One-piece closed bags for adults with a colostomy [GID-HTE10045]

Final EAG protocol

Produced by	Peninsula Technology Assessment Group (PenTAG) University of Exeter Medical School
Authors	Caroline Farmer[1] Val Santo[1] Alan Lovell[1] Maxwell S. Barnish[1] Ahmed Abdelsabour[1] Jenny Lowe[1] Edward C.F. Wilson[1] G.J. Melendez-Torres[1] Dawn Lee[1] [1] Peninsula Technology Assessment Group (PenTAG), University of Exeter Medical School, Exeter
Correspondence to	Caroline Farmer 3.09 South Cloisters, St Luke's Campus, Heavitree Road, Exeter, EX1 2LU; c.farmer@exeter.ac.uk
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Author contributions

Caroline Farmer	Clinical evidence lead and project manager. Input into the writing of assessment documents.
Val Santo	Health economist with responsibilities for the assessment of economic evidence and the development of the economic analysis. Input into the writing of assessment documents.
Alan Lovell	Information Specialist responsible for developing and conducting evidence searches.
Maxwell S Barnish	Clinical reviewer with responsibilities for conducting the evidence review and analysis of clinical effectiveness and safety evidence. Input into the writing of assessment documents.
Ahmed Abdelsabour	Health economist with responsibilities for the assessment of economic evidence and the development of the economic analysis. Input into the writing of assessment documents.
Jenny Lowe	Document management expert with responsibilities for supporting the conduct of evidence searches. Administrative support throughout the project.
Edward C.F. Wilson	Health economist with responsibilities for the assessment of economic evidence and the development of the economic analysis. Input into the writing of assessment documents.
G.J. Melendez-Torres	Statistician and clinical evidence reviewer. Responsibilities for conducting analyses of clinical effectiveness evidence. Input into the writing of assessment documents.
Dawn Lee	Project director, economic evidence lead, and guarantor of the EAG assessment. Input into the writing of assessment documents.

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1. INTRODUCTION AND BACKGROUND

1.1. Introduction

As described in the NICE scope for this assessment, this Late-Stage Assessment (LSA) aims to investigate the evidence base for one-piece closed bags for adults with a colostomy to assess whether price variations are justified by differences in features and whether technologies represent value for money in the NHS. This assessment protocol outlines what the External Assessment Group (EAG), an independent, academic group supporting NICE with the assessment, will do during its evaluation. This protocol was produced in response to the final NICE scope for this assessment.[1]

1.2. Decision problem

Table 1 summarises the decision problem to be addressed in this assessment. Further detail on each item can be found in the published scope. The table reports the EAG's comment on each of the decision problem areas. These comments outline the EAG's interpretation of the key areas of consideration for the assessment and therefore inform the eligibility criteria for the EAG's assessment, shown in Section 2.1.

Table 1: Summary table of the decision problem

Item	Description	EAG comment
Population	Adults 18 and over with a colostomy that use one-piece closed bags	All reasons for needing a colostomy were eligible for the assessment. The EAG was aware that those with ongoing treatments or particular needs due to the cause of their colostomy or their comorbidities may be at higher risk of certain outcomes. Clinical expert opinion was that the majority of people with a colostomy use a one-piece closed bag, so this is the focus of this assessment. The EAG understood that some people with a colostomy may use a two-piece bag (including some people with skin complications or manual dexterity issues) or drainable bags (such as those with a looser output). Two-piece and drainable bags will not be covered by this assessment. At the scoping workshop, clinical experts noted that colostomies can be reversed, although the potential for future reversal is difficult to predict at the time of surgery. In practice they considered that there is likely little difference in outcomes between populations defined as having had a 'temporary' or

Item	Description	EAG comment
		'permanent' colostomy. It was noted, however, that only people classified as having a 'permanent' stoma receive free NHS prescriptions of colostomy bags. The EAG was advised that classification of stomas into permanent and temporary differs by geographical area.
Subgroups	If the evidence allows, the following subgroups will be considered: ○ People with more fragile skin that is prone to tearing such as older people or people with an underlying skin disorder ○ People with conditions that may impact self-care (such as issues with manual dexterity, mobility and visibility) ○ People with a non-complex abdominal profile or peristomal anatomy or physiology ○ People with a complex abdominal profile (including but not limited to a stoma close to bony prominences, abdominal dips or creasing and scarring from prior surgery) ○ People with complex peristomal anatomy or physiology including but not limited to people with: ○ parastomal hernia or bulging ○ retracted or sunken stoma ○ prolapsed stoma	The EAG understood the population subgroups in the NICE scope to represent groups who have particular requirements from a one-piece closed bag and potentially may be at higher risk of poorer outcomes. The EAG will consult with clinical experts where required to identify study populations that meet subgroup criteria where this is unclear.

Item	Description	EAG comment
	○ stomal fistula ○ stomal stricture ○ stoma ischaemia ○ peristomal skin conditions ○ large stoma ○ thick faeces prone to pancaking ○ high output stoma ○ stoma positioned close to a wound, mucous fistula or device (such as a suprapubic catheter)	
Interventions	One-piece closed bags (flat and convex or concave) with one or more of the following features: • baseplate additives (e.g. alginate, ceramide, manuka honey, vitamin E, silicone, pH buffering system) • modified baseplate shapes (e.g. flower shaped, oval shaped, tapered) • modified baseplate adhesives (e.g. to improve adhesion, reduce residue or improve peristomal skin condition) • modified bag shapes (e.g. to be more discreet or allow water to drain off more easily)	The differentiation between features described as intervention and comparators was based on understanding of whether features are innovative and may be associated with an increase in cost. Features of interest may evolve depending on information provided by companies participating in this assessment. The impact of the intervention features on effectiveness and cost-effectiveness will be assessed where evidence allows. Where assessment is not possible due to lack of evidence or available evidence not being of suitable quality, this will be noted.

Item	Description	EAG comment
	• modified filters (e.g. to improve gas release or reduce odour) • modified material (e.g. to be more discreet, reduce noise, improve absorption, improve comfort, reduce odour or improve water repellence) • flushable disposal	Only those technologies listed in Part IXC of the Drug Tariff at the start of the assessment (April 2024) would be eligible for consideration in the assessment. No technologies added to the Drug Tariff after this month were eligible for consideration. People with a colostomy may use supporting products with their one-piece closed bag. These incur an additional cost and may be used to improve the way the bag works for a person. These products are not the focus of this assessment and therefore their costs will only be included in the economic evaluation where they are either (a) required with a particular feature or bag type or (b) there is evidence of a substantial difference in their use for a particular bag feature.
Comparators	One-piece closed bags (flat and convex or concave) without any of the features listed in the intervention section that: • have a range of baseplate sizes that are either pre-cut or cut-to-fit,	As noted above, features described as interventions and comparators were differentiated based on their impact on the overall cost of the one-piece closed bag. Comparators were features considered to cause little or no price variation and could therefore be considered as standard or basic features.

