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Development of a quality assessment tool for pharmacy and therapeutics committees and subsequent pilot testing

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ABSTRACT

Pharmacy and therapeutics committees (PTCs) are multidisciplinary hospital teams responsible for rational medication use. We aimed at developing and piloting an assessment tool for their operating quality.

We conducted a scoping literature review in PubMed and Embase to identify potential assessment items. Their relevance was systematically rated and consolidated into the final tool.

60 relevant items were included, grouped into eight focus topics: the committee's institutional integration, member characteristics, performance indicators, meeting structure, formulary decision-making and characteristics, strategies to guide medication use and medication use evaluations.

In combination with a SWOT (strengths, weaknesses, opportunities and threats) analysis, the tool helped the identification of improvement opportunities for a pilot hospital: adapting the committee's structure, improving the formulary decision-making, implementing strategies to guide formulary medication use and strengthening the committee's recognition within the institution.

The tool successfully identified improvement opportunities for a PTC and could therefore be interesting for other hospitals.

INTRODUCTION

Pharmacy and therapeutics committees (PTCs) are multidisciplinary hospital teams of healthcare professionals involved in the medication use process. One of the main tools of a PTC is a continually updated list of medications, known as a formulary, to be preferentially prescribed, along with related information to ensure safe and rational medication use.[1–3] The PTC should also provide guidance on subprocesses of the medication use process; for example, generic substitution and therapeutic interchange guidelines, or strategies integrating computerised physician order entry systems combined with clinical decision support systems.[4–7]

Assessment tools allow hospitals to determine the implementation level and quality of activities. For example, the Swiss Society of Public Health Administration and Hospital Pharmacists (GSASA) has developed the quality management standards for hospital pharmacies (QRHP).[4–8] Numerous surveys related to PTCs and formulary systems exist and some have developed tools to improve PTC decision-making. However, no validated tool is available to comprehensively assess PTCs' operating qualities.

Thus, the objective of this work was to systematically develop a PTC assessment tool that could thoroughly assess the operating quality and functionality of a specific hospital's PTC, and therefore enable the identification of areas for improvement.

METHODS

Development of the assessment tool

Literature review

A scoping review in PubMed and Embase was conducted to identify relevant publications for the following research question: What subjects are addressed in the current literature that are important to developing a structured assessment of a hospital's PTC and formulary system? The search strategy was elaborated in collaboration, and the selection and data extraction was performed by one reviewer. Index terms for PTCs and formulary systems were combined with index terms for guidelines, assessments and PTC responsibilities (ie, decision-making). Additionally, titles and abstracts were searched for these index terms and synonyms. Publications (published from January 2000 to March 2020) in English and German were retrieved and, after deduplication, screened for inclusion (description, assessment or practice guidelines for PTCs or formulary systems) and exclusion (focus on a specific substance or pharmacological class, settings other than hospitals, clinical studies or no full text available) criteria. The references of included publications were searched for additional relevant publications. (For details, see online supplemental appendix B.)

Consolidation of the assessment tool

The identified subjects were converted into potential assessment items. The items were categorised into focus topics and tabulated. To consolidate the assessment tool, we developed a weighting system, consisting of item weights and publications weights. The publication weight was estimated by assigning the following five score-types for each included publication and adding up the points.

1. Publication type: practice guideline (7 points), literature review (6), survey (4), research article (3), decision-making tool (2) and overview or summary (1).
2. 2017 health expenditure by financing schemes of the country of origin, current US$ per capita: >9000 (4 points), ≤9000 and >4000 (3), ≤4000 and >2000 (2) and ≤2000 (1).
3. Publication period: 2010 or after (2 points), before 2010 (1).

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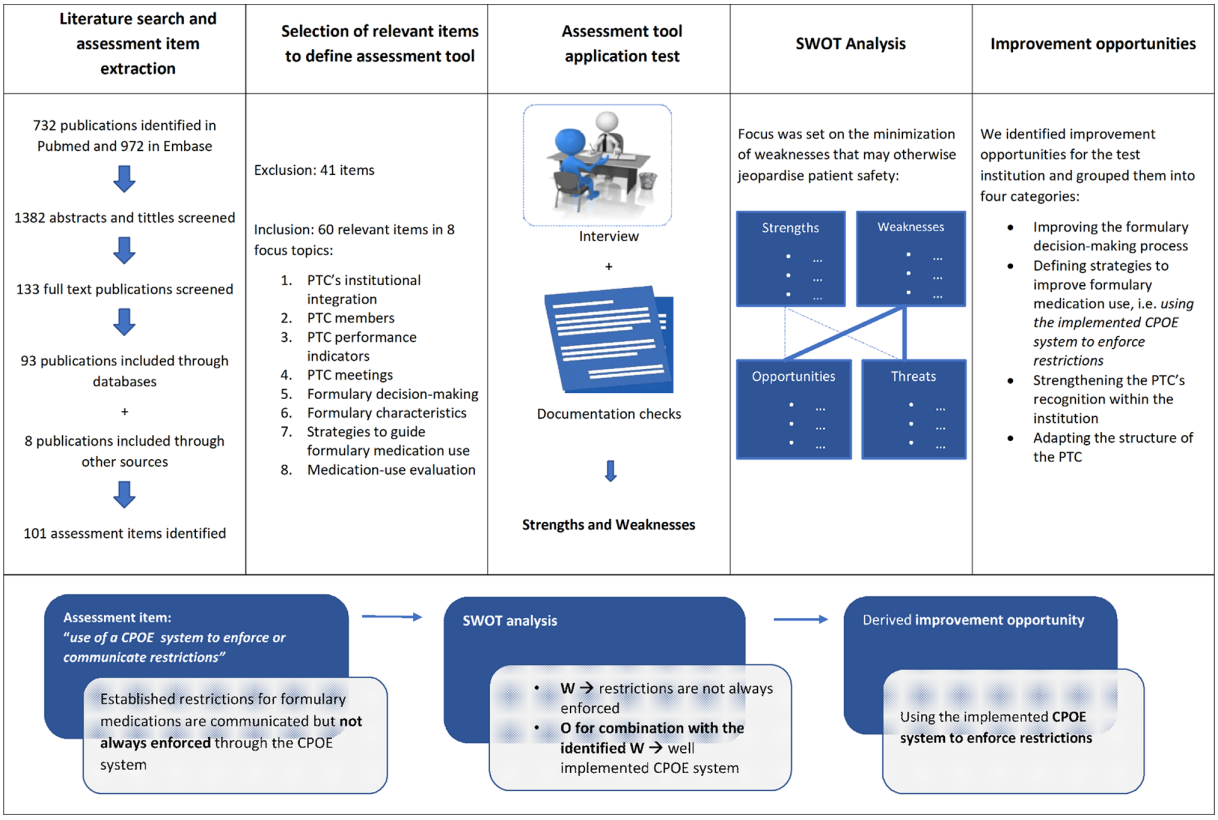

Figure 1 *Top*: Process carried out to systematically develop the assessment tool with subsequent pilot testing and identification of opportunities for improvement by using the developed tool in combination with a SWOT analysis. *Bottom*: Example of the tool application. CPOE, computerised physician order entry; PTC, pharmacy and therapeutics committee; SWOT, strengths, weaknesses, opportunities and threats.

4. SCImago Journal Rank: >1.000 (2 points), ≤1.000 or not applicable (1).
5. Setting: university hospital (2 points), other (1).

