

UCSF

UC San Francisco Previously Published Works

Title

Patient Engagement In Health Care Safety: An Overview Of Mixed-Quality Evidence.

Permalink

<https://escholarship.org/uc/item/3dn2v5pg>

Journal

Health affairs, 37(11)

ISSN

1544-5208

Authors

Sharma, Anjana E
Rivadeneira, Natalie A
Barr-Walker, Jill
[et al.](#)

Publication Date

2018-11-01

Peer reviewed

Patient Engagement In Health

Care Safety: An Overview Of

Mixed-Quality Evidence

Anjana E. Sharma¹, Natalie A. Rivadeneira², Jill Barr-Walker³, Rachel J. Stern⁴,
Amanda K. Johnson⁵, and Urmimala Sarkar⁶

Abstract

Patients and caregivers play a central role in health care safety in the hospital, ambulatory care setting, and community. Despite this, interventions to promote patient engagement in safety are still underexplored. We conducted an overview of review articles on patient engagement interventions in safety to examine the current state of the evidence. Of the 2,795 references we evaluated, 53 articles met our full-text inclusion criteria for synthesis in 2018. We identified robust evidence supporting patients' self-management of anticoagulation and mixed-quality evidence supporting patient engagement in medication and chronic disease self-management, adverse event reporting, and medical record accuracy. Promising modes of patient engagement in safety, such as anticoagulation management and patient portal access, are not widely implemented. We discuss major implementation priorities and propose directions for future research and policy to enhance patient partnership within safety efforts.

Since the publication of the patient safety report *To Err Is Human* in 1999,¹ the role of patient and family caregivers within the safety of health care has grown in prominence. In parallel, health care is increasingly delivered in the outpatient setting

with shorter inpatient stays, more frequent care transitions between the hospital and other care sites, growing shared responsibility among members of patient care teams, and increasingly complex chronic disease management in the home and community.² In the hospital, patients are under continual observation. In the ambulatory setting, patients, families, and caregivers have more frequent opportunities to promote safety in partnership with a multidisciplinary care team.

Patient engagement is the involvement of patients, families, and caregivers in improving health care and health care safety.³ Although some editorials on patient engagement have questioned whether patients wish to be engaged,⁴ patients have overwhelmingly expressed a desire for some form of engagement in a diverse range of health care settings. However, it is important to acknowledge that patients' preferences, self-efficacy, and power dynamics may impede engagement.⁵ There have been mandates to implement and evaluate patient engagement in safety from the Joint Commission, the Agency for Healthcare Research and Quality, and the World Health Organization.⁶⁻⁹ The Department of Health and Human Services lists patient engagement as a key strategy in its national action plan for the prevention of adverse drug events.¹⁰ Patient and family engagement also appeals to principles of equity, by recognizing patients as valued partners in developing safer health care systems.¹¹

Examples of patients' being engaged in the safety of their own care include monitoring and self-administration of medications, alerting care teams to concerning symptoms, and reporting adverse events.¹² As the loci of continuity during care transitions and the primary managers of chronic diseases in the home and community, patients and caregivers can identify disruptions during care transitions and alert care

providers to events leading to preventable harm that might otherwise go unrecognized. Patients and caregivers can also participate in hospital safety initiatives or advisory councils as a means of engaging at the level of the health care system.

In this era of patient-centered care, health care leaders are in search of efficacious strategies to involve patients and families in health care safety. However, the evidence base to guide engagement has been limited. A 2010 systematic review by Jill Hall and coauthors found poor-quality evidence that patient engagement can improve safety through self-monitoring of anticoagulation, designing patient educational materials, and participating in self-management with individualized teaching or counseling.¹³ We sought to update this review to describe the current state of the science of patient engagement within health care safety. Given that there has been an explosion of research on patient engagement within safety over the past decade, we conducted an overview of review articles to provide a high-level scan of the literature. This article highlights evidence-based strategies to support patient and family engagement in promoting safe care in the hospital, clinic, pharmacy, home, and community and to identify gaps to inform patient safety research and policy agendas.

Study Data And Methods

Search Strategy

We adapted the search concepts used in the review by Hall and coauthors¹³ to create two content areas for our search strategy: patient engagement and safety. We examined search strategies of several previous systematic reviews involving patient engagement and safety topics^{14–16} to add relevant terms to our search strategy. Because we were conducting an overview of reviews and wanted to capture a variety of

review article types, we added a “review methodology” component to the search. We developed the final search strategy in collaboration with a clinical librarian (Jill Barr-Walker) using an iterative process to test individual search terms, including keywords and controlled vocabulary (such as MeSH and Emtree terms) for each search concept. We developed the search for use in PubMed and then applied it to other databases, following Preferred Reporting Items for Systematic Reviews and Meta-Analyses (PRISMA) and review-of-reviews methodological guidelines.^{17,18} A second librarian (not among the authors) reviewed the final search strategy using the Peer Review of Electronic Search Strategy (PRESS) guidelines.¹⁹ The databases searched on February 13, 2018, were PubMed, Embase, CINAHL, PsycINFO, and the Cochrane Library. The search strategies are listed in online appendix exhibit A1.²⁰ The review protocol was registered in PROSPERO (ID: 2017 CRD42017071461), an international database of systematic reviews.

Study Selection

Four independent reviewers (authors Anjana Sharma, Natalie Rivadeneira, Amanda Johnson, and Rachel Stern) independently performed screening, as follows. Records were uploaded to DistillerSR, a software program, to manage the review process. All records retrieved through searches underwent title and abstract screening. All records tagged by one reviewer as potentially relevant, as well as those for which abstracts were unavailable, were screened for inclusion at the full-text level. To be included, articles had to be reviews (systematic, literature, narrative, or scoping) that involved patient engagement interventions and reported patient safety outcomes. Studies were excluded if they were not related to patient engagement; did not focus on

safety outcomes; were primary research (that is, not reviews); reported patient engagement in research (not clinical care); were conference posters or abstracts; were not in English; or had been published outside the period of 2007–17, as the inclusion terms for the review by Hall and coauthors¹³ ended in July 2008, by which time some 2007 references might not have been indexed. Full inclusion and exclusion criteria are available in appendix exhibit A2.²⁰ Studies required dual review for exclusion. When disagreements occurred, consensus was achieved through discussion between the two reviewers or an additional team member.

Data Extraction

We created a standardized form to extract the number of final studies included in each review; characteristics of the patient engagement intervention; characteristics of patient safety represented by the outcome; the level of harm of the outcome; an assessment of the quality of the review using the criteria specified in AMSTAR,²¹ a validated tool that assesses the methodological quality of systematic reviews on a scale of 0 (low quality) to 11 (high quality); and a summary of the review's conclusions. Three reviewers (Sharma, Rivadeneira, and Johnson) completed data extraction, with two reviewers (Stern and Urmimala Sarkar) available to resolve discrepancies.

Limitations

This overview had several limitations. First, it did not capture all published work on patient engagement in safety. We focused on published reviews and therefore excluded single trials that could have offered promising novel means of patient engagement in safety.

Second, as this was a conceptual overview with heterogeneous results, we performed a narrative synthesis, not a meta-analysis.

Third, we objectively rated the quality level of each review article, but the quality levels of all primary data were not available.

Fourth, few of our included reviews contained demographic summaries of the patients who were engaged in these studies. Thus, there were concerns that historically underserved patients such as members of racial and ethnic minority groups, people with limited health literacy or English proficiency, and those facing socioeconomic barriers might not have been represented.

Study Results

The database searches yielded 2,795 references after removal of duplicates. The abstract screening excluded 2,579 of these articles. Of the 216 articles that remained for full-text review, we excluded 163. The most common reasons for exclusion were that the article was not a review, the review did not report a patient engagement intervention or patient safety outcome, the review was published outside of the publication date range, the review was not in English, or the review was a conference poster. The final analysis included fifty-three reviews meeting inclusion criteria (appendix exhibit A3).²⁰ The mean AMSTAR quality rating was 4.7, corresponding with medium quality. Eleven reviews were high quality, twenty-four medium quality, and seventeen low quality. Exhibit 1 presents an overview of patient safety targets, engagement interventions, and summaries of evidence findings with quality levels (additional study details are in appendix exhibit A4).²⁰

The fifty-three included reviews encompassed a broad range of safety topics. We grouped the reviews into categories of safety targets, ordered by review quality: anticoagulation management (seventeen articles); hypoglycemia in management of type 1 diabetes (three); medication safety, which included medication adherence (four), patient or caregiver reports of an adverse event related to medication (nine), and medication administration errors (five); administrative errors (four); diagnostic errors (one); malpractice lawsuits (one); hospital readmissions (six); health care–associated infections (four); and pressure ulcers (one). Some studies addressed multiple outcomes.

Anticoagulation Management

Seventeen reviews (six of high, six of medium, and five of low quality) assessed the evidence for patient engagement in self-monitoring and titrating warfarin doses for anticoagulation. These studies, whether assessing self-monitoring alone or in combination with patient-directed dose adjustment, consistently found statistically significant reductions in thromboembolic events and mortality compared to usual care (appendix exhibit A5, articles 1–16).²⁰ Results for reduction of bleeding events were mixed.

