BMJ Open Consequences of health condition labelling: protocol for a systematic scoping review

Rebecca Sims ¹, Luise Kazda ², Zoe A Michaleff ¹, Paul Glasziou ¹,
Rae Thomas ¹

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¹Institute for Evidence-Based Healthcare, Bond University Faculty of Health Sciences and Medicine, Gold Coast, Queensland, Australia

²Sydney School of Public Health, The University of Sydney, Sydney, New South Wales, Australia

Correspondence to

Dr Rae Thomas;
rthomas@bond.edu.au

ABSTRACT

Introduction When health conditions are labelled it is often to classify and communicate a set of symptoms. While diagnostic labelling can provide explanation for an individual's symptoms, it can also impact how individuals and others view those symptoms. Despite existing research regarding the effects of labelling health conditions, a synthesis of these effects has not occurred. We will conduct a systematic scoping review to synthesise the reported consequences and impact of being given a label for a health condition from an individual, societal and health practitioner perspective and explore in what context labelling of health conditions is considered important.

Methods and analysis The review will adhere to the Joanna Briggs Methodology for Scoping Reviews. Searches will be conducted in five electronic databases (PubMed, Embase, PsycINFO, Cochrane, CINAHL). Reference lists of included studies will be screened and forward and backward citation searching of included articles will be conducted. We will include reviews and original studies which describe the consequences for individuals labelled with a non-cancer health condition. We will exclude hypothetical research designs and studies focused on the consequences of labelling cancer conditions, intellectual disabilities and/or social attributes. We will conduct thematic analyses for qualitative data and descriptive or meta-analyses for quantitative data where appropriate.

Ethics and dissemination Ethical approval is not required for a scoping review. Results will be disseminated via publication in a peer-reviewed journal, conference presentations and lay-person summaries on various online platforms. Findings from this systematic scoping review will identify gaps in current understanding of how, when, why and for whom a diagnostic label is important and inform future research.

INTRODUCTION

The diagnosis of physical and psychological health conditions is increasing in prevalence.^{1–5} Diagnoses often occur in the context of individuals seeking to identify and treat symptoms. However, diagnoses can also occur as a result of screening tests where individuals have no discernible signs or symptoms of disease (such as when a routine test determines an individual has hypertension),⁶

Strengths and limitations of this study

- A broad, comprehensive search strategy will be conducted in five electronic databases.
- We will include both qualitative and quantitative studies which will enhance our current understanding of the consequences of health condition labelling.
- Two reviewers will screen 10% of titles and abstracts, extract data and assess the quality of included studies.
- Eligibility will not be limited to specific health conditions, therefore, the consequences identified will be generalisable to health condition labelling more broadly.
- Articles will be limited to peer-reviewed publications and not include grey or theory-based literature.

from unanticipated findings in investigations for other health concerns (such as identifying an anomaly in a person's thyroid when conducting an MRI of the spine)⁷ or, when people are newly diagnosed with a health condition because of changes to diagnostic thresholds or cut-offs for the condition opposed to changes in individual circumstances (such as for gestational diabetes).¹ The value of a diagnosis, particularly in these latter contexts, is not always evident and the risk of overdiagnosis and misdiagnosis is significant.^{1 8 9}

Diagnostic labels provide healthcare professionals with a framework from which to organise and interpret clinical symptom presentations, support clinical decision making through directing treatment decisions, and provide information on possible condition course and overall prognosis.^{10 11} Further, diagnostic labels allow clinicians to assume homogeneity among members of patient groups, in addition to providing an efficient method for health professionals to communicate.¹²

Despite well-meaning intentions, application of diagnostic labels in real-world practice

can be problematic. Diagnostic criteria can often be ambiguous. For example, symptoms of anxiety, such as restlessness, fatigue or difficulty concentrating, may be explained by diagnoses of anxiety, depressive, or bipolar and related disorders.^{13 14} Similarly, chest pain symptoms may be explained by several alternative diagnostic categories such as inflammatory diseases, musculoskeletal conditions or coronary diseases.^{15 16} Lastly, non-specific low back pain is the leading cause of disability worldwide, yet for the majority of people, no pathoanatomical cause can be identified.¹⁷

From the perspective of a patient, a diagnostic label can have a significant impact (negative and positive) on their health outcomes, psychological well-being and behaviour, and can influence how they are viewed and managed by healthcare professionals and are perceived by other members in society (eg, school, workplace).^{3 5 18} In a cohort of over 33 000 adults, individuals who were aware that they had hypertension reported elevated levels of psychological distress compared with those individuals who had hypertension, however, were unaware of this.³ A study investigating the impact of labelling borderline personality disorder on clinician interpretation of patient symptoms found clinicians' prior awareness of a diagnosis of borderline personality disorder, compared to no awareness, resulted in a tendency to frame observations of the individual in terms of the label, and a failure to observe positive behaviours.¹²

