Do clinical practice guidelines consider evidence about test consequences? A critical document analysis

Mariska Tuut (mariska.tuut@maastrichtuniversity.nl)
UM CAPHRI: Universiteit Maastricht Care and Public Health Research Institute https://orcid.org/0000-0002-0880-6215
Jako Burgers
UM CAPHRI: Universiteit Maastricht Care and Public Health Research Institute
Trudy van der Weijden
UM CAPHRI: Universiteit Maastricht Care and Public Health Research Institute
Miranda Langendam
Amsterdam UMC Location AMC: Amsterdam UMC Locatie AMC

Research

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Abstract

Background

Supporting evidence for medical test recommendations in clinical practice guidelines (CPGs) should not only include diagnostic accuracy, but also the downstream consequences of the test result on patient relevant outcomes. The aim of this study is to assess the methodology of developing of evidence-based CPGs about medical tests, and to explore determinants of best CPGs.

Methods

We performed a systematic document analysis and quality assessment of publicly accessible CPGs about three common diagnostic topics: C-reactive protein (CRP), colonoscopy and fractional exhaled nitric oxide (FeNO). Evaluation of the complete test-treatment pathway (diagnostic accuracy as well as downstream consequences on patient relevant outcomes (i.e. burden of the test, natural course, treatment effectiveness, and link between test result and administration of treatment)) was considered best practice for developing medical test recommendations.

Results

We retrieved 15 recommendations in 15 CPGs. The methodological quality of the CPGs varied from poor to excellent. Seven CPGs reported the use of the GRADE approach. In three CPGs, however, we could not find elements of that approach in the guideline documents. Ten recommendations considered diagnostic accuracy. Four of these were supported with a systematic review of the literature and rating of the certainty in the evidence. None of the CPGs evaluated all steps of the test-treatment pathway. Burden of the test was considered in three CPGs, but not with a systematic review of the evidence. Natural course was considered in two CPGs, and also not with a systematic review of the evidence. In three recommendations, treatment effectiveness was considered, which was supported with a systematic review and rating of the certainty in the evidence in one CPG. The link between test result and administration of treatment was not considered in any CPG.

Conclusions

CPGs with recommendations about medical tests do not seem to consider evidence about test consequences on patient relevant outcomes. This might be explained by reporting issues and challenging methodology. Future research is needed to investigate how to facilitate guideline developers in explicitly and reliably considering all steps of a test-treatment pathway when developing medical test recommendations.

Contributions To The Literature

- Recommendations about medical tests in clinical practice guidelines are often supported with evidence on diagnostic accuracy and other test characteristics
- The impact of test results on patient relevant outcomes receives much less attention.
- Evaluating all steps of the test-treatment pathway in developing clinical practice guidelines about medical tests could improve the quality of diagnostic guideline recommendations.

Background

Clinical practice guidelines (CPGs) provide recommendations to support professionals and patients in clinical decision-making, with the ultimate goal of improving or maintaining patients' health. In the development of CPGs, the benefits and harms of the interventions of interest are systematically assessed with regard to patient-relevant outcomes. The Grading of Recommendations, Assessment, Development and Evaluation (GRADE) approach is designed to facilitate this process.(1)

Diagnostic CPGs provide recommendations about the use of a certain test (or test strategy). Supporting evidence for these recommendations consists of studies about diagnostic accuracy.(2) However, acceptable test characteristics (sensitivity and specificity) are not enough to improve patients' health. CPG developers should also consider downstream consequences on patient-relevant outcomes such as burden of the test and the proportion of patients with a certain test result who receive the recommended treatment (see Fig. 1).(3, 4)

The interpretation of evidence about the value of therapeutic interventions is complex, and there is room for improvement.(6) This applies even more to evidence about medical tests and its translation into CPG recommendations.(7–9) There have been few randomised controlled trials (RCTs) on the value of test-treatment pathways for patient-relevant outcomes.(10) Evaluating the value of medical tests on patient-relevant outcomes in CPGs is thus complex since it requires integration of various pieces of evidence for the different links in a chain (see Fig. 1).