The lowest possible publication weight for an individual publication was five and the highest was 17. The relevance of every item (item weight) was calculated by adding up publication weights of all included publications addressing the particular item in their full text. Assessment items with a weight <30, calculated based on the weights of the publications mentioning the item, were removed. It was important to exclude items to ensure the applicability of the assessment tool and the relevance of the assessment item. The reasoning behind a cut-off of 30 was that an assessment item was to be included if it was covered by at least two highly relevant publications, and excluded if it was only covered by one publication, to minimise the influence of selection bias.

Applicability of the assessment tool

The tool was pilot tested in an 800-bed Swiss university hospital. The individual items were answered in a descriptive manner by reviewing available documentation and conducting a semi-structured interview with a pharmacist PTC member. The answers were verified by another pharmacist PTC member. As the information gathered was purely descriptive, the tool on its own could not analyse a PTC's operating quality. Therefore, the collected information had to be additionally evaluated, which was done with a SWOT (strengths, weaknesses, opportunities and threats) analysis. This method is widely used for the structured identification of future organisational strategies. The internal factors (strengths and weaknesses that can be influenced by the institution) were based on the information obtained by the applied assessment tool. For the external factors (opportunities and threats) an environmental analysis was necessary. To structurally conduct it, the PEST framework (political, economic, social and technological) was used. The strategic consequences result from all possible combinations of the factors. To minimise subjectivity, three experts reached consensus about the SWOT and PEST categories. When identifying improvement opportunities, the focus of the future strategies should be the minimisation of weaknesses that may otherwise jeopardise patient safety. For this reason, the 'weaknesses combined with opportunities' and 'weaknesses combined with threats' strategies were the basis for the formulation of our improvement strategies.

RESULTS

Assessment tool development

A total of 1704 publications were identified. After removal of duplicates, title/abstract searching and full-text screening, 93 publications met our inclusion criteria. Additional eight publications were identified through other sources.

The included publications resulted in 101 potential assessment items. The subsequent weighting process determined 60 items with a weight of ≥30, categorised into eight PTC-related focus topics (for the focus topics and an item example see figure 1; for the final tool, see online supplemental appendix A)

Applicability of the assessment tool

In the pilot, all 60 items could be answered. The assessment tool allowed us to obtain a comprehensive picture of the pilot PTC's current situation and to identify 15 strengths and 18 weaknesses. In addition, we identified seven opportunities and nine threats

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by applying the PEST framework. These findings combined were used as a basis to identify future improvement strategies, which were grouped into four areas for improvement (see figure 1).

DISCUSSION

To our knowledge, this is the first comprehensive tool to assess PTCs. As we aimed to extensively assess PTCs, we used a broad research question and eligibility criteria for the scoping review. This yielded many records. Nevertheless, most included publications proved relevant for the formulation of the assessment items, as only four did not mention any included assessment item. Relevance was assigned with the self-developed weighting system instead of categorising levels of evidence. This approach was chosen because the information extracted from the publications were not primarily focused on outcomes. For instance, a PTC practice guideline is more relevant for the formulation of assessment items than a systematic literature review focused on one specific PTC task. In addition to the publication type, publications originating from a country with similar healthcare expenditure to Switzerland were graded higher than countries with lower expenditures, which potentially face different challenges in their PTCs.[9 10] Articles published after 2010 were graded higher to acknowledge more contemporary findings. Studies conducted in a university hospital were graded higher as we aimed to assess the highest possible complexity of healthcare systems. With a cut-off value of 30, we included 60 out of 101 assessment items. In our opinion, the applied weighting system did not exclude any relevant item and was especially successful in minimising redundant information.

We found two frameworks that assess PTCs and formulary systems.[10 11] Unlike our tool, which is more comprehensive, Lima-Dellamora's framework[11] is limited to structures and processes needed for medication selection and has a strong focus on Brazilian hospitals. The second framework outlines similar topics within a different structure; however, these relevant topics are rather descriptive and no assessment items are extracted.[12] Our assessment tool includes key PTC aspects, formulated as performance indicators elsewhere.[13 14] The Swiss QRHP includes a formulary section and our tool covers all topics addressed there as well.[8] Our tool has a higher level of detail than existing instruments and includes contemporary topics, like the use of technology to guide formulary medication use and considerations on biosimilars or drug shortages.

The assessment tool was pilot tested in one hospital and allowed us to obtain a comprehensive picture of this PTC. The tool helped to identify opportunities for improvement when combined with a SWOT analysis. However, further validation in other hospitals—and most importantly through researchers not involved in the development—would be advisable.

Limitations

The main limitations of the assessment tool are that the development based solely on a literature review and the many items may limit its usability. To improve this, the tool's scope could be narrowed to the most relevant items by applying a consensus method (eg, the Delphi technique). We addressed this problem by weighting the items, which proved to be beneficial in our case, as we showed that the most important items are still included. One limitation of this system, however, is that it is not validated but developed and piloted by our research team only. Another limitation is that the selection and data extraction processes of the literature review were not conducted independently by more than one reviewer. This could have been especially critical, as some extracted data were qualitative, and consequently, the development of the assessment tool relied on the interpretation of the reviewer. Since the assessment tool aims to evaluate contemporary PTCs, this was the main rationale for excluding articles published before the year 2000. However, relevant work was published before 2000; for example, a set of PTC indicators.[14] Nevertheless, we do not believe that additional publications would have caused extensive changes to the assessment tool, as we showed that the relevant topics are covered even when comparing our indicator set with the aforementioned indicators published earlier. As the tool was only tested in one hospital, its generalisability needs further research.

CONCLUSION

We systematically developed a comprehensive PTC assessment tool based on a scoping literature review. The tool was pilot tested and used in combination with a SWOT analysis to identify improvement opportunities for the pilot hospitals' PTC. Further consolidation and validation of the tool to facilitate its application in different hospitals would be advantageous.

Correction notice This article has been corrected since it was first published. In the section about the publication weighting system under the heading 'Consolidation of the assessment tool', the production team inadvertently changed the weighting points to citation numbers. We would like to apologise for this mistake and the reference citation numbers have been reverted to the original weighting points in brackets.

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Appendix A1: Included assessment tool items

Assessment items were included in the assessment tool if the total item weight was ≥30. The included items with their respective weights are listed in **Table** . The included assessment items were combined into the consolidated assessment tool.

Table A1. Consolidated assessment tool

Item[a]	Weight[b]
PTC's institutional integration	
Presence of an organisational regulation document: established policies and guidelines; defined responsibilities	74 248
Subcommittees or ad hoc committees: presence, type, and responsibilities	222
PTC member characteristics	
Number of members	128
Expertise of members	232
Disclosure of conflicts of interest: presence; frequency; strategy to deal with conflicts of interest	91 37 40
Chairperson: presence and expertise	53
Pharmacist: presence; responsibilities	47 66
PTC performance indicators	
Use of performance indicators by the PTC	81
PTC meeting structure	
Meeting frequency	183
Meeting duration	30
Meeting minutes: preparation; distribution and accessibility	52 42
Percentage of attendance in the last year	30
Formulary decision-making	
Responsible body for formulary decision-making	190
Established guidelines for decision-making	57
Request process: presence of standardised request form; allowance for request; disclosure of conflicts of interest of requestor; included information	76 44 53 68
Formulary additions: presence of standardised process	107
Formulary deletions: presence of standardised process; triggers	105 66
Revisions: presence of standardised process; established criteria which drugs are revised (e.g. newly added drugs); triggers; frequency; information used for revisions	211 167 40 86 53

