



PATIENT FOCUSED  
MEDICINES DEVELOPMENT



## Research on patient engagement (PE)

### A Literature Review and Framework Analysis

Patient engagement (PE) is increasingly recognised as essential to integrating the patient voice in the design and development of research on medicines. The field is young and fast-moving with a broad constellation of active players. However, while some strong research has been conducted on PE, the academic landscape is patchy and fragmented. This White Paper aims to address a significant unmet need for an overview of PE academic research that helps researchers to identify gaps that should be filled. In addition, we identify and analyse six existing frameworks for PE, exploring their strengths and weaknesses.

Patient Focused Medicines Development (PFMD; [www.pfmd.org](http://www.pfmd.org)) was established in October 2015 as an open, independent global coalition of health stakeholders. As an organisation with a track record in connecting stakeholders committed to PE, PFMD is well placed to provide an overview and summary of research in the field. We are bringing together and synergizing disparate but complementary efforts that integrate the voice of the patient across the lifecycle of medicine.

The white paper complements our work mapping PE initiatives through [PE Global Landscape](#), a PE global landscape mapping, resources and networking tool. Our research, along with various collaborations with PE stakeholders and consortia, was an important early activity towards our goal of building a connected and global PE ecosystem – a connection that is an essential step in co-creation of a meta-framework to deliver more integrated PE.

## Aim

This literature review aimed at gaining a holistic overview of academic articles published in the field of PE in the five-year period up to 2016 including existing PE frameworks, and was used to inform multi-stakeholder co-creation workshops held in 2016-2017. Outputs from workshops include Patient Engagement Quality Guidance, incorporating PE Quality Criteria and tools for development and assessment of planned, ongoing or completed PE activities (released May 2018). The review is not limited to specific medicines development phases, nor does it focus on particular diseases or geographical areas. The criteria to include publications in this review is further explained in the methodology below.

To aid readers, abstracts and summaries are presented in easy-to-browse grids, allowing for a quick overview of the topics addressed in the studies presented. There are five recommended reads (bolded in appendix 1), of which Bagley's (2016) article is especially relevant. It describes the methodology to support clinical trials for more effective and meaningful patient and public involvement (PPI). We also provide an at-a-glance summary of six PE frameworks, facilitating rapid understanding of their approach and limitations ([Patient Engagement Frameworks Analysis](#)).

In all of this we seek to serve the PE community and advance both the academic field and the burgeoning community of practice developing worldwide.

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## Methodology

Keyword searches on PubMed and British Medical Journal (BMJ) Open in September/October 2016.

- **Keywords:** patient engagement, patient and public involvement, clinical trials, patient and public involvement, patients benefit, PE benefit for pharmaceutical industry, PE benefit for patients, PE benefit for research
  - **Relevance criteria:** PE and PPI in the medicines development phases context, patients as partners, PE and PPI toolkits
  - **Time frame:** 2011- 2016
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## Search results

(see selected list of publications at the end of the document)

- **Pubmed:** 134 results, of which 12 were relevant or somewhat relevant to the subject.
- **BMJ:** 105 results, of which 13 were relevant or somewhat relevant to the subject.

# Results

## literature review

Despite the large number of publications, there is still a need for a widely-used, comprehensive and standardised toolkit, useful for all diseases as a basis to start PE. Of the results found, a 2016 publication *A patient and public involvement (PPI) toolkit for meaningful and flexible involvement in clinical trials – a work in progress*, by Heather **Bagley et al., (2016)** is the only article that describes concrete steps and tools to address PE in clinical trials. The article contains a flowchart describing the PPI activities that should be considered in a clinical trial pathway and the point at which these activities should take place. Three toolkits were identified: planning PPI, recording PPI and evaluating PPI. Four main activities and corresponding tools were distinguished under planning: developing a plan; identifying patient and public contributors; allocating appropriate costs; and managing expectations.