In the GRADE approach for diagnostic tests and test strategies, the first step to formulate the clinical question, including definition of patient-important outcomes and description of the aim of the test (add-on, replacement or triage). The next step is to assess diagnostic accuracy and downstream consequences of testing. These include the burden of the test, clinical management, natural course of the target condition (to estimate the outcomes of patients with a false negative test result), and the link between test result and management (proportion of patients with a certain test result who receive the recommended treatment). Ideally, each evidence component is based on a systematic review of the literature and the certainty in the evidence for each

component is determined separately.(7) Finally, the evidence components are integrated and the overall certainty in the evidence is assessed.(11, 12) To move from evidence to recommendation, guideline developers use the GRADE evidence-to-decision framework to formulate recommendations.(11)

Methods

Aim

The aim of this study is to assess the methodology of developing of evidence-based CPGs about medical tests.

Specific objectives are to assess the types of supporting evidence used for CPG recommendations about medical tests, and to explore determinants of best practices. In the context of CPG development about the value of a medical test, we formulated the following research questions:

- Which types of evidence (diagnostic accuracy, burden of the test, natural course, treatment effectiveness, link between test result and administration of treatment) are used to support the recommendations?
- Which variables of the guideline development process (e.g. composition of the guideline panel, use of the GRADE approach, methodological quality according to AGREE's domain methodology) are associated with the completeness of the evidence underlying the recommendations?
- To what extent can differences between CPG recommendations be explained by including different types of evidence?

Answers on these questions can help guideline developers, including guideline methodologists, with the implementation of good guideline development methods when developing recommendations about tests or test strategies.

Design

In order to assess the types of supporting evidence used for CPG recommendations about medical tests, and to identify best practices, we performed a systematic document analysis of recent versions of publicly accessible CPGs concerning 3 diagnostic topics.

Topics

We chose tests that are frequently used to diagnose three common diseases. We considered tests with different characteristics (primary vs. secondary care, negligible vs. reasonable risk of serious burden of the test, low vs. high costs) to identify possible clarifying factors for differences in methodological approach in the development of the CPGs. We therefore selected the following tests:

- C-reactive protein test (CRP) to increase the likelihood of pneumonia in primary care patients with cough (excluding diagnostic procedures in patients suspected of having a COVID-19 infection).
- Colonoscopy to detect colon cancer in secondary care patients suspected of having (primary) colon cancer (excluding screening and tests in patients at risk of hereditary types of colon cancer).
- Fractional exhaled nitric oxide (FeNO) to diagnose (severe) asthma in children and adults in primary and secondary care (excluding monitoring of asthma).

Search and selection of relevant CPGs

We defined the following eligibility criteria:

- The CPG contains recommendations about:

  CRP related to the diagnosis pneumonia in primary care patients with cough, OR
  Colonoscopy to detect colon cancer in secondary care patients, OR
  FeNO to diagnose (severe) asthma in primary and secondary care patients (children and adults) with signs and/or symptoms of asthma
- Exclusion of diagnostic procedures in patients suspected of having COVID-19, colonoscopy as a screening instrument, colonoscopy in patients at risk of hereditary types of colon cancer, and FeNO as monitoring test
- Publicly accessible and current guidelines (not retracted, nor updated)
- Publication date 2016–2020
- National or international CPGs
- Publication language of the CPG: English, German or Dutch

To identify relevant CPGs, one author (MT) performed the search and selected the CPGs. The selection was checked for accuracy by a second author (JB). The following databases were searched in February 2021 (see *Additional file 1* for full search details):

- International Guideline Library from Guidelines International Network (GIN) (https://guidelines.ebmportal.com/), including around 3000 CPGs, mostly developed by organizational members of GIN
- Databases from organizational members of Guidelines International Network, that stated to be active in guideline development (n = 103 members)
- TRIP (Turning Research Into Practice) database (https://www.tripdatabase.com/), containing around 10.000 English-language CPGs
- Medline through Ovid Silverplatter

Identification of recommendations

We analysed the content of the selected CPGs to identify relevant recommendations, including supporting evidence available online (e.g. tables with study characteristics, evidence documents, GRADE Evidence Profiles), as well as information about the methods of CPG development of the developing organisation (e.g. methodology manuals).

