One-to-One Observation: A Systematic Review

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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 <u>Nicole.Floyd@va.gov</u>.

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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.

Julia Neily, RN, MS, MPH Associate Director, Field Office National Center for Patient Safety

William Gunnar, MD Executive Director National Center for Patient Safety

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

Tatjana Bulat, MD, CMD Director, VISN 8 Patient Safety Center of Inquiry Associate Chief of Staff for Geriatrics and Extended Care, James A. Haley VA Hospital and



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David A. Ganz, MD, PhD Associate Director, VA HSR&D Center for the Study of Healthcare Innovation, Implementation & Policy, VA Greater LA Healthcare System Staff Physician, VA Greater LA Healthcare System, Geriatric Research, Education and Clinical Center (GRECC) 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.

EXECUTIVE SUMMARY

INTRODUCTION

Preventing adverse events in hospitalized patients is a priority goal of patient safety programs. In-facility falls and in-facility suicide are 2 priority conditions that are thought to be preventable. One-to-one sitters or constant observation is an intervention that has long been used, rooted in tradition: staff that are immediately at hand can help prevent a fall or redirect a patient from engaging in a harmful act. However, one-to-one sitters is a costly intervention, and evidence that it is effective is uncertain; hence, VA policymakers asked for an up-to-date review to inform policy and practice.

METHODS

Data Sources and Searches

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?

Study Selection

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. In order to be included, a study had to include one-to-one sitters as an intervention in an acute hospital's general medical/surgical or psychiatric hospital setting, and report an outcome of interest (falls, wandering, suicide/self-harm), and that preventing this outcome was the primary goal of the intervention. Observational studies were included.

Data Abstraction and Quality Assessment

Data extraction was completed in duplicate. 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,



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implementation details, outcomes, and post-implementation follow-up interval. We used the Risk of Bias In Non-randomized Studies – of Interventions (ROBINS-I) for observational studies to assess study quality/risk of bias.

Data Synthesis and Analysis

The observational studies were too clinically heterogeneous to support meta-analysis; hence our synthesis is narrative. We used the principles of the Grading of Recommendations Assessment, Development and Evaluation (GRADE) working group to assess the certainty of evidence.

RESULTS

Results of Literature Search

We identified 4,106 potentially relevant citations for a total of 1,845 articles whose titles were screened. Nineteen publications were identified at full-text review as meeting initial inclusion criteria. Only 2 studies assessed the effect of adding sitters to a 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.

Summary of Results for Key Questions

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 2 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 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 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.

DISCUSSION

Key Findings and Strength of Evidence

The key finding of this review is that, despite the strong mechanistic rationale for the use of oneto-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.

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	Time Series: Low	Inconsistent	Direct	Imprecise	Very Low		



sitter use and not adversely influence falls	Pre/post: High				
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

Applicability

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 a 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. The available data are most compatible with a hypothesis that sitters are at best only modestly effective for fall prevention.

ABBREVIATIONS TABLE

Agency for Healthcare Research and Quality	AHRQ
Centers for Disease Control and Prevention	CDC
Close Observation Unit	COU
Continuous Video Monitoring	CVM
Evidence Synthesis Program	ESP
Grading of Recommendations Assessment, Development and Evaluation	GRADE
Occupied Bed Days	OBD
Patient Care Assistant	PCA
Patient Safety Assessment Tool	PSAT
Risk of Bias in Non-Randomized Studies- of Interventions	ROBINS-I
Safety Technicians	ST
St. Thomas Risk Assessment Tool in Falling elderly patients	STRATIFY
Technical Expert Panel	TEP
Veterans Health Administration	VHA
Video Monitor Technician	VMT