don't evaluate the spectral components of spectral imaging, or don't use the spectral imaging, then indeterminant lesions end up being scanned with ultrasound or MRI, that's inappropriate, and it's wasteful, and it's time consuming. It's not patient sensitive, or patient centric.</p> <p>P1. Philips as a company has not been able to transform the end users thinking to make it important to the end user because the end user still gets paid for the second study. Until we remove the money from the second study, the needless inappropriate study, that's not going to change. Doing the right thing does not seem to be at the top of many people's lists.</p> <p>P1. Philips faces the same conflict that the radiology faces with respect to appropriateness. The radiologist does not want to anger the referring physician by saying you have to go back and fill out a bunch of paperwork.</p> <p>P1. The question of appropriateness means that everybody would be looking at the results with suspicion. And that's why the ACR and others have created the appropriateness criteria. It's also not the appropriate pathway, nor is it realistic to think that Philips as a company is going to somehow not only enable those solutions to be applied in terms of appropriateness, but to enforce them. It's a non starter. In some areas, Philips is a leader. In some areas, they're a follower</p>

Category/Content	Code	Description	Participant's comment
	<b>Diagnostic Imaging modalities target</b>	Imaging modalities that have proven to be more efficient than others and are currently part of the discussion in the medical community	<p>P2. I think that there is a large potential to get the European experience of the only utilization of ultrasound in particular, right. So in the United States, there's a lot of utilization of MRI and CT, because those are more common technologies like so we have much more access to those in the US. However, ultrasound is a cheaper, It's more portable and cheaper procedure to perform, and in Europe, it's being done much cheaper or like so much more commonly. So in the US, there is the authorization for use. And I think that where I'm seeing the shift is that was a portable equipment or like, so that the point of care ultrasound, we're seeing the increase in utilization of the ultrasound at the point of care for the clinicians.</p> <p>P1. So the problem in North America is that the reimbursement for the CTA is very poor relative to the amount of energy required to perform and interpret the studies, which is at the core of what I assume you're studying. And there's only one way to remedy that, and that is to change the acknowledgement by CMS, of how much work goes into reading dose. And there's a whole group called the RUC, that the RUC sets, how much work effort is recognized for the studies. This study requires a lot of work effort on the part of the radiologist or cardiologist, and yet doesn't have anywhere near the recognition and therefore the reimbursement is terrible. So that really needs to be the effort of industry that sells this equipment, cardiologists, radiologists that use the equipment, hospitals that purchase the equipment. If only the cardiac reimbursement would change, we would see further transformation of the map in a dramatic fashion. I don't think that that's going to happen anytime soon. But that's what really would be needed.</p>
	<b>Diagnostic Process consideration to analyze appropriateness</b>	Role of the diagnostic process in decision making by the industry and the medical community.	<p>P2. I think we are practically very far from having that complete care cycle view. So we have the data, we do have the, if you look at the data as the video stream of the patient journey, we have the snapshots of some of the episodes, but we do not have it all and by putting together those snapshots, were saying that, okay, this is your journey, it's not necessarily we might have a very good insight into particular segment of it, then we might have a huge gap because of the interoperability deficiencies, and then might have another insight. So but saying that we objectively seeing it, we're doing the best we can seeing that segment, right is the video loop. But indeed, it is the series of sections, which we have</p> <p>P1. It's totally part of the equation at the leadership level, about anticipating where the puck will be, and where we should be skating to. Implementation is constrained. As I pointed out, by human behavior, referring clinicians have too much on their plate, they don't need one more thing to do, radiologists have too much on their plate, and even if they try to get clinicians to abide by some of this, it backfires. So nobody's found the magic sauce to enable the switch towards value based care. We continue to be rewarded for all qualities, including inappropriate quality. Eventually, nobody knows when but eventually that will be remedied in some manner. But right now, it is so incremental as to largely not gain traction.</p>

