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Editor's Letter

Now is the time to memorialize this

John C. West, JD, MHA, DFASHRM, CPHRM

If you are like most people, you have become fatigued by the interminable bad news coming out of Washington, the CDC, and your state capital. It is difficult to become incensed by the rising case count, the rising death count, and the depressing effect on our national, state, local, and personal economy in the same way we once did. This is not, however, the time for despair. It is a time to act.

The novel coronavirus and COVID-19 may very well be a 100-year plague and pestilence. It will, undoubtedly, pass and be relegated to history. But that is not to say it will not recur. Some may say we were unprepared for a disaster on this scale. Be that as it may, shame on us if we are unprepared for the next one.

Now is the time to write the story of COVID-19 and all of the work that we have done to deal with it. The grief will subside; the losses will abate. Let us not let the memory of this awful time be lost. We are the survivors, and the history is always written by the survivors. Before the memory fades in the hustle and bustle of trying to get back to normalcy, let us hear your story. What were your issues? What were your concerns? What were your challenges? If you met them, how did you do it? If you did not meet them, what did you try that did not work? Future generations of risk managers and health care workers will look to us for guidance. Let us not let them down.

John C. West

Editor, *Journal of Healthcare Risk Management*

President's Message

Rising to the Challenge

Hala Helm, JD, MBA, CHC, CPHRM, DFASHRM

When I wrote my last President's message, I could not have imagined how much the world would change in just a short time. As I write this one, much of our country is beginning to take tentative steps towards reopening and recovery after months of lockdown due to Covid-19. Healthcare institutions and workers have been at the forefront in the brutal battle with this terrible disease and have suffered heavy casualties. Care providers have succumbed to illness, hospitals have experienced unimaginable financial losses despite being inundated with patients, and nearly everyone is exhausted and overwhelmed. Amid all this, I have been inexpressibly proud to see our risk management community rise to this unprecedented challenge. Years of practice and experience in disaster preparedness, FMEAs, and risk mitigation have been put to the test, as risk managers have helped their organizations navigate this crisis. This has been particularly apparent while observing communications on the ASHRM Exchange. There, risk managers have worked with their colleagues across the nation and around the world to strategize and develop best practices in a rapidly changing environment. It has been wonderful to see all the help and support so freely offered within our risk management community.

I hope that as you read this, several months after I have written it, the world is in a better place and we are on the road to recovery. I especially hope that you will all take a moment to feel proud of what you have accomplished during this extraordinary time. You are appreciated.

Stay safe.

[signature]

2020 ASHRM President

Operations

Review of disclosure and apology literature: Gaps and needs

By Doug Wojcieszak ⓘ

A review of the literature related to the disclosure movement was conducted to find gaps and needs while identifying areas where needs are being met. There are several articles that address claims and other economic factors. Moreover, there are many papers that define barriers to disclosure with suggested workarounds. There is also a wealth of training content that teaches how to say "sorry." However, gaps and needs were identified. The "gap list" was developed with a focus on concepts that are novel or not mentioned in the literature as well as issues in the disclosure movement that would benefit from greater attention: (1) lack of research and disclosure training content for health care professionals *beyond* acute care; (2) messaging and disclosure programs, including the meaning of "apology"; (3) insufficient integration between disclosure programs and second victim support programs; (4) confidentiality clauses; (5) the National Practitioner Data Bank and state licensure boards being viewed as an impediment to disclosure; (6) understanding awareness of the disclosure movement by consumers, personal injury bar, and payors; (7) measuring what medical and nursing schools are teaching about disclosure; and (8) encouraging states to pass apology laws that support the development of disclosure programs.

INTRODUCTION

The disclosure and apology movement for medical errors was unofficially launched in the United States in December 1999 with the publication of "Risk Management: Extreme Honesty May Be the Best Policy" by Dr. Steve Kraman, MD, and Ginny Hamm, JD.[1] Released around the same time as the Institute of Medicine's "To Err Is Human" Report, Kraman and Hamm's paper reviewed the efforts of their team at the Lexington, Kentucky, Veterans Affairs (VA) Medical Center disclosing errors—including errors unknown to patients and

families—and how this ethical yet radical approach did not result in more lawsuits and litigation expenses, but actually showed a trend toward lower liability exposure when compared to other VA hospitals. The Lexington program can be considered "ground zero" of the disclosure and apology movement because it showed potential *positive* claims and monetary consequences with disclosure and apology and, thus, encouraged other health care organizations to try disclosure. This included the University of Michigan Health System,[2] University of Illinois–Chicago Medical Center,[3] Stanford Hospital,[4] and several other health care facilities and organizations, including the labor and delivery leadership of the largest Catholic health care system in the United States[5] as well as an outside insurer (BETA Healthcare Group) that covers hospitals throughout California.[6] Many other hospitals and other health care organizations have quietly adopted some aspect of a disclosure program as well.

In 2005, a national advocacy group, Sorry Works!, was launched to promote disclosure and apology programs, and Sorry Works! eventually developed disclosure training materials for health care, insurance, and legal professionals.[7] Another disclosure advocacy and training group, the Collaborative for Accountability and Improvement ("the Collaborative"), was created in 2015 (conversation with Paulina Osinska, program manager for the Collaborative for Accountability and Improvement, July 2018).

Terms typically associated with the disclosure and apology movement are *disclosure* and *disclosure programs*. The label *communication and resolution programs* or *CRP*[8] has recently been introduced to the disclosure and apology movement. Both sets of terms are found in the literature, including a recently released (summer 2018) risk management book by the American Society for Healthcare Risk Management (ASHRM) which used the term *disclosure,*[9] and a 2017 document by the Agency for Healthcare Research and Quality (AHRQ).[10] For this article, the terms *disclosure* and *CRP* will be used jointly so no readers are confused.

In 2010, AHRQ, under the Obama administration, provided several large grants to pilot disclosure/CRP programs and further study this promising yet novel approach to adverse medical events.[11] This funding led to many studies and greatly increased the peer-reviewed literature on this topic.[12]

Much is known about disclosure/CRP; however, much remains to be learned. Disclosure/CRP is still a relativity new approach for health care, insurance, and legal professionals who, for *decades*, practiced "deny and defend" risk management strategies. The purpose of this study is to review the literature and the "knowledge base" thus far in the disclosure/CRP movement. This paper will help risk managers understand the current state of the disclosure movement, provide ideas for the future direction of the disclosure movement, and hopefully trigger discussion among risk managers about the needs of the disclosure movement.

All major disclosure/CRP articles in the peer-reviewed literature as well as publications (books, booklets, online manuals, etc) dating back to at least 2010 were reviewed. Terms such as *disclosure, disclosure and apology, communication and resolution,* and *CRP* were searched through Google and the online library system of The Ohio State University. Also reviewed were some articles and publications prior to 2010 that were cited in the papers identified during the aforementioned searches. Major gaps and needs for the disclosure/CRP movement were identified during this literature review and during discussions with leaders in the disclosure/CRP movement. The "gap list" was developed with a focus on concepts that are novel or not even mentioned in the literature as well as issues in the disclosure/CRP movement that would benefit from greater attention and planning.

FINDINGS

This section provides an overview and summary of the findings. First, the areas of the disclosure/CRP movement where much work/research has been accomplished (or is happening) and information needs are being met or will be met are reviewed. Next, areas of the disclosure/CRP movement that have not received enough attention from researchers and disclosure/CRP leaders are reviewed.

Work in progress/information needs being met

The disclosure/CRP program leaders for the University of Michigan Health System, University of Illinois Health, Stanford Health Care, Erlanger Health, Massachusetts hospitals, and others have widely shared details about their processes, including the management of their disclosure/CRP programs and data concerning claims, lawsuits, and defense expenses. This information has not only been shared widely in the peer-reviewed literature,[13–20] but also through advocacy groups and even more widely disseminated through news stories in trade publications and the popular/mainstream media. A quick search through Google with the term *disclosure and apology for medical errors* yields 3,980,000 results. The story line from these pioneering programs is basically the same: Disclosure/CRP leads to fewer lawsuits and lower liability/defense expenses with enhanced patient safety due to these hospitals having programs in place to quickly review potential errors while maintaining relationships with consumers and ultimately offering authentic apologies for true errors, including fair, upfront compensation. The disclosure/CRP story encompasses a variety of *acute* health care systems in many different venues (litigation environments), including an "open" organization with nonemployed physicians (Erlanger Health). Surely, more disclosure data and "success stories"

will be released in the near future via the peer-reviewed literature and other means.

Moreover, the different disclosure/CRP leaders from Michigan, Illinois, and elsewhere, along with leading researchers (Mello, Gallagher, and others) have teamed together to identify barriers to disclosure or areas of improvement for disclosure/CRP practices, including, but not limited to, better engagement with leadership of health care organizations, improved training for clinicians as well as risk and legal staff, more resources for risk management staff tasked with implementing disclosure, relations with outside insurers, regulatory concerns, and many other challenges.[21–26] More articles will likely be published regarding identified and yet-to-be-identified challenges for disclosure/CRP programs. There are several peer-reviewed articles as well as books, booklets, tool kits, online programs, and other publications that provide insight into how to train clinicians as well as risk, claims, and legal staff on the disclosure process.[27–32] This body of literature will surely grow and improve as more hospitals, medical practices, insurers, and attorneys gain experience with disclosure.

