One-to-One Observation: A Systematic Review

August 2019

Prepared for:
Department of Veterans Affairs
Veterans Health Administration
Health Services Research & Development Service
Washington, DC 20420

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PREFACE

The VA Evidence Synthesis Program (ESP) was established in 2007 to provide timely and accurate syntheses of targeted health care topics of importance to clinicians, managers, and policymakers as they work to improve the health and health care of Veterans. These reports help:

- Develop clinical policies informed by evidence;
- Implement effective services to improve patient outcomes and to support VA clinical practice guidelines and performance measures; and
- Set the direction for future research to address gaps in clinical knowledge.

The program is comprised of 4 ESP Centers across the US and a Coordinating Center located in Portland, Oregon. Center Directors are VA clinicians and recognized leaders in the field of evidence synthesis with close ties to the AHRQ Evidence-based Practice Center Program and Cochrane Collaboration. The Coordinating Center was created to manage program operations, ensure methodological consistency and quality of products, and interface with stakeholders. To ensure responsiveness to the needs of decision-makers, the program is governed by a Steering Committee comprised of health system leadership and researchers. The program solicits nominations for review topics several times a year via the program website.

Comments on this evidence report are welcome and can be sent to Nicole Floyd, Deputy Director, ESP Coordinating Center at Nicole.Floyd@va.gov.

Recommended citation: Shekelle PG, Greeley AM, Tanner EP, Mak SS, Begashaw MM, Miake-Lye IM, Beroes-Severin JM, One-to-One Observation: A Systematic Review. Washington, DC: Evidence Synthesis Program, Health Services Research and Development Service, Office of Research and Development, Department of Veterans Affairs. VA ESP Project #05-226; 2019. Posted final reports are located on the ESP search page.

This report is based on research conducted by the Evidence Synthesis Program (ESP) Center located at the **West Los Angeles VA Medical Center, Los Angeles, CA,** funded by the Department of Veterans Affairs, Veterans Health Administration, Health Services Research and Development. The findings and conclusions in this document are those of the author(s) who are responsible for its contents; the findings and conclusions do not necessarily represent the views of the Department of Veterans Affairs or the United States government. Therefore, no statement in this article should be construed as an official position of the Department of Veterans Affairs. No investigators have any affiliations or financial involvement (*eg*, employment, consultancies, honoraria, stock ownership or options, expert testimony, grants or patents received or pending, or royalties) that conflict with material presented in the report.

ACKNOWLEDGMENTS

This topic was developed in response to a nomination by Julia Neily, Associate Director, Field Office of the National Center for Patient Safety, and William Gunnar, Executive Director of the National Center for Patient Safety, for the purpose of supporting decisions related to determining whether to add patient sitters or one-to-one observation interventions to a patient safety assessment tool (PSAT) for falls. The scope was further developed with input from the topic nominators (*ie*, Operational Partners), the ESP Coordinating Center, the review team, and the technical expert panel (TEP).

In designing the study questions and methodology at the outset of this report, the ESP consulted several technical and content experts. Broad expertise and perspectives were sought. Divergent and conflicting opinions are common and perceived as healthy scientific discourse that results in a thoughtful, relevant systematic review. Therefore, in the end, study questions, design, methodologic approaches, and/or conclusions do not necessarily represent the views of individual technical and content experts.

The authors gratefully acknowledge Roberta Shanman, MLS and the following individuals for their contributions to this project:

Operational Partners

Operational partners are system-level stakeholders who have requested the report to inform decision-making. They recommend Technical Expert Panel (TEP) participants; assure VA relevance; help develop and approve final project scope and timeframe for completion; provide feedback on draft report; and provide consultation on strategies for dissemination of the report to field and relevant groups.

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Associate Director, Field Office
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William Gunnar, MD
Executive Director
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Technical Expert Panel (TEP)

To ensure robust, scientifically relevant work, the TEP guides topic refinement; provides input on key questions and eligibility criteria, advising on substantive issues or possibly overlooked areas of research; assures VA relevance; and provides feedback on work in progress. TEP members are listed below:

Christine Engstrom, PhD, CRNP, AOCN, FAANP
Acting Program Manager, Research & Analytics, Office of Nursing Services

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Associate Professor of Medicine, UCLA

Peer Reviewers

The Coordinating Center sought input from external peer reviewers to review the draft report and provide feedback on the objectives, scope, methods used, perception of bias, and omitted evidence. Peer reviewers must disclose any relevant financial or non-financial conflicts of interest. Because of their unique clinical or content expertise, individuals with potential conflicts may be retained. The Coordinating Center and the ESP Center work to balance, manage, or mitigate any potential nonfinancial conflicts of interest identified.

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EVIDENCE REPORT

INTRODUCTION

Preventing adverse events in hospitalized patients is a priority goal of patient safety programs. In-facility falls and in-facility suicide are 2 conditions identified as a priority by the technical expert panel involved in the Agency for Healthcare Research and Quality (AHRQ) 2013 report Making Health Care Safer II.[1] The patient safety practices reviewed in that report included multicomponent interventions to prevent falls, and did not explicitly deal with the use of sitters. Regarding suicide prevention, the report found that "use of staff to observe at-risk patients is frequently employed, but there is no evidence from controlled trials…." The rate of falls in acute-care hospitals is estimated to range from 1.3 to 8.9 per 1,000 patient days, which translates into well over 1,000 falls per year in a large hospital.[2] The rate of in-facility suicide is not well estimated, but it has been a Joint Commission patient safety goal since 2011. The Joint Commission has previously reported approximately 3% to 20% of inpatients fall at least once during their hospitalization and, in acute and rehabilitation hospitals, injurious falls ranged from 30% to 51% of falls.[3,4] Falls with serious injury are consistently among the Top 10 sentinel events reported to The Joint Commission's Sentinel Event database, with a majority of these falls occurring in hospitals. An estimated 700,000 to 1,000,000 hospitalized patients fall each year, and as much as one-third of these falls are considered preventable.[5,6] The Centers for Disease Control and Prevention (CDC) reported medical costs for falls totaled more than $50 billion in 2015 with evidence suggesting the annual cost is rising, especially with a rising older adult population who have an increased risk of falls with age.[5] In addition to their direct medical costs, these events cost hospitals an average of $55,000 in legal claims and proceedings and also the potential for revenue loss due to reputational concerns, since fall safety performance is frequently publicly reported.[7]

These adverse events are thought to be preventable to some degree. Nurses or other personnel have been used to monitor patient behavior in continuous or constant observation for more than 35 years[8] to prevent falls and reduce elopements and suicide/self-harm. The rationale is intuitive and rooted in tradition: with staff immediately at hand to help prevent a fall or redirect a patient from engaging in a harmful act, it has historically been considered proper to utilize the constant observation practice as a protective measure.[8] But the practice is costly. US acute care hospitals can each spend more than $1 million annually on sitters.[9]

With high costs and uncertain evidence for effectiveness, and even a lack of consensus in the literature about how constant observation should be carried out, our operational partners requested an up-to-date review of sitter use and its impact on patient outcomes, to better inform policy and practice regarding sitter use.