Formulary decision-making cont.	
Drug monograph: preparation for additions, deletions, and/or revisions; person preparing the drug monograph; considerations made in the drug monograph ; timeframe for preparation; established mechanism for expedited reviews; summary into advantages and disadvantages	54 40 48 30 40 31
Considerations: considerations made; safety; cost; efficacy; comparative effectiveness; clinical need; internal data; studies supported by the manufacturer; clinical practice guidelines; decisions by other hospitals; patient convenience; ease of medication preparation and administration; breadth of approved indications; expert opinions; use of minimal duplication strategy; standardised process for weighting considerations; required scientific level of studies and standardised process to evaluate studies	434 211 331 121 161 140 74 47 41 62 51 91 79 72 71 105 195
Activity of other committees (e.g. subcommittees)	49
Process to communicate decisions	79
Established tool for prioritising decisions	37
Formulary characteristics	
Type of formulary items (medications from different ATC codes, medical devices, nutritional supplements)	82
Presence of specialty medications	40
Validity of formulary: inpatient and/or outpatient	44
Establishment and enforcement of established restrictions by the formulary	196
Included supplementary information (e.g. established restrictions, administration route, or storage advices)	54
Listing of prices for each formulary item	54
Stockage: storage of all formulary drugs; storage of nonformulary medications	32 32
Accessibility of formulary	40
Strategies to guide formulary medication use	
Pharmacist interventions to guide formulary medication use	78
CPOE system: presence and used strategies to guide formulary medication use	199
Use of a CPOE system to enforce or communicate established restrictions	80
Medication information provided by the CPOE system	88
Information on doses provided by the CPOE system	67
Redirection of nonformulary item orders to formulary items	70
Communication of drug shortages and possible therapeutic alternatives by the CPOE system	33

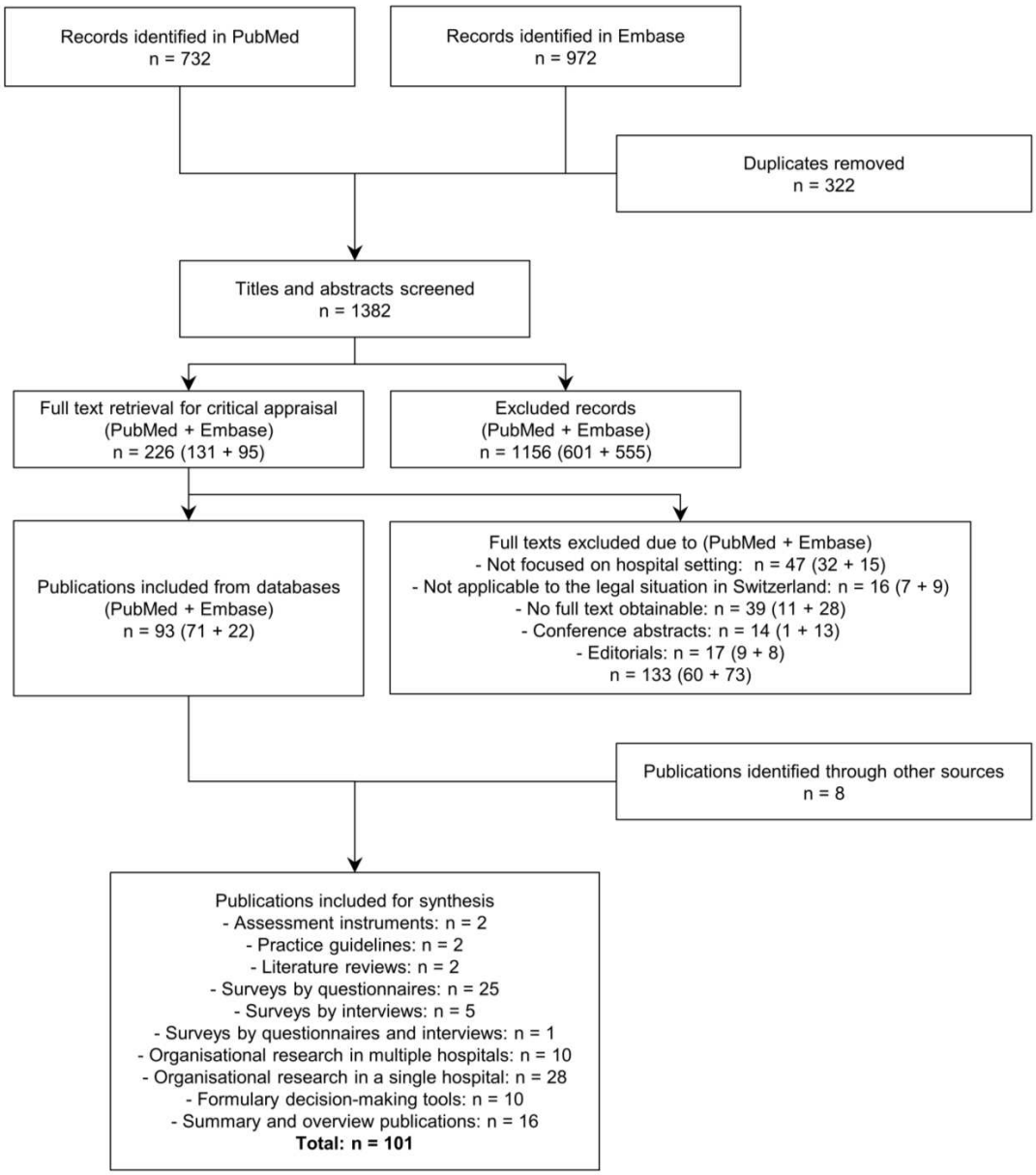
Strategies to guide formulary medication use cont.	
Requirement of indications for some medication orders	48
Written guidelines for formulary medication use: presence; responsibility; adherence monitoring; review frequency	216 154 98 53
Existence of therapeutic interchange guidelines	257
Guidelines on established-use criteria	149
Guidelines for off-label medication use	114
Guidelines for investigational medication use	93
Guidelines for medications with a high potential for medication errors	99
Guidelines on generic substitution	79
Guidelines for nonformulary medication use for patients stabilised on a nonformulary medication	63
Guidelines for managing drug shortages	83
Guidelines for managing high-cost medications	52
Guidelines for managing biosimilars	46
Established guidelines for nonformulary medication use: presence and type; possibility for prescription; requirement of prior authorisation	154 106 101
Clinical practice guidelines with included APIs: presence; involvement of the PTC	262 153
Embedment of clinical practice guidelines into the formulary	54
Educational programs on formulary and the PTC: existence and responsibility	180
Medication use evaluation	
Percentage of formulary medications of all prescribed medications (formulary compliance) and regular monitoring	103
Monitoring of medication use: presence; responsibility	308 56
Monitoring of adverse drug reactions: presence; responsibility	115 95
Monitoring of medication errors: presence and responsibility	30
Use of evaluation data by the PTC	40
Inclusion of top ten prescribed medications in the formulary	32

Abbreviations: ATC, Anatomical Therapeutic Chemical classification system; CPOE, computerised physician order entry; PTC, pharmacy and therapeutics committee. [a]The semicolons (;) in the description of the items mean that different publications were used to formulate the different parts of this item. If this is applicable, more than one respective weight and reference list appear in the respective weight and references column. The weights and reference lists are then sorted in the same way. [b]Item weights were calculated by adding up the publications weights of all publications which covered the respective assessment item in their full text.

Appendix B1: Results of the literature review

The results of the literature review are shown in Figure B. A total of 101 publications met our inclusion criteria and were retrieved for the development of the assessment tool.