Hypoglycemia In Diabetes Management

Three reviews described mixed results for the role of patient self-management to prevent hypoglycemia in type 1 diabetes. One high-quality review reported that digital self-management apps or other tools to promote self-management were associated with improved diabetic control but with a mixed effect on preventing hypoglycemia, based on heterogeneous studies with high risk for bias (appendix exhibit A6, article 2).²⁰ Another

high-quality review on interventions to promote patient activation—such as promoting increased knowledge, confidence, or skills for disease self-management—found improved diabetic quality outcomes but not hypoglycemia or mortality (appendix exhibit A6, article 1).²⁰ One low-quality review reported that patient education and training in self-management prevented hypoglycemia and diabetic ketoacidosis in patients with type 1 diabetes (appendix exhibit A6, article 3).²⁰

Medication Safety: Adherence, Pharmacovigilance, And Administration

Four reviews, ranging in quality from high to low, discussed patients' adherence to medication, which is a patient safety practice with risk for harm if medications are not taken as prescribed. Patient education, self-management programs, and access to online notes all improved medication adherence (appendix exhibit A7, articles 1–4).²⁰

Nine reviews, ranging in quality from medium to low, discussed patients' and caregivers' roles in safety-event reporting, which is typically related to reporting adverse medication events (appendix exhibit A7, articles 5–13).²⁰ These roles included opportunities for patients to disclose medication adverse events directly through mechanisms enabling pharmacovigilance to state-based databases, health care systems, or pharmaceutical companies. All but one of the reviews noted that patients and families reported events that were distinct, more frequent, or novel, compared to events identified by health care providers. For example, one medium-quality review showed that patients who received treatment for rectal cancer more frequently reported chemotherapy toxicity and bowel and sexual dysfunction than health care providers did (appendix exhibit A7, article 6).²⁰ Patients reported safety issues as well as events that

involved suboptimal service quality or communication problems (appendix exhibit A7, article 7).²⁰

Five reviews addressed patient engagement in reducing medication administration errors. Three reviews ranging in quality from medium to low described a positive impact of patient or family education that focused on medication reconciliation: improved medication administration accuracy (appendix exhibit A7, articles 15, 16, and 18).²⁰ One medium-quality review found that the prevalence of patients who contributed to medication self-administration error was 19–59 percent (appendix exhibit A7, article 14).²⁰ One low-quality review found that patients and families could reduce errors in chemotherapy administration (appendix exhibit A7, article 17).²⁰

Administrative Errors

Four reviews explored patient engagement to improve documentation and scheduling accuracy. One high- and one medium-quality systematic review reported how online patient portals in which patients could review their charts could allow patients to correct their medication lists or electronic medical records (EMRs) (appendix exhibit A8, articles 1 and 2).²⁰ One low-quality systematic review described how an advisory council led a communitywide initiative that resulted in patients' updating and correcting their medication lists (appendix exhibit A8, article 4).²⁰

One low-quality review (appendix exhibit A8, article 3)²⁰ assessed the impact of patient-accessed web-based medical appointment systems. It found that giving patients web-based access reduced administrative or access errors by improving appointment attendance and appointment type accuracy.

Diagnostic Errors

One high-quality review assessed the role of patient engagement in diagnostic error, reporting that patients seeking a second opinion found a major change in the diagnosis, treatment, or prognosis in 10–62 percent of cases. However, this finding was based on lower-quality primary data (appendix exhibit A9, article 1).²⁰

Malpractice Lawsuits

One high-quality review (appendix exhibit A10, article 1)²⁰ assessed shared decision-making tools as a patient engagement strategy to prevent malpractice litigation. The review found insufficient evidence of any impact.

Hospital Readmissions

Six medium-quality reviews assessed the impact of patient engagement on preventing hospital readmissions for conditions such as heart failure, pneumonia, and chronic obstructive pulmonary disease. Two reviews reported that patient or family education programs reduced readmissions (appendix exhibit A11, articles 2 and 6),²⁰ while one reported null results for a structured discharge process (appendix exhibit A11, article 1).²⁰ Two reviews assessed self-management strategies: One reported positive results (appendix exhibit A11, article 4),²⁰ and the other reported null results (appendix exhibit A11, article 3).²⁰ One review found null results of community health worker support (appendix exhibit A11, article 5).²⁰

Health Care–Associated Infections

Health care workers' failure to adhere to hand hygiene increases the risk of health care–associated infections. Four reviews, with quality ranging from medium to low (appendix exhibit A12, articles 1–4),²⁰ reported on the feasibility of patient and family engagement in hand hygiene initiatives. One study found that an educational

program to encourage patients to ask health care workers to wash their hands resulted in increased compliance with hand hygiene standards by 52 percent and a 32 percent decrease in infections (appendix exhibit A12, article 3).²⁰

Pressure Ulcers

One low-quality review detailed the effect of patients' and caregivers' involvement in preventing pressure ulcers. The authors reported that self-management technologies had low-to-moderate effectiveness in addressing some risk factors for pressure ulcer development (appendix exhibit A13, article 1).²⁰

Discussion

This overview of reviews demonstrates that a range of patient engagement interventions led to improved safety. While prior literature surveys have concluded that the evidence base is scant, there has been an abundance of research on patient engagement since Hall and coauthors' 2010 systematic review.¹³ This evidence base has been scattered across the literature for specific diseases and disciplines, which makes it challenging to identify common themes and interpret best practices.

The reviews varied in study quality and risk of bias. Our highest-quality, most robust finding was the consistently positive impact of patient self-management and self-monitoring of warfarin for anticoagulation to reduce mortality and thromboembolic events. With the majority of chronic disease management occurring between office visits, in the home and community, self-monitoring and self-management strategies can help patients and families maintain safety between visits with their health care providers (see appendix exhibit A14).²⁰

Despite high-quality evidence of its effectiveness, patients' self-monitoring of anticoagulation medication is rare in clinical practice. This is a major implementation gap. Contributing factors may include clinicians' discomfort with delegating responsibility to patients, challenges for patients in obtaining insurance coverage for home monitors, and the growing shift to novel oral anticoagulants.²² Similar barriers may prevent the implementation of other patient engagement strategies identified in our review, such as pressure ulcer self-monitoring, self-management support after discharge, and the use of self-management tools to prevent hypoglycemia.

Research Gaps

We identified multiple research gaps in this overview. The evidence for patient self-management to prevent anticoagulation medication adverse events and hypoglycemia suggests that other high-risk medications could be safer with patient self-management. Anti-arrhythmics, antihypertensives, and opioids require frequent monitoring or office visits and are commonly implicated in outpatient adverse events.²³ Their safety could be improved with patient engagement in between-visit symptom monitoring and dosage self-adjustment. In light of the growing opioid epidemic, further research on self-management and monitoring for opioid adverse effects should be prioritized. A recent program exemplified this approach: It used education and team-based support to engage patients in self-tapering of opioids, which showed reduction in opioid burden with no change in mean pain intensity.²⁴

We identified only one review that addressed system-level patient engagement: It reported that community advisory councils promoted correct medication lists on a population level (appendix exhibit A8, article 4).²⁰ Patient safety research should

examine the effects of system-level participation, such as participation in root-cause analysis, and the emerging field of experience-based codesign to redesign care processes. One example of system-level patient engagement research is a pre-post analysis that found a dramatic reduction in medication errors after patient and family advisers were embedded within quality and safety committees across an institution.²⁵

Other than studies of readmission prevention, we found little research on patient safety through engagement with other members of the care team, including family caregivers, home health aides, pharmacists, and nurses. No studies examined the integration of patient safety across the medical neighborhood—partnerships across the medical and social drivers of health that connect clinicians, patients, hospitals, home health, and community organizations.²⁶ Such models of care are better aligned to support all disciplines in a care team to promote patient and family engagement.

Only one of the systematic reviews addressed patient engagement in diagnostic errors, defined narrowly as seeking second opinions. Patients can reduce diagnostic errors in a variety of ways that merit further study, such as patient education regarding testing follow-up and patients' reporting of diagnostic errors or participating in advisory councils that review such errors.²⁷

Policy Implications

Unlike the situation highlighted by the findings of the 2010 review,¹³ we are now at a stage where diverse care settings are assessing patient engagement safety initiatives. No study has shown evidence of harm from patient engagement, and many have shown improvements in safety outcomes. Up to now, policy mandates for patient engagement within safety have typically been general and diffuse. We recommend that

policies supporting patient engagement specifically describe what the engagement modality entails, including a robust safety evaluation plan. Policies that encourage an implementation science approach will be paramount if the science is to move to the next stage.

Supportive policies for health information technology may enhance patient engagement within safety. Our review highlights the importance of EMR-based patient portals, which allow patients to access laboratory results and medication lists and communicate with providers. Programs such as OpenNotes, which patients can use to review all of their clinical documentation, were highlighted in our overview as a way to identify both administrative and diagnostic errors. However, only a small percentage of patients with higher educational attainment and literacy engage with portals,²⁸ and current EMRs are fragmented. For EMRs and patient portals to achieve their full potential as patient engagement tools for safety, policy shifts must encourage interoperable systems that accommodate patients with limited health literacy and English proficiency and facilitate access for caregivers as well.^{29,30}

Patient safety event reporting has a critical mass of evidence to support its efficacy and now needs broader implementation. Our review demonstrated that patients and families consistently identify and report adverse events that are unique and often more expansive than those identified by health care workers. Patient reports also capture outcomes that are more relevant to function and quality of life. However, few health care systems provide easy, anonymous systems for patients and families to submit reports of adverse events outside of a formal grievance process, especially in the office practice, home, and community. Some European countries already have

national reporting systems in place that could serve as templates (appendix exhibit A7).²⁰ EMR-based patient portals could also be a platform for the direct reporting of adverse events.^{31,32}

Investments in digital self-management tools and apps are growing. However, our review found little evidence supporting tech-based self-management devices. We identified only one high-quality review that addressed the role of digital apps (appendix exhibit A6, article 2),²⁰ and it reported mixed results for preventing hypoglycemia in diabetes, based on low-quality primary data. Digital self-management tools that support home monitoring of specific high-risk conditions deserve further exploration—with robust safety endpoints, rather than just feasibility or usability, as primary outcomes.

