School of Nursing and Human Sciences
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Patient engagement in the governance and development of national clinical effectiveness processes (i.e. clinical audit & guidelines): A systematic literature review and desk-top analysis

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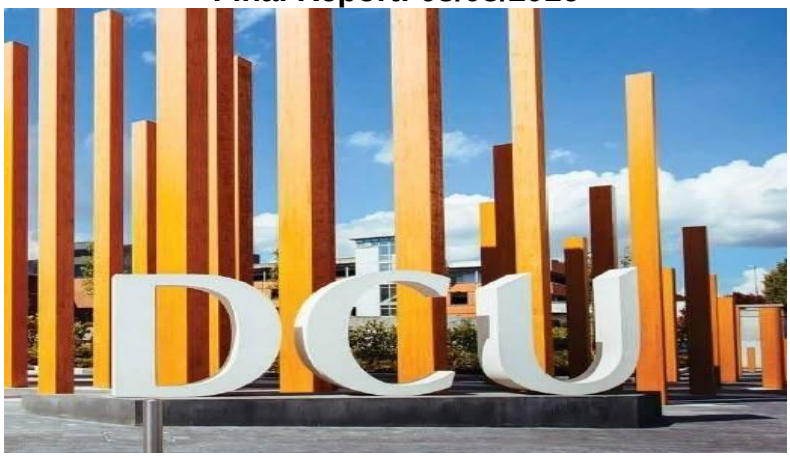

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PATIENT AND PUBLIC INVOLVEMENT IN CLINICAL EFFECTIVENESS PROCESSES
***EXECUTIVE SUMMARY* OF SYSTEMATIC REVIEW FINDINGS**

Aim and objectives

This commissioned systematic review aimed to synthesis available evidence (published and unpublished) on patient and public involvement (PPI) in the development and governance of national clinical effectiveness processes, including clinical guideline development and clinical audit processes. The five main objectives of the review focused on examining the benefits, barriers, enablers, approaches, supports and evaluation mechanisms in relation to patient and public involvement in clinical effectiveness processes.

Methodology

The methodology of this review was conducted and reported in accordance with the Centre for Reviews and Dissemination (CRD) (2008) guidance for undertaking systematic reviews in healthcare and the reporting of this review adhered to, as far as possible, the Preferred Reporting in Systematic Reviews and Meta-Analysis (PRISMA) criteria (Moher et al. 2009). Alongside having an expert by experience as a key member of the review team an Expert by Experience Advisory Group was established prior to commencement of the review with the remit to offer expertise through lived experience, patient advocate and service user involvement expertise on considering the emergent evidence on PPI in clinical effectiveness processes.

We used a comprehensive search methodology to retrieve published (peer-reviewed) and unpublished (grey) evidence nationally and internationally; including electronic databases, grey literature, clinical audit and clinical guidelines organisations. Documents were included if they reported specifically on patient and public involvement in the development, and or governance, of clinical effectiveness processes; inclusive of clinical audit processes and clinical guideline development at a national, or equivalent, level. No research study design limits were applied and we included primary and secondary research, descriptive pieces and manuals, toolkits, policies and strategies produced by national, government and/or other relevant organizations with remit for clinical guideline and audit processes.

Titles, abstracts and full text (as appropriate) of potentially eligible documents were assessed independently by two reviewers against the inclusion criteria; with a third reviewer resolving any discrepancies. Duplicate data extraction was also conducted by two independent reviewers with any discrepancies resolved through discussion and consensus with a third reviewer.

For primary and secondary research studies eligible for quality appraisal we used three different quality appraisal instruments to take account of diverse study designs including, the critical appraisal skills programme (CASP) appraisal tool for qualitative studies, a slightly modified version of a quality appraisal tool designed by Tsimicalis et al. (2005) for quantitative studies and AMSTAR (A Measurement Tool to Assess Systematic Reviews) for secondary review papers. For primary and secondary research studies we tabulated the level of evidence in accordance with the Scottish Intercollegiate Guidelines Network criteria for assignment of levels of research evidence. Results were summarised narratively according to the review objectives.

Results

From a total screening of 2,515 documents, we identified 41 documents as eligible for inclusion in the review. Of these 41 documents 13 were classified as discursive/descriptive/opinion pieces, 7 were original primary research studies, 7 were toolkits or reference manuals, 6 were secondary research reviews, 3 were evaluation

studies, 2 were protocols, 2 were policy or strategy documents and 1 was a research briefing summary.

Thirteen primary and secondary research studies were eligible for quality appraisal. All 13 studies were found to be of moderately high quality. It is important to note however that recorded ratings are representative, not only of study quality, but also reflective of methodological reporting and the match between the quality appraisal tool and the design of the research studies which impacted on the overall study quality assessment.

Findings

This review revealed evidence that PPI in national clinical effectiveness processes does take place internationally. However, robust empirical evidence on which PPI strategy or approach is most effective was limited. The majority of documents reviewed reported on PPI in clinical guideline development with a dearth of data on PPI in clinical audit processes. In considering the review objectives, some of the main findings identified are summarised below.

Benefits of PPI in clinical effectiveness processes

Despite a general consensus that patient and public representatives should be involved in clinical effectiveness processes, the added benefits of PPI in clinical effectiveness processes has yet to be established empirically. Notwithstanding this, the difficulty, or perhaps impossibility, of examining the effects of patient participation using randomised controlled trials was acknowledged, in addition to, the fact that decision-making processes may need to be studied in different ways.

Barriers and facilitators to PPI in clinical effectiveness processes

The review identified a number of potential barriers and facilitators to PPI in clinical effectiveness processes. As dual barriers and facilitators to PPI, core issues to take account of included; the representation and selection process for patient and public representatives; transparency in terms of the roles and responsibilities of patient and public representatives; training and support mechanisms, use of a range of PPI approaches, being committing to and valuing PPI and working in a mutually respectful environment.

Approaches to PPI in clinical effectiveness processes

Three main PPI strategies identified in this review were consultation, participation and communication. While there was limited data available on evidence based outcomes on the strengths and weaknesses of these three PPI strategies it was recognised that each strategy has strengths and limitations. Consequently, it was acknowledged that effective involvement should begin with finding the best approach tailored to the specific PPI goal in any given context; and the level of involvement should be clear and transparent for all concerned. Representation of lay members was often restricted to a select number of patient or patient representatives/organisations and did not by large include a diverse population of patients and/or the general public.

Methods and systems to support PPI in clinical effectiveness processes

The consensual evidence is that patient representatives should be trained, prepared, guided and educated for their role. Practical, emotional and financial assistance, as appropriate, should be provided. Limited reporting existed on the model, mode, delivery, timing, content, trainers, cost, evaluation of and effective impact of various training and support mechanisms.

Evaluation of PPI approaches or systems to support PPI in clinical effectiveness processes

There was a paucity of rigorous process and impact evaluations to determine the effectiveness of PPI approaches, and/or methods and systems to support PPI, in clinical effectiveness processes.

Conclusions

Despite a lack of empirical evidence, the documents appraised in this review do provide baseline data and valuable insights into the complex process of integrating PPI into clinical effectiveness processes. Further research is needed to establish the effectiveness of different PPI programmes (PPIP's) used in clinical effectiveness processes. Better evaluation of PPI in clinical effectiveness processes could potentially enhance the wider acceptance and development of PPIP's if seen to be effective.

Some important key principles identified from this review for the NCEC's consideration in relation to PPI in national clinical effectiveness processes include:

1. Despite a lack of robust evidence on the specific value of PPI in national clinical effectiveness processes, consideration should be given to the integration of PPI into these processes to strengthen public participation in healthcare decision-making and to bring expert experiential knowledge to these processes.

2. The three PPI strategies of consultation, participation and communication can be employed as required in each clinical effectiveness process, and full active public/patient participation should be explored where appropriate.

3. The most appropriate patient and public representation should be examined for each case, drawing on public, patient, carer and other peer or lay representatives; there is no evidence to recommend one approach to the selection and recruitment of patient and public representatives though a transparent process is required.

4. There is a need for comprehensive support for patient and public representatives, specifically in terms of support from the chair of the guideline development group, training, remuneration/compensation, physical, psychosocial and emotional support.

5. Several international organisations (e.g. NICE in the UK, SIGN in the UK, G-I-N International Network, HQIP in the UK) have developed structured PPI programmes, with supporting resources, to underpin their clinical effectiveness approaches. These offer potentially valuable models to examine further for any framework development.

6. There is a need for further research into the effectiveness of different approaches to PPI in clinical effectiveness processes.

PATIENT AND PUBLIC INVOLVEMENT – SYSTEMATIC REVIEW REPORT

1.0. Background

There is growing consensus about the crucial role of patient and/or patient representative, public advocate involvement in clinical effectiveness processes, including clinical guideline development and audit processes. This is important as health professionals perspectives on healthcare processes, priorities and outcomes may differ from the perspectives and priorities of patients. Ensuring that clinical effectiveness processes reflect the needs and concerns of patients may help with achieving the translation of recommendations into clinical practice. However, difficulties can ensue in making patient and public contribution effective as it remains unclear on how best to conduct this process of lay stakeholder engagement in the context of clinical practice guidelines and clinical audit processes. Consequently, this review aimed to synthesis available evidence (published and unpublished) on patient and public involvement in the development and governance of clinical effectiveness processes.

2.0. Aim

This review aimed to identify the available evidence to support, or not, public and patient (defined as patient or patient advocate) engagement/involvement in the development and governance of national clinical effectiveness processes, including clinical audit processes and clinical guideline development.

3.0. Objectives

The following objectives were addressed;

1. Identify the available evidence on the benefits of patient engagement for clinical practice generally, and, more specifically, in clinical effectiveness processes
2. Ascertain, from the evidence sourced, what barriers and enablers exist to patient engagement for clinical practice generally and, more specifically, in clinical effectiveness processes
3. Synthesis the evidence on the clinical effectiveness processes that patients are engaged in; including
    i. Summary of approaches used e.g. consultation, committee membership etc.
    ii. Describe the reported benefits and weaknesses of each approach
4. Synthesis the evidence on the methods and systems, including training, that are in place to engage and support patients in the development and governance of the clinical effectiveness processes of clinical audit and clinical guidelines at national (or equivalent) level
5. Identify what measurement or evaluation has occurred in relation to patient engagement or the systems and methods used to support patient engagement

These objectives were confirmed with the member of the DoH Clinical Effectiveness Unit assigned as the literature review contact point prior to the commencement of the review. In the absence of any hard evidence on PPI in clinical effectiveness processes, it was agreed with the contact points from the DoH, CEU, that we would report on key principles of PPI that were reported in the literature and this may include descriptive/opinion papers.

4.0. Statement in relation to terminology use – patient and public involvement (PPI)

As outlined above, the purpose of this review is to examine patient and public involvement (PPI) in clinical effectiveness processes. Acknowledging that PPI is an increasingly used term and acronym at our expert advisory group meetings we discussed terminology and its importance and reflected upon how it illustrates different positions. Perhaps the most widely used definition of PPI, in the context of research, is that of INVOLVE (UK) (http://www.invo.org.uk/) which has been adopted by the Irish Health Research Forum (2015) which views PPI as "research being carried out ***'with'*** or ***'by'*** members of the public rather than ***'to'***, ***'about'*** or ***'for'*** them. Notwithstanding this, we are cognisant of the diverse terminology that can represent ***public*** including but not limited to patient, patient

representative carer, family member, service user, lay member and/or consumer. From our perspective and that of the expert advisory group terms such as *expert by experience*, *expert through lived experience* and/or *experience in self-management of a condition(s)* are preferable terms. However, as this is a review of available evidence, in reporting outcomes and findings of this review we will use the terminology applied by the various authors of the documents included in the review i.e. we will traverse between multiple terms, as aforementioned, all of which could be framed in the context of PPI acknowledging that many terms are used interchangeably to represent PPI.

5.0. Methods

The methodology of this review was conducted and reported in accordance with the Centre for Reviews and Dissemination (CRD) (2008) guidance for undertaking systematic reviews in healthcare and the reporting of this review adhered to, as far as possible, the Preferred Reporting in Systematic Reviews and Meta-Analysis (PRISMA) criteria (Moher et al. 2009).

5.1. Expert by experience advisory group

Alongside having an expert by experience (OOC) as a key member of the review team an Expert by Experience Advisory Group was established prior to commencement of this review with the remit to offer expertise through lived experience, patient advocate and service user involvement expertise on considering the emergent evidence on PPI in clinical effectiveness processes. The Advisory Group met either face-to-face or via teleconference at three time-points over the review process, as illustrated in Figure 1, and also corresponded via email as required.

Figure 1: Expert by experience advisory group meetings

Meeting 1 *(at ouset of review)*	Meeting 2 *(mid-point of review)*	Meeting 3 *(end of the review)*
• To comment on the review proposal and review search strategy	• To discuss the evidence emerging from the review	• To review the draft/final review report

5.2. Search strategy

We used a comprehensive search methodology to retrieve published (peer-reviewed) and unpublished (grey) evidence nationally and internationally; including electronic databases, grey literature and clinical audit/guideline organisations. We also scanned bibliographies of all included papers/documents and identified any other relevant information on unpublished and ongoing work by contacting experts in the field.

Electronic databases

We searched PubMed, CINAHL, PsycINFO, EMBASE, Web of Science and Cochrane (inclusive of Cochrane Database of Systematic Review; Database of Abstracts of Review Effects (DARE), and CENTRAL - Cochrane Central Register of Controlled Trials) using various combinations of controlled vocabulary (e.g. MeSH) (Table 1) guided by our PICOS parameters (Table 2). We initially developed the search strategy for PubMed (Appendix 1) and once defined and tested we adapted it for application to other databases. Given the timeframe available for the review we limited the search by publication date (01/01/1990 to 09/11/2015), publication type (journal article) and language (English).

Table 1: Controlled vocabulary search terms

Group #1 terms	Group #2 terms
"patient and public involvement" OR "patient participation" OR "patient engagement" OR "patient consultation" OR "patient collaboration" OR "client engagement" OR "client participation" OR "client consultation" OR "client collaboration" OR "public engagement" OR "public participation" OR "public collaboration" OR "public consultation" OR "community engagement" OR "community participation" OR "community collaboration" OR "community consultation" OR "carer engagement" OR "carer participation" OR "caregiver engagement" OR "caregiver participation" OR "parent engagement" OR "parent participation" OR "parent consultation" OR "parent collaboration" OR "relative engagement" OR "relative participation" OR “patient empowerment” OR “patient rights”	"clinical effectiveness" OR "clinical audit" OR "audit" OR "guideline" OR "clinical guideline" OR "practice guideline" OR "clinical practice guideline"

Combine #1 AND #2 and apply limiters

Table 2: Population, Intervention, Comparison, Outcomes, Study Design (PICOS)

PICO	Indicative Terms
Population	Patient, or patient advocate, with personal experience of disease, condition, health intervention or service (including carers and family members) Public referred to as members of society interested in health care services or whose life is affected directly or indirectly by a clinical guideline/audit People representing a collective group of patients or carers (representatives or advocates)
Intervention	Any patient and public involvement (PPI) method/system that engages patient’s and the public in clinical practice generally, and more specifically, in clinical effectiveness processes (i.e. clinical audit and clinical guideline development), at any stage of the development and implementation process
Comparison	No, or non-use, of the PPI method/system or use of an alternative/comparative PPI method/system
Outcome	Types of PPI methods/systems/approaches Types of education/training for PPI Evaluation strategies/methods of PPI Number and type of toolkits for PPI
Study Design	Original research studies of any design inclusive of qualitative, quantitative or mixed methods designs and systematic review papers Documents/toolkits produced by national/international agencies/networks, governmental/policy institutions, clinical practice guideline and/or audit organisations to describe their PPI processes

Grey literature

For unpublished evidence in relation to PPI, we searched grey literature sites using a limited set of key words (e.g. “patient and public involvement”, “patient participation in clinical guidelines”; “public involvement in clinical guidelines”; “patient participation in clinical audit”; “public involvement in clinical audit” and “patient and public involvement AND clinical effectiveness processes”). We searched grey literature as follows:

(1) *specific grey literature databases* including the Open Grey System for Information on Grey Literature in Europe, the Agency for Healthcare Research and Quality (AHRQ), the UK Clinical Research Network (UKCRN), and the New York Academy of Medicine – Grey Literature Report; (Appendix 2)

(2) *national/international agencies/networks including* King’s Fund, Picker Institute Europe, Equator Network, Guidelines International Network (G-I-N); Scottish Intercollegiate Guidelines Network (SIGN), National Institute for Health and Care Excellence (NICE), Healthcare Quality Improvement Partnership (HQIP), New Zealand Guidelines Group (NZGG), eLSC Practice Guidance & Standards Database, Institute of Medicine, National Health and Medical Research Council (NHMRC) Australia, Australian Commission on Safety and Quality in Health Care, International

Society for Quality in Healthcare (ISQua) and Institute for Healthcare Improvement (IHI), European Network on Patient Empowerment; (Appendix 3)

(3) *clinical trial registers* (for ongoing (and complete unpublished) clinical trials) including the International Standard RCT Number Register (ISRCTN), the MetaRegister of Controlled Trials, clinicaltrials.gov, UK Clinical Trials Gateway, Australian New Zealand Clinical Trials Register (ANZCTR) and the WHO International Clinical Trials Registry Platform (Appendix 4).

5.3. Inclusion and exclusion criteria

To be included eligible papers had to refer to patient and public involvement (PPI) in the development, and or governance, of national clinical effectiveness processes; inclusive of clinical audits and clinical guidelines at a national, or equivalent, level. We included original research (with no study design restrictions i.e. qualitative, quantitative or mixed-method studies), secondary reviews and reports/toolkits produced by national, government and/or other relevant organizations with remit for clinical guideline and audit processes.

We excluded papers that focused on the incorporation of patient personal values, beliefs and preferences in relation to treatment management into recommendations of clinical guideline documents. These are recommendations for health professionals on supporting the involvement of patient in, taking account of their needs, circumstances and preferences, which differs from the involvement of patients in guideline development groups and formal consultation processes that take place with patients during guideline development. The establishment of this clear distinction was emphasised by Kelson et al. (2012 p. 262);

> *"a clear distinction needs to be made between the use of information on consumer values and preferences by guideline developers, and the direct involvement of consumers in guideline development processes. Sources of information on consumer values include the research literature and direct elicitation of values both from organizations representing consumer interests and from individuals. To complement the identification of consumer values, there are a range of methods for involving consumers at all stages of guideline development, from consultation to direct membership of guideline development groups".*

5.4. Screening and selection process

The *Covidence* online software product (https://www.covidence.org/) was used to assist with the screening and selection process. For this, titles, abstracts and full-texts, as required, were imported into *Covidence*. For stage 1 screening, two reviewers independently assessed each title and abstract retrieved from the electronic searches for relevance (REM, AM). Any discrepancies were resolved by discussion and consensus with a third reviewer (VL). If no abstract was available, the full-text paper was sourced and assessed. For studies deemed to meet the inclusion criteria, full texts of the studies were obtained. Full text papers were independently assessed by two-three reviewers (REM, AM, VL) against the inclusion criteria before a final decision regarding inclusion/exclusion was confirmed. Any discrepancies were resolved by discussion and consensus among all reviewers. We recorded studies excluded from the review; noting reasons for exclusion.

5.5. Appraisal of the evidence

We used three different quality appraisal instruments in order to take account of the different study designs that were eligible for quality appraisal (n=13 in total) i.e. primary qualitative, quantitative, and mixed method research studies and secondary review papers. The nature of the broad range of other documents (i.e. discursive/descriptive/opinion papers, process evaluations, briefings, policies/strategies, and protocols and toolkits) (n=28) precluded their quality appraisal. To assess the quality of primary qualitative studies (n=4) and the qualitative component a mixed method studies (n=1) we used the critical appraisal skills programme (CASP) appraisal tool (http://www.casp-uk.net). The CASP is a 10-question checklist that reports on the quality of qualitative research including appropriateness of the

methodology, recruitment strategy, data collection methods, data analysis processes, ethical considerations, research-participant relationships, findings and research value. Each question is assessed by reviewers selecting one of three answers (i.e. yes, no, or can't tell) to indicate whether the checklist items relevant to that question were addressed within the research paper. To assess the quality of quantitative cross-sectional surveys (n=1) and Delphi approach methods (principally quantitative) (n=1) we used a slightly modified version of a quality appraisal tool designed by Tsimicalis et al. (2005). This tool assesses the following five parameters; study design, participants and recruitment, comparison group, number of participants, and instrument psychometric properties/outcome measurement. Each parameter is rated from 0 to 3 with an overall maximum methodological quality score of 15 (indicative of robust methodological quality). To assess the quality of secondary review papers (n=6) we used AMSTAR (A Measurement Tool to Assess Systematic Reviews) (Shea et al. 2009). The AMSTAR quality appraisal tool consists of 11 question items for measuring the methodological quality of systematic reviews according to a number of factors including a priori design, duplicate study selection and data extraction, comprehensive literature search, inclusion criteria, list and characteristics of studies included and excluded, scientific assessment of included studies, appropriate synthesis methods, publication bias and conflict of interest. Each question item is assessed by reviewers selecting one of four answers (i.e. yes, no, can't answer, or not appropriate) to indicate whether that item was addressed within the review paper. Finally, we identified the level of evidence, for all primary and secondary research studies (n=13) eligible for inclusion in the review, in accordance with the Scottish Intercollegiate Guidelines Network (SIGN) criteria for assignment of levels of evidence, and presented this in an evidence table. One reviewer (VL) conducted the quality appraisal and level of evidence assessment which was cross-checked by a second reviewer (AM) with any discrepancies resolved through discussion and consensus.

5.6. Data extraction

Two reviewers independently extracted and managed data from the included studies/documents (VL, R EM). Any discrepancies were resolved through consultation with another reviewer (AM). A number of data extraction tables were developed, and piloted, to retrieve information pertaining to each document. Initially data was extracted on the characteristics of the document including bibliographic reference, aim, design/type of document and sample/methods as appropriate (see Table 4). Following this, a table mapping each document to the review objectives of benefits, barriers, enablers, approaches, support and evaluation was developed to provide a visual overall of all the documents (see Table 5). This then assisted with data extraction from each document according to each review objective, including; benefits of, barriers and enablers to patient engagement in clinical effectiveness processes; PPI approaches including strengths and weaknesses of such approaches if reported; supports including training for patients/carers and any evaluation methods/systems reported for patient engagement in clinical effectiveness processes (see Tables 10-12 and 14-16).

5.7. Synthesis of the evidence

Because of the heterogeneity of study designs and lack of standard approach employed to identity the best ways to engage patients and the public in the development and implementation of clinical effectiveness processes, it was not possible to conduct a meta-analysis and/or a meta-synthesis. Consequently, all data were narratively synthesised according to the review objectives.

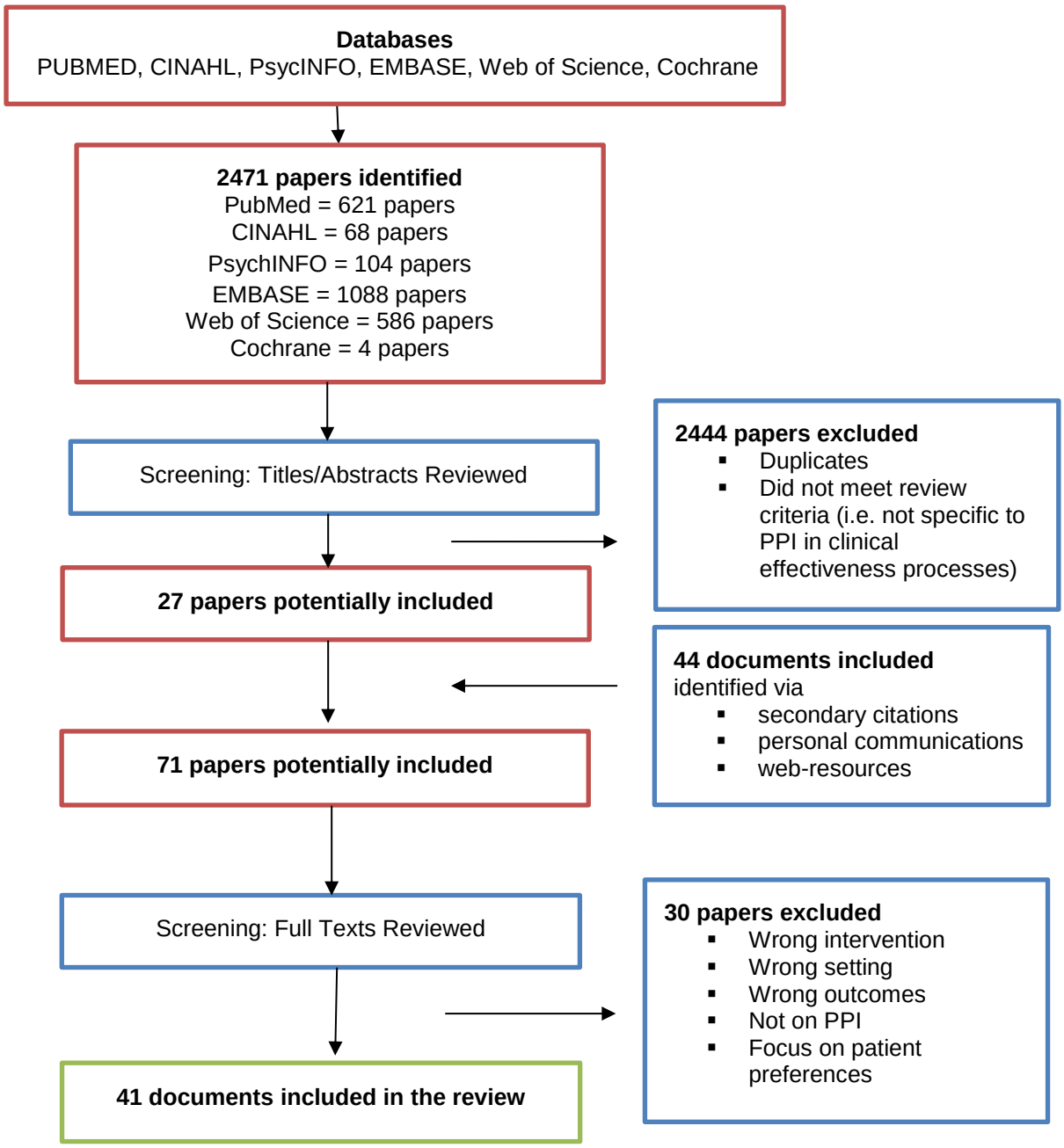
6.0. Results

6.1. Overall search and selection results

Figure 2, an adapted PRISMA flow chart, visually displays the search and selection process. Overall our search strategy identified 2,471 papers as potentially eligible for inclusion in the review. Following the first screening of titles and abstracts we excluded 2,444 papers because they were duplicate papers or not specifically related to PPI in clinical effectiveness

processes. We obtained full texts of the remaining 27 papers. Alongside this we sourced an additional 44 documents through secondary citations, personal communications and web-resources. This resulted in a total of 71 documents identified as potentially eligible for inclusion in the review. On the second screening of these 71 full text documents we excluded a further 30 papers because they were not specific to PPI in the context of clinical effectiveness processes (i.e. wrong intervention), they were not conducted at a national (or equivalent) level (i.e. wrong setting); they were focused on the reference to patient preference to treatment management in the guideline in relation to meeting guideline quality standards as opposed to PPI in the development and implementation of the guideline. We were left with 41 documents that met the inclusion criteria.