Finally, McMichael et al[33] released a study stating that statewide apology laws may actually increase the frequency of medical malpractice litigation for nonphysicians. Apology laws generally make certain empathetic expressions such as "sorry" inadmissible in medical malpractice litigation, but nothing more. McMichael and his colleagues were careful to stress that their data did *not* negate the findings of formal disclosure programs where clinical staff are typically trained in postevent discussions and receive other support, including assistance proactively settling cases. How to improve disclosure/CRP programs is the focus of the balance of this article.

Needs and gaps

Areas of the disclosure/CRP movement that have not received enough attention from researchers and disclosure/CRP leaders include the following:

1. Lack of disclosure training content outside acute care, including long-term care, ambulatory care, and other settings;

2. Messaging and CRP/disclosure programs;

3. Need for integrating second victim support components within disclosure programs;

4. Confidentiality agreements in settlements involving disclosure/CRP;

5. National Practitioner Data Bank (NPDB) and state medical boards;

6. Outreach to consumers, plaintiffs' bar, employers, and payors;

7. Measuring/assessing how medical and nursing schools are teaching disclosure/CRP; and

8. Encouraging states to pass apology laws that promote the development of formal disclosure/CRP programs.

Disclosure research and training content needs to move *beyond* acute care. The literature on disclosure/CRP was most noticeably quiet on long-term care, assisted living, and other senior living arrangements. In fact, long-term care terminology is integrated into training materials by only one disclosure/CRP training organization (Sorry Works!).[34] Granted, the disclosure/CRP movement actually began in acute care with the Lexington VA Medical Center, University of Michigan Health System, and other hospitals and their insurers. However, assisted living and long-term care organizations are an integral and growing part of the American health care system. Moreover, patients/residents and families can move back and forth between the nursing home or assisted living facility, hospital, and doctors' office. Also, many hospitals are now purchasing long-term care facilities. An adverse event for a patient/family could easily include clinicians from both the hospital/doctor's office and nursing home, yet the entire disclosure/CRP process could break down if the clinical staff in the nursing home are not trained or even aware of disclosure. Indeed, the time has come for the disclosure/CRP movement to recognize the importance of training health care professionals in long-term care and assisted living organizations. Research is needed here along with the development of content with appropriate terminology and cases.

Disclosure/CRP researchers should also investigate other health care organizations including ambulatory care, pharmacy, and other settings. There is a lot to research in disclosure *beyond* acute care.

As a new (or newer) movement, disclosure/CRP is spawning many different approaches to training, including the word choices to teach the concept to health care, insurance, and legal professionals as well as disagreements over how to market disclosure to stakeholder groups.

One major disconnect in the literature as well as training materials/content is what exactly does *apology* mean, and what are the implications (legal and otherwise) of providing an apology? Several papers and a recently released training book by ASHRM states that apology does not equate to responsibility, liability, fault, and the like. Consider the following sample passages:

- "An apology is simply an expression of emotion, not a legal conclusion. It may or may not support a factual determination of negligence, but the apology cannot alter the facts."[9]

- "Therefore, it is imperative that practitioners be aware of how to make statements that offer an apology or express regret but that do not include any indication of fault."[35]

- "Providers must understand that apologizing and accepting responsibility for the patient is distinct from an admission of guilt, both from the perspective of the law and in its effects on the patient-doctor relationship."[36]

Yet a sampling of other papers[23,26,37] and training manuals offer a different perspective on the meaning of *apology*. For example, one training book[38] suggests that "I am sorry this happened—we feel bad for you" is empathy (similar to the type of empathy a person would offer at a funeral), whereas "I am sorry this mistake happened—it's our fault," is an apology or an admission of liability. Clearly, this disconnect over the meaning/interpretation of *apology* in disclosure/CRP terminology needs to be addressed to avoid confusion among health care, insurance, and legal professionals.

Another area of disagreement over language and terminology is how disclosure/CRP is "marketed" or promoted to physicians and other stakeholders. There are three or more camps in this disagreement (conversation with Florence LeCraw, July 2018). Boothman[37] states that disclosure/CRP should primarily be positioned as a patient safety tool, while Gallagher[12] hopes that disclosure/CRP can be transitioned from a "crisis management tool" to a patient safety approach. Other commentators believe that disclosure/CRP should never be sold as a risk management tool and be promoted only in an ethical context ("Do the right thing").[9,39] Yet Mello et al said disclosure/CRP should be marketed in all three manners: litigation reduction, patient safety tool, and "do the right thing."[22]

Interestingly, when asked if her hospital is trying to avoid litigation with disclosure, Leilani Schweitzer, vice president at Stanford Hospital, replied "yes," but they are not trying to avoid accountability and responsibility for medical errors.[40]

Stepping back from this fray, the literature shows that there is physician resistance to disclosure.[41] One of the leading causes of this resistance is fear of litigation or increased litigation due to disclosure.[42] Historically, physicians and other health care professionals have been afraid of lawsuits and plaintiffs' lawyers, and organized medical groups have endorsed many reform proposals (namely, tort reform, mostly in the form of damage caps) to reduce liability exposure. Yet even tort reform does not effectively mitigate physician fears about medical malpractice lawsuits.[43] Clearly, there is a debate within the disclosure/CRP community regarding how to market disclosure/CRP. Adoption of disclosure by physicians is critical, yet there is documented resistance. Moreover, physicians are becoming more likely to suffer burnout and career dissatisfaction,[44] so new demands placed on physicians must be presented in a thoughtful and compelling manner. Perhaps the disclosure/CRP movement should consider following the sage advice of Dale Carnegie's best-selling book, *How to Win Friends and Influence People:* Talk about what the customer wants.[45] It is hoped that a survey of practicing physicians and nurses could quantify what messages will most likely encourage physicians to embrace disclosure/CRP and settle this debate. Moreover, survey work could be done to gauge the acceptance of disclosure among female and male physicians and among specialties.

There is a growing body on literature on the "second victim," a term coined by Dr. Albert Wu,[46] to describe physicians, nurses, and other health care professionals who experience emotional harm following involvement (or even knowledge of) an adverse medical event. Emotional harm experienced by impacted clinicians can range from mild depression to suicidal ideation and cause health care professionals to be involved in more adverse events, limit the scope of their practice going forward, quit or retire early, experience family problems (divorce, child abuse, etc), and even commit suicide.[47] Several articles describe in great detail how to develop programs in health care organizations to aid second victims.[48–50] At least two articles discussed how second victim support must be incorporated within a formal disclosure/CRP program.[23,24] Moreover, several advocacy groups, including Medically Induced Trauma Support Services,[51] actively support the development of content and programs for second victims. Nevertheless, according to conversations with Susan Scott, RN (July 2018), the nation's leading expert on the development of second victim support programs, the two concepts—disclosure and second victim support—are often not married or intertwined within health care organizations. A health care organization typically either has a disclosure/CRP program or second victim support program, but usually not both together. Interestingly, both disclosure/CRP and second victim support programs employ similar tactics of communicating with and helping people who are hurting after tragic events. Granted, clinicians and consumers are impacted in different ways by adverse medical events, but there are many commonalities in the trauma experienced by both groups, and trained professionals should be able to simultaneously assist grieving doctors, patients, and families. Indeed, work needs to be done fusing second victim support and disclosure/CRP.

There were a few peer-reviewed articles about confidentiality clauses in medical malpractice settlements.[52–56] Two of these articles explained the reasons why confidentiality clauses—or "gag orders" as the media sometimes refers to them—are necessary for settlement of cases, while other papers discussed the problems with confidentiality clauses, especially with disclosure/CRP and transparency taking root in health care. The advocacy and training group Sorry Works! released a report on confidentiality clauses in late 2017 providing an overview of the literature, interview comments from various stakeholders, and proposals for reforming or rethinking confidentiality clauses to align settlements with the disclosure/CRP principles espoused by health care organizations.[57] The Sorry Works! report suggested that confidentiality clauses are ethically

contradictory to the disclosure process and also inhibit patient safety, especially sharing information throughout the American health care system.

There was not much in the literature beyond these articles. Clearly, more attention is needed concerning confidentiality clauses or gag orders in light of the growing disclosure movement. How can a health care organization (hospital, nursing home, etc) disclose an error, apologize, and proactively compensate, yet enforce silence on the family at the end of the process?

Several papers identified the National Practitioner Data Bank (NPDB) and also state medical boards/licensure boards as impediments to the disclosure movement.[14,15,23,24,26,58] Physicians and other clinicians are concerned that disclosed and settled cases will result in reports to the NPDB, which can harm reputations and careers, as well as reports to state medical boards that can negatively impact licenses. This fear of reporting causes clinicians to shy away from endorsing or participating in disclosure/CRP programs, including proactive settlements of known medical errors.