Category/Content	Code	Description	Participant's comment
	<b>Industry vision and initiatives to enhance appropriateness</b>	Industry solutions and strategies	<p>P2. I think it's providing elixir because all the reimbursement is being driven by the medical community. So technically, there is no role for the industry in shaping up reimbursement at the current state, right. So industry is not being asked to provide the data or whatever it is and to reimburse All right, so well, we could offer the data and we do have the data, we have the data from across different customers, etc. So this is where we could come to our liaisons with the CMS, which is the professional society, such as the American Medical Association, like the Society for the MRI imaging, imagers like so society for ultrasound, images, etc, are right next to our Society of American Sonographers DMS that come in our diagnostic Medical Society of diagnostic medical sonography, our society of vascular ultrasound, etc. Right. So provide a work in tandem with those organizations to provide data, which is helping them to build the cause for the reimbursement, however, it's there's also lobbying efforts like so the societies are paying the lobbyists to continue increasing, like maintaining the reimbursement rates.</p> <p>P2. Where I am seeing that like so where it could have been like so the idealistic view of the future? Or would have been if we are designing the new equipment before we even do it, right. So it's like studying the case use cases on, what's the current model of reimbursement? so where can we shape up the market, where's the benefit to public health, etc, where the savings would be, start working with a CMS right away when we're designing those products, right. So that by the time of the market introduction, there will be reimbursement and customers will be motivated to purchase that, and, therefore improve the quality of care and efficiency.</p> <p>P2. In terms of the reduction of unnecessary procedures, I think that we first of all, do have the first time right initiatives. So all our equipment is designed with the notion of reduction of rescans. And also, we are building the equipment, which is having the capacity by any means whether it's workflow or AI or technical components of that equipment, which is allowing for reduction of unnecessary procedures.</p> <p>P2. We do have the product which is called performance bridge, right, which is assessing the number of exams, the speed of the exams, the start of exam, the turnaround time the etc like so there's all these metrics, which are being calculated, so certainly there are KPIs of performance bridge. So we are heavily utilizing that in our claims development.</p> <p>P1. I don't think Philips is by any means ignoring that. You're working with Bodo and his team. I think they are all over this, recognize this stuff. We have a whole team in Washington, the lobbying team and the government team, they're well aware of this. Every business unit within Philips is well aware of this. I think, yeah, people are totally focused on this kind of stuff. I'm anticipating when that shoe is going to drop, meaning when the change is going to start, but also trying to be in the right position that when it happens, it will benefit not only patients, not only physicians, but also benefit Philips, by being in the right spot.</p> <p>P1. I think it's not necessarily the responsibility in terms of legal responsibility. I'm not even sure about ethical responsibility or moral responsibility. I think it's the right thing to do. I think it's what in the longer run would benefit Philips tremendously with their customers to provide that service on every piece of equipment that a customer purchases. So that's my perspective, I'm sure I'm well in the minority, both among radiologists, and among industry.</p>

Category/Content	Code	Description	Participant's comment
<p><b>Interaction with decision making and generation of evidence-based information</b></p>	<p><b>Hospital-level evaluation instruments</b></p>	<p>Awareness of the different evaluation tools available for the measurement of value in medical imaging.</p>	<p>P2. This is something where I'm just surprised because we are conducting key opinion leader meetings, at C suite level where I'm clinician myself, I have colleagues who are working at the hospitals, I have colleagues who are former radiology directors, etc. And I've just been feeling absolute being absolutely out of tune. So thank you so much for bringing it to my attention. I'll ask around, but I'm not familiar. I cannot comment.</p> <p>P2. ROI calculators like so from North America perspective, we do have the ROI calculators, which are being created in Philips based on the reimbursement codes and time which is spent by customer or by patient, but I'm not sure if it's a part of like so for the evidence based practice centers never, ever heard of this.</p> <p>P2. It all depends on the contract because we do sell the product right? The solution is going to the customer and then customer owns the data and then whatever they choose to share. They share so it's either the peer review articles or it could be that sometimes we place for testing equipment. And based on the contract, we do have the information which comes back so we do have some proof points which are being published on our website.</p> <p>P2. This is more for salespeople to use, Yeah, no, I am aware like says the marketing person, I'm aware that they exist, but this is not like so I do not use them in in my job.</p> <p>P1. Whether we are required to do so is a separate question whether we should absolutely. When we deliver equipment, we should have built into that equipments software or bundled in a program that on an ongoing dashboard way reveals how one is performing on the ROI for having spent this money. That reveals whether studies were done when they didn't give an answer that had anything to do with the clinical question, or that ended up requiring another study afterwards? Because they didn't answer the question. And then somehow we have to look back and say, did we ordered the wrong study? Was it an inappropriate study?</p>