We excluded reviews that assessed patient engagement tools to reduce unnecessary medical treatments, such as shared decision making to reduce antibiotic use for upper respiratory infections.³³ We also excluded reviews that assessed patient engagement in chronic disease management and reported care quality outcomes that had risk for patient harm, such as seizure frequency among patients with known epilepsy.³⁴ While the scope of this review included known safety outcomes, health care systems that limit overtreatment and deliver high-quality chronic disease management may also be safer.

The strengths of this overview include an expansive search strategy to uncover and synthesize a broad range of the literature on patient engagement, spanning pharmacology, primary and subspecialty care, health information technology, and policy journals. Our review is the first to comprehensively organize patient engagement

evidence by principles of patient safety, rather than by subspecialty areas or specific disease states.

Conclusion

Patients and families experience adverse events and self-manage care between office visits and care transitions. The past ten years have yielded a major expansion in research and policy to explore the role of patient and family engagement in health care safety outcomes. Future work should foster the innovative use of EMRs, new modalities for patients and families to self-manage care and communicate easily with care teams, and patients' participation in system-level safety improvements. The patient has been "in" patient safety all along. The next step is for health care teams to partner with patients and caregivers to integrate effective patient engagement into clinical practice and health care systems.

Notes

<eref>1. Corrigan JM, Kohn LT, Donaldson MS, editors. To err is human: building a safer health system. Washington (DC): National Academies Press; 1999.</eref>

<unknown>2. Sarkar U, Wachter RM, Schroeder SA, Schillinger D. Refocusing the lens: patient safety in ambulatory chronic disease care. Jt Comm J Qual Patient Saf. 2009;35(7):377–83, 341.</unknown>

<jrn>3. Carman KL, Dardess P, Maurer M, Sofaer S, Adams K, Bechtel C, et al. Patient and family engagement: a framework for understanding the elements and developing interventions and policies. Health Aff (Millwood). 2013;32(2):223–31 [PubMed](#).</jrn>

<jrn>4. Davis RE, Sevdalis N, Vincent CA. Patient involvement in patient safety: how willing are patients to participate? BMJ Qual Saf. 2011;20(1):108–14 [PubMed](#).</jrn>

<jrn>5. Hibbard JH, Peters E, Slovic P, Tusler M. Can patients be part of the solution? Views on their role in preventing medical errors. Med Care Res Rev. 2005;62(5):601–16 [PubMed](#).</jrn>

<eref>6. Joint Commission. National patient safety goals effective January 2018: Ambulatory Health Care Accreditation Program [Internet]. Oakbrook Terrace (IL): Joint Commission; c 2018 [cited 2018 Oct 3]. Available from:

https://www.jointcommission.org/assets/1/6/NPSG_Chapter_AHC_Jan2018.pdf</eref>

<bok>7. Shekelle PG, Sarkar U, Shojania K, Wachter RM, McDonald K, Motala A, et al. Patient safety in ambulatory settings [Internet]. Rockville (MD): Agency for Healthcare Research and Quality; 2016 Oct [cited 2018 Oct 3]. (Technical Brief No. 27). Available from: https://effectivehealthcare.ahrq.gov/sites/default/files/pdf/ambulatory-safety_technical-brief.pdf</bok>

<eref>8. Agency for Healthcare Research and Quality. Improving primary care practice [Internet]. Rockville (MD): AHRQ; [last reviewed 2016 Nov; cited 2018 Oct 3]. Available from: <https://www.ahrq.gov/professionals/prevention-chronic-care/improve/index.html></eref>

<bok>9. World Health Organization. Safer primary care: a global challenge: summary of inaugural meeting: the Safer Primary Care Expert Working Group [Internet]. Geneva: WHO; 2012 [cited 2018 Oct 3]. Available from: http://www.who.int/patientsafety/summary_report_of_primary_care_consultation.pdf
</bok>

<bok>10. Department of Health and Human Services, Office of Disease Prevention and Health Promotion. National Action Plan for Adverse Drug Event Prevention [Internet]. Washington (DC): HHS; 2014 [cited 2018 Oct 3]. p. 17. Available from: <https://health.gov/hcq/pdfs/ADE-Action-Plan-508c.pdf></bok>

<jrn>11. Berwick DM. What “patient-centered” should mean: confessions of an extremist. Health Aff (Millwood). 2009;28(4):w555–65. DOI: 10.1377/hlthaff.28.4.w555
[PubMed](#)</jrn>

<jrn>12. Peat M, Entwistle V, Hall J, Birks Y, Golder S. Scoping review and approach to appraisal of interventions intended to involve patients in patient safety. J Health Serv Res Policy. 2010;15(Suppl 1):17–25 [PubMed](#).</jrn>

<jrn>13. Hall J, Peat M, Birks Y, Golder S, Entwistle V, Gilbody S, et al. Effectiveness of interventions designed to promote patient involvement to enhance safety: a systematic review. Qual Saf Health Care. 2010;19(5):e10 [PubMed](#).</jrn>

<jrn>14. Lawton R, McEachan RR, Giles SJ, Sirriyeh R, Watt IS, Wright J. Development of an evidence-based framework of factors contributing to patient safety incidents in hospital settings: a systematic review. *BMJ Qual Saf.* 2012;21(5):369–80

[PubMed](#).</jrn>

<jrn>15. Doyle C, Lennox L, Bell D. A systematic review of evidence on the links between patient experience and clinical safety and effectiveness. *BMJ Open.*

2013;3(1):e001570 [PubMed](#).</jrn>

<jrn>16. Daker-White G, Hays R, McSharry J, Giles S, Cheraghi-Sohi S, Rhodes P, et al. Blame the patient, blame the doctor, or blame the system? A meta-synthesis of qualitative studies of patient safety in primary care. *PLoS One.* 2015;10(8):e0128329

[PubMed](#).</jrn>

<jrn>17. Moher D, Liberati A, Tetzlaff J, Altman DG. Preferred Reporting Items for Systematic Reviews and Meta-Analyses: the PRISMA statement. *PLoS Med.*

2009;6(7):e1000097 [PubMed](#).</jrn>

<jrn>18. Smith V, Devane D, Begley CM, Clarke M. Methodology in conducting a systematic review of systematic reviews of healthcare interventions. *BMC Med Res Methodol.* 2011;11(1):15

[PubMed](#).</jrn>

<jrn>19. McGowan J, Sampson M, Salzwedel DM, Cogo E, Foerster V, Lefebvre C.

PRESS Peer Review of Electronic Search Strategies: 2015 guideline statement. *J Clin Epidemiol.* 2016;75:40–6

[PubMed](#).</jrn>

<unknown>20. To access the appendix, click on the Details tab of the article

online.</unknown>

- <jrn>21. Shea BJ, Hamel C, Wells GA, Bouter LM, Kristjansson E, Grimshaw J, et al. AMSTAR is a reliable and valid measurement tool to assess the methodological quality of systematic reviews. *J Clin Epidemiol*. 2009;62(10):1013–20 [PubMed](#).</jrn>
- <jrn>22. Barnes GD, Lucas E, Alexander GC, Goldberger ZD. National trends in ambulatory oral anticoagulant use. *Am J Med*. 2015;128(12):1300–5.e2 [PubMed](#).</jrn>
- <jrn>23. Budnitz DS, Layde PM. Outpatient drug safety: new steps in an old direction. *Pharmacoepidemiol Drug Saf*. 2007;16(2):160–5 [PubMed](#).</jrn>
- <jrn>24. Darnall BD, Ziadni MS, Stieg RL, Mackey IG, Kao MC, Flood P. Patient-centered prescription opioid tapering in community outpatients with chronic pain. *JAMA Intern Med*. 2018;178(5):707–8 [PubMed](#).</jrn>
- <conf>25. Conway JB, Nathan DG, Benz EJ, Shulman LN, Sallan SE, Ponte PR, et al. Key learning from the Dana-Farber Cancer Institute’s 10-year patient safety journey [Internet]. Paper presented at: 42nd Annual Meeting of the American Society of Clinical Oncology; 2006 Jun 2–6; Atlanta, GA [cited 2018 Oct 4]. Available from: <https://pdfs.semanticscholar.org/47e9/2029dc9ef4fd1dde183d884a3e5c86bc7ea9.pdf>
- </conf>
- <eref>26. Patient-Centered Primary Care Collaborative. Medical neighborhood [Internet]. Washington (DC): The Collaborative; c 2018 [cited 2018 Oct 4]. Available from: <https://www.pcpcc.org/content/medical-neighborhood></eref>
- <jrn>27. McDonald KM, Bryce CL, Graber ML. The patient is in: patient involvement strategies for diagnostic error mitigation. *BMJ Qual Saf*. 2013;22(Suppl 2):ii33–9 [PubMed](#).</jrn>

<jrn>28. Goldzweig CL, Orshansky G, Paige NM, Towfigh AA, Haggstrom DA, Miake-Lye I, et al. Electronic patient portals: evidence on health outcomes, satisfaction, efficiency, and attitudes: a systematic review. *Ann Intern Med*. 2013;159(10):677–87 [PubMed](#).</jrn>