The NPDB was primarily created by Congress in the 1980s to prevent incompetent and dangerous clinicians from leaving a state or region and availing their services to unknowing hospitals and medical practices.[59] The NPDB is a database of paid claims resulting from *written demands* as well as other disciplinary matters at the organizational and state level. The NPDB does not have disciplinary power over medical professionals, yet state licensure boards can suspend and even revoke licenses. Reporting requirements for the NPDB and individual state licensure boards were, in most instances, established before the advent of the formal disclosure/CRP movement.[60] Again, disclosure/CRP leaders routinely state that the NPDB and state boards are a major impediment to physicians and other clinicians participating in a disclosure process,[14,15,23,24,26,58] yet suggestions to reform or change the NPDB and/or state board can be met with hostile resistance from consumer advocates.[61] A pilot program in the state of Washington sought to seek cooperation from the state medical board for disclosure/CRP cases[62]; however, this same study[62] emphasized the importance of educating the public lest consumers believe that the program was/is simply a "get-out-of-jail-free card" for incompetent physicians. The state of Oregon's disclosure program provides a protection from the NPDB and state licensure for cases reported through their program.[20] An experienced health care lawyer provided a detailed road map to legally *not* report cases to the NPDB to encourage disclosure/CRP programs while highlighting there are new, different, and better ways to track incompetent clinicians.[60] Teninbaum[59] acknowledged that the NPDB resulted in fewer settled cases and longer time for cases to be settled (due to physician resistance to being reported to the NPDB), yet defended the value of the NPDB and instead suggested that reform should involve all cases against clinicians (closed, open, with or without written demand, individual or system error, etc) be reported to the NPDB. This approach would possibly remove the NPDB as an impediment to disclosure. However, the chances of getting Congress to dramatically expand reporting requirements when the NPDB is already scorned by the medical community are seemingly remote. Indeed, further discussions and research are needed about the NPDB and state licensure boards in light of the growing disclosure/CRP movement.

There were several articles (peer reviewed as well as essays and the like by advocacy groups) mentioning the need to educate the public and plaintiffs' personal injury bar. One conclusion from the Washington pilot program[62] that incorporated the state medical board was the need to educate the public lest consumers believe disclosure is a pass for bad doctors. A conclusion of participants of a 1-day conference[63] suggested, among other things, that more must be done to promote disclosure and apology with patient and family populations as well as better understand the experiences of patients/families who have experienced adverse events. The Massachusetts Alliance for Communication and Resolution Following Medical Injury (MACRMI) has worked to educate the public but has no data on the efficacy of their efforts (conversation with Melinda Van Neil, July 2018). Moreover, prominent researchers, disclosure program leaders, and advocacy groups have provided countless interviews for news stories about disclosure/CRP in trade and popular media outlets, but, again, there are no data on the effectiveness of these public relations efforts.

Medical errors are one of the leading causes of death in the United States,[64] but the average person or family probably believes they will never be victimized by substandard medical care. Surely, most patients and families don't have a game plan to deal with a potential medical error. Indeed, not enough hospitals, medical practices, and nursing homes even have a plan to deal with medical errors, yet these facilities experience adverse events on a frequent, if not daily, basis.[65] Moreover, the marketing messages directed at the public by health care organizations often feature heroic doctors, miracles, and quality rankings,[66] not frank messages about things that can and do go wrong in medicine. Educating the public about disclosure/CRP is a difficult but necessary proposition. Should it be part of the onboarding process for new patients and families?[67] Part of informed consent? Can it be part of the overall marketing message of health care systems? Should disclosure/CRP be marketed to employers and other payors? Other ideas? This area needs to be researched further.

Moreover, the plaintiffs' personal injury bar must be educated as well. MACRMI has formalized outreach with the plaintiffs' bar including the development of a list of plaintiffs' attorneys who have received education about disclosure/CRP programs,[68] yet MACRMI has no data on the efficacy of their outreach efforts (conversation with Melinda Van Niel, July 2018). Moreover, some

organizations and individuals have done their own outreach with the trial bar,[69] but more needs to be done. Finally, plaintiffs' attorneys could be included in research efforts to better understand how medical errors impact patients and families.[70] Possible research topics include the perspective of plaintiffs' attorneys regarding disclosure/CRP programs, including the experiences with well-known disclosure/CRP programs.

Beyond patients, families, and plaintiffs' attorneys, the perception and support of disclosure by payors (insurers, corporations, etc) should be investigated. There is no mention of payors in the disclosure/CRP literature.

No articles were found that measured or assessed what medical and nursing schools are teaching students about disclosure and apology/CRP and whether students feel adequately prepared by this content to have difficult conversations with consumers. For disclosure/CRP to take root, schools must teach this critical topic to future doctors and nurses. Moreover, students are ill-served by their schools if they are turned loose into the medical environment without effective training on how to have stressful and high-stakes conversations. A measurement of what is being currently taught and how it is being received could be illuminating for medical educators and also lead to national standards for curriculum on the topic.

Finally, state lawmakers can encourage the development of disclosure/CRP programs. As noted in McMichael et al,[33] traditional apology laws that simply protect empathetic expressions and apologies may actually increase litigation for some physicians because said laws do nothing to encourage or mandate the development of formal disclosure/CRP programs that train and support clinicians while providing upfront compensation and other forms of resolution that can stave off litigation. Recently, Colorado (Senate 19-201) and Iowa (Public Code 135) passed laws that provide protections for apologies for clinicians and health care organization so long as certain criteria are met that encourage development of disclosure/CRP programs.

Ultimately, what sets disclosure/CRP apart is no legislation is needed (unlike traditional tort reform measures such as caps on damages), yet state lawmakers can encourage the development of disclosure/CRP programs. More states need to re-visit their apology laws to include more comprehensive language as was adopted in Colorado and Iowa.

A list of the gaps and needs includes the following:

- *The lack of disclosure/CRP training materials/resources for long-term care, ambulatory, pharmacy and other areas beyond acute care.* The vast majority of disclosure/CRP research, content, and training is directed toward acute care. The disclosure/CRP movement needs to reach beyond acute care into other areas of health care including long-term care and other settings.

- *Messaging and CRP/disclosure programs:*
  ° Doing the right thing, patient safety tool, risk management strategy, or all of the above?
  ° Is an "apology" an admission of fault or not?

Like any new (or newer) movement, there are many ideas on how to sell the message as well as train willing participants. Disclosure/CRP is no exception, and these mixed signals can lead to confusion among health care, insurance, and legal professionals and slow adoption. More attention to word choices is needed, and research can help.

- *Need for integrating second victim support components within disclosure programs.* When adverse events happen, everyone hurts: patients, families, and clinicians. Though clinicians and consumers experience potential medical errors in different ways, there are commonalities as well. Unfortunately, most health care systems either have a disclosure/CRP program or a second victim support program but not both. More planning and discussion is needed here.

- *How do we change the thinking around confidentiality clauses in settlement agreements with the disclosure/CRP movement?* A hospital or nursing home can be completely ethical after an event, and disclose and resolve a case in a fair and expedited manner, but there may be a confidentiality clause or gag order in the final paperwork that contradicts the entire process, may anger the family, and derails external (outside the organization) patient safety efforts. Further discussion and advocacy is needed.

- *Confronting challenges for the disclosure/CRP movement with the NPDB and state licensure boards.* The research shows that the NPDB and state licensure boards are an impediment to the implementation of disclosure/CRP programs. Moreover, the reporting processes of the NPDB and many state licensure boards were implemented before the advent of the disclosure/CRP movement. Also, we now understand that many medical errors are caused by system flaws versus individual mistakes. Further research, discussion, and advocacy are needed.

- *Outreach to the public (patients and families), the plaintiffs' personal injury bar, and also employers and payors.* Are they receiving the message? What are their perspectives? Many among the general public as well as lawyers are conditioned to believe that doctors and nurses will employ "deny and defend" risk management strategies after an event. While this unethical approach is still prevalent, disclosure/CRP is taking root, and consumers, payors, and plaintiffs' attorneys need to be made aware, including their role in the disclosure/CRP process. What is their awareness? Moreover, how is disclosure/CRP currently perceived by consumers, plaintiffs' attorneys, and payors? Finally, what are the

most effective means to communicate about disclosure with these important stakeholders? These topics need to be researched.

- *Measurements/assessment of disclosure/CRP content in medical and nursing schools, and surveying of students to see if they believe schools are adequately preparing them to have difficult conversations with patients and families.* Future doctors and nurses need to know that disclosure/CRP is a professional expectation, and schools have a duty to prepare students for difficult conversations with patients and families. Assessments and surveys of schools and students is needed.

- Expand/revise state laws to encourage the development of actual disclosure/CRP programs. Legislative fixes are needed to implement disclosure/CRP programs, yet state lawmakers can hasten the development of these programs with legislative language similar to what has already been passed in Iowa and Colorado.

[Corrections added July 9, 2020, after first publication online. The article category was updated from Research to Operations.]

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ABOUT THE AUTHOR

Doug Wojcieszak *is the Founder and President of Sorry Works!, a 501c3 non-profit organization dedicated to advancing the disclosure & apology movement.*

Clinical/Patient Safety

Direct care nurses and support staff thoughts and feelings about the reasons patients fall at a cancer center

By Kathie McDonald, MPH, RN, LHRM ⓘ, Cassandra Vonnes, DNP, GNP-BC, AOCNP, FAHA, and Susan Hartranft, PhD, ARNP

Extensive research addresses the prevalence and high fall risk for cancer patients related to age, diagnosis, treatment side effects, pharmacological side effects, and cognitive and/or motor deficits. The purpose of the study was to explore the thoughts and feelings that inpatient and outpatient oncology direct care nurses (registered nurses) and support staffs have about reasons patients fall; as well as their thoughts on what might be done to prevent falls. This descriptive qualitative study used focus groups as the method for discovery. Six themes were identified: Effect on Me, Guilt, Noncompliance, Poor Choices, Inconsistency, and No Authority.