Category/Content	Code	Description	Participant's comment
<p><b>Coordination and alignment between the medical community and industry</b></p>	<p><b>National polices/programmes</b></p>	<p>Awareness of the different policies and programs implemented through public and private agents.</p>	<p>P2. So we are utilizing current guidelines, and appropriateness of use criteria. So there is also of course, the off label use like so for example, there's some exams which are with contrast, like so a lot of MRI with contrast is not approved, but it's being used off label. But, the majority of our customers are using what similar being recommended by American College of Radiology</p> <p>P2. Depending on a health insurance, like so there's different like, so sometimes there's a lack of a lack of reimbursement, which is coming up with certain modalities like so depending on the insurance like so at some point, there was lack of reimbursement for MRI for certain procedures, there was like in reverse, like, so there was cancellation of reimbursement for CT, there's the reduction of the budgeted payments for the vascular procedures.</p> <p>P2. CMS policy and also there is the value unit etc. So there is a whole co-formulas which are being calculated and how to address that. So I was involved with the, like essentially, is the RUC committee in professional societies. So professional societies it's not a vendor role to fight for the reimbursement, and I know that vendors are supporting the government relations to have reimbursement authorizations</p> <p>P1. I have no idea how Philips is working with that, but the appropriateness criteria are not going to be implemented on their own. Most radiologists are vaguely aware of it, but radiologists are not allowed to order studies. So it has to be the clinician that orders the appropriate or inappropriate study. So in the US, there was first several trials and then people brought forward these clinical decision support tools with appropriateness criteria embedded. And when they were obligated to use it, there was a dramatic flattening of the curve of studies that were being ordered, because of, for all sorts of reasons, but mainly because of COVID, the implementation of that has been on the back burner. Secondly, if a radiology group tells a referring physician, we can't do this study because you didn't fill out the appropriateness criteria information properly. The referring physician has the privilege of saying thank you very much hanging up and calling another radiology group, is self defeating, until penalties are applied to the referring physicians for performing stupid, or asking for the performance of stupid studies, this will not enable will not work. Because a radiologist has absolutely no incentive to fix this system, we're getting paid for the second study the wrong study number one and number two, until the referring physician says thank you for helping me order the right study instead of thank you very much click and calling the next person, It's a non-start.</p>

Category/Content	Code	Description	Participant's comment
	<p><b>Patient data management for DI assessment</b></p>	<p>Considerations to be taken into account in the management of patient information and the type of use it is being put to</p>	<p>P2. We talk a lot with our campaign leaders with the ethical use of data and also with the data credibility, right. So I think that the data which we possess is not necessarily objectively represented, because it's as available rather than it's available by the resident rather than representative data, right, because you have to sign up for the data use. So, that brings us to that conundrum of ethics, like so first of all medical ethics, representational data, objectivity of data, and you know, like data rights, like so, they basically fits into the first question of ethics.</p> <p>P2. So, we are looking for AI, which is which has proven trustworthiness and accuracy, right? So AI needs to have clinical context relevant and actionable insights to empower physician context, right? So then there is the data, or, which is on utilization of workflow data, right? So then there's the whole interoperability aspect of data management, etc. Right? So when are we building the seamless patient journey across all the settings, data is not being passed like, so data is incredibly fragmented simply because of the interoperability, kind of the limitations, so we don't have the holistic picture.</p>