METHODS

TOPIC DEVELOPMENT

This topic was developed in response to a nomination by Julia Neily, Associate Director, Field Office for the National Center for Patient Safety and William Gunnar, Executive Director for the National Center for Patient Safety. Key questions were then developed with input from the topic nominator, the ESP coordinating center, the review team, and the technical expert panel (TEP).

The Key Questions were:

KQ1. What is the effectiveness of patient sitters (one-to-one observation, patient safety companions, *etc*) for reducing falls?

KQ2. What is the effectiveness of patient sitters (one-to-one observation, patient safety companions, *etc*) for reducing suicide or self-harm?

KQ3. What is the effectiveness of patient sitters (one-to-one observation, patient safety companions, *etc*) for reducing wandering?

KQ4. What is the cost-effectiveness of one-to-one observations compared to usual care for patients at risk of falls, suicide, or wandering?

The review was registered in PROSPERO: CRD42019127424.

SEARCH STRATEGY

The search strategy, including the search terms and databases used, was created by a reference librarian with more than 25 years of experience performing searches for systematic reviews. We conducted searches in PubMed from inception to 12/18/2018, Web of Science from inception to 11/29/2018, Cochrane Database of Systematic Reviews and Cochrane Trials and PsycINFO from 01/01/1970 to 12/04/2018, and CINAHL from inception to 11/30/2018. The searches used included “sitter,” “patient-sitter,” and “one-to-one observation” as the set of terms. See Appendix A for complete search strategy. We performed a gray literature search on 7/10/19, using Google and the terms “patient sitter effectiveness”. From this search, we reviewed the first 30 hits for studies that would meet eligibility criteria. We also attempted to contact 1 original author for additional detail regarding her study, but she replied that those details of the study were no longer known to her.

STUDY SELECTION

Three team members (AMG, EPT, PGS), working independently, screened the titles of retrieved citations. For titles deemed relevant by at least 1 person, abstracts were then screened independently in triplicate by team members. All disagreements were reconciled through group discussion. Full-text review was conducted in duplicate by 2 independent team members, with any disagreements resolved through discussion. Because we expected few, if any, randomized trials, we did not reject observational studies, and included both time series studies and pre/post studies. In order to be included, a study had to include “one-to-one sitters” (or “specialing,” as it is called in some other countries) or “close observation” unit as an intervention in an acute

hospital general medical/surgical or psychiatric hospital setting, and report an outcome of interest (falls, wandering, suicide/self-harm), and report that preventing this outcome was the primary goal of the intervention. Thus, we rejected several studies that were multicomponent interventions that included one-to-one sitters to prevent delirium, and which then also reported falls.[10,11] We excluded these studies because they are prone to selective outcome reporting bias. We also rejected studies in rehabilitation settings, as the focus of our partner was the acute care hospital setting.

DATA ABSTRACTION

Data extraction was completed in duplicate (AMG/EPT). All discrepancies were resolved with full group discussion. We abstracted data on the following: setting, sample size, study design, use of existing theory/logic model, control/pre-intervention sitter practice, alternative(s) to sitters, implementation details, outcomes, and post-implementation follow-up interval.

QUALITY ASSESSMENT

We used the Risk of Bias In Non-randomized Studies – of Interventions (ROBINS-I) for observational studies.[12] This tool requires an assessment of whether a study is at critical, serious, moderate, or low risk of bias (or no information) in 7 domains: confounding, selection bias, bias in measurement classification of interventions, bias due to deviations from intended interventions, bias due to missing data, bias in measurement of outcomes, and bias in selection of the reported result (see Appendix B for tool; Table 1 for ROBINS-I table). Since observational studies are not required to have published an *a priori* protocol, we operationalized the last domain (bias in selection of the reported result) as requiring that studies report the most common outcomes. We used the latest advice from the Cochrane Methods group on the application of ROBINS-I to time series studies of interventions.

DATA SYNTHESIS

The observational studies were too clinically heterogeneous to support meta-analysis; hence our synthesis is narrative.

RATING THE BODY OF EVIDENCE

Where possible, a summary of findings and quality of evidence table was used to summarize the existing evidence. We used the principles of the Grading of Recommendations Assessment, Development and Evaluation (GRADE) working group[13] plus those advocated by Howick and colleagues[14] to assess the quality of the evidence as follows:

High: We are very confident that the true effect lies close to that of the estimate of the effect.

Moderate: We are moderately confident in the effect estimate: The true effect is likely to be close to the estimate of the effect, but there is a possibility that it is substantially different.

Low: Our confidence in the effect estimate is limited: The true effect may be substantially different from the estimate of the effect.

Very Low/Insufficient: We have very little confidence in the effect estimate: The true effect is likely to be substantially different from the estimate of effect.

PEER REVIEW

A draft version of the report was reviewed by technical experts. Reviewer comments and our response are documented in Appendix C.

RESULTS

LITERATURE FLOW

We identified 4,106 potentially relevant citations for a total of 1,845 articles whose titles were screened. Of these, 131 were included at the abstract screening. From these, a total of 75 abstracts were excluded. Excluded abstracts were categorized as background (n=32), commentary (n=1), duplicate (n=1), wrong intervention (n=18), no original data (n=3), non-systematic review (n=6), no outcome of interest (n=5), not a population of interest (n=1), and setting (n=8). This left 71 publications for full-text review, of which 52 publications were excluded for the following reasons: background (n=15), condition (n=1), duplicate (n=1), wrong intervention (n=4), letter (n=2), no outcome of interest (n=12), systematic review (n=4), and unavailable (n=13). A full list of studies excluded at full-text review is included in Appendix D. A total of 19 publications were identified at full-text review as meeting initial inclusion criteria. (See Figure 1 for literature flow.) Only 2 studies[15,16] assessed the effect of adding sitters to usual care that did not include sitters; both assessed only falls as an outcome. The remaining 17 studies all assessed the effect of interventions aimed at reducing sitter use. All 17 of these studies assessed falls as the outcome of interest. There were no studies that assessed wandering or suicide-related measures as the outcome of interest. Descriptions of these studies are available in the Evidence Table (Appendix E).

The quality of the evidence was limited in that we identified no randomized trials of the intervention. Therefore, the data presented here are all from observational studies, primarily time series analyses of the effect of an intervention that may have been implemented as part of routine hospital care. Due to their design, observational studies are in general less able than randomized studies to support causal conclusions about the effectiveness of interventions. However, among our 19 observational studies we did identify 12 studies that used a time series design, and in some situations well-done time series studies can provide nearly as much support for causal conclusion as randomized studies. Our assessment of the methodologic quality/risk of bias of the included studies is presented in Table 1, using the ROBINS-I tool. Time series studies with at least 3 pre-intervention data points and 3 post-intervention datapoints were rated as low risk of bias due to confounding, since we are unaware of seasonal changes in rate of in-facility falls. Pre/post studies were rated as high risk of bias due to the possibility of confounding. As most studies were of entire wards or even hospitals, we rated them as low risk of selection bias. Bias in measurement of classification of interventions or deviations from intended interventions was rated uniformly as low risk of bias, again due to the nature of the study design and intervention, which in general was a time series or pre/post design of an entire ward or hospital before and after the implementation of an intervention. After implementation of the intervention, certainly some patients may not have gotten the intended intervention exactly the way it was intended, but we viewed this as an issue of real-world effectiveness rather than an issue of bias. Again, because of the nature of the intervention – affecting whole wards or hospitals – we judged bias due to missing data to be at low risk of bias. However, nearly all studies were judged as being at high risk of bias in measurement of outcomes, because they did not define what constituted a “fall”, and the person recording whether or not an event was a fall was not blinded to the presence or absence of the intervention. Since almost all studies were about reducing sitter use while not adversely effecting fall rates, and reported falls as their outcome, we judged almost all

studies as being at low risk of bias for selection of the reported result. Overall, all but 1 study had at least 1 domain judged as being at high risk of bias.