Item	Description	EAG comment
	• have different levels of convexity, such as light, soft, flexible, deep or firm (convex bags only) • have a filter, • are available in a range of sizes (such as mini, midi or maxi), • are available in either transparent or opaque, • are available in various colours, • are available with or without a viewing window.	As with intervention bags, and noted above, people may use additional supporting products with their bag to improve outcomes. Comparator features will not be individually assessed and will instead be considered to be of similar cost and effectiveness.
Outcomes eligible for inclusion	Outcome measures for consideration may include but are not limited to: <u>Intermediate outcomes</u> • Leakage • Length of time before switching bags • Number of appointments with clinical nurse specialists in stoma care • Medicine use (e.g. topical steroids or barrier creams) • Number of or time to ballooning events • Odour control	The EAG recognised that all outcomes listed in the NICE scope were relevant for understanding the potential benefits and limitations of one-piece closed bags. Based on discussions at the scoping workshop, with clinical experts and information from published research (e.g. Naffees et al.[2]), the key outcomes (i.e. those with the largest impact on the choice of bag) were expected to be: • Leakage • Skin complications • Psychological impact

Item	Description	EAG comment

	• Supporting product use for attachment and removal (e.g. adhesive removers, flange extenders, belts or underwear, irrigation supporting products, skin fillers and skin protectors)
	• Pancaking events
	
	<u>Clinical outcomes</u>
	
	• Intervention-related adverse events including but not limited to:
	  ○ Peristomal skin complications (e.g. skin excoriation, folliculitis, infection, allergic reactions, granulomas, pyoderma gangrenosum, psoriasis, erythema, papules, skin erosions, ulcers, vesicles)
	  ○ Mucocutaneous separation
	
	<u>Patient reported outcomes</u>
	
	• Ease of use and acceptability (e.g. bag security, durability, ease of attachment and removal, noise, pain, discomfort or itching, performance in water)
		The EAG also noted that a key outcome for the economic analysis would be the length of time that someone continued to use a particular bag type before needing to change to a different bag type.
		
		The EAG intends to seek input on the key adverse events that should be considered in its assessment. This will include adverse events that are caused by the use of one-piece closed bags as well as adverse events experienced by people with a colostomy that may dictate the choice of bag type and their effectiveness. Adverse events may include:
		
		• Infection
		• Mucocutaneous separation
		• Parastomal hernia
		• Stenosis
		• Bleeding
		• Necrosis

Item	Description	EAG comment

	• Health-related quality of life
	• Psychological and social impact
	
	<u>Costs and resource use</u>
	
	• Cost of the technology
	• Cost of supporting products (e.g. adhesive removers, flange extenders, belts or underwear, irrigation supporting products, skin fillers and skin protectors)
	• Costs of medicines (e.g. topical steroids or barrier creams)
	• Cost of other resource use including:
	  ○ Health care professional appointments or visits (primary, community and secondary care)
	  ○ Costs associated with managing stoma-related complications, frequency of bag change, waste disposal of excess bags, prescribing and dispensation
	
	User preference will be assessed to identify and understand features of the technologies that	

Item	Description	EAG comment
	influence decision making when selecting which technology to use. This will be done alongside the assessment of the clinical and economic evidence.	
Setting	Prescribing in primary and community care	The EAG received advice that it was in primary and community care where the majority of one-piece closed bags are sourced from and therefore would be the most appropriate target for this assessment. In some areas of the country, people with a colostomy have access to a specialist stoma care nurse who can advise on stoma bag options. This may occur during a regular, scheduled review appointment or it may happen upon initiation by the person with a colostomy. Prescriptions of bags are predominantly issued by a GP, although this would typically be informed by a recommendation from a specialist stoma care nurse. Given that this assessment will focus on prescribing in primary and community care, the EAG therefore assumed that the aim of the assessment was to inform bag choice once a person has been

Item	Description	EAG comment
		discharged from hospital and has some experience with managing their stoma and using stoma bags. The EAG was aware that specialist stoma care nurses working in the community can be sponsored by (i.e. their wages are paid by) manufacturers of certain colostomy products. This may influence the choice of bags or supporting products that a person receives for various reasons. E.g. a nurse may have greater awareness of or training on the products available through that manufacturer.
Economic analysis	A health economic model will be developed, where possible, comprising a cost-comparison or cost utility analysis. Costs will be considered from an NHS and Personal Social Services perspective. Sensitivity and scenario analysis should be undertaken to address the relative effect of parameter or structural uncertainty on results. The time horizon should be long enough to reflect all important differences in costs or outcomes between the technologies being compared.	The decision model anticipated to be developed is discussed in Section 3. What will be achievable will depend upon the evidence base identified. We are proposing to use a one-year time horizon to represent an average year for a person with a colostomy. The year would be designed to represent the time after a person has healed from their surgery and have some experience with using a stoma bag. The start point of the year will be determined following the evidence review and with clinical expert advice, although the EAG has considered a

Item	Description	EAG comment
		time period of 3-months or 1-year following surgery. A one year time horizon was used in previous studies[3,4] and was expected to be appropriate given the limitations of the expected evidence base, and the acute nature of possible events, which may not be time-dependent following the initial period following surgery (variable but typically around 3 months).

Abbreviations: EAG, External Assessment Group

1.3. Objectives

The objective of this assessment is to identify evidence for the effectiveness of one-piece closed bags for adults with a colostomy to inform guidance on their use in the NHS. Specifically, the assessment will attempt to address the following research questions:

- What evidence is available to determine the clinical and cost effectiveness of one-piece closed bags for adults with a colostomy?
- Which features of one-piece closed bags are associated with benefits for adults with a colostomy and are these commensurate with the price charged by manufacturers?

Ultimately, the findings of this assessment are intended to be used by adults with a colostomy, clinicians and commissioners to inform decisions about the use of one-piece closed bags in practice.

The assessment will involve a systematic search for published evidence that evaluates one-piece closed bags. Evidence will also be sought from the manufacturers of one-piece closed bags, who may hold data that has not been published. Evidence that is useful to the decision problem for this assessment (i.e. represents the relevant population, interventions, outcomes, settings and is of suitable quality to inform clinical decisions) will be extracted and appraised by the EAG. A tabulated overview of the evidence landscape will be constructed to represent the evidence available and where there are meaningful gaps for the decision problem. Intervention components analysis (ICA)[5] will be used to evaluate the features of one-piece closed bags associated with improvements in outcomes. Where feasible, an economic analysis will be conducted to compare the benefits of intervention features with their price. Full details of the stages of the assessment are provided in Sections 2 and 3.

2. EVIDENCE REVIEW

During the preparation of this protocol, the EAG conducted a literature search for published systematic literature reviews (SLRs) that identified and evaluated published evidence for stoma bags for people with a colostomy to consider whether it would be feasible to update an existing SLR for this assessment. The search identified 260 records, of which 22 were screened in full text. Ultimately, one published SLR[6] was identified that provided an overview of intestinal stoma interventional studies listed on ClinicalTrials.gov before May 25th 2022. The EAG considered that ClinicalTrials.gov would not include a comprehensive list of studies relevant to this assessment, and therefore did not consider an update of this SLR to be appropriate for this LSA.

The EAG therefore intend to conduct its own evidence review to identify evidence evaluating the features of one-piece closed bags. The evidence review will involve two systematic literature searches for published evidence relevant to the decision problem:

- one literature search will be conducted to identify evidence for the clinical effectiveness and safety of the features of one-piece closed bags for adults with a colostomy.
- one literature search will be conducted to identify published economic evaluations of stoma bags for people with a colostomy and health-related quality of life (HRQoL) and utility studies relevant to the decision problem.