Figure B1. Flow diagram of the literature review



Appendix B2: Search strategies

We defined a search strategy in PubMed for the main topics (PTC and formulary system), using Medical Subject Heading (MeSH) Major Topics and synonyms in the title or abstract and combined this search string with search strings for the subtopics guidelines, assessment, activities and challenges. Search strings were developed based on applicable MeSH terms (if available). Additionally, the titles and abstracts were searched for the MeSH terms or subcategories, synonyms, or additional key words. Finally, the defined limitations regarding publication date, language and study type were applied. Afterwards, we translated the search strategy from PubMed into a search strategy for Embase. We identified the Emtree terms which matched the chosen MeSH terms best. The process at arriving at the final search string can be traced in Table B1 for PubMed and in Table B2 for Embase.

Table B1. Search strategy for PubMed

Main topic	MeSH terms	Title/Abstract
PTC, Formulary system	"Pharmacy and Therapeutics Committee"[MAJR] "Formularies, Hospital as Topic"[MAJR]	"Pharmacy and Therapeutics Committee*"[TIAB] "Pharmacy & Therapeutics Committee*"[TIAB] "P and T Committee*"[TIAB] "P&T Committee*"[TIAB] "Drug and Therapeutics Committee*"[TIAB] "Drug Committee*"[TIAB] "Medicine and therapeutics committee*"[TIAB] "Formulary committee*"[TIAB] "Hospital Formular*"[TIAB] "Drug Formular*"[TIAB]
	"Pharmacy and Therapeutics Committee"[MAJR] OR "Formularies, Hospital as Topic"[MAJR] OR "Pharmacy and Therapeutics Committee*"[TIAB] OR "Pharmacy & Therapeutics Committee*"[TIAB] OR "P and T Committee*"[TIAB] OR "P&T Committee*"[TIAB] OR "Drug and Therapeutics Committee*"[TIAB] OR "Drug Committee*"[TIAB] OR "Medicine and therapeutics committee*"[TIAB] OR "Formulary committee*"[TIAB] OR "Hospital Formular*"[TIAB] OR "Drug Formular*"[TIAB]	
Subtopic	**MeSH terms**	**Title/Abstract**
Guidelines	"Guidelines as Topic"[MH]	"Guid*"[TIAB]
	("Pharmacy and Therapeutics Committee"[MAJR] OR "Formularies, Hospital as Topic"[MAJR] OR "Pharmacy and Therapeutics Committee*"[TIAB] OR "Pharmacy & Therapeutics Committee*"[TIAB] OR "P and T Committee*"[TIAB] OR "P&T Committee*"[TIAB] OR "Drug and Therapeutics Committee*"[TIAB] OR "Drug Committee*"[TIAB] OR "Medicine and therapeutics committee*"[TIAB] OR "Formulary committee*"[TIAB] OR "Hospital Formular*"[TIAB] OR "Drug Formular*"[TIAB]) AND ("Guidelines as Topic"[MH] OR "Guid*"[TIAB])	
Assessment	"Health Care Evaluation Mechanisms"[MH]	"Assess*"[TIAB] "Characteri*"[TIAB] "Survey*"[TIAB] "Questionnaire*"[TIAB] "Checklist*"[TIAB] "Classif*"[TIAB] "Polic*"[TIAB] "Framework*"[TIAB]
	("Pharmacy and Therapeutics Committee"[MAJR] OR "Formularies, Hospital as Topic"[MAJR] OR "Pharmacy and Therapeutics Committee*"[TIAB] OR "Pharmacy & Therapeutics Committee*"[TIAB] OR "P and T Committee*"[TIAB] OR "P&T Committee*"[TIAB] OR "Drug and Therapeutics Committee*"[TIAB] OR "Drug Committee*"[TIAB] OR "Medicine and therapeutics committee*"[TIAB] OR "Formulary committee*"[TIAB] OR "Hospital Formular*"[TIAB] OR "Drug Formular*"[TIAB]) AND ("Health Care Evaluation Mechanisms"[MH] OR "Assess*"[TIAB] OR "Characteri*"[TIAB] OR "Survey*"[TIAB] OR "Questionnaire*"[TIAB] OR "Checklist*"[TIAB] OR "Classif*"[TIAB] OR "Polic*"[TIAB] OR "Framework*"[TIAB])	

Activities	"Pharmacy Service, Hospital"[MH] "Decision Making"[MH] "Decision Making, Organizational"[MH]	"Hospital Pharac*"[TIAB] "Decision Making"[TIAB] "Activit*"[TIAB] "Role*"[TIAB]
	("Pharmacy and Therapeutics Committee"[MAJR] OR "Formularies, Hospital as Topic"[MAJR] OR "Pharmacy and Therapeutics Committee*"[TIAB] OR "Pharmacy & Therapeutics Committee*"[TIAB] OR "P and T Committee*"[TIAB] OR "P&T Committee*"[TIAB] OR "Drug and Therapeutics Committee*"[TIAB] OR "Drug Committee*"[TIAB] OR "Medicine and therapeutics committee*"[TIAB] OR "Formulary committee*"[TIAB] OR "Hospital Formular*"[TIAB] OR "Drug Formular*"[TIAB]) AND ("Pharmacy Service, Hospital"[MH] OR "Decision Making"[MH] OR "Decision Making, organizational"[MH] OR "Hospital Pharmac*"[TIAB] OR "Decision Making"[TIAB] OR "Activit*"[TIAB] OR "Role*"[TIAB])	
Challenges	NA	"Challenge*"[TIAB] "Problem*"[TIAB] "Issue*"[TIAB]
	("Pharmacy and Therapeutics Committee"[MAJR] OR "Formularies, Hospital as Topic"[MAJR] OR "Pharmacy and Therapeutics Committee*"[TIAB] OR "Pharmacy & Therapeutics Committee*"[TIAB] OR "P and T Committee*"[TIAB] OR "P&T Committee*"[TIAB] OR "Drug and Therapeutics Committee*"[TIAB] OR "Drug Committee*"[TIAB] OR "Medicine and therapeutics committee*"[TIAB] OR "Formulary committee*"[TIAB] OR "Hospital Formular*"[TIAB] OR "Drug Formular*"[TIAB]) AND ("Challenge*"[TIAB] OR "Problem*"[TIAB] OR "Issue*"[TIAB])	
Limitations	**Final search string**	
Publication date: Since 01 Jan 2000 Languages: English and German Publication type: No clinical studies, except observational studies No articles with nonhuman species	("Pharmacy and Therapeutics Committee"[MAJR] OR "Formularies, Hospital as Topic"[MAJR] OR "Pharmacy and Therapeutics Committee*"[TIAB] OR "Pharmacy & Therapeutics Committee*"[TIAB] OR "P and T Committee*"[TIAB] OR "P&T Committee*"[TIAB] OR "Drug and Therapeutics Committee*"[TIAB] OR "Drug Committee*"[TIAB] OR "Medicine and therapeutics committee*"[TIAB] OR "Formulary committee*"[TIAB] OR "Hospital Formular*"[TIAB] OR "Drug Formular*"[TIAB]) AND ("Guidelines as Topic"[MH] OR "Guid*"[TIAB] OR "Health Care Evaluation Mechanisms"[MH] OR "Assess*"[TIAB] OR "Characteri*"[TIAB] OR "Survey*"[TIAB] OR "Questionnaire*"[TIAB] OR "Checklist*"[TIAB] OR "Classif*"[TIAB] OR "Polic*"[TIAB] OR "Framework*"[TIAB] OR "Pharmacy Service, Hospital"[MH] OR "Decision Making"[MH] OR "Decision Making, organizational"[MH] OR "Hospital Pharmac*"[TIAB] OR "Decision Making"[TIAB] OR "Activit*"[TIAB] OR "Role*"[TIAB] OR "Challenge*"[TIAB] OR "Problem*"[TIAB] OR "Issue*"[TIAB]) AND ("2000"[DP] : "2020"[DP]) AND ("English"[LA] OR "German"[LA]) NOT (("Clinical study"[PT] NOT "Observational Study"[PT]) OR "Clinical Trial"[PT]) NOT ("Animals"[MH] NOT "Humans"[MH])	