This study is significant and relevant because there is little previous research addressing staff thoughts and feelings about why patients fall and what additional interventions they think can be implemented to prevent falls. Findings from this study may be helpful in developing and/or refining current fall policies. Existing research suggests unlicensed patient care providers often have minimal participation in postfall reviews. This study suggests they can provide insight into why patients fall. Additionally, both registered nurses and unlicensed providers describe barriers that often impede their ability to work as a team to prevent patient falls. Findings from this study identified the need for the patient care team to strengthen collaborative work to create safer patient environments.

INTRODUCTION

Patients receiving treatment for cancer are often at greater risks for falls due to age, diagnosis, treatment side effects, pharmacological side effects, and cognitive and/or motor deficits.[1] Falls occur in about 33% of older adults with cancer versus 29% of those without cancer.[2] Per the Institute of Medicine,[3] the number of cancer diagnoses in older adults is expected to increase by 67% in the next 20 years. Physical, cognitive, and other risk factors associated with cancer are important reasons for maintaining a safe environment to prevent falls and falls with injury.

The cancer center in this study has a comprehensive fall and fall-related injury risk reduction program in both inpatient and outpatient areas. Assessment, education, and interventions for patients and family regarding risks for a fall or fall-related injury begin on admission. Creating and maintaining a safe environment to prevent falls and falls with injury is a primary responsibility of all members of the oncology patient care team.

Although at the health center falls and falls with injury consistently fall below the mean on a national measure, and despite an evidence-based fall prevention approach in the outpatient and inpatient setting, falls still occur. Registered nurses (RNs) and other frontline support staff can provide crucial information needed to evaluate current practices for reducing patient falls. Performing interviews of frontline staff may enrich the cancer center's understanding of why patients fall. The primary purpose of this study was to interview and identify registered nurses' and support staff's thoughts and feelings about why patients fall. An additional objective was to elicit the licensed and unlicensed care provider's thoughts on what more could be done to decrease falls.

BACKGROUND

Patients diagnosed with cancer are at increased risk for falls due to cancer treatments, which can cause innumerable physical impairments such as fatigue along with cognitive and nutritional deficiencies.[4] The prevalence of falls in cancer patients is well documented in inpatient and outpatient oncology settings. Several study findings show that community-dwelling patients with cancer sustain more injuries and fall more frequently than patients without cancer.[2,5–7] About 20% of patients aged 65 or older with newly diagnosed cancers report a fall at home within the first 6 months of their cancer diagnosis.[8]

A systematic review of research describing factors associated with outpatient falls in older adults with cancer was conducted by Wildes and colleagues.[9] Common risk factors include needing assistance with activities of daily living and evidence of a previous fall.[9] Review of the research confirms that more evidence is needed to develop and evaluate specific fall prevention strategies in outpatient oncology settings. Further, Wildes describes that older cancer patients who fall in the inpatient setting have similar risk factors to the general population of elders.

Factors leading to falls in cancer patients can be intrinsic and extrinsic. Intrinsic factors such as pain, fatigue, muscle weakness, and ambulation problems occur with cancer treatment. Extrinsic or environmental risk factors include poor lighting, slippery floors, improper footwear, and uneven walking surfaces.[10] Risk factors associated with cancer patients' falls in the inpatient setting include those associated with "geriatric domains, including comorbidities, functional status and physical function, medications, cognition and depression."[9] Comprehensive screening and assessment during hospitalization for cancer treatment may help identify patients at risk for falls.[11]

Prior to developing a fall prevention program in nursing homes and assisted living facilities, Phillips and colleagues[12] conducted focus groups with certified nursing assistants (CNAs) and care assistants (CAs) to determine their knowledge about falls and strategies for preventing falls. Findings indicated that both CNAs and CAs had limited knowledge about fall prevention interventions and had limited participation in postfall reviews. Phillips and colleagues propose that sustaining fall prevention programs depends on licensed and nonlicensed staff cooperation. Focus groups were also conducted to determine RNs' and CNAs' perceptions of why patients fall and if falls could be prevented in non–oncology care settings.[13] They found 6 components to decreasing falls: patient report, information access, signage, environment, teamwork, and involving patient/family.[13]

There were no studies found that examined the thoughts and feelings of RNs and nonlicensed staff in an oncology setting. Therefore, the primary objective of this study was to obtain thoughts and feelings of licensed medical personnel (such as RNs and radiology and imaging technicians) and unlicensed personnel (such as valet, environmental, and cafeteria services) of reasons why oncology patients fall during inpatient and outpatient visits to a cancer center. An additional objective was to elicit the licensed and unlicensed personnel's thoughts on what more could be done to decrease falls.

METHODS

The conceptual framework guiding this study is Joanne Duffy's Quality-Caring Model.[14] Foundational to Duffy's model are relationship-centered professional encounters. During health care encounters, the patient with health care needs connects with the direct care nurse and other team members who "function independently and collaboratively with them."[14] These independent, yet collaborative, relationships are grounded in 8 caring factors. Direct care nurses assess patients for falls guided by specific caring factors including creating a safe environment (caring factor: healing environment), educating and seeking

feedback from patients and families about strategies for fall prevention (caring factor: mutual problem solving), and collaborating with clinical and nonclinical providers to create a safe patient care environment (caring factor: healing environment and basic human needs).

The design for this study was a descriptive qualitative study, using focus groups as the method for exploration. The focus group method was chosen as it provides a setting for participant expression of opinions.[15]

Setting and sample

This study was conducted at an NCI Comprehensive Cancer Center with Magnet designation located in the southeastern United States. There are 204 designated inpatient beds, with an average daily census of 160. Twenty-seven ambulatory units provide 250,000 clinic visits yearly. There are approximately 9500 surgical procedures annually.

A purposive sample of RNs and support staff were recruited using patient fall occurrence reports, which listed names of individuals who witnessed a fall. All participants witnessed a fall within 6 months of the focus group session. The participants for the inpatient groups consisted of one group with inpatient RNs and another group with inpatient oncology technicians. The outpatient groups were composed of one group with outpatient RNs and another group with non-RN staff such as outpatient medical assistants, medical office assistants, transporters, patient access representatives, and valets, for a total of 13 RN and 10 nonlicensed participants. Participation was voluntary, and responses were anonymous.

Ethical considerations

This study adhered to legal and ethical guidelines and all policies of human participants required by the center's Scientific Review Committee and Institutional Review Board. Participants were able to leave the focus group at any time with no adverse consequences. At the conclusion of the focus group, the participants were able to review all notes taken by the focus group leader and research assistants. Audiotapes were transcribed by an outside transcription service and were destroyed after the principal investigators (PIs) verified transcription accuracy. The study posed little to no risk to participants, and the steps listed above supported the minimal risk.

Data collection

Each focus group met for one 60-minute tape-recorded session in a private conference room. A minimum of two of the individuals listed as research assistants and or co-PI functioned as recorder/assistant focus group moderators for each session. Their roles included taking written notes throughout the focus group sessions, operating and monitoring of recording equipment, and debriefing with the group leader.

Focus groups were led by the PI, an experienced focus group researcher with health care professionals, who holds postgraduate certification in developing and leading focus groups. The facilitator is an active participant in the interprofessional fall and injury prevention committee providing data on falls received through the safety reporting system.

An open ended "ice-breaker" question began each session. After that, structured interview questions were used (**Figure 1**). The study team included the facilitator with experience facilitating focus groups, a doctor of pharmacy, a geriatric nurse practitioner, a fall prevention team leader, and three direct care nurses who were members of the fall prevention team. A PhD-prepared nurse was also on the study team. She has no clinical responsibilities, had not witnessed any falls, and did not attend the focus group sessions. She did, however, review the verbatim transcripts and facilitated the study team members regarding their interpretation of the data.

ANALYSIS OF DATA

The focus groups consisted of Group 1, inpatient RNs (5); Group 2, inpatient nonlicensed personnel (n = 5); Group 3, outpatient RNs (n = 8); and Group 4, outpatient nonlicensed personnel (n = 5), for a total of 13 licensed and 10 nonlicensed participants.

Credibility was accomplished through the use of audiotaping of focus groups, member checking, and a summary of key points at the close of the focus group. Credibility was also established through peer debriefing; the focus group moderators reviewed the transcripts and identified codes, compared codes for similarities and differences, and developed themes.[16,17] Confirmability was demonstrated by the inclusion of the participants' direct quotes in the discussion and through participants approving verbal summaries of notes and observations before the close of the focus groups as well as through the opportunity to review transcripts.

Verbatim transcriptions were reviewed individually. Once the individual team members were comfortable with the material and had identified preliminary themes, the team met as a group to establish study themes. The themes were developed by group analysis of responses to each individual question. Consistent with recommendations for analysis of focus group data, the notations of the observers (participant vehemence of response, participants nodding in agreement or disagreement) were also considered in the analysis.[15] Through this process, 6 themes were identified. There was also agreement that data saturation was reached, and therefore no further focus groups were needed.

RESULTS

Four focus groups were conducted with a total of 23 participants from both inpatient and outpatient areas. The participants were all current employees who had witnessed a fall within the past 6 months.

Figure 1:

Structured Interview Questions

Structured Interview Questions
1. Tell us the department you work in and how long you have been working here?

The tape recorder was turned on and note taking began after introductions.
2. Remember back to when you first began working at Moffitt. Do any special feelings or observations come to mind about your initial experience when you first came to work here?