In *Models and impact of patient and public involvement in studies carried out by the Medical Research Council Clinical Trials Unit at University College London: findings from ten case studies*, by **South, A. et al. (2016)**, authors categorise findings from ten case studies of PPI conducted by the UK Medical Research Council Clinical Trial Unit (MRC CTU) between 2003-2011 to document and share good practices. Findings were categorised into “aims and motivations for PPI, models of involvement, impacts of involvement and lessons learnt”.

**Buck et al. (2014)** compared PPI plans from 28 clinical trial grant applications (funded between 2006-2010) to research the implementation of those plans in the actual trials. Overall, 20 of these fully implemented their PPI plans, but the results also revealed that late or minimal PPI engagement diminishes its value. Challenges include the debate around the purpose of PPI, the lack of evidence of its impact, power-sharing complexities between contributors and researchers, and difficulties in ensuring sufficient resources for PPI. In addition to this, a clear gap lies in the limited evidence base as there has been no systematic evaluation of which PPI efforts have been put into practice.

**Parsons et al. (2015)** take another angle by identifying a gap in the research of the public’s knowledge of and interest in medicines development. The results from 6,931 completed questionnaires across Great Britain, France, Italy, Poland and Germany show that those with current or previous experience of medical research were more likely to report good knowledge of medicines R&D than those without experience. The findings also suggest that *public interest* in medical R&D was greater than *public knowledge*, with 60% of respondents being interested in some particular aspects of the R&D process. Parson et al. conclude, that there is a need to increase patients’ and public’s knowledge and awareness of their roles in and about medicines development, to overcome the challenges of their active involvement in the process in the future.

In their qualitative study of five complex healthcare interventions to provide new insights on patient perspective, **Webster et al. (2015)** identified five broad themes that capture patients’ experience and highlight issues that might not be adequately addressed in complex interventions. Their findings also suggest, that while patients have historically been only objects of care, “they are instead active components within systems of care delivery who experience their health concerns, healthcare and social lives simultaneously”. The article does not point to specific medicines

development phases, but acknowledges that multiple models of PE and PPI with potentially shared features and similar target patients, are being implemented simultaneously all over the world and thus, a “meta-evaluation” approach would offer “an opportunity for cumulative learning at a system level”.

*All 25 articles reviewed for this paper are listed in appendix 1.*

## Existing frameworks

The work of six different associations in relation to patient engagement has been analysed (and summarised in a separate document [Patient Engagement Frameworks Analysis](#)):

- Clinical Trials Transformation Initiative (CTTI)
- University of Maryland Centre of Excellence in Regulatory Science Innovation (M-CERSI)
- National Health Council (NHC) Framework
- Patient-Centred Outcomes Research Institute (PCORI) Patient Engagement Rubric
- Perfetto et al. Framework
- FasterCures Value Framework

This summary table provides an overview of the phases at which PE is prioritised by each framework. CTTI and M-CERSI are seen to be the most comprehensive, with others tending to prioritise evidence communication and clinical development.

## Overview

	Pre-Discovery	Research Questions	Pre-clinical Development	Clinical Development	FDA Approval	Post Approval Surveillance	Evidence Communication
CTTI - Clinical Trials Transformation Initiative	X	X	X	X	X	X	X
M-CERSI Conference on PFDD	X	X	X	X	X	X	X
Dialogue/Advancing Meaningful Patient Engagement in R&D and Review of Drugs, NHC & Genetic Alliance				X	X	X	X
PCORI Engagement Rubric		X		X			X
Perfetto et al Framework						X	X
FasterCures - Integrating the Patient Perspective into the Development of Value Frameworks				X		X	X

# Analysis

## CTTI - Clinical Trials Transfor- mation Initiative

With the FDA's emphasis on patient-focused drug development and patient engagement in trans-  
lational research, CTTI has put forth a set of recommendations to improve Patient Group (PG) par-  
ticipation in the work of clinical trial sponsors (pharma and academia), which includes meaningful  
engagement of patients in the development of therapeutic products from study endpoint selection,  
recruitment and retention, and post-marketing safety.