Figure 1: Literature Flow Chart

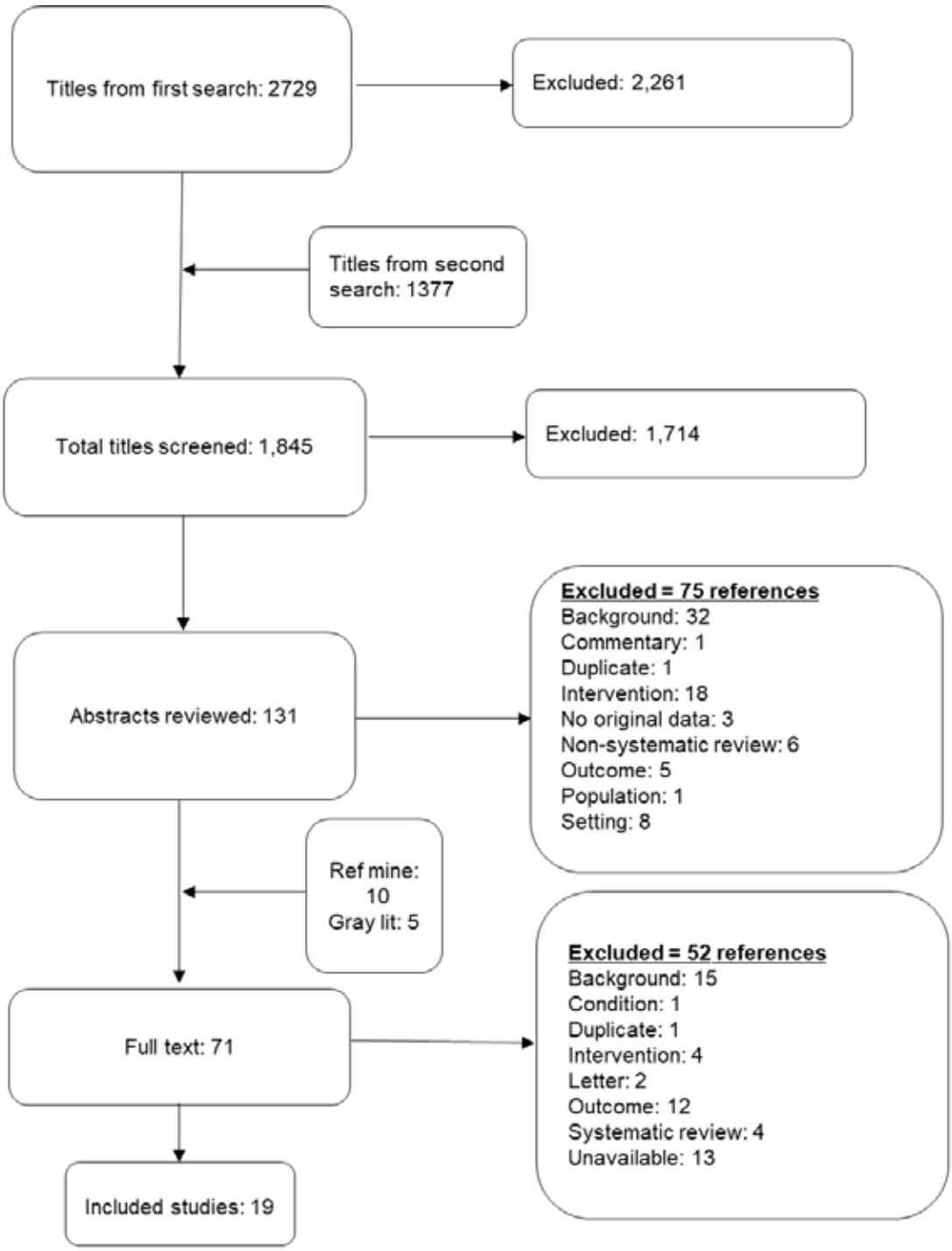

Table 1: ROBINS-I Table

	Confounding	Selection bias	Bias in measurement classification of interventions	Bias due to deviations from intended interventions	Bias due to missing data	Bias in measurement of outcomes	Bias in selection of the reported result
Adams, 2013[17]	Low	Low	Low	Low	Low	High	Low
Bock, 2016[18]	High	Low	Low	Low	Low	High	Low
Burston, 2015[19]	Low	Low	Low	Low	Low	High	Low
Cournan, 2018[20]	High	Low	Low	Low	Low	High	Low
Davis, 2017[21]	High	Low	Low	Low	Low	Low for falls Low for self-harm	Low
Donoghue, 2005[16]	Low	Low	Low	Low	Low	High	Low
Giles, 2006[15]	Low	Low	Low	Low	Low	High	Low
Jeffers, 2013[22]	Low	Low	Low	Low	Low	High	Low
McNicoll, 2013[23]	Low	Low	Low	Low	Low	High	Low
Rausch, 2010[24]	Low	Low	Low	Low	Low	High	Low
Sand-Jecklin, 2016[25]	High	Low	Low	Low	Low	High	Low
Skowronsky, 2015[26]	High	Low	Low	Low	Low	High	Low
Spano-Szekely, 2018[27]	Low	Low	Low	Low	Low	High	Low
Spiva, 2012[9]	High	Low	Low	Low	Low	High	Low

	Confounding	Selection bias	Bias in measurement classification of interventions	Bias due to deviations from intended interventions	Bias due to missing data	Bias in measurement of outcomes	Bias in selection of the reported result
Tzeng, 2008[28]	High	Low	Low	Low	Low	High	Low
Vortuba, 2016[29]	High	Low	Low	Low	Low	High	High
Weeks, 2011[30]	High	Low	Low	Low	Low	High for falls Low for fracture	Low
Westle, 2019[31]	Low	Low	Low	Low	Low	High	Low
Wray, 2014[32]	Low	Low	Low	Low	Low	High	Low

KEY QUESTION 1: What is the effectiveness of patient sitters (one-to-one observation, patient safety companions, *etc*) for reducing falls?

We identified 19 studies relevant to this question.[9,15-29,30,31,32] Of these, only 2 studies[15,16] assessed adding sitters as an intervention in order to reduce falls, whereas all other studies assessed some alternative such that sitter use could be reduced without a worsening of the number of falls or the fall rate. Nearly all studies assessed multicomponent interventions, which could include education, environmental interventions, use of formal assessment tools, video monitoring, *etc*). The components included in each study's intervention are presented in Table 2.