3. When you hear the words *patient fall*, what comes to mind or what do you think about when you hear those words?

4. I want you to think about any particular patient behaviors you may have noticed regarding falls. Write down three things that come to mind and then we will share answers.

5. Now I want you to think about any particular staff behaviors you may have noticed regarding falls. Write down three things that come to mind and then we will share answers.

6. Tell me how you feel when a patient you are caring for falls?

7. What specific actions do you think staff or patients could take to help prevent patient falls?

8. All things considered, suppose you had one minute to speak about the patient falls you've witnessed. What would you say we could or should do to prevent patient falls?

9. Does this summary capture the important points that were made today?

10. We wanted you to help us identify important actions we can take to help our patients make their time here safer. Is there anything we missed or should have asked about today?

A total of 6 themes were identified, 5 of which were through data analysis of the licensed nurses: Effect on Me, Guilt, Noncompliance, Poor Choices, and Inconsistency. The sixth, No Authority, came from analysis of the nonlicensed focus group participants. The themes emerged from the responses to the specific questions.

Theme 1: Effect on Me

The question generating this theme was: What do you *think* when you hear the words *patient fall?* One nurse's immediate response was "cringe, cringe, cringe," followed immediately by "like, oh man, really, especially when they are a walkie talkie." (The nurse's use of the term *walkie talkie* is slang for a patient who is alert and able to communicate and ambulate independently). Another response referred to need to attend "post huddle" debriefing and the "extra paperwork" of completing an occurrence report. Additional comments highlighting effect of falls on staff include a nurse who mentioned "the paperwork" to complete as well as having to attend the "fall meeting." The fall meeting is held twice a month, and the nurse caring for the patient at the time of the fall presents the contributing factors and potential gaps in care.[18]

Theme 2: Guilt

When asked about *feelings* when they hear the words *patient fall,* several nurses responded with the term *angry,* although "guilty" was the overwhelming response. One nurse said "defeated" and then "guilty." The nonlicensed

participants responded in a similar way, with "guilty" as the overwhelming response. One participant's response seemed to sum it up for all participants: "I feel so bad, though. It makes you really want to cry."

Theme 3: Noncompliance

Perceived patient noncompliance emerged as a theme and appeared to be what fueled the nurses' anger, as noted in Theme 1. One nurse's response spoke for many:

> What comes to mind are the uncooperative noncompliant patients. They've been instructed, told—I mean, we've put in every safety feature we can. And they're stubborn. And don't call. And it's like, REALLY? (Capitalized to capture the emphasis of the speaker) … But the ones we just went overboard on, instructing them and getting the contract signed and the whole schlemiel.

Another nurse stated, "They overrate their abilities. No matter what the alarms, they will just jump out of the bed."

During these statements no one attempted to interrupt the speakers. All the participants nodded their heads in agreement with the speakers.

Theme 4: Poor Choices

One inpatient nurse had a different view of noncompliance: "This is the last bit of control they have,

going to the bathroom on their own and different things. And there is just so much they can take in from education. But they are still going to try to live out their life and do things and try to be independent." This statement received nods and voicing of agreement by participants and appear to show the participants moving away from a belief that patients who fall are willfully noncompliant to perhaps not understanding their current condition, leading them to make poor choices.

Further indication that some participants looked at noncompliance as poor choices is their mention of inappropriate footwear, specifically "flip-flops," a footwear staple in Florida. Additionally, some of the outpatient nurses noted: "They refuse wheelchairs"; "they just can't differentiate when they really need a wheelchair"; and "they do not know how tired they are." This is especially true in the outpatient department, where patients may walk long distances between various diagnostic and physician visits. The walks often occur after the patient has been NPO for lab work and then did not have the time to eat before a physician appointment.

Theme 5: Inconsistency

This theme emerged during the discussion from the question, "List 3 staff behaviors you believe may contribute to falls." The participants mentioned two types of inconsistency: inconsistency in instructions to patients and inconsistency in application of evidence-based practices.

> I know we do a lot of education. But I think a lot of is in the approach of that education. So you have some nurses who kind of approach it a little gentler. And then, some nurses may be a little pushier with it. And maybe patients may respond to how the education is presented.

> Lack of consistency, maybe? You have a day nurse doing one thing and then a night nurse doing another. The patient gets resistant because the other nurse didn't put on the bed alarm; why do you have to?"

The nurse went on to describe the conflict created:

> You obviously can't say well the other nurse was wrong but you have to follow the policy, so you have to say it in an appropriate way, so it doesn't look bad.

This comment supports the inconsistency in approach to fall prevention intervention among nurses but also points to the difficulties nurses face daily. The nurse should follow the procedure and apply fall prevention strategies but at the same time not say anything that may make the patient think the care administered by the other nurse was below standards.

Inconsistency of application of evidence-based practice is illustrated with the following examples. Inconsistency with

who answers call lights was mentioned during the discussion about staff behaviors. Several participants mentioned, "The techs don't answer the lights." The nonlicensed participants related, "The nurse will be sitting and they call for us to answer the light. Lots of times we are busy." Although this is inconsistency in application of evidenced-based practice (closest person answers the call light), it appears to illustrate a lack of teamwork and communication and perhaps skewed perceptions.

Theme 6: No Authority

This particular theme emerged only in the nonlicensed focus group; several participants mentioned that they thought patients would not listen to them about not getting out of bed without help because they were not the RN. This theme is perhaps best summed up by this participant:

> If they know we are the tech and not the RN—because I've had several patients tell me that I'm not an RN—they don't listen to us educating them on "you should not be getting up by yourself. You should be wearing your socks when you get out of bed. I have to put the gait belt on you." "Oh no, no, no. I don't want that. I don't want that. I can do it myself. I'm not going to fall." They don't listen to us.

During this discussion, all focus group members nodded their heads in agreement.

Fall prevention strategies

There was a focus group question that asked participants for suggestions regarding fall prevention. The suggestions brought forward were broad suggestions to address the themes presented above. Improved teamwork was suggested, as was consistency in applying evidence-based practices. There were some specific suggestions for patient teaching regarding appropriate footwear as well as suggestions to examine the strategies in place for inclement weather, as they believe the rugs and water-absorbing methods in place create further hazards for the patient as they maneuver from the outside to the inside. An additional suggestion was to make snacks available in the clinics.

DISCUSSION

When viewed through the lens of Duffy's conceptual framework and 8 caring factors, one can see elements found in the nurses' responses. Recognizing that patient behavior may be a result of exercising the only control they have over their lives at this time is recognition of the caring factor and appreciation of unique meanings. In contrast, the identified theme of Noncompliance may indicate the appreciation of unique meaning is not complete. The nurses have a concern for patient safety; however, their inability to gain compliance with explanations and

education is a source of frustration. Another possibility is that the nurse may be experiencing compassion fatigue, making it difficult to empathize with the patient and creating their focus on the effect the patient behavior has on their workload.

The study findings led to several changes. Outpatients are asked by the intake clerks if they have fallen in the last month or if they use an assistive device. If they answer yes, a yellow band is placed on their wrist as an indication of fall risk. Patient education materials have been modified to include appropriate footwear. Snacks are now available free of charge in some clinics. Additionally, there are ongoing initiatives aimed at improving communication among the patient care staff as well as teamwork. These changes have not been in effect long enough to assess their effect on falls or on the thoughts and feelings of the licensed and unlicensed staff.

An area for further exploration is the nurses' perception of postfall follow-up as punitive. The health center administration believe they have a nonpunitive approach to fall follow-up; however, it appears that the staff may not view it as nonpunitive. Moving from a focus of *patient fall* to *fall with injury* can alleviate this burden from the direct care team. While it has been demonstrated that patient falls may not be prevented, aligning the strategies around injury prevention may be a more realistic goal in both an inpatient and outpatient setting.

STRENGTHS AND LIMITATIONS

Strengths of this study include the following: The focus groups were homogeneous. Unlicensed team members were included in a dedicated focus group. The literature review suggests that these individuals are not often included when studying falls. This study supports including nonlicensed personnel; they were observant and offered insight into reasons for falls.

Limitations include that this study occurred in one center, participants were invited to attend, and those who attended may have chosen to participate to vent frustration. Additionally, the data analysis may have benefited from a consumer member without clinical knowledge of falls. Although there was a small number of participants in the focus groups, responses were consistent across the groups, and the team agreed that the number appeared sufficient for data saturation.

IMPLICATIONS FOR FURTHER RESEARCH

This study provided a description of cancer center health care workers' thoughts and feelings about patient falls. Further research is recommended in other cancer centers to determine if the findings are consistent with the findings of this study.

Methods to provide consistent patient education and consistent implementation of evidence-based fall prevention strategies by staff should be studied. All team members need to be equipped to provide background and offer explanations of interventions intended to focus on injury prevention. An additional area to explore in focused discussions around fall prevention is to include the patient and family advisors.

The administration believe a nonpunitive approach to fall safety exists in this institution. However, it may be that some of the practices (postfall huddles, occurrence reports, and peer review) may be considered punitive by the staff. Further study is indicated to determine what aspects of the evidence-based approaches health care workers consider punitive and what actions are viewed as nonpunitive.