The searches will be conducted separately as the inclusion criteria vary according to each evidence type (Section 2.1).

The literature search will not specifically target studies publishing cost and resource use data associated with one-piece closed bags for people with a colostomy (i.e. searches will not include filters and free-text terms for cost and resource use). Cost and resource use data are rarely identified independently from economic evaluations or standard data sources (e.g. NHS reference costs, PSSRU) but require substantial additional resource to identify and screen, and so this decision was taken within the pragmatic methods recommended for use within LSAs. Further detail of the search strategy is provided in Section 2.1.2.

Searches developed for the purposes of the evidence review will be devised by an experienced information specialist and quality assured by a second information specialist. The review will employ methods used to conduct SLRs (e.g. as outlined by the Centre for Reviews and

Dissemination[7]), including undertaking a systematic and transparent approach to the identification and analysis of published evidence. However, consistent with methods for NICE LSAs,[8] the evidence review will also incorporate pragmatic methods to ensure the evidence review best addresses the NICE decision problem within the timeframe of the assessment. This includes the use of artificial intelligence to identify relevant studies and a tiered evidence selection process (Section 2.3). Within the timeline of the LSA, the EAG estimates that it will be feasible to include up to fifty studies across the evidence review (i.e. clinical effectiveness, safety, economic evaluations, HRQoL/utility studies). If the volume of high-quality evidence identified exceeds these limits the EAG will flag this to the NICE team for discussion. Further details of the review methods are provided in this section of the protocol.

2.1. Inclusion criteria

2.1.1. Clinical effectiveness

The inclusion and exclusion criteria for the clinical effectiveness and safety evidence are shown in

Table 2. These criteria were informed by the NICE scope, discussion with the NICE team, and feedback from stakeholders to this assessment given in the scoping workshop and in consultation with the EAG. The criteria have also been informed by the need to capture the key evidence for the purposes of the assessment objectives. The inclusion criteria are generally consistent with the decision problem for this assessment (Section 1.2), but with the following modifications:

- Eligible comparators for the review now also include head-to-head comparisons between one-piece closed bags containing one or more features of interest. As the aim of the evidence review is to identify the incremental benefit of intervention features, comparisons between bags with and without an intervention feature are pertinent.
- Eligibility criteria now include additional detail about the way each of the criteria will be defined. For example, the criteria clarify the way in which supporting products used to accompany one-piece closed bags will be handled.
- Minimum quality criteria have been specified, where relevant. This includes the requirement for scaled measures assessing HRQoL and patient-reported outcomes (PROs) to be measured using tools that have been psychometrically validated to ensure that the results are reliable and valid for the purposes of decision-making. In addition, we have specified the study designs that will be eligible for inclusion to ensure that effect estimates identified provide a meaningful representation of the effects of intervention features and their order of priority for inclusion in the review. Single-arm studies (those reporting outcomes before and after a change in an intervention feature in a single group of people with a colostomy) will be considered for inclusion provided these are considered to be robust. Conference abstracts without the accompanying poster, slide presentation or a sister full-text publication (perhaps from an earlier study follow-up) will not be included given the limited detail available about the study methods.
- We have specified that all evidence included in the review must be in English.
- As part of the pragmatic approach to the evidence review, a subset of outcomes specified on the NICE scope have been prioritised for consideration. These are outcomes that were considered by the EAG to be the strongest determinants of the effectiveness of one-piece closed bags. This determination was based on feedback from stakeholders given during the NICE scoping workshop for this assessment. In addition, it was based on assumptions of

the relationship between outcomes. For example, patient-reported acceptability of a bag was assumed to capture multiple outcomes important to people with a colostomy, including both clinical outcomes and the useability of the bag (e.g. discreetness, ease of attachment, discomfort). In addition, the outcomes prioritised for consideration were split into two categories:

  - **Critical outcomes**: these are outcomes that will be extracted from all included studies if the data are available.
  - **Important outcomes**: these are outcomes that will be extracted from included studies if feasible for the EAG to do so.

- If there is a large amount of evidence for critical outcomes, it may not be possible for the EAG to extract evidence for important outcomes within the timeframe of the LSA. Critical outcomes are those that are required for the economic analysis and are considered to be crucial for decision-making.

Table 2: Inclusion and exclusion criteria, clinical effectiveness

	Inclusion criteria	Exclusion criteria
Population	Adults 18 and over with a colostomy that use one-piece closed bags	Children and young people aged <18 years with a colostomy Adults with a colostomy who do not use a one-piece closed colostomy bag Adults with an ileostomy who use a one-piece closed bag.
Intervention	The following features included in one-piece closed bags (flat and convex or concave): • baseplate additives (e.g. alginate, ceramide, manuka honey, vitamin E, silicone, pH-buffering system) • modified baseplate shapes (e.g. flower shaped, oval shaped, tapered) • modified baseplate adhesives (e.g. to improve adhesion, reduce residue or improve peristomal skin condition) • modified bag shapes (e.g. to be more discreet or allow water to drain off more easily)	Supporting products that are bought for use with one-piece closed bags (e.g. adhesive removers, skin protectors) will not be evaluated independently, i.e. participants in included studies may use supporting products and the frequency of their use will be extracted as an outcome of the review, however, outcomes associated with the use of supporting products themselves will not be evaluated.

	Inclusion criteria	Exclusion criteria
	• modified filters (e.g. to improve gas release or reduce odour) • modified material (e.g. to be more discreet, reduce noise, improve absorption, improve comfort, reduce odour or improve water repellence) • flushable disposal	
Comparators	One-piece closed bags (flat and convex or concave) without any of the features listed above A one-piece closed bag that includes one or more of the features described above (i.e. head-to-head comparison).	
Outcomes	<u>Critical outcomes</u> • Leakage • Peristomal skin complications including mucocutaneous separation • Psychological impact as defined as the impact of features on a person's mental wellbeing	Continuous outcomes measured using scales that have not been psychometrically validated (HRQoL, utilities, psychological wellbeing, patient-reported acceptability, patient reported odour control) Other outcomes, including those specified as outcomes of interest on the NICE scope.

	Inclusion criteria	Exclusion criteria
	• Impact on social functioning as defined as the impact of features on a person's engagement in social activities with friends and family • HRQoL • Use of medicines to improve bag outcomes and manage complications (e.g. barrier cream, topical steroids) • Supporting product use to improve bag outcomes (e.g. adhesive removers, flange extenders, belts or underwear, irrigation supporting products, skin fillers and skin protectors) • Length of time before switching bags • Frequency of bag change • Patient-reported ease of use and acceptability • Number of or time to ballooning events (including bursting) • Pancaking events <u>Important outcomes</u> • Number of appointments with GPs and clinical nurse specialists in stoma care • Patient-reported odour control	

	Inclusion criteria	**Exclusion criteria**
Study design	Priority • RCTs and quasi-randomised studies • Prospective observational studies Secondary • Retrospective observational studies Tertiary • Time series analyses • Single-arm studies Eligible studies will be peer-reviewed, full-text publications. Conference abstracts will only be included if accompanied by the respective poster or slide presentation, or if they report new data from a study for which a sister full-text publication has been included in the review. Conference abstracts will be de-prioritised for inclusion.	• Case control studies • Cross-sectional studies Conference abstracts without the accompanying poster or slide presentation, or without a sister, full-text publication from the same study.
Setting	Prescribing in primary and community care. Studies in any country will be considered for inclusion, though studies set in the UK or in countries with	Studies evaluating treatment in hospital, including bags prescribed immediately after colostomy surgery.

