Journal of Clinical Epidemiology 158 (2023) 34−43

Journal of Clinical Epidemiology

REVIEW ARTICLE

A systematic review of studies reporting the development of core outcome sets for use in routine care

Anna Kearney[a,*], Elizabeth Gargon[a], James W. Mitchell[b], Stephen Callaghan[c], Farheen Yameen[c], Paula R. Williamson[a], Susanna Dodd[a]

[a]*Department of Health Data Science, University of Liverpool, Liverpool, UK*
[b]*Institute of Systems, Molecular and Integrative Biology, University of Liverpool, Liverpool, UK*
[c]*NIHR ARC NWC public advisor, University of Liverpool, Liverpool, UK*

Accepted 14 March 2023; Published online 21 March 2023

Abstract

Objectives: Core outcome sets (COS) represent the minimum health outcomes to be measured for a given health condition. Interest is growing in using COS within routine care to support delivery of patient-focused care. This review aims to systematically map COS developed for routine care to understand their scope, stakeholder involvement, and development methods.

Methods: Medline (Ovid), Scopus, and Web of Science Core collection were searched for studies reporting development of COS for routine care. Data on scope, methods, and stakeholder groups were analyzed in subgroups defined by setting.

Results: Screening 25,301 records identified 262 COS: 164 for routine care only and 98 for routine care and research. Nearly half of the COS (112/254, 44%) were developed with patients, alongside input from experts in registries, insurance, legal, outcomes measurement, and performance management. Research publications were often searched to generate an initial list of outcomes (115/198, 58%) with few searching routine health records (47/198, 24%).

Conclusion: An increasing number of COS is being developed for routine care. Although involvement of patient stakeholders has increased in recent years, further improvements are needed. Methodology and scope are broadly similar to COS for research but implementation of the final set is a greater consideration during development.

Keywords: Core outcome sets; Routine care; Healthcare evaluation; Health outcomes; COMET; Clinical audit; Value-based healthcare; Patient-centered outcome measures

1. Introduction

The aim of every healthcare system is to improve health outcomes for patients and the public [1,2]. Health outcomes are defined as the effect of an intervention or treatment on a person's health or quality of life or the progression of a health condition if no intervention is given [3].

Since the development of organized healthcare, there has been interest in collecting and analyzing data on patient health outcomes to improve health interventions and practices [3−5]. Measurement of patient health outcomes can be used for research purposes or within routine care for individual clinical decision-making between patients and clinicians, for auditing clinical practice and supporting quality improvement programs [6].

Health outcomes are frequently measured in research to provide evidence on the effectiveness and safety of new practices and treatments. For any given clinical condition,

Author contributions: Anna Kearney: Conceptualization, methodology, data curation, project administration, investigation, and writing−original draft. Elizabeth Gargon: Methodology, investigation, and writing−review and editing. James W Mitchell: Investigation and writing−review and editing. Stephen Callaghan: Methodology and writing−review and editing. Farheen Yameen: Methodology and writing−review and editing. Paula R Williamson: Conceptualization, methodology, writing−review and editing, supervision, and funding acquisition. Susanna Dodd: Conceptualization, methodology, writing−review and editing, supervision, and funding acquisition.

Declarations of interest: J.W.M. is involved in developing a COS for research and is acting as a consultant for an ICHOM expert panel developing a COS for routine clinical practice. J.W.M. was not involved in reviewing any ICHOM publications for this review. P.W. chairs the COMET Management Group. All other authors have no competing interests.

* Corresponding author. Health Data Science, University of Liverpool, Block F Waterhouse Building, 1-5 Brownlow Street, Liverpool, UK L69 3GL. Tel.: +1-51-794-9719.

E-mail address: a.kearney@Liverpool.ac.uk (A. Kearney).

https://doi.org/10.1016/j.jclinepi.2023.03.011

What is new?

Key findings

- Only 44% of COS for routine care included patient stakeholders but this may be improving.

What this adds to what was known?

- What this adds toMethodology is similar to COS for research except feasibility of implementation is a key consideration.
- These findings are the first steps in deciding if separate COS is needed for research and routine care.

What is the implication and what should change now?

- Next steps are to assess the influence of setting on outcome selection.

there is a vast number of potential health outcomes that can be assessed across a range of domains such as physiological outcomes, physical functioning, social functioning, emotional wellbeing, quality of life, resource use, and adverse effects [7]. Consequently, clinical trials within the same health condition would often measure different outcomes preventing comparison of studies [8,9]. Core Outcome Sets (COS) have been developed to address this, reduce research waste, and minimize biased reporting [10]. A COS is a minimum set of health outcomes that should be measured in every clinical trial for a particular condition [11]. Well-designed COS includes patients, clinicians, and researchers in the process of deciding which outcomes are most important and should be included in the set. Although uptake varies across different health areas, consideration of COS is now part of the SPIRIT 2013 protocol reporting guidelines and has been encouraged by several funders including the UK National Institute of Health and Care Research Health Technology Assessment program [12,13]. Consequently, there is a growing interest in using COS within routine care to support patient-focused care. In the most recent update of the systematic review of COS for research, 27% of all newly identified COS were developed for use in both routine care and research, up from 11% across previous reviews [14].