CONCLUSION

This study is significant because there is little previous research addressing health care workers' thoughts and feelings about why patients fall. Focus groups were shown to be an effective methodology to elicit these thoughts and feelings. Suggestions for fall prevention strategies were also elicited. Some of these strategies may be used by the patient care team to strengthen collaborative work in creating safer patient environments and team communication in the inpatient and outpatient oncology setting.

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ABOUT THE AUTHORS

Kathie McDonald, MPH, RN, LHRM, *is the senior risk manager at Moffitt Cancer Center in Tampa, Florida, and has worked in risk management for 11 years. She previously worked at Moffitt as the senior nurse epidemiologist for 3 years (2006-2008), where she managed the Infection Prevention Program, and as the nursing supervisor for 5 years (2001-2006). Prior to working at Moffitt, she worked at Florida Medical Quality Assurance Inc. (the Florida quality improvement organization) as the state epidemiologist for Medicare (1996-2001). She is an RN and received a BA degree in education in 1981 and master of public health in 1989. Kathie had also been certified in Infection Control and Epidemiology for 25 years. She additionally has 19 years of emergency room experience.* ***Cassandra Vonnes, DNP, GNP-BC, AOCNP, FAHA,*** *attended the University of South Florida for her BS, MS, and DNP degrees. She worked as a direct care nurse and patient care manager in the intensive care unit for 10 years before receiving her gerontological nurse practitioner degree and certification. Her 25-year nurse practitioner experiences include acute care and outpatient nephrology and cardiovascular medicine. She was inducted as a Fellow of the American Heart Association for her contributions in cardiovascular medicine. Dr. Vonnes has taught clinical and didactic at the USF College of Nursing for undergraduate and nurse practitioner students. Dr. Vonnes uses her geriatric expertise in oncology as the Nurses Improving the Care of Healthsystem Elders (NICHE) coordinator at Moffitt Cancer Center, an exemplar organization for NICHE. In April 2019, Dr. Vonnes received the Oncology Nurses Society Excellence in Care for the Older Adult With Cancer Award. Under Dr. Vonnes's leadership, Moffitt became the first Florida hospital to be identified as an Age-Friendly Health System by the IHI and John Hartford Foundation in June 2019.* ***Susan Hartranft, PhD, ARNP,*** *has been the director of nursing research at Moffitt Cancer Center for 5 years and is responsible for assisting staff nurses who have researchable ideas through all phases of the research process. Prior to her tenure at Moffitt, she was employed for 25 years in various roles within Morton Plant Mease Hospitals, a part of the BayCare Health System. Dr. Hartranft received a BS in nursing in 1977 from Albright College in Reading, Pennsylvania. Her MS in nursing (1984) and PhD in nursing (2009) are from the University of South Florida in Tampa.*

Clinical/Patient Safety

The development and implementation of a postfall template to improve the content of provider documentation related to falls in the hospital setting

By Leah M. Schmitz, MPAS, PA-C, Peter Hakos, MPAS, PA-C, Mary Kirsch, BSN, RN, CCRN-K, Joann Palmer, BS, RN, CPHRM, CPPS, Beth Poltorek, BSN, RN, CRRN, and Cynthia J. Stives, APRN, CNP

Patient falls are the focus of many hospital prevention and continuous improvement initiatives. This is due to the potential negative impact on patient quality and safety outcomes, cost of care, and litigation risk. The published literature includes an abundance of information regarding fall-prevention programs; however, there is a gap in the knowledge base pertaining to implications of what is documented by providers (physicians, nurse practitioners, physician assistants). There is concern that inadequate documentation may be associated with patient safety and quality issues. These include potential delays in the identification and treatment of fall-related injuries and increased legal risk. A routine analysis of submissions to the hospital's Safety Event Reporting System identified inconsistencies in provider postfall documentation. Because of the potential impact on patient care, safety, financial, and medical-legal implications, a project team was created to optimize the workflow and improve provider documentation as part of the comprehensive postfall program. This article describes the process of creating and implementing a postfall template to standardize and improve the content of postfall notes. The standardized template aligns with the organization's current initiatives to increase caregiver awareness of the impact of patient falls, and to improve patient safety and quality of care.

ORGANIZATIONAL OVERVIEW

The site of this continuous improvement project is a newly built 126-bed regional community hospital that is part of a large nonprofit, academic, quaternary care health system. The hospital first opened in November 2016 and provides access to multispecialty care to patients 18 years of age and older. It consists of medical, surgical, step-down, intensive care, and rapid observation units. A culture of continuous improvement, high reliability, and safety has existed since day one and is introduced to all employees (who are referred to as *caregivers*) as part of the orientation and onboarding process. This culture is supported by the executive leadership team and is truly part of the daily mind-set of caregivers involved in every aspect of the patient's experience. Every caregiver is encouraged to follow the "see something, say something" principle, and all safety events, concerns, and near-misses are encouraged to be reported in the hospital's Safety Event Reporting System (SERS). Daily tiered safety huddles create an environment for reporting safety and quality concerns and provide a standardized method of escalating significant or systemic concerns to the regional and organizational leadership so that they can be addressed efficiently. Emphasis is placed on process improvement and education as opposed to a punitive approach, which helps engage caregivers in the reporting process.

INTRODUCTION

Patient falls are a focus for continuous improvement initiatives in hospitals. This is driven by the potential negative impact of falls on patient satisfaction, quality and safety outcomes, cost of care, and legal risk. Every year, between 700,000 and 1,000,000 patient falls occur in hospitals with approximately 30% to 35% of falls resulting in injury.[1,2] Falls are defined as "an unplanned descent to the floor with or without injury to the patient."[1] When injury occurs as a result of a patient fall, reimbursement may be decreased due to the linking of payment to quality, as seen in the No-Pay Policy for hospital-acquired conditions.[3,4] An analysis of falls with injury in the Joint Commission's Sentinel Event database demonstrates that inadequate assessment, communication failures, and lack of adherence to protocols are common contributing factors to poor outcomes.[4] Poor or absent documentation can lead to patient safety and quality-of-care issues including delays in identifying and treating injuries, risk of subsequent falls, or increased legal liability.[5-7] The purpose of this article is to demonstrate the rationale for and process utilized when creating a template for providers to use when performing a postfall evaluation of a hospitalized patient.

FALL PREVENTION STRATEGIES AND PROTOCOLS

There are numerous articles pertaining to fall prevention programs and the implementation of associated initiatives. The goals of fall prevention programs include decreasing the incidence of falls and the severity of injuries associated with falls. Many of these initiatives have been shown to be effective, and this has led to most hospitals implementing multifaceted fall prevention programs. Analysis of fall incidents and systematic reporting are noted to be important components of a comprehensive fall prevention program by The Joint Commission.[2] A Web-based application provided by The Joint Commission Center for Transforming Healthcare is dedicated to assisting organizations in using evidence-based solutions to decrease the incidence of falls.[8] Postfall management, including a postfall huddle, discussion of contributing factors, and updates to the patient's plan of care is recommended.[2] This facilitates increased communication between members of the health care team as it relates to patient fall events. When falls do occur, it is important for a provider to be notified immediately to ensure that a timely evaluation is performed.[7,9] Many hospitals incorporate notification of the provider into the initial phase of the fall protocol.[6,7,10] The protocol developed by Gordon et al[6] is an example of one that incorporates notification of the charge nurse and a physician involved in the patient's care as part of the postfall workflow. This is similar to the workflow outlined in our nursing protocol for patient falls.

IMPORTANCE OF APPROPRIATE DOCUMENTATION

Clinical documentation was initially developed to record information related to a patient's condition and communicate with other health care professionals.[11] The addition of evaluation and management guidelines for measuring cognitive services added complexity to the requirements of clinical documentation. Defensive medicine practices have also contributed to the inclusion of pertinent negative findings. The growth of value-based care and accountable care models have led to additional documentation requirements over time.[11]

Appropriate documentation is defined as being accurate, relevant, clear, complete, and confidential.[12] Accurate and thorough documentation by a provider (physician, nurse practitioner [NP], physician assistant [PA]) is particularly important in the event of a patient fall in a hospital setting and can help to mitigate potential adverse outcomes.[9] Timely evaluation and comprehensive documentation may prevent delays in identifying fall-related injuries and potentially decrease adverse outcomes related to patient falls. Poor or inadequate documentation can lead to patient safety and quality-of-care issues. These include delays in identifying and treating injuries, increased risk of additional falls if the contributing factors are not addressed, and risk of litigation.[5-7,10] A recent systematic review of 6 studies concluded that the rates of falls and documentation errors are decreased with the use of electronic documentation interventions by nurses.[13] Although this was a study that evaluated nursing documentation rather than provider notes, the results

demonstrate value in using the tools available in the electronic medical record to improve outcomes by focusing on better documentation.

RATIONALE FOR CONTINUOUS IMPROVEMENT INITIATIVE

While the hospital had a comprehensive fall prevention and management program in place since its opening, an area of opportunity was discovered related to provider documentation (Figure 1). There are several universal fall precautions that are part of routine daily patient care such as removing trip hazards and educating patients to call for assistance when getting out of bed. Caregivers are encouraged to review medications that can cause dizziness or hypotension, which may increase the patient's fall risk. Additional fall prevention strategies include the use of visual indicators, such as a yellow wristband, yellow nonslip socks, and a light or sign outside the patient's room to indicate high fall risk. Bed and chair alarms are also used to alert caregivers of patient activity that may require timely intervention to prevent a safety event. Unfortunately, despite these preventative measures, falls do occur.

