Mapping of modifiable barriers and facilitators with interdisciplinary chronic obstructive pulmonary disease (COPD) guidelines concordance within hospitals to the Theoretical Domains Framework: a mixed methods systematic review protocol

Hancy Issac, Clint Moloney, Melissa Taylor, Jackie Lea

ABSTRACT

Introduction Multifarious chronic obstructive pulmonary disease (COPD) guidelines have been published by local, national and global respiratory societies. These guidelines subsume holistic evidence based on recommendations to diagnose, treat, prevent and manage acute exacerbation with COPD. Despite the existing comprehensive recommendations, readmission rates and hospitalisations have increased in the last decade. Evidence to date has reported suboptimal clinical guidelines concordance. Acute exacerbations of COPD (AECOPD) is a common hospital presentation due to varied causes such as infective exacerbations, worsening disease condition, medication non-adherence, lack of education and comprehensive discharge planning. AECOPD directly and indirectly causes economic burden, disrupts health-related quality of life (HRQol), hasten lung function decline and increases overall morbidity and mortality. COPD being a multimodal chronic disease, consistent interdisciplinary interventions from the time of admission to discharge may reduce readmissions and enhance HRQol among these patients and their families.

Methods and analysis This protocol adheres to the Joanna Briggs Institute methodology for mixed methods systematic reviews and the Preferred Reporting Items for Systematic Reviews and Meta-Analyses extension for Scoping Reviews reporting guidelines. Qualitative, quantitative and mixed methods studies will append this study to explore determinants of COPD guidelines concordance. Comprehensive three-tier search strategies will be used to search nine databases (COCHRANE, EBSCO HOST, MEDLINE, SCIENCE DIRECT, JBI, SCOPUS, WEB OF SCIENCE, WILEY and DARE) in May 2020. Two independent reviewers will screen abstracts and full-text articles in consonance with inclusion criteria. The convergent integrative method narrative review will contribute a deeper understanding of any discrepancies found in the existing evidence. Quality of the studies will be reported and Theoretical Domains Framework (TDF) will be used as a priori to synthesis data. Identified barriers, facilitators and corresponding clinical behavioural change solutions will be categorised using TDF indicators to provide future research and implementation recommendations.

Ethics and dissemination Ethical approval is not required and results dissemination will occur through peer-reviewed publication.

BACKGROUND

Chronic obstructive pulmonary disease (COPD) is a preventable, treatable, irreversible lung disease characterised by chronic airflow obstruction that impedes a normal breathing pattern. COPD, being a debilitating multisystem disease often leads to a steady decline, in terms of illness trajectory, and heavily impacts health-related quality of life (HRQol). The WHO has predicted COPD to become the third leading cause of death by 2030 considering its increase in prevalence and morbidity rate.
second leading cause of preventable hospitalisation in Australia and accounted for more than two-thirds of global respiratory fatal incidences. In Australasian research reports, 5% of all emergency department (ED) presentations included shortness of breath and 14% of these presentations were COPD. Acute exacerbation of COPD (AECOPD) is defined as acute variation in patient’s stable state with both respiratory and non-respiratory symptoms that demand medication changes or hospitalisation.

Exacerbation episodes have a significant and prolonged impact on health status, HRQol, patient outcomes and the negative effects on pulmonary function decline. AECOPD is a common hospital presentation due to a variety of causes such as infective exacerbations, worsening disease condition, medication non-adherence, inefficient care planning, lack of education and discharge without comprehensive support plan. AECOPD, directly and indirectly, is associated with an increased economic burden to the health industry by hastening lung function decline, negatively affecting patients and families and increasing overall morbidity and mortality. Major causal factors of exacerbations include smoking, environmental and genetic factors, airway hyperactivity, chronic bronchitis and infection. Breathlessness, reduced activity level, malnutrition, social isolation, loss of independence, reduced HRQol and depression are some of the issues these patients tackle in their daily lives. COPD is a multimodal chronic disease that requires consistent interdisciplinary interventions from admission to discharge. The importance of the care and interventions provided in the hospitals may reduce readmissions and enhance HRQol in these patients and their families.