Key PubMed

1. " ": Phrase search
2. [MAJR]: MeSH (subject heading) as major topic of the article
3. Asterisk (*): Truncation
4. [TIAB]: Terms in either the title or abstract fields
5. [MH]: MeSH (subject heading)
6. [DP]: Publication date search field
7. [LA]: Language search field
8. [PT]: Publication type search field

Table B2. Search Strategy for Embase

Main topic	Emtree	Title/Abstract
PTC, Formulary system	'pharmacy and therapeutics committee'/mj 'frug formulary'/mj	'pharmacy and therapeutics committee*':ti,ab 'pharmacy & therapeutics committee*':ti,ab 'p and t committee*':ti,ab 'p&t committee*':ti,ab 'drug and therapeutics committee*':ti,ab 'drug committee*':ti,ab 'medicine and therapeutics committee*':ti,ab 'formulary committee*':ti,ab 'hospital formular*':ti,ab 'drug formular*':ti,ab
	'pharmacy and therapeutics committee'/mj OR 'drug formulary'/mj OR 'pharmacy and therapeutics committee*':ti,ab OR 'pharmacy & therapeutics committee*':ti,ab OR 'p and t committee*':ti,ab OR 'p&t committee*':ti,ab OR 'drug and therapeutics committee*':ti,ab OR 'drug committee*':ti,ab OR 'medicine and therapeutics committee*':ti,ab OR 'formulary committee*':ti,ab OR 'hospital formular*':ti,ab OR 'drug formular*':ti,ab	
Subtopic	**Emtree**	**Title/Abstract**
Guidelines	'practice guideline'/exp	'guid*':ti,ab
	('pharmacy and therapeutics committee'/mj OR 'drug formulary'/mj OR 'pharmacy and therapeutics committee*':ti,ab OR 'pharmacy & therapeutics committee*':ti,ab OR 'p and t committee*':ti,ab OR 'p&t committee*':ti,ab OR 'drug and therapeutics committee*':ti,ab OR 'drug committee*':ti,ab OR 'medicine and therapeutics committee*':ti,ab OR 'formulary committee*':ti,ab OR 'hospital formular*':ti,ab OR 'drug formular*':ti,ab) AND ('practice guideline'/exp OR 'guid*':ti,ab)	
Assessment	'assessment'/exp 'outcome assessment'/exp	'assess*':ti,ab 'characteri*':ti,ab 'survey*':ti,ab 'questionnaire*':ti,ab 'checklist*':ti,ab 'classif*':ti,ab 'polic*':ti,ab 'framework*':ti,ab
	('pharmacy and therapeutics committee'/mj OR 'drug formulary'/mj OR 'pharmacy and therapeutics committee*':ti,ab OR 'pharmacy & therapeutics committee*':ti,ab OR 'p and t committee*':ti,ab OR 'p&t committee*':ti,ab OR 'drug and therapeutics committee*':ti,ab OR 'drug committee*':ti,ab OR 'medicine and therapeutics committee*':ti,ab OR 'formulary committee*':ti,ab OR 'hospital formular*':ti,ab OR 'drug formular*':ti,ab) AND ('assessment'/exp OR 'outcome assessment'/exp OR 'assess*':ti,ab OR 'characteri*':ti,ab OR 'survey*':ti,ab OR 'questionnaire*':ti,ab OR 'checklist*':ti,ab OR 'classif*':ti,ab OR 'polic*':ti,ab OR 'framework*':ti,ab)	
Activities	'hospital pharmacy'/exp 'decision making'/exp	'hospital pharmac*':ti,ab 'decision making':ti,ab 'activit*':ti,ab 'role*':ti,ab
	('pharmacy and therapeutics committee'/mj OR 'drug formulary'/mj OR 'pharmacy and therapeutics committee*':ti,ab OR 'pharmacy & therapeutics committee*':ti,ab OR 'p and t committee*':ti,ab OR 'p&t committee*':ti,ab OR 'drug and therapeutics committee*':ti,ab OR 'drug committee*':ti,ab OR 'medicine and therapeutics committee*':ti,ab OR 'formulary committee*':ti,ab OR 'hospital formular*':ti,ab OR 'drug formular*':ti,ab) AND ('hospital pharmacy'/exp OR 'decision making'/exp OR OR 'hospital pharmac*':ti,ab OR 'decision making':ti,ab OR 'activit*':ti,ab OR 'role*':ti,ab)	

Challenges	'problem identification'/exp	'challenge*':ti,ab 'problem*':ti,ab 'issue*':ti,ab
	('pharmacy and therapeutics committee'/mj OR 'drug formulary'/mj OR 'pharmacy and therapeutics committee*':ti,ab OR 'pharmacy & therapeutics committee*':ti,ab OR 'p and t committee*':ti,ab OR 'p&t committee*':ti,ab OR 'drug and therapeutics committee*':ti,ab OR 'drug committee*':ti,ab OR 'medicine and therapeutics committee*':ti,ab OR 'formulary committee*':ti,ab OR 'hospital formular*':ti,ab OR 'drug formular*':ti,ab) AND ('problem identification'/exp OR 'challenge*':ti,ab OR 'problem*':ti,ab OR 'issue*':ti,ab)	
Limitations	**Final search string**	
Publication date: Since 01 Jan 2000 Languages: English and German Study type: No in vivo studies, no in vitro studies, no controlled studies, no randomized controlled trials, no clinical audit, clinical protocols, no models, no clinical trials No articles with nonhuman species	('pharmacy and therapeutics committee'/mj OR 'drug formulary'/mj OR 'pharmacy and therapeutics committee*':ti,ab OR 'pharmacy & therapeutics committee*':ti,ab OR 'p and t committee*':ti,ab OR 'p&t committee*':ti,ab OR 'drug and therapeutics committee*':ti,ab OR 'drug committee*':ti,ab OR 'medicine and therapeutics committee*':ti,ab OR 'formulary committee*':ti,ab OR 'hospital formular*':ti,ab OR 'drug formular*':ti,ab) AND ('practice guideline'/exp OR 'Guid*':ti,ab OR 'assessment'/exp OR 'outcome assessment'/exp OR 'assess*':ti,ab OR 'characteri*':ti,ab OR 'survey*':ti,ab OR 'questionnaire*':ti,ab OR 'checklist*':ti,ab OR 'classif*':ti,ab OR 'polic*':ti,ab OR 'framework*':ti,ab OR 'hospital pharmacy'/exp OR 'decision making'/exp OR 'hospital pharmac*':ti,ab OR 'decision making':ti,ab OR 'activit*':ti,ab OR 'role*':ti,ab OR 'problem identification'/exp OR 'challenge*':ti,ab OR 'problem*':ti,ab OR 'issue*':ti,ab) AND (english:la OR german:la) AND [1-1-2000]/sd NOT ('in vivo study'/exp OR 'in vitro study'/exp OR 'controlled study'/exp OR 'randomized controlled trial'/exp OR 'clinical audit'/exp OR 'clinical protocol'/exp OR 'model'/exp OR 'nonhuman'/exp)	

Key Embase

1. ' ': Phrase search
2. /mj: Emtree subject heading as major topic of the article
3. Asterisk (*): Truncation
4. :ti,ab: Terms in either the title or abstract fields
5. /exp: Emtree subject heading (indexing term) exploded
6. /la: Language search field
7. /sd: Entry date search field

Appendix A1: Included assessment tool items

Assessment items were included in the assessment tool if the total item weight was ≥30. The included items with their respective weights are listed in **Table** . The included assessment items were combined into the consolidated assessment tool.