## APPENDIX 5

### *Studies analyzed according to the diagnostic imaging phase*

<b>Diagnostic Imaging Phase</b>	<b>Author, country, year</b>	<b>Study Design</b>	<b>Organ system</b>	<b>Modality (Radiology)</b>	<b>Target</b>
<b>Pre-Pre-Analytical Phase</b>	Goldzweig, USA, 2015	Systematic Revision	Head, back, renal, abdomen, chest, heart	Ct, MRI, CTCA, X-ray, U	To review interventions that use the computerized clinical decision-support (CCDS) capabilities of electronic health records to improve appropriate use of diagnostic radiologic test ordering.
<b>Pre-Pre-Analytical Phase</b>	Paul g, USA, 2015	Systematic Revision	Head and chest	CT, MRI, CTCA and X-ray	Review of published studies assessing the effect of electronic health record (EHR)-based interventions to improve the appropriateness of imaging.
<b>Pre-Pre-Analytical Phase</b>	Moriarty, USA, 2015	Obs study - Retrospective	Neuro	CT, MRI, NM	To examine the effect of integrating point-of-care clinical decision support (CDS) using the ACR Appropriateness Criteria (AC) into an inpatient computerized provider order entry (CPOE) system for advanced imaging requests.
<b>Pre-Pre-Analytical Phase</b>	Murthy, South Africa, 2015	Obs study - Retrospective	Lung	CT, MRI, NM	To determine the impact of an electronic CDS for PE on the efficiency of CTPA utilisation in a resource-limited setting.
<b>Pre-Pre-Analytical Phase</b>	Ip, USA, 2015	Obs study - Prospective	Brain	CT	examined the impact of computerized clinical decision support (CDS) on head CT utilization in MTBI emergency department (ED) visits.
<b>Pre-Pre-Analytical Phase</b>	Min, Canada, 2017	Obs study - Prospective	Back	CT, MRI, X-ray	To determine whether point-of-care clinical decision support can effectively reduce inappropriate medical imaging of patients who present to the emergency department (ED) with low-back pain (LBP).
<b>Pre-Pre-Analytical Phase</b>	Deblois, Canada, 2018	Systematic Revision	Lung	CTPA, X-ray and NM	The purpose of this systematic review is to summarize the evidence associated with the interventions aimed at reducing the overuse of imaging in the diagnostic workup of PE in the emergency department and hospital wards.
<b>Pre-Pre-Analytical Phase</b>	Edge, Canada, 2019	Health Technology Assessment	Back, ankle, abdomen and lung	US, CT, CTCA, CTPA, MRI	is to retrieve and review the existing evidence on the clinical benefit, safety, harms, and cost-effectiveness of CDS system for appropriate medical image ordering.
<b>Pre-Pre-Analytical Phase</b>	Gabelloni, Italy, 2020	Obs study - Retrospective	Abdomen	CT, MRI	Our purpose was to assess the performance of ESR iGuide for assisting the selection of the most appropriate imaging tests based on clinical signs and symptoms in patients with hepatocellular carcinoma (HCC) or cholangiocarcinoma (CC).
<b>Pre-Pre-Analytical Phase</b>	Chen, USA, 2020	Obs study - Retrospective	Back	CT, MRI, X-ray	To assess the effectiveness of a clinical decision support tool consisting of an electronic medical record best practice alert (BPA) on the frequency of lumbar imaging in patients with acute low back pain in the ambulatory care setting, and to explore why providers order imaging outside of clinical guidelines.
<b>Pre-Pre-Analytical Phase</b>	Hynes, Irland, 2020	Obs study - Retrospective	Back	X-ray	To rationalize the ordering of trauma cervical spine radiographs via the institution of electronic clinical decision support criteria.

<b>Pre-Pre-Analytical Phase</b>	Bruner, USA, 2020	Obs study - Prospective	Shoulder	US and MRI	To examine whether co-designing clinical decision support (CDS) with referring providers will reduce barriers to adoption and facilitate more appropriate shoulder ultrasound (US) over magnetic resonance imaging (MRI) in diagnosing Veteran shoulder pain, given similar efficacies and only 5% MRI follow-up rate after shoulder US.
<b>Pre-Pre-Analytical Phase</b>	Medina-Lara, UK, 2020	Health Technology Assessment	Abdomen	CT	The objectives were to evaluate the evidence on the validation, clinical effectiveness, cost-effectiveness, and availability and use of cancer diagnostic tools in primary care.
<b>Pre-Pre-Analytical Phase</b>	Kharbanda, USA, 2021	Randomized Cronrolled Trial	Abdomen	CT and US	To evaluate the effectiveness of an electronic health record-linked clinical decision support intervention, AppyCDS, on diagnostic imaging, health care costs, and safety outcomes for patients with suspected appendicitis.
<b>Pre-Pre-Analytical Phase</b>	Lee, USA, 2021	Quasi-experimental	Back	N/R	Measure the impact of a time-saving quality improvement intervention to increase engagement with a CDS tool for low back pain imaging ordering.