Conversely, a diagnostic label may have positive effects on the individual. These include timely referral to necessary healthcare which, in turn, can reduce morbidity and mortality, improve predictions regarding condition progression as well as facilitate access to support, services and resources (eg, diagnosis-based school funding^{19 20} and social support⁵), and provide an explanation and validation of an individual's signs and symptoms. A recent study exploring the impact of chronic fatigue syndrome using hypothetical scenarios of a close friend's diagnosis reported a label of chronic fatigue, compared with no label, elicited higher sympathetic responses from participants, greater potential social support and greater support for active treatment.⁵

The terms used to describe a diagnostic label have been found to influence an individual's behaviour, psychological well-being and treatment preferences. Specifically, a diagnostic label that uses medicalised and precise terminology compared with a description of symptoms has been found to result in higher patient anxiety, greater perceived severity of the condition and a patient preference of more invasive treatments.^{18 21–23} This has been evidenced in conditions including gastro-oesophageal reflux disease, polycystic ovary syndrome, bone fracture and low back pain.^{18 21–23} Similarly, research suggests that patients diagnosed with diabetes demonstrate a propensity to medical interventions, including insulin use, oral medication taking and blood glucose monitoring, compared to less invasive interventions, such as changes to diet and exercise practices.²⁴ The use of a medicalised

label over a descriptive label for a health condition is also suggested to result in increased confidence in the medical professional and greater adoption of sick role behaviour.²⁵ Alternatively, use of descriptive labels for health conditions was found to be associated with greater patient ownership of the condition.²⁵

To date, our understanding of the consequences and impacts of a diagnostic label has been limited to a single perspective (eg, patient, healthcare practitioner), single condition (eg, gastro-oesophageal reflux disease), or restricted to a specific study design (eg, hypothetical research design) and a comprehensive synthesis of this information across health conditions is lacking.^{26 27} Further, exploring the real-world impact of a diagnostic label including benefits and harms has received little attention.^{22 28 29} Therefore, the aims of this systematic scoping review are to systematically review original and synthesised research exploring the consequences of being given a label for a health condition to:

1. Identify the range of potential consequences of labelling of health conditions from an individual, societal and health practitioner viewpoint.
2. Explore why, for whom, and in what contexts labelling of health conditions is, or is not, influential.
3. Evaluate the methods used to study the impact of labelling health conditions.

METHODS AND ANALYSIS

Scoping reviews are suggested as an alternative to systematic reviews, allowing for a broader examination and synthesis of existing research and identification of research gaps.³⁰ The proposed systematic scoping review will adhere to the Joanna Briggs Methodology for Scoping Reviews,³¹ and adhere to the Preferred Reporting Items for Systematic Reviews and Meta-Analyses Extension for Scoping Reviews (PRISMA-ScR).³² This approach was selected to allow sufficient documentation of the review process. An initial search was conducted in August 2019 to pilot the screening process and data extraction spreadsheet. The review is expected to be complete by October 2020.

Consumer involvement in scoping review design and framework development

A convenience sampling survey was conducted to explore the public's opinion of the consequences of a diagnostic label for health conditions. In April 2019, we posted the questions 'What are the labelling consequences of being given a health diagnosis? We're working up a list and so far we have: anxiety, relief, more tests, stigma, medico-legal problems. What else?' on two social media platforms, Facebook and Twitter. Responses on Facebook included 14 comments from 6 individuals, while Twitter responses resulted in 45 comments from 40 individuals. The results of this survey were used to inform the development of the search strategy, inclusion and exclusion criteria, data extraction form and an initial qualitative