Table 2: Intervention Components

Intervention Components	Adams, 2013[17]	Bock, 2016[18]	Burtson, 2015[19]	Cournan, 2018[20]	Davis, 2017[21]	Donoghue, 2005[16]	Giles, 2006[15]	Jeffers, 2013[22]	McNicoll, 2013[23]	Rausch, 2010[24]	Sand-Jecklin, 2016[25]	Skowronsky, 2015[26]	Spano-Szekely, 2018[27]	Spiva, 2012[9]	Tzeng, 2008[28]	Votruba, 2016[29]	Weeks, 2011[30]	Westle, 2019[31]	Wray, 2014[32]
Video monitoring			X	X	X			X			X		X			X		X	
Creation of multi-bed close observation room						X	X		X			X							
New patient companion program (where one did not previously exist)						X	X												
Formal criteria/ guideline(s) for sitter implementation	X		X													X		X	
Nurse Assessment Tool													X	X	X				X
Gap analysis of best practices for fall prevention		X																	
Staff education	X	X	X		X		X		X		X	X				X	X	X	
Increased rounding	X										X		X						X
Intentional rounding		X								X									X
Geriatrician rounding									X										
Medication review/ avoidance														X	X				
Pain management															X				
Physical/ chemical restraints										X									
Sleep hygiene															X				

Intervention Components	Adams, 2013[17]	Bock, 2016[18]	Burtson, 2015[19]	Cournan, 2018[20]	Davis, 2017[21]	Donoghue, 2005[16]	Giles, 2006[15]	Jeffers, 2013[22]	McNicoll, 2013[23]	Rausch, 2010[24]	Sand-Jecklin, 2016[25]	Skowronsky, 2015[26]	Spano-Szekely, 2018[27]	Spiva, 2012[9]	Tzeng, 2008[28]	Votruba, 2016[29]	Weeks, 2011[30]	Westle, 2019[31]	Wray, 2014[32]
Diversional activities (*eg*, activity aprons, massage, music, *etc*)	X					X			X						X				
Frequent reorientation															X				
Encourage/ request family member presence															X		X		X
Environmental intervention not otherwise specified									X		X								
Wristbands, posters, other identifying tools	X										X		X		X		X		
Move patient closer to nursing station						X					X	X		X					
Alarms (bed or chair)	X	X		X					X		X		X				X		
Raised toilet seat									X										
Cordless chairs		X																	
Low beds	X			X					X		X	X			X				
Fall mats									X		X								X
No-skid socks	X																X		
Mobility support equipment		X																	
Non-restraint roll belts		X																	

Adding Sitters as an Intervention to Reduce Falls

We identified 2 studies[15,16] that added sitters as an intervention to reduce falls. The first of these studies[16] introduced the use of volunteer sitters, "companion-observers", on an acute aged care ward in Australia. The volunteer sitters/companion observers staffed a 4-bed room of patients (from 08:00-20:00) who were assessed by the nursing staff to be high risk for falls. Companion observer duties included engaging the patients in conversation, playing cards, listening to music, providing assistance with finding belongings, and meal set-up. They additionally observed the patients for increasing agitation or risky behavior and would use the call bell to summon the nurse if the patients attempted to move from the bed or chair without assistance. Unit fall rates were expressed as falls per 1,000 occupied bed days (OBD). During the 6-month pilot phase, there was a 51% reduction in the rate of falls on the unit (16.4 falls/1000 OBD to 8.4 falls/1000 OBD). Eighteen-month post-pilot data also demonstrated a decrease in the fall rate (15.6/1000 OBD to 8.8/1000 OBD). This was calculated by the authors to be a 44% reduction of risk (Fisher's exact Chi square, $p<0.000$; Odds Ratio (OR) 0.56, 95% Confidence Interval (CI) 0.45-0.68) which equated to an average monthly reduction of 6.8 falls per 1,000 bed days. Additionally, the percent of patients falling repeatedly decreased during the companion observer intervention from 32% to 15.5% ($p<0.01$; OR 0.39; 95% CI 0.20-0.77).

The second study[15] also used volunteer companions/sitters to staff 2 Australian 4-bed "safety bay" rooms from 09:00-17:00 Monday through Friday and a 4-hour morning shift on Saturday. One "safety bay" was located in an acute general medicine unit and the second in a dementia and behavioral unit. Patients at high risk for falls were identified with the STRATIFY (St. Thomas Risk Assessment Tool in Falling elderly patients) risk screening tool and clinical judgement. The role of the volunteer companion/sitter was to notify the nursing staff of all observed actions that could result in a fall, in addition to engaging the patients in social interactions and diversional activities. Four months of pre-implementation data (February to May 2002) was compared to 4 months of post-implementation data (February to May 2003) and demonstrated a non-statistically significant increase in falls from 14.5 falls/1,000 OBD to 15.5 falls/1,000 OBD (Incidence Rate Ratio =1.07; 95% CI 0.77-1.49; $p=0.346$). Twenty-four percent of the falls during the post-implementation period occurred in the "safety bays" when the volunteer companions were not present. The companion volunteers donated a total of 2,345 hours, which was calculated to represent a value of $56,866 ($AU 24.25/hr).

Using Alternatives to Try and Reduce Sitter Use

We identified 17 studies that assessed an alternative to try and reduce sitter use while not adversely affecting the rate or number of falls.[9,17-32] Almost all of these alternatives were multicomponent interventions. We further divided these studies into 4 categories, based on the kind of intervention, and discuss the evidence for each in turn:

- Interventions that include video monitoring of patients
- Interventions that involve designation of physical space specific for higher risk patients, such as a "close observation" unit
- Interventions that featured nurse assessment and decision tools
- Miscellaneous sitter reduction interventions

Interventions that Include Video Monitoring of Patients

We identified 8 studies that included video monitoring of patients. Five studies used a time series design[19,21,22,27,31] and 3 studies used a pre/post design.[20,25,29]

The first time series study[19] introduced the use of a mobile video monitoring program combined with a nursing-driven sitter protocol in a 595-bed Magnet academic health system with 2 university-affiliated hospitals. Criteria for video monitoring were established and included high fall risk, low risk for elopement (low mobility, low intent), pulling tubes/lines, low-moderate risk for suicide, and potential harm to others (with appropriate level of observation documented by psychiatry in their consultation note). Video monitor technicians (VMTs) received an initial 2-hour training and were required to complete a competency. A VMT station was located close to a nursing station and standardized work flows were created to assist with handoff for initiation of video monitoring, shift reports, and order of call for when staff intervention was required. Baseline pre-intervention data were collected for 6 quarters (1.5 years) and post-intervention data for 8 quarters (2 years). After the intervention, the use of sitters dropped dramatically, from about 5,000-6,000 hours per month to approximately 2,000 hours per month. Post-intervention data demonstrated that there was no change in falls per 1,000 patient days (between about 2.1 and 2.7 falls per 1,000 patient days). Falls with injury decreased from 0.6-0.8 per 1,000 patient days to 0.3-0.6 per 1,000 patient-days. Formal statistical testing was not done for comparisons. Also, falls with injury was not defined in the study. The combined video monitoring and nursing driven sitter protocol resulted in an estimated savings of $771,919 in the first year and $1,718,823 in the second year. This was based upon a 23.9% (16 FTE) and 53.6% (33.9 FTE) reduction in combined VMT and sitter staffing, respectively. Although elopement and suicide were included in the admission criteria for video monitoring, there were no results reported for these 2 outcomes. The authors estimated the return on investment over a 2-year period was 29.2 times the initial investment.