### CTTI Clinical Trial Transformation Initiative

*CTTI recommendations: effective engagement with patient groups around clinical trials*, October  
2015.

**Accessible here:** <https://www.ctti-clinicaltrials.org/files/pgctrecs.pdf>

## M-CERSI Conference on PFDD

The University of Maryland sought to provide a forum for patient groups, the FDA, biopharmaceu-  
tical industry, payer and other organizations to voice views, challenges, activities and aspirations  
for patient focused drug development, as well as future direction and opportunity for collabora-  
tion. Through a day-long event on March 9, 2015, the University Center of Excellence in Regulatory  
Science and Innovation (M-CERSI) held the "M-CERSI Conference on PFDD". Outputs from the event  
included a suggested definition, rubric and framework for PFDD.

### University of Maryland M-CERSI Framework

*Assessing meaningful patient engagement in drug development: a definition, framework, and rubric*,  
March 2015.

**Accessible here:** <http://www.pharmacy.umaryland.edu/media/SOP/wwwpharmacyumarylandedu/centers/cersievents/pfdd/mcersi-pfdd-framework-rubric.pdf>

## Dialogue/Advancing Meaningful Patient Engagement in R&D and Review of Drugs, NHC & Genetic Alliance

The NHC dialogue event aimed to build consensus around a vision and targeted set of actions for  
advancing patient engagement in drug research, development and approval.

### National Health Council (NHC) Framework

*Dialogue / Advancing Meaningful Patient Engagement in Research, Development, and Review of  
Drugs*, September 22, 2015.

**Accessible here:**

<http://www.nationalhealthcouncil.org/sites/default/files/PatientEngagement-WhitePaper.pdf>

## Patient Centered Outcomes Research In- stitute (PCORI) Engage- ment Rubric

These reports aim to illustrate and provide guidance around how input from patients and other  
stakeholders can be incorporated throughout the entire research process.

### PCORI Patient Engagement Rubric

*Engagement Rubric for Applicants*, Feb 4, 2014 (updated June 6, 2016).

**Accessible here:** <http://www.pcori.org/sites/default/files/Engagement-Rubric.pdf>

*CORI Funded Projects: Sample Engagement Plans From Methods Portfolio*, August 6, 2014.

**Accessible here:** <http://www.pcori.org/sites/default/files/PCORI-Sample-Methods-Engage-ment-Plans.pdf>

## Perfetto et al Framework

This framework seeks to provide guidance around how input from patients and other stakeholders  
can be incorporated throughout the entire research process.

### Perfetto et al. Framework

*When is evidence sufficient for decision-making? A framework for understanding the pace of evidence  
adoption*, in *Journal of Comparative Effectiveness Research*, July 2013, Vol. 2, No. 4, Pages 383-391.

**Accessible here:** <http://www.futuremedicine.com/doi/pdfplus/10.2217/ce.13.39>

### FasterCures

-Integrating the Patient Perspective into the Development of Value Frameworks

FasterCures sought to determine gaps in assessing value of treatment options and create a patient perspective value framework.

### FasterCures Value Framework

*Integrating the Patient Perspective into the Development of Value Frameworks*, March 2016.

**Accessible here:** <http://www.fastercures.org/reports/view/56>

## Conclusions

Over the past decade, there has been an increasing number of publications on PE and PPI. Most of them are related to a specific disease, with cancer being the most frequently concerned condition. However, a 2016 analysis showed that only 21% of the top 50 pharmaceutical firms routinely invest in PE (Patient Centricity 2.0, by Cutting Edge Information, 2016). The positive impacts of PPI and PE (i.e. on the sustainability of medicines R&D) are highlighted in the articles, but there is a clear gap in the PE literature with regard to the discovery and preclinical phases of medicines development.

All publications refer to the need for more and better PE at all stages of research, clinical development and treatment. Efficacy, effectiveness, safety, compliance, and cost benefits from early PE have been highlighted. Two main requirements have been identified: training of patients and better identification of patient needs. Training has received much attention and a comprehensive training program has taken place in Europe via the European Patients Academy (EUPATI) project under the auspices of the International Medicines Initiative (IMI). The majority of publications (identified in this literature review) refer to clinical development and the post-marketing period; although the preclinical stage is identified as crucial for PE, few publications are focused on that phase of research.