Table A1. Consolidated assessment tool

Item[a]	Weight[b]
PTC's institutional integration	
Presence of an organisational regulation document: established policies and guidelines; defined responsibilities	74 248
Subcommittees or ad hoc committees: presence, type, and responsibilities	222
PTC member characteristics	
Number of members	128
Expertise of members	232
Disclosure of conflicts of interest: presence; frequency; strategy to deal with conflicts of interest	91 37 40
Chairperson: presence and expertise	53
Pharmacist: presence; responsibilities	47 66
PTC performance indicators	
Use of performance indicators by the PTC	81
PTC meeting structure	
Meeting frequency	183
Meeting duration	30
Meeting minutes: preparation; distribution and accessibility	52 42
Percentage of attendance in the last year	30
Formulary decision-making	
Responsible body for formulary decision-making	190
Established guidelines for decision-making	57
Request process: presence of standardised request form; allowance for request; disclosure of conflicts of interest of requestor; included information	76 44 53 68
Formulary additions: presence of standardised process	107
Formulary deletions: presence of standardised process; triggers	105 66
Revisions: presence of standardised process; established criteria which drugs are revised (e.g. newly added drugs); triggers; frequency; information used for revisions	211 167 40 86 53

Formulary decision-making cont.	
Drug monograph: preparation for additions, deletions, and/or revisions; person preparing the drug monograph; considerations made in the drug monograph ; timeframe for preparation; established mechanism for expedited reviews; summary into advantages and disadvantages	54 40 48 30 40 31
Considerations: considerations made; safety; cost; efficacy; comparative effectiveness; clinical need; internal data; studies supported by the manufacturer; clinical practice guidelines; decisions by other hospitals; patient convenience; ease of medication preparation and administration; breadth of approved indications; expert opinions; use of minimal duplication strategy; standardised process for weighting considerations; required scientific level of studies and standardised process to evaluate studies	434 211 331 121 161 140 74 47 41 62 51 91 79 72 71 105 195
Activity of other committees (e.g. subcommittees)	49
Process to communicate decisions	79
Established tool for prioritising decisions	37
Formulary characteristics	
Type of formulary items (medications from different ATC codes, medical devices, nutritional supplements)	82
Presence of specialty medications	40
Validity of formulary: inpatient and/or outpatient	44
Establishment and enforcement of established restrictions by the formulary	196
Included supplementary information (e.g. established restrictions, administration route, or storage advices)	54
Listing of prices for each formulary item	54
Stockage: storage of all formulary drugs; storage of nonformulary medications	32 32
Accessibility of formulary	40
Strategies to guide formulary medication use	
Pharmacist interventions to guide formulary medication use	78
CPOE system: presence and used strategies to guide formulary medication use	199
Use of a CPOE system to enforce or communicate established restrictions	80
Medication information provided by the CPOE system	88
Information on doses provided by the CPOE system	67
Redirection of nonformulary item orders to formulary items	70
Communication of drug shortages and possible therapeutic alternatives by the CPOE system	33

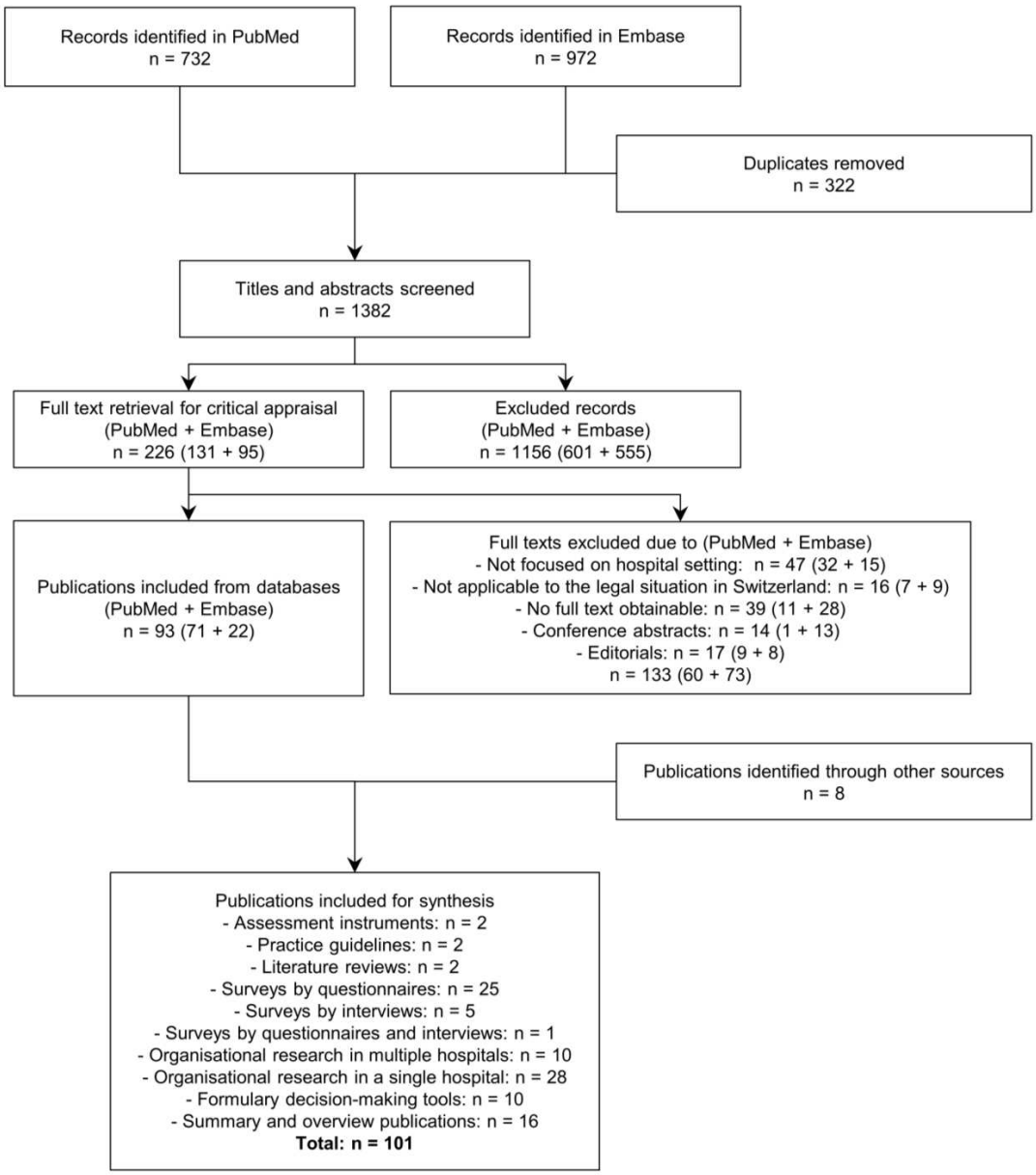
Strategies to guide formulary medication use cont.	
Requirement of indications for some medication orders	48
Written guidelines for formulary medication use: presence; responsibility; adherence monitoring; review frequency	216 154 98 53
Existence of therapeutic interchange guidelines	257
Guidelines on established-use criteria	149
Guidelines for off-label medication use	114
Guidelines for investigational medication use	93
Guidelines for medications with a high potential for medication errors	99
Guidelines on generic substitution	79
Guidelines for nonformulary medication use for patients stabilised on a nonformulary medication	63
Guidelines for managing drug shortages	83
Guidelines for managing high-cost medications	52
Guidelines for managing biosimilars	46
Established guidelines for nonformulary medication use: presence and type; possibility for prescription; requirement of prior authorisation	154 106 101
Clinical practice guidelines with included APIs: presence; involvement of the PTC	262 153
Embedment of clinical practice guidelines into the formulary	54
Educational programs on formulary and the PTC: existence and responsibility	180
Medication use evaluation	
Percentage of formulary medications of all prescribed medications (formulary compliance) and regular monitoring	103
Monitoring of medication use: presence; responsibility	308 56
Monitoring of adverse drug reactions: presence; responsibility	115 95
Monitoring of medication errors: presence and responsibility	30
Use of evaluation data by the PTC	40
Inclusion of top ten prescribed medications in the formulary	32