The second time series study[27] added a video monitoring component into the fall prevention program (nurse assessment tool, injury risk assessment tool, medication review, mobility assessment, standardized bed and chair alarm settings, purposeful hourly rounding, and post-fall debriefing) implemented in a 245-bed Magnet community hospital. The video monitoring component was introduced 5 quarters after the fall prevention program started due to persistent falls being noted in a subset of patients with impulsive behaviors. Unlicensed patient care assistants (PCAs) were trained as safety technicians (STs). Responsibilities included monitoring up to 12 patients at one time, verbally redirecting the patients via intercom and notifying the care team members to go in and help a patient attempting to get up. Baseline fall data were collected for 4 quarters. Combined post-fall prevention program and video monitoring intervention data was also collected for 4 quarters and demonstrated a 54% reduction in falls (2.51 falls/1,000 patient days to 1.15 falls/1,000 patient days; no formal statistical testing performed). A baseline falls with injury rate of 0.77 was reported in the background of the study; however, there were no post-intervention data provided for this outcome. Additionally, the authors report a 72% reduction in sitter usage with an estimated $84,000 annual cost savings, but no data are presented to support these conclusions.

The third time series study[22] implemented a continuous video monitoring (CVM) program into a 525-bed acute care facility. The program reallocated certified nursing assistants (CNAs) from the role of sitter to that of video monitor technicians (VMTs). A centralized monitoring room was

constructed which allowed immediate audio contact with nursing staff and patients. VMTs underwent competency evaluations and ancillary staff were educated regarding the surveillance program. A standardized workflow was introduced including formalized hand-off of information, daily rounding on each nursing unit, admission to the program, escalating procedures, and downtime operations. Post-implementation falls per 1,000 patient-days decreased slightly (from 4.7-5.0 falls per 1,000 patient days to 3.9-4.7 falls per 1,000 patient days; formal statistical testing not performed). Falls with injury were not reported in this study. A deferred cost savings of $392,000 in the first quarter post-implementation exceeded the original technology investment of $305,000 with an overall $2.02 million deferred cost savings in 1.5 years. The study additionally reported that within the first 3 months post-implementation, 57 falls were prevented by VMT interventions resulting in an estimated savings of $24,225. Due to the static camera view, which allowed patients to move outside of the camera's range, patients at risk for elopement did not meet criteria for video monitoring and this outcome was not measured.

The fourth time series study compared a "virtual sitter" technology (which consisted of an infrared camera that can visualize full body 3-D movement) versus traditional sitters.[31] The outcomes were falls, falls with injuries (not defined), and staffing/cost savings. The authors first performed a pilot study on a neuroscience unit where the patients with the highest risk for falls were assigned to the "virtual sitter". During the 3-month pilot, there were no falls or falls with injuries in the patients with "virtual sitters" compared with a fall rate/fall with injury rate of 4.06/2.45 for the remainder of the patients on the unit. Based on these favorable results, the pilot was then expanded to 12 months on the neuroscience unit. Compared to 12 months of pre-intervention, there was a 28% reduction in fall rate and a 19% reduction in the rate of falls with injury ($p<.001$). Before implementation of the "virtual sitter", the hospital was spending $680,000 a year on sitters, with an average cost of $350 per patient per day for whom a sitter was ordered. The authors estimated that with the "virtual sitter" this would drop to $29 per patient per day. Based on these favorable results, hospital administration decided to "scale up" the "virtual sitter" program, from 6 cameras on 1 unit to 21 cameras on 3 units. A pre/post analysis of the scaled-up implementation showed similar reductions in falls and falls with injury.

The fifth time series study assessed yearly outcomes of a video monitoring intervention implemented on 2 units.[21] The outcomes reported were falls, self-harm events, and costs. The yearly results demonstrated no statistically significant change in fall rates post-implementation, but with a decreasing trend in falls. Self-harm events were too rare to perform inferential statistics. Both units demonstrated a decrease in monthly expense for sitters at year 4 ($p<.05$) and a statistically significant decrease of in-room sitter days at year 2 (Unit 1 $p<.05$ and Unit 2 $p<.001$) and year 4 ($p<.001$, both units).

The remaining 3 studies used a pre/post study design. The first study[20] implemented a video monitoring system in a 115-bed freestanding inpatient rehabilitation facility which included a brain injury unit. Although rehabilitation units were in general an exclusion for this review, we included this one as the authors describe the facility as a "hospital" and the description of other services available in the facility makes it seem more similar to an acute care hospital than a traditional rehabilitation facility. A video monitoring room was established, and the VMTs were trained to look for behaviors in the patients that could lead to falls. Exclusion criteria for being placed on video monitor included patients pulling at tubes/devices, restlessness and agitation requiring undivided attention, and suicidal patients. This study reported a statistically significant

decrease in the brain injury unit fall rate per 1,000 patient days (10.26 pre-video to 6.87 post-video, t (18) = 2.647, p=.016), as well as the hospital-wide falls per month (6.34 pre-video to 5.09 post-video, t (31) = 2.043, p=.0496). Since not all patients could be video monitored, the authors compared the fall rate between patients who were or were not video monitored. There was no statistically significant difference in falls per 1,000 patient days over a 12-month post-implementation period on the brain injury unit when comparing video monitored and non-monitored patients (7.63 vs 6.70). An estimated $40,000 cost savings due to reduction in falls and fall-related injuries over a 21-month time period and $186,120 one-year staff cost savings were reported. The second study[25] created a video monitoring program on 2 units, including a neuroscience unit, in a large academic medical center. An algorithm was used to determine high fall risk patients appropriate for video monitoring. The VMTs observed patients for "at risk behaviors" and were able to redirect the patients via communication into the room, a telephone call to the nurse or nursing assistant, or use of the patient call bell to sound an alarm. The study reported a 28.5% statistically significant reduction in falls per 1,000 patient days (3.9 to 2.8; z = 1.85, p=.032). Falls with injuries of monitored (0/15) versus unmonitored (6/34) patients in the post-implementation period were reported; however, statistical testing was not performed. A cost savings due to reduction in sitter hours was reported. No data were provided to confirm this reported cost savings. The final study[29] implemented a video monitoring program into a critical care/intermediate care, neuroscience and senior care unit of a 350-bed Magnet hospital. The VMTs/telesitters received 8 hours of cognitive, affective, and psychomotor training and protocols were developed for how to react to potential patient falls or other safety concerns. All patients admitted to 1 of the 3 study units were eligible to be selected for video monitoring with the exception of those with behavioral restraints or at risk of harm to self or others. There was a statistically significant 35% decrease in falls reported (85 to 53; p<.0001, 95% CI) comparing 9 months of baseline pre-intervention data with 9 months of intervention data on the 3 units. The authors estimated an avoidance of 3 to 5 injurious falls annually; however, this was based upon a fall with injury estimate from another source referenced in their article. Projected fall cost avoidance of $52,000 to $87,000/year and decrease in sitter costs of $25,200/year were calculated using extrapolated data from the CDC and not internal institution costs. These combined cost savings were reported to offset the annual telesitter cost of $120,000/year. The authors note that based on the results of their study, the hospital "chose to continue funding the telesitter FTE after completion of the study". The study also reported that nursing staff used the video monitors to prevent elopement; however, no data were provided for this outcome.