These publications highlight the importance of the pharmaceutical industry and/or academic research to identify the needs of the patients for specific diseases. Once these needs are clearly identified by the patients and the research field, it is important to define Patient Reported Outcome Measures (PROMs). These PROMs need to be described in the study protocols in parallel with the usual statistical analysis performed for all clinical studies.

An established PE model is needed. Of the six patient engagement frameworks analysed, those developed by CTTI and University of Maryland M-CERSI were the most comprehensive. The divergences between these two approaches highlight the need for a unified, common PE framework. By building on areas of overlap and working through points of difference, the community can together develop a meta-framework which would serve as a catalyst for PE initiatives in all fields.



# Appendix 1: Search results from PubMed

Suggested articles summarised here are **bolded in the first column**.

Name	Brief Summary	Access
Alhassan, RK. et al. 30 November 2015  Effect of Community Engagement Interventions on Patient Safety and Risk Reduction Efforts in Primary Health Facilities: Evidence from Ghana.	Patient safety and quality care remain major challenges to Ghana's healthcare system. Like many health systems in Africa, this is largely because demand for healthcare is outstripping available human and material resource capacity of healthcare facilities and new investment is insufficient. In the light of these demand and supply constraints, systematic community engagement (SCE) in healthcare quality assessment can be a feasible and cost-effective option to augment existing quality improvement interventions. SCE entails structured use of existing community groups to assess healthcare quality in health facilities. Identified quality gaps are discussed with healthcare providers, improvements identified and rewards provided if the quality gaps are closed.	<a href="http://www.ncbi.nlm.nih.gov/pubmed/26619143">http://www.ncbi.nlm.nih.gov/pubmed/26619143</a>
Armstrong, N. et al. 10 December 2012  Optimizing patient involvement in quality improvement	Patient and public involvement in healthcare planning, service development and health-related research has received significant attention. However, evidence about the role of patient involvement in quality improvement work is more limited. We aimed to characterize patient involvement in three improvement projects and to identify strengths and weaknesses of contrasting approaches.	<a href="http://onlinelibrary.wiley.com/doi/10.1111/hex.12039/epdf">http://onlinelibrary.wiley.com/doi/10.1111/hex.12039/epdf</a>
<b>Bagley, H. et al.</b> <b>23 March 2015</b>  <b>A patient and public involvement (PPI) toolkit for meaningful and flexible involvement in clinical trials – a work in progress</b>	Patient and public involvement (PPI) in research is increasingly a funder requirement due to the potential benefits in the design of relevant, participant friendly, ethically sound research. The use and sharing of resources can benefit PPI, but available resources are not consistently used leading to duplication of effort. This paper describes a developing toolkit to support clinical trials teams to undertake effective and meaningful PPI.	<a href="https://www.ncbi.nlm.nih.gov/pubmed/29062516">https://www.ncbi.nlm.nih.gov/pubmed/29062516</a>
Brett, J. et al. 5 April 2012  Mapping the impact of patient and public involvement on health and social care research: a systematic review	There is an increasing international interest in patient and public involvement (PPI) in research, yet relatively little robust evidence exists about its impact on health and social care research. Objective: To identify the impact of patient and public involvement on health and social care research.	<a href="http://onlinelibrary.wiley.com/doi/10.1111/j.1369-7625.2012.00795.x/epdf">http://onlinelibrary.wiley.com/doi/10.1111/j.1369-7625.2012.00795.x/epdf</a>
<b>Buck, D. et al.</b> <b>4 December 2014</b>  <b>From plans to actions in patient and public involvement: qualitative study of documented plans and the accounts of researchers and patients sampled from a cohort of clinical trials.</b>	<b>Objective:</b> Inform the evidence base by describing how plans for PPI were implemented within clinical trials and identifying the challenges and lessons learnt by research teams.	<a href="http://www.ncbi.nlm.nih.gov/pubmed/25475243">http://www.ncbi.nlm.nih.gov/pubmed/25475243</a>