Figure 2: Flowchart of search strategy outputs and screening process



6.2. Description of included documents

The documents were classified as discursive/descriptive/opinion pieces *(n=13)*; original primary research studies *(n=7)*, inclusive of qualitative studies *(n=4)*, quantitative surveys *(n=1)*, Delphi-method *(n=1)* and mixed method *(n=1)*; toolkits/reference manuals *(n=7)*; secondary literature review papers *(n=6)*; evaluation studies *(n=3)*; study/review protocols *(n=2)*; policy/strategy documents *(n=2)* and a briefing report *(n=1)*. See Table 3.

Table 3: Classification of included documents

Classification of included documents	Number of documents	Citations
Discursive/descriptive/ opinion papers	13	Rigge 1994, Newton 1996, Bastain 1996, Duff et al. 1996, Kelson 2001, van Wersch & Eccles 2001, Baker 2005, Boivin et al. 2010, Del Campo et al. 2011, Harding et al. 2011, Rao 2011, Wedzicha et al. 2011, Roman & Feingold 2014
Original primary research studies *Qualitative studies (4)* *Quantitative survey (1)* *Delphi method (1)* *Mixed method (1)*	7	 Harding et al. 2010, Legare et al. 2012, van der Ham et al. 2014, van der Ham et al. 2015 Rankin et al. 2000 Serrano-Aguilar et al. 2015 van de Bovenkamp & Zuiderent-Jerak 2013
Toolkits/reference manuals/report	7	IOM 2011, NHMRC 2011, SIGN 2014, NICE 2014a, NICE 2014b, NICE 2015, GIN 2015
Secondary literature review papers	6	Nilsen et al. 2006, Schunemann et al. 2006, van de Bovenkamp & Trappenburg 2009, Legare et al. 2011, Kelson et al. 2012, Young et al. 2015
Evaluation studies	3	Jarrett & PIU 2004, Den Breejen et al. 2012, Den Breejen et al. 2014
Protocol (study/review)	2	Legare et al. 2009, Lamontagne et al. 2014
Policy/Strategy	2	NICE 2013, HQIP 2015
Briefing report (on an evaluation study)	1	Thomas undated
Total	**41**	

The overall characteristics of the 41 included documents are summarised in Table 4. The documents were published from 1994 to 2015 and originated from the UK *(n=10)* (Duff et al. 1996, Newton 1996, Kelson 2001, van Wersch and Eccles 2001, Baker 2005, Harding et al. 2010, Harding et al. 2011, Rigge 2011, Wedzicha et al. 2011, HQIP 2015), Netherlands *(n=7)* (van de Bovenkamp & Trappenburg 2009, Boivin et al. 2010, Den Breejen et al. 2012, van de Bovenkamp & Zuiderent-Jerak 2013, Den Breejen et al. 2014, van der Ham et al. 2014, van der Ham et al. 2015), England *(n=6)* (Jarrett & PIU 2004, Thomas undated, NICE 2013, NICE 2014a, NICE 2014b, NICE 2015) , Canada *(n=4)* (Legare et al. 2009, Legare et al. 2011, Legare et al. 2012, Lamontagne et al. 2014), Australia *(n=4)* (Bastian 1996, Rankin et al. 2000, NHMRC 2011, Young et al. 2015), Spain *(n=2)* (Del Campo et al. 2011, Serrano-Aguilar et al. 2015), on behalf national organisations/international networks *(n=2)* (Kelson et al. 2012, GIN 2015), USA *(n=2)* (IOM 2011, Roman & Feingold 2014), Norway *(n=1)* (Nilsen et al. 2006), Scotland *(n=1)* (SIGN 2014), Italy *(n=1)* (Schunemann et al. 2006) and India *(n=1)* (Rao 2011).

Table 4: Characteristics of included documents

Author/date Origin	Aim	Design	Sample (if applicable)	Method of data collection (if applicable)
Baker 2005 **UK**	To discuss published guidelines on referral for suspected cancer to illustrate approaches NICE adopted to assist decision making by patients	Discussion paper	Not applicable (NA)	NA
Bastian 1996 **Australia**	To advocate for combination of 3 types of strategies to enable better consideration of consumers' views in guideline development	Opinion piece	NA	NA
Boivin et al. 2010 **Netherlands**	To develop an international practice and research agenda on patient and public involvement in CPG	Descriptive paper	Reporting on international consultation 56 people from 14 countries inclusive of 35 guideline developers, 16 researchers & 5 public and patient representatives	Workshop 4 subgroups to discuss (1) expectations and goals of PPIP (2) participation and consultation in CPG development (3) the integration of patient decision support technologies (4) priorities for research and international collaboration
Del Campo et al. 2011 **Spain**	To present a strategy for patient involvement that includes both robust patient consultation in CPG preparation phase and participation in the development process	Descriptive paper	Reporting on a strategy	Based authors' experience in development of four CPGs included in Spanish National CPG Development Program
Den Breejen et al. 2012 **Netherlands**	To assess feasibility of a Wiki as participatory tool for patients in development of a guideline on infertility (1) use of wiki (2) benefits of wiki & (3) facilitators, barriers and the challenges to be overcome in improving wiki	Evaluation – multi-method	<u>Developing wiki content</u> Interviews with 12 infertile couples; recruited from OPD clinics in Nijmegen & Amsterdam Participants asked to specify perceived bottlenecks in fertility care pathway; these were then translated into 90 draft recommendations and entered into the wiki <u>Structure of wiki tool</u> FreyaWIKI structured through division of recommendations into 6 sections; each further divided into 8 subsections <u>Patient participation in CPG development</u> Mailings to members of Freya (Dutch patients' association for infertility), advertisements in Freya's quarterly journal, links on websites of Freya and professional societies (e.g. general practitioners, gynaecologists, urologists, and clinical embryologists), links in social media (e.g. Twitter, Facebook), and	<u>Wiki tool development</u> Conventional wiki website developed using MediaWiki software; accessible through Freya website In-depth interviews conducted to obtain initial content for the wiki <u>Wiki tool structure</u> The wiki then structured according to topics of the recommendations derived from the interviews <u>Obtaining recommendation from wiki participants</u> -Patients invited to modify, refine and/or add new recommendations in the wiki -Recommendations modified i.e. removed duplicates, moved recommendations into appropriate sections -2 researchers & chief executive of Freya independently assessed implementability of all recommendations using the Guideline Implementability Appraisal (GLIA) instrument -After consensus on final recommendations reached re-entered into wiki -All patients visiting the wiki website were invited to prioritize their top 3-5 (modified) recommendations in various sections -The entire CP GDG (n = 11) assessed eligibility of

			advertising posters to all 103 clinics offering fertility treatments in the Netherlands *Wiki Use and Users' Characteristics* During 7 months of access 36,473 wiki pages viewed (298 unique users, 81 registered users who provided background characteristics) *Wiki Content Quality* Collected 265 recommendations; modified to 289 unique recommendations; after prioritization (n=80 patients) 23 recommendations selected for eligibility assessment by CPG development group; 21 recommendations accepted and integrated into the CPG	recommendations for inclusion (i.e. in line with scope of guideline) Wiki evaluation 1. Evaluation of wiki use and users' characteristics (number of page views & visitors) 2. Evaluation of wiki content quality (i.e. recommendations) 3. Evaluation of wiki system quality (e.g. ease of use, layout), and to identify facilitators, barriers, and potential areas of improvement (online questionnaire & in-depth interviews)
Den Breejen et al. 2014 **Netherlands**	To assess feasibility of a patient-centered network approach	Evaluation – mixed method	Five (four MoG and one MuG) groups 32 participants involved in the 5 groups All participants received evaluation questionnaire; response rate was 79% (n = 27) 8 key figures interviewed: chairpersons of the four MoG groups, four members of the MuG group, and the steering committee (one patient representative, two project leaders, and the project coordinator)	Mixed-method evaluation including examination of secondary resources (such as project descriptions), interviews with key figures, and a written questionnaire survey
Duff et al. 1996 **UK**	To describe a national seminar which was held to examine patient and service user involvement in development and use of clinical guidelines & provides guidance points for collaborative working	Descriptive paper	Patient representatives, health professionals, researchers and actual patients	Seminar – 3 groups worked with a facilitator with the following questions used to focus the discussions - At what point within the process of developing guidelines would patients and service users like to, and could most effectively be involved? - How can patients most effectively be involved in developing clinical guidelines, and to their satisfaction? Feedback session at end of the day – audio-recorded and notes taken Results of the seminar were used to develop a set of guidance points for collaborative working between patients and health care professionals.
G-I-N Public Working Group 2015 (updated) Guidelines International Network/Scottish Charity	To provide practical advice based on published literature as well as the authors' experiences with PPI activities and methods	Toolkit	NA	NA
Harding et al. 2010 **UK**	To explore service users' experiences of involvement in development of NICE guidelines	Qualitative *Preliminary grounded theory study*	12 service user representatives from 9 completed/ongoing mental health guideline development groups	Semi-structured interviews

Harding et al. 2011 **UK**	Theoretical discussion to extend findings of Harding et al. 2010, alongside observations from research in guideline development and insights from the mental health recovery movement and shared decision making clinical model	Discussion paper *Theoretical*	NA	NA
Healthcare Quality Improvement Partnership (HQIP) 2015 **UK**	Describes HQIP's vision, commitment and approach to involving, engaging and informing patients and their representative organisations throughout their work	Strategy	NA	NA
Institute of Medicine 2011 **USA**	To develop a set of standards for developing rigorous, trustworthy clinical practice guidelines	Report	NA	NA
Jarrett & Patient Involvement Unit (PIU), NICE 2004 **England**	To explore the experiences of patient/carer members (PCMs) and chairs of Guideline Development Groups, to report on their experiences of patient/carer involvement on the groups, identify good practice, highlight problems, and to improve the process for future GDGs.	Evaluation – quantitative & qualitative data from interviews	36 PCMs (patient/carer members) & 19 chairs (20 GDGs in total; 18 GDGs with responses from both the Chair and at least one PCM) PCM characteristics • *22* had personal experience of the condition or topic under review • *5* were carers • *20* were employees of patient/carer organisations • *1* was a staff member from the Patient Involvement Unit *(some people fell into more than one category)*	Telephone of face-to-face interviews First eight interviews (5 with PCMs and 3 with chairs) carried out by a member of PIU. Remaining 47 interviews conducted by a freelance researcher Interview schedule adapted as the pilot progressed All participants asked to respond to a set of core questions in their own words After the first 6 interviews a scoring scheme was added - interviewees replied to questions in their own words and were then asked to summarise their views on related sets of questions by using a five point rating scale
Kelson 2001 **UK**	Discusses potential for, and progress made in, involving patients and carers in the development of national clinical guidelines (NICE)	Discursive paper	NA	NA
Kelson et al. 2012 **On behalf of American Thoracic Society (ATS) and & European Respiratory Society (ERS)**	How to involve consumers and integrate their values and preferences in guideline development	Review paper	Limited information reported on search screening and output process; narrative review presented	Searched PubMed and other databases for individual research studies that focused on COPD Searches supplemented by rapid appraisal of 34 qualitative studies concerning consumer involvement in guidelines undertaken by German Institute for Quality and Efficiency in Health Care (IQWiG) (personal communication) and with data gathered from authors with experience in guideline development and consumer involvement methodologies and workshop discussions.
Lamontagne et al. 2014	To document the acceptability, feasibility and	Protocol - study	Propose 20 patients with traumatic brain injury Recruited from members	Propose a single-blind, randomized, crossover pragmatic pilot trial Two alternative methods of producing

Canada	effectiveness of two methods of involving patients with a *disability* (traumatic brain injury) in CPG development.		of the Québec community-based association of individuals with TBI Randomized into 2 groups 20 experts, blinded to method of producing the recommendations, will independently rate the recommendations produced by the participants for clarity, accuracy, appropriateness and usefulness	recommendations • a discussion group (control intervention) • a Wiki (experimental intervention) <u>Outcomes</u> Acceptability and feasibility (indicators such as number of participants who accessed and completed the two methods, and the number of support interventions required) Effectiveness
Legare et al. 2009 **Canada**	To identify and refine underlying PPIP theories by conducting a systematic literature review	Protocol - review	Eligible publications: original qualitative, quantitative or mixed methods study designs and documents produced by CPGs organizations Studies focused on PPIP in other areas of health care (*e.g.*, health technology assessment, health research) will be excluded	4 phases proposed Phase 1: search for evidence Phase 2: appraise and extract data from identified primary studies Phase 3: synthesise evidence and draw conclusions Phase 4: achieve consensus with our decision-maker partners on a proposed toolkit on PPIP that could be tested in a subsequent study
Legare et al. 2011 **Canada**	To identify and appraise the key components of PPIPs in the development and implementation of CPGs	Literature Review	<u>Search Outputs</u> 71 documents 31 from peer-reviewed publications & 40 reports from grey literature	<u>Data sources</u> Searched bibliographic databases & reference lists of relevant articles for English & French documentation on PPIPs in development & implementation of CPGs published before January 2009 With help from G-I-N PUBLIC searched for grey literature by writing to the e-mail lists of relevant organizations & by contacting provincial and national institutions involved in production & implementation of CPGs
Legare et al. 2012 **Canada**	To obtain information from CPG developers about characteristics of PPIPs as well as barriers and facilitators they perceived to patient involvement	Qualitative study	11 participants (5 males and 6 females) across 6 countries (Canada, Germany, New Zealand, United Kingdom, The Netherlands, Australia) (10 completed the interview) Identified using personal networks and the G-I-N PUBLIC network 4 participants belonged to international organizations, 3 to national organizations and 3 to provincial organizations 8 participants reported assuming the role of manager, 1 was a patient representative and 1 was a volunteer member	Semi-structured telephone interviews
National Health & Medical Research Council (NHMRC) 2011 Australia	To describe the NHMRC standard for clinical practice guidelines	Manual	NA	NA

Newton 1996 **UK**	To explore how patients might be more actively involved in process of medical audit	Descriptive	NA	NA
NICE 2013 **England**	This policy -sets out NICE's commitment and approaches to PPI -outlines the principles of NICE's approach to involving lay people -explains support available to lay people and organisations	Policy	NA	NA
NICE 2014a **England**	To explain the processes and methods NICE uses for developing, maintaining and updating NICE guidelines	Reference Manual	NA	NA
NICE 2014b **England**	Describes the types of guidelines eligible for accreditation and NICE's procedure to assess the quality of the processes guidance producers follow	Reference Manual	NA	NA
NICE 2015 **England**	To explain how NICE supports patients, service users, carers and the public	Guide/ Manual	NA	NA
Nilsen et al. 2006 **Norway**	To assess the effects of consumer involvement and compare different methods of involvement in developing healthcare policy and research, clinical practice guidelines, and patient information material	Cochrane Review	<u>Selection criteria</u> Randomised controlled trials assessing methods for involving consumers in developing healthcare policy and research, clinical practice guidelines or patient information material.	<u>Outcome measures</u> Participation or response rates of consumers; consumer views elicited; consumer influence on decisions, healthcare outcomes or resource utilisation; consumers' or professionals' satisfaction with the involvement process or resulting products; impact on the participating consumers; costs. <u>Findings</u> No randomised controlled trials about consumer involvement in the development of clinical practice guidelines were identified
Rankin et al. 2000 **Australia**	To assess the relative importance to women who had experienced breast cancer, of the psychosocial issues that were incorporated into the guidelines	Quantitative Survey	313 women invited to participate; 45% (n=140) completed the survey Women identified through convenient sample of 8 radiation oncologists (women diagnosed with breast cancer during preceding 2 years eligible to take part)	Structured telephone survey
Rao 2011 **India**	Discusses patient involvement in clinical governance including clinical audit and guidelines	Discursive piece	NA	NA
Rigge 1994 **UK**	Discusses how patients or their representatives should be involved in clinical audit	Opinion piece	NA	NA
Roman & Feingold	To review the evidence and	Discussion piece	NA	NA

2014 **USA**	recommendations for patient involvement in guideline development from the Institute of Medicine and G-I-N and discuss how the American Academy of Otolaryngology – Head and Neck Surgery Foundation has adopted these practices throughout the process of guideline development			
Schunemann et al. 2006 **Italy**	Whose values should WHO use when making recommendations? How should WHO ensure that appropriate values are integrated in recommendations? How should users and consumers be involved in generating recommendations? How should values be presented in recommendations?	Review	Reviewed existing guidelines for guidelines to identify processes for integrating consumer values and consumer involvement. <u>Outcome</u> Did not find a systematic review of methods for integrating values in guidelines, but found several reviews that dealt with related topics	Searched PubMed and other databases of methodological studies (e.g. Cochrane library, Methodology registry and databases maintained by the Agency for Healthcare Research and Quality and Guidelines International Network) for existing systematic reviews and relevant methodological research. Reviewed titles of all citations and retrieved abstracts and full text articles if citations appeared relevant to the topic. Checked reference lists of articles relevant to the questions and used snowballing as a technique to obtain additional information. Did not conduct a full systematic review.
Serrano-Aguilar et al. 2015 **Spain**	To describe both the process used and the outcomes obtained by involving patients in the development of a CPG for Systemic Lupus Erythematosus (SLE) Patient involvement was addressed to identify the main health problems and needs of care related to SLE to warrant that the contents of the CPG are really patient-centered	Delphi-Method	<u>Systematic review</u> 980 potentially relevant references identified, 19 studies (involving more than 2187 participants) met the pre-established selection criteria <u>Consultation to patients</u> Sample of SLE adult patients recruited from different regions of Spain; recruited through Spanish Federation of Patient Associations of SLE (FELUPUS) A total of 102 complete answers were obtained after inviting 500 associated patients from FELUPUS Participation rate was 20.40% for the three Delphi rounds	<u>Systematic review</u> (SR) of international literature <u>Consultation to patients</u> Delphi consensus method with three rounds; templates built on Survey Monkey Data Analysis tool *Round 1*: structured questionnaire with three open questions *Round 2*: targeted at setting priorities from the ranked list of categories from round 1 *Round 3*: purpose of reaching a final consensus <u>Merging results</u> Results of SR + topics from patient consultative process presented at first GDG meeting to feed the identification of key questions underpinning the CPG. GDG multidisciplinary in composition, with 16 representatives from all relevant scientific and professional groups related to SLE management; a patient representative was also recruited for the GDG. Once a preliminary list of key questions was prepared, a research member compared these questions with the issues highlighted by patients and by the SR to warrant their inclusion among the key questions. At a subsequent GDG meeting, the results of this comparison were presented and agreed after discussion.

SIGN 2014 **Scotland**	To provide a reference tool for members of guideline development groups as they work through the development process To be transparent about the methods used to develop SIGN guidelines, and to instil confidence that the potential biases of guideline development have been adequately addressed, & that recommendations are both internally & externally valid, & feasible for practice	Reference Manual	NA	NA
Thomas undated **England**[1]	To evaluate lay members' experiences of being part of a GDG	Briefing report	126 individuals were eligible to participate in the survey; 86 patients or carers and 40 chairs Response rate 59% (50% chairs and 63% lay members) 24% of lay participants (and none of chairs) described themselves as having a disability Majority of lay members had tertiary-level education 95% of chairs were medical doctor 41% of lay members and 70% of chairs were male	Evaluation - mixed-method questionnaire survey (both qualitative and quantitative responses)
van de Bovenkamp & Zuiderent-Jerak 2013 **Netherlands**	To study why problems arise in participation practice and to think critically about the consequence for future participation practices *Research Questions were*: Are patients involved in development of Dutch guidelines? What are the experiences with this? How can participation practices be improved?	Mixed method study	<u>Quantitative</u> 62 Dutch guidelines analysed <u>Qualitative</u> 25 semi-structured interviews conducted with actors involved in guideline development Respondents selected based expertise on guideline development & participation in guideline development processes [both professionals and people responsible for the organization of guideline development (n = 15)]. Additionally, interviews with representatives of patient organizations	<u>Quantitative</u> Scored guidelines using AGREE instrument - instrument item on patient participation & extended it to include; patient participation used in development process, input of patients can be identified in the guideline and importance of patient participation is not only emphasized in collective health-care decision making but also on the individual patient level. <u>Qualitative</u> Semi-structured interviews Topics discussed were; ideas on importance of patient participation, experiences with participation and ideas about the future of participation.

[1] This evaluation briefing report is based on a report submitted as part of an examined component of a project module within the Open University postgraduate awards in science; Thomas V. 2008. *The experiences of involving patients and carers in developing national clinical practice guidelines – an evaluation:* this evaluation was based on NICE services and is available upon request from the author.

			(n = 10) were conducted to learn more about their views on and experiences with participation, including in guideline development.	
van de Bovenkamp & Trappenburg 2009 **Netherlands**	*Review Question*: What is the current state of the debate and the current state of affairs regarding patient participation in guideline development?	Literature Review	<u>Search Outputs</u> 42 documents 20 from electronic databases & 22 from grey literature/secondary citations	<u>Data sources</u> Searched Pubmed/Medline, Cochrane, Web of Science & sourced additional publications from secondary citations and 'grey' literature Excluded studies not written in either English or Dutch
van der Ham et al. 2014 **Netherlands**	To obtain insights into practices and experiences of service user involvement in mental health guideline development	Qualitative *Case study & desk based study*	<u>Case Study Interviews</u> 24 interviews with different stakeholders, including: guideline development professionals (n = 4), health care professionals (n = 10), service user representatives (n = 9) and carer representative (n = 1)	<u>*Desk based study*</u> of guidelines to assess service user participation in mental health guidelines <u>*Case study*</u> Service user participation in 5 guideline cases explored using document analysis, in-depth interviews & observation of guideline processes
van der Ham et al. 2015 **Netherlands**	To provide insights into process and outcomes of patient participation in CPGs & to contribute to development of comprehensive approaches for monitoring and evaluating of patient involvement	Qualitative *Case Study*	<u>Case description</u> Patient participation in development of Multidisciplinary Guideline on Employment and Severe Mental Illness	
Wedzicha et al. 2011 **UK**	Making ERS guidelines relevant and accessible: involving patients and the public	Opinion piece	NA	NA
Van Wersch,& Eccles 2001[2] **UK**	To describe and discuss experiences with 4 different methods of consumer involvement in developing guidelines in North of England evidence based guideline development programme	Discussion paper of a case series evaluating PPI methods	<u>Individual patients in GDGs</u> Recruitment challenges – failed to recruit through Community Health Council; 2 reps identified through secondary care clinicians within the guideline group <u>A "one off" meeting with patients</u> Patients invited to attend via a local group of National Asthma Campaign <u>A series of workshops with patients</u> Four workshops, average attendance 10 patients per workshop <u>Consumer advocate in GDG</u> Consumer advocate was lead of national cardiac patient group	<u>Individual patients in GDGs</u> Audiotaped GDG meetings and conducted content analysis of transcripts to analysis the contribution of the patient <u>A "one off" meeting with patients</u> Discussion of an advanced draft version of guideline with group of patients at a single evening meeting Audio recorded the meeting and conducted content analysis of transcripts <u>A series of workshops with patients</u> Series of workshops to explore potential to increase patients understanding of the meaning of scientific evidence, their ideas of cost effectiveness and views on patient information (explored outside the guideline development process) <u>Consumer advocate in GDG</u> Single interview conducted covering the experiences and satisfaction of the patient advocate involvement in the GDG

[2] Conducted in the North of England, van Wersch & Eccles (2001) evaluation might not be regarded as national in terms of meeting the inclusion criteria of the review; however it is regarded as a seminal paper often cited as first paper to present data evaluating methods on consumer involvement in development of clinical guidelines.

Young et al 2015 **Australia**	To review clinical practice guidelines (comorbid conditions) to determine extent they (1) incorporate patient-preference recommendations; (2) use consumer-engagement processes in their development phase; (3) meet standard criteria for guideline quality, particularly in relation to the stakeholder-involvement processes	Review	Inclusion criteria Australian clinical practice guidelines developed to support single chronic conditions, but which included recommendations for comorbid conditions Search Outputs 4,866 citations identified 4,835 excluded based on title/abstract 31 full-text reviewed 18 excluded 13 eligible for inclusion	Search Strategy *Databases*: Medline, Web of Science, Embase, Cinahl, PsycINFO, Cochrane and PubMed *Search terms*: "guideline", "Australia", "primary care" *Australian websites:* Department of Health, NHMRC, National Institute of Clinical Studies, Royal Australian College of General Practitioners and relevant non-profit organization websites *Journal searches:* Medical Journal of Australia & the Internal Medicine Journal

6.3. Mapping of included documents content to review objectives

In Table 5 below, we summarised the overall content of the 41 documents according to the objectives of the review. This assisted with data extraction and synthesis of the findings narratively. In total, 27 documents made some reference to potential benefits of involving patients and/or public representatives in clinical effectiveness process; 20 documents mentioned barriers and 16 documents highlights facilitators to involving patients and/or public representatives in clinical effectiveness process; specific PPI approaches were identified in 35 of the 41 documents reviewed and 20 documents made some reference of methods/systems to support PPI in clinical effectiveness processes and 10 documents highlighted measurement/evaluation processes in relation to PPI approaches or systems/methods to support PPI.

Table 5: Mapping of included document content to review objectives

Document	Benefits	Barriers	Enablers	Approaches	Support	Evaluation
Legare et al. 2011	✓	✓	✓	✓	✓	✓
van der Ham et al. 2015	✓	✓	✓	✓	✓	✓
Bastian 1996	✓	✓	✓	✓	✓	
Del Campo et al. 2011	✓	✓	✓	✓	✓	
Legare et al. 2012	✓	✓	✓	✓	✓	
Thomas undated	✓	✓	✓	✓	✓	
van der Ham et al. 2014	✓	✓	✓	✓	✓	
Den Breejen at al. 2014	✓	✓	✓	✓		
Harding et al. 2011	✓	✓	✓	✓		
Kelson 2001	✓	✓	✓	✓		
Serrano-Aguilar et al. 2015	✓	✓	✓	✓		
van de Bovenkamp & Zuiderent-Jerak 2013	✓	✓	✓	✓		
Harding et al. 2010	✓	✓	✓			
van de Bovenkamp & Trappenburg 2009	✓	✓		✓	✓	
Den Breejen at al. 2012	✓	✓		✓		
Kelson et al. 2012	✓	✓		✓	✓	✓
Van Wersch& Eccles 2001	✓	✓		✓	✓	✓
Newton 1996	✓	✓				
Boivin et al. 2010	✓		✓	✓	✓	✓
Duff et al. 1996	✓		✓	✓	✓	
G-I-N Public 2015	✓			✓	✓	
SIGN 2014	✓			✓	✓	
Young et al. 2015	✓			✓	✓	
Baker 2005	✓			✓		
Rao 2011	✓			✓		
Roman & Feingold 2014	✓			✓		
Wedzicha et al. 2011	✓					
Lamontagne et al. 2014		✓		✓	✓	✓
Schunemann et al. 2006		✓	✓			✓
HQIP 2015				✓	✓	✓
IOM 2011				✓	✓	
Jarrett & PIU 2004				✓		✓
NICE 2013				✓	✓	
NICE 2014a				✓	✓	
NMHRC 2011				✓		
NICE 2014b				✓		
Rankin et al. 2000				✓		
Rigge 1994				✓		
Legare et al. 2009						
NICE 2015						
Nilsen et al. 2006						

6.4. Quality appraisal of included studies

The methodological quality of 4 qualitative studies and 1 mixed method study (i.e. qualitative component) was assessed using CASP across 10 key parameters (see Table 6 below). Overall, this quality appraisal deemed studies to be of a moderately high quality. Ratings are representative of methodological reporting and details not reported resulted in many ratings achieving 'can't tell' scores which affected the overall study quality assessment. A quality appraisal tool designed by Tsimicalis et al. (2005) was used to assess the methodological quality of 1 quantitative study and 1 Delphi approach according to 5 parameters (see Table 7 below). All studies assessed, with a slightly modified version of Tsimicalis et al.'s (2005) appraisal tool, obtained a score of 6-7 out of a possible maximum 15. With a score of 15 reflecting robust methodological quality a score of 6-7 would be deemed of moderate quality; however caution needs to be exercised in interpreting these assessment findings based on both methodological reporting and the match between the quality appraisal tool and the design of the research studies (for example there is a criterion of comparison group which would not be expected in most non-experimental designs such as cross-sectional survey designs or Delphi approaches). Finally, the methodological quality of the 6 review papers eligible for inclusion in the review were assessed using the 11 item AMSTAR quality appraisal tool for systematic reviews (see Table 8 below). Based on this assessment, all reviews appraised could be regarded as low to moderate quality (with exception of Nilsen et al. 2006 Cochrane review); however this assessment does not necessarily reflect the methodological rigour of the review papers as many items were rated as 'can't answer' which were reflective of the inability to make a clear judgement as a consequence of missing methodological reporting (for example one was a review of guidelines rather than of literature on guidelines). Furthermore, this tool has been developed to assess *"systematic"* review studies and many of these review papers would be reflective of narrative and/or scoping reviews which would account perhaps for many *'no'* ratings.