<b>Diagnostic Imaging Phase</b>	<b>Author, country, year</b>	<b>Study Category</b>	<b>Title of study</b>
<b>Analytical Phase</b>	ESR, EU, 2019	Patient experience & safety	Patient safety in medical imaging: A joint paper of the European Society of Radiology (ESR) and the European Federation of Radiographer Societies (EFRS)
<b>Analytical Phase</b>	Swan, USA, 2016	Patient experience & safety	Developing a Patient-Centered Radiology Process Model
<b>Analytical Phase</b>	Harvey, USA, 2017	Radiology service workflow	Predicting No-Shows in Radiology Using Regression Modeling of Data Available in the Electronic Medical Record
<b>Analytical Phase</b>	Andre, USA, 2015	Patient experience & safety	Toward Quantifying the Prevalence, Severity, and Cost Associated With Patient Motion During Clinical MR Examinations
<b>Analytical Phase</b>	Subbe, Australia, 2017	Radiology service workflow	Effect of an automated notification system for deteriorating ward patients on clinical outcomes
<b>Analytical Phase</b>	Krupinski, Spain, 2016	Radiology service workflow	A New Software Platform to Improve Multidisciplinary Tumor Board Workflows and User Satisfaction: A Pilot Study
<b>Analytical Phase</b>	Shanafelt, USA, 2016	HCP Experience & Safety	Longitudinal Study Evaluating the Association Between Physician Burnout and Changes in Professional Work Effort
<b>Analytical Phase</b>	Flory, USA, 2011	HCP Experience & Safety	Distress in the radiology waiting room
<b>Analytical Phase</b>	Pifarré, Spain, 2011	Patient experience & safety	Diagnostic imaging studies: do they create anxiety?
<b>Analytical Phase</b>	Hardin, USA, 2014	Patient experience & safety	Incidence of distress and associated factors in women undergoing breast diagnostic evaluation
<b>Analytical Phase</b>	Grey, UK, 2000	Patient experience & safety	Reduction of anxiety during MR imaging: a controlled trial
<b>Analytical Phase</b>	Vogel, Neth, 2012	Patient experience & safety	Intervention to lower anxiety of 18F-FDG PET/CT patients by use of audiovisual imagery during the uptake phase before imaging
<b>Analytical Phase</b>	Doyle, UK, 2012	Patient experience & safety	A systematic review of evidence on the links between patient experience and clinical safety and effectiveness



<b>Analytical Phase</b>	Carisson, Sweden, 2013	Patient experience & safety	The situation and the uncertainty about the coming result scared me but interaction with the radiographers helped me through': a qualitative study on patients' experiences of magnetic resonance imaging examinations
<b>Analytical Phase</b>	Törnqvist, Sweden, 2006	Patient experience & safety	Impact of extended written information on patient anxiety and image motion artifacts during magnetic resonance imaging
<b>Analytical Phase</b>	Herbst, Germany, 2014	Diagnostic technology performance	Reproduction of motion artifacts for performance analysis of prospective motion correction in MRI
<b>Analytical Phase</b>	Powel, Malaysia, 2015	Diagnostic technology performance	Improving magnetic resonance imaging (MRI) examinations: Development and evaluation of an intervention to reduce movement in scanners and facilitate scan completion
<b>Analytical Phase</b>	Durand, USA, 2015	Radiology service workflow	Mandatory Child Life Consultation and Its Impact on Pediatric MRI Workflow in an Academic Medical Center
<b>Analytical Phase</b>	Harned RK 2nd, USA, 2001	Patient experience & safety	MRI-compatible audio/visual system: impact on pediatric sedation
<b>Analytical Phase</b>	Frija, EU, 2021	Patient experience & safety	Cumulative effective dose from recurrent CT examinations in Europe: proposal for clinical guidance based on an ESR EuroSafe Imaging survey
<b>Analytical Phase</b>	Vano, EU, 2020	HCP Experience & Safety	Harmonisation of imaging dosimetry in clinical practice: practical approaches and guidance from the ESR EuroSafe Imaging initiative
<b>Analytical Phase</b>	Loose, EU, 2021	HCP Experience & Safety	Radiation dose management systems-requirements and recommendations for users from the ESR EuroSafe Imaging initiative
<b>Analytical Phase</b>	ESR, EU, 2020	HCP Experience & Safety	Performance indicators for radiation protection management: suggestions from the European Society of Radiology
<b>Analytical Phase</b>	Mieloszyk, USA, 2019	Patient experience & safety	Environmental Factors Predictive of No-Show Visits in Radiology: Observations of Three Million Outpatient Imaging Visits Over 16 Years
<b>Analytical Phase</b>	McEnergy, 2014	Radiology service workflow	Coordinating patient care within radiology and across the enterprise
<b>Analytical Phase</b>	Knopp, USA, 2020	Patient experience & safety	Enhancing Patient Experience With Internet Protocol Addressable Digital Light-Emitting Diode Lighting in Imaging Environments: A Phase I Study
<b>Analytical Phase</b>	Brédart, France, 2011	Patient experience & safety	Anxiety and specific distress in women at intermediate and high risk of breast cancer before and after surveillance by magnetic resonance imaging and mammography versus standard mammography
<b>Analytical Phase</b>	Gyftopoulos, USA, 2020	Patient experience & safety	Imaging-based patient-reported outcomes (PROs) database: How we do it
<b>Analytical Phase</b>	Suchsland, USA, 2020	Patient experience & safety	Patient-Centered Outcomes Related to Imaging Testing in US Primary Care
<b>Analytical Phase</b>	Carlos, USA, 2012	Patient experience & safety	Patient Reported Outcomes in Interventional Radiology: Time to Measure What We Do
<b>Analytical Phase</b>	Gyftopoulos, USA, 2020	Patient experience & safety	Imaging-based patient-reported outcomes (PROs) database: How we do it
<b>Analytical Phase</b>	Bhayana, CAN, 2020	Radiology service workflow	Optimising after-hours workflow of computed tomography orders in the emergency department
<b>Analytical Phase</b>	Paushter, USA, 2016	Radiology service workflow	Quality assurance methodology and applications to abdominal imaging PQI
<b>Analytical Phase</b>	Mamlouk, USA, 2015	Radiology service workflow	Adding value in radiology: establishing a designated quality control radiologist in daily workflow
<b>Analytical Phase</b>	Yu, USA, 2014	Radiology service workflow	The radiologist's workflow environment: evaluation of disruptors and potential implications
<b>Analytical Phase</b>	Schemmel, USA, 2016	Radiology service workflow	Radiology Workflow Disruptors: A Detailed Analysis