The primary intent of publishing COPD guidelines was to facilitate an anticipated shift from the predominant emphasis of pharmacological treatment to a more holistic multidisciplinary intervention approach. The global initiative for chronic obstructive lung disease (GOLD), originally launched and developed by international leadership experts in 1997, aims to improve HRQol and medical management around the globe. COPD-X plan guidelines, originally derived from GOLD, published in 2003 by Thoracic Society of Australia and New Zealand (TSANZ) and the Lung Foundation Australia (LFA) aim to promote consistent evidence-based changes in clinical practice. A range of interventions recommended through the published COPD guidelines such as pulmonary rehabilitation, smoking cessation, self-management of exacerbations, palliative care, psychological support or counselling for patients and families has proven to improve HRQol factors in patients with COPD. Advances in the management of COPD are updated quarterly in the national COPD guidelines by LFA and TSANZ. The prime emphasis of these guidelines is around accurate case diagnosis, functional optimisation, preventing deterioration, developing a plan of care and managing exacerbation. Despite the existing comprehensive recommendations, readmission rates and hospitalisations have increased in the last decade.

The publication of GOLD and national clinical practice guidelines (COPD-X plan) is only the first step in a process that ends with an actual change in clinician behaviour, hence effective guideline dissemination methods cannot be overlooked. An Australian retrospective observational study conducted on 381 patients explored compliance with a patients’ COPD bundle of care, the results revealed 49% adherence to the established plan. This study suggested that further research is required to improve guidelines and adherence plans for patients with COPD. A qualitative Australian study, using semistructured interviews of nine hospital-based registrars or interns, and seven general physicians found that barriers to implementation of evidence-based recommendations for COPD plans included a lack of supportive enablers and a complexity of the behavioural change needed in patients. An identified barrier was the lack of guidelines in a readily, user-friendly and easily accessible manner with checkpoints, cues and time intervals of when they are required at point-of-care. The studies suggest that improvement in guideline adherence can be translated into improved patient care and HRQol in patients with COPD.

Prospective research in knowledge translation and effective ways to implement evidence into everyday clinical practice for AECOPD are imperative. Implementation of a COPD checklist and the resultant adherence conducted among respiratory ward staff in Australia had two groups of patient admissions, prechecklist implementation and postchecklist implementation. Adherence to the checklist used by ward medical staff in the respiratory ward identified a report of 51%. Concordance with COPD guideline recommendations was high overall for patient assessment and initial treatment; however, concordance was lower for longer term issues such as referral to rehabilitation programmes (36%). Patients discharged from the ED had not been included in this study nor was the interdisciplinary perspective explored. The Asia, Australia and New Zealand Dyspnoea in Emergency Departments (AANZDEM) cohort study was conducted in 46 EDs in Australia, New Zealand, Singapore, Hong Kong and Malaysia to explore epidemiology, clinical features, treatment outcomes, hospital length of stay and in-hospital mortality. The findings of this study identified most acute exacerbation patients with COPD arrive in the ED by ambulance and have increased hospitalisations’ and significant in-hospital mortality. A planned substudy of AANZDEM concluded compliance with COPD evidence-based guidelines is suboptimal in EDs and suggested further research is required to improve compliance with care based on published guidelines.

COPD exacerbations and their management were explored in an Ireland hospital through a prospective before and after study. Following the education of staff and the implementation of a COPD care bundle, the outcome for 51 consecutive patients was analysed. Bundle of care improved the delivery of care for patients with COPD. However, care indicators did not suggest or assess
interdisciplinary services (pulmonary rehabilitation, smoking cessation, self-management education, dietician or psychosocial support).19 Spirometry and non-invasive ventilation are two other variables identified in the treatment plan by another retrospective audit of frequent patients with COPD presenting in an Australian ED.20 Imperative evidence collectively resulting from these studies have suggested exploring barriers and enablers of holistic COPD assessment and management could be beneficial in providing holistic care options for patients with COPD. Decreased awareness, familiarity, low concordance, suboptimal primary, secondary and tertiary care provided by health professionals have immensely affected HRQol in patients with COPD.11 16 18