Name	Brief Summary	Access
<p>Collins, K. et al. 9 September 2014</p> <p>Making patient and public involvement in cancer and palliative research a reality: academic support is vital for success.</p>	<p>Patient and public involvement (PPI) has become an established theme within the UK health research policy and is recognised as an essential force in the drive to improve the quality of services and research. These developments have been particularly rapid in the cancer field.</p>	<p><a href="http://shura.shu.ac.uk/8478/1/PPI_paper_bmjspcare-2014-000750_full.pdf">http://shura.shu.ac.uk/8478/1/PPI_paper_bmjspcare-2014-000750_full.pdf</a></p>
<p>Dudley, L. et al. 8 June 2015</p> <p>What Difference Does Patient and Public Involvement Make and What Are Its Pathways to Impact? Qualitative Study of Patients and Researchers from a Cohort of Randomised Clinical Trials</p>	<p>Patient and public involvement (PPI) is advocated in clinical trials yet evidence on how to optimise its impact is limited. We explored researchers' and PPI contributors' accounts of the impact of PPI within trials and factors likely to influence its impact.</p>	<p><a href="https://www.ncbi.nlm.nih.gov/pmc/articles/PMC4459695/pdf/pone.0128817.pdf">https://www.ncbi.nlm.nih.gov/pmc/articles/PMC4459695/pdf/pone.0128817.pdf</a></p>
<p>Polechuck, E. et al. 30 April 2015</p> <p>Using patient engagement in the design and rationale of a trial for women with depression in obstetrics and gynecology practices</p>	<p>Significant health disparities exist among socioeconomically disadvantaged women, who experience elevated rates of depression and increased risk for poor depression treatment engagement and outcomes. We aimed to use stakeholder input to develop innovative methods for a comparative effectiveness trial to address the needs of socioeconomically disadvantaged women with depression in women's health practices.</p>	<p><a href="https://www.ncbi.nlm.nih.gov/pubmed/25937505">https://www.ncbi.nlm.nih.gov/pubmed/25937505</a></p>
<p>Rise, MB.; Steinbekk, A. 14 March 2016</p> <p>Long Term Effect on Professionals' Knowledge, Practice and Attitudes towards User Involvement Four Years after Implementing an Organisational Development Plan: A Controlled Study.</p>	<p>Health service organisations are increasingly implementing user involvement initiatives according to requirements from governments, such as user representation in administrative boards, better information to users, and more involvement of the users during treatment. Professionals are vital in all initiatives to enhance user involvement, and initiatives to increase involvement should influence the professionals' practice and attitudes. The implementation of a development plan intending to enhance user involvement in a mental health hospital in Central Norway had no effect on the professionals after 16 months. The objective was therefore to investigate the long term effect on the professionals' knowledge, practice and attitudes towards user involvement after four years.</p>	<p><a href="https://www.ncbi.nlm.nih.gov/pubmed/26974971">https://www.ncbi.nlm.nih.gov/pubmed/26974971</a></p>
<p>Simmons, R. et al. 11 May 2016</p> <p>A global survey of HIV-positive people's attitudes towards cure research.</p>	<p><b>Objectives:</b> Involvement of people living with HIV (PLHIV) in the design of HIV cure studies is important, given the potential risks to participants. We present results of an international survey of PLHIV to define these issues and inform cure research.</p>	<p><a href="https://www.ncbi.nlm.nih.gov/pubmed/27167600">https://www.ncbi.nlm.nih.gov/pubmed/27167600</a></p>