Interventions that Involve Designation of Physical Space Specific for Higher Risk Patients, such as a "Close Observation" Unit

We identified 2 studies[23,26] that focused on designating some physical space specifically for higher-risk patients. This intervention will be referred to here as the creation of a close observation unit (COU). The study by McNicoll and colleagues[23] involved designating existing hospital space to create a COU. Alternatively, in the study by Skowronsky and colleagues,[26] this involved construction of a newly designed COU for their quality improvement initiative and reported in-hospital falls data in the newly constructed COU. Both studies were conducted at single hospitals in US. The study by McNicoll and colleagues used a time series design for analysis of fall rates while the study by Skowronsky and colleagues used a complicated design that was a low-quality time series (too few data points) in terms of sitter use and a variant of a non-randomized intervention study for the assessment of falls.

In the study by McNicoll and colleagues, presented only in poster form,[23] an 8-bed area of the Medicine-Surgery ward was re-designated as an Acute Care for the Elderly Unit, allowing close observation of patients from a central area. Criteria for admission to the new unit included age >70, brittle bones and risk of falls and fractures, coagulopathy and risk of bleeding, and delirium or dementia, as these patients were found to be the highest risk in a preliminary analysis and 4 times more likely to have falls, pressure ulcers, and restraints. Falls and falls with injuries were monitored for the entire 24-bed unit, although only 8 beds were within the COU. Unit falls were analyzed for 1 calendar year pre- and post-intervention. While fall rates did not improve for the entire unit, injurious fall rates decreased by 12% and monthly constant observation hours decreased by 23%. Additional benefits included improvements in Press Ganey scores in patient satisfaction, communication of nurses, and pain satisfaction. However, in addition to the designated space, the intervention also included environmental modifications (*eg*, low beds, floor mats, gait belts, walking aides, a walking path, scheduled walking times, *etc*), diversional activities (*eg*, game times, pet therapy, music therapy, evening entertainment, and social hour to prevent delirium), increased nursing staff, and a gerontological nurse practitioner who rounded twice weekly to provide support and consultation to staff.

A second study, by Skowronsky and colleagues,[26] created a 4-bed COU by opening a wall between 2 semi-private patient rooms. Glass partitions and 2 nursing workstations were placed in the central area to increase visibility of and access to patients. No baseline fall rate was reported for the internal medicine unit. Patients could be admitted to either the COU or the internal medicine unit, based on "nursing assessment and judgment" that the patient was at higher risk of falling and "general need for closer observation". Sitters continued to be used in the internal medicine unit when the clinicians so ordered them, while sitters were not used at all in the COU. After implementation of the COU, the overall use of sitters across both units dropped by more than 50%, from about 240 shifts per month to about 57 shifts per month. While there are no data presented on pre-intervention fall rates in the internal medicine unit, after the intervention there was no statistically significant difference in fall rates between the internal medicine unit (29/1878; 1.5%) and COU (3/145; 1.6%) (p=.476), despite the patients on the COU being selected as being at higher risk for falls and having more neurologic and psychiatric problems. On the basis of falls per 100 patient-days, fall rates were 31 of 8,408 (0.369%) in the internal medicine unit and 4 of 700 (0.571%) in the COU. The relative risk and 95% confidence intervals of a fall in the COU compared with the internal medicine unit were 1.55 (0.45- 5.30) (p=.486). After adjusting for hospital length of stay and discharge disposition, the relative risk and 95% confidence intervals of a fall in the COU compared with the internal medicine unit were 1.40 (0.42-4.75) (p=.584).

Two additional studies, one by Donoghue and another by Giles, also designated in-patient bed areas for the purpose of constant close observation; however, the primary intervention in these studies was initiation of a constant observation program where there was not one previously implemented.[15,16] Those studies are discussed separately above in the appropriate context ("Adding Sitters as an Intervention to Reduce Falls").

Nurse Assessment and Decision Tools

We identified 3 studies[9,28,32] that assessed interventions that included nurse assessment and decision tools to reduce the use of sitters. All 3 studies were at single hospitals in the US, and all

3 used locally developed tools. Two of the studies[28,32] printed their tool. One study used a time series design for the analysis,[32] while the other 2 presented only pre/post data.[9,28]

The time series study assessed "Safety Watch", a locally developed tool for management of patients at risk of harm.[32] Patients who were considered a suicide risk were not eligible, and all such patients were channeled to constant observation. For patients at risk of falls or injury, the tool used an algorithmic approach to assess and treat possible causes, re-evaluation of effect, and escalation of interventions, if needed. It was accompanied by instructions to initially utilize unit resources for observation, the discouragement from calling physicians for constant observation orders except in cases of suicide risk, the encouragement of family members to stay with the patient, and the requirement that nursing units report their unit constant observation utilization data. It also encouraged safety rounds every 15 minutes, and re-assessment of need every 4 hours. Lastly, nurses could implement and discontinue interventions, whereas prior to this constant observation was initiated and discontinued on physician orders. The number of hours of constant observation hours per 100 patient days dropped from 48.4 before the intervention to 26.4 after the intervention, a reduction of 45%, although statistical testing was not performed. The authors report that after the intervention the hospital was able to eliminate 15 full-time equivalent positions as a result of decreased constant observation use. The rate of falls also decreased, from 3.2 to 2.9 per 1000 patient-days, although again no statistical testing was done. Lastly, the authors report that the hospital spent $534,000 less on constant observation following implementation of the intervention.

The other 2 studies used a pre/post design. The first study[28] assessed the use of the locally developed Patient Attendant Assessment Tool, which was triggered after an order for a sitter had been placed. This tool assessed various risks and assigned a numeric score, and patients with scores below a certain threshold were recommended to receive alternatives to sitter use from a long list of alternatives (this included items like "requesting the patient's family members' help", "using door barrier", and "having the patient seat in the corridor"). This study reported decreases in sitter use of about 10% on 1 unit where it was implemented, but an increase of about 4% on another unit. The rate of falls per 1,000 patient days decreased after implementation in both units (about 10%), but the falls with injuries increased (from 0.25 to 0.59 per 1,000 patient days in 1 unit, and from 0.49 to 0.58 per 1000 patient days in the other unit). The authors report that only the increase in injurious falls was statistically significant at the 0.05 level. The second pre/post study assessed a locally developed sitter reduction program that included a sitter decision tree, sitter justification and evaluation form, letters to nurses and physicians, and scripting for family and patient by nursing staff. The sitter decision tree was not presented but was described as "an algorithm for the nurse to refer to when making decisions about sitter use". Following implementation of the program, the number of sitter hours decreased by 63% with a reported total cost savings of $321,822. Both of these reductions were reported as statistically significant (p=.001). The overall number of falls and rate of falls were both unchanged.