<b>Analytical Phase</b>	Kansagra, USA, 2016	Radiology service workflow	Disruption of Radiologist Workflow
<b>Analytical Phase</b>	Goldberg-Stein , USA, 2018	Radiology service workflow	Making Feedback Easy: A Workflow-Integrated Quality Improvement Tool Increases Radiologist Engagement in the Technical Quality of Imaging Examinations
<b>Analytical Phase</b>	Kruskal, USA, 2012	Radiology service workflow	Quality initiatives: lean approach to improving performance and efficiency in a radiology department
<b>Analytical Phase</b>	Succi, USA, 2020	Radiology service workflow	Turning around cancer: Oncology imaging and implications for emergency department radiology workflow
<b>Analytical Phase</b>	Hitti, Lebanon, 2017	Radiology service workflow	Improving Emergency Department radiology transportation time: a successful implementation of lean methodology
<b>Analytical Phase</b>	Katzman, USA, 2018	Radiology service workflow	The Effect of a Technologist-Centered Electronic Review and Feedback System on Image Quality
<b>Analytical Phase</b>	Iyer, USA, 2014	Radiology service workflow	Radiology peer-review feedback scorecards: optimizing transparency, accessibility, and education in a children's hospital
<b>Analytical Phase</b>	Maikusa, Japan, 2013	Diagnostic technology performance	Improved volumetric measurement of brain structure with a distortion correction procedure using an ADNI phantom
<b>Analytical Phase</b>	Godenschweger , Germany, 2016	Diagnostic technology performance	Motion correction in MRI of the brain
<b>Analytical Phase</b>	Zaitsev, Germany, 2017	Diagnostic technology performance	Prospective motion correction in functional MRI
<b>Analytical Phase</b>	Mattern , Germany, 2018	Diagnostic technology performance	Prospective motion correction enables highest resolution time-of-flight angiography at 7T
<b>Analytical Phase</b>	Kecskemeti, USA, 2020	Diagnostic technology performance	Test-retest of automated segmentation with different motion correction strategies: A comparison of prospective versus retrospective methods
<b>Analytical Phase</b>	Aksoy, USA, 2011	Diagnostic technology performance	Real-time optical motion correction for diffusion tensor imaging
<b>Analytical Phase</b>	Maclaren, Germany, 2013	Diagnostic technology performance	Prospective motion correction in brain imaging: a review
<b>Analytical Phase</b>	Anand, USA, 2020	Diagnostic technology performance	validity of an mri-compatible motion capture system for use with lower extremity neuroimaging paradigms
<b>Analytical Phase</b>	J Ma, USA, 2020	Diagnostic technology performance	diagnostic image quality assessment and classification in medical imaging: opportunities and challenges
<b>Analytical Phase</b>	Reischl, Germany, 2019	Diagnostic technology performance	Motion prediction enables simulated MR-imaging of freely moving model organisms
<b>Analytical Phase</b>	Alejo, Spain, 2018	HCP Experience & Safety	Radiation dose optimisation for conventional imaging in infants and newborns using automatic dose management software: an application of the new 2013/59 EURATOM directive
<b>Analytical Phase</b>	Martiin, UK, 2011	HCP Experience & Safety	Management of patient dose in radiology in the UK
<b>Analytical Phase</b>	Howlett, EU,, 2020	HCP Experience & Safety	The Current Status of Radiological Clinical Audit and Feedback on the ESR Guide to Clinical Audit in Radiology and the ESR Clinical Audit Tool (Esperanto) - an ESR Survey of European Radiology Departments
<b>Analytical Phase</b>	Loose, Germany, 2020	HCP Experience & Safety	The new radiation protection framework since 2019 - Implementation in Germany and comparison of some aspects in seven European countries
<b>Analytical Phase</b>	Simeonov, Luxemburg, 2013	HCP Experience & Safety	Criteria for acceptability of medical radiological equipment in Euratom legislation
<b>Analytical Phase</b>	Roch, France, 2018	HCP Experience & Safety	Using diagnostic reference levels to evaluate the improvement of patient dose optimisation and the influence of recent technologies in radiography and computed tomograph
<b>Analytical Phase</b>	Howlett, EU, 2019	HCP Experience & Safety	The current status of radiological clinical audit - an ESR Survey of European National Radiology Societies