	Inclusion criteria	Exclusion criteria
	comparable healthcare systems will be prioritised for inclusion.	
Language	English	Studies not reported in English

Abbreviations: GPs, general practitioners; HRQoL, health-related quality of life; RCT, randomised controlled trial; UK, United Kingdom

2.1.2. Economic evaluations and quality of life

Economic and HRQoL evidence will be conducted for inclusion using a broader set of criteria than the clinical effectiveness review in order to capture evidence related to the impact of colostomies more generally. This decision was due to the findings of scoping searches, which did not find any economic evaluations related specifically to one-piece closed bags (Table 3), and the expectation that other types of study in this population may be useful to the appraisal. Papers identified in a broader population will be used to inform the conceptual model and the quality of life, resource use and cost impacts of complications and events where there is expected to be the potential for a difference in rates or scale of impact on the outcome for interventions featured in the decision problem relative to use of a basic bag. ICERs from economic evaluations will be extracted if studies provide information relevant to the features of one-piece closed bags.

Table 3: Inclusion and exclusion criteria, economic evaluations and quality of life

	Inclusion criteria	Exclusion criteria
Population	Adults 18 and over with a colostomy and/or ileostomy bag	Children and young people aged <18 years with a colostomy

	Inclusion criteria	**Exclusion criteria**
Intervention	All interventions for the target population will be included. Studies reporting outcomes for one-piece closed bags will be the highest priority, though useful data may be identified from studies reporting outcomes from other stoma products or interventions delivered to people with a colostomy or ileostomy.	Bags used for urostomy.
Comparators	Any comparator. No comparator.	NA
Outcomes	<u>Economic evaluations</u> • Model structure • ICERs – one-piece closed bags only • Cost savings (cost comparison studies only) – one-piece closed bags only <u>HRQoL studies and HRQoL data identified in economic evaluations</u> • HRQoL data regardless of the method of elicitation and valuation. Data expressed in the form of utilities will be prioritised	Studies not reporting an included outcome

	Inclusion criteria	Exclusion criteria
	<u>Cost and resource use identified in economic evaluations</u> • Resource use identified in OECD studies • Bag costs identified in OECD studies • Other cost sources identified in UK studies • Resource use and costs of interest include average bag numbers required per day, health care professional appointments or visits, management of stoma related complications, switching bags, wastage, dispensation and necessary add-on supporting products	
Study design	• Economic evaluations (cost-effectiveness, cost-benefit, cost-consequence or cost comparison) • Primary studies reporting HRQoL data • Mapping studies reporting HRQoL data • Systematic reviews of economic evaluations or HRQoL • Conference abstracts will be included unless data are superseded by another conference abstract or full journal article	• Abstracts with insufficient methodological details • Editorials and commentaries

	Inclusion criteria	**Exclusion criteria**
Setting	Economic evaluations must be set in the UK or countries with comparable healthcare systems. HRQoL studies can be conducted in any country.	Economic evaluations set in other countries.
Language	English	Studies not reported in English
Data limit	Studies published in 1999 or later; 1999 was chosen as no relevant publications before this date were identified in scoping searches	Studies before 1999

Abbreviations: HRQoL, health-related quality of life; ICER, incremental cost effectiveness ratio' OECD, The Organization for Economic Cooperation and Development

2.2. Search strategy

The literature searches for the evidence review are intended to capture a broad range of sources so as to capture evidence relevant to the assessment that may or may not be indexed in traditional literature databases. This includes searching for grey literature sources.

The databases that we shall search are:

- Medline (via OVID)
- Embase (via OVID)
- Cochrane Library (trials and systematic reviews, via Wiley)
- British Nursing Index (via ProQuest)
- CINAHL (via EBSCOhost)
- International HTA database (INAHTA)
- CEA registry
- ScHARR HUD
- NHS EED (note that the last records added to NHS EED were in March 2015)

In addition, we will search the following:

- Ongoing clinical trials will be searched in ICTRP and clinicaltrials.gov. This latter search will identify updated or new entries since the search of clinicaltrials.gov conducted for the Vuyyuru et al (2023)[6] SLR .
- NICE and SIGN will be searched for relevant UK guidance
- MHRA field safety notices and the MAUDE database will be searched for adverse events
- ASCN (Association of Stoma Care Nurses) conference abstracts, from 2019 to the present, will be hand-searched where available for relevant studies

The clinical searches will not be limited by date. The economic and utility searches will be limited from 1999 to the present. While the EAG anticipates that outcomes for people with a colostomy have improved over time, the EAG also considered that evidence for some features

of one-piece closed bags in use may have not been published in recent years and may therefore be missed by a date limit.

Search results, supplemental records and submitted information that meet the inclusion criteria will be added to an Endnote (v20) database for deduplication.

Example search strategies (based on the search to be used in Medline) – one for clinical records and one for economics and utilities – are listed in the appendices. The clinical search combines terms for "colostomy" and "bag" with published filters for 1) RCTs,[9] and 2) observational studies.[10] The observational studies filter has been modified to remove terms associated with case studies and case controls, and terms added to include interrupted time series, before and after studies, and single arm studies. The search delivered 978 hits.

The economics and utilities search combines terms for "colostomy" with published filters for 1) economic evaluations[11] and 2) utilities.[11] The economic evaluations filter has been modified to remove terms associated with costs and resourcing studies – it has also been combined with the NICE OECD countries studies filter. The utilities filter has been modified by adding terms for three commonly used HRQoL scales: Ostomy-Q, Stoma Quality of Life Questionnaire, and Ostomy Adjustment Inventory. The economic and utility searches also included terms for ileostomy (as described in section 2.1.2, above). The search delivered 2,928 hits. The economics search will be restricted to studies published from 1999 to the present day (see Table 3).

These Medline searches will be fully translated into Embase. We will use shorter search strategies for other databases, however, given their smaller sizes and less comprehensive indexing.

Information sent from companies and other stakeholders to NICE will be scrutinised to identify additional relevant studies. We will not formally review manufacturer websites, given the large number of manufacturers and products potentially in scope. However, submitted documents and information from manufacturers' request for information (RFI) will be incorporated into our search results (further details provided in Section 4).

If the above search process provides insufficient evidence (see section 2.3), supplemental searching, using Scopus (Elsevier) or Google Scholar may be used. In this case, up to ten of the included studies will be used as the basis for forward and backward citation chasing to identify evidence.

To inform the assessment, staff at NICE have conducted searches for real world evidence sources relevant to this assessment. Identified sources will be appraised by the EAG and considered for inclusion in the evidence review, where feasible. At the time this protocol was being prepared, the EAG was informed that there may be the potential to access primary care data from the Clinical Practice Research Datalink (CPRD).[12] The feasibility of accessing product specific data is currently being assessed for the following types of information: duration of use of particular types of bags before needing to switch to a different bag type, number of different types of bags people try over a lifetime, number of bags used per day, resource use, usage of supportive products, complication rates and demographic data.