One of the likely drivers of the increased interest in using COS within routine care is the concept of Value Based Health Care (VBHC) which is gaining traction internationally. VBHC proposes focusing healthcare around delivering the health outcomes that matter most to patients to create the biggest impact from the resources available [15]. The key principles of organizing healthcare around cycles of care and measuring patient health outcomes to benchmark impact [16,17] align strongly with COS. The International Consortium of Health Outcome Measurement (ICHOM) [18] have developed several sets of ''patient-centered outcome measures'' for use with VBHC [19–23] which are similar in aim to COS.

Measurement of patient health outcomes within routine care is not new [3,24] and health outcomes are collected alongside data on patient demographics, healthcare processes, and structures to assess healthcare effectiveness. There are likely to be many more sets of health outcomes that are comparable to COS given the different initiatives and organizations seeking to harmonize data collection [24–26]. Although some sets focus solely on health outcomes [24], others contain COS alongside demographic, treatment, and administrative data [27,28]. Consequently, it is unclear how many COS for routine care exist and how a well-designed COS for this setting should be defined.

COS developed for use in research are regularly mapped through annual systematic reviews conducted by the Core Outcome Measures in Effectiveness Trials (COMET) initiative [11,29–32] and included in a free online database (https://www.comet-initiative.org). The COMET database plays an important role in supporting uptake of COS within clinical trials [13] and avoiding duplication of sets [33]. However, no such mapping exercise and curation exists for COS for routine care.

This study aims to systematically map COS developed for use in routine care without restriction on health area, intervention, or geographical setting.

2. Methods

A protocol for this review was published a priori within PROSPERO [34].

2.1. Search strategy and identification of studies

A search strategy was developed for Medline (Ovid) (from 1946) with the input of an information specialist (Supplementary material). The strategy was tested and refined against a sample of 37 eligible papers that had previously been identified in COMET reviews [11,29–32] before being adapted for use in Scopus and Web of Science Core Collection (SCI-expanded, SSCI, CPCI-S, CPCI-SSH, ESCI) (from 1900). Searches were run between May 13 and 17, 2021 with no restriction on dates or language. Results were combined and duplicates removed in Endnote. Additional papers were identified through reference checks undertaken during the full-text review and searches of websites (Supplementary material). The COMET database was searched on February 24, 2022 for ''COS for practice'' and cross-referenced to the systematic review results.

2.2. Selection of articles

Title and abstract screening was undertaken independently by two reviewers (A.K. and E.G.). Full-text papers

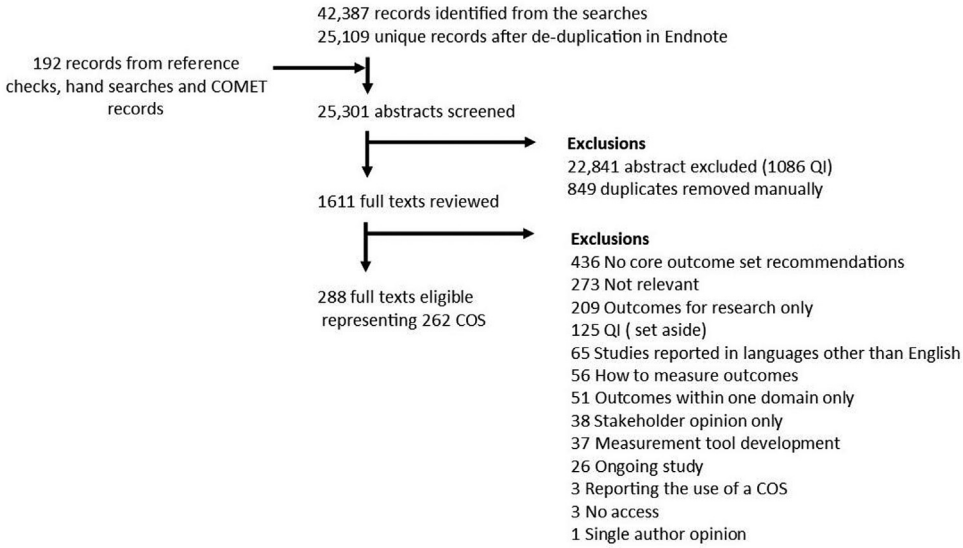

Fig. 1. PRISMA table.

were then obtained for all potentially eligible papers and assessed independently by A.K. and E.G. A moderation process was undertaken to ensure consistency. Two hundred abstracts and 50 full texts were dual-reviewed by both A.K. and E.G. before the remaining papers were split and reviewed by one author. A.K. and E.G. met regularly to resolve any uncertainties and any disagreements were discussed with the wider team (S.D. and P.W.).

2.3. Inclusion and exclusion criteria

Eligible studies reported the development of a COS for use in routine care. For the purposes of this review, outcomes for routine care were defined as data collected as part of clinical practice and not solely for the purposes of research. This would include outcomes collected for individual clinical decision-making or inclusion in patient health records, clinical audits, quality improvement, and VBHC delivery. Studies reporting the development of a COS for use in both routine care and research were included. Minimum datasets and other core datasets were included if they contained a set of outcomes within them. Papers describing the development of minimum datasets for registries, which included a COS, were included due to the broad role of registries globally in health data collection.

The following studies were excluded.

- COS developed solely for use in research studies.
- COS designed to cover only one outcome domain, for example, physical functioning.
- Outcome recommendations from a single author.