Name	Brief Summary	Access
<p>South, A. et al. 29 July 2016</p> <p><b>Models and impact of patient and public involvement in studies carried out by the Medical Research Council Clinical Trials Unit at University College London: findings from ten case studies.</b></p>	<p>Patient and public involvement (PPI) in studies carried out by the UK Medical Research Council Clinical Trials Unit (MRC CTU) at University College London varies by research type and setting. We developed a series of case studies of PPI to document and share good practice.</p>	<p><a href="https://www.ncbi.nlm.nih.gov/pubmed/27473060">https://www.ncbi.nlm.nih.gov/pubmed/27473060</a></p>
<p>Stewart, D. et al. 2011</p> <p>Patient and public involvement</p>	<p>The involvement of patients and the public in the development of clinical research initiatives in the UK has been central and is increasing. Whilst initially developed in relation to cancer research and cancer care, this activity has now generalized to all of healthcare research particularly through organizations such as INVOLVE (<a href="http://www.invo.org.uk">www.invo.org.uk</a>).</p> <p>Patients and Public Involvement (PPI) has been evaluated and shown to be established across the NHS in the UK. The National Institute for Health Research in England has made PPI central in its development. More recently evidence is accumulating that PPI has significant impact on the quality and delivery of clinical research in healthcare but more work on the evaluation of its impact is required.</p>	<p><a href="http://annonc.oxfordjournals.org/content/22/Suppl_7/vii54.full.pdf">http://annonc.oxfordjournals.org/content/22/Suppl_7/vii54.full.pdf</a></p>

## Search results from BMJ

Name	Brief Summary	Access
<p>Barber, S. et al. 14 August 2014</p> <p>Evaluation of My Medication Passport: a patient-completed aide-memoire designed by patients, for patients, to help towards medicines optimisation</p>	<p><b>Objectives:</b> A passport-sized booklet, designed by patients for patients to record details about their medicines, has been developed as part of a wider project focusing on improving prescribing in the elderly ('ImPE'). We undertook an evaluation of 'My Medication Passport' to gain an understanding of its value to patients and how it may be used in communications about medicines.</p>	<p><a href="http://bmjopen.bmj.com/content/4/8/e005608.full?sid=8d8d13e9-4df2-4a14-a136-7244aab89a64">http://bmjopen.bmj.com/content/4/8/e005608.full?sid=8d8d13e9-4df2-4a14-a136-7244aab89a64</a></p>
<p>Barello, S. et al. 16 March 2015</p> <p>'Engage me in taking care of my heart': a grounded theory study on patient-cardiologist relationship in the hospital management of heart failure</p>	<p><b>Objective:</b> In approaching the study and practice of heart failure (HF) management, authors recognise that the patient-doctor relationship has a central role in engaging patients in their care. This study aims at identifying the features and the levers of HF patient engagement and suggestions for orienting clinical encounters.</p>	<p><a href="http://bmjopen.bmj.com/content/5/3/e005582.full?sid=8d8d13e9-4df2-4a14-a136-7244aab89a64">http://bmjopen.bmj.com/content/5/3/e005582.full?sid=8d8d13e9-4df2-4a14-a136-7244aab89a64</a></p>