2.3. Study selection

Three levels of screening will be used to select relevant evidence for the assessment:

Level 1: titles and abstracts of identified publications will be screened using the population, intervention, comparator, and study design criteria shown in Table 2

Table 2. Machine learning-powered priority screening algorithms will be investigated to support screening.

Level 2: full texts of publications included at level 1 will be screened according to the full eligibility criteria shown in

Table 2. Reasons for exclusion will be noted. Included studies will be tagged using the following categories to aid prioritisation decisions: randomised controlled trial; single arm; UK trial.

Level 3: a final list of included studies will be prioritised for inclusion from those included at level 2. Where feasible, all studies identified at level 2 will be included, although if a large evidence base is identified, then a subset of the most relevant and influential studies will be prioritised for inclusion. Studies tagged as randomised trials and UK studies at level 2 (randomised controlled trials, UK study) will be considered first for inclusion. To guide the prioritisation of other studies included at level 2, we will use the following criteria: economic evaluations conducted using a UK NHS and PSS perspective; studies with no obvious quality concerns (e.g. selection bias, high rates of missing data); studies addressing gaps in the prioritised evidence (e.g. evidence for intervention features for which no studies have yet been prioritised for inclusion); studies including utility data; economic evaluations presenting quality of life and cost and resource use data. Reasons why studies were not prioritised for inclusion will be noted and reported in the appendix of the report.

Real world evidence sources will also be considered for inclusion in reference to the eligibility criteria outlined in Table 2 and Table 3 and will be considered for prioritisation using the same criteria as described in Level 3 for publications.

The flow of studies through all three levels of screening will be recorded and displayed on a PRISMA diagram. Studies that do not meet the inclusion criteria specified in

Table 2 and Table 3 will not be included in the assessment. This will be the case even if, for example, the only evidence for a particular feature does not meet these criteria meaning that it will not be considered in the assessment. This is because evidence that does not meet the eligibility criteria is unlikely to address the objectives of the LSA and thus be informative to decision-making. As stated previously, the EAG expects that up to fifty studies can be included across the evidence review. A list of prioritised studies will be shared with NICE prior to data extraction for comment.

Consistent with NICE methods for conducting LSAs,[8] a single reviewer will screen each study at each level. Studies will be marked uncertain if further discussion about inclusion is required. Studies marked as uncertain will be discussed in team meetings and a determination made. As a quality assurance step, all studies included at level 2 but not prioritised for inclusion in the review will be screened by a second reviewer and discussed in team meetings as required.

2.4. Data extraction strategy

Data from prioritised studies will be extracted into a data extraction table (DET) in Microsoft Excel. The DET will be developed *a priori* and piloted on three studies of each study type (economic evaluations; primary utility studies; clinical effectiveness studies) to inform any final changes. A separate tab in the DET will be used for each study type, including real world evidence sources. The data extracted for each study or real-world evidence source will be aligned with the decision problem for the assessment, i.e., information about the study population, interventions, outcomes and study design that characterise its relevance for the decision problem. Information about the study interventions will include a detailed breakdown of the bag features. Information about intervention features will be extracted in free-text form from intervention descriptions provided in publications or in information provided by manufacturers. To guide decisions on data extraction where studies report the same outcome in multiple formats and at multiple timepoints, we will extract formats most likely to be comparable across studies.

In addition, we will prioritise the following:

- Prioritisation of HRQoL data in the form of utilities for the HRQoL review
- Prioritisation of economic evaluations most closely meeting the decision problem specification and carried out from a UK NHS and Personal Social Services (PSS) perspective.

2.5. Quality assessment strategy

Quality assessment will be in accordance with Section 3 of NICE's health technology evaluations manual. Pivotal studies will be quality assured using a standardised tool specific to the research design. More broadly, a general comment about the strengths and applicability of the studies included in the review will be provided in the report.

Economic evaluations will only be formally quality assessed if they compare one-piece closed bags in a UK setting. Quality of life studies identified will not be formally quality assessed as no suitable assessment tool currently exists (although one is in development[13]). Quality of life studies will instead have their quality considered informally as part of the consideration for selection of utility data to be included within the decision model.

Consistent with NICE's real-world evidence framework, the Data Suitability Assessment Tool (DataSAT) will be completed to provide structured information on data suitability including provenance, quality and relevance.

The judgements made in the critical assessment of included evidence will be presented in the EAG report and considered in the evidence landscape and gap map. Where feasible and relevant, critical assessment judgements will be considered in the synthesis/analysis.

2.6. Methods of synthesis/analysis

Intervention components analysis (ICA) will be used to evaluate the relationship between intervention features of one-piece closed bags and outcomes. The findings from the ICA will be used to inform the economic analysis, which is described further in Section 3.

ICA is an inductive approach to categorising and evaluating intervention components in an evidence base. Prior to the analysis, the EAG will develop a matrix of the intervention features of one-piece closed bags, as categorised in the NICE scope, and the hypothesised influence they have on clinical outcomes extracted in the evidence review. For example, within the category of modified baseplate shapes, certain shapes may be hypothesised to improve the fit of the bag to a person's stoma, thus reducing the risk of leakage and skin complications. The EAG's starting matrix will be based on evidence in published studies and input from stakeholders to this assessment. The matrix may be updated if new information is identified from studies included in the evidence review. This matrix will be used to organise coding of included studies.

Template analysis-based coding will be used to identify the features of interventions for which evidence has been included in the evidence review. A reviewer will code intervention features as described in free-text descriptions of interventions using the EAG's starting template as a guide. New intervention features will be added to the template where required, and where very similar features are identified, these will be collapsed into one code. Where feasible and appropriate, the EAG will seek feedback on the codes from device manufacturers and stakeholders to this assessment.

Outcomes for each comparison in the review will be presented alongside a description of the difference in intervention features between comparators. The strongest evidence will be based on comparisons where one-piece closed bags vary in a single feature, however it is anticipated that studies included in the review will more likely compare interventions that vary in more than one feature of interest. For each feature, the EAG will draw upon all relevant comparisons to identify patterns in review outcomes associated with the presence of that feature. Initially, this will result in an assessment of the features associated with positive outcomes, negative outcomes, or no change in outcomes. Where feasible, the EAG will also attempt to identify plausible effect sizes associated with each feature. Where comparisons include variation in more than one feature, we will draw upon the broader evidence base, including regression and mediation analyses reported in included studies and HRQoL data reported in primary utility studies, to evaluate the plausible relationships between features and outcomes.

Based on scoping searches, it is expected that the evidence base for one-piece closed bags will be too heterogeneous for meta-analysis of effect estimates associated with features. As a consequence, the EAG expects to conduct a narrative synthesis of the findings. This will include the reporting of the plausible range in effect estimates available for each intervention feature. The identification of a plausible range will be based on the applicability and certainty of evidence sources included in the review for each feature. The synthesis will also consider the presence of patterns in the results, including variation in feature effectiveness across population subgroups.

3. ECONOMIC ANALYSIS

This section describes the EAG's plan for the economic evaluation of features of one-piece closed bags. The approach is based on the NICE methods for LSAs, scoping searches conducted by the EAG, and input from stakeholders at the NICE scoping workshop for this assessment. The approach is subject to change dependent on the evidence identified in the evidence review.