These eligibility criteria mirror those used in the systematic review of COS for research, where COS are defined as considering a range of health outcomes across multiple outcome domains (e.g., physical function, quality of life, physiological signs and symptoms, resource impact) with the final set agreed by consensus among more than one person.

2.4. Changes to the protocol

Originally, studies describing the development of quality indicators (QI) were to be eligible in the review where they included health outcomes. However, due to the breadth of QI identified during screening, it was felt that further work was needed to establish where QI include the equivalent of a COS. Consequently, QI identified in the screening process have been set aside for future review. Additionally, given the number of eligible COS, analysis of outcomes within the COS will be reported in a companion paper, alongside investigation of different document types, for example, minimum datasets.

2.5. Data extraction

Data were extracted by A.K. and J.W.M. using a piloted data extraction form on the scope of the COS (health area, population, interventions), development methods, and stakeholders involved in the consensus process. Data extraction was designed to mirror existing data collected by COMET within their systematic review of COS for research [14] to enable future comparison.

Full quality and risk of bias assessments were not possible for this review. Although standards for development and reporting of COS for research exist [35–38], not all of them are applicable to routine care such as the key stakeholders to be included in the consensus process. Instead data extraction included the availability of a

published protocol; development methods; and the involvement of patients, carers, or patient organizations (patient stakeholders) as indicators of quality.

2.6. Analysis

Studies were grouped as per setting (COS designed for use in routine care only; COS designed for use in routine care and research). For COS developed for use in registries, the purpose of the registry was categorized as supporting research, routine care, or both to assign them to one of the two subgroups. Descriptive statistics for eligible articles are reported within each group. Results were compared against previously published systematic reviews of COS developed for use in research [11,14,29–32].

Analysis was undertaken in SAS 9.4.

3. Results

The search strategies identified 42,387 records (Fig. 1). A total of 25,301 abstracts were reviewed and 1,611 full texts assessed. Two hundred and eighty eight papers representing 262 COS were eligible for inclusion (Supplementary Table 1), of which 164 (63%) were for use in routine care only and 98 (37%) were for use in research and routine care. Eligible papers were published between 1989 and 2022.

COS covered a range of health conditions (Table 1 and Supplementary Table 2) but were most frequently designed for use in heart and circulation (35/262, 13%), cancer (30/262, 11%), and orthopedics and trauma (29/262, 11%).

Sixty percent of all COS (157/262) included recommendations on how the outcomes should be measured.

3.1. COS development methods

A published protocol was cited in 18/262 (7%) of COS, 4/164 (2%) for routine care, and 14/98 (14%) for routine care and research. Four studies did not report methods for developing COS. More than three-quarters (198/258, 77%) used multiple methods to decide which outcomes should be in the set. However, the Delphi survey was the most frequently reported consensus method for studies that used a single method (21/60, 35%) and studies using multiple methods (137/198, 70%) (Supplementary Table 5).

Of the 198 (76%) studies that reported methods for generating the initial list of outcomes for consideration, searching research publications was the most frequent approach (115/198, 58%) (Table 2). COS for routine care only were more than twice as likely to search routine care records but this was still low at only 30% (38/127 COS). Patient perspectives were more frequently incorporated within COS for research and routine care (24/71, 34% compared to 23/127, 18%) through interviews, focus groups, or review of qualitative literature.

COS for routine care only were also more likely to consider factors other than the importance of the outcome when selecting which outcomes should be included in the set (61/164, 37% compared to 21/98, 21%). Where reported, feasibility of data collection followed by availability of acceptable measures were the most frequent considerations.

3.2. Stakeholders involved in COS development

Studies involved stakeholders in the COS development process from across continents (Supplementary Table 6). The median (interquartile range) of number of countries was 1 [1, 9], ranged 1–68 countries in COS for routine care only, and 5 [1, 10], ranged 1–97 countries in COS for research and routine care.

Eight COS (of which six were for routine care only) did not report stakeholder groups. Clinical experts were involved in 245/254 (96%) COS (Table 3). Service providers were involved in 22/158 (14%) of COS for routine care only but service commissioner involvement was much lower at 6/158 (4%). Additional stakeholders identified in the review included information specialists, registry experts, social workers, outcomes specialists (e.g., those with experience in selecting and using quality of life measures or patient-reported outcome measures), insurance experts, legal exports, and people with expertise in performance management.

Just less than half the COS (112/254, 44%) included patient stakeholders or patient representatives in the COS development process. The number of COS published each year is increasing from 2013 (Fig. 2) but only in 2020 and 2021 does the percentage of studies involving patients outweigh those not including patient stakeholders. Of the 112 COS with patient stakeholders, 21 (19%) reported the demographics of patient stakeholders and only eight (7%) reported any methods for maximizing the diversity of patient stakeholders, for example, optional paper Delphi or survey, use of wheelchair accessible venue, or inviting patients from a range of clinics or organizations (Supplementary Table 7). Two of these included more detailed methods for engaging patients who might traditionally struggle to be involved due to their health condition, language barriers, or digital literacy.

Most patient stakeholders were involved through online activities during COS development (survey/Delphi 61/112, 54% or meetings 39/112, 35%) (Supplementary Table 8). Methods for identifying and inviting patient stakeholders were poorly reported. Where reported, patient organizations (46/71, 65%) were the most frequent means of identifying patients or patient representatives and e-mail was the most frequent mode of invitation (15/32, 47%).