When a patient sustains a fall, the emphasis is on timely patient evaluation and treatment. The postfall nursing protocol focuses on an immediate assessment of the patient for injury, evaluation of what factors contributed to the fall, notification of a provider, and reporting of any fall or near fall in SERS. Notification of the provider is important so that evaluation and treatment are not delayed and to ensure that all members of the care team are aware of the fall. A postfall huddle is also performed to ensure that all aspects of the patient's safety and care have been addressed. This is in alignment with The Joint Commission's suggested actions for management of falls and fall-related injury.[2] The postfall huddle includes the person(s) who witnessed the fall (if applicable), the patient's nurse, the patient care nurse assistant, and the nursing supervisor. A nursing documentation template and checklist is completed as part of the postfall workflow.

The patient safety coordinator reviews all of the events reported in SERS to ensure that there is follow-up regarding any opportunities for education or process improvement. While conducting a review of the initial fall-related events, inconsistencies in the documentation by providers (physicians, NPs, and PAs) were noted as related to patient falls. This was brought up at our daily safety huddle and prompted discussion with provider leadership to determine if there were guidelines in place to determine what information should be included in a postfall progress note. At the time, no standardized guidelines for postfall documentation by providers were available for use when evaluating a patient who had fallen.

A review of documentation of several fall events revealed that the postfall notes completed by providers were found to vary in the amount and type of information included. In several cases, pertinent information regarding the fall, contributing factors, components of the physical exam, and information regarding the plan of care were lacking. In some situations, there was a fall or near-fall event reported in SERS; however, there was no documentation by a provider. A review of the literature included studies that demonstrated similar inconsistencies in provider documentation.[5,7,10] The importance of a thorough assessment after a patient fall was discussed in several studies.[5,10] In the study by Nelson and Reynolds, it was shown that upon review of free text postfall notes, 50% of the expected data points were not recorded.[7] Brown and Doyle[5] evaluated the management of patients who had fallen in a single hospital over a 5-day period and found inconsistencies in postfall documentation. They concluded that patients are often suboptimally managed and that a comprehensive and systematic approach may improve care.[5]

FORMATION OF POSTFALL COMMITTEE

Following the initial discussions between the patient safety coordinator and clinician (physician and NP/PA) leaders, a multidisciplinary project team was created to optimize our postfall workflow and provider documentation. We felt it was important to get input from clinical, administrative, and risk management perspectives to ensure that we included the desired content for what would be considered optimal documentation. Representatives from the following groups and departments were invited to participate: Clinical Risk Management, Hospitalist Providers (physician, NP/PA), Patient Safety, Quality, Physical Therapy, Pharmacy, Nurse Management, Nutrition, Electronic Health Record (EHR) specialists, and Hospital Administration. It is important to note that we had support and buy-in from the hospital leadership team, which is vital for the success of any continuous improvement initiative.

The multidisciplinary committee met and reviewed the existing fall prevention and postfall protocols. The committee determined that it would be best to align the workflow of the providers with the existing nursing workflow to ensure that all members of the care team were using a similar process. The committee also reviewed examples of provider postfall notes to identify the potential causes of the inconsistent documentation. The recommendation of the committee was to create a postfall template based on what were considered to be high-quality notes as a tool for providers to use when documenting a postfall evaluation. The rationale for using a template was to provide a systematic approach that could improve the content quality of postfall notes and potentially improve the quality of patient care and decrease risk and subsequent adverse outcomes.

- Hester Davis Fall Risk Assessment Scale (18)
- Completed at time of
  - admission
  - transfer
  - change in caregiver
- Postfall evaluation

- Universal fall precautions
- Visual indicators
- Yellow wrist band
- Yellow nonskid socks
- Bed/chair alarm

Safety Assessment

Fall Prevention Strategies

Postfall Management

If Fall Event Occurs

- Caregiver roles
- RN
- Provider
- Nursing supervisor
- Patient safety officer

- Prompt assessment
- Limit risk of further harm
- Notify provider
- Postfall huddle

RN
- Postfall assessment
- Notify provider
- Postfall huddle form
- Postfall documentation
- Report safety event (SERS)

Provider
- Postfall evaluation and physical examination
- Postfall diagnosis and treatment
- Notify family if indicated
- Postfall documentation using template*

Nursing Supervisor
- Facilitate Postfall huddle
- Document on daily census report (communication to leadership)

Patient Safety Officer
- Analyze reported event
- Provide education and feedback to staff
- Address opportunities for improvement

Hester Davis Fall Risk Assessment scale[18]

DEVELOPMENT OF POSTFALL TEMPLATE

Tools within the EHR such as order sets and templates can be used to guide clinicians in evaluation, treatment, and documentation. Mehta et al[14] found that the use of a problem-oriented charting template improved the accuracy, usefulness, organization, and consistency of provider documentation as measured by the Physician Documentation Quality Instrument. Templates have been shown to improve the content and quality of documentation and can be used to prompt providers to complete the pertinent components of a postfall evaluation.[13] They can remind providers to include specific information, perform a complete assessment and physical exam, and ensure proper monitoring, and additional diagnostic tests are ordered if indicated. Templates can also contribute to risk management strategies using standard processes to reduce the likelihood of subsequent patient harm.[15]

The content included in the template was determined by the members of the postfall committee based on recommendations from The Joint Commission and National Patient Safety Agency, as well as prior studies.[4,7,9] The method of using a multidisciplinary expert panel and recommendations from governing health care organizations is supported in prior studies.[10,16,17] The information that was considered to be important for postfall documentation included potential causes or contributing factors to the fall, medications that may be a fall or bleeding risk, physical exam (including musculoskeletal, skin, and neurological exams specifically), injury status, and plan-of-care details including additional fall risk precautions (Table 1). The committee agreed on the content, and then a draft of the template was created by clinician project team members and EHR specialists. The template was then presented to the committee, and after a few revisions, was approved for use by a group of hospitalist physicians and NP/PAs who agreed to pilot it. The postfall template was initially designed as a "smart phrase" that was owned by the EHR physician specialist and had to be manually shared with each provider for them to access the note. After presenting the postfall improvement initiative to the organization's Quality Forum, a "system smart phrase" was created for the template so that any provider could access it. This process encountered multiple delays but was completed in February 2018.

IMPLEMENTATION

The template was initially trialed by a small group of providers during the development phase in the first half of 2017. The designers of the postfall template then shared it using a "dot phrase" with additional providers from the hospitalist and NP/PA teams in August of 2017. These groups were chosen to pilot the use of the template because they provide consistent coverage for a large percentage of patients at the hospital, and their leadership was involved

Table 1: Key Components of Provider Postfall Documentation

Time of assessment by provider

Potential cause(s) or contributing factors of fall

Location of fall

Medications (particularly those that may contribute to a fall or bleeding risk)

Review of recent laboratory results

Vital signs

Pain assessment

Physical exam completed

    Skin assessment

    Musculoskeletal evaluation

    Neurologic evaluation

    Mental Status assessment

Injury status

Plan of care updated

Family notification addressed

in the development process. A communication was sent to the groups to introduce the template, and instructions were given to providers regarding how to add this to the list of "favorites" in the Epic smart phrase list. Epic physician specialists were available to assist with this process. Reminders were sent to ensure that the providers were aware of the template and had added it to their list of favorites. The patient safety coordinator reviewed the documentation associated with each fall reported in SERS and notified the manager or director if a provider did not use the template for postfall documentation. Education was then provided to the individual clinicians to ensure that the template was included in their favorites and used for postfall evaluations. A poster presentation was also created for the hospital's Safety Fair during this time to demonstrate the alignment of our recommended documentation template with the organization's current initiatives regarding patient falls.

As part of the process of expanding the use of the template to other providers, the initiative was presented to the Enterprise Falls Committee in February 2018. At that time, the enterprise-level committee recommended minor changes, which were incorporated. This was combined with feedback from the providers who were piloting the template to create the revised version. A system smart text for the revised template was then created and approved for use by any provider in Epic in February 2018. This eliminated the barrier of the owner of the smart text having to manually add each provider to the list of those who were able to access the template. A message was sent

Figure 2:
Provider Postfall Template Use
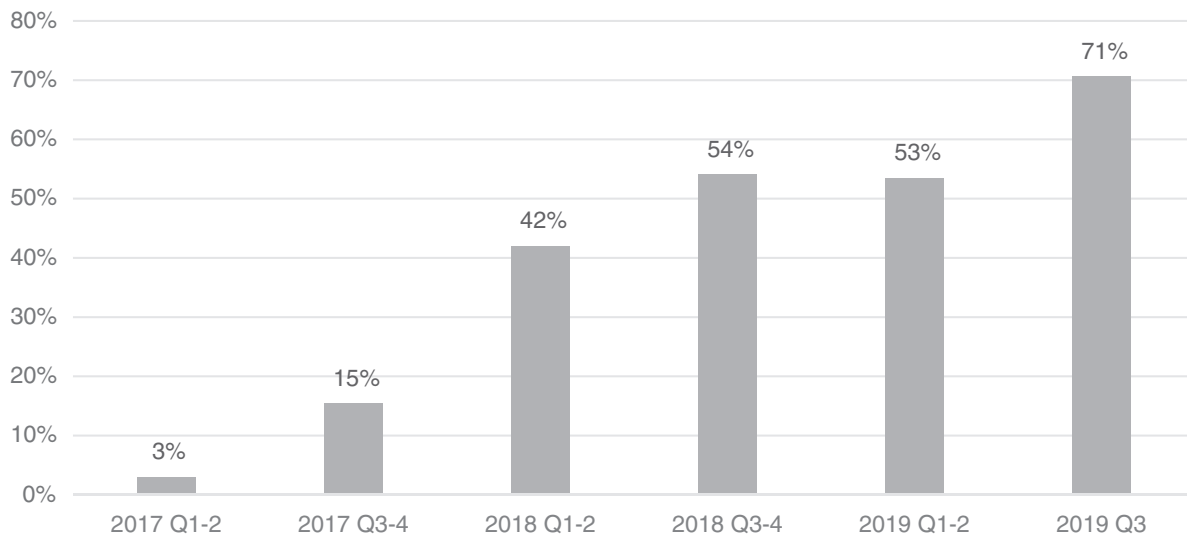
Note: The first note using the template was in the second quarter of 2017. Data were collected through August 2019.

to all hospitalists and NP/PAs with this updated information prior to the "go live" date of March 1, 2018. During the following months, information was sent to all providers with privileges at the hospital to expand its use to private and surgical services as well.