Data extraction

In the preparatory phase of this study, we piloted data extraction on two recommendations with four authors (MT, ML, JB, TvdW) to refine the data extraction form and define the variables for which we needed data extraction in duplicate. One author (MT) extracted the initial characteristics of each recommendation and CPG, consisting of the following variables:

- Full title of the CPG
- English translation of the CPG title (in case of a non-English CPG)
- Initial organisation that developed the CPG
- Country of the CPG organisation
- Publication year
- Full text of the recommendation
- English translation of the recommendation (in case of a non-English recommendation)
- Topic of the recommendation (CRP/colonoscopy/FeNO)

Detailed information about each recommendation and CPG was extracted by one author (MT) and checked by another author (ML, JB or TvdW) using a predefined and piloted data extraction form. The form consisted of questions about:

- Scope and target audience of the CPG and composition of the CPG panel
- Involvement of methodologist(s)
- Methodological quality of the CPG (using AGREE II, domain methodology, items 7–12)(13, 14)
- Patient involvement (using AGREE II item 5)(13, 14)
- The types and extent of supporting evidence for the recommendation (consideration and inclusion of systematic evaluation with assessment of the certainty in the evidence about diagnostic accuracy, burden of the test, natural course, treatment effectiveness and link between test result and administration of treatment)
- Grading of the recommendation and use of the GRADE approach
- Direction of the recommendation
- Characteristics of the test and target condition

Analysis

We tabulated basic and detailed characteristics of the included recommendations and CPGs. We analysed correlations between differences in evidence base and possible clarifying variables (e.g. composition of the CPG panel, involvement of patients and methodologists, development approach).

Results

Search and selection of relevant CPGs

Full details of the search and selection process are described in Additional file 1. In short, the search identified 15 unique relevant recommendations in 15 CPGs: four about CRP related to the diagnosis pneumonia in primary care,(15–18) five about colonoscopy in secondary care patients suspected of having colon cancer,(19–23) and six about the use of FeNO to diagnose (severe) asthma.(24–29) The search and selection process is illustrated in Fig. 2.

In Table 1, we present the included CPGs with information about the developing organisation, the country of publication and the publication year. All guidelines originated from high-income countries.

Table 1
Basic characteristics of the included CPGs

Organisation	Year	Country	Title (original language)	English-translated title in case of non-English language CPG
CRP				
Deutschen Gesellschaft für Pneumologie und Beatmungsmedizin (DGPB)(16)	2016	Germany	Behandlung von erwachsenen Patienten mit ambulant erworbener Pneumonie und Prävention	Prevention and management of adult patients with community acquired pneumonia
American College of Chest Physicians (ACP)(17)	2019	United States	Adult Outpatients with acute cough due to suspected pneumonia or influenza	
Ministry of Public Health, Qatar (MoPH)(15)	2019	Qatar	The diagnosis & management of community acquired pneumonia	
Deutschen Gesellschaft für Pädiatrische Infektiologie (DGPI)(18)	2017	Germany	Management der ambulant erworbenen Pneumonie bei Kindern und Jugendlichen (pädiatrische ambulant erworbene Pneumonie, pCAP)	Management of community acquired pneumonia in children and adolescents
Colonoscopy				
European Society for Medical Oncology (ESMO)(21)	2020	Europe	Localised colon cancer: ESMO Clinical Practice Guidelines for diagnosis, treatment and follow-up	
Arbeitsgemeinschaft der Wissenschaftlichen Medizinischen Fachgesellschaften e.V. (AWMF)(19)	2019	Germany	Kolorektales Karzinom	Colorectal cancer
Association of Coloproctology of Great Britain & Ireland (ACPGBI)(22)	2017	Great Britain and Ireland	Guidelines for the Management of Cancer of the Colon, Rectum and Anus (2017) – Diagnosis, Investigations and Screening	
Federatie Medisch Specialisten (FMS)(20)	2019	The Netherlands	Colorectaal carcinoom	Colorectal cancer
Nederlands Huisartsen Genootschap (NHG)(23)	2017	The Netherlands	Rectaal bloedverlies	Rectal bleeding
FeNO				
Arbeitsgemeinschaft der Wissenschaftlichen Medizinischen Fachgesellschaften e.V. (AWMF)(24)	2020	Germany	Nationale VersorgungsLeitlinie Asthma	National Guideline on asthma
Ministry of Public Health (MoPH_A)(27)	2019	Qatar	The diagnosis & management of asthma in adults	
Ministry of Public Health (MoPH_C)(28)	2019	Qatar	The diagnosis & management of asthma in children	
National Asthma Education and Prevention Program (NAEPP)(25)	2020	USA	Managing Asthma in Adolescents and Adults	
National Institute for Health and Care Excellence (NICE)(26)	2020	UK	Asthma: diagnosis, monitoring and chronic asthma management	
Scottish Intercollegiate Guidelines Network (SIGN)(29)	2019	UK	British guideline on the management of asthma	