Name	Brief Summary	Access
<p>Barr, P. et al 8 January 2016</p> <p>Competing priorities in treatment decision-making: a US national survey of individuals with depression and clinicians who treat depression</p>	<p><b>Objective:</b> To identify information priorities for consumers and clinicians making depression treatment decisions and assess shared decision-making (SDM) in routine depression care.</p>	<p><a href="http://bmjopen.bmj.com/content/6/1/e009585.full?sid=9fb002d6-ec68-42ab-a98a-92e68c3032ac">http://bmjopen.bmj.com/content/6/1/e009585.full?sid=9fb002d6-ec68-42ab-a98a-92e68c3032ac</a></p>
<p>De Wit, M. et al. 9 May 2013</p> <p>Involving patient research partners has a significant impact on outcomes research: a responsive evaluation of the international OMERACT conferences</p>	<p><b>Objective:</b> To assess the inclusion of patients as international research partners in Outcome Measures in Rheumatology (OMERACT) conferences and how this has influenced the scope and conduct of outcomes research in rheumatology.</p>	<p><a href="http://bmjopen.bmj.com/content/3/5/e002241.full?sid=455709c1-631a-45ea-97e1-639612286ce3">http://bmjopen.bmj.com/content/3/5/e002241.full?sid=455709c1-631a-45ea-97e1-639612286ce3</a></p>
<p>Durand, M-A. et al. 2 February 2016</p> <p>‘Much clearer with pictures’: using community-based participatory research to design and test a Picture Option Grid for underserved patients with breast cancer</p>	<p><b>Objective:</b> Women of low socioeconomic status (SES) diagnosed with early stage breast cancer experience decision-making, treatment and outcome disparities. Evidence suggests that decision aids can benefit underserved patients, when tailored to their needs. Our aim was to develop and test the usability, acceptability and accessibility of a pictorial encounter decision aid targeted at women of low SES diagnosed with early stage breast cancer.</p>	<p><a href="http://bmjopen.bmj.com/content/6/2/e010008.full?sid=9fb002d6-ec68-42ab-a98a-92e68c3032ac">http://bmjopen.bmj.com/content/6/2/e010008.full?sid=9fb002d6-ec68-42ab-a98a-92e68c3032ac</a></p>
<p>Kandelaki, K. et al. 8 January 2016</p> <p>Patient-centredness as a quality domain in Swedish healthcare: results from the first national surveys in different Swedish healthcare settings</p>	<p><b>Objectives:</b> Patients’ perception of the quality and patient-centredness of healthcare has gained increasing interest in the last decade in Sweden, as in other countries. The purpose of the study was to evaluate to what extent patients perceived Swedish healthcare as patient-centred and to explore the satisfaction levels related to gender, education level and to having or not having Swedish as one’s mother tongue.</p>	<p><a href="http://bmjopen.bmj.com/content/6/1/e009056.full?sid=9fb002d6-ec68-42ab-a98a-92e68c3032ac">http://bmjopen.bmj.com/content/6/1/e009056.full?sid=9fb002d6-ec68-42ab-a98a-92e68c3032ac</a></p>
<p>Kayyali, R. et al. 17 June 2016</p> <p>Qualitative investigation into a wearable system for chronic obstructive pulmonary disease: the stakeholders’ perspective.</p>	<p><b>Objective:</b> To ascertain the stakeholders’ views and devise recommendations for further stages of the Wearable Sensing and Smart Cloud Computing for Integrated Care to Chronic Obstructive Pulmonary Disease (COPD) Patients with Co-morbidities (WELCOME) system development. This system aims to create a wearable vest to monitor physiological signals for patients concerned incorporating an inhaler adherence monitoring, weight, temperature, blood pressure and glucose metres, and a mobile health application for communication with healthcare professionals (HCPs).</p>	<p><a href="http://bmjopen.bmj.com/content/6/8/e011657.full.pdf+html?sid=a0fae442-af8c-458d-a902-b64421f41efe">http://bmjopen.bmj.com/content/6/8/e011657.full.pdf+html?sid=a0fae442-af8c-458d-a902-b64421f41efe</a></p>