Abbreviations: ATC, Anatomical Therapeutic Chemical classification system; CPOE, computerised physician order entry; PTC, pharmacy and therapeutics committee. [a]The semicolons (;) in the description of the items mean that different publications were used to formulate the different parts of this item. If this is applicable, more than one respective weight and reference list appear in the respective weight and references column. The weights and reference lists are then sorted in the same way. [b]Item weights were calculated by adding up the publications weights of all publications which covered the respective assessment item in their full text.

Appendix B1: Results of the literature review

The results of the literature review are shown in Figure B. A total of 101 publications met our inclusion criteria and were retrieved for the development of the assessment tool.

Figure B1. Flow diagram of the literature review



Appendix B2: Search strategies

We defined a search strategy in PubMed for the main topics (PTC and formulary system), using Medical Subject Heading (MeSH) Major Topics and synonyms in the title or abstract and combined this search string with search strings for the subtopics guidelines, assessment, activities and challenges. Search strings were developed based on applicable MeSH terms (if available). Additionally, the titles and abstracts were searched for the MeSH terms or subcategories, synonyms, or additional key words. Finally, the defined limitations regarding publication date, language and study type were applied. Afterwards, we translated the search strategy from PubMed into a search strategy for Embase. We identified the Emtree terms which matched the chosen MeSH terms best. The process at arriving at the final search string can be traced in Table B1 for PubMed and in Table B2 for Embase.

Table B1. Search strategy for PubMed

Main topic	MeSH terms	Title/Abstract
PTC, Formulary system	"Pharmacy and Therapeutics Committee"[MAJR] "Formularies, Hospital as Topic"[MAJR]	"Pharmacy and Therapeutics Committee*"[TIAB] "Pharmacy & Therapeutics Committee*"[TIAB] "P and T Committee*"[TIAB] "P&T Committee*"[TIAB] "Drug and Therapeutics Committee*"[TIAB] "Drug Committee*"[TIAB] "Medicine and therapeutics committee*"[TIAB] "Formulary committee*"[TIAB] "Hospital Formular*"[TIAB] "Drug Formular*"[TIAB]
	"Pharmacy and Therapeutics Committee"[MAJR] OR "Formularies, Hospital as Topic"[MAJR] OR "Pharmacy and Therapeutics Committee*"[TIAB] OR "Pharmacy & Therapeutics Committee*"[TIAB] OR "P and T Committee*"[TIAB] OR "P&T Committee*"[TIAB] OR "Drug and Therapeutics Committee*"[TIAB] OR "Drug Committee*"[TIAB] OR "Medicine and therapeutics committee*"[TIAB] OR "Formulary committee*"[TIAB] OR "Hospital Formular*"[TIAB] OR "Drug Formular*"[TIAB]	
Subtopic	**MeSH terms**	**Title/Abstract**
Guidelines	"Guidelines as Topic"[MH]	"Guid*"[TIAB]
	("Pharmacy and Therapeutics Committee"[MAJR] OR "Formularies, Hospital as Topic"[MAJR] OR "Pharmacy and Therapeutics Committee*"[TIAB] OR "Pharmacy & Therapeutics Committee*"[TIAB] OR "P and T Committee*"[TIAB] OR "P&T Committee*"[TIAB] OR "Drug and Therapeutics Committee*"[TIAB] OR "Drug Committee*"[TIAB] OR "Medicine and therapeutics committee*"[TIAB] OR "Formulary committee*"[TIAB] OR "Hospital Formular*"[TIAB] OR "Drug Formular*"[TIAB]) AND ("Guidelines as Topic"[MH] OR "Guid*"[TIAB])	
Assessment	"Health Care Evaluation Mechanisms"[MH]	"Assess*"[TIAB] "Characteri*"[TIAB] "Survey*"[TIAB] "Questionnaire*"[TIAB] "Checklist*"[TIAB] "Classif*"[TIAB] "Polic*"[TIAB] "Framework*"[TIAB]
	("Pharmacy and Therapeutics Committee"[MAJR] OR "Formularies, Hospital as Topic"[MAJR] OR "Pharmacy and Therapeutics Committee*"[TIAB] OR "Pharmacy & Therapeutics Committee*"[TIAB] OR "P and T Committee*"[TIAB] OR "P&T Committee*"[TIAB] OR "Drug and Therapeutics Committee*"[TIAB] OR "Drug Committee*"[TIAB] OR "Medicine and therapeutics committee*"[TIAB] OR "Formulary committee*"[TIAB] OR "Hospital Formular*"[TIAB] OR "Drug Formular*"[TIAB]) AND ("Health Care Evaluation Mechanisms"[MH] OR "Assess*"[TIAB] OR "Characteri*"[TIAB] OR "Survey*"[TIAB] OR "Questionnaire*"[TIAB] OR "Checklist*"[TIAB] OR "Classif*"[TIAB] OR "Polic*"[TIAB] OR "Framework*"[TIAB])	