<jrn>29. Tieu L, Schillinger D, Sarkar U, Hoskote M, Hahn KJ, Ratanawongsa N, et al. Online patient websites for electronic health record access among vulnerable populations: portals to nowhere? *J Am Med Inform Assoc*. 2017;24(e1):e47–54 [PubMed](#).</jrn>

<jrn>30. Sarkar U, Bates DW. Care partners and online patient portals. *JAMA*. 2014;311(4):357–8 [PubMed](#).</jrn>

<jrn>31. Giles SJ, Reynolds C, Heyhoe J, Armitage G. Developing a patient-led electronic feedback system for quality and safety within Renal PatientView. *J Ren Care*. 2017;43(1):37–49 [PubMed](#).</jrn>

<jrn>32. Schwartzberg L. Electronic patient-reported outcomes: the time is ripe for integration into patient care and clinical research. *Am Soc Clin Oncol Educ Book*. 2016;35:e89–96 [PubMed](#).</jrn>

<jrn>33. Coxeter P, Del Mar CB, McGregor L, Beller EM, Hoffmann TC. Interventions to facilitate shared decision making to address antibiotic use for acute respiratory infections in primary care. *Cochrane Database Syst Rev*. 2015;(11):CD010907 [PubMed](#).</jrn>

<jrn>34. Shaw EJ, Stokes T, Camosso-Stefinovic J, Baker R, Baker GA, Jacoby A. Self-management education for adults with epilepsy. *Cochrane Database Syst Rev*. 2007;(2):CD004723 [PubMed](#).</jrn>

Exhibit List

Exhibit 1 (table)

EXHIBIT

Exhibit 1: Safety domains addressed by systematic review for which research gaps remain

Safety target or condition	Patient engagement intervention key findings	Readiness for broad-scale adoption	Recommendations for closing research gaps
Anticoagulation management: bleeding, and thromboembolism, anticoagulant-related mortality	INR self-monitoring and/or anticoagulant self-titration reduces thromboembolism, bleeding, and mortality Self-efficacy intervention reduces thromboembolism and bleeding.	High readiness for adoption, but implementation lags behind; limitations include patient and provider readiness, distribution costs, and clinic infrastructure	Delineate barriers to implementation Explore whether anticoagulation evidence is applicable to the self-management of other high-risk medications such as insulin and opioids
Hypoglycemia in type 1 diabetes	Self-management education reduces hypoglycemia in people with type 1 diabetes Digital apps/tools: mixed evidence Patient activation interventions: mixed evidence	Limited readiness for adoption given the mixed evidence base; patient self-management support lacks a reimbursement mechanism	Meta-analyses are needed to explore the safety of digital apps/tools
Medication safety: medication adherence	Positive impact on adherence: medication self-monitoring and self-management; online access to notes; pharmacist education; simplified dosing regimens	High readiness for adoption; safety benefits of patient engagement to support medication adherence are not currently disseminated	Explore caregiver role in supporting medication administration
Medication safety: pharmacovigilance, other adverse events	Patients' reports of adverse events and postmarketing medication adverse events are distinct from and more expansive than provider reports	Already implemented in many European countries; US limitations include interoperability between EMRs, the FDA, and pharmaceutical companies	Investigate prospectively whether patients' reports reduce or prevent adverse events.
Medication safety: medication administration	Effective reduction of administration errors: patient education, patient monitoring	Adequate evidence base; EMR interoperability across prescribers, pharmacy, and home care limits adoption	Home and community-based studies needed Trials should be integrated between community pharmacies and prescribers

Hospital readmissions	Postdischarge symptom self-monitoring and self-management: mixed evidence Patient and family discharge education: mixed evidence Community health worker support: null impact	Moderate readiness for adoption; efficacy is mixed, but postdischarge monitoring may be important for high-risk patients	Explore the role of family education and support Study the roles of health coaches, navigators, and health care workers explicitly for readmission and safety outcomes
-----------------------	---	--	---

SOURCE Authors' analysis of major findings from fifty-three articles that met the study's inclusion criteria. NOTES A version of the table with full results is available as online appendix exhibit A4 (see note 20 in text). INR is international normalized ratio, which is an important element of monitoring anticoagulants. EMR is electronic medical record. FDA is Food and Drug Administration.

Acknowledgment

Anjana Sharma, Natalie Rivadeneira, and Urmimala Sarkar were supported by the Gordon and Betty Moore Foundation (Award No. 6890). Sarkar was also supported by the National Cancer Institute (Grant No. K24 CA212294-01). An earlier version of the manuscript was presented at a working paper review session in Washington, D.C., April 10, 2018, organized by *Health Affairs* and supported by the Gordon and Betty Moore Foundation.

Bios for 2018-0716_Sharma

Bio 1: Anjana E. Sharma (anjana.sharma@ucsf.edu) is an assistant professor of family and community medicine at the University of California San Francisco (UCSF) and a primary care physician at the Zuckerberg San Francisco General Hospital's Family Health Center.

Bio 2: Natalie A. Rivadeneira is a research data analyst in the Center for Vulnerable Populations in the UCSF Division of General Internal Medicine at Zuckerberg San Francisco General Hospital and Trauma Center.

Bio 3: Jill Barr-Walker is a clinical librarian at the Zuckerberg San Francisco General Hospital and Trauma Center and UCSF.

Bio 4: Rachel J. Stern is an assistant professor of medicine at UCSF and a primary care physician and hospitalist at the Zuckerberg San Francisco General Hospital and Trauma Center. .

Bio 5: Amanda K. Johnson is director of primary care integration, NYC Health+Hospitals, in New York City.

Bio 6: Urmimala Sarkar is an associate professor of medicine in the Division of General Internal Medicine, UCSF, and a primary care physician at Zuckerberg San Francisco General Hospital's Richard H. Fine People's Clinic.

Appendix

Appendix Exhibit A1. Search strategies for all databases.

Database	Search strategy	Number of results
PubMed	<p>((("Patient Participation"[Mesh] OR "patient involvement"[tiab] OR "patient involved"[tiab] OR "patient engagement"[tiab] OR "patient engaged"[tiab] OR "patient participant"[tiab] OR "patient participation"[tiab] OR "patient contribution"[tiab] OR "patient complaint"[tiab] OR "patient report"[tiab] OR "patient reporting"[tiab] OR "patient-empowering"[tiab] OR "patient empowerment"[tiab] OR "patient partnership"[tiab] OR "patient activation"[tiab] OR "patient led"[tiab] OR "patient initiated"[tiab] OR "patient and public involvement"[tiab] OR co-creation[tiab] OR cocreation[tiab] OR co-created[tiab] OR co-create[tiab] OR co-design[tiab] OR codesign[tiab] OR co-designed[tiab] OR "family participation"[tiab] OR "family involvement"[tiab] OR "family engagement"[tiab] OR "family empowerment"[tiab] OR "family partnership"[tiab] OR "family activation"[tiab] OR "caregiver participation"[tiab] OR "caregiver involvement"[tiab] OR "caregiver engagement"[tiab] OR "caregiver empowerment"[tiab] OR "caregiver partnership"[tiab] OR "caregiver activation"[tiab] OR "patient role"[tiab] OR "patient roles"[tiab] OR "patient decision making"[tiab] OR "shared decision making"[tiab] OR "self management"[tiab]))</p> <p>AND</p> <p>("Adverse Drug Reaction Reporting Systems"[Mesh] OR "Safety Management"[Mesh] OR "Medical Errors"[Mesh] OR "Diagnostic Errors"[Mesh] OR "Medication Errors"[Mesh] OR "Patient Safety"[Mesh] OR "Patient Harm"[Mesh] OR "Iatrogenic Disease/prevention and control"[Mesh] OR "Cross Infection/prevention and control"[Mesh] OR "Risk Assessment"[Mesh] OR "Root Cause Analysis"[Mesh] OR adverse[tiab] OR safe[tiab] OR safety[tiab] OR harm[tiab] OR harms[tiab] OR harmed[tiab] OR harmful[tiab] OR unsafe[tiab] OR "safety management"[tiab] OR "safety monitoring"[tiab] OR "safety monitor"[tiab] OR "adverse reporting"[tiab] OR negligence[tiab] OR negligent[tiab] OR "near miss"[tiab] OR "near misses"[tiab] OR "risk assessment"[tiab] OR "event review"[tiab] OR iatrogenic[tiab] OR iatrogenesis[tiab] OR misdiagnosis[tiab] OR "missed diagnosis"[tiab] OR "drug interactions"[tiab] OR "inappropriate prescribing"[tiab] OR falling[tiab] OR "home safety"[tiab] OR "outdated medication"[tiab] OR "medication reconciliation"[tiab] OR overdos*[tiab] OR underdos*[tiab] OR ((error*[tiab] OR mistake*[tiab]) AND (medical[tiab] OR medication*[tiab] OR diagnos*[tiab] OR prevent*[tiab] OR detect*[tiab] OR disclos*[tiab])))</p> <p>AND</p> <p>(review[pt] OR review[tw] OR meta-analysis[tw] OR systematic[sb]))</p>	1727