Table 1 Coding framework of social media responses

Name	Description	Examples
Psychological impact	Psychological impact of diagnosis	<ul style="list-style-type: none"> ► Increased self-understanding ► Stigma (internalised stigma (self); perceived stigma from others) ► Increased psychological distress (anxiety, depression, phobia, worry, fear, stress)
Support	Support gained or lost as a result of diagnosis	<ul style="list-style-type: none"> ► Support groups: increased support of others with a similar diagnosis; network with other patients ► Others less respectful, more withdrawn and judgemental
Development		
Education	Seeking to become more informed on diagnoses, testing, intervention	<ul style="list-style-type: none"> ► Increase in health literacy due to motivation to find about treatment options
Planning	Forward planning and decision making as a result of diagnosis	<ul style="list-style-type: none"> ► Ability to plan—even if there may not be treatment, provides an opportunity to get affairs in order (eg, wills)
Lifestyle		
Behaviour	Behaviour changes as a result of diagnosis	<ul style="list-style-type: none"> ► Change diet ► Change lifestyle
Employment	Effect of diagnosis on employment	<ul style="list-style-type: none"> ► More sick days; time off work; absenteeism
Financial	Effect of diagnosis on finances	<ul style="list-style-type: none"> ► Diagnosis provides access to funds (eg, Medicare, National Disability Insurance Scheme (NDIS), insurance)
Service use		
Testing	Further assessment and tests as a result of diagnosis (including testing of family)	<ul style="list-style-type: none"> ► Seeking more investigations ► Scans and imaging ► Encourages screening of other family members at low-risk of the condition
Treatment	Treatment and intervention as a result of diagnosis	<ul style="list-style-type: none"> ► Clear treatment path; clearer treatment protocols ► Side-effects (of medication: sexual, agitation, suicidality, emotional numbing)

framework (table 1) that will be used in this scoping review.

Inclusion criteria

Peer-reviewed publications including systematic or literature reviews and original studies which describe the perceived consequences for individuals labelled with a non-cancer health condition will be included. Perceived consequences can be reported from the perspectives of the individuals, their family, friends and/or carers or health professionals. As we expect individuals labelled as having a cancer condition will have different experiences to those labelled with general health conditions, studies that focus on these samples are excluded. Similarly, studies that report the consequence of labels for people using hypothetical case scenarios, or individuals with intellectual disabilities and/or social attributes such as race, sexual identity or orientation will also be excluded (see table 2 for more details).

Search strategy

A structured search, developed in collaboration with an information specialist, of five electronic databases (PubMed, Embase, PsycINFO, Cochrane, CINAHL) will be conducted to identify relevant publications. Databases will be searched from their inception. Preliminary

searches were conducted in August 2019 and will be updated in June 2020. Reference lists of included articles will be searched and forward citation searching of included articles will be conducted. The full search strategy to be used is reported in the online supplemental material.

Study selection

Titles and abstracts of 10% of articles retrieved through electronic and manual searches will be independently screened by two reviewers (RS and LK) for eligibility against the pre-specified inclusion criteria. Disagreements will be resolved through discussion and consultation with additional reviewers as required. When interrater reliability (κ) >0.8 is achieved for the screened studies, remaining studies will continue to be screened by one reviewer (RS). Articles identified as unclear for inclusion will be reviewed by an additional reviewer as required.

Data extraction and framework revision and validation

Full-text publications will be obtained and the reference list reviewed. Any relevant studies found in the reference list will be screened (RS) for inclusion against the same inclusion criteria. Additional uncertainties regarding eligibility for inclusion will be resolved through discussion with other reviewers (RT or PG). Two reviewers (RS and

Table 2 Inclusion criteria

Aspect	Inclusion criteria	Exclusion criteria
Types of studies	Original studies (cohort, case-controlled, cross-sectional, observational, Randomised Controlled Trial (RCT), focus groups)* Synthesised studies (systematic reviews)	Protocols (final study to be sourced) Opinion pieces and commentaries Quantitative cohort, case-controlled and cross-sectional studies without comparator Hypothetical or vignette-based studies
Participants	Individuals, no age limit (eg, adults, children, family, carers, health professionals, general public)	Animal subjects
Condition	Screening and/or labelling of physical or psychological health condition/s Self-reported (eg, response to questions such as 'has your GP ever told you that you have hypertension?') Health condition confirmed (eg, medical examination and testing completed as part of the study)	Labelling of intellectual impairment, race, ethnicity, sexual identity or sexual orientation Labelling of cancers and cancer-related conditions Self-reported conditions provided by unqualified professional (eg, physiotherapist telling patient they have hypertension) Self-identified conditions (eg, googling of symptoms, no confirmation by a medical professional)
Outcomes	Consequences, impact, effects of the health condition label or diagnosis Perceived harms and/or benefits (eg, illness burden) ► Lived experience ► Psychological impact (eg, anxiety, quality of life) ► Behaviour change (eg, participation in employment) ► Support (eg, financial, social support)	Effect of the health condition (eg, disease mechanisms/traits) Gene labelling Food or nutrition labelling Drug effects/effectiveness Intervention effects/effectiveness (eg, intervention A vs intervention B)
Language	No language limitations	–
Date	No date limitations	–

*Studies using qualitative methodologies do not require multiple group comparisons for inclusion.