<b>Analytical Phase</b>		HCP Experience & Safety	Hoffmann TC, Del Mar C. Patients' expectations of the benefits and harms of treatments, screening, and tests: a systematic review. JAMA Intern Med 2015; 175:274–286.
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<b>DI Phase</b>	<b>Author, country, year</b>	<b>Study Design</b>	<b>Organ system</b>	<b>Modality (Radiology)</b>	<b>Target</b>
<b>Post-Post-Analytical Phase</b>	Teljeur, Ireland, 2017	Health Technology Assessment	Breast	Mammo, MRI	A review of the Health Information and Quality Authority's (HIQA) assessment of breast cancer surveillance cancer criticized how the results were presented and interpreted.
<b>Post-Post-Analytical Phase</b>	Mehanna, UK, 2017	Health Technology Assessment	Head/neck	PET-CT	To determine the efficacy and cost-effectiveness of PET-CT-guided surveillance, compared with planned ND, in a multicentre, prospective, randomised setting.
<b>Post-Post-Analytical Phase</b>	McDonnell, USA, 2016	Randomized Controlled Trial	Lung	CT	This study's purpose was to examine knowledge, attitudes, and practices regarding LDCT among NPs who work in primary care settings.
<b>Post-Post-Analytical Phase</b>	Qureshi, UK, 2016	Cost Effectiveness Analysis	Lung	CT, DCE-CT, FDG-PET-CT	The SPUTNIK study will assess the diagnostic accuracy, clinical utility and costeffectiveness of DCE-CT, alongside the current CT and 18-fluorodeoxyglucose-positron emission tomography)
<b>Post-Post-Analytical Phase</b>	2016	N/A	All	PET-CT, PET-MRI	N/A
<b>Post-Post-Analytical Phase</b>	Ruile, Gemany, 2015	Cost Effectiveness Analysis	Breast	CT	In this study, the potential of the application of BCT in breast cancer screening is evaluated by simulating its impact onto the performance of the German BCSP in a prospective health technology assessment (ProHTA) simulation. A health economic evaluation is performed from the perspective of the German healthcare system.
<b>Post-Post-Analytical Phase</b>	Halligan, UK, 2015	Health Technology Assessment	Abdomen	CTC	To compare the diagnostic efficacy, acceptability, safety and cost-effectiveness of CTC with barium enema (BE) or colonoscopy.
<b>Post-Post-Analytical Phase</b>	Wardlawm, UK, 2014	Health Technology Assessment	Neuro	MRI, CT	Is MR with DWI cost-effective in stroke prevention compared with computed tomography (CT) brain scanning in all patients, in specific subgroups or as 'one-stop' brain-carotid imaging? What is the current UK availability of services for stroke prevention?
<b>Post-Post-Analytical Phase</b>	Wild, Austria, 2014	Health Technology Assessment	All	MRI	N/A
<b>Post-Post-Analytical Phase</b>	Westwood, UK, 2013	Health Technology Assessment	Abdomen	US, CT, MRI	To compare the clinical effectiveness and cost-effectiveness of contrast-enhanced ultrasound (CEUS) using SonoVue(®) with that of contrast-enhanced computed tomography (CECT) and contrast-enhanced magnetic resonance imaging (CEMRI) for the assessment of adults with focal liver lesions (FLLs) in whom previous liver imaging is inconclusive.
<b>Post-Post-Analytical Phase</b>	Gorenoi, Germany, 2012	Health Technology Assessment	Cardio	CTCA	The present report aims to evaluate the clinical efficacy, diagnostic accuracy, prognostic value cost-effectiveness as well as the ethical, social and legal implications of CT coronary angiography versus invasive coronary angiography in the diagnosis of CHD.
<b>Post-Post-Analytical Phase</b>	Douglas, UK, 2015	Randomized Controlled Trial	Cardio	CTCA	N/A
<b>Post-Post-Analytical Phase</b>	Newby, UK, 2015	Randomized Controlled Trial	Cardio	CTCA	We aimed to assess the effect of CTCA on the diagnosis, management, and outcome of patients referred to the cardiology clinic with suspected angina due to coronary heart disease.