Embase	<p>('patient participation'/exp OR "patient involvement":ab,ti OR "patient involved":ab,ti OR "patient engagement":ab,ti OR "patient engaged":ab,ti OR "patient participant":ab,ti OR "patient participation":ab,ti OR "patient contribution":ab,ti OR "patient complaint":ab,ti OR "patient report":ab,ti OR "patient reporting":ab,ti OR "patient-empowering":ab,ti OR "patient empowerment":ab,ti OR "patient partnership":ab,ti OR "patient activation":ab,ti OR "patient led":ab,ti OR "patient initiated":ab,ti OR "patient and public involvement":ab,ti OR co-creation:ab,ti OR cocreation:ab,ti OR co-created:ab,ti OR co-create:ab,ti OR co-design:ab,ti OR codesign:ab,ti OR co-designed:ab,ti OR "family participation":ab,ti OR "family involvement":ab,ti OR "family engagement":ab,ti OR "family empowerment":ab,ti OR "family partnership":ab,ti OR "family activation":ab,ti OR "caregiver participation":ab,ti OR "caregiver involvement":ab,ti OR "caregiver engagement":ab,ti OR "caregiver empowerment":ab,ti OR "caregiver partnership":ab,ti OR "caregiver activation":ab,ti OR "patient role":ab,ti OR "patient roles":ab,ti OR "patient decision making":ab,ti OR "shared decision making":ab,ti OR "self management":ab,ti)</p> <p>AND</p> <p>('adverse drug reaction'/exp OR 'cross infection'/exp OR 'medical error'/exp OR 'patient safety'/exp OR 'patient harm'/exp OR 'root cause analysis'/exp OR "adverse event":ab,ti OR "adverse events":ab,ti OR safe:ab,ti OR safety:ab,ti OR harm:ab,ti OR harms:ab,ti OR harmed:ab,ti OR harmful:ab,ti OR unsafe:ab,ti OR "safety management":ab,ti OR "safety monitoring":ab,ti OR "safety monitor":ab,ti OR "adverse reporting":ab,ti OR negligence:ab,ti OR negligent:ab,ti OR "near miss":ab,ti OR "near misses":ab,ti OR "risk assessment":ab,ti OR "event review":ab,ti OR iatrogenic:ab,ti OR iatrogenesis:ab,ti OR misdiagnosis:ab,ti OR "missed diagnosis":ab,ti OR "drug interactions":ab,ti OR "inappropriate prescribing":ab,ti OR ((error*:ab,ti OR mistake*:ab,ti) AND (medical:ab,ti OR medication*:ab,ti OR diagnos*:ab,ti OR prevent*:ab,ti OR detect*:ab,ti OR disclos*:ab,ti)))</p> <p>AND</p> <p>('review'/it OR review:ab,ti OR meta-analysis:ab,ti)</p>	1647
CINAHL	<p>((MH "Consumer Participation") OR (AB "patient involvement" OR "patient involved" OR "patient engagement" OR "patient engaged" OR "patient participant" OR "patient participation" OR "patient contribution" OR "patient complaint" OR "patient report" OR "patient reporting" OR "patient-empowering" OR "patient empowerment" OR "patient partnership" OR "patient activation" OR "patient led" OR "patient initiated" OR "patient and public involvement" OR co-creation OR cocreation OR co-created OR co-create OR co-design OR codesign OR co-designed OR "family participation" OR "family involvement" OR "family engagement" OR "family empowerment" OR "family partnership" OR "family activation" OR "caregiver participation" OR "caregiver involvement" OR "caregiver engagement" OR "caregiver empowerment" OR "caregiver partnership" OR "caregiver activation" OR "patient role" OR "patient roles" OR "patient decision making" OR "shared decision making" OR "self management"))</p> <p>AND</p> <p>((MH "Patient Safety") OR (MH "Iatrogenic Disease/PC") OR (MH "Cross Infection/PC") OR (MH "Risk Assessment") OR (MH "Root Cause Analysis")) OR</p>	475

	<p>(AB "adverse event" OR "adverse events" OR safe OR safety OR harm OR harms OR harmed OR harmful OR unsafe OR "safety management" OR "safety monitoring" OR "safety monitor" OR "adverse reporting" OR negligence OR negligent OR "near miss" OR "near misses" OR "risk assessment" OR "event review" OR iatrogenic OR iatrogenesis OR misdiagnosis OR "missed diagnosis" OR "drug interactions" OR "inappropriate prescribing" OR ((AB error* OR mistake*) AND (AB medical OR medication* OR diagnos* OR prevent* OR detect* OR disclos*)))</p> <p>AND</p> <p>((AB review OR meta-analysis) OR (TI review OR meta-analysis))</p>	
PsycINFO	<p>((MAINSUBJECT.EXACT("Client Participation")) OR (ALL "patient involvement" OR "patient involved" OR "patient engagement" OR "patient engaged" OR "patient participant" OR "patient participation" OR "patient contribution" OR "patient complaint" OR "patient report" OR "patient reporting" OR "patient-empowering" OR "patient empowerment" OR "patient partnership" OR "patient activation" OR "patient led" OR "patient initiated" OR "patient and public involvement" OR co-creation OR cocreation OR co-created OR co-create OR co-design OR codesign OR co-designed OR "family participation" OR "family involvement" OR "family engagement" OR "family empowerment" OR "family partnership" OR "family activation" OR "caregiver participation" OR "caregiver involvement" OR "caregiver engagement" OR "caregiver empowerment" OR "caregiver partnership" OR "caregiver activation" OR "patient role" OR "patient roles" OR "patient decision making" OR "shared decision making" OR "self management"))</p> <p>AND</p> <p>((MAINSUBJECT.EXACT("Side Effects (Drug)") OR MAINSUBJECT.EXACT("Side Effects (Treatment)") OR MAINSUBJECT.EXACT("Patient Safety") OR MAINSUBJECT.EXACT("Risk Assessment")) OR (ALL adverse OR safe OR safety OR harm OR harms OR harmed OR harmful OR unsafe OR "safety management" OR "safety monitoring" OR "safety monitor" OR "adverse reporting" OR negligence OR negligent OR "near miss" OR "near misses" OR "risk assessment" OR "event review" OR iatrogenic OR iatrogenesis OR misdiagnosis OR "missed diagnosis" OR "drug interactions" OR "inappropriate prescribing" OR ((ALL error* OR mistake*) AND (ALL medical OR medication* OR diagnos* OR prevent* OR detect* OR disclos*))))</p> <p>AND</p> <p>(ALL review OR meta-analysis)</p>	390
Cochrane Library	<p>("patient involvement" OR "patient involved" OR "patient engagement" OR "patient engaged" OR "patient participant" OR "patient participation" OR "patient contribution" OR "patient complaint" OR "patient report" OR "patient reporting" OR "patient-empowering" OR "patient empowerment" OR "patient partnership" OR "patient activation" OR "patient led" OR "patient initiated" OR "patient and public involvement" OR co-creation OR cocreation OR co-created OR co-create OR co-design OR codesign OR co-designed OR "family participation" OR "family involvement" OR "family engagement" OR "family empowerment" OR "family partnership" OR "family activation" OR "caregiver participation" OR "caregiver involvement" OR "caregiver engagement" OR "caregiver empowerment" OR "caregiver partnership" OR "caregiver activation" OR "patient role" OR "patient roles" OR "patient decision making" OR "shared decision making" OR "self management")</p>	191

	<p>AND</p> <p>(adverse OR safe OR safety OR harm OR harms OR harmed OR harmful OR unsafe OR "safety management" OR "safety monitoring" OR "safety monitor" OR "adverse reporting" OR negligence OR negligent OR "near miss" OR "near misses" OR "risk assessment" OR "event review" OR iatrogenic OR iatrogenesis OR misdiagnosis OR "missed diagnosis" OR "drug interactions" OR "inappropriate prescribing" OR ((error* OR mistake*) AND (medical OR medication* OR diagnos* OR prevent* OR detect* OR disclos*)))</p>	
Total number of results		4430
Total number of duplicates		1339
Total number of results after de-duplication		3091

NOTES: All searches were conducted on February 13, 2018. No language or date limits were used.

Appendix Exhibit A2. Inclusion and exclusion criteria

Include

-
1. Self-identified review

 2. Intervention includes the involvement of patients/families/caregivers in their own care in the individual level or the system level