Activities	"Pharmacy Service, Hospital"[MH] "Decision Making"[MH] "Decision Making, Organizational"[MH]	"Hospital Pharac*"[TIAB] "Decision Making"[TIAB] "Activit*"[TIAB] "Role*"[TIAB]
	("Pharmacy and Therapeutics Committee"[MAJR] OR "Formularies, Hospital as Topic"[MAJR] OR "Pharmacy and Therapeutics Committee*"[TIAB] OR "Pharmacy & Therapeutics Committee*"[TIAB] OR "P and T Committee*"[TIAB] OR "P&T Committee*"[TIAB] OR "Drug and Therapeutics Committee*"[TIAB] OR "Drug Committee*"[TIAB] OR "Medicine and therapeutics committee*"[TIAB] OR "Formulary committee*"[TIAB] OR "Hospital Formular*"[TIAB] OR "Drug Formular*"[TIAB]) AND ("Pharmacy Service, Hospital"[MH] OR "Decision Making"[MH] OR "Decision Making, organizational"[MH] OR "Hospital Pharmac*"[TIAB] OR "Decision Making"[TIAB] OR "Activit*"[TIAB] OR "Role*"[TIAB])	
Challenges	NA	"Challenge*"[TIAB] "Problem*"[TIAB] "Issue*"[TIAB]
	("Pharmacy and Therapeutics Committee"[MAJR] OR "Formularies, Hospital as Topic"[MAJR] OR "Pharmacy and Therapeutics Committee*"[TIAB] OR "Pharmacy & Therapeutics Committee*"[TIAB] OR "P and T Committee*"[TIAB] OR "P&T Committee*"[TIAB] OR "Drug and Therapeutics Committee*"[TIAB] OR "Drug Committee*"[TIAB] OR "Medicine and therapeutics committee*"[TIAB] OR "Formulary committee*"[TIAB] OR "Hospital Formular*"[TIAB] OR "Drug Formular*"[TIAB]) AND ("Challenge*"[TIAB] OR "Problem*"[TIAB] OR "Issue*"[TIAB])	
Limitations	**Final search string**	
Publication date: Since 01 Jan 2000 Languages: English and German Publication type: No clinical studies, except observational studies No articles with nonhuman species	("Pharmacy and Therapeutics Committee"[MAJR] OR "Formularies, Hospital as Topic"[MAJR] OR "Pharmacy and Therapeutics Committee*"[TIAB] OR "Pharmacy & Therapeutics Committee*"[TIAB] OR "P and T Committee*"[TIAB] OR "P&T Committee*"[TIAB] OR "Drug and Therapeutics Committee*"[TIAB] OR "Drug Committee*"[TIAB] OR "Medicine and therapeutics committee*"[TIAB] OR "Formulary committee*"[TIAB] OR "Hospital Formular*"[TIAB] OR "Drug Formular*"[TIAB]) AND ("Guidelines as Topic"[MH] OR "Guid*"[TIAB] OR "Health Care Evaluation Mechanisms"[MH] OR "Assess*"[TIAB] OR "Characteri*"[TIAB] OR "Survey*"[TIAB] OR "Questionnaire*"[TIAB] OR "Checklist*"[TIAB] OR "Classif*"[TIAB] OR "Polic*"[TIAB] OR "Framework*"[TIAB] OR "Pharmacy Service, Hospital"[MH] OR "Decision Making"[MH] OR "Decision Making, organizational"[MH] OR "Hospital Pharmac*"[TIAB] OR "Decision Making"[TIAB] OR "Activit*"[TIAB] OR "Role*"[TIAB] OR "Challenge*"[TIAB] OR "Problem*"[TIAB] OR "Issue*"[TIAB]) AND ("2000"[DP] : "2020"[DP]) AND ("English"[LA] OR "German"[LA]) NOT (("Clinical study"[PT] NOT "Observational Study"[PT]) OR "Clinical Trial"[PT]) NOT ("Animals"[MH] NOT "Humans"[MH])	

Key PubMed

1. " ": Phrase search
2. [MAJR]: MeSH (subject heading) as major topic of the article
3. Asterisk (*): Truncation
4. [TIAB]: Terms in either the title or abstract fields
5. [MH]: MeSH (subject heading)
6. [DP]: Publication date search field
7. [LA]: Language search field
8. [PT]: Publication type search field

Table B2. Search Strategy for Embase

Main topic	Emtree	Title/Abstract
PTC, Formulary system	'pharmacy and therapeutics committee'/mj 'frug formulary'/mj	'pharmacy and therapeutics committee*':ti,ab 'pharmacy & therapeutics committee*':ti,ab 'p and t committee*':ti,ab 'p&t committee*':ti,ab 'drug and therapeutics committee*':ti,ab 'drug committee*':ti,ab 'medicine and therapeutics committee*':ti,ab 'formulary committee*':ti,ab 'hospital formular*':ti,ab 'drug formular*':ti,ab
	'pharmacy and therapeutics committee'/mj OR 'drug formulary'/mj OR 'pharmacy and therapeutics committee*':ti,ab OR 'pharmacy & therapeutics committee*':ti,ab OR 'p and t committee*':ti,ab OR 'p&t committee*':ti,ab OR 'drug and therapeutics committee*':ti,ab OR 'drug committee*':ti,ab OR 'medicine and therapeutics committee*':ti,ab OR 'formulary committee*':ti,ab OR 'hospital formular*':ti,ab OR 'drug formular*':ti,ab	
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Guidelines	'practice guideline'/exp	'guid*':ti,ab
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Assessment	'assessment'/exp 'outcome assessment'/exp	'assess*':ti,ab 'characteri*':ti,ab 'survey*':ti,ab 'questionnaire*':ti,ab 'checklist*':ti,ab 'classif*':ti,ab 'polic*':ti,ab 'framework*':ti,ab
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Activities	'hospital pharmacy'/exp 'decision making'/exp	'hospital pharmac*':ti,ab 'decision making':ti,ab 'activit*':ti,ab 'role*':ti,ab
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Challenges	'problem identification'/exp	'challenge*':ti,ab 'problem*':ti,ab 'issue*':ti,ab
	('pharmacy and therapeutics committee'/mj OR 'drug formulary'/mj OR 'pharmacy and therapeutics committee*':ti,ab OR 'pharmacy & therapeutics committee*':ti,ab OR 'p and t committee*':ti,ab OR 'p&t committee*':ti,ab OR 'drug and therapeutics committee*':ti,ab OR 'drug committee*':ti,ab OR 'medicine and therapeutics committee*':ti,ab OR 'formulary committee*':ti,ab OR 'hospital formular*':ti,ab OR 'drug formular*':ti,ab) AND ('problem identification'/exp OR 'challenge*':ti,ab OR 'problem*':ti,ab OR 'issue*':ti,ab)	
Limitations	**Final search string**	
Publication date: Since 01 Jan 2000 Languages: English and German Study type: No in vivo studies, no in vitro studies, no controlled studies, no randomized controlled trials, no clinical audit, clinical protocols, no models, no clinical trials No articles with nonhuman species	('pharmacy and therapeutics committee'/mj OR 'drug formulary'/mj OR 'pharmacy and therapeutics committee*':ti,ab OR 'pharmacy & therapeutics committee*':ti,ab OR 'p and t committee*':ti,ab OR 'p&t committee*':ti,ab OR 'drug and therapeutics committee*':ti,ab OR 'drug committee*':ti,ab OR 'medicine and therapeutics committee*':ti,ab OR 'formulary committee*':ti,ab OR 'hospital formular*':ti,ab OR 'drug formular*':ti,ab) AND ('practice guideline'/exp OR 'Guid*':ti,ab OR 'assessment'/exp OR 'outcome assessment'/exp OR 'assess*':ti,ab OR 'characteri*':ti,ab OR 'survey*':ti,ab OR 'questionnaire*':ti,ab OR 'checklist*':ti,ab OR 'classif*':ti,ab OR 'polic*':ti,ab OR 'framework*':ti,ab OR 'hospital pharmacy'/exp OR 'decision making'/exp OR 'hospital pharmac*':ti,ab OR 'decision making':ti,ab OR 'activit*':ti,ab OR 'role*':ti,ab OR 'problem identification'/exp OR 'challenge*':ti,ab OR 'problem*':ti,ab OR 'issue*':ti,ab) AND (english:la OR german:la) AND [1-1-2000]/sd NOT ('in vivo study'/exp OR 'in vitro study'/exp OR 'controlled study'/exp OR 'randomized controlled trial'/exp OR 'clinical audit'/exp OR 'clinical protocol'/exp OR 'model'/exp OR 'nonhuman'/exp)	

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