Table 6: Quality assessment of qualitative studies (n=4) and qualitative component of mixed method studies (n=1)

Studies	Aims clearly stated	Qualitative methodology appropriate	Research design appropriate	Appropriate recruitment strategy	Appropriate data collection method	Relationship between researcher & participant considered	Ethical issues considered	Data analysis sufficiently rigorous	Findings clearly stated	Value of the research
Harding et al. 2010	Yes	Yes	Yes	No	Yes	Yes	Can't tell	Can't tell	Can't tell	Yes
Legare et al. 2012	Yes	Yes	Yes	Yes	Yes	Can't tell	Yes	Yes	Yes	Yes
van de Bovenkamp &Zuiderent-Jerak 2013[3]	Yes	Yes	Yes	Yes	Yes	Cant' tell	Can't tell	Can't tell	Yes	Yes
van der Ham et al. 2014	Yes	Yes	Yes	Yes	Yes	Can't tell	Can't tell	Yes	Yes	Yes
van der Ham et al. 2015	Yes	Yes	Yes	Yes	Yes	Yes	Can't tell	Yes	Yes	Yes

[3] The mixed method study (van de Bovenkamp & Zuiderent-Jerek 2013) was assessed for quality under the qualitative appraisal framework because while reported as a mixed method study the main element appropriate for quality appraisal was the qualitative aspect of the work. The quantitative element of this work included an analysis of Dutch guidelines using the AGREE instrument to see if patients were involved in the development of Dutch guidelines and therefore precluded quality assessment using standardised research quality appraisal tools.

Table 7: Quality assessment of quantitative (n=1) and Delphi (n=1) approaches

Study	Study design	Participants & recruitment	Comparison group	Number of participants	Instrument	Total
Rankin et al. 2000	1	2	NA	3	0	6
Serrano-Aguilar et al. 2015[4]	2	2	NA	3	0	7
Study Parameter	**Rating**		**Rating Criteria**			
Study Design		3	Longitudinal prospective design (explicitly stated)			
		2	Retrospective or mixed design (explicitly stated)			
		1	Cross-sectional (explicitly stated)			
		0	Survey or did not report			
Participants and recruitment		3	Description of the population (1), and eligibility criteria for participants (2), precise details of the recruitment process (3), accounted for the numbers recruited (4), and lost to follow-up (5) Minimal description of at least four criteria			
		2	Two criteria missing			
		1	More than two criteria missing			
		0				
Comparison group		3	Healthy, age-appropriate comparison			
		2	Reference sample			
		1	Other comparison group			
		0	No comparison group			
Number of participants		3	N>100			
		2	N=50-100			
		1	N<50			
		0	Did not report			
Instruments		3	Psychometrically sound properties of measures			
		2	Some psychometrically weak properties of measures			
		1	Psychometric properties of measure inadequate or not reported			
		0	Investigator constructed rating with no psychometric properties			

[4] The Delphi approach study (Serrano-Aguilar et al. 2015) was assessed for quality under the quantitative appraisal framework because the main element of consensus was established through Survey Monkey and a ranking process.

Table 8: Quality assessment of review papers (n=6)

Author/ Year	'a prior' design	Duplicate study selection & data extraction	Comprehensive literature search	Status of publication (i.e. grey literature) used as inclusion criterion	List of studies (included and excluded) provided	Characteristics of the included studies provided	Scientific quality of included studies assessed and documented	Scientific quality of include studies used appropriately in formulating conclusion	Methods used to combine finding of studies appropriate	Likelihood of publication bias assessed	Conflict of interest included
Kelson et al. 2012	Yes	Can't answer	Can't answer	Yes	No	No	No	Can't answer	Can't answer	No	Yes
Legare et al. 2011	Yes	Yes	Yes	Yes	No	Yes	Can't answer	Can't answer	Yes	Can't answer	Yes
Nilsen et al. 2006	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Can't answer	Yes
Schunemann et al. 2006	Can't answer	Can't answer	Yes	Yes	No	No	No	Can't answer	Can't answer	No	Yes
van de Bovenkamp & Trappenburg 2009	Yes	Yes	Can't answer	Yes	No	No	Can't answer	Can't answer	Can't answer	No	No
Young et al. 2015	Can't answer	Can't answer	Yes	Yes	No	Yes	Yes	Yes	Can't answer	No	Yes

6.5. Levels of evidence of included studies

A key limitation of this quality assessment was determining any comparative quality across eligible studies included in this review due to methodological heterogeneity. Notwithstanding this, to gain some understanding of the body of evidence available, for all primary and secondary research studies included in the review (n=13), we also classified the type of study according to the hierarchy of evidence by drawing on the SIGN criteria for assignment of levels of evidence (see Table 9 below). The remaining documents (n=28) precluded classification according to level of evidence as they were largely descriptive/opinion papers, process evaluations, policies/strategies, protocols or reference manuals/toolkits).

All 7 primary research studies were classified as level-3 evidence based on *expert opinion* (defined as opinions and/or clinical experience of respected authorities, descriptive studies, or reports of expert committees) approaches inclusive of qualitative studies, quantitative surveys, consensus methods (i.e. Delphi) and mixed method designs. Five of the secondary research studies (i.e. review papers) were classified as level-2(-) evidence based on the application of a narrative review methodological with many methodological and quality criteria unreported. One of the secondary research studies was classified as level-1(-) evidence as it followed the Cochrane systematic review processes and reported on clinical trials; although it did not identify any randomised controlled trials about consumer involvement in the development of clinical practice guidelines.

Table 9: Levels of evidence of included primary/secondary research studies

Study	Study type	Level of evidence	Judgement	Rationale for judgement
Harding et al. 2010	Qualitative study	4	Expert opinion *(i.e. opinions and/or clinical experience of respected authorities, descriptive studies, or reports of expert committees)*	Interviews with 12 service user representatives from 9 GDGs
Kelson et al. 2012	Review	2-	Narrative review; unsure risk of bias	Limited methodological details reported e.g. screening process, included/excluded studies, quality assessment and synthesis approach
Legare et al. 2011	Review	2-	Literature review reporting on qualitative, quantitative, mixed method studies and grey literature reports	Outline of search/screening process provided; quality assessment not reported; results reported narratively on mostly descriptive and qualitative studies
Legare et al. 2012	Qualitative study	4	Expert opinion	Telephone interviews with 10 participants across 6 countries
Nilsen et al. 2006	Cochrane Review	1-	Systematic review reporting on randomised controlled trials with high risk of bias	Results presented in narrative summary
Rankin et al. 2000	Quantitative Survey	4	Expert Opinion	Structured telephone survey (designed by authors) with 140 women; convenient sample ; 45% response rate; self-report data
Schuneman et al. 2006	Review	2-	Literature review; unsure risk of bias	Outline of search/screening process provided; quality assessment not reported; results reported narratively on mostly reviews
Serrano-Aguilar et al. 2015	Delphi method	4	Expert opinion	Consensus method; templates for structured questionnaire built on Survey Monkey by authors; sample recruited through national patient association; n=102; 20% response rate; potential for non-response bias

van de Bovenkamp & Trappenburg 2009	Review	2-	Literature review reporting on empirical (of various designs) and non-empirical studies	Outline of search/screening process provided; quality assessment not reported; results reported narratively on mostly descriptive and qualitative studies
van de Bovenkamp & Zuiderebt-Jerek 2013	Mixed method	4	Expert opinion	62 guidelines analysed for PPI using AGREE instrument; semi-structured interviews with 25 participants involved in guideline development; self-report data on practices and beliefs and expert opinion on analysed guidelines
van der Ham et al. 2014	Qualitative study	4	Expert opinion	Case study of service user participation in 5 guideline cases; document analysis, 24 in-depth interviews with various stakeholders & observation of guideline processes; self-report data on practices and beliefs and expert opinion on analysed guidelines
van der Ham et al. 2015	Qualitative study	4	Expert opinion	Case description; patient self-report expert opinion
Young et al. 2015	Review	2-	Review reporting on clinical practice guidelines	Outline of search/screening process provided; quality assessment performed using AGREE Instrument; results reported narratively

7.0. FINDINGS

Findings are presented narratively according to the five questions posed at the outset of the review.

Key Questions

7.1. Question 1: What are the benefits of patient engagement for clinical practice generally, and, more specifically, in clinical effectiveness processes?

Data extracted in relation to question 1 is presented in Table 10.

There is limited empirical evidence on the benefits of patient engagement in clinical effectiveness processes, however there seems to be a general acceptance that the experiential knowledge of patients is valuable, positive and effective and thought to increase the quality, democracy and acceptability of guidelines (e.g. Harding et al. 2010, Kelson et al. 2012, van der Ham et al. 2014, Serrano-Aguilar et al. 2015); and by extension perhaps audit processes. One benefit of patient involvement in guideline development groups is that it may assist with the advancement of health service provision towards patient centred-care by ensuring or at least enhancing the probability that guidelines reflect patient values, priorities, needs, concerns and expectations (Boivin et al. 2010). It would enable the guideline development process to be representative of all stakeholders and not restricted to a few unrepresentative parties (e.g. academics, specialists) (Bastain 1996). Roman & Feingold (2014), drawing on the Institute of Medicine's (2011) recommendations, state that including consumers in the process of guideline development fosters a heterogeneous group dynamic and makes for more universally applicable multidisciplinary guidelines.

Service user presence has been described as a quality control mechanism preventing inappropriate or erroneous assumptions and language by health professionals where the service user can complement science/professional knowledge by contributing 'expertise by experience' (van de Bovenkamp & Trappenburg 2009, Harding et al. 2010). Patients can provide expert views on many issues including, experiences of living or coping with their condition/illness, access to services, perceived benefits, limitations and harms of treatment and care regimes, social circumstances, habits, values and preferences for treatment options and care regimes, patient experiences of services, outcomes important to patients

(including longer term outcomes; quality of life issues) and patient information and support needs (Kelson 2001, Del Campo et al. 2011, Kelson et al. 2012). Serrano-Aguilar et al. (2015) found that engaging patients' early in the guideline development process helped to identify, prioritise and include topics/questions of relevance to patients that might have been overlooked by clinical experts and researchers. This is important because patients may have different perspectives on healthcare processes, priorities and outcomes from those of health professionals (SIGN 2014). SIGN (2014) highlights that patient representatives can draw out a wider range of issues to make sure that the guideline addresses the needs of all those affected by a condition, for example, the influence that religion/beliefs might have on compliance with different treatments. Kelson et al. (2012) also drew attention to the benefits of involving caregivers highlighting that caregivers are important in articulating values and preferences of patients who may be unable to speak for themselves, in addition to, offering insights into the physical, emotional and financial needs of caregivers themselves who provide practical and emotional support to patients.

The majority of documents reviewed focused on patient involvement in clinical guideline development processes. One document did however outline benefits of patient involvement in medical audit (Newton 1996) including; it keeps clinicians focused on their ultimate goal of caring for patients, enables users to share in the responsibility for decisions about their health, users' views on the performance of clinicians are important and can lead to improved quality of care, the process of clinical audit should be made accessible to users as part of a process of public accountability and the criteria for measurement of the effectiveness of services should reflect the values of users.

Patient participation is assumed to result in higher quality guidelines in terms of applicability, acceptability, usefulness, responsiveness and enhancement of implementation (Den Breejen et al. 2012, Legare et al. 2012). It has been described as an accountability mechanism that fosters guideline social legitimacy, ability to be implemented in practice (Boivin et al. 2010, Legare et al. 2012) and the achievement of community compliance (Bastian 1996). Another platform for considering the benefit of patient engagement in clinical effectiveness processes included the promotion of rights, protection of autonomy and freedom of choice/decision-making (Boivin et al. 2010). This could be situated further within the context of patient empowerment thereby providing an avenue for bringing about social change and shifting the balance of power amongst the various actors in the health care sector (Bastian 1996, van de Bovenkamp & Trappenburg 2009). Common themes of ethical, moral, social and political benefits to patient involvement emerged from the reviewed documents. These are reflected in the G-I-N (2015) toolkit which describes three main models that advocate for patient and public involvement in health care, including;

- *Consumerist model*: draws on consumer rights and emphasises active and empowered consumers to ensure free and well-informed choice in personalised health care
- *Democratic model*: draws on social rights of citizens and taxpayers, insisting public engagement is essential to make health care policy democratic, accountable and in line with public values and interest
- *Expert patient* emphasises patients' experiential knowledge (of their own body, illness, life and trajectory through the health care system) which can contribute to improvements in the quality of health care

G-I-N (2015) suggested that all of these three models are relevant to patient and public involvement in guideline development, as guidelines may be used for decision-making in the care of individual patients, in the design of health care policies and in quality improvement initiatives.

Table 10: Data extraction: benefits of patient engagement

Citation	Benefits/goals/role of patient engagement
Baker 2005	▪ Patients contribute their own experience and perspective to the deliberations of the guideline development group (GDG) ▪ Patients present an opportunity for health professionals to talk within the GDG group to non-clinical individuals about the recommendations
Bastian 1996	▪ To improve services and decision making ▪ To gain legitimisation and/or community compliance ▪ To bring about social change with distribution of power or resources (empower consumers) ▪ Ensure genuine agreement so reports do not solely emanate from few unrepresentative parties (e.g. academics, specialists)
Boivin et al. 2010	▪ A way to develop recommendations that will improve the quality of health care and its responsiveness to population needs and expectations ▪ An accountability mechanism that fosters clinical practice guideline (CPG) social legitimacy and its ability to be implemented in clinical practice ▪ Can be geared towards promotion of individual rights and protection of patient autonomy and freedom of choice ▪ Promoting informed choice to ensure that patient-provider interaction is patient centred and responsive to individual needs, values and priorities
Del Campo et al. 2011	By conducting patient consultation in preparation phase of CGD information regarding patient perspectives, experiences with illness, social circumstances, habits, values and preferences can be obtained and incorporated in CPGs
Den Breejen at al. 2012	Patient participation is particularly assumed to result in higher-quality guidelines in terms of applicability, acceptability, usefulness, and enhancement of implementation
Den Breejen at al. 2014	▪ MuG (multidisciplinary guidelines) group respondents described patient representative participation as 'valuable' (e.g., influencing discussions by refocusing on the patient) and their contributions as 'beneficial to the final product' (e.g., affecting formulations of considerations or expert-based recommendations). ▪ More than one-half the respondents described the final patient recommendations as 'valuable' or 'eye-openers,' and 'useful' in formulating professional recommendations
Duff et al. 1996	▪ Patients are a valuable source of evidence about what constitutes clinically effective healthcare ▪ Patients and the general public can provide information about what will or will not work in the real world ▪ Patients are more likely to change their behaviour if they can understand the reasons for a change and if they feel their views have been considered
G-I-N Public Working Group 2015	<u>Models that advocate for patient and public involvement in health care</u> ▪ *'Consumerist' model*: draws on consumers' rights and emphasises active and empowered consumers to ensure free and well-informed choice in personalised health care ▪ *'Democratic' model*: draws on the social rights of citizens and taxpayers, insisting public engagement is essential to make health care policy democratic, accountable and in line with public values and interest ▪ *'Expert patient'* emphasises patients' experiential knowledge (of their own body, illness, life and trajectory through the health care system) can contribute to improvements in the quality of health care All three models relevant to PPI in guideline development, as guidelines may be used for decision-making in the care of individual patients, in design of health care policies and in quality improvement initiatives. PPI in guideline development may aim for more patient-centred health care provision, more democratic health care policy-making or quality improvement of care and policy
Harding et al. 2010	▪ Expertise by experience complements science/professional knowledge ▪ Can influence research questions and identify priorities or outcomes for treatment that are personally meaningful to people ▪ Get to the heart of lived experience where recommendations can be complemented by "know-how & experience" ▪ Service users can judge recommendations in terms of what is "useful" ▪ Might challenge 'taken-for-granted' knowledge given their unfamiliarity with, or scepticism of, accepted notions ▪ Service user presence as a quality control mechanism, preventing inappropriate assumptions and language

Harding et al. 2011	Guidelines are not direct conversion of evidence to recommendation; they also need to take account of how socio-political and other influences impact on the end product therefore emphasising the importance of taking into account and making explicit social values and using them to inform the guideline development process – service users can play a role in advising on the acceptability to patient groups of guideline recommendations in terms of content and style
Kelson 2001	Patients can provide their own expert views on a range of issues including: living/coping with their condition, access to services, perceived benefits, limitations and harms of treatment and care regimes, patient preferences for treatment options and care regimes, patient experiences of services, outcomes important to patients (including longer term outcomes; quality of life issues) and patient information and support needs. Patients' values and views are central to concepts of health, quality of life, standards of care and outcomes.
Kelson et al. 2012	• The aim is that guidelines address patient and caregiver values and preferences. • Patients have unique perspectives on their condition, on what constitutes good and poor care and on outcomes they hope to achieve (and avoid) as a result of any intervention. <u>Rationale for inclusion of patient, caregiver and/or public values;</u> ▪ Integration of health care experience to improve quality of guidelines ▪ Increase legitimacy for guidelines if process is more open and transparent ▪ Fundamental principle that patients are affected by decisions and should have an opportunity to provide input ▪ Caregivers are important in articulating values and preferences of patients who may be unable to speak for themselves ▪ Caregivers are important in highlighting the physical, emotional and financial needs of caregivers who provide practical and emotional support to patients ▪ Published research available to GDG may not have taken into account the range of outcomes that patients identify as important or considered the range of interventions that may achieve these outcomes ▪ Addressing patient and caregiver values and preferences may help make the guideline recommendations more acceptable to them and thus their implementation more likely Guideline developers should make an explicit commitment to integrate consumer values into guideline development processes and products. The goal is to take account of consumer views and preferences and, where possible, accommodate different consumer preferences. A clear distinction needs to be made between the use of information on consumer values and preferences by guideline developers, and the direct involvement of consumers in guideline development processes.
Legare et al. 2011	▪ To incorporate patient values, preferences, knowledge or perspective in CPG recommendations ▪ To improve implementation of CPG ▪ Increase comprehensiveness of CPG ▪ Promote patient or public influence over the CPG development process ▪ Adapt CPGs to target population ▪ PPIP helped formulate extra key questions, changed existing questions or encouraged patients to join health care professionals in making decisions
Legare et al. 2012	<u>Objectives and expected benefits</u> ▪ Eliciting patients' views and needs ▪ Improving implementation ▪ Informing the public ▪ Improving the perceived acceptability and legitimacy of CPG recommendations Some informants believed involvement should depend on the guideline topic, implying that in some cases patient and public participation may be inappropriate
Newton 1996	Keeps clinicians focused on their ultimate goal of caring for patients Enables users to share in the responsibility for decisions about their health Users' views on the performance of clinicians are important and can lead to improved quality of care Process of clinical audit should be made accessible to users as part of a process of public accountability Criteria for measurement of the effectiveness of services should reflect the values of users
Rao 2011	• There is increasing agreement that involving individuals in decision

	making about their care increases the effectiveness of their treatments • Patient involvement can provide a means for NHS organisations to determine accountability to the population they serve; improve staff patient communication; understanding and relationships and engage the specific expertise that patients have to offer. • Patient views on both the process and outcomes of care and the measures used to assess process and outcomes are needed to ensure that professionals do not make erroneous assumptions about the quality of care delivered
Roman & Feingold 2014	Drawing on the IOM 2011 recommendations states that; ▪ Including consumers in the process of guideline development fosters a heterogeneous group dynamic and makes for more universally applicable multidisciplinary guidelines IOM describes 3 specific level of impact of consumer engagement ▪ Increased transparency – safeguard against conflicts of interest that may shew guideline recommendations ▪ Helps define scope of problem being addressed and focuses recommendations on achieving patient-centered outcomes ▪ Consumers play important role in making guideline recommendations comprehensible which can increase adherence to the recommendations
Serrano-Aguilar et al. 2015	▪ Found that patient engagement at earlier stage of CPG development helped to identify, prioritise and include several topics relevant for patients, as questions to be answered in the CPG, that otherwise would have been missed by clinical experts and researchers ▪ Stated that involving patients in CPG development is needed to help the advance of health service advances towards patient-centred care
SIGN 2014	▪ Patients may have different perspectives on healthcare processes, priorities, and outcomes from those of health professionals. Therefore, the involvement of patients in guideline development is important to ensure that guidelines reflect their needs and concerns. ▪ Patients can identify issues that may be overlooked by health professionals, can highlight areas where the patient's perspective differs from the views of health professionals, and can ensure that the guideline addresses key issues of concern to patients. ▪ A wide range of other issues can be drawn out by patient representatives to make sure a guideline addresses the needs of all those affected by a condition e.g. influence of religion/belief on compliance with treatment. ▪ Patient representatives can also assist the group on the use of clear and sensitive language in the guideline.
Thomas undated	▪ The chairs expressed enthusiasm for the value of patient involvement: *"Following my experience on a GDG I am even more convinced that development of guidelines must involve the people that the care, treatment or system is for."*
van de Bovenkamp & Zuiderent-Jerak 2013	▪ Patients can bring additional subjects to the table (e.g. how they experience care at a certain point in the care trajectory) ▪ Knowledge of patients is about aspects of clinical questions that are not well covered in studies ▪ Patients can be critically important for getting the clinical recommendation right; patients can provide more experience based information about living with a certain condition (in relation to guideline recommendations)
van de Bovenkamp & Trappenburg 2009	▪ Better decision-making and hence improved quality ▪ Because of their experience with health care services patients have additional knowledge to that of physicians and researcher ▪ Integrating patient preferences into guidelines will make the guidelines more applicable to health care practice and the chance of implementing the guidelines is increased ▪ Increased legitimacy ▪ Principle based desirability ▪ Patients are the ones affected most by these decision-making processes and, therefore, it seems only fair that they should have a say in the matter ▪ Patients' participation could contribute to their empowerment as well as induce social change and shift the balance of power between the actors in the health care sector ▪ Participation is politically desirable because it encourages participative democracy Note: Stated that general consensus that patient participation in guideline

	development increases the quality of the guidelines, there is little evidence in support of this supposition and added value of patient participation has yet to be established
van der Ham et al. 2014	The involvement of service users in clinical practice guideline (CPGs) development has been advocated for many years because it is thought to increase the quality, democracy and acceptability of guidelines
van der Ham et al. 2015	▪ Patients have a moral right to participate in decisions that affect them ▪ Patient involvement can contribute to guideline implementation in practice ▪ Patient involvement thought to increase relevance and quality of guidelines as their experiential knowledge can complement scientific evidence
Wedzicha et al. 2011	▪ Patients can identify issues that maybe overlooked by health care professionals ▪ Patients can highlight areas where their perspective differ from professionals ▪ Patients can ensure that guidelines address key issues of concern to patients
van Wersch,& Eccles 2001	Consumers will have different knowledge, understanding and experience of diagnosis and management of illness process from health care professionals
Young et al. 2015	▪ Experiential input is the cornerstone of consumer engagement: it extends the clinicians' focus from disease to incorporate the patients' social context, experiences, and feelings ▪ Without effectively engaging consumers, guideline developers risk producing guidelines that may not fully address the topics and outcomes of importance to patients, particularly those experiencing multiple conditions

7.2. Question 2: What barriers and enablers exist to patient engagement for clinical practice generally and, more specifically, in clinical effectiveness processes?

Data extracted in relation to question 2, *barriers*, are presented in Table 11.

Barriers

One main barrier discussed by many authors was the tension between evidence based medicine philosophy and consumer experiential knowledge (Bastain 1996, van de Bovenkamp & Trappenburg 2009, van de Bovenkamp & Zuiderent-Jerek 2013). Some authors suggested that consumer opinions could arguably be regarded as introducing a potential invitation to bias (i.e. consumer emotional investment) into the guideline recommendations rather than focusing on the derived best possible scientific evidence (Bastian 1996, van de Bovenkamp & Zuiderent-Jerek 2013). This could result in some organisations not seeing the added value of patient participation with the belief that professionals hold the knowledge needed to develop clinical practice guideline (Bovenkamp & Zuiderent-Jerek 2013). However, Bastain (1996) also points out that health care professionals may also introduce bias by bringing their own invested interests to the table. Bastain (1996) goes on to say that no matter how intensely anyone is focused on objective analysis levels of judgement are always involved in trying to interpret evidence and in determining how it should be applied to people's lives; and these judgements should not be made by professionals alone. Notwithstanding this, van de Bovenkamp & Zuiderent-Jerek (2013) highlight the challenge of integrating patients into the decision making structure of the guideline development process, nominally, because the focus is on evidence based medicine and the evaluation of scientific studies and categorisation of the strength of the evidence makes discussions difficult for patients to follow; including finding a place for the experiential knowledge of patients. Lack of familiarity with complex scientific and technical medical professional language can pose difficulties for patients and the public in understanding and interpreting the evidence (van Wersch & Eccles 2001, van de Bovenkamp & Trappenburg 2009, Harding et al. 2010, 2011, Legare et al. 2011, 2012).

These different kinds of knowledge can result in clashes between patient representatives and professionals in guideline development groups and impact on the integration of

professional, research and user expertise. Building on this, some concerns were expressed in relation to the lack of clarity around how decisions were made especially when service user contribution was overturned and/or recommendations overruled (Harding et al. 2010). This led service users to feel that there were unspoken customs or rules concerning decision-making and how recommendations were developed (Harding et al. 2011). Perhaps as a consequence of this patient's contributions became limited (Legare et al. 2011, 2012) and how their preferences were transparently integrated/explicated into clinical practice guideline recommendations was unclear (Den Breejen et al. 2012). There are other potential interpretations of patient's non-contribution such as the *number* of patient/public representatives (Legare et al. 2012), for example, a single patient member of a guideline development group might often be/become a non-participating observer of technical discussions (Kelson 2001, van Wersch & Eccles 2001). Indeed, Serrano-Aguilar et al. (2015) contended that most patients have difficulty with holding their own when facing a team of professionals; they can easily become overwhelmed by professionals causing collaborations to degenerate into tokenism. van de Bovenkamp & Zuiderent-Jerak (2013) stated that the embodied experience of patients puts them in a dependent position and, equipped with evidence weighing procedures, health professionals have much of a say about when patient knowledge is allowed to enter the scene. This brings into question whether it is wise for patients to participate in such a group if knowledge brought in by patients is vulnerable and at risk of being easily discarded (van de Bovenkamp & Zuiderent-Jerak 2013). These differentials in knowledge are potentially intrinsically linked to differences in social status and power differentials between professionals and service users which can contribute to problems in group dynamics (Harding et al. 2010). On another note, van Bovenkamp & Zuiderent-Jerak (2013) also draw attention to the risk of the professionalization of patients, in scientific terms, through conforming to dominant discourses and working methods which would lead members to challenge whether such patient representatives are 'still' in the best position to bring experiential knowledge they were asked to contribute.