 3. Comparison group is usual care or non-engaged patients

 4. Outcome measures patient safety event, either quantitatively or qualitatively

 5. Article published in English language

 6. Study setting in any country

Exclude

-
1. Not a review

 2. Intervention does not involve patient engagement

 3. Outcome does not track patient safety outcomes

 4. Published before 2007 or after 2017

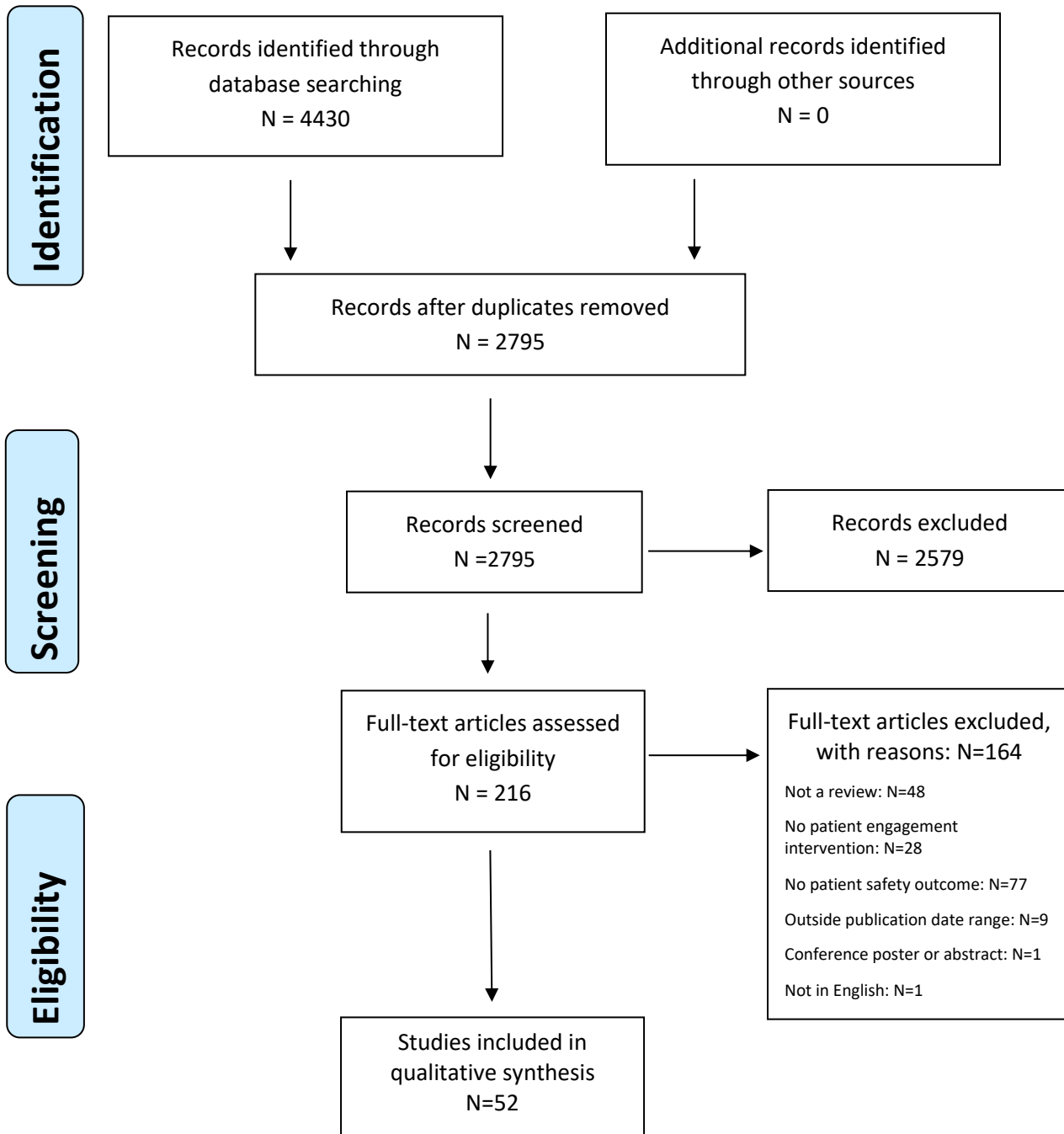
 5. Conference poster or abstract

 6. Not related to health care

 7. The original review that this review is updating

 8. No summary estimates provided

Appendix Exhibit A3. PRISMA flowchart



SOURCE: Adapted from Moher et al¹⁷

Appendix Exhibit A4. Exhibit 1, expanded. Summary of included studies, evidence, and review quality

SAFETY TARGET/CONDITION		PATIENT ENGAGEMENT INTERVENTION	REVIEW STUDY QUALITY WITH APPLICABLE STUDIES (AMSTAR 8-11 = HIGH quality; 4-7 = MEDIUM; 0-3 = LOW quality)	APPLICABLE STUDIES (with reference)	READINESS FOR BROAD SCALE ADOPTION	RESEARCH GAPS
Anticoagulation management/Prevention of bleeding, thromboembolism, mortality related to anticoagulant use		Patient self-monitoring of INR (patient self-testing with clinic-directed dose adjustment). Patient self-management (patient self-testing and patient-directed dose adjustment)	High:(11: Garcia; 10: Ryan; 9: Wells, Bloomfield 2011a; 8: Heneghan 2016, Christensen); Medium: (7: Sharma 2015a and 2015b, Heneghan 2012; 6: Heneghan 2006; 5: Medical Advisory Secretariat, Bloomfield 2011b); Low: (3: Cumberworth; 2: Pozzi; 0: Swedish Council, Cayley, Koerfer)	1) Self-monitoring and self-management: Reduced clot (Heneghan 2016; Cumberworth, Bloomfield 2011 ^{a,b} , Cayley, Garcia, Heneghan 2006); Reduced mortality (Cumberworth, Garcia, Cayley, Heneghan 2006); Mixed effect on bleed (Cumberworth mixed, Cayley (reduction in minor bleed), Heneghan 2006 null). 2) Self-management alone: Reduced clot (Sharma ^{a,b} , Ryan Secretariat, Swedish); Reduced mortality (Ryan, Christensen), null on bleeding (Swedish), improved time in therapeutic range (Pozzi), fewer "major complications" (Christensen). 3) Self-monitoring alone: Reduced clot (Heneghan 2012, Wells), reduced mortality (Heneghan 2012, Wells) and Null on bleed (Heneghan 2012). 4) Self testing/self-management is non-inferior (Bloomfield VA); self-efficacy associated with fewer bleeds and clots (Koerfer)	High readiness for adoption; however, most studies had some parameters for patient and provider eligibility. Up-front distribution costs of self-management devices and clinic communication infrastructure must be considered.	Barriers to implementation for patients and providers are unexplored; research needed to assess if anticoagulation can be extrapolated to other high-risk medications such as insulin or antiarrhythmics.
Diabetes/Prevention of hypoglycemia		Digital apps/tools; self-management education; patient activation interventions	High: (8: Wu, Bolen). Low: (1: Iqbal)	Wu: Apps have mixed effect for reducing hypoglycemia in type 1 and type 2 (3/4 trials null; 1/4 trials showed reduction); Bolen: Patient activation interventions had a null impact on hypoglycemia for type 2; Iqbal: Self-management education prevents hypoglycemia and DKA in type 1 DM.	Limited and may only be impactful for type 1 DM; lack of insurance reimbursement may impede implementation of patient self-management interventions	Robust meta-analyses are needed to explore safety outcomes for of digital tools or apps; only 1 review addressed digital self-management.
Medication safety	Medication adherence	Medication self-monitoring and self-management programs, pharmacist education, simplified dosing regimens	High (10: Ryan); Medium (6: Williams; 5: Vermeir); Low (0: Bourbeau)	Ryan: Various education and self-management programs may benefit med adherence; Williams: Patient education improves adherence; Vermeir 2017: Patient access to online notes improves adherence; Bourbeau: Patient education improves COPD treatment adherence.	High readiness for adoption; easy tools to support patient education for med adherence are not currently disseminated	Research on education to support caregiver medication administration is needed
	Pharmacovigilance and other adverse events	Patient reporting of adverse events/post-marketing medication adverse events	Medium: (6: Harrison, Gilbert; 5: Lang; 4: Ward, Blenkinsopp, Inacio), to Low (2: Avery; 1: Kinnunen; 0:Berrewaerts)	Patients report more expansive adverse events than healthcare providers (Harrison, Gilbert, Lang, Blenkinsopp, Inacio, Kinnunen, Berrewaerts); Patient reporting is feasible (Ward, Avery)	Is already implemented in many European countries. US-based systems will require adaptations in EMR or links between FDA and providers to improve direct patient reporting.	Prospective trials needed for how actual patient reporting translates into long-term reduction or prevention of future adverse events
	Medication administration errors	Patient education, patient monitoring	Medium (5: Mira; 4: CADTH; 4: Kim; Low (1: Schwappach, Woodward)	Mira: Patients commit med errors 19-59% of the time; CADTH: Family discharge education reduced home med preparation errors; Kim: Patient education and patient-led medication reconciliation improved medication administration safety and medication accuracy; Schwappach: Patients/families can participate in reducing chemotherapy administration errors; Woodward: Patient engagement reduces medication errors	Need for integration between prescriber and pharmacist medication education; current lack of accountability for who provides home medication education	Home and community-based studies needed, such as integrated trials between pharmacy and medication prescribers
Administrative errors/Errors in patient chart		Patients access EMR-portal to review and correct medication lists; schedule appointments; community engagement	High (9: Mold); Medium (5: Vermeir); Low (3: Zhao, 0: Leonhardt)	Mold: Patient portal was associated with twice as many corrections to the medication list; Vermeir: Patient portal access to notes can reduce administration errors; Zhao: Portal access reduces no-shows and wrong appointment	High readiness for adoption as most EMRs have built-in patient portals; must account for HIPAA and online security as well as	Prospective trials lacking that correlate patient portal access with medication safety