COPD is a multimodal disease, where interdisciplinary care holds a pivotal role in reducing COPD exacerbations.21–23 Current evidence reports doctors, nurses and interdisciplinary health professionals in Australia, do not consistently adhere to COPD guidelines.8 14 24 25 Bartels et al26 postulate from their 1-year retrospective study in Canada that patients with COPD discharged from EDs have a significantly higher risk of readmission due to variability in treatment as less than 50% of patients with AECOPD in their study, who presented to ED received recommended COPD therapy.26 Exploring the barriers and enablers for interdisciplinary team members to provide holistic care as per COPD guidelines (medical, physical, psychological, social, spiritual and palliation) is crucial.18 27 Interdisciplinary care has proven to significantly optimise functionality and prevent deterioration in patients with COPD, which subsequently reduces hospital admissions and hospital days per person.16 21 Initiation of consistent interdisciplinary healthcare interventions for patients with COPD will extrude any implementation gap and prevent readmissions.21

Low concordance is indubitably associated with low awareness of clinical guidelines and role confusion that may subsequently lead to suboptimal clinical care for patients in primary, secondary and tertiary care.17 25 According to an observational study in Australia, COPD guidelines developed with detailed processes and a plethora of international evidence are not well adhered to, where the study also reports a lack of clinician knowledge nationally and internationally.16 Globally, the results of this review with implementation recommendations will avail interdisciplinary clinicians treating patients with COPD and clinical decision-makers. Existence of the guidelines alone does not often aid patients with better health outcomes; hence, exploration of the contributing factors to the already established lack of concordance through this review is in need. Existing evidence and reviews have ascertained that a lack of COPD guideline concordance will increase ED readmissions, imploring the need to better examine contributing factors inhibiting recommended clinical practice.

Implementation research suggests better implementation of guideline demand interdisciplinary clinical behavioural change in an individual and collective manner.28 Theoretical Domains Framework (TDF) had aimed to deliver a comprehensive and theory-informed advanced methodology to help identify the fundamentals of non-concordance behaviour among interdisciplinary professionals.28 Integrating theoretical framework will assist cross-disciplinary implementation and research synthesis to create specific recommendations for local, national and international health systems.28 29 A preliminary search of the topic showed a lack of knowledge, skills, environmental and beliefs of health professionals contribute to lack of concordance. TDF allows researchers to explore, understand and target clinician behaviour change interventions to provide recommendations to improve concordance.30 This theoretical scaffolding allows identification and accumulation of salient determinants from existing evidence towards a lack of COPD guidelines adherence to 14 domains.31 The 14 domains according to Cane et al are (1) knowledge, (2) skills, (3) social influences, (4) memory, attention and decision processes, (5) behavioural regulation, (6) professional/social role and identity, (7) beliefs about capabilities, (8) belief about consequences, (9) optimism, (10) intentions, (11) goals, (12) emotion, (13) environmental context and resources and (14) reinforcement (see table 1).29 Any determinants that do not fit within the existing domains will be organised into an ‘others’ domain.

Framework synthesis of data allows robust filtration of evidence from multiple sources to provide better implementation strategies and clinical behaviour change solutions to COPD guideline concordance.30 31 TDF was originally developed to identify determinants and influences on health professionals behaviour to inform better implementation efforts.28 29 A further benefit of TDF is its linkage to behaviour change techniques which may provide an early identification of implementation issues associated with clinician behaviour to recommend intervention designs (see table 1).28 29 This systematic review will identify the contributing factors to the lack of COPD guidelines concordance from the time of admission in the hospital to discharge. Given the scarcity of research in interdisciplinary guidelines concordance with COPD, the proposed mixed methods approach will enable all available evidence to be incorporated into the review.

Review questions
What core elements of the COPD guidelines are adhered to by interdisciplinary health professionals?
What are the contributing factors to the lack of COPD guideline concordance among interdisciplinary health professionals in hospitals?

Inclusion criteria
Studies and reports published in English including interdisciplinary COPD guidelines concordance, compliance or adherence in the hospital setting will be used for this review. GOLD guidelines and COPD-X plan guideline reviews will be included in this study.
**Table 1** Data synthesis table for using TDF (adapted from Atkins et al. and Cane et al.)