<b>Post-Post-Analytical Phase</b>	Dekkers, Netherlands, 2016	Randomized Cronrolled Trial	Circulatory	CT	N/A
<b>Post-Post-Analytical Phase</b>	Hoffmann, USA, 2012	Randomized Cronrolled Trial	Cardio	CTCA	N/A
<b>Post-Post-Analytical Phase</b>	Greenwood, UK, 2014	Randomized Cronrolled Trial	Cardio	MRI	The aim of this study was to establish the diagnostic accuracy of a multiparametric cardiovascular magnetic resonance (CMR) protocol with x-ray coronary angiography as the reference standard, and to compare CMR with SPECT, in patients with suspected coronary heart disease.
<b>Post-Post-Analytical Phase</b>	Senft, Germany, 2010	Randomized Cronrolled Trial	Neuro	MRI	The aim of this study is to report on the influence of the use of iMRI on the extent of resection and survival of patients with glioblastoma multiforme (GBM)
<b>Post-Post-Analytical Phase</b>	Jackson, UK, 2014	Randomized Cronrolled Trial	Abdomen	MRI	The purpose of this study was to evaluate distortion-corrected MRI as a radiotherapy planning tool for prostate cancer and the resultant implications for dose sparing of organs at risk
<b>Post-Post-Analytical Phase</b>	Fukuba, Japan, 2020	Obs study - Retrospective	Abdomen	MRI	The aim was to clarify the sensitivity and specificity of diffusion-weighted imaging, as well as of that in combination with magnetic resonance cholangiopancreatography for pancreatic tumor diagnosis in real-world clinical setting.

*N/A: Little information on this study.*

**Titre :** Évaluation de la pertinence de l'imagerie diagnostique : une perspective mixte sur la façon dont l'utilisation de l'imagerie diagnostique est actuellement gérée.

## **RÉSUMÉ**

**Contexte :** Nous vivons actuellement une époque dichotomique où, d'une part, l'imagerie diagnostique à coût élevé est essentielle à la gestion des stratégies de santé publique telles que le diagnostic précoce du cancer et des maladies cardiovasculaires, mais où, d'autre part, nous vivons dans un système dont les carences en ressources financières et humaines affectent intentionnellement la santé publique. D'où l'intérêt de ce rapport sur la manière dont est évaluée la pertinence de l'utilisation de l'imagerie diagnostique à coût élevé.

**Méthodes :** Une revue de la portée a été effectuée pour fournir une vue d'ensemble de la littérature existante sur l'évaluation de la pertinence de l'imagerie diagnostique. En outre, des entretiens semi-structurés ont été menés avec des experts en imagerie diagnostique de l'industrie de l'imagerie médicale afin de recueillir leurs points de vue sur le sujet. Une analyse de contenu a été utilisée pour décrire les thèmes communs.

**Résultats :** En considérant le processus par lequel passe un patient au cours de son parcours d'imagerie, au stade de la commande (pré-analytique), 2 revues systématiques (SR), 2 essais contrôlés randomisés (RCT) et 5 études observationnelles (OS) ont été trouvés ; à l'étape de l'interaction du patient avec le service de radiologie (analytique), 55 études qualitatives ont été recensées, notamment sur l'expérience et la sécurité du patient (38 %), le flux de travail du service de radiologie (24 %), l'expérience du radiologue (21 %) et la performance de la technologie de diagnostic (17 %) ; et à l'étape de la prise de décision sur la base des résultats de l'examen d'imagerie (post-analytique), 9 évaluations des technologies de la santé (46 % CT ; 27 % IRM ; 18 % PET-CT ; 9 % CTCA), 8 ECR et 1 OS ont été trouvés. Les avis des experts ont corroboré une partie de la complexité et de la pratique actuelle de l'évaluation de l'imagerie médicale dans le continuum des soins.

**Conclusion :** Il existe un haut degré de dispersion des informations sur l'impact de l'imagerie diagnostique. Des efforts sont nécessaires pour rassembler ces informations et considérer l'impact de manière holistique afin de définir la valeur de l'imagerie diagnostique et de fournir le meilleur diagnostic, traitement et expérience patient.

**Mots clés :** Imagerie diagnostique, critères de pertinence, processus d'imagerie.