			type; Leonhardt: Community engagement/education can reduce patient med list discrepancies	limited English proficiency or lower digital literacy	outcomes or correlation with diagnostic errors
Diagnostic error	Patients/families question a diagnosis or seek a second opinion from a new provider	High (8: Payne)	Payne: Patient pursuit in a second opinion can change diagnosis, treatment and prognosis (10-62%)	Low readiness; more research needed	Lack of gold standards for diagnosis; limited research in general on diagnostic error and the patient experience; research needed to explore how providers can be notified about a diagnostic error
Malpractice lawsuits	Shared decision-making tools	High (8: Durand)	Durand: There is insufficient evidence for shared decision-making tools to reduce malpractice suits	Low readiness; emerging area	Need for patient and caregiver involvement in review of malpractice lawsuits to identify upstream contributors
Hospital readmissions/High morbidity chronic conditions: CHF, COPD, Pneumonia	Community health worker support; post-discharge symptom self-monitoring and self-management; patient and family discharge education	Medium (7: Domingo, Mackie; 6: Ditewig; 5: Burke; 4: CADTH, Moriartes)	Domingo: Structured discharge (w patient engagement) had no effect on pneumonia readmissions; Mackie: Family engagement had modest reduction on readmissions; Ditewig: Impact of self-management is unknown for CHF readmissions; Burke 2014: Patient self-monitoring and self-managing symptoms after d/c reduced readmissions (disease-agnostic); CADTH: Community health workers had null impact on hospital readmission, but reduction in subgroup of those who were already re-admits; Moriartes: Patient education and patient activation reduce readmissions	While results are mixed, there are net positive moderate quality results for positive impact of patient self-monitoring and self-management post-discharge.	Role of family education/support and health coaches/navigators/health workers merits more research with discrete safety outcomes
Healthcare associated infection	Patients educated and supported to monitor health workers and to request them to wash hands	Medium (7: Butenko); Low (2: McGuckin; 1: Woodward; 0: Landers).	Butenko and Berger: Patients can participate in hand hygiene; McGuckin: Patient education for hand hygiene engagement resulted in lower healthcare-acquired infections; Woodward: Patient participation improves hand hygiene; Landers: Patient engagement increases hand hygiene	Currently limited as there has been little assessment of absolute reduction in infections	Prospective trials to evaluate healthcare-acquired infections is needed; work needed to explore how to overcome identified barriers and facilitators to patient capacity to "speak up"
Pressure Ulcers	Self-management; patient notification of providers for warning signals for ulcers	Low (3: Tung)	Tung: There is low-to-moderate effectiveness in self-management technologies for reducing risk factors for pressure ulcer development	Limited, but enhancing mechanisms for patients to report pressure ulcer warning signs is low-risk and may be appropriate for long-term care settings	Research needed to address patient education, implementation facilitators and barriers

Notes: INR: International Normalized Ratio, DKA: Diabetic ketoacidosis, DM: Diabetes mellitus, COPD: Chronic obstructive pulmonary disease, US: United States, EMR: Electronic medical record, FDA: Food and Drug Administration, HIPAA: Health Insurance Portability and Accountability Act, CHF: Congestive heart failure.

Appendix Exhibit A5. Reviews on anticoagulation management

High Quality

1. Garcia-Alamino JM, Ward AM, Alonso-Coello P, Perera R, Bankhead C, Fitzmaurice D, et al. Self-monitoring and self-management of oral anticoagulation. *Cochrane Database Syst Rev.* 2010 Apr 14;(4):CD003839.
2. Ryan R, Santesso N, Lowe D, Hill S, Grimshaw J, Prictor M, et al. Interventions to improve safe and effective medicines use by consumers: an overview of systematic reviews. *Cochrane Database Syst Rev.* 2014 Apr 29;(4):CD007768.
3. Wells, P. S., Brown, A., Jaffey, J., et al. Safety and effectiveness of point-of-care monitoring devices in patients on oral anticoagulant therapy: a meta-analysis. *Open medicine : a peer-reviewed, independent, open-access journal.* 2007;1(3):e131-46.
4. Bloomfield HE, Krause A, Greer N, Taylor BC, MacDonald R, Rutks I, et al. Meta-analysis: effect of patient self-testing and self-management of long-term anticoagulation on major clinical outcomes. *Ann Intern Med.* 2011 Apr 5;154(7):472–82.
5. Heneghan, C J, Garcia A, J M, Spencer, E A, et al. Self-monitoring and self-management of oral anticoagulation. *The Cochrane database of systematic reviews.* 2016 Jul 5;7:Cd003839.
6. Christensen, T D, Johnsen, S P, Hjortdal, V E, et al. Self-management of oral anticoagulant therapy: a systematic review and meta-analysis. *International journal of cardiology.* 2007 May 16;118:54–61.

Medium Quality

7. Sharma, P, Scotland, G, Cruickshank, M, et al. Is self-monitoring an effective option for people receiving long-term vitamin K antagonist therapy? A systematic review and economic evaluation. *BMJ Open.* 2015 Jun 25;5:e007758.
8. Sharma, P, Scotland, G, Cruickshank, M, et al. The clinical effectiveness and cost-effectiveness of point-of-care tests (CoaguChek system, INRatio2 PT/INR monitor and ProTime Microcoagulation system) for the self-monitoring of the coagulation status of people receiving long-term vitamin K antagonist therapy, compared with standard UK practice: systematic review and economic evaluation. *Health technology assessment (Winchester, England).* 2015 Jun;19:1–172.
9. Heneghan, C J, Ward, A, Perera, R, et al. Self-monitoring of oral anticoagulation: systematic review and meta-analysis of individual patient data. *Lancet (London, England).* 2012 Jan 28;379:322–34.
10. Heneghan, C J, Alonso C, P, Garcia A, J M, et al. Self-monitoring of oral anticoagulation: A systematic review and meta-analysis. *Lancet.* 2006;367:404–11.

11. Medical Advisory Secretariat. Point-of-Care International Normalized Ratio (INR) Monitoring Devices for Patients on Long-term Oral Anticoagulation Therapy: An Evidence-Based Analysis. *Ont Health Technol Assess Ser.* 2009;9(12):1–114.
12. Bloomfield, H E, Taylor, B C, Krause, A, et al. VA Evidence-based Synthesis Program Reports. Safe and Effective Anticoagulation in the Outpatient Setting: A Systematic Review of the Evidence. 2011;

Low Quality

13. Cumberworth A, Mabvuure NT, Hallam M-J, Hindocha S. Is home monitoring of international normalised ratio safer than clinic-based monitoring? *Interact Cardiovasc Thorac Surg.* 2013 Feb;16(2):198–201.
14. Pozzi, M., Mitchell, J., Henaine, A. M., et al. International normalized ratio self-testing and self-management: improving patient outcomes. *Vascular health and risk management.* 2016;12:387–92.
15. Swedish Council on Health T, Assessment. SBU Systematic Review Summaries. Self-Testing and Self-Management of Oral Anticoagulation. 2007;
16. Cayley Jr, W. E. Self-monitoring and self-management of anticoagulation therapy. *American Family Physician.* 2011;84(3):266–8.
17. Koerfer R, Reiss N, Koertke H. International normalized ratio patient self-management for mechanical valves: is it safe enough? *Curr Opin Cardiol.* 2009 Mar;24(2):130–5.

Appendix Exhibit A6. Reviews on diabetes management/prevention of hypoglycemia

High Quality

1. Bolen SD, Chandar A, Falck-Ytter C, Tyler C, Perzynski AT, Gertz AM, et al. Effectiveness and safety of patient activation interventions for adults with type 2 diabetes: systematic review, meta-analysis, and meta-regression. *J Gen Intern Med.* 2014 Aug;29(8):1166–76.
2. Wu, Y, Yao, X, Vespasiani, G, et al. Mobile App-Based Interventions to Support Diabetes Self-Management: A Systematic Review of Randomized Controlled Trials to Identify Functions Associated with Glycemic Efficacy. *JMIR mHealth and uHealth.* 2017 Mar 14;5:e35.

Low Quality

3. Iqbal A, Heller SR. The role of structured education in the management of hypoglycaemia. *Diabetologia.* 2018 Apr;61(4):751–60.

Appendix Exhibit A7. Reviews on medication safety

Medication adherence

High Quality

1. Ryan R, Santesso N, Lowe D, Hill S, Grimshaw J, Pritcor M, et al. Interventions to improve safe and effective medicines use by consumers: an overview of systematic reviews. *Cochrane Database Syst Rev*. 2014 Apr 29;(4):CD007768.

Medium Quality

2. Williams A, Manias E, Walker R. Interventions to improve medication adherence in people with multiple chronic conditions: a systematic review. *J Adv Nurs*. 2008 Jul;63(2):132–43.
3. Vermeir P, Degroote S, Vandijck D, Van Tiggelen H, Peleman R, Verhaeghe R, et al. The patient perspective on the effects of medical record accessibility: a systematic review. *Acta Clin Belg*. 2017 Jun;72(3):186–94.

Low Quality

4. Bourbeau J, Bartlett SJ. Patient adherence in COPD. *Thorax*. 2008 Sep;63(9):831–8.

Pharmacovigilance and adverse events reporting

Medium Quality

5. Harrison, R, Walton, M, Manias, E, et al. The missing evidence: a systematic review of patients' experiences of adverse events in health care. *International journal for quality in health care : journal of the International Society for Quality in Health Care*. 2015 Dec;27:424–42.
6. Gilbert, A, Ziegler, L, Martland, M, et al. Systematic Review of Radiation Therapy Toxicity Reporting in Randomized Controlled Trials of Rectal Cancer: A Comparison of Patient-Reported Outcomes and Clinician Toxicity Reporting. *International journal of radiation oncology, biology, physics*. 2015 Jul 1;92:555–67.
7. Lang, S, Velasco G, M, Heintze, C. Patients' views of adverse events in primary and ambulatory care: a systematic review to assess methods and the content of what patients consider to be adverse events. *BMC family practice*. 2016 Jan 27;17:6.
8. Ward, J K, Armitage, G. Can patients report patient safety incidents in a hospital setting? A systematic review. *BMJ quality & safety*. 2012 Aug;21:685–99.