Many of these issues relate to the potential interpersonal barrier of professional/clinical guideline developer resistance to including patients in clinical practice guideline groups (Legare et al. 2011, 2012, Den Breejen et al. 2012, 2014). A further interpersonal barrier, somewhat related to these discussions, are the challenges of dealing with discrepancies in perspectives such as those between expert patients and professionals (Legare et al. 2011); disagreements among different service user priorities (Harding et al. 2010), conflicts among the interests of patients and caregivers and differences in public views and who these represent (Kelson et al 2012). In light of many of these challenges some authors raised the need to give consideration to identifying skills patient representatives recruited to guideline development groups might need including personal experience, some understanding of medical language and research methods/evidence, and experience of effective group working processes (Kelson 2001, Legare et al. 2011).

A core barrier that emerged across many documents reviewed was the issue of service user representativeness and what this means for the articulation of all service user perspectives/all patients affected by the condition/disease (Del Campo 2011, Legare et al. 2011, Legare et al. 2012, van der Ham et al. 2014). Questions were raised about 'who is a good service user' with potential risks related to service users focusing too much on their own experience with the risk of insufficient articulation of service user perspectives by service user representatives (van der Ham et al. 2014). Alongside this, is the recruitment challenge of identifying willing and able consumer contributors; Kelson et al. (2012) offered some insight into factors that need to be considered including; representativeness; clarity about roles (knowledgeable vs lack of experience); open and transparent selection processes; training and support processes; boundaries of participation (i.e. practicalities of involvement such as time commitment/pacing) and disclosure of conflicts of interest. van der Ham et al. (2014) also drew attention to giving consideration to the physical ability and emotional wellbeing of service users after experiencing the drop-out of service users due to

mental illness, and reported difficulties with reading long guideline texts. A critique of representativeness is that patients perspectives often reflect the opinion of a small articulate group (van de Bovenkamp & Trappenburg 2009) and for representativeness attention needs to be given to the variability in patient values and preferences at different stages of disease with different disease severity and when considering different issues; in addition to considering how preferences might differ according to age, sex, socio-economic status, ethnicity and culture (Kelson et al. (2012). Kelson et al. (2012) also highlighted that eliciting wider public perspectives is not widespread (an exception is the NICE Citizen's Council) and perhaps a challenge inherent in this approach is that public views are often based on hypothetical judgements, as opposed to patients/caregivers who draw on personal experiences (Kelson et al. 2012).

Other barriers reported concentrated on resource issues such as financial costs (e.g. for consultation approaches, patient education etc.), time constraints and work commitment (Del Campo et al. 2011, Legare et al. 2011, Legare et al. 2012, Den Breejen et al. 2012). van de Bovenkamp & Trappenburg (2009) highlight that intensive participation processes involve considerable costs for both guideline development organisations (who have to invest a considerable amount of time and money) and patient representatives (who also have to invest a substantial amount of time and effort). Transportation was highlighted as a consideration in context of the development of national guidelines (Lamontagne et al. 2014).

Table 11: Data extraction: barriers to patient engagement

Citation	Barriers to patient engagement
Bastian 1996	▪ Guideline advocates based in evidence based medicine philosophy with view that evidence is meant to be derived from best possible evidence and not merely a consensus of expert opinions; the process of bringing in consumer opinions is a potential invitation to bias (i.e. they have an emotional investment in the issue) ▪ Health professionals may also have an invested interest and also introduce bias ▪ No matter how intensely anyone is focused on objective analysis, levels of judgement must be involved in trying to interpret evidence and in determining how it should be applied in people's lives ▪ These judgements should not be made by professionals alone; there should not be a choice between cure and care rather the goal of best practice should incorporate both
Del Campo et al. 2011	▪ Time ▪ Resources ▪ Lack of knowledge ▪ Tokenism ▪ Representativeness of all patients affected by the disease
Den Breejen at al. 2012	▪ Transparently integrating patients' preferences into CPG recommendations is difficult and often unclear ▪ Organizational (e.g. recruitment of participants), financial (e.g. costs of patients' education or for conducting focus groups), and socio-political barriers (e.g. CPG developers' resistance to including patients in the CPG group) may impede patient participation in CPG development
Den Breejen at al. 2014	▪ Perceived political barriers ▪ Competing professional interests of those involved ▪ The lack of a more detailed MuG (multidisciplinary guidelines) format
Harding et al. 2010	▪ Professionals speaking a foreign language/jargon which patients have difficulty understanding/interpreting ▪ Lack of clarity on how decisions made ▪ Undermining service user contribution with decisions overturned, recommendations overruled; research and user expertise not always well integrated ▪ Patients make few contributions and their input rarely incorporated into final product ▪ Disagreements among different service user priorities ▪ Differences in social status/power differentials between professionals and service users
Harding et al. 2011	• Asking professionals to explain unfamiliar technical language

	• Service users felt that there were unspoken 'customs' or rules concerning decision making and how recommendations were developed. At times it was felt that group consensus was overturned and some recommendations 'overruled' • Problems in the group dynamic
Kelson 2001	▪ Single patient members of guideline development groups might often be non-participating observers of technical discussion to which they can offer no input ▪ Counterbalancing this does consideration need to be given to identifying the skills that patient members recruited on to the guideline development group might need to participate effectively (for example, personal experience of the condition, some understanding of medical language and research methods, and experience of group working). ▪ Also is there lack of description of what, if any, induction or support was offered to the patient participants
Kelson et al. 2012	▪ There is the challenge with representativeness in terms of variability in patient values and preferences at different stages of disease with different disease severity and when considering different issues; also preferences may differ according to age, sex, socio-economic status, ethnicity and culture ▪ Patient and caregiver interests sometimes conflict; and/or could have large degrees of inaccuracies in ascertaining/predicting patient wishes/expectations ▪ Eliciting wider public perspectives is not widespread however NICE Citizens Council is example of attempt to integrate the values of the public without a specific condition of interest. It is composed of 30 members of the public representing the sociodemographic characteristics of England and Wales and provides overarching principles for guideline development regardless of topic ▪ Public views often based on hypothetical judgements (compared with patients and caregivers who can draw on personal experiences) ▪ General public may have beliefs that conflict with the interests of patients/caregivers A challenge is identifying willing and able consumer contributors to the GDG ▪ Representativeness ▪ Clarity about roles (knowledgeable vs lack of experience) ▪ Open and transparent selection processes ▪ Training and support processes ▪ Boundaries of participation (i.e. practicalities of involvement such as time commitment/pacing) ▪ Disclosure of conflicts of interest
Lamontagne et al. 2014	• Transportation issues when developing 'national' guidelines
Legare et al. 2011	▪ Discrepancies between expert and patient/ public perspective ▪ Recruitment difficulties ▪ Representativeness of patients/public ▪ Involving 'expert' patient helpful but may not be representative ▪ Lack of familiarity with complex scientific and medical language (patients/ public find material/medical terminology difficult to understand) ▪ Significant work commitment ▪ Time constraints ▪ Professional resistance to patient participation ▪ Feeling isolated ▪ Financial issues ▪ Resource intensive ▪ Feeling little affected by the problem ▪ Patient contribution sometimes limited ▪ Patients underestimate their capabilities ▪ Large documents sent by e-mail not practical for consumers (too expensive to print at home) ▪ Participation in CPG development group requires abilities or skills necessary for effective group processes such as communication skills, teamwork and ability to present the views of a wider group
Legare et al. 2012	<u>Institutional barriers</u> ▪ Recruitment ▪ Lack of financial resources ▪ Volunteering ▪ Lack of human resources ▪ Low public profile of organisation ▪ Misunderstanding of the organisations mission – bad reputation

	Individual barriers ▪ Representativeness ▪ Lack of familiarity with complexity of scientific and medical terminology ▪ Conflict of interest ▪ Lack of interest ▪ Patient/public contribution sometimes limited ▪ Number of participants Interpersonal barriers ▪ Professional resistance to patient/public participation ▪ Discrepancies between expert and patient/public perspectives Socio-political barriers ▪ Recent shift in social paradigm
Newton 1996	In context of general practice ▪ Doctor—patient relationship (e.g. doctor dominated, guidance-cooperation model, participative relationships) ▪ Culture of general practice (i.e. characterised by individualist ethos) ▪ Existing pattern of audit (lack of training) ▪ Lack of organization amongst patients
Schunemann et al. 2006	Difficult medical terminology/jargon barrier to involvement
Serrano-Aguilar et al. 2015	Most patients have difficulties with holding their own when facing a team of professionals becoming easily overwhelmed by professionals causing the collaborations to degenerate into tokenism
Thomas undated	▪ Most of the lay members expressed positivity about the final guideline, but were often concerned that the hard work that had gone into developing the recommendations was not realised in terms of actual changes in practice
van de Bovenkamp & Zuiderent-Jerak 2013	▪ Patient representatives bring interests to the table that should not be part of discussion in working group meetings – relates to conflict of interest when discussing scientific literature (i.e. difficulty of articulating experience based expertise in the setting of evidence based guideline development) ▪ Tensions between evidence based medicine (EBM) and experiential knowledge ▪ The way the guideline development processes are organised – patients do not easily fit into the decision making structure ▪ Some make deliberate choice not to involve patients because they feel that patient contribution will be too general for the question the specific guideline is trying to make ▪ Respondents from patient organisations do not always see the added value of patient participation as according to them professionals have the knowledge needed to develop guidelines ▪ Focus on EBM and the system used to evaluate the scientific studies and categorize them in terms of the strength of the evidence does not only make discussions difficult to follow for patients, but it also makes it hard to give the experiential knowledge of patients a place in the guideline ▪ Different types of knowledge can lead to clashes in the development group between patient representatives and clinicians ▪ The embodied experience of patients puts them in a dependent position ▪ Professionals, equipped with evidence weighing procedures, have much of a say about when knowledge of patients is allowed to enter the scene ▪ This situation, where patient participants have difficulty being heard in the guideline development group and the dependent position they find themselves in, causes some patient representatives to question whether it is wise to participate in such a group ▪ Challenging to explicate what patients contribute in the guideline (it is possible that their input is incorporated without specific attention to the fact that it concerned patient input) ▪ Knowledge brought in by patients is vulnerable and can be easily discarded ▪ Professionalisation of patients – conforming to the dominant discourse and working methods causes patient representatives to professionalise in scientific terms which at times leads to other members challenging whether such representatives are still in best position to bring in experiential knowledge they were asked to contribute
van de Bovenkamp & Trappenburg 2009	▪ Difficulty assessing contribution patients make to the decision-making process ▪ Uncertainty amongst participants about the goals of participation ▪ Patients have difficulty following medical jargon and assessing technical medical literature ▪ Patients give little input

	▪ Patient representation – often the opinion of a small, articulate group is represented ▪ Integration of patients' experiential knowledge in an otherwise evidence-based guideline ▪ Intensive participation processes involve considerable costs; guideline development organisation has to invest a considerable amount of time and money and the process also requires a substantial amount of time and effort from the patient representatives who participate in GDGs ▪ Risk that patient involvement in the guideline development process could hamper patient-centred care at the individual level i.e. with patient preferences already incorporated in the guidelines the danger is that this could become a reason for the users of the guidelines not to pay as much attention to preferences at the individual level. A guideline based on active participation of all actors involved becomes a consensus document from which it could become difficult to deviate in individual cases - the uniqueness of every patient that is emphasised at physician–patient level is no longer reflected in the guidelines. Attention in the guidelines for individual patient preferences can be accomplished by including a separate section or chapter on patient–physician communication. Research into patient preferences can be used as evidence in the development process, but it should still be made clear that this research merely serves as a general overview of patient preferences and that it does not represent an individual patient's preferences.
van der Ham et al. 2014	<u>Process</u> *Characteristics of a 'good' service user representative* Insufficient articulation of service user perspective by service user representatives Service users focusing too much on own experience Service users lacking knowledge/experience on guideline development *Service user recruitment and representation* Difficult recruitment of service user representatives Doubts about representativeness of service user representatives *Participation and the course of mental illness* Drop-out of service users due to mental illness Difficulties reading long guideline texts *Clarity and transparency of roles/structure* Lack of transparency servicer user representative role Lack of clarity on methods for user consultation Poor communication about guideline process *Phase of involvement* Service user representatives joining halfway guideline process Service user involvement in literature review *Service user consultation methods* Presenting guideline information in a comprehensive way to service users Incorporating data from service user consultation methods in the guideline *Attitudes to service user involvement* Experiential knowledge lower in hierarchy than scientific knowledge <u>Outcomes</u> *Service user agreement with the Guideline* Lack of service user agreement with scope of guideline *Incorporation of user perspective in guideline* Insufficient incorporation of service user perspectives Lack of clarity on how to incorporate service user perspective in final guideline *Practical applicability of the guideline* Doubts about practical applicability of guideline recommendations
van der Ham et al. 2015	▪ Difficulty reconciling preferences of patients with views of professionals and with evidence from literature ▪ Lack of clarity about roles and tasks of patient in the process ▪ Lack of resources for supporting patient representatives in GDGs

	▪ Doubts about representativeness of patients selected/recruited
van Wersch,& Eccles 2001	Patient involvement in a guideline group will not work if the patient does not receive enough information on the aims of, and their role in, the group, is not briefed properly, and does not feel comfortable in the group When individual patients were included in a guideline development group they contributed infrequently and had problems with the use of technical language.

Data extracted in relation to question 2, *facilitators*, are presented in Table 12.

Facilitators

The primary facilitators, suggested by many authors, of effective patient engagement in clinical effectiveness processes are *recruitment, training and support* (Kelson 2001, Boivin et al. 2010, Del Campo et al. 2011, Legare et al. 2011, Del Campo et al. 2012, Legare et al. 2012, van der Ham et al. 2015). Training and support will be covered in more detail in answer to question 4 of this review, but briefly, the documents did not generally explicate what specific training was needed but some examples were suggested such as providing training days/seminars, having supportive documents/materials and providing help with understanding complex scientific and technical issues (van Wersch & Eccles 2001, Legare et al. 2011, 2012). Patient support could take the form of support tools such as telephone, e-mail assistance, teleconferencing facilities, electronic tools (websites) or support staff such as the chair of the guideline development group, mentoring or coaching, contact with other consumers and support from patient organisations (Legare et al. 2011, 2012). Support mechanisms and training was also suggested for all members of the guideline group, most especially the chair/head of the guideline development group to ensure they had the necessary skills to involve the patient/public representative/s (Legare et al. 2011, 2012). Other practical facilitators suggested were financial assistance/reimbursement for lay representative time and expenses (Legare et al. 2011, 2012).

Transparent and clear lines of communication, including instructions and guidance for patient/public roles and responsibilities (i.e. clear schedule of tasks, timelines/deadlines, time commitment expected, the purpose of lay involvement and explicit communication on guideline scope), was deemed important to enhance patient/public engagement (Kelson 2001, Legare et al. 2011, Del Campo et al. 2012, Den Breejen et al. 2014, van der Ham et al. 2014, van der Ham 2015). Legare et al. (2012) recommended having a well-established methodology for patient and public involvement. Some papers advocated for actively involving patients early in the developmental process, at every stage of the guideline development process, and at the patients desired level of involvement, stating that this could lead to enhanced engagement and improved outcomes (Legare et al. 2011, van der Ham et al. 2014, van der Ham et al. 2015). Others recommended thinking critically about *when to involve* and *when not to involve patients* in the development process with movement away from a participation ladder with ideological connotations that more intensive participation is better (van de Bovenkamp & Zuiderent-Jerek 2013). Indeed, combining different methods of involving patients was suggested as a key facilitator to effective patient engagement (Legare et al. 2011). This will be discussed in more detail in answer to question 3 of this review.

Considering that a key barrier reported to effective patient and public involvement in clinical effectiveness processes was the recruitment, selection and representativeness of patient and public figures, it is not surprising that many authors recommend the need for consideration to be given to who should represent the patient community (including competence, dedication, relevant skills and experience, representation of different patient perspectives, gender balance and previous experience of participation) (Kelson 2001, Legare et al. 2011, Legare et al. 2012, Den Breejen et al. 2014, van der Ham et al. 2015); in addition to, giving consideration to the number of patients who should join the guideline development group (i.e. involve more than one or a group of patients rather than just one representative) (Legare et al. 2011).

Interpersonal communication was deemed important for keeping the patients and public informed, monitoring dialogue and enhancing engagement with particular reference made to establishing a working environment that created a sense of belonging and an atmosphere of mutual respect with positive working relationships which promote equality and opportunities for discussion and deliberations, thereby ensuring that the guideline development group are open to, and listen, to the views expressed by patient and public representatives (Legare et al. 2011, 2012). This extends to developing positive relationships between the guideline development organisation and patient organisations (Legare et al. 2012). Including the service user perspective as an agenda item in guideline development group meetings was proposed as an important facilitator to encourage patient engagement by van der Ham et al. (2014). Alongside modelling and reinforcing involvement by making debates accessible, giving consideration to transparency was suggested as having potential to assist with the redistribution of power (Harding et al. 2010). Serrano-Aguilar et al. (2015) proposed that an advantage of using a Delphi consultation approach was that it avoided face to face interaction between professionals and patients and therefore in some way protected patients from influences of the group and prestige or power of other contributors.

Some authors suggested including patient participation as a criterion against which to develop and evaluate grant applications (van de Bovenkamp & Zuiderent-Jerek 2013) and/or regulating patient and public participation by law (Legare et al. 2012) as a way of enhancing PPI. Some countries have already adopted such principles as highlighted by Bastian (1996) who stated that public consultation and patient involvement was a mandatory element of all stages (i.e. methodology development and topic selection) of guideline development processes in Australia. Notwithstanding this, a number of authors eluded to the fact that guideline development groups need to be committed to and in favour of PPI and genuinely feel that it is important (Legare et al. 2011, van de Bovenkamp & Zuiderent-Jerek 2013, van der Ham et al. 2014) and also patients and the public need to express a positive level of interest in being involved (Legare et al. 2012).

Table 12: Data extraction: facilitators to patient engagement

Citation	Enablers to patient engagement
Bastian 1996	Public consultation and consumer involvement is mandatory element of guideline development process in Australia; involved at all levels including developing the methodology and selecting the topics
Boivin et al. 2010	Key conditions for meaningful involvement of public and patient representatives include *recruitment, support and training*
Del Campo et al. 2011	▪ Appropriate *support* critical to facilitate effective patient engagement ▪ Provision of clear *guidance on roles on responsibilities* within the group ▪ Ensuring opportunities to attend *training* events for all GDG members
Den Breejen at al. 2014	▪ Selection of the most competent and dedicated participant ▪ The introduction of the project coordinator ▪ Patient contributions <u>Suggestions for improvement</u> ▪ Communication of clear instructions for individual roles and responsibilities ▪ A strict schedule including deadlines ▪ A clear format for the guidelines ▪ Supportive staff and support for literature searches
Duff et al. 1996	▪ Preparation, training and support ▪ Ensure everyone understands the language, the purpose of the group and the roles within it ▪ Process of working together in a group ▪ The receptivity of an organisation and its willingness to collaborate with patients ▪ Commitment to involving patients in guideline development
Harding et al. 2010	▪ Transparency leading to redistribution of power ▪ Involvement modelled and reinforced by making debates accessible
Harding et al. 2011	Proposal for integration of evidence on patient involvement with the recovery model and shared decision-making to improve service user involvement in guideline development
Kelson 2001	A survey of lay members of guideline development groups in Scotland identified the need for guideline groups to;

	▪ be clear about the purpose of lay involvement and the tasks of the lay representatives ▪ ensure 'appropriate' representation (recruiting patients or carers with relevant experience and skills) ▪ provide support, training and financial reimbursement
Legare et al. 2011	• Training (training days/seminars) • Support (telephone/email assistance, mentoring) • Supporting staff (mainly chair of the guideline development group) • Help with complex scientific and technical issues (to increase participants' understanding) • Supporting documents/material (an analysis grid for knowledge synthesis) • Contact and interactions with other consumers • Support from organizations • Clear expectations about the process (who is involved, roles, time commitment expected, funding etc.) • Involve a group of patients rather than just one patient • Representation of different patients' perspectives • Gender representation and balance • Development group committed to and in favour of patient involvement • Good preparation • Reimbursement/sufficient financial assistance • Keeping patients/the public informed and maintaining dialogue • Involving patients from the start • Past experiences • Smaller subgroups • Sense of belonging • Actively involving patients at every stage of the process and at patients' desired level of involvement • Combining methods of involving patients • Atmosphere of mutual respect and positive working relationships with other members of the group
Legare et al. 2012	<u>Institutional facilitators</u> ▪ Training and preparation ▪ Supporting documents (material resources) ▪ Support staff/coaching ▪ Financial assistance for patient/public representatives ▪ Well established methodology for patient/public involvement ▪ Electronic tools (websites) ▪ Positive relationships between CPG organisations and patient organisations ▪ Training for head of guideline development ▪ Teleconferencing <u>Individual facilitators</u> ▪ Professional background ▪ Positive level of interest from patients/public ▪ Previous experience of participation ▪ Experiential knowledge of the problem ▪ Active involvement ▪ Involvement in socio-political networks <u>Interpersonal facilitators</u> ▪ Mutual respect and positive relationships ▪ Open to the views expressed ▪ Equality and opportunities for discussion and deliberations <u>Socio-political facilitators</u> ▪ Network and partnerships among CPG organisations ▪ Patient/public participation regulated by law ▪ Government funding/non-government organisations (independent) ▪ Members appointed by government ▪ Activism and public campaigns ▪ Government initiatives such as large public consultation
Schunemann et al 2006	▪ Well informed and experienced consumers are more likely to interact with guideline development
Serrano-Aguilar et al. 2015	Delphi consultation avoided face to face interaction between clinicians, researchers and patients overcoming the barrier of patients becoming overwhelmed by professionals and also preventing contamination effects amongst patients. Participants therefore protected from influences of the group and prestige or power of

	other contributors suggesting that their opinions and proposals might be more realistic
Thomas undated	▪ Constructive debate and disagreement, in an atmosphere of mutual respect, was identified as a crucial aspect of the success of the group. ▪ Those who considered working relationships with the other lay members of the group to be positive commented on the camaraderie
van de Bovenkamp & Zuiderent-Jerak 2013	▪ Patient participation as a criteria to development grants ▪ Guideline development group genuinely felt that patient participation was important ▪ Think critically about when to involve and when not to involve patients in the development process - involvement of patient at certain stages in guideline development (e.g. deciding on the key questions that are at the heart of the guideline) and not necessarily as part of the development group (move away from participation ladder with ideological connotations that more intensive participation is better) ▪ Taking account of preferences and experiences of individual patients and recognising the importance of communication
van der Ham et al. 2014	<u>Process</u> *Characteristics of a 'good' service user representative* Helicopter view; having insight in the different perspective of the service user population Knowledge of or previous experience with guidelines Training on guideline development to service user representatives *Service user recruitment and representation* Access to/use of network of service user organisation Using the network of GDG Attention for subgroups of service users *Participation and the course of mental illness* Involving multiple service user representatives Offering content-related support to service user representatives Providing process-related support to service user representatives *Clarity and transparency of roles/structure* Use of feedback sheets about given input Use of clear action plan on service user participation Chair and project manager monitoring service user involvement *Phase of involvement* Early involvement of service user representatives in guideline process Assisted involvement in literature review *Service user consultation methods* Provide service users with a summary of the guideline's key points Organising a dialogue to integrate input from different stakeholders *Attitudes to service user involvement* GDG members having a supportive attitude towards service user involvement Service user perspective as an agenda item in GDG meetings <u>Outcomes</u> *Service user agreement with the Guideline* Early involvement of service user representatives Explicit communication about guideline scope *Incorporation of user perspective in guideline* Careful weighing of different options to incorporate service user perspective *Practical applicability of the guideline* Lay/service user versions of guidelines Action plan on implementation involving service users
van der Ham et al. 2015	▪ Active involvement of patients in all phases of guideline development ▪ Clarification of roles of patient representatives ▪ Attention to adequate selection of patient representatives ▪ Provision of training and support for patient representatives

7.3. Question 3: What clinical effectiveness approaches are patients are engaged in; and what the reported benefits and weaknesses of these approaches?

Data extracted in relation to question 3 are presented in Table 14.

The majority of the documents referred to clinical effectiveness approaches that patients were, or could be, engaged in. The documents specifically referred to patient/public involvement in clinical guideline development, with a limited number of documents making any reference to consumer involvement in clinical audit processes. In relation to clinical guideline development processes, a commonality across review papers (Legare et al. 2011), discussion papers (Baker 2005) and qualitative studies (Legare et al. 2012) in terms of patient and public involvement (PPI) approaches included direct and indirect involvement of patients at various stages of the guideline development. In line with the G-I-N (2015) public toolkit, on PPI in guidelines, PPI approaches can be classified according to three main strategies based on the flow of information between organisations and the public, namely:

- Consultation: information collected *from* patients/public
- Participation: patients/public *exchange* information with other stakeholders
- Communication: information communicated *to* patients/public

Within these three main strategies a number of different methods/approaches were reported across all the documents reviewed; these are briefly summarised in Table 13.

Consultation strategies included review of primary and secondary literature and/or the conduct of primary research to establish insight into patient experiences (e.g. SIGN 2014, van der Ham et al. 2014, van der Ham et al. 2015, Serrano-Aguilar et al. 2015). Such research was deemed particularly useful either at the beginning of the guideline development process when little evidence on patient preference was available or at the end to test recommendations and improve the guideline's potential for implementation (Boivin et al. 2010). Open community consultations, questionnaires/survey's and written submissions by patient organisations were also mentioned as useful methods to engage with patients and the public in defining clinical practice guideline topics, scope and commenting on the draft guideline before final submission (e.g. Rankin et al. 2000, Boivin et al. 2010, Institute of Medicine 2011, Legare et al. 2012). Holding a national open meeting to discuss draft recommendations of the guidelines with patients, carers and voluntary organisation representatives was cited as the main consultative phase of SIGN guideline development (SIGN 2014). The draft SIGN guideline is also made accessible online on the SIGN website for one month to enable those unable to attend the open meeting to comment on the guideline (SIGN 2014).

The most commonly reported ***participation*** strategy was the direct involvement of patients and/or patient advocate organisations as representatives on guideline development groups (or an associated panel/advisory committee) to provide consumer perspectives in the interpretation of the evidence and development of recommendations that are relevant to patients (e.g. Baker 2005, Boivin et al. 2010, Legare et al. 2011, Den Breejen et al. 2012, van der Ham et al. 2014, NICE 2014a, SIGN 2014). SIGN (2014) and the Institute of Medicine (2011) recognise that guideline development groups should be multidisciplinary and balanced, comprising a variety of methodological experts and clinicians, and populations expected to be affected by the guideline; and patient and public involvement should be facilitated by including (at least at the time of clinical question formulation and draft CPG review) a current or former patient, and a patient advocate or patient/consumer organization representative in the guideline development group. All NICE advisory committees and working groups have at least two lay members (patients, service users, carers, members of the public) (NICE 2012, 2014a, 2014b, 2015).