4. Discussion

A systematic review has identified 262 COS developed for use in routine care which have been added to the

Table 1. Characteristics of COS, overall and by subgroup

COS scope	Routine care only (n = 164)	Routine care and research (n = 98)	All (n = 262)
Health area[a,b]			
Heart and circulation	23 (14%)	12 (12%)	35 (13%)
Cancer	22 (13%)	8 (8%)	30 (11%)
Orthopedics and trauma	13 (8%)	16 (16%)	29 (11%)
Rheumatology	14 (9%)	7 (7%)	21 (8%)
Neurology	11 (7%)	9 (9%)	20 (8%)
Infectious diseases	10 (6%)	2 (2%)	12 (5%)
Lungs and airways	4 (2%)	8 (8%)	12 (5%)
Blood disorders	5 (3%)	6 (6%)	11 (4%)
Child health	9 (5%)	2 (2%)	11 (4%)
Effective practice/health systems	9 (5%)	1 (1%)	10 (4%)
Eyes and vision	4 (2%)	6 (6%)	10 (4%)
Population age			
Not reported explicitly	118 (72%)	53 (54%)	171 (65%)
Adults	22 (13%)	17 (17%)	39 (15%)
Children	15 (9%)	16 (16%)	31 (12%)
Adults and children	9 (5%)	12 (12%)	21 (8%)
Population sex			
Either	158 (96%)	92 (94%)	250 (95%)
Female	3 (2%)	4 (4%)	7 (3%)
Male	3 (2%)	2 (2%)	5 (2%)
Health intervention			
Not reported explicitly	73 (45%)	48 (49%)	121 (46%)
Surgery	19 (12%)	14 (14%)	33 (13%)
All interventions	16 (10%)	10 (10%)	26 (10%)
Other[c]	14 (9%)	10 (10%)	24 (9%)
Nursing	13 (8%)	0 (0%)	13 (5%)
Multiple interventions[c]	12 (7%)	1 (1%)	13 (5%)
Health program delivery	7 (4%)	1(1%)	8 (3%)
Drug	3 (2%)	3 (3%)	6 (2%)
Behavioral	3 (2%)	2 (2%)	5 (2%)
Exercise/physiotherapy	2 (1%)	2 (2%)	4 (2%)
Rehabilitation	1(1%)	3 (3%)	4 (2%)
Device	0 (0%)	2 (2%)	2 (1%)
Healthcare transition	0 (0%)	2 (2%)	2 (1%)
Vaccine	1 (1%)	0 (0%)	1 (<1%)
Geographical location where COS to be applied			
Geographical location not specified	68 (41%)	63 (64%)	131 (50%)
Single country[d]	45 (27%)	16 (16%)	61 (23%)
International	42 (26%)	13 (13%)	55 (21%)
Continent[e]	2 (1%)	4 (4%)	6 (2%)
Region[f]	3 (2%)	1 (1%)	4 (2%)
Countries[g]	2 (1%)	1 (1%)	3 (1%)
LMIC	2 (1%)	0 (0%)	2 (1%)
Measurement (“What” and “how” to measure)			
Decided what to measure and how to measure it at the same time (one stage)	67 (41%)	44 (45%)	111 (42%)
Only decided what to measure	38 (23%)	29 (30%)	67 (26%)

(*Continued*)

Table 1. Continued

COS scope	Routine care only (n = 164)	Routine care and research (n = 98)	All (n = 262)
Decided what to measure and then how to measure it (two stages)	32 (20%)	14 (14%)	46 (18%)
Decided what to measure, with some discussion of how to measure it but no recommendations	15 (9%)	9 (9%)	24 (9%)
Unclear[h]	12 (7%)	2 (2%)	14 (5%)
Document type[b]			
COS was not part of a wider document	89 (54%)	70 (71%)	159 (61%)
COS was within a Minimum Data Set (MDS)	56 (34%)	25 (26%)	81 (31%)
COS was within a Nursing Outcomes Classification (NOC) set	11 (7%)	0 (0%)	11 (4%)
COS was within a Clinical Guideline	6 (4%)	1 (1%)	7 (3%)
COS was within Common Data Element (CDE)	2 (1%)	2 (2%)	4 (2%)

[a] Areas shown with $\geq$ 4%. A full set of results for health area are available in Supplementary Table 2.
[b] COS could be classified as more than one health area and document type. Two COS covered three health conditions and 15 COS covered two health areas. Six COS were within two different document types.
[c] See Supplementary Table 3 for a breakdown of other interventions and multiple interventions.
[d] See Supplementary Table 4 for a breakdown of countries.
[e] One COS for use in routine care that was to be used in North America. The remaining five COS were for use in Europe.
[f] Three COS for routine care were to be used in Colorado and two Iranian Provinces. One COS for research and routine care was for use in South West UK.
[g] Two COS were to be used in Australia and New Zealand (one for routine care only and one for routine care and research). One COS for routine care was for use in Sweden, Denmark, Norway, Finland, and the Netherlands.
[h] For 14 COS we were unable to ascertain whether the COS included definitions of how to measure the outcomes due to poor reporting.