Name	Brief Summary	Access
<p>Malhotra, K. et al. 20 June 2016</p> <p>Electronic capture of patient-reported and clinician-reported outcome measures in an elective orthopaedic setting: a retrospective cohort analysis</p>	<p><b>Objectives:</b> To determine whether an entirely electronic system can be used to capture both patient-reported outcomes (electronic Patient-Reported Outcome Measures, ePROMs) as well as clinician-validated diagnostic and complexity data in an elective surgical orthopaedic outpatient setting. To examine patients' experience of this system and factors impacting their experience.</p>	<p><a href="http://bmjopen.bmj.com/content/6/6/e011975.full?sid=cf3061ce-1797-4583-9aac-bdbbec-450edf">http://bmjopen.bmj.com/content/6/6/e011975.full?sid=cf3061ce-1797-4583-9aac-bdbbec-450edf</a></p>
<p>Parsons, S. et al. 8 April 2015</p> <p><b>What the public knows and wants to know about medicines research and development: a survey of the general public in six European countries.</b></p>	<p><b>Objectives:</b> To explore public knowledge of, and interest in, learning more about medicines R&amp;D in six European countries.</p>	<p><a href="http://bmjopen.bmj.com/content/5/4/e006420.full?sid=c30b007f-bd26-47b1-acc1-9b7ceb13bad0">http://bmjopen.bmj.com/content/5/4/e006420.full?sid=c30b007f-bd26-47b1-acc1-9b7ceb13bad0</a></p>
<p>Stolee, P. et al. 3 November 2015</p> <p>Choosing Healthcare Options by Involving Canada's Elderly: a protocol for the CHOICE realist synthesis project on engaging older persons in healthcare decision-making</p>	<p><b>Introduction:</b> While patient and citizen engagement has been recognised as a crucial element in healthcare reform, limited attention has been paid to how best to engage seniors—the fastest growing segment of the population and the largest users of the healthcare system. To improve the healthcare services for this population, seniors and their families need to be engaged as active partners in healthcare decision-making, research and planning. This synthesis aims to understand the underlying context and mechanisms needed to achieve meaningful engagement of older adults in healthcare decision-making, research and planning.</p>	<p><a href="http://bmjopen.bmj.com/content/5/11/e008190.full?sid=280e4a26-3d7b-4552-a29d-883a77a3f7c2">http://bmjopen.bmj.com/content/5/11/e008190.full?sid=280e4a26-3d7b-4552-a29d-883a77a3f7c2</a></p>
<p>Sudore, R. et al. 18 May 2016</p> <p>Improving advance care planning for English-speaking and Spanish-speaking older adults: study protocol for the PREPARE randomised controlled trial</p>	<p>Advance care planning (ACP) is a process that allows patients to identify their goals for medical care. Traditionally, ACP has focused on completing advance directives; however, we have expanded the ACP paradigm to also prepare patients to communicate their wishes and make informed decisions. To this end, we created an ACP website called PREPARE (<a href="http://www.prepareforyourcare.org">http://www.prepareforyourcare.org</a>) to prepare diverse English-speaking and Spanish-speaking older adults for medical decision-making. Here, we describe the study protocol for a randomised controlled efficacy trial of PREPARE in a safety-net setting. The goal is to determine the efficacy of PREPARE to engage diverse English-speaking and Spanish-speaking older adults in a full spectrum of ACP behaviours.</p>	<p><a href="http://bmjopen.bmj.com/content/6/7/e011705.full.pdf+html?sid=b34614a0-0951-408b-a65b-442c0b138e10">http://bmjopen.bmj.com/content/6/7/e011705.full.pdf+html?sid=b34614a0-0951-408b-a65b-442c0b138e10</a></p>
<p>Tilburt, J. et al.</p> <p>Shared decision-making as a cost-containment strategy: US physician reactions from a cross-sectional survey</p>	<p><b>Objective:</b> To assess US physicians' attitudes towards using shared decision-making (SDM) to achieve cost containment.</p>	<p><a href="http://bmjopen.bmj.com/content/4/1/e004027.full?sid=95b-7b6e4-716e-407d-ba7a-f4c4fe13e182">http://bmjopen.bmj.com/content/4/1/e004027.full?sid=95b-7b6e4-716e-407d-ba7a-f4c4fe13e182</a></p>
<p>Webster, F. et al. 8 September 2015</p> <p><b>Capturing the experiences of patients across multiple complex interventions: a meta-qualitative approach</b></p>	<p><b>Objectives:</b> The perspectives, needs and preferences of individuals with complex health and social needs can be overlooked in the design of healthcare interventions. This study was designed to provide new insights on patient perspectives drawing from the qualitative evaluation of 5 complex healthcare interventions.</p>	<p><a href="http://bmjopen.bmj.com/content/5/9/e007664.full?sid=280e4a26-3d7b-4552-a29d-883a77a3f7c2">http://bmjopen.bmj.com/content/5/9/e007664.full?sid=280e4a26-3d7b-4552-a29d-883a77a3f7c2</a></p>