The EAG will endeavour to perform a pragmatic economic evaluation of the features of one-piece closed bags from the perspective of the UK NHS and PSS, consistent with the methods recommended in the NICE reference case and ISPOR Good Practices Report. Any deviation from the NICE reference case (see NICE Manual) will be identified and discussed as appropriate.

As no suitable published models were identified during scoping searches, a *de novo* Microsoft Excel decision model is expected to be constructed. The model will be constructed using available evidence, including any models submitted by stakeholders, and following guidance on good practice in decision analytic modelling for HTA.

The structure of any model will be determined on the basis of evidence identified via the evidence review, company RFIs, and from clinical expert advice. This includes input on:

- Appropriate assumptions to make if there are data gaps in the information available to populate resource use or quality of life information per health state
- Which outcomes should be included in the model (rather than considered separately within the separate user preference exercise).

All assumptions applied in the modelling framework will be clearly stated and all data inputs and their source will be clearly identified. A decision model will not be developed if no suitable data are available.

If a *de novo* model is developed, it is expected to be a state transition model with a one-year time horizon. A state transition model structure has been selected as stoma is a chronic condition with repeat acute events and we did not consider likely that the evidence base would be sufficient to warrant a more complex model structure. A one-year time horizon has been used in published economic evaluations of other interventions for people with an stoma.[3,4] A one-year time horizon is expected to be appropriate given the acute nature of key outcomes, for which we understand there is limited time dependency in rates after the initial adjustment period (variable but typically around 3 months). The one-year time horizon would be designed to represent an average year

for patients that have largely healed from their colostomy surgery and have some experience with using a stoma bag (this may be either from 3 months or one year onwards following surgery, the timepoint used will be determined following review of the evidence and expert input). While a longer time horizon is more aligned with the NICE reference case, given the limited data expected to be available, it is considered unlikely that modelling a longer time horizon would be meaningful for decision-making. The model is expected to have monthly cycles as patients are usually prescribed boxes of bags for one month.

Consistent with the ICA approach of clinical effectiveness evidence (Section 2.6), comparisons in the economic evaluation are expected to be conducted at the feature, rather than bag, level with comparison to a bag without additional features (a standard or 'basic' bag). The output of the economic analysis will be the economically justifiable price (eJP), and uncertainty around that, for each of the intervention features in the NICE scope. The eJP will then be compared to the additional cost currently being charged for bags with those additional features, where possible, to identify which bags provide value for money.

The expected model structure is subject to change during the assessment, principally in response to the evidence identified in the evidence review. Clinical experts will be consulted to provide input to key features and assumptions of the model structure. In addition, the model structure will be reviewed once the evidence review has been completed and company RFIs have been received.

Health benefits will be calculated through disutilities relative to an average utility for the most common conditions requiring stoma, for the outcomes below. These outcomes were considered key events that may impact on the assessment. This list is subject to change, including input from the evidence review or from any expert elicitation process:

- Leakage
- Peristomal skin complications
- Mucocutaneous separation
- Pancaking
- Ballooning
- Odour
- Appearance (discreetness)
- Ballooning
- Length of time before switching bags

If feasible within the timeframe of the assessment, the EAG will use structured expert elicitation techniques to estimate quantitative values for model inputs where there are no published evidence.[14] Given the requirements of this process, if used, it is likely that this will be focussed

towards a small number of model inputs and conducted with experts/SCMs with support from the NICE team.

It is expected that outcomes such as leakage, odour or pancaking will impact not only the "anxiety/depression" and the "usual activities" dimensions of the EQ-5D measure of quality of life but will also impact on costs as they are likely to result in requests for additional support from health care professionals, and more bags may be used or a change of bag type may be requested. Some of the outcomes may be related, e.g. increased leakage rates may lead to an increased risk of skin complications. As part of the ICA (Section 2.6), we will develop a matrix outlining the proposed mechanism of action through which each bag feature is expected to influence outcomes, which will be validated by clinical experts. This matrix will be used to aid understanding of the relationship between modelled outcomes and the impact of each feature on HRQoL and costs.

Outcomes will only be included in the model where there is an expected difference in either the rates or the scale of impact on cost and HRQoL across different types of bags.

The average duration of use before people with a colostomy discontinue a particular bag and switch to another will be included as an average annual cost. If data are available, the cost and HRQoL impact due to the need to switch per bag will also be included as an average annual impact. It is expected that bags with a shorter duration prior to people with a colostomy requiring a switch will incur a higher cost and quality of life impact. It will be important to understand the reason for switch and to only include reasons that are clinically, or patient preference, motivated and not due to the promotion of products by companies. The EAG may also consider the importance of temporary switching between products according to clinical needs and personal preferences.

Costs will be considered from an NHS and Personal Social Services perspective. Costs for consideration may include:

- Costs of the technologies as identified from the Part IX drug tariff, including wastage and customisation costs, where applicable
- Cost of add-on supporting products that are required for the function of a particular bag or where rates of use differ substantially between bags with different features
- Cost of dispensation including home delivery will be included only if there is a difference expected between types of bags

- Cost of appointments in relation to stoma care or add-on supporting product use reviews
- Cost of other resource use (e.g., associated with managing adverse events, complications, and switching of bags):
    - GP appointments
    - Medication
    - Clinical nurse specialists
    - Hospital stays for more serious events

The EAG understands that manufacturers of stoma bags provide sponsorship both to specialist stoma wards and community nurses. Information about this has been requested via company RFIs. These data will be presented for consideration by the NICE Committee but not included formally within the economic analysis as it does not relate to specific bag features. If the EAG identifies uncertainties in the evidence base due to the influence of sponsorship, these issues will be noted and may be considered in the analysis.

The EAG will select a cost estimate to represent the price of comparator interventions for use in the economic analysis. This cost will be selected to be representative of closed one-piece bags that do not have any of the intervention features. Uncertainty in this estimate will be explored in sensitivity analyses where feasible.

The eJP for additional features will be calculated based upon a willingness-to-pay threshold of £20,000 per QALY, in line with the NICE methods guidance for LSAs.

This eJP will then be compared to the additional cost currently being charged for bags with those additional features, where possible, to identify which bags provide value for money. The cost effectiveness of one-piece closed bags with intervention features will therefore be estimated in terms of an incremental cost per additional QALY gained and net monetary benefit in comparison to the predetermined price range for a one-piece closed bag without intervention features. Base case analyses will be probabilistic as this generates expected outcomes and costs and is in line with the NICE LSA methods. Additional scenario and one-way sensitivity analyses will be conducted where these add value and clarity. For example, scenario analysis may be explored to look at the impact of history of complications (e.g. leaks) on cost-effectiveness.

Where appropriate and if data allow, sensitivity analyses will be undertaken to explore uncertainty. These may include one-way and multi-way sensitivity analyses and use of probabilistic sensitivity

analyses (PSA). The use of PSA involves sampling of parameter inputs from distributions that characterise uncertainty in the mean estimate of the parameter. PSA is used to characterise uncertainty in a range of parameter inputs simultaneously, to consider the combined implications of uncertainty in parameters. Parameter uncertainty around the eJP for each add-on feature will be presented as the 95% confidence interval from PSA.