Table 2. Reporting of consensus methods by subgroup

Consensus methods reported	Routine care only (n = 164)	Routine care and research (n = 98)	All (n = 262)
Reported how an initial list of outcomes was created. If yes	127 (77%)	71 (72%)	198 (76%)
a) Were outcomes identified from routine care records?[a]	38 (30%)	9 (13%)	47 (24%)
b) Were outcomes identified from research?[b]	68 (54%)	47 (66%)	115 (58%)
c) Were patient views included?[c]	23 (18%)	24 (34%)	47 (24%)
Consensus definition reported	93 (57%)	58 (59%)	151 (58%)
Criteria reported for adding/dropping domains	65 (40%)	45 (46%)	110 (42%)
COS development considered factors other than the importance of the outcome	61 (37%)	21 (21%)	82 (31%)
Feasibility of data collection	47 (77%)	12 (57%)	59 (72%)
Availability of acceptable measures	14 (23%)	6 (29%)	20 (24%)
Frequency of outcome	12 (20%)	1 (5%)	13 (16%)
Outcome is modifiable	8 (13%)	3 (14%)	11 (13%)
Existing measures	8 (13%)	2 (10%)	10 (12%)
Able to capture change	6 (10%)	2 (10%)	8 (10%)
Clarity/outcome is understandable	3 (5%)	2 (10%)	5 (6%)
Evidence for use of the outcome	4 (7%)	1 (5%)	5 (6%)

[a] Two COS for routine care and one for routine care and research were unclear.
[b] Ten COS for routine care and three COS for routine care and research were unclear.
[c] Five COS within routine care and one COS within routine care and research were not clear.

Table 3. Stakeholder groups involved in COS development

Stakeholders	Routine care (n = 158)[a]	Routine care and research (n = 96)[b]	All (n = 254)
Clinical experts (all)	151 (96%)	94 (98%)	245 (96%)
Clinical experts	150 (95%)	93 (97%)	243 (96%)
Clinical experts with research experience	28 (18%)	28 (29%)	56 (22%)
Patient representation (all)	65 (41%)	47 (49%)	112 (44%)
Patients	54 (34%)	35 (36%)	89 (35%)
Patient support group representatives	25 (16%)	17 (18%)	42 (17%)
Carers	14 (9%)	17 (18%)	31 (12%)
Children	6 (4%)	7 (7%)	13 (5%)
Service users	2 (1%)	3 (3%)	5 (2%)
Nonclinical experts			
Nonclinical researchers	22 (14%)	23 (24%)	45 (18%)
Epidemiologists	23 (15%)	8 (8%)	31 (12%)
Statisticians	14 (9%)	3 (3%)	17 (7%)
Methodologists	8 (5%)	6 (6%)	14 (6%)
Academic researchers	7 (4%)	6 (6%)	13 (5%)
Economists	6 (4%)	3 (3%)	9 (4%)
Authorities			
Government agencies	9 (6%)	7 (7%)	16 (6%)
Service commissioners	6 (4%)	8 (8%)	14 (6%)
Regulatory agencies	2 (1%)	10 (10%)	12 (5%)
Policy makers	4 (3%)	4 (4%)	8 (3%)
Charities	3 (2%)	2 (2%)	5 (2%)
Industry			
Pharma	2 (1%)	8 (8%)	10 (4%)
Device manufacturers	1 (1%)	3 (3%)	4 (2%)
Other			
Service providers	22 (14%)	7 (7%)	29 (11%)
Information specialists	14 (9%)	8 (8%)	22 (9%)
Registry experts	15 (9%)	6 (6%)	21 (8%)
Social worker	6 (4%)	7 (7%)	13 (5%)
Conference participants[c]	7 (4%)	4 (4%)	11 (4%)
QOL/PROM specialists	6 (4%)	4 (4%)	10 (4%)
Insurance experts	9 (6%)	0 (0%)	9 (4%)
Known interest	6 (4%)	2 (2%)	8 (3%)
Quality performance experts	7 (4%)	0 (0%)	7 (3%)
Legal experts	3 (2%)	0 (0%)	3 (1%)
Journal editors	1 (1%)	2 (2%)	3 (1%)
Ethicists	0 (0%)	0 (0%)	0 (0%)

[a] Six COS for routine care did not report the stakeholder group.
[b] Two COS for routine care and research did not report stakeholder groups.
[c] Outcomes were discussed with those attending medical conferences.

COMET database. The mapping exercise demonstrated an increase over time in the number of COS for routine care but less than half included patient stakeholders. Methodology is broadly similar to COS for research but new stakeholders and additional considerations during the development process have been identified.

4.1. Effective involvement of patient stakeholders

The number of COS developed for use in routine care has been increasing since 2013 but only 44% included patient stakeholder groups in the development of the outcome set. This review covers COS created over the last 40 years and inclusion of patients in older publications is unlikely to be