ZAM) will independently extract study data from 10% of included qualitative studies and 10% of included quantitative studies using a standardised data extraction form that will be piloted prior to use. Conflicts will be resolved by a third party as required. Once interrater reliability (κ) >0.8 is achieved for extracted data, one reviewer (RS) will undertake the remaining data extraction in a staged process, with this detailed below in the *extraction* sections. The same staged process will be used when extracting data from quantitative and qualitative studies. Queries will be resolved through discussion with a second reviewer (ZAM).

The methods used to extract and synthesise the results of qualitative and quantitative studies are based on the meta-analytic techniques described by Sandelowski *et al*,³³ Thomas and Harden³⁴ and Timulak.³⁵ Extracted data will include study characteristics (author, journal, year of publication, study country and setting), participant characteristics (number of participants, age, health condition) and quantitative or qualitative outcomes (consequences, impact, effects of the diagnostic label).

Qualitative data extraction

Data for thematic analysis will be extracted from the published study and include the authors abstracted themes and relevant, supporting quotes, reported in the primary study. Direct quotes will not be extracted in isolation to ensure data 'retains its meaning' and is not

interpreted or extracted out of the context of the primary study. This qualitative meta-analysis technique has been described by Sandelowski *et al*,³³ Thomas and Harden³⁴ and Timulak.³⁵

Quantitative data extraction

For studies with quantitative outcomes, extracted data will include, the text and numerical data from the results section reporting primary outcomes.³⁶ Examples of potential quantitative measures include the Short Form Health Survey (SF-36),³⁷ General Health Questionnaire (GHQ)³⁸ or work absenteeism.

Qualitative data analysis

The coding framework developed from social media responses will be iteratively revised using eligible studies retrieved by the electronic database search. Qualitative data will initially be extracted from a random sample of one-third of included qualitative studies and mapped to the coding framework. This framework will be expanded as additional themes emerge. The second third of included qualitative studies will be randomly selected, data extracted and mapped to the updated coding framework until data thematic saturation has been achieved. If new themes are still emerging at this point, the remaining third of qualitative studies will be analysed against the developed framework. Data saturation will be defined using indicative thematic saturation, which states data

saturation as the non-emergence of new codes or themes that will result in expansion or revision of the coding framework.³⁶

Quantitative data analysis

Quantitative data will be summarised narratively.³³ For example, we will collate data from studies that used the SF-36, GHQ or absenteeism and summarise the findings reported in the results section. Unlike the large volume of expected qualitative studies, fewer quantitative studies with comparators are expected. Therefore, outcomes from all of the included quantitative studies will be extracted and, if possible, tabulated by condition and outcomes.

Patient and public involvement

This scoping review has no direct patient involvement.

PRESENTATION OF RESULTS

We will present study selection in a flow diagram according to PRISMA-ScR and included studies will be described in a table of characteristics.³² Results will be aggregated as appropriate. Results pertinent to the consequences of labelling of health conditions will be collated to expand those provided in table 1, with empirical data regarding the rate and severity of these consequences also examined. Additionally, a compendium of methods used to elicit the consequences of health condition labelling will be developed and methodology appraised. For quantitative studies, extracted data will be tabulated in a descriptive and/or statistical manner depending on the availability of data (ie, number of studies reporting similar outcome measures or measurement of similar constructs, such as quality of life or symptoms of anxiety) and degree of heterogeneity between studies (eg, population, clinical conditions). Should data not support a meta-analysis, results from studies which provide quantitative data will be reported in a narrative synthesis and interpreted alongside results from qualitative studies. Qualitative data will be analysed using developed frameworks (see table 1) and following established protocols for the qualitative analysis of information in the social sciences.³⁹ The characteristics and results of all included studies will be reported in tables and summarised in text.

Ethics and dissemination

As the current study is a systematic scoping review protocol, ethics is not required. Dissemination of results will be made public via peer-reviewed publications, conference presentations and lay-person summaries on various on-line platforms (eg, The Conversation).

Twitter Rae Thomas @rthomasEBP

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ZAM contributed to screening and data analysis. RS, ZAM, RT and PG contributed to the drafting of the manuscript and all authors approved the final version.

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ORCID iDs

Rebecca Sims <http://orcid.org/0000-0002-1604-8354>

Luise Kazda <http://orcid.org/0000-0003-4105-0402>

Zoe A Michaleff <http://orcid.org/0000-0002-0360-4956>

Paul Glasziou <http://orcid.org/0000-0001-7564-073X>

Rae Thomas <http://orcid.org/0000-0002-2165-5917>

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