Quality of the guidelines and use of the GRADE approach

Table 2 presents detailed information about the composition of the CPG panel, the methodological quality of the included CPGs, the direction and grading of the recommendation and the reported and actual use of the GRADE approach. Nine out of 15 CPGs included a methodologist in the development, in the CPG panel and/or at bureau level. In all CPGs about FeNO a methodologist was involved, and in none of the CPGs about CRP. Patient involvement and inclusion of patient perspective varied a lot between the CPGs. AGREE methodology domain scores varied from 8 to 42 (possible range from worst to best: 6–42), with the highest scores for the CPGs about FeNO. Thirteen of the included recommendations were in favor of the test of interest, only one recommendation about CRP and one recommendation about FeNO advised against the use of the test. Eleven recommendations were graded, which included all recommendations about CRP, 2 out of 5 recommendations about colonoscopy, and 5 out of 6 recommendations about FeNO. Seven CPGs reported to have used the GRADE approach; in 4 of these elements of the GRADE approach (such as a GRADE evidence profile) were recognized. No clear differences between the topics were identified in the (reported) use of the GRADE approach.

Table 2
Detailed characteristics of the CPG quality, the recommendation and the (reported) use of GR

Topic	Guideline	CPG panel		Methodology (AGREE scores)					
		Methodologist involvement	Patient involvement (AGREE score)	Systematic evidence search methods	Clear criteria for evidence selection	Clear description of the strengths and limitations of the body of evidence	Clear description methods for formulating recommendations	Health benefits, side effects and risks have been considered	Explicit link between recommendatic and supporting evidence
CRP	DGPB, 2016(16)	-	2	4	2	3	6	3	5
	ACP, 2019(17)	-	5	6	5	2	6	2	6
	MoPH, 2019(15)	-	1	2	1	2	1	1	1
	DGPI, 2017(18)	-	2	3	1	1	7	5	2
Colonoscopy	ESMO, 2020(21)	-	1	1	1	1	3	1	2
	AWMF, 2019(19)	+	3	7	7	5	7	3	6
	ACPGBI, 2017(22)	-	1	2	1	3	2	1	4
	FMS, 2019(20)	+	5	2	1	2	4	6	7
	NHG, 2017(23)	+	1	5	1	1	5	6	7
FeNO	AWMF, 2020(24)	+	7	7	7	7	7	6	7
	MoPH_A, 2019(27)	+	3	4	4	2	2	2	2
	MoPH_C, 2019(28)	+	3	3	3	2	2	2	2
	NAEPP, 2020(25)	+	7	7	7	7	7	7	7
	NICE, 2020(26)†	+	7	7	7	7	6	7	7
	SIGN, 2019(29)	+	7	7	3	3	4	5	7

+: yes; +/-: unclear; -: no

** possible range: 6–42*

† *This CPG contains two separate recommendations concerning the use of FeNO in the diagnosis of childhood respectively adult onset asthma; the scores a*

Supporting evidence for the recommendations

Detailed information about the supporting evidence for the included recommendations is presented in Table 3. Ten CPGs out of 15 considered diagnostic accuracy,(16–18, 20, 22–26, 29), of which 4 underpinned these considerations with a systematic review of the literature and a judgement of the certainty in the evidence.(17, 24–26) Burden of the test was considered in 3 CPGs,(20, 23, 25) and 2 CPGs considered the natural course of the disease,(15, 29) all without systematically reviewing the literature. Three CPGs considered treatment effectiveness,(15, 21, 24) of which 1 performed a systematic review of the literature with judgement of the certainty in the evidence.(24) Not any CPG considered the link between the test result and administration of treatment. As a consequence, there were no CPGs that considered all test consequences of the test-treatment pathway.