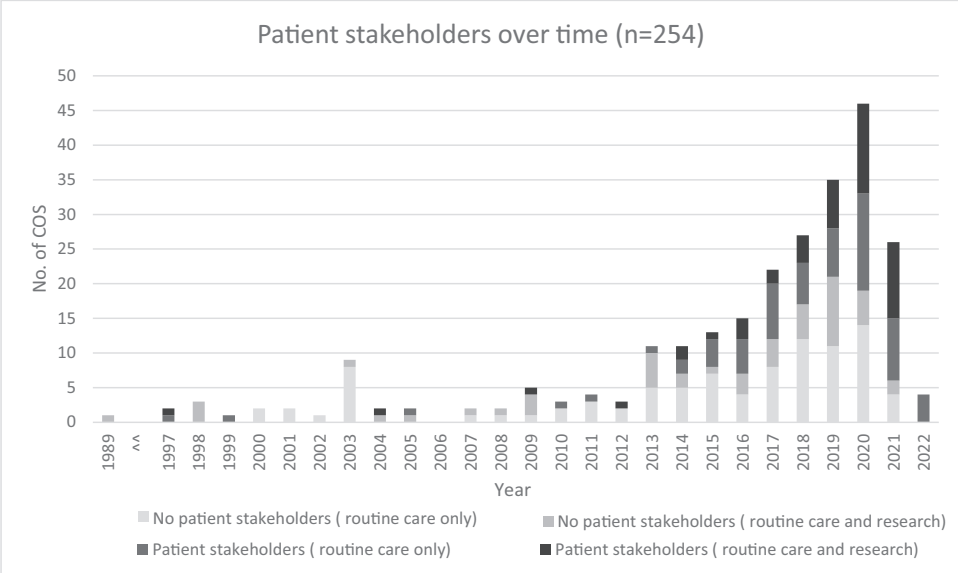

Fig. 2. COS involving patients according to year the study was published.

optimal. Within COS for research, patient involvement has been strongly encouraged such that 76% of newly identified COS for research include patient stakeholder groups [14]. Future updates of this review will be needed to confirm whether the higher number of studies including patients in 2020 and 2021 can be considered a sign of improvement.

Concerns exist among COS developers as to whether outcome selection differs depending on patient characteristics such as place of residence, gender, and socioeconomic status [39]. Ideally, COS should include a diverse range of patient stakeholders [40] that represent the patient population to help address health inequalities. The findings from this review mirror those from COS for research, with patient stakeholders most frequently identified through patient organizations or healthcare settings, invited by e-mail and engaged through online activities [41]. These may impact participation and representativeness both positively and negatively yet patient demographics are infrequently reported [41] hampering evaluation of the overall effect of these methods on representativeness and COS quality. Continued monitoring and promotion of patient participation is needed to maximize the number of well-designed COS for use within patient-focused care. Given the similarities with COS for research, COS for routine care will benefit from existing research exploring how best to include patients in the development process [41–43].

4.2. Development methods compared to COS for research

As expected, healthcare professional stakeholders varied compared to COS for research. Service providers were more commonly included and researchers less so. Newly identified stakeholders included those with expertise in data management and outcome measurement and stakeholders likely to be relevant for specific healthcare systems such as legal experts and insurance experts. Identification of minimum stakeholder groups to be included in COS for routine care is needed. This would promote patient participation but could be challenging given the breadth of application and the variation of healthcare systems globally.

The COS identified in this review were largely similar to COS for research in terms of coverage of health areas and scope. Like COS for research, the COS in this review would benefit from explicit reporting when intended to be used across all interventions and age ranges. Although consensus methods were also similar, considerations around implementation had a larger impact on the development process within COS for routine care. They were much more likely to include how outcomes should be measured (60% compared to 38% in COS for research [11]) and nearly a third considered factors such as feasibility of data collection and availability of measurement tools when selecting outcomes for the set. Despite this, research publications were still the main method for identifying an initial list of outcomes for consideration with few assessing which outcomes are currently measured within routine health records. This is surprising given the need for adequate infrastructure for data collection and the challenges of adapting electronic health records [44,45]. This finding may carryover from methods for COS for research or may represent concerns that health outcomes are currently not well reported within routine records.

4.3. Limitations

This review benefited from an experienced team of reviewers and transparent methods but has several

limitations. First, QI were not included due to the number of other studies identified by the review and the need for further clarity as to when QI are comparable to COS. This is likely to impact our results given that there are potentially a number of QI that might be relevant and will have been developed using similar methodology. Evaluating the studies and comparing the patient health outcomes within them to the results presented here will be an important piece of future work. Identification of COS was challenging given the different datasets and nomenclature. We constructed a broad search strategy and hand-searched relevant records to address this. However, it is possible that some studies may have been missed. Readers are encouraged to contact COMET where this may be the case. It is intended that this review will be updated regularly and any missed studies along with ongoing studies will be included in the future reports. Studies in languages other than English were not included due to lack of resources for translation but only 65/1,611 (4%) were excluded for this reason and not all may have been eligible.

4.4. Future work

This review is the first step in understanding more about COS developed for routine care. Several avenues for future work have been identified including development of guidelines to improve methodology and reporting, identification of minimum stakeholder groups, and assessment of patient representativeness. However, most pertinent is the comparison of outcomes within COS for the same condition but developed for use in different settings to understand whether outcome selection differs by setting [46]. This will inform whether existing COS for research can be applied in routine care or whether they need to be adapted and validated first. This is likely to have a significant impact on research resources and will determine to what extent implementation of COS in routine care may increase availability of routinely collected health outcomes for research purposes.

5. Conclusion

A growing number of COS has been developed for routine care, especially in the last decade. Methodology and scope are broadly similar to COS for research, but feasibility of implementation is a greater consideration when developing the outcome set. Less than half of the studies identified included patient stakeholder groups, although this may be starting to improve. Work is needed to promote the inclusion of patient stakeholder groups so that most future COS are well placed to support evaluation of patient-centered care. The COS identified in this review will facilitate future research to explore the impact of setting on outcome selection to determine whether a single COS is appropriate for use in both research and routine care settings.