Communication strategies involved the production of lay translated versions of the practice guideline, and some linked decision aids, for patients and public stakeholders (e.g. Legare et al. 2012, van der Ham et al. 2014, NICE 2013, SIGN 2014). SIGN (2014) highlights that the purpose of the patient version of the guidelines are intended to assist patients and carers to understand the latest evidence around diagnosis, treatment and self-care, empower patients to participate in decisions around management of their condition, highlight for patients areas of uncertainty and encourage implementation of the guideline by patients acting as champions for change.

Table 13: Overview of patient/public engagement approaches

Strategy	Consultation	Participation	Communication
Methods	Review of/use of primary (qualitative studies) and/or secondary (systematic reviews) research evidence on people's experiences Conduct of primary research studies e.g. satisfaction surveys, focus groups, individual interviews, public polls and/or workshops/seminars *Others mentioned included case studies, observational studies, patient tracking, patient stories/narratives, dialogue sessions and diaries* Open/online community consultation on draft guideline before final acceptance (also includes written submissions by patient organisations)	*Direct involvement in developmental stages of GDG* Participation of patient/public /consumer advocates as representatives on guideline development groups, panels, advisory committees and/or working groups	Consultations on preparation of information for patients with aim of producing readily understandable information Production of plain language versions of clinical practice guidelines Development of patient decision aids or education material
Strength	Useful to gather views of a large number of individuals regarding their needs, experience, and expectations Can help assess public acceptability of draft guideline recommendations and identify topics that appear most important for the public, and are therefore useful in early stages of the guideline development process.	Useful to foster deliberation and mutual learning between participants with different expertise Enables patients/public to be present and actively participate in deliberations, which can foster mutual influence between patients and professionals, fostering the development of a collective perspective on guideline development Can be useful to support compromise or consensus between people with different perspectives	Useful in dissemination and implementation stage of guideline production For guideline recommendations where a single best course of action is clear - can increase public's knowledge and awareness of recommended interventions in order to influence patients' health behaviours and increase uptake When more than one alternative is acceptable - patient decision aids can help expand the range of options available to patients and assist them in weighing pros and cons of different choices
Weakness	Tendency to seek out individual viewpoints, presenting an average of 'the need' of patients.	Often allows for the involvement of a small number of people and may miss the perspective of vulnerable groups who may feel threatened to participate in meetings with health professionals.	

	A critical issue for successful participation is to support participants' legitimacy as patient and public members, and their ability to contribute credible knowledge and experience relevant to guideline development.

Other less commonly reported PPI approaches were the inclusion of patient/public representatives on the practice guideline ***external review boards*** (Institute of Medicine 2011, Roman & Feingold 2014, SIGN 2014) and as ***expert witnesses*** (i.e. invited to give testimony to the Committee or members of a reference group, focus group or other advisory group set up when standard involvement and consultation processes are insufficient such as when a topic covers a population group that is not part of the Committee e.g. children or people with a learning disability) (NICE 2014a). The Institute of Medicine (2011) suggest that external review is a standard for developing trustworthy clinical practice guidelines. SIGN (2014) sends all draft guidelines to at least two lay reviewers and has produced specific guidance for lay reviewers (http://www.sign.ac.uk/pdf/patient_peer_review_leaflet_2011.pdf).

At the National Institute for Clinical Effectiveness (NICE) organisations can ***register as a stakeholder*** (i.e. national organisations for people who use health and social care services, their families and carers, and the public) and individuals can join (or advise) a Committee that works on guidelines (NICE 2014a). During guideline development NICE keeps registered stakeholders and the public informed of progress by email and by adding information to the guideline page on the NICE website (NICE 2012a). Stakeholders can comment on draft scope, draft guideline, provide evidence and support implementation of the guideline and NICE responds formally to all stakeholder comments with responses published on the NICE website (NICE 2014a). NICE has a specific ***Public Involvement Programme*** that provides advice and support to Committees, Developers and NICE staff, about involving the public in developing NICE guidelines and a ***public involvement adviser*** is allocated to each topic (NICE 2014a, NICE 2015).

There was also some evidence describing the potential use of ***online technologies***, nominally ***wiki's***, as a participatory tool for involving patients/public in developing national guidelines (e.g. Den Breejen et al. 2012, 2014, Lamontagne et al. 2014). SIGN (2014) highlighted that ***social media*** are often used as a forum for discussion around the public consultation meeting on the content of draft guidelines.

While the literature reviewed is limited in reporting any empirical evidence on the specific strengths and weaknesses of any specific approaches/methods to engaging patients and/or the public in clinical effectiveness processes (see Table 13), some contend that irrespective of methodology, *consultation* alone is not sufficient and a truly collaborative approach must be taken (Duff et al. 1996). This interpretation could be developed as a consequence of the lens through which PPI approaches are viewed and the different potential levels of PPI, such as passive input, active participation and partnerships as described by Rao (2011). For some people, 'real' participation is viewed as an *active* process with direct patient/public involvement, with shared decision-making powers, in which participants should at least have the potential to influence (Bastain 1996). Bastain (1996) presents this view in the context of a framework for considering *levels of consumer participation* in an activity with three lower and two upper levels. The two upper levels (i.e. open involvement and wide participation) indicate processes that provide active roles for consumers, whereas the three lower levels (i.e. none, manipulation and restricted scope) all place the consumer in a passive role (i.e. sources or recipients of information or consulted in a way that allows little room for truly affecting the course of events). Considering this in the context of PPI approaches, consultation and communication approaches could be seen as lower level with patients and

public being indirectly involved to gather information on their values and preferences which the guideline development group may then use to inform their deliberations (Kelson et al. 2012). Participation approaches could be seen within the context of the 2 upper levels where patients/public representatives are directly involved as active members of the guideline development group where they may have an opportunity to influence, alongside professional members, both the deliberations and outputs of the guideline development group (Kelson et al. 2012). This aligns with Arnstein's ladder of citizen participation consisting of non-participation (i.e. manipulation and therapy), tokenism (i.e. informing, consultation and placation) and citizen power (i.e. partnership, delegated power and citizen control). Viewing PPI in such a hierarchal way could be problematic because it is not about adopting either a consultation approach or participation approaches but rather finding the best method to fit the goal of PPI and guideline development within a given context. What matters is being clear and transparent about that level of involvement with all concerned, particularly the public/patients involved in each process.

Others have also proposed different models as an alternative lens to consider for improving service user involvement in guideline development. Harding et al. (2011), for example, proposed combining previous research by Harding et al. (2010), and other research, with the recovery model and shared decision-making model postulating that it could lead to progression in 3 main areas; translating evidence to recommendations, optimising acceptability of recommendations and reconciling different types of knowledge.

Perhaps a slight reconfiguration of hierarchal models to a cyclical representation might be more illustrative of the challenges inherent in employing any PPI approach with G-I-N (2015) highlighting that each approach (consultation, participation and communication) has specific strengths and weaknesses and effective involvement starts with finding the *right approach/method*; *tailored to the specific contexts and goals of the guideline development and patient/public involvement*. Rao (2011) suggested that the choice of method may depend on the purpose of the initiative, the type of participating patients, staff expertise in different methodologies and the patient's preference for different approaches.

Indeed, to account for the strengths and weaknesses of different approaches many recommend combining *consultation and participation methods t*o build more comprehensive patient and public involvement interventions (Bastian 1996, Del Campo et al. 2011, Serrano-Aguilar et al. 2015). Serrano-Aguilar et al. (2015) is an example of the use of a multi-component strategy to involve patients in the development of clinical practice guidelines for Systemic Lupus Erythematosus (SLE). Three complimentary approaches were employed including (i) a systematic review of literature internationally, (ii) a consultation process using an online Delphi consensus approach (3 rounds) and (iii) patient representative participation in the guideline development group. Patient recruitment was managed by the Spanish Federation of Patient Association of SLE and Serrano-Aguilar et al. (2015) reported that the use of the online (i.e. Survey Monkey) Delphi approach meant that a relatively scarce scattered population of disabled patients affected by SLE could participate. Notwithstanding this however, while electronic communication technologies helped improve the efficiencies of the Delphi consultative and consensus process, potential sources of bias to consider in using such approaches are differences in computer literacy, uneven availability of computers and potential technical problems of communications (Serrano-Aguilar et al. 2015).

As previously mentioned under facilitating factors to patient engagement, the timing and stage of involvement of patients/public was referred to in a number of documents. Many suggested that patients/patient organisations should be involved at every stage of the guideline development process, this should commence from the very start of the guideline development process (i.e. at time of confirming the guideline scope) and should also take account of patient's desired level of involvement (Baker 2005, Boivin et al. 2010, Legare et al. 2011, HQIP 2015). Some authors go into specific tasks that lay members should be

involved in such as guideline topic selection, determining the focus and boundaries of the guideline, identifying and reviewing the evidence, formulate and comment on draft guideline recommendations, dissemination of, and development of lay versions of the guidelines (Kelson et al. 2001, Del Campo et al. 2011, Rao 2011, Legare et al. 2011).

Alongside PPI approaches, a key item for discussion among many of the documents was who the representative for patients should be, and how should this representative be selected. While Baker (2005) suggested that methods of direct consultation should take place with patients rather than through the intermediary of patient organisations, many documents made reference to recruiting either individual patients, patient representatives (i.e. family, caregiver) or people from organisations representing the interests of patients (Legare et al 2011, Kelson et al. 2012, SIGN 2014, HQIP 2015). Having a well-structured selection process is suggested including detailed eligibility criteria which take account the representative's experience of the condition addressed by the guideline, an understanding of the experiences/needs of the wider network of patients, some familiarity with medical/research language, time to commit to the work, ability to convey an opinion, ability to be objective, good communication and ability to work as a team member (Kelson et al. 2012, SIGN 2014). Giving consideration to a balanced socio-demographic representation was also proposed (Boivin et al. 2010). Reported recruitment methods were usually through patient organisations, by sending invitations, by receiving referrals and recruitment by clinicians (Legare et al. 2011).

As previously mentioned there was limited reference to clinical effectiveness processes that engaged patients in clinical audit processes. In 1994, Rigge highlighted that a complementary approach to clinical audit was developed called the *consumer audit* which involved using a range of qualitative methods (i.e. interviews/focus groups) with patients, carers, staff at all levels of the organisation and other potential service users. However, such approaches were not widely published and in a more recent discursive paper, Rao (2011) claimed that patients and representatives could be more involved at a strategic level in clinical audit processes including selecting audit topics, setting criteria and standards, monitoring, disseminating findings and implementing changes.

Table 14: Data extraction: approaches to patient engagement

Citation	Approaches to patient engagement (+ any reported strengths and/or weaknesses)
Baker 2005	• Consultation with stakeholders including patient organisations from start i.e. at time of confirming guideline scope • Involve at least 2 representatives of patients and carers in guideline development group (GDG) • Patient involvement in recommendations • Patient representative consulted on *"preparation of information for patients"* with aim of producing information that is readily understood Suggests that; ▪ Methods of direct consultation with patients rather than through the intermediary of patient groups would be a useful next step ▪ Also give thoughts to more effective ways of getting information to patients about the content of the guidelines
Bastian 1996	Participation is an active process in which participants should at least have the potential for significant influence; real participation implies sharing of decision-making power Presents a *framework* for considering the 'level of consumer participation' in an activity ▪ Three lower levels (i.e. none, manipulation and restricted scope) all place consumer in a passive role i.e. sources or recipients of information or consulted in a way that allows little room for truly affecting the course of events ▪ Two upper levels (i.e. open involvement and wide participation) indicate where processes open up to provide active roles for consumers Methods for seeking consumer views fall into 3 categories ▪ Involvement of consumer representatives in group decision making (e.g. at least 1 consumer representative on GDG and a consumer advocate chairs one

	of the GDG; consumer rep selected by Consumer Health Forum, a national coalition of consumer groups with an interest in health) ▪ Community consultation (e.g. draft guidelines undergo a process of community consultation before final acceptance) ▪ Use of research literature describing people's experiences (e.g. each GDG reviews the relevant literature on people's experiences and concerns) Advocates for use of these 3 types of strategies in combination to enable better consideration of consumer views in the guideline development process States that relying on any one strategy of patient involvement in isolation has drawbacks as each offers different strengths and weaknesses; however does not outline what these are
Boivin et al. 2010	Involvement methods may include; • Communication – information is communicated to patients/public (e.g. patient versions of the CPG) to promote more active and informed health decisions • Consultation – information is collected from patients/public (e.g. consultation of draft CPG) • Participation – patients / public exchange information with other stakeholders (e.g. patient member on GDG) <u>PPIP can be used at different stages</u> • Macro level – of CPG development (topic selection, evidence review, recommendations, development of ancillary products) • Meso level – of implementation to specific target groups • Micro level – of the clinical consultation <u>Approaches</u> Inclusion of *patient members in guideline development group* to provide consumer perspectives in the interpretation of the evidence and develop recommendations that are relevant to patients NICE – citizens council used deliberate participation methods to involve members of the general public to discuss social values related to CPG development *Open consultations and written submissions by patient organisations* particularly useful in defining CPG topics and commenting on draft CPG *Focus groups* useful at beginning of CPG development process when little evidence on patient preference available or at end of process to test recommendations and improve its potential for implementation Participants noted little done currently to synthesis existing published evidence on patient and public views and preferences and suggested that the range of consultation methods currently used in PPIP could be expanded to include *satisfaction surveys and web-based consultations* Stated that the range of reported methods to involve patients/public appears to make little use of alternative methods proposed in literature such as; ▪ Systematic review of published evidence on patient views and preferences ▪ Integration of patient decision aids ▪ Use of decision analysis to integrate patient utilities in CPG recommendations ▪ Their involvement in strategic aspects of CPG development, including CPG evaluation <u>Recruitment considerations</u> • Recruit patient/public members early in the process • Give consideration to a balanced socio-demographic representation (many CPG disproportionately impact certain subgroups) • Clarification of expectations of patient/public involvement
Del Campo et al. 2011	<u>Methods of involvement</u> ▪ Review available evidence on patient experiences – qualitative studies ▪ Patient representatives participate in final draft review ▪ Include patients/patient representative as member of GDG Reports on combining *patient consultation* and *patient participation* as a strategy for patient involvement; ▪ patient consultation in CPG preparation stage included quantitative and qualitative primary research and secondary research involving a systematic review of patient perspective studies

	▪ patient participation in development process included involvement of the patient in all stages of the GDG <u>Stage of involvement</u> ▪ Patient helped identify and review the evidence ▪ Review recommendations ▪ Dissemination of CPGs ▪ Development of patient versions of CPG
Den Breejen at al. 2012	Two representatives of the Dutch patients' association for infertility, Freya, participated in the CPG development group For direct patient participation in the guideline a wiki was concurrently used with the guideline development phase
Den Breejen at al. 2014	*Patient-centred network approach* to develop five harmonized guidelines (one multidisciplinary and four mono-disciplinary) around clinical pathways in fertility care ▪ Used advertisements and mailings over a 7 month period to invite patients with fertility problems to formulate recommendations via the Dutch online Wiki based tool at www.freyawiki.nl ▪ A patient representative and 2 members of steering committee including implementation expert modified and assessed the implement-ability of the patient recommendations with the Guideline Implementability Appraisal tool ▪ Patients then asked to select their top 3-5 recommendations for each Wiki section
Duff et al. 1996	A wide range of qualitative and quantitative methods can be used to obtain patient/user opinions including: ▪ Surveys of patient/user opinions ▪ Focus groups ▪ Active participation in developing the clinical guideline ▪ Consultation on draft clinical guideline ▪ Review of research literature to identify research-based evidence of patient/user views, needs etc. Need to further investigate, evaluate, refine, and develop current methods for collaborating with patients, for use in developing national clinical guidelines Whatever method is used, consultation alone is not sufficient a truly collaborative approach must be taken <u>Selection of patient / service user representative(s)</u> ▪ Who and when to select depends on patient / service user interests, confidence, resources, skills and the needs of the clinical guideline development process ▪ Should be more than one patient representative on guideline development group to spread representation and to help enhance patients confidence in contributing within the group ▪ For some topics both patients / service users and patient / service user organisations may be involved to ensure a representative voice <u>When to involve patient / service user</u> ▪ Patients and service users should be involved at the start or very early on in the development of the clinical guideline ▪ The amount and type of involvement might change during the time the guideline is being developed ▪ Different patient / service users may be needed for each stage of development <u>Role of patient / service</u> ▪ Identify topics for guideline development ▪ Initiate projects such as patient focused guidelines to complement clinically focused guidelines ▪ Provide information about patient/ service user perceptions of what constitutes quality care and preferences ▪ Ensure focus of the guideline is clinically effective care, not cost ▪ Disseminate the clinical guideline ▪ Educate groups interpreting and implementing the guideline ▪ Evaluate the guideline ▪ Assist in updating the guideline
G-I-N Public Working Group 2015	<u>3 general involvement strategies based on flow of information between organisations and public</u> i. *Consultation*: the collection of information *from* patients and the public e.g.

	surveys, focus groups, individual interviews, online consultation, the use of primary research on patients' needs and expectations, or the use of a systematic review of studies on patients' and the public's perspective ii. *Participation*: *exchange* of information between guideline developers and public e.g. participation of patient and public representatives on guideline development groups and other methods iii. *Communication*: communication of information *to* patients and the public to support their individual health care decisions and choices e.g. production of plain language versions of clinical practice guidelines or development of patient decision aids or education material <u>Each strategy has specific strengths and weaknesses</u> Effective involvement starts with finding the *right method*. Each strategy must be tailored to specific contexts and goals. *Consultation* ▪ Useful to gather views of a large number of individuals regarding their needs, experience, and expectations ▪ Can help assess public acceptability of draft guideline recommendations and identify topics that appear most important for the public, and are therefore useful in early stages of the guideline development process. ▪ A *drawback* is that it tends to seek out individual viewpoints, presenting an average of 'the need' of patients. *Consultation processes covered in more depth in chapter 1 & 2* *Participation* ▪ Useful to foster deliberation and mutual learning between participants with different expertise ▪ Participation as member of the GDG has advantage of enabling patients or public members to be present and actively participate in deliberation, which can foster mutual influence between patients and professionals, fostering the development of a collective perspective on guideline development ▪ Participation methods are usually put in place to agree on *common group decisions* over guideline content and can be useful to support compromise or consensus between people with different perspectives ▪ When used alone, a *drawback* is that it often allows the involvement of a small number of people and may miss the perspective of vulnerable groups who may feel threatened to participate in meetings with health professionals. ▪ A critical issue for successful participation is to support participants' legitimacy as patient and public members, and their ability to contribute credible knowledge and experience relevant to guideline development. *Participation processes covered in more depth in chapter 3,4,5,6* Note: chapter 6 provides an example of how the Cancer Council Australia adapted *web-based technologies to support PPI (i.e. wiki)* *Communication* ▪ Useful in the dissemination and implementation stage of guideline production ▪ For strong 'black and white' guideline recommendations—where a single best course of action is clear—communication methods can increase the public's knowledge and awareness of recommended interventions in order to influence patients' health behaviours and increase uptake ▪ In cases of 'grey zone' decisions—when more than one alternative is acceptable—patient decision aids can help expand the range of options available to patients and assist them in weighing the pros and cons of different choices *Communication processes covered in more depth in chapter 7,8,9* *Combination of involvement strategies* It is common to combine different involvement strategies to build more comprehensive patient and public involvement interventions
Harding et al. 2011	Proposal for improving servicer user involvement in guideline development by combining previous findings from Harding et al. 2010 and other research with the recovery model and shared decision-making. Contended that this could lead to progression in 3 main areas of guideline development and service user involvement, including; ▪ Translating evidence to recommendations ▪ Optimising acceptability of recommendations

	▪ Reconciling different types of knowledge
HQIP 2015	HQIP has adapted 7 principles to explain their approach to PPI. *Representation*: Participating patients will be broadly representative of the relevant, affected population. Consultations will be carried out through organisations such as National Voices to ensure broader representation on generic issues *Inclusivity*: HQIP will provide sufficient resources to overcome barriers such as issues of access or communication *Root and branch*: Patients will be involved as early as possible in a process / activity and continue to be involved throughout. Patients will be involved in all areas of HQIP *Transparency*: Those involved will be able to see and understand how decisions are made and Information on audit data and consultant outcomes will be published in clear and understandable formats *Clarity of purpose*: The nature and scope of involvement will be clearly defined prior to involvement. It will be clear how publications can be used to inform patients about the quality of services available *Cost Effectiveness*: Involvement must add value and be cost effective *Feedback*: The outcomes of PPI activities will be fed back to participants. Feedback on our products will be used to review and improve our publications
Institute of Medicine 2011	▪ GDG should be multidisciplinary and balanced, comprising a variety of methodological experts and clinicians, and populations expected to be affected by the CPG. ▪ Patient and public involvement should be facilitated by including (at least at the time of clinical question formulation and draft CPG review) a current or former patient, and a patient advocate or patient/consumer organization representative in the GDG. ▪ External reviewers should comprise a full spectrum of relevant stakeholders, including scientific and clinical experts, organizations (e.g., health care, specialty societies), agencies (e.g., federal government), patients, and representatives of the public. ▪ A draft of the CPG at the external review stage or immediately following it (i.e., prior to the final draft) should be made available to the general public for comment.
Jarrett & PIU 2004	▪ Patient/carer participation in guideline development group
Kelson 2001	▪ Survey of user/carer views to identify areas where guidelines most needed ▪ Recruitment of users and carers on to the steering group and individual guideline working group
Kelson et al. 2012	<u>Sources of information on consumer values</u> 1. Published literature e.g. systematic review of patient preference for specific interventions 2. Direct elicitation of consumer values a. Member of guideline panel b. Separate patient panel c. Workshops, focus groups, interviews d. Consultation on guideline products <u>Who to involve?</u> • Individual patients or caregivers • People from organisations representing the interests of patients <u>Recruitment</u> • Select patient/public representatives through a well-structured selection process usually via patient associations • Establish detailed eligibility criteria, for example; ✓ Experience of the condition addressed by the guideline ✓ Level of knowledge and understanding ✓ Time to commit to the work ✓ Ability to convey their opinion ✓ Ability to work as a team member <u>Stage of involvement</u> • Guideline topic selection • Determining focus and boundaries of guideline • Work of the GDG • Commenting on draft of recommendations <u>Recommendations</u>

	A review of the literature on consumer values and preferences should be an integral part of the guideline development process. Identified values and preferences (relating, e.g., to interventions, comparators, and outcomes considered by the guideline group) can inform the refining of clinical questions, the interpretation of evidence from the research literature, and the development and wording of recommendations. Guideline developers should consider involving consumers in the guideline development process, indirectly and/or directly. ▪ Indirect involvement includes consultation with representative consumer groups and/or surveys or focus groups with guideline-relevant consumers to obtain information on their values and preferences. Such information may then inform the deliberations of the guideline development group. ▪ Direct involvement typically involves recruiting consumers as members of guideline steering, development, and/or working groups. Such involvement helps ensure that consumers have the opportunity to influence, alongside professional members, both the deliberations and outputs of the guideline development group.
Lamontagne et al. 2014	Protocol for cross-over trial in which 2 methods were proposed (specific for patients with disability i.e. traumatic brain injury - TBI) • Discussion group/face-to-face focus group • Wiki Participants asked to discuss 2 recommendations from a selected SIGN guideline Participants selected from Quebec community association for individuals with TBI
Legare et al. 2011	Review found that in general studies and reports provided a superficial description of the process of developing the CPG and the components of the PPIP involved <u>Participation format</u> ▪ CPG working group ▪ Workshop, meetings or seminar ▪ Literature review ▪ Focus groups ▪ Individual interviews ▪ Public poll or survey <u>Stage of involvement</u> ▪ Formulating recommendations ▪ Synthesising the knowledge ▪ Revising drafts Involve at every stage; at individuals desired level of involvement; involve them before process begins <u>Who to involve?</u> Individual patients and patient representatives (family, caregivers) most frequently involved in PPIP followed by group of individuals (organisation) <u>Recruitment methods</u> ▪ Through patient/public organisations ▪ Sending invitations ▪ Receiving referrals ▪ Recruitment by clinicians
Legare et al. 2012	<u>Methods of PPIP classified as;</u> ▪ Direct participation in GDG and in workshops ▪ Collection of information through consultation e.g. written commentaries, focus groups, interviews and questionnaires on patient organisation websites ▪ Communication of information to patients and/or public using patient version of CPG <u>When to incorporate patient involvement?</u> ▪ At all stages of CPG development and implementation ▪ Not at all stages such as exclusion from the literature review ▪ Involvement most common at implementation especially development of patient/public versions of CPGs; formulating or reviewing recommendations and reviewing drafts
NHMRC 2011	Standard for CPG in relation to PPI – must be developed by a multidisciplinary group that includes relevant experts, end users and consumers affected by CPG and must undergo a process of public consultation (public notice inviting submissions on draft guideline for minimum period of 30 days); companion document to the guideline for the

	public may also be developed and the public should be involved in this process
NICE 2013	Patients, service users, carers and the public can be involved directly in producing or promoting NICE guidelines, quality standards and other products as formal members of NICE committees and working groups. They can also be involved in NICE's work by commenting, through their organisation, on draft versions of NICE guidance scope and draft recommendations, and by submitting evidence. (p.4) All NICE advisory committees and working groups have at least **two lay members** (patients, service users, carers, members of the public) NICE also make their guidance available in language and formats suitable to patients, service users, carers and the public
NICE 2014a	▪ All NICE Committees include at least 2 lay members (people with personal experience of using health or care services, or from a community affected by the guideline) (p.5) ▪ Regular consultation allows organisations and individuals to comment on our recommendations (p.5) ▪ People using health and care services, carers and the public also contribute to ensure that guidelines address issues relevant to them, reflect their views, and meet their health and social care needs (p.6) ▪ There are 2 main ways to get involved: organisations can register as a stakeholder and individuals can join (or advise) a Committee that works on guidelines (p.6) ▪ The Public Involvement Programme at NICE provides advice and support to Committees, Developers and NICE staff, about involving the public in developing NICE guidelines. A public involvement adviser is allocated to each topic (p.6, 11) ▪ Practitioners and people who use health and care services, family members, carers and the public may also be involved as: expert witnesses invited to give testimony to the Committee or members of a reference group, focus group or other advisory group set up when standard involvement and consultation processes are insufficient (for example, when the topic covers a population group that is not part of the Committee, such as children or people with a learning disability) (p.6) Re: Registered Stakeholders (p.8) ▪ During guideline development NICE keeps registered stakeholders and the public informed of progress by email and by adding information to the guideline page on the NICE website. ▪ Registered stakeholders comment on the draft scope and draft guideline, may provide evidence, and support implementation of the guideline. ▪ NICE formally responds to all comments from registered stakeholders, and these responses are published on the NICE website. ▪ Stakeholders can include: national organisations for people who use health and social care services, their families and carers, and the public
NICE 2014b	There are various methods for ensuring that patients' and carers' perspectives directly inform guidance development. These include: ▪ involving patients and carers as members of the group developing guidance ▪ involving patients and carers during consultation ▪ using focus groups, interviews and other qualitative methodological approaches.
NICE 2015	The Public Involvement Programme (PIP) is a team at NICE that develops and supports the organisation's public involvement activities. The PIP works across all of NICE's programmes to ensure that there are opportunities for lay people, and the organisations that support them, to participate meaningfully in NICE's activities, and that those opportunities are appropriately supported. Specific PIP activities include: ▪ Developing, implementing and reviewing methodologies to identify opportunities for lay involvement in NICE's work ▪ Providing guidance and support on approaches to lay involvement for NICE's Board, its internal teams, and the external groups NICE commissions to develop its guidance ▪ Working with voluntary and community sector organisations to support their involvement in specific guidance or quality standard topics ▪ Providing information, training and support to individual lay people who contribute directly to NICE's work