Table 3
Detailed information about the supporting evidence for the recommendations

Topic	Guideline	Diagnostic accuracy			Burden of the test			Natural course		
		Considered	Considered with systematic review of the literature	Considered with systematic review of the literature and certainty in the evidence	Considered	Considered with systematic review of the literature	Considered with systematic review of the literature and certainty in the evidence	Considered	Considered with systematic review of the literature	Considered with systematic review of the literature and certainty the evidence
CRP	DGPB, 2016(16)	+	-	-	-	-	-	-	-	-
	ACP, 2019(17)	+	+	+	-	-	-	-	-	-
	MoPH, 2019(15)	-	-	-	-	-	-	+	-	-
	DGPI, 2017(18)	+	-	-	-	-	-	-	-	-
Colonoscopy	ESMO, 2020(21)	-	-	-	-	-	-	-	-	-
	AWMF, 2019(19)	-	-	-	-	-	-	-	-	-
	ACPGBI, 2017(22)	+	-	-	-	-	-	-	-	-
	FMS, 2019(20)	+	-	-	+	-	-	-	-	-
	NHG, 2017(23)	+	-	-	+	-	-	-	-	-
FeNO	AWMF, 2020(24)	+	+	+	-	-	-	-	-	-
	MoPH_A, 2019(27)	-	-	-		-	-	-	-	-
	MoPH_C, 2019(28)	-	-	-	-	-	-	-	-	-
	NAEPP, 2020(25)	+	+	+	+	-	-	-	-	-
	NICE, 2020(26)*	+	+	+	-	-	-	-	-	-
	SIGN, 2019(29)	+	-	-	-	-	-	+	-	-

+: yes; +/-: unclear; -: no

** This CPG contains two separate recommendations concerning the use of FeNO in the diagnosis of childhood respectively adult onset asthma; the scores a*

Since no CPG systematically evaluated all steps of the test-treatment pathway, we were not able to identify a best practice, nor could we study possible relationships between clarifying factors and supporting evidence for a recommendation.

Discussion

Our document analysis on a sample of 15 CPGs about CRP, colonoscopy and FeNO tests revealed that none of these CPGs reported evidence on all components of a test-treatment pathway. Consideration of test consequences on patient-relevant outcomes was barely described. Systematic review of the literature, including a judgement of the certainty in the supporting evidence was only reported for a few recommendations and mainly covered diagnostic accuracy.

The importance of systematically evaluating test consequences for the purpose of developing CPGs has been recognised,(4, 11, 12) but this study suggests that implementation is lagging behind. This also applies to CPGs that claim to use the GRADE approach. There seems to be a gap between following a methodologically robust approach and developing CPGs in practice.

Two issues may explain that gap. First, guideline developers may have considered the downstream consequences of a test but did not explicitly report these. It may not be strictly necessary to systematically evaluate all evidence components. However, we still recommend transparent documentation of choices made in the guideline development process. A guideline user should be able to read which elements of a test-treatment pathway were considered and how, and which were not considered and why.

Second, performing systematic literature reviews of the complete test-treatment pathway – including assessment of the certainty in the evidence of test accuracy and downstream consequences – is complex and time-consuming The use of the GRADE approach for the evaluation of medical tests and test strategies is considered challenging.(8, 9) Strategies to facilitate the use of this approach, such as training of CPG panel members, may improve the application. Unfortunately, we could not determine factors that contribute to successful use of the GRADE approach, because we could not identify a 'best practice'.

A lack of transparency in combination with the use of state-of-the-art methods was also described by Arevalo-Rodriguez and colleagues, who studied the methods and reports of 191 rapid reviews of medical tests.(30) In the majority of those reviews, the study selection method was not reported. Although almost 20% of the reviews claimed to have applied the GRADE approach, few actually reported the data extraction and quality appraisal methods.

This finding is consistent with a recent report on the application of GRADE in U.S. guidelines.(31) Although guideline developers indicated that they used the GRADE approach, only 10% of the included CPGs reported on all 8 criteria for assessing the certainty in the evidence (e.g. indirectness and dose-response gradient), and around half of these included an evidence profile or summary of findings table.

Gopalakrishna et al. studied barriers in the development of recommendations about medical tests in a qualitative study among European CPG developers.(32) They also reported challenges in the development of recommendations about medical tests, e.g. in the definition of key questions, the types of evidence and outcomes included in the CPG, and synthesizing and appraising the evidence. Awareness and education were reported as the most important ways to solve these challenges.

Our study emphasises the need for more knowledge and expertise among CPG developers when evaluating medical tests. Currently available competency-based frameworks for CPG developers do not include a special focus on medical test evaluation.(33, 34) This also applies for current training programs of CPG panel members, e.g. INGUIDE.(35) Facilitating the implementation of GRADE for diagnosis by defining competencies and training needs may improve CPGs.