Acknowledgments

We acknowledge the work of Michelle Maden in helping develop the core search strategy. This report is independent research funded by the National Institute for Health and Care Research Applied Research Collaboration North West Coast (ARC NWC). The views expressed in this publication are those of the author(s) and not necessarily those of the National Institute for Health and Care Research or the Department of Health and Social Care.

Supplementary data

Supplementary data to this article can be found online at https://doi.org/10.1016/j.jclinepi.2023.03.011.

References

[1] Kelley E, Hurst J. Health care quality indicators project conceptual framework paper. 2006. Available at https://www.oecd.org/els/health-systems/36262363.pdf. Accessed April 11, 2023.
[2] Organisation WH. Health systems responsiveness: World Health Organisation. Available at https://www.who.int/responsiveness/hcover/en/. Accessed March 12, 2021.
[3] Donabedian A. An introduction to quality assurance in health care. New York, NY: Oxford University Press; 2002.
[4] Nightingale F. *Notes on Hospitals: Being Two Papers Read before the National Association for the Promotion of Social Science, at Liverpool, in October 1858* (Cambridge Library Collection - History of Medicine). Cambridge: Cambridge University Press; 2013. https://doi.org/10.1017/CBO9781139867047.
[5] Donabedian A. Evaluating the quality of medical care. Milbank Mem Fund Q 1996;44(3):166−206.
[6] Kampstra NA, Zipfel N, van der Nat PB, Westert GP, van der Wees PJ, Groenewoud AS. Health outcomes measurement and organizational readiness support quality improvement: a systematic review. BMC Health Serv Res 2018;18:1005.
[7] Dodd S, Clarke M, Becker L, Mavergames C, Fish R, Williamson PR. A taxonomy has been developed for outcomes in medical research to help improve knowledge discovery. J Clin Epidemiol 2018;96:84−92.
[8] Miyar J, Adams CE. Content and quality of 10,000 controlled trials in schizophrenia over 60 years. Schizophr Bull 2013;39(1):226−9.
[9] Tugwell P. OMERACT conference on outcome measures in rheumatoid arthritis clinical trials: introduction. J Rheumatol 1993;20:528.
[10] Kirkham JJ, Dwan KM, Altman DG, Gamble C, Dodd S, Smyth R, et al. The impact of outcome reporting bias in randomised controlled trials on a cohort of systematic reviews. BMJ 2010;340:c365.
[11] Gargon E, Gurung B, Medley N, Altman DG, Blazeby JM, Clarke M, et al. Choosing important health outcomes for comparative effectiveness research: a systematic review. PLoS One 2014;9:e99111.
[12] Williamson PR, Barrington H, Blazeby JM, Clarke M, Gargon E, Gorst S, et al. Review finds core outcome set uptake in new studies and systematic reviews needs improvement. J Clin Epidemiol 2022;150:154−64.
[13] Hughes KL, Kirkham JJ, Clarke M, Williamson PR. Assessing the impact of a research funder's recommendation to consider core outcome sets. PLoS One 2019;14:e0222418.