Miscellaneous Sitter Reduction Interventions

We identified 4 remaining studies[17,24,30] which assessed interventions that we could not place into any of the previous classifications, and thus discuss them here. One study[30] described the intervention as "no more sitters" and on a certain date, stopped physicians from writing orders for sitters. It went on to state that "with RNs able to make decisions regarding patient safety, sitters are now rarely recommended". The author reports that after implementation of this

intervention, the hospital "uses fewer companions", although no data are presented about sitter use. The rate of falls and fall-related fractures were lower post-intervention (from 5.43 to 4.36 falls per 1,000 patient days and from .065 to .058 falls with fractures per 1,000 patient days), but no statistical testing was reported. The second study[24] reported the intervention as the hiring of a "psychiatric liaison nurse" to act as a resource to "support and educate bedside nursing staff to collaboratively identify and implement alternatives". After hiring this nurse, the number of constant observation hours decreased by about half (from 1,280 shifts to 606 shifts in the 4 months before to 4 months after "well-established" implementation) with an estimated cost saving of $97,000. The rate of falls over this period of time remained approximately constant. No statistical testing was performed.

The third of these studies tested described the development over time of a multicomponent intervention designed to reduce sitter use while not adversely affecting the rate of patient falls.[17] The authors describe a careful process seeking to understand local motivators for use of sitters and potential alternative strategies to prevent falls. These alternatives went through a local vetting process which resulted in a few being selected for implementation: low beds, chair alarms, activity aprons, arm bands, and non-skid socks, which were then coupled with implementation strategies including education, benchmarking to other similar hospitals and information technology-enabled order packages. In a time series design, different components of the intervention were phased in. Sitter reduction dropped by more than half in the first year and has been maintained since then. Expenditures on the agency providing sitters dropped more than 80%, from $477,000 to $92,000. The rate of falls remained unchanged at around 4 per 1,000 patient-days. The use of restraints was reduced from around 12% of patients to less than 4% of patients. No statistical testing was performed for any of these comparisons.

The last study is a dissertation that describes a quality improvement project implemented on 2 hospital units with the aim of reducing sitter use while also reducing falls and falls with injuries.[18] The intervention was the introduction of best practices for fall prevention that was done via a gap-analysis, plus the use of new vendor products (including cordless chairs, non-restraint roll belts, and patient mobility support equipment). Compared to pre-intervention data, there was a decrease in sitter use (that was not statistically significant) and slight increase in fall rates in the units (which was also not statistically significant) over 60 days of post-intervention data. Falls with injuries were not analyzed for statistical significance due to the extreme infrequency of such events.

Summary of Findings

Regarding the use of sitters added to usual care, there are only 2 observational, time series studies identified, and both also used designated space as part of their intervention. The 2 studies reported conflicting results with regards to change in fall rate, and the baseline rate of falls in these Australian studies was 3 to 4 times that in a typical US acute care hospital.

Regarding alternatives to sitter use, the most evidence was identified for the use of video monitoring, with 8 studies (5 of which used a time series design) reporting mostly consistent results, with either no change or a decrease in falls following implementation, and a dramatic drop in sitter use. Although formal statistical testing was often not performed in these articles, the differences or lack thereof have face validity based on figures presenting the time series data. Most articles reported cost savings in terms of sitter use, but not costs associated with the

acquisition of the information technology system, training, and/or maintenance. Some studies explicitly stated that hospital administration decided to continue or even scale-up the intervention based on the results of the study. Two studies of designating space for close observation were difficult to interpret because 1 study had numerous additional co-interventions and the other study was limited by design (pre/post) and lacked precision (clinically significant higher falls risk in the COU, but not statistically significant). Three studies of nurse assessment and decision tools were limited by design (2 studies were pre/post), inconsistent results, and by co-interventions in the single time series study (for example, the observed reduction in use of sitters may have been due to a co-intervention such as the requirement that nursing units report their monthly use of sitter utilization, or the use of 15-minute rounding). Among the miscellaneous intervention studies, 1 time series study described a well-planned and conducted quality improvement intervention that convincingly shows that a multicomponent intervention tailored to meet local needs and challenges reduced sitter use while not adversely influencing fall rates in this setting.

Certainty of Evidence for Key Question 1

While adding one-to-one sitters to usual care to prevent falls has a strong mechanistic rationale (if someone is there to help assist a patient, they are less likely to fall), the empiric evidence base for it is surprisingly thin, and the only 2 studies we identified reached conflicting results. Therefore, despite the strong rationale, we judged the certainty of evidence as Very Low that the use of one-to-one sitters reduces falls. Regarding interventions to reduce the use of sitters without adversely affecting fall rates, we judged that the use of video monitoring interventions had Moderate certainty evidence that it would achieve these aims, although we note that every study used a different kind of video intervention, and thus there is no “off-the-shelf” video monitoring intervention that can be recommended. The remaining interventions were all judged by us as having Very Low certainty evidence that they would achieve their aims, based on study design limitations, inconsistent results, and the possibility of confounding due to co-interventions. The 1 exception to this was the study by Adams and colleagues that described the result of a customized intervention. We judged this as being Low certainty evidence that the process followed by Adams, meaning not the particular components chosen but rather the careful consideration of challenges and barriers and the selection of specific intervention components customized to the local challenges and barriers, would achieve the aims of decreasing sitter use while not adversely affecting fall rates. See Table 3 below for certainty of evidence for one-to-one sitters.

Table 3. Certainty of Evidence for One-to-One Sitters

Intervention/Outcome	Study Limitations	Consistency	Directness	Precision	Certainty of Evidence
Adding Sitters to Usual Care					
Preventing falls	Observational studies: High	Inconsistent	Direct	Imprecise	Very Low
Removing Sitters					
Using video monitoring to reduce sitter use and not adversely influence falls	Time Series: Low Pre/post: High	Consistent	Direct	Imprecise	Moderate
Using designated spaces to reduce sitter use and not adversely influence falls	Time Series: High Pre/post: High	Inconsistent	Direct	Imprecise	Very Low
Using nurse assessment and decision tools to reduce sitter use and not adversely influence falls	Time Series: Low Pre/post: High	Inconsistent	Direct	Imprecise	Very Low
Using a multicomponent intervention tailored to meet local needs and challenges to reduce sitter use and not adversely influence falls	Time Series: Low	N/A	Direct	N/A	Low

KEY QUESTION 2: What is the effectiveness of patient sitters (one-to-one observation, patient safety companions, *etc*) for reducing suicide or self-harm?

We identified no studies reporting the effects of sitters, or alternatives to removing sitters, on the outcomes of suicide or self-harm.

Summary of Findings

No studies were identified.

Certainty of Evidence for Key Question 2

Since no studies were identified, the certainty of evidence for this outcome is Very Low.

KEY QUESTION 3: What is the effectiveness of patient sitters (one-to-one observation, patient safety companions, *etc*) for reducing wandering?

We identified no studies reporting the effects of sitters, or alternatives to removing sitters, on the outcome of wandering.

Summary of Findings

No studies were identified.

Quality of Evidence for Key Question 3

Since no studies were identified, the certainty of evidence for this outcome is Very Low.