<table>
<thead>
<tr>
<th>TDF for data synthesis</th>
<th>TDF domain</th>
<th>Guidelines uptake barrier</th>
<th>Guidelines uptake enablers</th>
<th>Behaviour change technique</th>
<th>Reported implementation and results</th>
</tr>
</thead>
<tbody>
<tr>
<td>Lack of knowledge of guidelines, scientific rationale</td>
<td>Knowledge</td>
<td></td>
<td></td>
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<tr>
<td>Lack of skills to care for patients with COPD, lack of interprofessional communication skills and assessment skills</td>
<td>Skills</td>
<td></td>
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<tr>
<td>Professional identity, interprofessional boundaries, organisational identity</td>
<td>Social/professional role and identity</td>
<td></td>
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<tr>
<td>Lack of self or confidence in clinical decision-making</td>
<td>Beliefs about capabilities</td>
<td></td>
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<tr>
<td>Clinician and interdisciplinary staff attitude about COPD prognosis</td>
<td>Optimism</td>
<td></td>
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<td></td>
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<tr>
<td>Nihilistic views on causes, prognosis and management of COPD</td>
<td>Beliefs about consequences</td>
<td></td>
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<tr>
<td>Clinician knowledge utilisation and provision</td>
<td>Reinforcement</td>
<td></td>
<td></td>
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<tr>
<td>Lack of awareness, motivation and initiative to change and better care</td>
<td>Intentions</td>
<td></td>
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<tr>
<td>Lack of goals to improve COPD care</td>
<td>Goals</td>
<td></td>
<td></td>
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<td></td>
</tr>
<tr>
<td>Difficulty recalling all treatment and management modality from COPD guidelines</td>
<td>Memory, attention and decision processes</td>
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<tr>
<td>Lack of cues from COPD guidelines in workplace</td>
<td>Environmental context and resources</td>
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<tr>
<td>Lack of clinician and multidisciplinary team cooperation</td>
<td>Social influences</td>
<td></td>
<td></td>
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<tr>
<td>Nihilistic views of treating staff (smoking causes COPD)</td>
<td>Emotion</td>
<td></td>
<td></td>
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<tr>
<td>Failure to abide COPD guidelines or related quality initiative</td>
<td>Behavioural regulation</td>
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</tbody>
</table>

COPD, chronic obstructive pulmonary disease; TDF, Theoretical Domains Framework.

**Exclusion criteria**

Studies not reported in English and studies which had not measured COPD guideline concordance will be excluded from this study. Primary healthcare and community-based COPD guidelines concordance studies will not be included in this study.

**Population**

This review will consider studies that involve doctors, nurses and allied health reports on COPD guidelines concordance.

**Context**

This review will consider studies that involve doctors, nurses and allied health reports on COPD guidelines concordance. Data from EDs, inpatient hospital units and hospital-based rehabilitation will be used in this review.

**Types of studies**

This review will consider quantitative, qualitative and mixed methods studies. Quantitative studies will include experimental, quasi-experimental and non-experimental studies including descriptive studies, correlative studies, randomised controlled trials, non-randomised controlled trials, before and after studies, and interrupted time-series studies. Mixed methods studies will only be considered if data from the quantitative or qualitative components can be extracted. In order to ensure that all reports on COPD guidelines are included any studies that mention COPD guidelines concordance, adherence or compliance will be included for potential inclusion. Studies published in English will be included. Studies published from 1997 from nine databases (COCHRANE, EBSCO HOST, MEDLINE, SCIENCE DIRECT, JBI, SCOPUS, WEB OF SCIENCE, WILEY and DARE) to the present will be included as international guidelines and have been in circulation since 1997. In addition, analytical observational studies including prospective and retrospective cohort studies, case–control studies and analytical cross-sectional studies will be considered for inclusion. This review will also consider observational study designs.
including case series, individual case reports and descriptive cross-sectional studies for inclusion. Studies that focus on qualitative data including, but not limited to, designs such as phenomenology, grounded theory, ethnography, action research and feminist research will also be included for review.

**METHODS**

The proposed systematic review will be conducted in accordance with the Joanna Briggs Institute (JBI) methodology for mixed-method systematic reviews and the Preferred Reporting Items for Systematic Reviews and Meta-Analyses extension for Scoping Reviews (PRISMA-ScR) reporting guidelines (see online supplementary appendix 1). A mixed methods review provides a comprehensive synthesis compared with a single-method review as it combines quantitative and qualitative evidence to assist clinical decision and policymakers to adopt an appropriate implementation strategy. A convergent integrative method where quantitative evidence is qualitative is provided to form a narrative review will deepen a better understanding of any discrepancies noted in the evidence.