	▪ Offering advice to guidance developers on issues relevant to the scoping and development of NICE guidance ▪ Contributing to the development of the lay versions of NICE guidance ▪ Evaluating lay involvement in NICE activities. Payment is also offered as an incentive to participate All draft guidance and quality standards are posted on the NICE website for a period of consultation and stakeholder organisations are invited to comment. This is a stakeholder's only opportunity to comment on the content and wording of the guidance and quality statements. The Public Involvement Programme (PIP) usually encourages voluntary and community sector stakeholders to comment to ensure that the views of patients, service users and carers are included.
Rankin et al. 2000	Reports on a method of eliciting consumer perspectives for guideline development i.e. survey asking women to rate importance of draft guideline items
Rao 2011	<u>Clinical Audit</u> Patients and representatives can be involved at more strategic levels for example in selecting audit topics, setting criteria and standards, monitoring, disseminating findings and implementing changes <u>Clinical guidelines</u> *Patient input at different stages* ▪ selection of topic ▪ focus and content of clinical governance activities ▪ measures to set standards and assess outcomes ▪ reviewing evidence ▪ improving the method of care ▪ structure and presentation of patient information materials *Patient involvement at different levels* ▪ Passive input: patient provides feedback on service but no say in what questions are asked or how the answers are interpreted/acted upon ▪ Active participation: patients identify issues that inform the ways in which information can be collected and acted upon ▪ Partnerships: patients work with professionals to determine the scope, focus and outcomes of an initiative *Methods for involving patients* ▪ Patient surveys ▪ Case studies, observational studies, patient tracking, patient stories and diaries ▪ Workshops and conferences ▪ Patient councils and panels ▪ Consultation with patient representatives and groups *Choice of methods will depend on* ▪ Purpose of initiative ▪ Type of participating patients ▪ Staff expertise in different methodologies ▪ Preference of patient for different methods
Rigge 1994	A complementary approach to clinical audit developed at College of Health over past 5 years called *consumer audit* ▪ Involves range of qualitative methods e.g. interviews with patients and carers in their homes, interviews with staff at every level, including medical records clerks and secretaries ▪ Conduct of focus groups with members of voluntary organisations, with ethnic or cultural minority groups, and with others who are potential users of services
Roman & Feingold 2014	Drawing on IOM recommendations states; ▪ Current or former patients/consumer organisation representatives should facilitate PPI throughout the GD process ▪ Once draft complete patients and representatives of the public should be on the board of external reviewers ▪ Guideline drafts at external review stage should be made available for general public comment In relation to AA0-HNSF (American Academy of Otolaryngology-Head and Neck Surgery Foundation) states that; ▪ Patients and consumer groups are an integral part of the guideline

	development groups ▪ Often consumers participate as either primary or secondary authors of key action statements supporting guideline text which dictate what clinicians should and should not do according to the complied research ▪ Consumers also involved in reviewing and editing guideline manuscripts ▪ Consumer advocacy organisations are invited, alongside other stakeholders, to participate as a board of 30-40 reviewers for external peer review ▪ Consumer organisations are solicited for input and review during a 2-week public comment period after the guideline manuscript is publicly available
Serrano-Aguilar et al. 2015	Describes process used and outcomes obtained by involving patients in development of CPG for SLE <u>Three complementary activities</u> 1. Systematic review on international literature 2. A consultative and consensus process ▪ Patients recruitment managed by Spanish Federation of Patient Association of SLE-email invites ▪ Participants were consulted using Delphi consensus method with 3 rounds (Survey Monkey) 3. Patient representative recruited for GDG <u>Delphi Consultation</u> ▪ Delphi consultation made possible the participation of relatively scarce, scattered and disabled patients affected by SLE ▪ The Delphi consultation improved its efficiency by use of electronic mail (use of communicative technologies that can access wide regions and is inexpensive ▪ However need to take account of differences in computer literacy, the uneven availability of computers and potential technical problems of communications aa potential source of bias Recommended a multicomponent strategy for patient involvement in CPG development
SIGN 2014	Recognises that guideline development groups should be multidisciplinary in composition, with representation from all relevant professional groups, and participation of patients, carers and appropriate voluntary organisations (p.6) <u>Addressing patient issues in the literature review (p.16)</u> ▪ Incorporating the patient's perspective from the beginning of the development process is essential if it is to influence the coverage of the final guideline. ▪ One of the measures used to achieve this is to conduct a specific search on patient issues in advance of the first meeting of the guideline development group. <u>Evidence to recommendations: how do patients value the different outcomes? (p.38)</u> ▪ A first step should be to consult patient representatives on the guideline development group and through them a wider body of patient opinion. ▪ If time and resources allow a literature search can be carried out looking specifically for information on patient values in relation to the question being addressed. ▪ If acceptability of a recommendation to patients is seen as critical to its effective implementation, and no clear idea of patient views has been identified by the above methods, it may be necessary to run a series of focus groups to establish patient values and preferences. <u>Consultation (p.42 and section 10.6)</u> ▪ National open meeting held to discuss draft recommendations of the guidelines (with patients, carers and voluntary organisation representatives) ▪ The draft guideline is also available on the SIGN website for a month at this stage to allow those unable to attend the meeting to submit comments on the guideline. Social media is also used as a forum for discussion around the consultation meeting and content of the draft guideline. ▪ The national open meeting is the main consultative phase of SIGN guideline development <u>Peer review (p.42)</u> Draft SIGN guidelines are sent to at least two lay reviewers in order to obtain comments from the patient's perspective. Specific guidance for lay reviewers have been produced. <u>Patient version (p.46)</u>

	SIGN patient versions of guidelines are lay translations of the clinical guidelines. They are intended to: help patients and carers understand what the latest evidence supports around diagnosis, treatment and self-care; empower patients to participate fully in decisions around management of their condition in discussion with healthcare professionals and highlight for patients where there are areas of uncertainty. Patient versions of guidelines can be produced in languages other than English upon receipt of requests from users. Languages covered include those community languages identified by the Scottish Government, Gaelic, or British Sign Language (BSL). Large print versions can also be made available. A small selection of patient versions has been published in alternative electronic formats such as Apple and Android apps and e-books. <u>Implementation: patients as champions for change (p.49)</u> Patients are a powerful agent for change in the health service. Many guidelines are published with an accompanying patient and carer version of the guideline and by being aware of a clinical guideline, patients can ask for their care to be in line with the latest recommendations. Making use of connections with patient groups and voluntary organisations also affords more opportunities to raise awareness of guidelines. Lay representatives on guideline development groups are supported to raise awareness at conferences and other events. <u>Chapter 10: Involving patients and their representatives (p.52)</u> <u>Identifying patient views</u> ▪ Literature search ▪ Patient organisations and the SIGN patient network (the patient network is a database of patient, carer and other service user representatives) ▪ Other NHS organisations (any local research on patient views such as focus groups or questionnaires on patient satisfaction) ▪ Direct feedback from users of the service Findings are then presented by the Patient Involvement Officer at the 1st GDG meeting. Guideline groups are not obliged to take on board all the issues raised through the patient consultative process, but they are expected to give explicit reasons if they choose to omit particular topics that have arisen from this source (p.53) <u>Recruitment of patients to GDG (p.54)</u> SIGN recruits a minimum of two patient representatives to guideline development groups by inviting nominations from the relevant 'umbrella', national and/or local patient focused organisations in Scotland. <u>Role of patient representatives on GDG</u> A key role for patient and carer representatives is to ensure that patient views and experiences inform the group's work (see p.54 for further details including eligibility criteria such as experience of guideline condition; an understanding of experiences/needs of wider network of patients; time to commit to the work; some familiarity with medical/research language; willingness to feed in the views of patient/carer groups not represented on the guideline group; ability to be objective and good communication and team working skills)
Thomas undated	▪ Most were enthusiastic about the version for patients and carers ('Understanding NICE guidance') and its intended use ▪ Many lay people stated the personal development opportunities that involvement in the GDG had given them
van de Bovenkamp & Zuiderent-Jerak 2013	▪ Participation in guideline development group (most used) ▪ Focus groups ▪ Commenting on concept version of guideline ▪ Literature review on patient preferences ▪ Surveys ▪ Patient participation committee
van de Bovenkamp & Trappenburg 2009	▪ Survey into patient preferences on a certain subject at time of guideline development ▪ Literature search of GDG concerning patient preferences ▪ Patient focus groups to gain insight on patient preferences ▪ Patient representatives feedback on draft guidelines ▪ Enrolling patient representatives in GDG ▪ Special patient version of the guidelines
van der Ham et al. 2014	<u>Most common methods for service user involvement</u> • Service user representatives in guideline development groups (GDGs); or

	advisory committees • Service users reviewing final drafts of the guideline • Consultation of service users through panels, focus groups or questionnaires • Alternative methods of service user involvement such as case studies, dialogue session and personal narratives • Results from earlier study on service user preferences • Involvement of National Committee of Service User Participation which assessed the quality of the participation process and the service user orientation of the guideline recommendations • Guideline summary specifically developed for service users and carers (some linked to decision-making tool)
van der Ham et al. 2015	<u>Most common methods</u> Patient representation in GDG Patients reviewing drafts of guidelines Consultation of patient through focus group discussions or questionnaires This paper reports on the development of a framework for monitoring and evaluating patient involvement during development of guidelines; both common methods of patient involvement were employed, including *patient representation in GDG and advisory committee & focus group discussions*; alongside innovative approaches – *case studies and dialogue sessions* (dialogue-based approach)
van Wersch,& Eccles 2001	<u>4 methods</u> ▪ Incorporating individual patients in guideline development groups ▪ A "one off" meeting with patients ▪ A series of workshops with patients ▪ Incorporating a consumer advocate in guideline development groups
Young et al. 2015	Strategies to engage consumers in guideline development include: ▪ Providing drafts for feedback ▪ Involving consumers in guideline-development groups ▪ Conducting surveys of consumers or running consumer focus groups or workshops parallel to the clinical guideline development groups

7.4. Question 4: What methods and systems, including training, are in place to engage and <u>support</u> patients in the development and governance of the clinical effectiveness processes of clinical audit and clinical guidelines at national (or equivalent) level?

Data extracted in relation to question 4 are presented in Table 15.

The most commonly cited methods and systems available to support patient engagement in clinical effectiveness processes were both *formal and informal training and support* mechanisms. Indeed, training and support was recognised as critical to the facilitation of effective patient engagement in clinical effectiveness processes (Del Campo et al. 2011, van der Ham et al. 2014). It was suggested that training and support may facilitate understanding of the technical aspects of clinical practice guideline development, address financial and organisational barriers to participation and enhance mutual understanding regarding the role of PPI (Boivin et al. 2010). Notwithstanding this, many of the documents did not provide extensive details on the specifics of what these training and support structures are/should entail. Boivin et al. (2010) for example state that training may cover the fundamentals of guideline development, approaches for reporting back to consumer constituencies and offer mentoring opportunities from other patient/public representatives.

G-I-N, NICE and SIGN provide the most details on suggested methods and systems to support patient engagement. SIGN (204), for example, states that SIGN supports patient representatives by delivering *'Introduction to SIGN' training*, based on the SIGN 100: A handbook for patient and carer representatives for patient representatives; offers telephone and email support; invites new patient representatives to join the SIGN Patient Network; provides clear guidance on roles and responsibilities within the group; ensures opportunities to attend training events are open to all guideline development group members including patient representatives and invites patient representatives to informal events.

G-I-N (2015) classifies support into *practical, financial, informal support and training*.

In relation to *practical support* mechanisms G-I-N sets this in the context of giving consideration to making reasonable adjustments to the physical environment of group meetings, for example, adjustments for people with sensory impairments, or those who experience fatigue, wheelchair access facilities and making adjustments for specific conditions (e.g. lupus, autism spectrum condition).

For *financial support* G-I-N highlights that it is important to consider what compensation will be made to patient and public members. At minimum, G-I-N PUBLIC strongly recommends providing out-of-pocket expenses (i.e. travel costs) and also providing compensation for the time and effort and work done where possible; however does go onto say that voluntary participation is preferable to none at all. Another consideration was the provision of financial support for carer's for the care for a dependent relative or for childcare if someone has children. Similar financial supports are offered to lay representatives by NICE (2013) and SIGN (2014) including travel, subsistence, child care/carer expenses and any other reasonable out of pocket expenses to enable them to attend guideline development group meetings. NICE (2013) also report offering an attendance payment for each meeting that lay representatives attend, and have produced a set of policy principles (payments for lay contributors to NICE's work available at http://www.nice.org.uk/media/default/About/NICE-Communities/Public-involvement/Patient-and-public-involvement-policy/Lay-contributor-payments-policy-principles.pdf) and 'frequently asked questions' document (payments for lay contributors to NICE's work – frequently asked questions available at http://www.nice.org.uk/media/default/About/NICE-Communities/Public-involvement/Patient-and-public-involvement-policy/Lay-contributor-payments-frequently-asked-questions.pdf) which explain their approach to attendance payments in more detail.

A number of *informal support* mechanisms were suggested including communication before the guideline group's first meeting to provide an opportunity to address any questions lay representatives might have; providing patient and public members with a named contact person who they know that they can call on if they have any difficulties; providing other potential contacts such as former patient and public members or a project manager independent of the group; and give consideration to the emotional impact of taking part in a guideline development group for individuals (e.g. people can become frustrated if they feel their ideas are not being considered or become angry or upset when the group discusses sensitive condition related issues/treatments). G-I-N recommends that informal supports be tailored to the needs of the individual.

G-I-N (2015) states that patient and public members may benefit from *training* and this training could be in technical areas such as how to understand the terminology around medical research or around how to take part in the group effectively (for example, assertiveness). Training could take various formats such as provided in-house, out-of-house, or self-directed (i.e. online training). Networking opportunities with other patient group members or other patients with the health condition and/or having someone to talk to who has been through the guideline development process was also suggested as valuable. The types and avenues of training opportunities may depend on the size of organisations and what is possible for them to deliver. If funding was available it might open opportunities for organisations to use existing external training events or courses on areas such as committee skills, medical research or critical appraisal for consumers, and/or without funding there might be some free online resources to support self-directed learning e.g. Cochrane consumer online learning available at http://community.cochrane.org/news/tags/authors/online-course-understanding-evidence-based-healthcare-foundation-action. G-I-N also proposed that patient and public members may be willing to help with the training and support for future patient and public members (e.g. speaking at training or networking events).

Two further areas highlighted by G-I-N as important to consider for supporting lay member participation included group dynamics and giving attention to what happens after the guideline is developed. In relation to *group dynamics*, G-I-N recommends that the chair of the guideline development group is aware of their responsibility to ensure a safe, inclusive atmosphere in the group, and that the patient and public members are aware of how to contact the chair with concerns. Suggestions for assisting with power imbalances in group dynamics include: publicly stressing/delivering a presentation on the importance of patient and public involvement early in the guideline development process; highlighting that patient and public members have equal status, that they have essential contributions to make, and use examples of where patient and public representatives have previously improved a guideline; discourage the use of medical and other jargon; and give consideration to where patient and public members are seated (i.e. not in an isolated area and somewhere where it is easy to get the attention of the chair). The chair of the guideline development group is seen as a vital support for patient and public members. SIGN (2014) outlined how the chair of each guideline development group is asked to support patient representatives by: ensuring patient representatives are fully engaged with the group; addressing the group if contributions by patient representatives are not acknowledged appropriately and welcoming and encouraging contributions from patient representatives. The chair should be specifically briefed to bring the patient and public member into conversations and some groups have previously found it useful to have a specific agenda item on patient and public concerns (G-I-N 2015). Another possibility might be to have a patient or public moderator chair the meeting to ensure that jargon and power imbalances are addressed.

Once the guideline has been developed an important aspect of showing support and appreciation for patient/public contribution is acknowledging their input through a consistent and timely 'thank you' process, and in cases where guideline development groups are credited as authors this should also include patient and public members (G-I-N 2015).

NICE has a specific team, the Public Involvement Programme (PIP) that develops and supports patients, service users, carers and public involvement (NICE 2013, NICE 2014a, NICE 2015). PIP supports individual patients, service users, carers, lay members, and voluntary, charitable and community organisations involved with NICE's work. The supports PIP provides ranges from informal telephone and email advice to training workshops. Contact is initiated by the lay member and the frequency and nature of the contact varies between lay members (NICE 2015), for example, some lay members may need additional support because of a particular physical or mental health condition or learning/ physical disability that might make working on a committee more challenging. In such cases PIP works directly with lay members to establish what their support needs are and how both the PIP and the guideline developers can work to meet those needs. The specific functions of PIP are to identify opportunities for lay involvement in NICE's work; to provide guidance and support on approaches to lay involvement; to work with organisations representing lay people's interests to support their involvement in developing and implementing specific guidance/quality standards; to provide information, training and support to lay people who are interested in or contribute directly to NICE's work; to contribute to the development of lay versions of NICE guidance; to offer advice to guidance developers on patient, service user, carer and public issues relevant to the scoping and development of NICE guidance and to evaluate patient, carer and public involvement in NICE activities (NICE 2013). For lay members who sit on NICE committees, PIP runs training sessions and workshops which include induction training sessions for lay members at the beginning of their work and workshops for those who have been involved for some time. The main purpose of the day is to explore how guidance is developed and the role of lay members to help participants contribute effectively on their group/committee (NICE 2015). PIP has developed a range of written resources to support the involvement of lay members on NICE committee (see Appendix 5).

According to HQIP (2015) training needs assessment should be carried out with all relevant stakeholders to establish the specific type and quality of support and training needed. HQIP, the Healthcare Quality Improvement Partnership (an independent organisation led by the Academy of Medical Royal Colleges, The Royal College of Nursing and National Voices in the UK), was established in 2008 to promote quality in healthcare, and in particular to increase the impact that clinical audit has on healthcare quality improvement. HQIP has recently released e-learning packages for patients and the public on quality improvement including clinical effectiveness. Alongside this they have developed a guide to developing a patient panel and a clinical audit manual for lay members of audit teams (see Appendix 5). A new document highlighting these resources is due for release soon by HQIP entitled *developing a patient and public involvement panel for quality improvement* (2016). While not specific to clinical effectiveness processes the Consumer Health Forum (CHF) of Australia offers online training for consumers or community representatives working on committees. These and other resources are listed in Appendix 5.

Table 15: Data extraction: methods/systems to support patient engagement

Citation	Methods/systems to support patient engagement
Bastian 1996	▪ Some training and support available to consumer representatives through Consumer Health Forum (& a pilot introductory workshop for all GDG members offered by the body producing the guidelines) ▪ Financial support for consumer attendance at meetings
Boivin et al. 2010	Key conditions for meaningful involvement include; Recruitment, Support and Training Training may cover; • Fundamentals of guideline development • Approaches for reporting back to consumer constituencies • Offer mentoring opportunities from other patient/public representatives Participants concluded that training and support may facilitate understanding of the technical aspects of CPG development, address financial and organisational barriers to participation, and enhance mutual understanding regarding the role of PPIP. Recommended; Development of recruitment methods, training and support strategies, information material and tools, and glossaries of technical terms used in CPG
Del Campo et al. 2011	Appropriate support was also critical to facilitate effective patient engagement, overall *providing clear guidance on their roles and responsibilities within the group and ensuring the opportunities to attend training events for all GDG members.*
Duff et al. 1996	Preparation for guideline development essential Training might include; ▪ Training about clinical guidelines and research methodology ▪ Ensuring all understand their role and that of others in the group ▪ Ensuring all participants know how to contribute to the group ▪ Ensuring all participants understand the time commitment necessary to develop guidelines ▪ Giving participants choice about how they wish to, and feel able to contribute to the clinical guideline Support mechanisms might include: Within guideline development group ▪ Conduct work in small groups ▪ Avoid tokenism by ensuring more than one patient representative ▪ Use a neutral facilitator to help group dynamics ▪ Make explicit commitment to patient involvement from the start The facilitator should: ▪ Understand status/power hierarchy of the participants ▪ Understand the roles and potential contribution of all participants ▪ Ensure all participants understand their roles ▪ Stress the use of plain speaking and openness ▪ Ensure there is clarity of purpose among participants ▪ Protect participants boundaries where necessary Outside the group: ▪ Communicate and network with and between patient/user representative groups

	▪ Establish a system for regular communication by patient/user representatives and organisations ▪ Provide financial support for patient/user of services involvement
G-I-N Public Working Group 2015	<u>Supporting individuals—practical, financial, informal support and training</u> *Practical support* Provision should be made for 'reasonable adjustments' to be made to the physical environment of group meetings, the way in which meetings are conducted, and in how communication takes place in the group. Practical support can take a number of forms e.g. ▪ Adjustments for people with sensory impairments, for example, providing large print documents, or microphones in meetings ▪ Booking meeting rooms large enough for an electric wheelchair to be manoeuvred, and with stair-free access ▪ Adjustments for people who experience fatigue, such as longer breaks or having a room available in which people can rest ▪ Adjustments to lighting for people who have lupus ▪ Providing documents on coloured paper for people who have an autism spectrum condition and who find this helps them ▪ Providing a dedicated toilet for people who need one ▪ Providing financial support for care for a dependent relative if a carer has been recruited, or for childcare if someone has children ▪ Ensuring any food provided meet people's dietary needs *Valuing members—the problem of payment* ▪ It is important to consider what compensation you will make to patient and public members, and whether payments will include only travel (and other out of pocket) expenses, or also compensation for the work done. ▪ G-I-N PUBLIC would strongly recommend providing out-of-pocket expenses such as travel costs as a minimum and providing compensation for time and effort where possible, but voluntary participation is preferable to none at all. ▪ NICE pays an attendance fee to patient and public members, as well as travel and subsistence expenses and, where necessary, an overnight hotel. It also contributes to carer costs, both where the patient and public member requires a carer themselves, or has caring responsibilities at home (e.g. childcare) *Informal support* ▪ Tailor informal support to the needs of each individual ▪ Make contact with each individual before the group's first meeting allows an opportunity to address any questions the person has. ▪ Provide patient and public members with a named contact person who they know that they can call on if they have any difficulties e.g. NICE provides a contact person from a dedicated patient and public involvement programme (PPIP) team member ▪ Other potential contacts can be former patient and public members from other groups who are willing to help, or a project manager independent of the group. ▪ Consider the emotional impact of taking part in a guideline development group for individuals e.g. idividuals can sometimes become frustrated if they feel their ideas are not being considered, or can become angry or upset when the group discusses areas such as survival statistics or the advisability of aggressive treatments *Training* ▪ Patient and public members may benefit from training ▪ Training could be in technical areas such as how to understand the terminology around medical research or around how to take part in the group effectively (for example, assertiveness). ▪ Training can be in-house, provided out-of-house, or self-directed (for example, online training). ▪ Large organisations are better able to provide tailored in-house support. ▪ NICE provides a full day training event for new patient and public members, including presentations and group exercises, covering research terminology, what makes a good or bad scientific paper, health economics and a chance to hear previous patient and public members talk about their experiences. ▪ This is followed up later in development with a workshop for patient and public members focusing on the end stages of guideline development, publication and support for implementation ▪ Provide networking opportunities for individuals - this can take place before

	patient and public members start on a group, and could include other patient group members or other patients with the health condition allowing for a wider range of viewpoints to be brought to the group. It can also take place once groups are underway. ▪ Having someone who has been through the guideline development process to talk to could be a valuable source of help and support. ▪ In-house training and providing networking opportunities may not be possible in smaller organisations. ▪ If there are funding and local opportunities, organisations may choose to use existing external training events or courses on areas such as committee skills or critical appraisal. ▪ Some organisations provide training in medical research for consumers. Where this is not possible, there may be free online resources to support self-directed learning e.g. Cochrane consumer online learning http://community.cochrane.org/news/tags/authors/online-course-understanding-evidence-based-healthcare-foundation-action *Supporting Individuals—group dynamics* ▪ Ensure Chair of the group is aware of their responsibility to ensure a safe, inclusive atmosphere in the group, and patient and public members are aware of how to contact them with concerns. To assist with power imbalances in group dynamics consider; ▪ Publicly stress the importance of patient and public perspectives - consider delivering a presentation on the importance of patient and public involvement early in the guideline development process. ▪ Stress that patient and public members have equal status they have essential contributions, and provide examples of where patient and public members have improved a guideline in the past. ▪ Strongly discourage the use of medical and other jargon in meetings, which can exclude patients. ▪ It may be possible to have a patient or public moderator Chair the meeting, to ensure that jargon and power imbalances are addressed ▪ Patient and public members should not be seated in an isolated area of the meeting, and should be somewhere where it is easy to get the attention of the Chair and other supportive members of the group. ▪ The Chair should be specifically briefed to bring the patient and public member into conversations, and some groups find it helpful to have a specific agenda item on patient and public concerns. *After the guideline is developed* ▪ Acknowledging patient/public input is an important aspect of showing support and appreciation for their contributions. A consistent and timely 'thank you' process is essential and will help ensure repeat volunteers in the future ▪ If guideline development groups are credited as authors on the guideline, patient and public members should receive the same authorship ▪ Patient and public members may be willing to help with the training and support for future patient and public members, for example, by speaking at training or networking events. Keeping records of who is willing to do this is a good way to support new patient and public members.
HQIP 2015	Information, guidance and training for commissioners, healthcare providers, clinicians and patients will be designed and consulted upon in line with The Information Standard criteria. Training needs assessment will be carried out and training made available where required for patients involved in particular activities.
Institute of Medicine 2011	Strategies to increase effective participation of patient and consumer representatives, including training in appraisal of evidence, should be adopted by GDGs.
Kelson et al. 2012	None reported but recommends that guideline developers should assess the training needs of both professional and consumer participants and provide adequate support and training to promote effective collaborative working.
Lamontagne et al. 2014	Participants first received in-person training on guidelines and IPP using educational materials on the subject developed by Health Council Canada – understanding CPG a video series primer
Legare et al. 2011	<u>Support took the form of:</u> ▪ Telephone and e-mail assistance ▪ Mentoring ▪ A supportive chair of the guideline development group ▪ An analysis grid for knowledge synthesis, or a "welcome pack" for selected

	patients ▪ Providing assistance with complex scientific and technical issues was valuable way to optimize participation of patients and public ▪ Also offering participants opportunities to interact with other patients who had participated in the development of CPGs <u>Chair of each guideline development group</u> is asked to support patient representatives by ensuring they are: ▪ Fully engaged with the group ▪ Addressing the group if their contributions are not acknowledged appropriately ▪ Welcoming and encouraging their contributions <u>Suggestions for support</u> ▪ Structured training and support is required to help overcome barriers such as challenges of reconciling differences in preferences of patients/public with experts/health professionals and assisting patients/public to affirm their views and experiences in presence of evidence based information and complex scientific and medical terminology ▪ Training and supporting patients/public should focus on critical appraisal skills but also on the skills needed to participate in group processes ▪ Attention should also be given to the role of chairs and other guideline developers on the role they play in supporting PPIP participants
Legare et al. 2012	▪ Support staff – offer expertise and time - to patients and public participants ▪ Material resources such as participant handbooks
NICE 2013	The Public Involvement Programme (PIP) is a team at NICE that develops and supports patient, service user, carer and public involvement. The PIP: ▪ develops, implements and reviews methodologies to identify opportunities for lay involvement in NICE's work ▪ provides guidance and support on approaches to lay involvement for NICE's Board, its internal teams, and the external groups NICE commissions to develop its guidance ▪ works with organisations that represent lay people's interests to support their involvement in developing and implementing specific guidance or quality standard topics ▪ provides information, training and support to individual lay people who are interested in or contribute directly to NICE's work ▪ contributes to the development of the lay versions of NICE guidance ▪ offers advice to guidance developers on patient, service user, carer and public issues relevant to the scoping and development of NICE guidance ▪ evaluates patient, carer and public involvement in NICE activities Support from the PIP ranges from informal telephone and email advice to training workshops. The PIP supports individual patients, service users, carers and lay members as well as voluntary, charitable and community organisations involved with NICE's work. Also Patients Involved in NICE (PIN) exists to provide patient organisations who engage with NICE with a system of mutual support and information sharing, and to act as a 'critical friend' to NICE. *Payments for lay involvement* All lay members of NICE's committees and working groups are offered an attendance payment for each meeting they come to, as well as their travel and subsistence expenses, and a contribution to childcare or other carer costs, where applicable NICE has produced a set of policy principles and a 'frequently asked questions' document which explain our approach to attendance payments in more detail.
NICE 2014a	*Public Involvement Programme* The Public Involvement Programme (PIP) advises on ways to effectively involve people who use health and care services, family members, carers and the public, and supports their participation in guideline development. PIP encourages organisations representing service user, carer and community interests to register as stakeholders. It also advertises for people using services, carers and the public to apply to join Committees and supports them in their roles as Committee members.
NICE 2015	▪ All lay people recruited to work with NICE in an individual capacity are allocated a named member of the PIP who supports them throughout their tenure. ▪ The PIP aims to support the voluntary and community sector organisations in understanding the importance of lay experience as part of expert witness testimony, and encourages diverse and appropriate nominations. ▪ Once the lay expert witnesses have been selected, the PIP will offer them support: by telephone before the meeting at which they will be giving testimony; face to face at the Committee meeting; by email after the Committee meeting