KEY QUESTION 4: What is the cost-effectiveness of one-to-one observations compared to usual care for patients at risk of falls, suicide, or wandering?

We identified 1 older (2001) study that called itself a cost-effectiveness study.[7] However, despite having as its title, "The cost-effectiveness of a patient-sitter program in an acute care hospital: a test of the impact of sitters on the incidence of falls and patient satisfaction", we had to reject this study as we could not determine where the parameter estimates came from for the effect of sitters on falls. Also, the number of falls with injury and the costs associated with falls from injury were not measured directly but rather extrapolated from data now nearly 25 years old.

Thus, we have no data about the cost-effectiveness of sitters for the prevention of any of the outcomes of interest. However, costs or cost savings were reported in many of the studies assessing alternatives to sitters. These are summarized in Table 4, below. These costs were almost always the costs saved by not using sitters and did not include the costs of the alternative interventions.

Table 4: Cost Savings

Interventions that Include Video Monitoring of Patients

Author, Year	Cost Savings
Burtson, 2015[19]	Estimated savings $772,000 year 1, $1,720,000 year 2
Cournan, 2018[20]	Net $40,000 savings in 21-month period for Falls and fall-related injuries. $186,120 saved on one-to-one sitters in 12 months
Jeffers, 2013[22]	$2.02 million in deferred cost savings in 1.5 years $24,225 in first 3 months from 57 prevented falls First quarter deferred staff savings of $392,000 exceeded original technology investment of $305,000
Spano-Szekely, 2018[27]	$84,000 annual savings
Votruba, 2016[29]	Projected fall cost avoidance of $52,000-$87,500/year (using the CDC's 2013 estimate of $17,500 per fall, not internal data) Projected decrease in sitter cost of $25,200/year (extrapolated from CDC data rather than internal institution costs) 24/7 telesitter cost ($120,000) almost completely offset by combined fall cost avoidance and sitter reduction savings ($77,200-$112,700)

Nurse Assessment and Decision Tools

Author, Year	Cost Savings
Spiva, 2012[9]	Decreased from $536,955 to $215,132, total cost savings of $321,822. (t=4.76, p=.001).
Wray, 2014[32]	41.3% ($533,917) decrease in CO expenditures ($1,292,228 to $758,311)

Miscellaneous Sitter Reduction Interventions

Author, Year	Cost Savings
Adams, 2013[17]	$1.2 million annual savings; $400,000 sitter agency savings ($477, 561.86 FY09 to $491,991.27 FY10)

Summary of Findings

We identified no studies reporting the cost-effectiveness of sitters.

Certainty of Evidence for Key Question 4

Since no studies were identified, the certainty of evidence for this outcome is Very Low.

SUMMARY AND DISCUSSION

The key finding of this review is that, despite the strong mechanistic rationale for the use of one-to-one sitters, there is surprisingly little evidence of its effect, with only 2 studies assessing the effect on falls and no studies assessing the effect on wandering or suicide/self-harm. Of the alternatives to sitters that have published results, the use of interventions with video monitoring is the most promising, although like any information technology intervention, the success is likely to be highly context-dependent.

SUMMARY OF EVIDENCE BY KEY QUESTION

Key Question 1: What is the effectiveness of patient sitters (one-to-one observation, patient safety companions, *etc*) for reducing falls?

Regarding the use of sitters added to usual care, there are only 2 observational, time series studies identified, and both also used designated space as part of their intervention. The 2 studies reported conflicting results with regards to change in fall rate, and the baseline rate of falls in these Australian studies was 3 to 4 times that in a typical US acute care hospital.

Regarding alternatives to sitter use, the most evidence was identified for the use of video monitoring, with 8 studies (5 of which used a time series design) reporting mostly consistent results, with either no change or a decrease in falls following implementation, and a dramatic drop in sitter use. Although formal statistical testing was often not performed in these articles, the differences or lack thereof have face validity based on figures presenting the time series data. Most articles reported cost savings in terms of sitter use, but not costs associated with the acquisition of the information technology system, training, and/or maintenance. Two studies of designating space for close observation were difficult to interpret because 1 study had numerous additional co-interventions and the other study was limited by design (pre/post) and lacked precision (clinically significant higher falls risk in the close observation unit, but not statistically significant). Three studies of nurse assessment and decision tools were limited by design (2 studies were pre/post), inconsistent results, and by co-interventions in the single time series study (for example, the observed reduction in use of sitters may have been due to a co-intervention such as the requirement that nursing units report their monthly use of sitter utilization). Among the miscellaneous intervention studies, 1 time series study described a well-planned and well-conducted quality improvement intervention that convincingly shows that a multicomponent intervention tailored to meet local needs and challenges can reduce sitter use while not adversely influencing fall rates.

Key Question 2: What is the effectiveness of patient sitters (one-to-one observation, patient safety companions, *etc*) for reducing suicide or self-harm?

We identified no studies reporting the effects of sitters, or alternatives to removing sitters, on the outcomes of suicide or self-harm.

Key Question 3: What is the effectiveness of patient sitters (one-to-one observation, patient safety companions, *etc*) for reducing wandering?

We identified no studies reporting the effects of sitters, or alternatives to removing sitters, on the outcome of wandering.

Key Question 4: What is the cost-effectiveness of one-to-one observations compared to usual care for patients at risk of falls, suicide, or wandering?

We identified no studies reporting the cost-effectiveness of sitters. Many studies of alternatives to sitters reported cost savings due to less use of sitters, and these amounts could be quite substantial, but rarely were the costs of the alternative intervention included in the reporting.

LIMITATIONS

Publication Bias

Publication bias is a major concern for a topic such as this. Particularly for the "alternatives to sitters" articles, it is highly likely that unsuccessful alternative interventions are less likely to be published. This colors the evidence base for each topic and was considered in our overall rating of the certainty of evidence.

Study Quality

Study quality is a major concern for this topic. While some of the studies used a time series design sufficient to support causal relationships, most did not. Study quality was considered in our overall rating of the certainty of evidence.

Heterogeneity

Heterogeneity is a major concern for this topic. Studies' interventions most often included multiple components, and these were all idiosyncratic—no study tested the same intervention, in all its components, as any other study. We attempted to group study interventions into categories of interventions that shared some similarities, but nevertheless within each category there is still substantial heterogeneity in interventions.

Applicability of Findings to the VA Population

We did not identify any studies in VA populations. We can only speculate as to the applicability of these findings to VA populations.

RESEARCH GAPS/FUTURE RESEARCH

The fundamental value of one-to-one sitters remains a question in search of an answer. Their use may be so ingrained into usual care that a standard randomized control trial comparing sitter use to no sitter use is not feasible to conduct, in which case the "alternatives to sitters" research route should be pursued. This can be done as controlled before-and-after studies within hospital, which will provide a much stronger basis for causal conclusions than a pre/post study, or as a time series study with incremental additions of intervention components.

CONCLUSIONS

The effect of one-to-one sitters on reducing falls, wandering, or suicide/self-harm has yet to be established. Of the alternatives to sitters that have published results, the use of interventions with video monitoring is the most promising, although success is likely to be highly context-dependent.

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