Strengths and limitations

This study evaluated the supporting evidence of recommendations in CPGs on 3 medical tests. The selection of only 3 topics is a limitation of this study. However, we chose 3 tests with divergent characteristics (e.g. invasiveness, possible burden of the test, disease of interest, costs) allowing comparison of many CPGs. The homogenous results in all 3 clusters of CPGs strengthens the external validity of our findings. Additionally, we found large variance in methodological quality of the included CPGs. However, high scoring CPGs on the AGREE domain methodology did not reflect a better or more transparent underpinning of the recommendations than lower scoring CPGs.

Due to the document analysis design we could not retrieve information about the dynamics in the CPG panels that could explain their decisions and reasons for lack of transparency in the CPG documents. We did not contact the CPG developers, since in our opinion CPG users should be able to find the considerations of the panel beyond the recommendations in the published documents of the CPG.

Implications for practice

We suggest that developers of CPGs with diagnostic topics clearly describe which elements of a test-treatment pathway were or were not considered and why. In addition, CPG developers should indicate the presence or absence of systematic reviews of the evidence, including determination of the certainty in that evidence, which is also usual in recommendations about therapy. Facilitating the implementation of GRADE for diagnosis will be useful to improve the clinical content of CPGs.

Implications for research

This study highlighted the lack of (transparency about) supporting evidence for medical test recommendations in CPGs. A next step could be to study why CPG developers do not report all elements of the test-treatment pathway, including a review of the evidence and its quality. Furthermore, it is worthwhile to research how to facilitate CPG developers in explicitly and reliably considering all relevant steps of a test-treatment pathway when developing medical test recommendations.

Conclusion

Medical test recommendations in CPGs are mainly based on evidence and considerations on diagnostic accuracy. Other steps of the test-treatment strategy, such as burden of the test, natural course of the disease of interest, effectiveness of treatment of the disease of interest and the link between the test result and the administration of treatment should receive more attention in CPGs in order to consider evidence about test consequences on patient-relevant outcomes.

Abbreviations

CPG

clinical practice guideline
CRP
C-reactive protein
FeNO
fractional exhaled nitric oxide
GIN
Guidelines International Network
GRADE
Grading of Recommendations Assessment, Development and Evaluation
RCT
randomised controlled trial
TRIP
Turning Research Into Practice

Declarations

Ethics approval and consent to participate: not applicable.

Consent for publication: not applicable.

Availability of data and materials: Full data are in the additional file.

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Authors' contributions: MT conceptualized the study, including methodology, extracted, analyzed and interpreted the data, and wrote the original draft of the manuscript. JB, TvdW and ML were involved in the conceptualization of the study, including methodology, performed data checks, reviewed and edited the manuscript and had a supervising role. All authors read and approved the final manuscript.