9. Blenkinsopp, A, Wilkie, P, Wang, M, et al. Patient reporting of suspected adverse drug reactions: a review of published literature and international experience. *British journal of clinical pharmacology*. 2007 Feb;63:148–56.
10. Inacio, P, Cavaco, A, Airaksinen, M. The value of patient reporting to the pharmacovigilance system: a systematic review. *British journal of clinical pharmacology*. 2017 Feb;83:227–46.

Low Quality

11. Avery, A J, Anderson, C, Bond, C M, et al. Evaluation of patient reporting of adverse drug reactions to the UK “Yellow Card Scheme”: literature review, descriptive and qualitative analyses, and questionnaire surveys. *Health technology assessment (Winchester, England)*. 2011 May;15:1–234, iii–iv.
12. Kinnunen U-M, Sarantob K. It is time for self-incident-reporting for patients and their families in every health care organization: a literature review. *Stud Health Technol Inform*. 2013;192:92–6.
13. Berrewaerts J, Delbecq L, Orban P, Desseilles M. Patient Participation and the Use of Ehealth Tools for Pharmacovigilance. *Front Pharmacol*. 2016;7:90.

Medication administration errors

Medium Quality

14. Mira JJ, Lorenzo S, Guilabert M, Navarro I, Pérez-Jover V. A systematic review of patient medication error on self-administering medication at home. *Expert Opin Drug Saf*. 2015 Jun;14(6):815–38.
15. CADTH Rapid Response Reports. Patient- and Family-Centered Care Initiatives in Acute Care Settings: A Review of the Clinical Evidence, Safety and Guidelines. 2015.
16. Kim, J M, Suarez C, C, Berger, Z, et al. Evaluation of Patient and Family Engagement Strategies to Improve Medication Safety. *The patient*. 2017 Aug 9.

Low Quality

17. Schwappach DLB, Wernli M. Medication errors in chemotherapy: incidence, types and involvement of patients in prevention. A review of the literature. *Eur J Cancer Care (Engl)*. 2010 May;19(3):285–92.

18. Woodward HI, Mytton OT, Lemer C, Yardley IE, Ellis BM, Rutter PD, et al. What Have We Learned About Interventions to Reduce Medical Errors? *Annual Review of Public Health*. 2010 Mar;31(1):479–97.

Appendix Exhibit A8. Reviews on administrative errors

High Quality

1. Mold, F, de L, S, Sheikh, A, et al. Patients' online access to their electronic health records and linked online services: a systematic review in primary care. *The British journal of general practice : the journal of the Royal College of General Practitioners*. 2015 Mar;65:e141-51.

Medium Quality

2. Vermeir P, Degroote S, Vandijck D, Van Tiggelen H, Peleman R, Verhaeghe R, et al. The patient perspective on the effects of medical record accessibility: a systematic review. *Acta Clin Belg*. 2017 Jun;72(3):186–94.

Low Quality

3. Zhao P, Yoo I, Lavoie J, Lavoie BJ, Simoes E. Web-Based Medical Appointment Systems: A Systematic Review. *Journal of Medical Internet Research*. 2017;19(4):e134.
4. Leonhardt, K K. HRET patient safety leadership fellowship: the role of "community" in patient safety. *American journal of medical quality : the official journal of the American College of Medical Quality*. 2010 Jun;25:192–6.

Appendix Exhibit A9. Reviews on diagnostic errors

High Quality

1. Payne VL, Singh H, Meyer AND, Levy L, Harrison D, Graber ML. Patient-initiated second opinions: systematic review of characteristics and impact on diagnosis, treatment, and satisfaction. *Mayo Clin Proc.* 2014 May;89(5):687–96.

Appendix Exhibit A10. Reviews on malpractice lawsuits

High Quality

1. Durand, M A, Moulton, B, Cockle, E, et al. Can shared decision-making reduce medical malpractice litigation? A systematic review. BMC health services research. 2015 Apr 18;15:167.

Appendix Exhibit A11. Reviews on hospital readmissions

Medium Quality

1. Domingo, G. R., Reyes, F. C., Thompson, F. V., et al. Effectiveness of structured discharge process in reducing hospital readmission of adult patients with community acquired pneumonia: A systematic review. *JBHI library of systematic reviews*. 2012;10(18):1086–121
2. Mackie, Benjamin R., Mitchell, Marion, Marshall, Prof Andrea. The impact of interventions that promote family involvement in care on adult acute-care wards: An integrative review. *Collegian*. 2018;25(1):131–40.
3. Ditewig, J B, Blok, H, Havers, J, et al. Effectiveness of self-management interventions on mortality, hospital readmissions, chronic heart failure hospitalization rate and quality of life in patients with chronic heart failure: a systematic review. *Patient education and counseling*. 2010 Mar;78:297–315.
4. Burke, R E, Guo, R, Prochazka, A V, et al. Identifying keys to success in reducing readmissions using the ideal transitions in care framework. *BMC health services research*. 2014 Sep 23;14:423.
5. CADTH Rapid Response Reports. Patient- and Family-Centered Care Initiatives in Acute Care Settings: A Review of the Clinical Evidence, Safety and Guidelines. 2015 Aug.
6. Moriates C, Mourad M. Striving for optimal care: Updates in quality, value, and patient experience. *J Hosp Med*. 2016 Feb;11(2):145–50.

Appendix Exhibit A12. Reviews on hospital acquired infections

Medium Quality

1. Butenko, S, Lockwood, C, McArthur, A. Patient experiences of partnering with healthcare professionals for hand hygiene compliance: a systematic review. JBI database of systematic reviews and implementation reports. 2017 Jun;15:1645–70.
2. Berger, Z, Flickinger, T E, Pfoh, E, et al. Promoting engagement by patients and families to reduce adverse events in acute care settings: a systematic review. BMJ quality & safety. 2014 Jul;23:548–55.

Low Quality

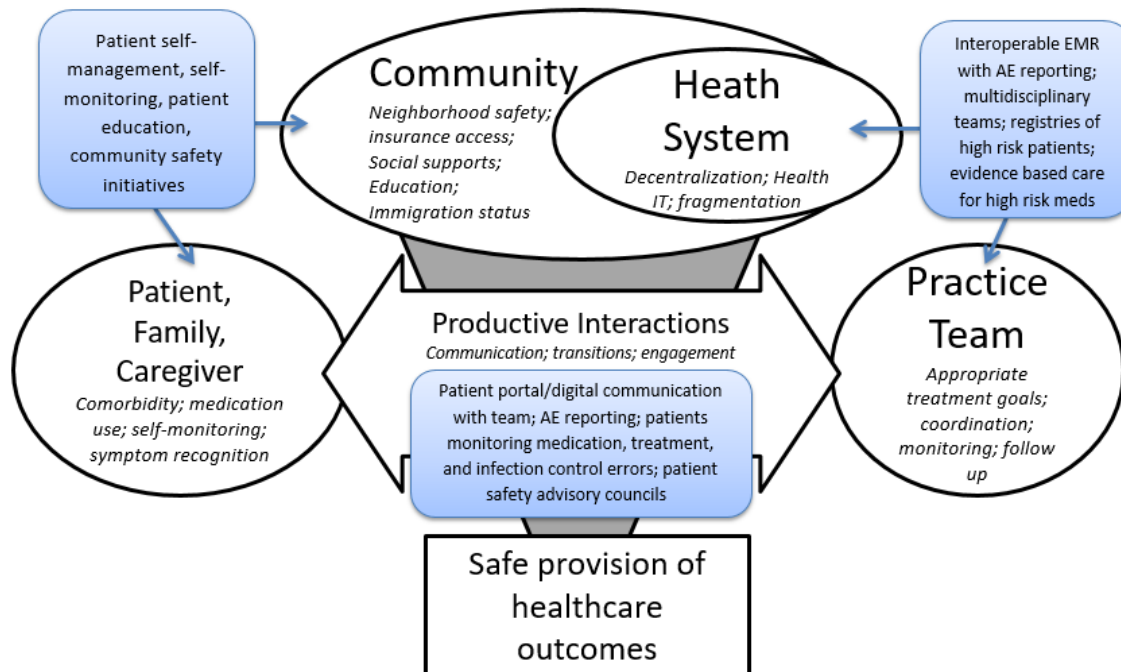
3. McGuckin, M, Storr, J, Longtin, Y, et al. Patient empowerment and multimodal hand hygiene promotion: a win-win strategy. American journal of medical quality : the official journal of the American College of Medical Quality. 2011 Feb;26:10–7.
4. Woodward HI, Mytton OT, Lemer C, Yardley IE, Ellis BM, Rutter PD, et al. What Have We Learned About Interventions to Reduce Medical Errors? Annual Review of Public Health. 2010 Mar;31(1):479–97.
5. Landers, T., Abusalem, S., Coty, M. B., et al. Patient-centered hand hygiene: The next step in infection prevention. American Journal of Infection Control. 2012;40(4 SUPPL.):S11–7.

Appendix Exhibit A13. Reviews on pressure ulcers

Low Quality

1. Tung JY, Stead B, Mann W, Ba'Pham, Popovic MR. Assistive technologies for self-managed pressure ulcer prevention in spinal cord injury: a scoping review. *J Rehabil Res Dev.* 2015;52(2):131–46.

Appendix Exhibit A14. Conceptual map of ecological model of patient engagement within care safety applying the Wagner chronic care model.



SOURCE: Adapted from Sarkar et al. (note 2 in the text)