	▪ In addition to this personalised support, the PIP has developed factsheets that provide further general, detailed information about the role of the expert witness and the support available from the PIP. ▪ PIP emails supporting documents such as hints and tips documents to the expert witness for them to refer to throughout their involvement with NICE. *Resources and support for public involvement* ▪ The Public Involvement Programme (PIP) offers informal support and advice to lay members, expert witnesses and voluntary and community sector organisations throughout their time working with NICE. ▪ Once lay members are established on their committees, PIP provides support on an ad hoc basis by contacting them by email periodically, attending a committee meeting, and responding to any contact made. Contact is initiated primarily by the lay member and the frequency and nature of the contact will vary between lay members. ▪ Some lay members need additional support. This may be because they have a particular health condition that might make working on a committee more challenging, have a learning or physical disability, or a mental health condition. In these situations PIP works with them to establish what their support needs are and how both PIP and the guidance and standards developers can work to meet those needs. Examples of support provided by PIP could include more frequent telephone contact, or a PIP staff member attending a committee meeting with a lay member if they are having a particularly difficult time. <u>For lay members and lay expert witnesses.</u> The Public Involvement Programme (PIP) has developed a range of resources to support the involvement of lay members on NICE committees. This written information includes: ▪ further information about the NICE programme with which they will be working ▪ support and advice about making a valuable contribution to the work of the committee ▪ a glossary of key terms ▪ a list of useful websites. <u>Training offered by PIP</u> <u>For lay members</u>. ▪ The Public Involvement Programme (PIP) runs training sessions and workshops for lay members who sit on NICE committees. This includes induction training sessions for lay members who are at the beginning of their work and workshops for those who have been involved for some time. ▪ All newly recruited topic specific lay members are invited to a PIP training day and encouraged to attend. The main purpose of the day is to explore how guidance is developed and the role of lay members, to help participants contribute effectively on their group or committee.
SIGN 2014	Patient representatives can claim travel, subsistence, child care/carer expenses and any other reasonable out of pocket expenses to enable them to attend guideline development group meetings (p.5) SIGN supports patient representatives by (p.55): ▪ delivering 'Introduction to SIGN' training, based on SIGN 100: A handbook for patient and carer representatives for patient representatives ▪ offering telephone and email support ▪ inviting new patient representatives to join the SIGN Patient Network ▪ providing clear guidance on roles and responsibilities within the group ▪ ensuring opportunities to attend training events are open to all guideline development group members, including patient representatives ▪ inviting patient representatives to informal events The Chair of each guideline development group is asked to support patient representatives by: ▪ ensuring patient representatives are fully engaged with the group ▪ addressing the group if contributions by patient representatives are not acknowledged appropriately ▪ welcoming and encouraging contributions from patient representatives
Thomas undated	▪ Of the lay members, 89% rated the support they received from the chair as 'excellent' or 'very good': ▪ Those who had received training during the meetings were generally positive ▪ The majority considered the training and support from the PPIP to be helpful "*Using past lay members … in the induction session for the new ones is good"* ▪ 'Informal' activities were helpful in giving lay members the support they needed

van de Bovenkamp & Trappenburg 2009	▪ Stated consensus is that patient representatives should receive guidance during the process and that patient participants ought to be trained, prepared and educated to fulfil their task. ▪ Stated that when participation is studied in practice the conclusion is usually that patients can participate provided they receive proper support. It is generally assumed that patients can be trained to become full members in a GDG. ▪ However, arguably if patients who have been trained and supported become fellow academics; they may no longer be able to contribute the experiential knowledge for which they were asked to participate in the first place. Whereas, patients who were not properly trained do contribute this experiential knowledge, but it can be difficult to incorporate this in EBM guidelines.
van der Ham et al. 2014	▪ Provision of additional support to service user representatives a potential facilitator. ▪ Process-related support such as monitoring of service user representatives and their needs throughout the process by the project manager ▪ Content related support such as organising collective input from the service user organisation that is represented
van der Ham et al. 2015	▪ Paper mentions informal support provided ▪ Formal training and support were absent but sometimes needed ▪ What methods and systems are in place to support and engage patients in the development and governance of clinical effectiveness processes were not addressed
van Wersch,& Eccles 2001	Consumers (like all guideline development group members) need support to be able to understand the detail of the science behind the issues they will hear discussed and to be able to contribute to discussion; however states that it is less clear how much support needs to be provided to help consumers (or other group members) to understand the detail of the science behind the issues they will hear discussed
Young et al. 2015	▪ Consumers (like all guideline development group members) need support to be able to understand the detail of the science behind the issues they will hear discussed and to be able to contribute to discussion ▪ Unless guideline developers provide consumers participating in development groups with education and training, a clear explanation of their role, and sufficient support (e.g. more than one consumer representative), their involvement is likely to be tokenistic and relatively ineffective

7.5. Question 5: What measurement or <u>evaluation</u> has occurred in relation to patient engagement or the systems and methods used to support patient engagement?

Data extracted in relation to question 5 are presented in Table 16.

This review revealed limited evidence on any measurement or evaluation of the effectiveness of patient and public engagement in clinical effectiveness processes, or of the systems/methods used to support patient and public engagement in clinical effectiveness processes. The paucity of rigorous process and impact evaluations to determine the effectiveness of patient and public involvement programmes (PPIPs) was highlighted by Boivin et al. (2010) who recommended the need for primary research to expand its examination of the advantages and disadvantages of different PPI methods and the impact of these on practice guideline development and implementation, in addition to, perceived validity, acceptability and legitimacy for health professionals, patients and the public, in addition to, the need to study in greater detail the contextual and process factors that influence PPIP effectiveness.

Three documents did refer to evaluation processes. Two documents reported on multi-method evaluations, one specifically assessed the feasibility of a wiki as a participatory tool for patients in guideline development (Den Breejen et al 2012) and the second one evaluated patient/carer members and chairs of guideline development groups experience of being involved in guideline development groups associated with NICE (Jarrett & PIU 2004). The third document was the only source identified which compared four different PPI methods through a case series conducted within the North of England evidence-based

guideline development programme (van Wersch & Eccles 2001). The outcomes of these evaluations largely support the data presented in this review and the conclusions that lay representatives should be involved in various stages of the guideline development process through the use several PPI approaches and methods at once, and lay representatives should be supported throughout the engagement process.

Notwithstanding this, the need for further empirical research to establish the most effective ways, and key components of successful PPI approaches, in which consumer values and preferences can be incorporated into clinical guidelines was reiterated by many authors (Legare et al. 2011, Kelson et al. 2012, van der Ham 2015). There was also the call for better evaluation of patient involvement with the acknowledgement that there is a lack of formal assessment of patient/public satisfaction following their participation in the clinical practice guideline development process (Legare et al. 2011, va der Ham et al. 2015). Boivin et al. (2010) contended that lack of evaluation of PPIP's is a potential barrier to wider the acceptance and development of PPIP's. The need for experimental work to compare different strategies of PPI in guideline development, and examine alternative methods of PPI, to determine whether different resource intensive resource approaches lead to different recommendations or other important differences (Schunemann et al. 2006, van der Ham et al. 2015). The need for more comparative research to evaluate different PPI programmes and methods and their impact on guideline development and implementation was also a recommendation of Boivin et al. (2010); along with highlighting the need to investigate in more detail the contextual and process factors that influence the effectiveness of PPIPs. The HQIP (2015) strategy states that HQIP will develop indicators to demonstrate the impact of PPI which will include measuring; (i) whether the level of patient involvement/engagement increased; (ii) if the intended outcomes were achieved and (iii) if any actual differences occurred or outcomes improved as a consequence of involving patients. One published study protocol (Lamontagne et al. 2014), *with no data available as yet (confirmed through personal communication with the corresponding author),* proposed a single-blind, randomized, crossover pragmatic pilot trial to examine the acceptability, feasibility and effectiveness of two methods (i.e. a control discussion group and an experimental Wiki group) of involving patients with a disability (traumatic brain injury) in clinical practice guideline development.

Table 16: Data extraction: evaluations of approaches/methods/systems used to support patient engagement

Citation	Evaluation of approaches/methods/systems used to support patient engagement
Boivin et al. 2010	There is a paucity of rigorous process and impact evaluation to determine effectiveness of PPIP Recommended; ▪ The expansion of primary research on the pros and cons of different methods of involvement, including its impact on CPG development and implementation, as well as on CPG perceived validity, acceptability and legitimacy for health professionals, patients and the public ▪ Suggested that there is a need to study in greater detail the contextual and process factors that influence PPIP effectiveness ▪ To foster comparative research and evaluation of PPIP methods and impact on guideline development and implementation Lack of evaluation of PPIP potential barrier to wider acceptance & development of PPIP
Den Breejen at al. 2012	Studies on the effectiveness and impact of patient participation are limited <u>*Online evaluation questionnaire*</u> Of 80 patients who participated in the prioritization, 45 completed the questionnaire *Facilitators* not identified. Main *barriers* were findability (82%) and accessibility (78%) of website, and suitability of wiki for obtaining recommendations for CPG development (71%). *Advantages* were privacy, structure of website linking recommendations to sections on care delivered by fertility professionals, ease of navigation through website and additional value of wiki website as a source of information and opportunity to

	provide feedback to care services. *Disadvantages* of wiki were content of wiki website, in terms of unstructured recommendations not being formulated in a similar way, too much content visible on one screen, and non-attractive layout of wiki website. Main potential *areas of improvement* were providing information on treatment options and causal factors of infertility on wiki website, broadening the marketing of the wiki by placing advertisements in commercial magazines, and communicating information on related activities. 98% of the patients would recommend the website and 84% would participate again in a similar project. *In-Depth Interviews* n=3 of participants who gave their email address in the evaluation questionnaire All patients reported problems with formulating a recommendation and expressed their wish to add a personal touch to the recommendation (e.g. to explain why something should be done). Patients also embraced the missing community feeling as mentioned in the evaluation questionnaire. Introducing a monthly newsletter and automatically sending an email to the person who made the recommendation were suggested. All 3 interviewees regarded the website as a valuable source of information, rather than as a tool for modifying recommendations for CPG development. Challenges faced by users in understanding the purpose of the website would be addressed by clearer instructions.
HQIP 2015	▪ Patient involvement must be used to add value to a decision or activity. Indicators will be developed to measure the impact of increased PPI throughout HQIP. KPIs will be developed that demonstrate: ▪ Has the level of patient involvement/ engagement increased (flow) ▪ Were the intended outcomes achieved (quality) ▪ What actual difference did involving patients make and was the outcome improved (impact)
Jarrett & PIU 2004	Evaluation carried out by PIU, NICE to explore involvement experiences of patients/carer members (PCM) and chair of GDG Patient's /Carer experiences ▪ Some challenges included not knowing what to expect, previous bad experience, unsupportive chair or other members of the guideline group ▪ Facilitating factors included a facilitative chair who supported them, gave them an opportunity to contribute and were accessible outside the meeting ▪ Supports available were: PIU (some called upon the PIU, others did not but new support was available and others did not know about the PIU or were not fully aware of the PIU role); support from other PCMs; support from their patient organisation/collaborating centre ▪ Not forewarned about commitment needed in terms of workload, involvement, amount of reading required to do between meetings etc. ▪ Scope – frustrated that scope of guideline determined before group was set up felt patient focus was undermined ▪ Understanding scientific / technical material ▪ Difficulty grasping concept of evidence / statistics – felt had no contribution to make on these issues and felt excluded ▪ GDG decisions/requests overturned / denied by NICE ▪ Those used to working on multidisciplinary (MD) groups felt confident to express view ▪ Without experience of MD groups felt uncomfortable making their voice heard ▪ Given protected opportunity (i.e. dedicated slot on agenda) ▪ Difficulty / barrier – medical bias to GDG discussion ▪ Facilitator – chair made effort to include PCMs ▪ Barrier – specific issues/recommendations they considered important not included ▪ Impact on guideline – influence structure and language used ▪ Felt they strengthened guideline around issues of communication with patients, information and support for patients and carers ▪ Influenced individual recommendations ranging from responsibilities for care to specific therapeutic interventions ▪ Inclusion of topics that might have otherwise have been left out ▪ Felt confident and empowered by the nature of the group

	Chair experiences ▪ Rated having patient/carer member involved in GDG as valuable/positive ▪ Some concerned about ability of PCMs to operate as full members of the group because they would not understand the technical detail of the work or because they would not be able to contribute ▪ Wondered if PCMs would come with their own agenda (although did acknowledge this could apply to any member if the group) ▪ Felt they themselves supported the PCMs mainly by giving them time to say what they wanted, time for explanation of complex data and time to listen ▪ Encouraging the PCMs to challenge the group so that they would bring reality to the guideline that would otherwise be medically dominated ▪ PCMs needed training on the evidence framework and critical appraisal ▪ Involving an experienced PCM in training of GDGs ▪ PCMs have a valuable contribution to make ▪ Sometimes PCMs had less than adequate understanding of science ▪ Generally chairs thought that PCMs were able to contribute effectively to the process and were instrumental in bringing discussions back to the patient experience ▪ The most important contribution of patient members cited were reminder to talk in patient centred terms, there to test recommendations against, have a much less medical focus, creating services that are acceptable to service users, about support/information for patients and user's perspective of treatment
Kelson et al. 2012	None reported but recommended that further research and evaluation is needed to establish the most effective ways in which consumers values and preferences can be incorporated into clinical guidelines
Lamontagne et al. 2014	Protocol which proposes to evaluate intervention accessibility, feasibility and effectiveness
Legare et al. 2011	None reported, however stated that few organisations formally assess patient/public satisfaction following their participation in a CPG development process Stated that better evaluations of methods to involve patient/public are needed
Schunemann et al. 2006	Experimental work is needed that compares different strategies of consumer involvement in guideline development
van der Ham et al. 2015	None reported – but stated that more research needed to identify key components of successful patient involvement initiatives; better evaluation of patient involvement and research on alternative methods of patient involvement
van Wersch & Eccles 2001	Evaluated 4 methods of consumer involvement Incorporating individual patients in guideline development groups Recruitment challenges – failed to recruit through Community Health Council; 2 reps identified through secondary care clinicians within the guideline group Audiotaped GDG meetings and conducted content analysis of transcripts to analysis the contribution of the patient ▪ Patients contributed infrequently to the discussions ▪ Patients had problems with use of technical language ▪ Patients contributed most to discussions of patient education ▪ Patient contributions were not subsequently acted upon A "one off" meeting with patients Discussion of an advanced draft version of guideline with group of patients at a single evening meeting Patients invited to attend via a local group of National Asthma Campaign Audio recorded the meeting and conducted content analysis of transcripts ▪ Patients reported problems with medical terminology and jargon ▪ Patients were most interested in sections on patient education and self-management ▪ Patients understanding of the use of scientific evidence in order to contribute to a more cost effective health care remained unclear Given the greater degree of discussion within the "one off" group of patients than by the sole patients within the guideline groups, it seems reasonable to at least offer consumers within guideline groups the option of being one of a pair. This would not only provide more tangible support, but also lessen the risk of only hearing from a "lone" or "token" consumer.

A series of workshops with patients
Series of workshops to explore potential to increase patients understanding of the meaning of scientific evidence, their ideas of cost effectiveness and views on patient information (explored outside the guideline development process)
Four workshops, average attendance 10 patients per workshop

- It was possible to explain the technical elements of guideline development to patients
- Patients could engage with such a process and make relevant suggestions as a consequence
- The process was relatively resource intensive

Incorporating a consumer advocate in guideline development groups
Consumer advocate was lead of national cardiac patient group
Single interview conducted covering the experiences and satisfaction of the patient advocate involvement in the GDG

- The advocate had previous similar experiences
- The advocate felt confidence to speak within the group
- The advocate was used to having discussions with health professionals
- The advocate was familiar with the medical terminology

Having involved consumers within the guideline development process, their contributions did not necessarily alter the content of the guidelines;

- the scope of the guidelines had been defined in fairly narrow medical terms and at a stage when consumers were not involved
- the process of guideline development—with its focus on validity and underlying evidence—deals less comfortably with "non-evidence based" views and preference

Each of the 4 methods had advantages (and disadvantages), none were ideal and, even if optimised, each alone would be likely to remain limited
To avoid hearing only a single view (where it is likely there is a range), broader views can be gathered from outside the groups; this could be addressed by using more than a single method of consumer involvement

8.0. CONCLUSIONS

This systematic review aimed to synthesis available evidence (published and unpublished) on patient and public involvement in the development and governance of national clinical effectiveness processes; including clinical guideline development and clinical audit processes. The five main objectives of the review focused on examining the benefits, barriers, enablers, approaches, supports and evaluation mechanisms in relation to PPI in clinical effectiveness processes. Overall, the review revealed evidence that PPI in national clinical effectiveness processes does take place; however empirical evidence on which PPI strategy or approach is most effective was limited. The majority of documents reviewed reported on PPI in clinical guideline development with a dearth of data on PPI in clinical audit processes. Notwithstanding this however, it is possible that the main conclusions and key "*take-home"* messages from this review could also be applied to PPI in national clinical audit processes. The main conclusions of this review are summarised below according to the five main objectives of the review.

1. *Benefits of PPI in clinical effectiveness processes*

While the benefit of improving the applicability of guidelines by involving patients and public in the guideline development process appears as a common theme across the literature there is little empirical evidence to support these assumed benefits, which are seen to be self-evident as a *'good thing'*. Despite a general consensus that patient and public representatives should be involved in clinical effectiveness processes, the added benefits of PPI in clinical effectiveness processes has yet to be established empirically. Indeed, van de Bovenkamp & Trappenburg (2009) challenged the general consensus that patient participation in guideline development increases the quality of the guidelines based on the assertion that there is little evidence in support of this supposition. van de Bovenkamp & Trappenburg (2009) do however highlight the difficulty, or perhaps impossibility, of

examining the effects of patient participation using randomised controlled trials (i.e. challenge of setting up a research study of guideline development groups with and without patient representatives engaging in the exact same processes). They go on to highlight that decision-making processes must be studied in different ways, for example, through case studies, surveys, interviews and guideline analysis and such studies cannot be dismissed as methodologically flawed as many will provide valuable insights into complicated processes.

2. *Barriers and facilitators to PPI in clinical effectiveness processes*

A number of potential barriers and facilitators to PPI in clinical effectiveness processes were referred to in the documents reviewed. Barriers, nominally included, tensions associated with differentials in knowledge (i.e. evidence based vs experiential) and how these might be integrated; the effective collaboration of individuals with varied power differentials and different perspectives and how these might be managed; the representativeness of, and selection processes for, patient and public members and how these are reflective of the diverse variability in patient values and preferences; and finally, challenges for patient representatives in relation to their physical ability and emotional wellbeing to participate. Perhaps a key issue here is transparently defining the goals of patient and/or public participation as many documents highlighted that often there was a lack of clarity and uncertainty in relation to the patient/public representative roles and responsibilities and poor communication about the guideline development process and consultation methods (van de Bovenkamp & Trappenburg 2009, van der Ham et al. 2014, 2015). Indeed, a number of authors referred to transparent and clear lines of communication as a key facilitator to PPI, alongside, recruitment and selection processes, training, support, using a combination of different PPI approaches, being committed to and in favour of PPI and creating a working environment that promotes mutual respect and positive working relationships.

3. *Approaches to PPI in clinical effectiveness processes*

PPI approaches identified in this review included both direct and indirect involvement of patients and the public at various stages of guideline development. Three main PPI strategies were uncovered; consultation, participation and communication. There was limited data available on evidence based outcomes on the strengths and weaknesses of these three PPI strategies (i.e. consultation, participation and communication); however it was recognised that all approaches had different strengths and weaknesses and combining strategies may in some way help overcome this. While some authors would argue that consultation strategies alone are not enough for a truly collaborative approach, others see the value and limitation of each strategy in isolation and acknowledge that effective involvement begins with finding the best approach tailored to the specific PPI goal in any given context. The level of involvement should be clear and transparent for all concerned. There are also various methods (e.g. interviews/focus groups to explore patients' preferences, including patients/representatives in GDG, lay versions of the guideline document) for involving patient's and the public at various participatory levels in the development of clinical practice guidelines, however *practical guidance* on how and when to apply these methods is limited. Often representation of lay members is restricted to a select number of patient or patient representatives/organisations and does not include a large diverse population of patients and/or the general public. There was very limited data sourced on patient and/or public involvement in clinical audit processes.

4. Methods and systems to support PPI in clinical effectiveness processes

There was a general consensus that patient representatives should be trained, prepared, guided and educated for their role, in addition to being providing with practical, emotional and financial assistance as appropriate. A limitation of the body of evidence, however, in relation to methods and systems to support patient engagement in clinical effectiveness processes, is the scant reporting on the model, mode, delivery, timing, content, trainers, cost, evaluation of and effective impact of various training and support mechanisms.

5. *Evaluations of PPI approaches or of methods/systems used to support PPI in clinical effectiveness processes*

There was a paucity of rigorous process and impact evaluations to determine the effectiveness of patient and public involvement approaches, and/or methods and systems to support PPI in clinical effectiveness processes. Many authors did however reiterate the need for empirical research to establish the most effective ways, and key components of successful PPI approaches.

Key "take-home" messages

Notwithstanding the availability of limited empirical evidence, the findings of this review do provide some baseline data and valuable insights into the complex process of integrating PPI into clinical effectiveness processes with some important key principles identified for the NCEC's consideration (see Box 1).

Box 1: PPI in national clinical effectiveness processes: key principles to consider

1. Despite a lack of robust evidence on the specific value of PPI in national clinical effectiveness processes, consideration should be given to the integration of PPI into these processes to strengthen public participation in healthcare decision-making and to bring expert experiential knowledge to these processes.

2. The three PPI strategies of consultation, participation and communication can be employed as required in each clinical effectiveness process, and full active public/patient participation should be explored where appropriate.

3. The most appropriate patient and public representation should be examined for each case, drawing on public, patient, carer and other peer or lay representatives; there is no evidence to recommend one approach to the selection and recruitment of patient and public representatives though a transparent process is required.

4. There is a need for comprehensive support for patient and public representatives, specifically in terms of support from the chair of the guideline development group, training, remuneration/compensation, physical, psychosocial and emotional support.

5. Several international organisations (e.g. NICE in the UK, SIGN in the UK, G-I-N International Network, HQIP in the UK) have developed structured PPI programmes, with supporting resources, to underpin their clinical effectiveness approaches. These offer potentially valuable models to examine further for any framework development.

6. There is a need for further research into the effectiveness of different approaches to PPI in clinical effectiveness processes.

Finally, in the nomenclature of Duff et al. (1996 p.111);

> *"For collaborative working to become a reality rather than remain just a good idea we need to have more understanding of how we might work in partnership with patients and patient representatives"*.

Consequently, further research is needed to establish the effectiveness of different PPI approaches in clinical effectiveness processes. Better evaluation of PPI in clinical effectiveness processes could potentially enhance the wider acceptance and development of PPIP's if seen to be effective.

9.0. Acknowledgement: Expert Advisory Group

An expert advisory group was established prior to commencement of this review with the remit to offer expert through lived experience, patient advocate and service user involvement expertise on considering the emergent evidence on patient and public involvement in clinical effectiveness processes. We would like to acknowledge and thank the group members for their insightful input.

Mr Stephen McMahon	Director of the Irish Patient's Association
Dr Liam MacGabhann	Expert on service user/patient engagement, lead researcher for development of 'Expert by Experience' in Mental Health, Co-ordinator of national mental health leadership programme, Lecturer in Mental Health, Dublin City University

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APPENDICES

APPENDIX 1
Search Strategy: PubMed

ID	Search Term	Hits
#1	"patient and public involvement"	#180
#2	"patient participation"	#20,010
#3	"patient engagement"	#758
#4	"patient collaboration"	#70
#5	"patient consultation"	#280
#6	patient empowerment	#14178
#7	“patient rights”	#39829
#8	"client engagement"	#97
#9	"client participation"	#78
#10	"client collaboration"	#3
#11	"client consultation"	#3
#12	"public engagement"	#399
#13	"public participation"	#488
#14	"public collaboration"	#5
#15	"public consultation"	#172
#16	"community engagement"	#995
#17	"community participation"	#1991
#18	"community collaboration"	#194
#19	"community consultation"	#209
#20	"carer engagement"	#4
#21	"carer participation"	#29
#22	"caregiver engagement"	#22
#23	"caregiver participation"	#38
#24	"parent engagement"	#61
#25	"parent participation"	#119
#26	"parent consultation"	#5
#27	"relative engagement"	#16
#28	"relative participation"	#77
#29	**OR #1 - #28**	**#24,382**
#30	"clinical effectiveness"	#6,756
#31	"clinical audit"	#2,164
#32	"audit"	#30,296
#33	"guideline"	#60,482
#34	"clinical guideline"	#993
#35	"practice guideline"	#18,131
#36	"clinical practice guideline"	#1,763
#37	**OR #30 - #36**	**#95,962**
#38	**#29 AND #37**	**#621**

Filters activated: Journal Article, Publication date from 1990/01/01 to 2015/11/09, English.