**Search strategy**

A preliminary search of databases has been undertaken and no existing or ongoing mixed methods or individual systematic reviews on the topic have been identified in November 2019. A comprehensive three-tier search will be aimed to locate both published and unpublished studies in May 2020. An initial search of MEDLINE and CINAHL will commence the review followed by the identification of keywords found in each title and abstract and a match to the subject terms used in articles on the topic. This will enable the development of an extensive full search strategy for a second search in databases (COCHRANE, EBSCO HOST, MEDLINE, SCIENCE DIRECT, JBI, SCOPUS, WEB OF SCIENCE, WILEY and DARE) (see online supplementary appendix 2. Electronic search strategy). Reference lists from all included studies will be examined to screen any additional studies relevant to the review question.

**Study selection**

All identified studies following the search will be collated and retrieved into EndNote V.X8.1 and duplicates will be removed. Covidence systematic review management software will be used to assist with further data management. Two independent reviewers will screen titles and abstracts in phase 1 assessment towards the inclusion criteria for the selection of articles. Phase 2 will include full-text screening by two independent reviewers where the inclusion and exclusion processes are performed. Exclusion of full-text studies will be recorded and reported in the systematic review. Authors of papers will be contacted to request missing or additional data for clarification, where required. Disagreements that arise between the reviewers at each stage of the study selection process will be resolved through discussion, or with a third reviewer. The results of the search will be reported in the final review and presented in a PRISMA flow diagram (see online supplementary appendix 3).

**Assessment of methodological quality**

Eligible studies will undergo critical appraisal to establish the internal validity and risk of bias by two independent reviewers. Any disputes will be settled through discussion or third reviewer’s opinion. Specific standardised critical appraisal instruments from JBI system for the unified management assessment and review of information (SUMARI) will be used separately for quantitative studies (including the quantitative component of mixed methods studies) and qualitative studies (including qualitative component of mixed methods studies), that are selected for retrieval. Regardless of the methodological quality, all studies will undergo extraction and synthesis (where possible). Critical appraisal results will be appended to the review using ConQual approach in the summary of findings table (see table 2).

**Data extraction**

Mixed methods data extraction tool designed for convergent integrated approach (integration of qualitative data and ‘qualitised’ data following data transformation) will be used to extract data in this study (see table 3). This extraction tool includes the type of the study, methodology, number and characteristics of participants, phenomenon to lack of concordance, guideline type, context (cultural and geographic), setting (hospitals, EDs and inpatient units), concordance with main recommendations of COPD guideline, implementation method, evaluation

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**Table 2** Summary of findings table to depict assessment of methodological quality of eligible studies (adapted from Aromataris and Munn and Munn et al)

<table>
<thead>
<tr>
<th>Systematic review title:</th>
<th>Population:</th>
<th>Phenomena of interest:</th>
<th>Context:</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
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</tbody>
</table>

<table>
<thead>
<tr>
<th>Synthesised finding</th>
<th>Type of research</th>
<th>Dependability</th>
<th>Credibility</th>
<th>ConQual score</th>
<th>Comments</th>
</tr>
</thead>
<tbody>
<tr>
<td>Insert each synthesised finding and complete the columns per synthesised finding</td>
<td></td>
<td></td>
<td></td>
<td></td>
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</tr>
</tbody>
</table>

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Table 3 Data extraction table for convergent integrated approach mixed methods systematic review (adapted from Lizarondo et al.33)