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Figures

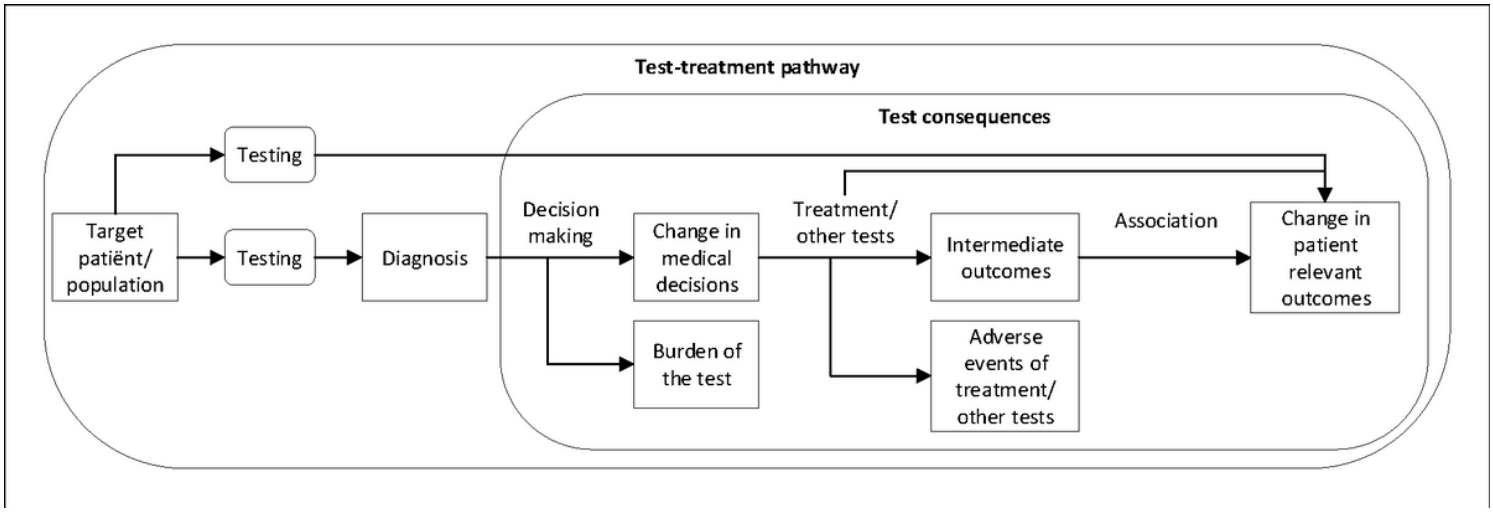

Figure 1

Test-treatment pathway (adapted from Harris et al, 2001

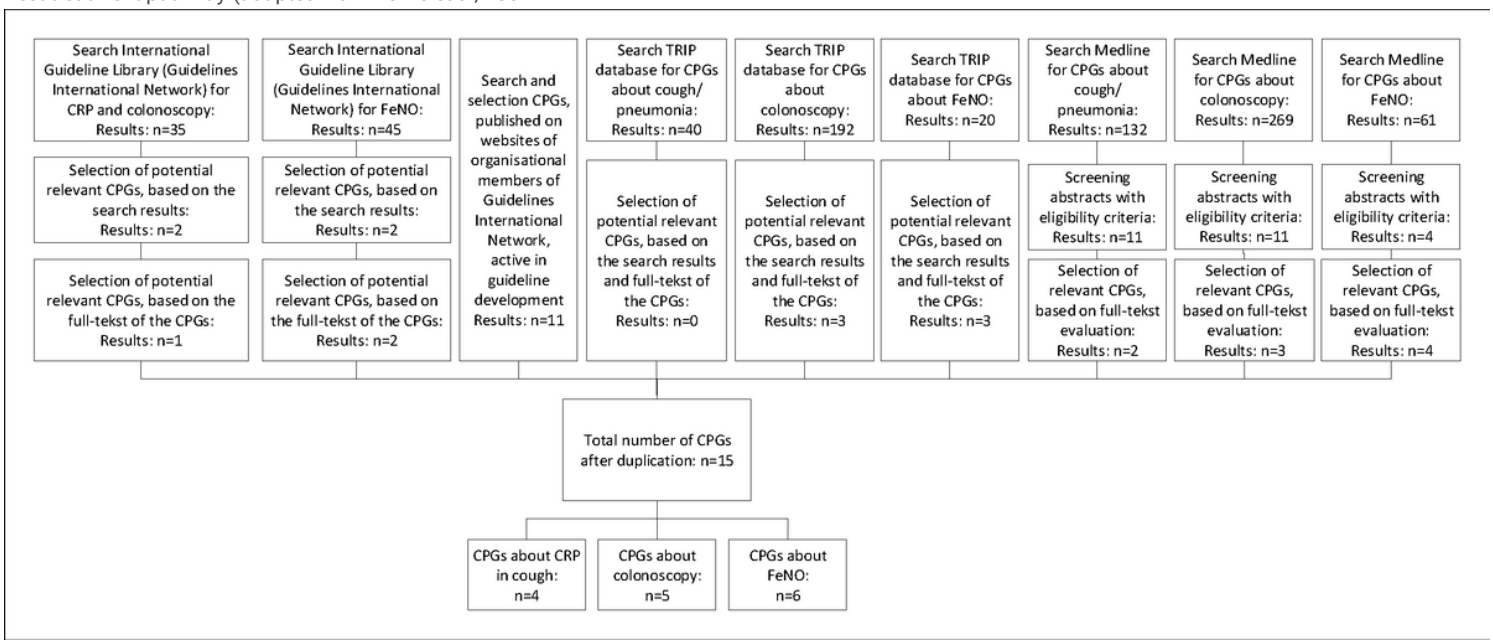

Figure 2

Search and selection of relevant CPGs

Supplementary Files

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- Additionalfile1SearchforCPGs10052021.docx