APPENDIX 2
Grey Literature Databases Searches and Outputs

Database/Organisation	Search terms	Date searched	Hits	Screen for eligibility EXCLUDE	Screen for eligibility INCLUDE
Agency for Healthcare Research and Quality (AHRQ) http://www.ahrq.gov/	“patient and public involvement”	12/11/15	39	N=39 List reasons for exclusion None relevant to clinical guidelines	N=0
	"patient participation in clinical guidelines"	12/11/15	0	N=0	N=0
	“public involvement in clinical guidelines”	12/11/15	2	N=2 List reasons for exclusion Duplicates	N=0
	“patient participation in clinical audit”	12/11/15	0	N=0	N=0
	“public involvement in clinical audit”	12/11/15	0	N=0	N=0
	“patient and public involvement AND clinical effectiveness processes”	12/11/15	0	N=0	N=0
Open Grey (System for Information on Grey Literature in Europe) www.opengrey.eu	“patient and public involvement”	11/11/15	7	N=7 List reasons for exclusion Not specific to clinical effectiveness processes	N=0
	“patient participation in clinical guidelines”	11/11/15	2	N=2 List reasons for exclusion Content not relevant Not specific to PPI in guidelines	N=0

Database/Organisation	Search terms	Date searched	Hits	Screen for eligibility EXCLUDE	Screen for eligibility INCLUDE
	"public involvement in clinical guidelines"	11/11/15	1	N=1 List reasons for exclusion Concerned with child assent	N=0
	"patient participation in clinical audit"	11/11/15	2	N=2 List reasons for exclusion Content not relevant	N=0
	"public involvement in clinical audit"	11/11/15	0	N=0	N=0
	"patient and public involvement AND clinical effectiveness processes"	11/11/15	0	N=0	N=0
The New York Academy of Medicine – Grey Literature Report www.greylit.org	patient and public involvement	11/11/15	22	N=22 List reasons for exclusion Not specific to clinical effectiveness processes	N=0
	patient participation in clinical guidelines	11/11/15	2	N=2 List reasons for exclusion No specific information on guidelines	N=0
	public involvement in clinical guidelines	11/11/15	2	N=2 List reasons for exclusion Discussed guidelines but not in relation to PPI	N=0
	patient participation in clinical audit	11/11/15	1	N=1 List reasons for exclusion Contained both terms but not as they relate to each other	N=0

Database/Organisation	Search terms	Date searched	Hits	Screen for eligibility EXCLUDE	Screen for eligibility INCLUDE
	public involvement in clinical audit	11/11/15	1	N=1 List reasons for exclusion No specific mention of public involvement in clinical audit	N=0
	patient and public involvement AND clinical effectiveness processes	11/11/15	0	N=0	N=0
UK Clinical Research Network (UKCRN) http://public.ukcrn.org.uk/search/	patient and public involvement	12/11/15	0	N=0	N=0
	patient participation in clinical guidelines	12/11/15	0	N=0	N=0
	public involvement in clinical guidelines	12/11/15	0	N=0	N=0
	patient participation in clinical audit	12/11/15	0	N=0	N=0
	public involvement in clinical audit	12/11/15	0	N=0	N=0
	patient and public involvement AND clinical effectiveness processes	12/11/15	0	N=0	N=0

APPENDIX 3
National/International Agencies/Networks Searches & Outputs

Database/Organisation	Search terms	Date searched	Hits	Screen for eligibility EXCLUDE	Screen for eligibility INCLUDE
Australian Commission on Safety and Quality in Healthcare http://www.safetyandquality.gov.au/	"patient and public involvement"	12/11/15	0	N=0	N=0
	"patient participation in clinical guidelines"	12/11/15	0	N=0	N=0
	"public involvement in clinical guidelines"	12/11/15	0	N=0	N=0
	"patient participation in clinical audit"	12/11/15	0	N=0	N=0
	"public involvement in clinical audit"	12/11/15	0	N=0	N=0
	"patient and public involvement AND clinical effectiveness processes"	12/11/15	0	N=0	N=0
eLSC Practice Guidance and Standards Database http://www.scie-socialcareonline.org.uk/	"patient and public involvement"	13/11/15	3438	N=3438 List reasons for exclusion Content not relevant	N=0
	"patient participation in clinical guidelines"	13/11/15	569	N=569 List reasons for exclusion Nothing on PPI as it relates to guidelines	N=0
	"public involvement in clinical guidelines"	13/11/15	206	N=206 List reasons for exclusion Content not relevant	N=0
	"patient participation in clinical audit"	13/11/15	497	N=497 List reasons for	N=0

Database/Organisation	Search terms	Date searched	Hits	Screen for eligibility EXCLUDE	Screen for eligibility INCLUDE
				exclusion Content not relevant	
	"public involvement in clinical audit"	13/11/15	161	N=161 List reasons for exclusion Not relevant to the review	N=0
	patient and public involvement AND clinical effectiveness processes	13/11/15	455	N=455 List reasons for exclusion Not relevant to the review	N=0
Equator Network http://www.equator-network.org/	"patient and public involvement"	13/11/15	0	N=0	N=0
	"patient participation in clinical guidelines"	13/11/15	0	N=0	N=0
	"public involvement in clinical guidelines"	13/11/15	0	N=0	N=0
	"patient participation in clinical audit"	13/11/15	0	N=0	N=0
	"public involvement in clinical audit"	13/11/15	0	N=0	N=0
	patient and public involvement AND clinical effectiveness processes	13/11/15	0	N=0	N=0
European Network on Patient Empowerment http://www.enope.eu/	"patient and public involvement"	14/11/15	0	N=0	N=0
	"patient participation in clinical guidelines"	14/11/15	0	N=0	N=0
	"public involvement in clinical guidelines"	14/11/15	0	N=0	N=0
	"patient participation in clinical audit"	14/11/15	0	N=0	N=0
	"public involvement in clinical audit"	14/11/15	0	N=0	N=0

Database/Organisation	Search terms	Date searched	Hits	Screen for eligibility EXCLUDE	Screen for eligibility INCLUDE
	patient and public involvement AND clinical effectiveness processes	14/11/15	0	N=0	N=0
Guidelines International Network (G-I-N) http://www.g-i-n.net/	"patient and public involvement"	14/11/15	34	N=33 List reasons for exclusion Duplicates	N=1
	"patient participation in clinical guidelines"	14/11/15	28	N=28 List reasons for exclusion Duplicates	N=0
	"public involvement in clinical guidelines"	14/11/15	31	N=31 List reasons for exclusion Duplicates	N=0
	"patient participation in clinical audit"	14/11/15	5	N=5 List reasons for exclusion Content not relevant	N=0
	"public involvement in clinical audit"	14/11/15	5	N=5 List reasons for exclusion Content not relevant	N=0
	patient and public involvement AND clinical effectiveness processes	14/11/15	6	N=6 List reasons for exclusion Content not relevant	N=0

Database/Organisation	Search terms	Date searched	Hits	Screen for eligibility EXCLUDE	Screen for eligibility INCLUDE
Healthcare Quality Improvement Partnership (HQIP) http://www.hqip.org.uk/	"patient and public involvement"	15/11/15	11	N=10 List reasons for exclusion Only 1 document relevant to PPI	N=1
	"patient participation in clinical guidelines"	15/11/15	0	N=0	N=0
	"public involvement in clinical guidelines"	15/11/15	0	N=0	N=0
	"patient participation in clinical audit"	15/11/15	0	N=0	N=0
	"public involvement in clinical audit"	15/11/15	1	N=1 List reasons for exclusion Not national	N=0
	patient and public involvement AND clinical effectiveness processes	15/11/15	0	N=0	N=0
Institute for Healthcare Improvement (IHI) http://www.ihi.org/Pages/default.aspx	"patient and public involvement"	16/11/15	46	N=46 List reasons for exclusion No detail Content not relevant	N=0
	"patient participation in clinical guidelines"	16/11/15	33	N=33 List reasons for exclusion No detail Content not relevant	N=0

Database/Organisation	Search terms	Date searched	Hits	Screen for eligibility EXCLUDE	Screen for eligibility INCLUDE
	"public involvement in clinical guidelines"	16/11/15	7	N=7 List reasons for exclusion No detail Content not relevant	N=0
	"patient participation in clinical audit"	16/11/15	8	N=8 List reasons for exclusion No detail Content not relevant	N=0
	"public involvement in clinical audit"	16/11/15	2	N=2 List reasons for exclusion No detail Content not relevant	N=0
	patient and public involvement AND clinical effectiveness processes	16/11/15	8	N=8 List reasons for exclusion No detail Content not relevant	N=0
Institute of Medicine http://iom.nationalacademies.org/	"patient and public involvement"	16/11/15	0	N=0	N=0
	"patient participation in clinical guidelines"	16/11/15	1	N=1 List reasons for exclusion Not relevant to the review	N=0
	"public involvement in clinical guidelines"	16/11/15	0	N=0	N=0

Database/Organisation	Search terms	Date searched	Hits	Screen for eligibility EXCLUDE	Screen for eligibility INCLUDE
	"patient participation in clinical audit"	16/11/15	1	N=1 List reasons for exclusion Content not relevant	N=0
	"public involvement in clinical audit"	16/11/15	0	N=0	N=0
	patient and public involvement AND clinical effectiveness processes	16/11/15	7	N=7 List reasons for exclusion Content not relevant	N=0
International Society for Quality in Healthcare (ISQua) http://www.isqua.org/	"patient and public involvement"	17/11/15	183	N=183 List reasons for exclusion No detail Content not relevant	N=0
	"patient participation in clinical guidelines"	17/11/15	98	N=98 List reasons for exclusion No detail Content not relevant	N=0
	"public involvement in clinical guidelines"	17/11/15	97	N=97 List reasons for exclusion No detail Content not relevant	N=0

Database/Organisation	Search terms	Date searched	Hits	Screen for eligibility EXCLUDE	Screen for eligibility INCLUDE
	"patient participation in clinical audit"	17/11/15	81	N=81 List reasons for exclusion No detail Content not relevant	N=0
	"public involvement in clinical audit"	17/11/15	81	N=81 List reasons for exclusion No detail Content not relevant	N=0
	patient and public involvement AND clinical effectiveness processes	17/11/15	83	N=83 List reasons for exclusion No detail Content not relevant	N=0
Kings Fund http://www.kingsfund.org.uk/	"patient and public involvement"	17/11/15	433	N=433 List reasons for exclusion Nothing specific to the objectives of the review	N=0
	"patient participation in clinical guidelines"	17/11/15	3663	N=3663 List reasons for exclusion Search contained both terms but not as they relate to each other	N=0

Database/Organisation	Search terms	Date searched	Hits	Screen for eligibility EXCLUDE	Screen for eligibility INCLUDE
	"public involvement in clinical guidelines"	17/11/15	3679	N=3679 List reasons for exclusion Content not relevant	N=0
	"patient participation in clinical audit"	17/11/15	3663	N=3663 List reasons for exclusion Content not relevant	N=0
	"public involvement in clinical audit"	17/11/15	3679	N=3679 List reasons for exclusion Content not relevant	N=0
	"patient and public involvement AND clinical effectiveness processes"	17/11/15	208	N=208 List reasons for exclusion Content not relevant	N=0
National Health and Medical Research Council (NHMRC) Australia http://www.nhmrc.gov.au/	"patient and public involvement"	18/11/15	5209	N=5209 List reasons for exclusion Nothing specific to review objectives	N=0
	"patient participation in clinical guidelines"	18/11/15	3380	N=3380 List reasons for exclusion Nothing specific to review objectives	N=0

Database/Organisation	Search terms	Date searched	Hits	Screen for eligibility EXCLUDE	Screen for eligibility INCLUDE
	"public involvement in clinical guidelines"	18/11/15	5497	N=5497 List reasons for exclusion Nothing specific to review objectives	N=0
	"patient participation in clinical audit"	18/11/15	3076	N=3076 List reasons for exclusion Nothing specific to review objectives	N=0
	"public involvement in clinical audit"	18/11/15	5302	N=5302 List reasons for exclusion Nothing specific to review objectives	N=0
	patient and public involvement AND clinical effectiveness processes	18/11/15	909	N=909 List reasons for exclusion Nothing specific to review objectives	
National Institute for Health and Care Excellence (NICE) https://www.nice.org.uk/	"patient and public involvement"	18/11/15	0	N=0	N=0
	"patient participation in clinical guidelines"	18/11/15	0	N=0	N=0
	"public involvement in clinical guidelines"	18/11/15	0	N=0	N=0
	"patient participation in clinical audit"	18/11/15	0	N=0	N=0
	"public involvement in clinical audit"	18/11/15	0	N=0	N=0

Database/Organisation	Search terms	Date searched	Hits	Screen for eligibility EXCLUDE	Screen for eligibility INCLUDE
	patient and public involvement AND clinical effectiveness processes	18/11/15	245	N=245 List reasons for exclusion Duplicates	N=0
Picker Institute Europe http://www.pickereurope.org/	"patient and public involvement"	19/11/15	176	N=208 List reasons for exclusion Nothing of direct relevance	N=0
	"patient participation in clinical guidelines"	19/11/15	163	N=163 List reasons for exclusion Content not relevant for PPI in guidelines	N=0
	"public involvement in clinical guidelines"	19/11/15	85	N=85 List reasons for exclusion Content not relevant	N=0
	"patient participation in clinical audit"	19/11/15	164	N=164 List reasons for exclusion Content not relevant	N=0
	"public involvement in clinical audit"	19/11/15	86	N=86 List reasons for exclusion Content not relevant	N=0

Database/Organisation	Search terms	Date searched	Hits	Screen for eligibility EXCLUDE	Screen for eligibility INCLUDE
	patient and public involvement AND clinical effectiveness processes	19/11/15	181	N=181 List reasons for exclusion Content not relevant	N=0
Scottish Intercollegiate Guidelines Network (SIGN) http://sign.ac.uk/	"patient and public involvement"	19/11/15	17,200	N=17,198 List reasons for exclusion Duplicates	N=2
	"patient participation in clinical guidelines"	19/11/15	47	N=46 List reasons for exclusion Duplicates	N=0
	"public involvement in clinical guidelines"	19/11/15	7330	N=7330 List reasons for exclusion Duplicates	N=0
	"patient participation in clinical audit"	19/11/15	13	N=13 List reasons for exclusion Duplicates	N=0
	"public involvement in clinical audit"	19/11/15	35	N=35 List reasons for exclusion Duplicates	N=0
	patient and public involvement AND clinical effectiveness processes	19/11/15	24	N=24 List reasons for exclusion Duplicates	N=0

Database/Organisation	Search terms	Date searched	Hits	Screen for eligibility EXCLUDE	Screen for eligibility INCLUDE
Social Care Institute for Excellence http://www.scie.org.uk/	"patient and public involvement"	19/11/15	533	N=533 List reasons for exclusion Content not relevant	N=0
	"patient participation in clinical guidelines"	19/11/15	149	N=149 List reasons for exclusion Content not relevant	N=0
	"public involvement in clinical guidelines"	19/11/15	236	N=236 List reasons for exclusion Content not relevant	N=0
	"patient participation in clinical audit"	19/11/15	138	N=138 List reasons for exclusion Content not relevant	N=0
	"public involvement in clinical audit"	19/11/15	229	N=229 List reasons for exclusion Content not relevant	N=0
	patient and public involvement AND clinical effectiveness processes	19/11/15	280	N=280 List reasons for exclusion Content not relevant	N=0

APPENDIX 4
Clinical Trial Register Searches and Outputs

Clinical trial registers	Search terms	Date searched	Hits	Screen for eligibility EXCLUDE	Screen for eligibility INCLUDE
Australian New Zealand Clinical Trials Register (ANZCTR) http://www.anzctr.org.au/	"patient and public involvement"	13/11/15	5	N=5 List reasons for exclusion Content not relevant to review	N=0
	"patient participation in clinical guidelines"	13/11/15	13	N=13 List reasons for exclusion Content not relevant to review	N=0
	"public involvement in clinical guidelines"	13/11/15	1	N=1 List reasons for exclusion Content not relevant to review	N=0
	"patient participation in clinical audit"	13/11/15	3	N=3 List reasons for exclusion Content not relevant to review	N=0
	"public involvement in clinical audit"	13/11/15	1	N=1 List reasons for exclusion Content not relevant to review	N=0
	"patient and public involvement AND clinical effectiveness processes"	13/11/15	0	N=0	N=0
clinicaltrials.gov https://clinicaltrials.gov/	"patient and public involvement"	12/11/15	195	N=195 List reasons for exclusion Content not relevant to review	N=0

Clinical trial registers	Search terms	Date searched	Hits	Screen for eligibility EXCLUDE	Screen for eligibility INCLUDE
	"patient participation in clinical guidelines"	12/11/15	127	N=127 List reasons for exclusion Content not relevant to review	N=0
	"public involvement in clinical guidelines"	12/11/15	6	N=6 List reasons for exclusion Content not relevant to review	N=0
	"patient participation in clinical audit"	12/11/15	17	N=17 List reasons for exclusion Content not relevant to review	N=0
	"public involvement in clinical audit"	12/11/15	0	N=0 List reasons for exclusion Content not relevant to review	N=0
	"patient and public involvement AND clinical effectiveness processes"	12/11/15	9	N=9 List reasons for exclusion Content not relevant to review	N=0
International Standard RCT Number Register (ISRCTN) http://www.isrctn.com/	"patient and public involvement"	12/11/15	115	N=115 List reasons for exclusion Content not relevant to review	N=0
	"patient participation in clinical guidelines"	12/11/15	216	N=216 List reasons for exclusion Content not relevant to review	N=0

Clinical trial registers	Search terms	Date searched	Hits	Screen for eligibility EXCLUDE	Screen for eligibility INCLUDE
	"public involvement in clinical guidelines"	12/11/15	13	N=13 List reasons for exclusion Content not relevant to review	N=0
	"patient participation in clinical audit"	12/11/15	32	N=32 List reasons for exclusion Content not relevant to review	N=0
	"public involvement in clinical audit"	12/11/15	1	N=1 List reasons for exclusion Content not relevant to review	N=0
	"patient and public involvement AND clinical effectiveness processes"	12/11/15	4	N=4 List reasons for exclusion Content not relevant to review	N=0
MetaRegister of Controlled Trials http://www.isrctn.com/page/mrct	"patient and public involvement"	12/11/15	115	N=115 List reasons for exclusion Content not relevant to review	N=0
	"patient participation in clinical guidelines"	12/11/15	216	N=216 List reasons for exclusion Content not relevant to review	N=0
	"public involvement in clinical guidelines"	12/11/15	13	N=13 List reasons for exclusion Content not relevant to review	N=0

Clinical trial registers	Search terms	Date searched	Hits	Screen for eligibility EXCLUDE	Screen for eligibility INCLUDE
	"patient participation in clinical audit"	12/11/15	32	N=32 List reasons for exclusion Content not relevant to review	N=0
	"public involvement in clinical audit"	12/11/15	1	N=1 List reasons for exclusion Content not relevant to review	N=0
	"patient and public involvement AND clinical effectiveness processes"	12/11/15	4	N=4 List reasons for exclusion Content not relevant to review	N=0
UK Clinical Trials Gateway https://www.ukctg.nihr.ac.uk/	"patient and public involvement"	13/11/15	14	N=14 List reasons for exclusion Content not relevant to review	N=0
	"patient participation in clinical guidelines"	13/11/15	78	N=78 List reasons for exclusion Content not relevant to review	N=0
	"public involvement in clinical guidelines"	13/11/15	6	N=6 List reasons for exclusion Content not relevant to review	N=0
	"patient participation in clinical audit"	13/11/15	9	N=9 List reasons for exclusion Content not relevant to review	N=0

Clinical trial registers	Search terms	Date searched	Hits	Screen for eligibility EXCLUDE	Screen for eligibility INCLUDE
	"public involvement in clinical audit"	13/11/15	2	N=2 List reasons for exclusion Content not relevant to review	N=0
	"patient and public involvement AND clinical effectiveness processes"	13/11/15	1	N=1 List reasons for exclusion Content not relevant to review	N=0
WHO International Clinical Trials Registry Platform http://www.who.int/ictrp/en/	"patient and public involvement"	14/11/15	5	N=5 List reasons for exclusion Content not relevant to review	N=0
	"patient participation in clinical guidelines"	14/11/15	0	N=0	N=0
	"public involvement in clinical guidelines"	14/11/15	0	N=0	N=0
	"patient participation in clinical audit"	14/11/15	0	N=0	N=0
	"public involvement in clinical audit"	14/11/15	0	N=0	N=0
	"patient and public involvement AND clinical effectiveness processes"	14/11/15	0	N=0	N=0

APPENDIX 5
Useful PPI Resources

PPI Resource	Available at:
Cochrane Community - consumer online learning *Understanding Evidence-based Healthcare: A Foundation for Action* Designed to help consumer advocates understand the fundamentals of evidence-based healthcare concepts and skills	http://community.cochrane.org/news/tags/authors/online-course-understanding-evidence-based-healthcare-foundation-action
Consumer Health Forum Australia G*uidelines for Consumer Representatives* working on committees	https://www.chf.org.au/resources-guidelines.php
HQIP Service User Network; members work alongside HQIP in helping develop patient and public involvement (PPI) and quality improvement work, and also as an expert consultation group to HQIP on all relevant projects.	http://www.hqip.org.uk/involving-patients/service-user-network/
HQIP's Introduction to quality improvement for patients and public; e-learning package that seeks to support service users who wish to become involved in quality improvement work in healthcare Developing clinical audit patient panels Includes links to a guide to developing a patient panel (revised 2013) and a training manual (clinical audit manual for lay members of audit teams) New document which will be published soon is *Developing a patient and public involvement panel for quality improvement* (2016)	http://www.hqip.org.uk/resources/introduction-to-quality-improvement-for-patients-and-public/ www.hqip.org.uk/resources/developing-clinical-audit-patient-panels/ .
NHMRC How to present the evidence for consumers: preparation of consumer publications This handbook focuses on how to prepare guideline information in a way that consumers can readily access and understand.	https://www.nhmrc.gov.au/guidelines-publications/cp66
NICE Citizens Council is a panel of 30 members of the public that largely reflect the demographic characteristics of the UK. The Council provides NICE with a public perspective on overarching moral and ethical issues that NICE has to take account of when producing guidance. The Council's recommendations and conclusions are incorporated into a document called social value judgements. The Council does not produce NICE's guidance (such as for health, local government or social care services), nor does it input directly into any individual pieces of guidance that NICE produces.	http://www.nice.org.uk/Get-Involved/Citizens-Council https://www.nice.org.uk/Media/Default/About/what-we-do/Research-and-development/Social-Value-Judgements-principles-for-the-development-of-NICE-guidance.pdf
NICE Public Involvement Programme (PIP) is a team at NICE that develops and supports patient, carer and public involvement. PIP's has produced two reports to evaluate the experiences of patient and carer members involved in Guideline Development Groups completed in 2004 and 2008.	https://www.nice.org.uk/about/nice-communities/public-involvement/public-involvement-programme https://www.nice.org.uk/media/default/About/NICE-Communities/Public-involvement/Public-involvement-programme/PIU-GDG-evaluation-report-2004-1.pdf https://www.nice.org.uk/media/default/Abou

	t/NICE-Communities/Public-involvement/Public-involvement-programme/PIU-GDG-evaluation-summary-2008-1.pdf
PIP has also produced a guide summarising how it involves patients, service users, carers and the public in NICE's work - *Putting patients & the public at the heart of NICE's work*	https://www.nice.org.uk/media/default/About/NICE-Communities/Public-involvement/Public-involvement-programme/PPIP-leaflet-1.pdf
Each year PIP runs a set of *workshops to help patient, carer and service user organisations* learn more about NICE's activities and the opportunities to participate in NICE's work.	https://www.nice.org.uk/About/NICE-communities/Public-involvement/Masterclasses
Factsheets for the public - contributing to a NICE clinical guideline	http://www.nice.org.uk/about/nice-communities/public-involvement/develop-NICE-guidance
Factsheet 1: How NICE develops clinical guidelines and what documents we publish	http://www.nice.org.uk/media/default/About/NICE-Communities/Public-involvement/Developing-NICE-guidance/Factsheet-1-contribute-to-developing-clinical-guidelines.pdf
Factsheet 2: How organisations representing patients and carers can get involved	http://www.nice.org.uk/media/default/About/NICE-Communities/Public-involvement/Developing-NICE-guidance/Factsheet-2-contribute-to-developing-clinical-guidelines.pdf
Factsheet 3: How individual patients and carers can get involved - joining a GDG	http://www.nice.org.uk/media/default/About/NICE-Communities/Public-involvement/Developing-NICE-guidance/Factsheet-3-contribute-to-developing-clinical-guidelines.pdf
Factsheet 4: Support for patients and carers involved in developing a guideline	http://www.nice.org.uk/media/default/About/NICE-Communities/Public-involvement/Developing-NICE-guidance/Factsheet-4-contribute-to-developing-clinical-guidelines.pdf
Factsheet 5: Helping to put NICE recommendations into practice (implementation)	http://www.nice.org.uk/media/default/About/NICE-Communities/Public-involvement/Developing-NICE-guidance/Factsheet-5-contribute-to-developing-clinical-guidelines.pdf
Patients Involved in NICE (PIN) is a coalition of over 80 patient organisations and is committed to enabling patient groups to engage productively with NICE. Independent from NICE and pharmaceutical industry, they use their combined knowledge, experience and direct contact with patients from a wide range of conditions, to ensure NICE puts patients, carers, and patient groups at the centre of all of its work. They provide a forum for enabling patient groups to engage with NICE, working alongside NICE's Public Involvement Programme Mission statement available at this link	http://www.nice.org.uk/About/NICE-communities/Public-involvement/PIN http://www.nice.org.uk/media/default/About/NICE-Communities/Public-involvement/PIN/PIN-mission-statement.pdf

Memorandum of Understanding PIN-NICE available at this link	http://www.nice.org.uk/media/default/About/NICE-Communities/Public-involvement/PIN/NICE-PIN-memorandum-of-understanding-November-2013.pdf
NICE Patient and public involvement policy	http://www.nice.org.uk/about/nice-communities/public-involvement/patient-and-public-involvement-policy
Payments for lay contributors to NICE's work	http://www.nice.org.uk/media/default/About/NICE-Communities/Public-involvement/Patient-and-public-involvement-policy/Lay-contributor-payments-policy-principles.pdf
Payments for lay contributors to NICE's work – frequently asked questions	http://www.nice.org.uk/media/default/About/NICE-Communities/Public-involvement/Patient-and-public-involvement-policy/Lay-contributor-payments-frequently-asked-questions.pdf
The *patient involvement section of the SIGN website* is available at the following link	http://www.sign.ac.uk/patients/index.html
Here you can download the booklet *SIGN Guidelines: information for patients, carers and members of the public*	http://www.sign.ac.uk/pdf/patient_general_booklet_2011.pdf
How SIGN identify patient and carer views into their guidelines can be found at this link	http://www.sign.ac.uk/patients/views.html
SIGN Patient Network; a virtual group of patients, carers, members of public and patient involvement staff within NHS Scotland	http://www.sign.ac.uk/patients/network.html
Information on why involve patients/carers and information on joining guideline development group	http://www.sign.ac.uk/patients/joining.html
Information on consultation processes (i.e. national open meetings, peer review of guidelines, peer review of patient booklets, focus groups and survey) for patients/public including a booklet on *Reviewing a draft SIGN guideline: information for lay reviewers*	http://www.sign.ac.uk/patients/consultation.html http://www.sign.ac.uk/pdf/patient_peer_review_leaflet_2011.pdf
Examples of patient booklets produced by SIGN based on their guidelines are available at this link	http://www.sign.ac.uk/patients/publications.html
SIGN 100: A handbook for patient and carer representatives for patient representatives	http://www.sign.ac.uk/index.html http://www.sign.ac.uk/pdf/sign100.pdf
Using social media SIGN's patient involvement Facebook page allows us to ask people what they think our guideline should cover:	www.facebook.com/SIGNPatientnetwork