<table>
<thead>
<tr>
<th>Domain/subdomain</th>
<th>Description</th>
</tr>
</thead>
<tbody>
<tr>
<td>Reviewer name:</td>
<td>Name of reviewer and date of review</td>
</tr>
<tr>
<td>Authors</td>
<td>Authors of article</td>
</tr>
<tr>
<td>Journal year, number, record</td>
<td>Name of journal and its details</td>
</tr>
<tr>
<td>Type of study and aims</td>
<td>(Quantitative, qualitative, mixed) Aims and objectives of the selected study</td>
</tr>
<tr>
<td>Geographical and cultural context</td>
<td>Country of study</td>
</tr>
<tr>
<td>Methodology and results</td>
<td>Study design Results of study Recommendations from the study Future research recommendations</td>
</tr>
<tr>
<td>Number and characteristics of participants</td>
<td>(Clinicians, nurses, allied health)</td>
</tr>
<tr>
<td>Phenomenon to lack of concordance (barriers and enablers)</td>
<td>TDF domains: (1) lack of knowledge of COPD-X guidelines, (2) lack of skills caring for patients with COPD, (3) social influences, (4) memory, attention and decision processes, (5) behavioural regulation, (6) professional/social role and identity, (7) beliefs about capabilities, (8) belief about consequences, (9) optimism, (10) intentions, (11) goals, (12) emotion, (13) environmental context and resources and (14) reinforcement (see table 3)</td>
</tr>
<tr>
<td>Guideline type</td>
<td>GOLD, COPD-X plan</td>
</tr>
<tr>
<td>Context and setting</td>
<td>Acute care, ED, inpatient care</td>
</tr>
<tr>
<td>COPD guidelines recommendations adherence</td>
<td>Studies reporting on spirometry, non-pharmacological and pharmacological, pulmonary rehabilitation, short-acting and long-acting inhaled bronchodilators, anti-inflammatory agents, inhaled corticosteroids use, inhaler technique and adherence, smoking cessation, influenza and pneumococcal vaccinations, COPD action, exacerbations promptly with bronchodilators, corticosteroids and antibiotics, comorbidities identification and management, palliative and end-of-life care, self-management education and primary and tertiary partnership care</td>
</tr>
<tr>
<td>Implementation method (ED and inpatient units)</td>
<td>Clinical pathways, proforma, bundle of care</td>
</tr>
<tr>
<td>Evaluation of implementation</td>
<td>Audits, reviews, reports</td>
</tr>
<tr>
<td>Readmissions, remissions or exacerbation within 30 days</td>
<td>Remission or readmission of disease due to inadequate care or discharge planning</td>
</tr>
<tr>
<td>Implications of guidelines</td>
<td>Implications of guideline in healthcare setting, patients and interdisciplinary staff</td>
</tr>
<tr>
<td>Sustainability measures</td>
<td>Frequency of audits, educational sessions, staff recruitment, change champions</td>
</tr>
<tr>
<td>Authors’ conclusion</td>
<td>Study conclusion by the author</td>
</tr>
<tr>
<td>Reviewer comments</td>
<td>Study conclusion and comments by reviewer</td>
</tr>
</tbody>
</table>

Table 3 Continued

<table>
<thead>
<tr>
<th>Domain/subdomain</th>
<th>Description</th>
</tr>
</thead>
<tbody>
<tr>
<td>COPD, chronic obstructive pulmonary disease; ED, emergency department; GOLD, global initiative for chronic obstructive lung disease; TDF, Theoretical Domains Framework.</td>
<td></td>
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</tbody>
</table>

and sustainability of implementation, remissions within 30 days of hospital discharge. Two independent reviewers will extract data from articles and any disagreements will be settled using the third reviewer. Applying computer software program Nvivo V.1236 a second extraction of data and mapping of modifiable determinants of COPD guideline adherence to the domains of the TDF will be performed. 28 29 37

Data transformation

Quantitative data will be converted to ‘qualitised data’ following extraction according to the JBI convergent integrated approach. 33 34 Quantitative numerical data will be transfigured to textual or narrative interpretations to answer the overarching review question.

Data synthesis and integration

Extracted data in shape of qualitised textual description from quantitative studies and themes and subthemes from qualitative studies will be collated and categorised in congruence to 14 domains of TDF (see table 3). 28 Factors contributing to the lack of concordance with the guideline will be integrated based on similarity in meaning. Using TDF will assist in organising literature identified determinants of lack of COPD guidelines concordance. Identified barriers and enablers in guideline uptake will be aligned with standard taxonomy of behavioural change technique to report existing and future recommendations of implementation strategies. 30 31 This review will adhere to the PRISMA-ScR reporting guidelines. 32

ETHICS AND DISSEMINATION

Ethics approval is not required for this study as all data are obtained from publicly available studies. Knowledge and interpretations from this review will provide recommendations towards prominent implementation strategies to increase COPD guideline concordance. The results of this study will be presented before industry stakeholders, interdisciplinary clinicians and appropriate future conferences to develop and assist with implementation initiatives.

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Contributors HI led the design and conceptualisation of this protocol. CM, MT and JL have made intellectual contributions and worked collaboratively in the development and editing of this protocol.

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Patient and public involvement Patients and/or the public were not involved in the design, or conduct, or reporting, or dissemination plans of this research.

Patient consent for publication Not required.

Provenance and peer review Not commissioned; externally peer reviewed.

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REFERENCES