Where probabilistic modelling is undertaken, results will be presented using the cost effectiveness plane and cost effectiveness acceptability curves/frontier (CEACs/CEAF).

The EAG will consult clinical experts to assess the face validity of the final model and the results. This includes:

- the plausibility of the assumptions used
- that the model accurately reflects current stoma care within primary care and community settings
- the plausibility and interpretation of model results.

4. HANDLING INFORMATION FROM THE COMPANIES

Manufacturers of one-piece closed bags have been invited by NICE to submit evidence relevant to the LSA through a request for information (RFI). It is likely that the EAG will not be able to consider any additional company RFI documents or new evidence (except where clarification has been sought by the EAG) after the 24th April 2024. Only publicly available information will be used for companies that do not submit an RFI.

RFIs received from companies will be appraised using the eligibility criteria used for the evidence review (Section 2.1). Only evidence that meets the eligibility criteria will be considered in the assessment. Evidence in RFIs will also be subject to the prioritisation criteria used in Level 3 of the study selection process (Section 2.3). Evidence from companies included in the evidence review will be extracted into its own tab on the DET for the evidence review, including a description of the characteristics of the evidence source comparable with the approach used for published studies. Evidence that is supplementary to information about a study that is reported in published literature will be considered as part of the quality assessment for that study. Quality assessment of evaluations of one-piece closed bags will be conducted using the methods described in Section 2.5 where sufficient information has been provided. Evidence submitted by companies based on surveys or qualitative data with relevant populations will be quality appraised informally. This will include a summary of any important limitations in the evidence, informed by criteria relevant for determining the quality of this evidence.[16,17]

For pivotal evidence submitted by the companies and where necessary and feasible, the EAG will seek clarification or further information from the submitting manufacturer to inform the assessment.

As part of the RFI, NICE advises manufacturers to highlight any data that is sensitive and unable to be published in the public domain. Consistent with NICE methods for LSA, the EAG will prioritise evidence that can be published unredacted to increase the transparency of the assessment. However, where confidential data are pivotal to the assessment, the EAG will highlight these for redaction in published documents.

5. ADDITIONAL INFORMATION SOURCES

NICE will recruit experts and specialist committee members for this assessment who will provide input at various stages of the assessment. The EAG has plans to meet with specialist stoma care nurses registered as stakeholders to the NICE assessment and based at two hospital trusts to (a) view the features of a subset of one-piece closed bags, (b) discuss the process through which people with a colostomy receive their first bag and are discharged into community settings, (c) discuss questions that will inform understanding of the decision problem. This was intended to inform initial understanding and key assumptions to be confirmed with NICE-recruited experts and SCMs. In particular, the EAG will seek input on the ICA (including EAG understanding of the way in which intervention features are expected to influence outcomes and the features of each one-piece closed bag for which evidence is identified) and EAG plans for the decision model structure and assumptions to be used. As noted in Section 3, where feasible and necessary to the assessment, the EAG will explore methods for identifying quantitative inputs to the economic analyses through structured expert elicitation. If used, the methods used for this process will be detailed in full in the final EAG report.

6. COMPETING INTERESTS OF AUTHORS

The authors have no conflicts of interest. The EAG will not separately collect conflict of interest information from stakeholders it consults as part of its assessment. The EAG expects that this information has been collected by the NICE team and the EAG will only consult with experts recruited by NICE as stakeholders to the assessment.

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Appendix A: Example search strategy

Example search strategies (for Medline).

RCTs and observational studies

Database(s): **Ovid MEDLINE(R) ALL** 1946 to April 15, 2024
Search Strategy:

#	Searches	Results
1	Surgical Stomas/	2521
2	Colostomy/ or ostomy/	11190
3	(stoma or stomas or colostom* or ostom*).ti,ab,kw.	22674
4	"stoma care".tw.	705
5	or/1-4	27530
6	(bag* or pouch* or product* or accessor* or appliance* or equip* or aid or aids or reservoir* or appliance* or filter*).ab,ti,kw.	3043335
7	5 and 6	2769
8	randomized controlled trial.pt.	610939
9	controlled clinical trial.pt.	95515
10	randomized.ab.	642066
11	placebo.ab.	247433
12	clinical trials as topic.sh.	202038
13	randomly.ab.	431385
14	trial.ti.	307064
15	or/8-14	1592779
16	Epidemiologic Methods/	31618
17	exp Epidemiologic Studies/	3268699
18	Observational Studies as Topic/	9695
19	Clinical Studies as Topic/	828
20	(Observational Study or Validation Studies or Clinical Study).pt.	160327
21	(observational adj3 (study or studies or design or analysis or analyses)).ti,ab,kf.	241743
22	cohort*.ti,ab,kf.	935242
23	(prospective adj7 (study or studies or design or analysis or analyses)).ti,ab,kf.	562423
24	((follow up or followup) adj7 (study or studies or design or analysis or analyses)).ti,ab,kf.	178483
25	((longitudinal or longterm or (long adj term)) adj7 (study or studies or design or analysis or analyses or data)).ti,ab,kf.	368508
26	(retrospective adj7 (study or studies or design or analysis or analyses or data or review)).ti,ab,kf.	739357
27	((case adj control) or (case adj comparison) or (case adj controlled)).ti,ab,kf.	167222
28	(case-referent adj3 (study or studies or design or analysis or analyses)).ti,ab,kf.	642
29	(population adj3 (study or studies or analysis or analyses)).ti,ab,kf.	247346
30	((multidimensional or (multi adj dimensional)) adj3 (study or studies or design or analysis or analyses)).ti,ab,kf.	5300
31	(quasi adj (experiment or experiments or experimental)).ti,ab,kf.	22377
32	(interrupt* time* series or (segment$2 adj3 regression) or (before adj2 after)).ti,ab,kf.	353831
33	("single-arm" or "single arm" or "non random*" or "non-random").ti,ab,kf.	42155
34	or/16-33	4672362
35	7 and (15 or 34)	991
36	exp animals/ not humans.sh.	5212238
37	35 not 36	978

Economic evaluations and utilities search

Database(s): **Ovid MEDLINE(R) ALL** 1946 to April 09, 2024
Search Strategy:

#	Searches	Results
1	Surgical Stomas/	2518
2	Colostomy/ or ostomy/ or Ileostomy/	16840
3	(stoma or stomas or colostom* or ostom* or ileostom*).ti,ab,kw.	28381
4	"stoma care".tw.	703
5	or/1-4	34996
6	"Value of Life"/	5824
7	Quality of Life/	286173
8	quality of life.ti,kf.	123991
9	((instrument or instruments) adj3 quality of life).ab.	4040
10	Quality-Adjusted Life Years/	16265
11	quality adjusted life.ti,ab,kf.	18489
12	(qaly* or qald* or qale* or qtime* or life year or life years).ti,ab,kf.	30156
13	disability adjusted life.ti,ab,kf.	6049
14	daly*.ti,ab,kf.	5460
15	(sf36 or sf 36 or short form 36 or shortform 36 or short form36 or shortform36 or sf thirtysix or sfthirtysix or sfthirty six or sf thirty six or shortform thirtysix or shortform thirty six or short form thirtysix or short form thirty six).ti,ab,kf.	31801
16	(sf6 or sf 6 or short form 6 or shortform 6 or sf six or sfsix or shortform six or short form six or shortform6 or short form6).ti,ab,kf.	2758
17	(sf8 or sf 8 or sf eight or sfeight or shortform 8 or shortform 8 or shortform8 or short form8 or shortform eight or short form eight).ti,ab,kf.	647
18	(sf12 or sf 12 or short form 12 or shortform 12 or short form12 or shortform12 or sf twelve or sftwelve or shortform twelve or short form twelve).ti,ab,kf.	8072
19	(sf16 or sf 16 or short form 16 or shortform 16 or short form16 or shortform16 or sf sixteen or sfsixteen or shortform sixteen or short form sixteen).ti,ab,kf.	42
20	(sf20 or sf 20 or short form 20 or shortform 20 or short form20 or shortform20 or sf twenty or sftwenty or shortform twenty or short form twenty).ti,ab,kf.	468
21	(hql or hqol or h qol or hrqol or hr qol).ti,ab,kf.	25802
22	(hye or hyes).ti,ab,kf.	78
23	(health* adj2 year* adj2 equivalent*).ti,ab,kf.	48
24	(pqol or qls).ti,ab,kf.	480
25	(quality of wellbeing or quality of well being or index of wellbeing or index of well being or qwb).ti,ab,kf.	751
26	nottingham health profile*.ti,ab,kf.	1258
27	sickness impact profile.ti,ab,kf.	1101
28	exp health status indicators/	345495
29	(health adj3 (utilit* or status)).ti,ab,kf.	96976
30	(utilit* adj3 (valu* or measur* or health or life or estimat* or elicit* or disease or score* or weight)).ti,ab,kf.	16862
31	(preference* adj3 (valu* or measur* or health or life or estimat* or elicit* or disease or score* or instrument or instruments)).ti,ab,kf.	15256
32	disutilit*.ti,ab,kf.	673
33	rosser.ti,ab,kf.	112

34	willingness to pay.ti,ab,kf.	9356
35	standard gamble*.ti,ab,kf.	922
36	(time trade off or time tradeoff).ti,ab,kf.	1717
37	tto.ti,ab,kf.	1487
38	(hui or hui1 or hui2 or hui3).ti,ab,kf.	2083
39	(eq or euroqol or euro qol or eq5d or eq 5d or euroqual or euro qual).ti,ab,kf.	24439
40	duke health profile.ti,ab,kf.	94
41	functional status questionnaire.ti,ab,kf.	134
42	dartmouth coop functional health assessment*.ti,ab,kf.	14
43	Ostomy-Q.ti,ab,kf.	3
44	Stoma Quality of Life Questionnaire.ti,ab,kf.	7
45	Ostomy Adjustment Inventory.ti,ab,kf.	29
46	or/6-45	783222
47	exp "Costs and Cost Analysis"/	269731
48	(cost* adj2 (effective* or utilit* or benefit* or minimi* or analy* or outcome or outcomes)).ab,kf.	223191
49	(value adj2 (money or monetary)).ti,ab,kf.	3184
50	exp models, economic/	16277
51	economic model*.ab,kf.	4425
52	markov chains/	16093
53	markov.ti,ab,kf.	30580
54	monte carlo method/	32756
55	monte carlo.ti,ab,kf.	62758
56	exp Decision Theory/	13607
57	(decision* adj2 (tree* or analy* or model*)).ti,ab,kf.	42140
58	or/47-57	561449
59	afghanistan/ or africa/ or africa, northern/ or africa, central/ or africa, eastern/ or "africa south of the sahara"/ or africa, southern/ or africa, western/ or albania/ or algeria/ or andorra/ or angola/ or "antigua and barbuda"/ or argentina/ or armenia/ or azerbaijan/ or bahamas/ or bahrain/ or bangladesh/ or barbados/ or belize/ or benin/ or bhutan/ or bolivia/ or borneo/ or "bosnia and herzegovina"/ or botswana/ or brazil/ or brunei/ or bulgaria/ or burkina faso/ or burundi/ or cabo verde/ or cambodia/ or cameroon/ or central african republic/ or chad/ or exp china/ or comoros/ or congo/ or cote d'ivoire/ or croatia/ or cuba/ or "democratic republic of the congo"/ or cyprus/ or djibouti/ or dominica/ or dominican republic/ or ecuador/ or egypt/ or el salvador/ or equatorial guinea/ or eritrea/ or eswatini/ or ethiopia/ or fiji/ or gabon/ or gambia/ or "georgia (republic)"/ or ghana/ or grenada/ or guatemala/ or guinea/ or guinea-bissau/ or guyana/ or haiti/ or honduras/ or independent state of samoa/ or exp india/ or indian ocean islands/ or indochina/ or indonesia/ or iran/ or iraq/ or jamaica/ or jordan/ or kazakhstan/ or kenya/ or kosovo/ or kuwait/ or kyrgyzstan/ or laos/ or lebanon/ or liechtenstein/ or lesotho/ or liberia/ or libya/ or madagascar/ or malaysia/ or malawi/ or mali/ or malta/ or mauritania/ or mauritius/ or mekong valley/ or melanesia/ or micronesia/ or monaco/ or mongolia/ or montenegro/ or morocco/ or mozambique/ or myanmar/ or namibia/ or nepal/ or nicaragua/ or niger/ or nigeria/ or oman/ or pakistan/ or palau/ or exp panama/ or papua new guinea/ or paraguay/ or peru/ or philippines/ or qatar/ or "republic of belarus"/ or "republic of north macedonia"/ or romania/ or exp russia/ or rwanda/ or "saint kitts and nevis"/ or saint lucia/ or "saint vincent and the grenadines"/ or "sao tome and principe"/ or saudi arabia/ or serbia/ or sierra leone/ or senegal/ or seychelles/ or singapore/ or somalia/ or south africa/ or south sudan/ or sri lanka/ or sudan/ or suriname/ or syria/ or taiwan/ or tajikistan/ or tanzania/ or thailand/ or timor-leste/ or togo/ or tonga/ or "trinidad and tobago"/ or tunisia/ or turkmenistan/ or uganda/ or ukraine/ or united arab emirates/ or uruguay/ or uzbekistan/ or vanuatu/ or venezuela/ or vietnam/ or west indies/ or yemen/ or zambia/ or zimbabwe/	1335270
60	"Organisation for Economic Co-Operation and Development"/	599
61	australasia/ or exp australia/ or austria/ or baltic states/ or belgium/ or exp canada/ or chile/ or colombia/ or costa rica/ or czech republic/ or exp denmark/ or estonia/ or europe/ or finland/ or exp france/ or exp germany/ or greece/ or hungary/ or iceland/ or ireland/ or israel/ or exp italy/ or exp japan/ or korea/ or latvia/ or lithuania/ or luxembourg/ or mexico/ or netherlands/ or new zealand/ or north america/ or exp norway/ or poland/ or portugal/ or exp "republic of korea"/ or "scandinavian	3542222

	and nordic countries"/ or slovakia/ or slovenia/ or spain/ or sweden/ or switzerland/ or turkey/ or exp united kingdom/ or exp united states/	
62	European Union/	17963
63	Developed Countries/	21517
64	or/60-63	3558505
65	59 not 64	1244601
66	58 not 65	527653
67	5 and (46 or 66)	2928