[14] Gargon E, Gorst SL, Matvienko-Sikar K, Williamson PR. Choosing important health outcomes for comparative effectiveness research: 6th annual update to a systematic review of core outcome sets for research. PLoS One 2021;16:e0244878.
[15] Michael EP, Elizabeth Olmsted T. Redefining Health Care : Creating Value-based Competition on Results. Boston, Mass: Harvard Business Review Press; 2006.
[16] Porter ME, Larsson S, Lee TH. Standardizing patient outcomes measurement. N Engl J Med 2016;374:504−6.
[17] Porter ME. A strategy for health care reform–toward a value-based system. N Engl J Med 2009;361:109−12.
[18] ICHOM. International consortium for health outcomes measurement. Available at https://www.ichom.org/patient-centered-outcome-measures/. Accessed April 11, 2023.
[19] Wouters RM, Jobi-Odeneye AO, de la Torre A, Joseph A, Hand I, Wrist Working G, et al. A standard set for outcome measurement in patients with hand and wrist conditions: consensus by the international Consortium for health outcomes measurement hand and wrist working group. J Hand Surg Am 2021;46(10):841−855.e7.
[20] Nijhuis W, Franken A, Ayers K, Damas C, Folkestad L, Forlino A, et al. A standard set of outcome measures for the comprehensive assessment of osteogenesis imperfecta. Orphanet J rare Dis 2021;16(1):140.
[21] Gangannagaripalli J, Albagli A, Myers SN, Whittaker S, Joseph A, Clarke A, et al. A standard set of value-based patient-centered outcomes and measures of overall health in adults. Patient 2022;15(3):341−51.
[22] Verberne WR, Das-Gupta Z, Allegretti AS, Bart HAJ, van Biesen W, Garcia-Garcia G, et al. Development of an international standard set of value-based outcome measures for patients with chronic kidney disease: a report of the international Consortium for health outcomes measurement (ICHOM) CKD working group. Am J kidney Dis 2019;73(3):372−84.
[23] Prevolnik Rupel V, Jagger B, Fialho LS, Chadderton LM, Gintner T, Arntz A, et al. Standard set of patient-reported outcomes for personality disorder. Qual Life Res 2021;30:3485−500.
[24] Moorhead S, Johnson M, Maas ML, Swanson E. Nursing outcomes classification (noc) - e-book : measurement of health outcomes. St. Louis, Missouri: Mosby; 2018.
[25] NIH CDE repository. Available at https://cde.nlm.nih.gov/home. Accessed April 11, 2023.
[26] International Sci core data sets. Available at https://www.iscos.org.uk/international-sci-core-data-sets. Accessed April 11, 2023.
[27] Schults J, Kleidon T, Chopra V, Cooke M, Paterson R, Ullman AJ, et al. International recommendations for a vascular access minimum dataset: a Delphi consensus-building study. BMJ Qual Saf 2020;30(9):722−30.
[28] Cadilhac DA, Bagot KL, Demaerschalk BM, Hubert G, Schwamm L, Watkins CL, et al. Establishment of an internationally agreed minimum data set for acute telestroke. J Telemed Telecare 2020;27(9).
[29] Gargon E, Gorst SL, Harman NL, Smith V, Matvienko-Sikar K, Williamson PR. Choosing important health outcomes for comparative effectiveness research: 4th annual update to a systematic review of core outcome sets for research. PLoS One 2018;13:e0209869.
[30] Gargon E, Gorst SL, Williamson PR. Choosing important health outcomes for comparative effectiveness research: 5th annual update to a systematic review of core outcome sets for research. PLoS One 2019;14:e0225980.
[31] Gorst SL, Gargon E, Clarke M, Smith V, Williamson PR. Choosing important health outcomes for comparative effectiveness research: an updated review and identification of gaps. PLoS One 2016;11:e0168403.
[32] Davis K, Gorst SL, Harman N, Smith V, Gargon E, Altman DG, et al. Choosing important health outcomes for comparative effectiveness research: an updated systematic review and involvement of low and middle income countries. PLoS One 2018;13:e0190695.
[33] Gorst SL, Gargon E, Clarke M, Blazeby JM, Altman DG, Williamson PR. Choosing important health outcomes for comparative effectiveness research: an updated review and user survey. PLoS One 2016;11:e0146444.
[34] Kearney A, Williamson P, Dodd S, Woolfall K, Callaghan S, Yameen F. A systematic review of Core Outcome Sets (COS) intended for use in routine care. 2021. Available at https://www.crd.york.ac.uk/prospero/display_record.php?ID=CRD42021254830. Accessed April 11, 2023.
[35] Kirkham JJ, Gorst S, Altman DG, Blazeby JM, Clarke M, Tunis S, et al. Core outcome set-STAndardised protocol items: the COS-STAP Statement. Trials 2019;20(1):116.
[36] Kirkham JJ, Davis K, Altman DG, Blazeby JM, Clarke M, Tunis S, et al. Core outcome set-STAndards for development: the COS-STAD recommendations. PLoS Med 2017;14(11):e1002447.
[37] Kirkham JJ, Gorst S, Altman DG, Blazeby JM, Clarke M, Devane D, et al. Core outcome set-STAndards for reporting: the COS-STAR Statement. PLoS Med 2016;13(10):e1002148.
[38] Williamson PR, Altman DG, Bagley H, Barnes KL, Blazeby JM, Brookes ST, et al. The COMET Handbook: version 1.0. Trials 2017;18(Suppl 3):280.
[39] Petkovic J, Barton JL, Flurey C, Goel N, Bartels CM, Barnabe C, et al. Health equity considerations for developing and reporting patient-reported outcomes in clinical trials: a report from the OMERACT equity special interest group. The J Rheumatol 2017;44(11):1727−33.
[40] de Wit M, Abma T, Koelewijn-van Loon M, Collins S, Kirwan J. Involving patient research partners has a significant impact on outcomes research: a responsive evaluation of the international OMERACT conferences. BMJ open 2013;3(5).
[41] Barrington H, Young B, Williamson PR. Patient participation in delphi surveys to develop core outcome sets: systematic review. BMJ Open 2021;11(9):e051066.
[42] Biggane AM, Williamson PR, Ravaud P, Young B. Participating in core outcome set development via Delphi surveys: qualitative interviews provide pointers to inform guidance. BMJ Open 2019;9(11):e032338.
[43] Potter S, Brookes ST, Holcombe C, Ward JA, Blazeby JM. Exploring methods the for selection and integration of stakeholder views in the development of core outcome sets: a case study in reconstructive breast surgery. Trials 2016;17(1):463.
[44] Ackerman IN, Cavka B, Lippa J, Bucknill A. The feasibility of implementing the ICHOM Standard Set for Hip and Knee Osteoarthritis: a mixed-methods evaluation in public and private hospital settings. J Patient Reported Outcomes 2018;2(1):1−16.
[45] Laureij LT, Been JV, Lugtenberg M, Ernst-Smelt HE, Franx A, Hazelzet JA, et al. Exploring the applicability of the pregnancy and childbirth outcome set: a mixed methods study. Patient Education Couns 2020;103(3):642−51.
[46] Keeley T, Sayers R, Pinfold V, Mathers J, Williamson P, Calvert MJ. Can core outcome sets designed for research inform the standardisation of outcome measurement in primary care? Qual Life Res 2016;25:9−10.