Figure 2 demonstrates the increase in use of the template for provider postfall notes over time. A limited rollout of the template occurred in the third quarter of 2017 followed by a more widespread initiative in the first quarter of 2018. A hold was placed on further rollout in the first quarter of 2019 due to minor revisions suggested by the organization-level committee. This is reflected in the leveling off of growth in template use during early 2019, followed by an increase when the implementation initiative resumed in the second quarter of 2019. The increase in the third quarter of 2019 corresponds to the expanded rollout to consultant providers, as well as the dissemination of a reminder message and additional education to all providers (Figure 2).

DISCUSSION

This continuous improvement initiative was developed after an opportunity was discovered to optimize our postfall workflow and provider documentation. A comprehensive and systematic approach was taken to create a project committee with multi-disciplinary expertise to improve the process related to postfall assessment and documentation. The committee decided to optimize the overall postfall workflow in alignment with the existing nursing protocol and to design a documentation template to be used by any provider

responding to a patient fall. As demonstrated in many areas of health care, protocols are beneficial in clinical settings because they "reduce variation, maintain the quality of patient care, and are documentary evidence of the standard of care to be provided."[15] The use of a postfall template allows for a more standardized approach to the evaluation of a patient who has sustained a fall and the related documentation. This initiative aligns with The Joint Commission's National Patient Safety Goal 9, as it facilitates incentives to ensure prompt evaluation and treatment of postfall complications as well as increasing communication between caregivers.

We experienced some unanticipated delays and challenges throughout this process. Despite informing providers of the new postfall documentation template, it was not initially used as frequently as intended. Reminders were provided, and over time the use of the template increased. We also added a reminder to the nursing checklist that prompted the nurse to remind the provider to use the template after evaluating the patient. There were delays in creating the system smart phrase in Epic. This was partially due to personnel changes as well as logistical issues with the process of obtaining approval for a system-wide template. We discovered that in addition to the local and enterprise falls committees, we also needed approval from the Documentation Governance Committee prior to obtaining the full endorsement for enterprise-wide use. Concerns about the length of the template were raised, as well as the potential for contradictory information with nursing documentation. We are currently working with the organization to resolve these concerns and have been permitted to continue using the template at this hospital as a pilot initiative.

CONCLUSION

This health care system promotes continuous improvement in all aspects of patient care and strives to be a high-reliability organization. In alignment with this culture, hospital caregivers are constantly looking for opportunities to improve processes and workflows. Postfall documentation is an important part of a comprehensive fall prevention and management program. Because of our culture of continuous improvement, we were able to identify an opportunity to improve our postfall workflow and provider documentation. Our findings related to inconsistent documentation were also seen in the literature, and thus provided rationale for developing a template with a goal of improving the content quality of postfall documentation.

A well-designed post-fall documentation template may improve the content of provider post-fall notes and could potentially lead to improved patient safety and quality of care, as well as decreased cost and legal risk related to patients who sustain falls in a hospital. If this can be demonstrated, it would support the concept of using a template for postfall documentation in other hospitals. Further research is needed to determine if the use of the postfall template improves the content of postfall documentation. Additional investigation of relationships between documentation content and potential adverse outcomes is also needed.

There are future plans to add an order set that will include the most common lab, imaging, and consultation orders for patients who have sustained a fall. There is also a plan for a quantitative analysis to compare the content of notes with and without the use of the postfall template. If the pilot is successful, the template and order set will be available to the other hospitals in the organization, and will be supported as a best practice recommendation for postfall care. Our goal is to continue to work toward decreasing the incidence and severity of patient falls. We will continue to reassess our postfall protocols and workflows to ensure that we optimize patient outcomes following a fall and minimize the risk of subsequent adverse events.

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[Corrections added July 9, 2020, after first publication online. The article category was updated from Research to Clinical/Patient Safety.]

ABOUT THE AUTHORS

Leah Schmitz, MPAS, PA-C completed her Physician Assistant education at East Carolina University and The University of Nebraska Medical Center. She is currently pursuing a Doctorate of Health Sciences with a concentration in Organizational Leadership at A. T. Still University. Her interests include patient safety, continuous improvement initiatives, and optimization of physician and NP/PA collaboration in team-based practice. She was a co-presenter at the Society of Hospital Medicine Annual Conference in 2019 on models of care in the hospital setting. She was the recipient of the Cleveland Clinic Physician Assistant Manager of the Year Award in 2017, as well as several Caregiver Excellence and Teamwork Awards. *Peter Hakos, MPAS, PA-C* graduated from the University of Toledo with a Bachelors of Science in Pharmacology/Toxicology in 2012. While completing his degree, he participated in several research projects, including a retrospective cohort study on the management of Anaphylaxis at a local hospital in comparison to national guidelines. He graduated from Lock Haven University's Physician Assistant Program in 2014 and shortly after began working with Cleveland Clinic. Since becoming a PA, he has been an active member of the American Academy of Physician Assistants (AAPA) and worked with both Hospital Medicine and Hematology/Oncology in the Taussig Cancer Institute. He also serves as a preceptor to PA students and a guest lecturer at Baldwin Wallace University's PA program on the topics of anemia, bone marrow disorders, and coagulopathies. *Mary Kirsch, BSN, RN, CCRN-K, HACP* is the Accreditation and Patient Safety Coordinator for Cleveland Clinic Avon Hospital. She is responsible for the daily review and follow-up on all safety events and facilitation of the hospital's daily safety huddle. She participates in weekly Environment of Care and safety rounds and facilitates proactive risk assessments. She performs chart reviews to assess patient safety concerns and is responsible for the follow-up of all events reported in the hospital's Safety Event Reporting System (SERS). Mary has been a Registered Nurse for greater than forty years, having spent more than thirty years at the bedside in Critical Care and the last seven years in her current role of Accreditation and Patient Safety. Her vast clinical experience is invaluable when explaining how the clinical and regulatory worlds mesh to positively impact safety. *Joann Palmer BS, RN, CPHRM, CPPS*, has over 10 years of risk management experience at the Cleveland Clinic. She has served as the Clinical Risk Manager at Avon Hospital since its opening in 2016, in addition to her responsibilities at the main campus. She had the unique opportunity of working in a risk management role in an international setting at Cleveland Clinic Abu Dhabi. Prior to entering Risk Management, she spent 30 years in the health care field as a registered nurse in a variety of settings including adult and pediatric nursing in both hospital and ambulatory settings. In addition to caring for medical and surgical patients as a clinical nurse, she was involved in research coordination. As an ASHRM member, she had the opportunity to complete the HRM Certificate Program Modules, obtain the ASRHM Safety Certificate, and contributed to the Patient Safety Risk Management Playbook as a co-author. *Beth Poltorek, BSN, RN, CRRN* serves as the Nursing Quality Program Manager for Avon Hospital as well as the Magnet Program Director. She is involved with nurse sensitive indicator activities such as reduction of falls, pressure injuries, restraints, and hospital-acquired infections. She completes chart reviews to ensure that the documentation by nursing caregivers supports the mission of the organization and focuses on patient-centered care. She has been a nurse for 25 years, spending the last 5 years in nursing quality. Prior to this, she was the Nurse Manager and Program Manager of an Acute Rehab Unit, Nursing Supervisor, and the Pathway to Excellence Coordinator in a previous organization. She participates in the annual Patient Safety Fair, Shared Governance Day, Community Outreach, and performance improvement activities. Additionally, she facilitates the Interdisciplinary Falls Committee, Nursing Professional Practice Council, and Clinical Support Council. She is also involved in professional development activities such as nurse certification, professional ladder, and college advancement for BSN and MSN degrees. *Cynthia J. Stives, MS, APRN, CNP* is a Nurse Practitioner working in hospital medicine at Cleveland Clinic Avon Hospital. She graduated from Wright State University with a Bachelors of Science in 1993 and worked as a medical surgical nurse at a large hospital in Dayton before going back to pursue her Master's Degree at Wright State University. She then completed her Family Nurse Practitioner certification in 2000. Prior research includes a Master's thesis titled "A retrospective comparison of pressure versus flow as measures for detecting stenotic complications in dialysis vascular access sites". She is currently pursuing her Doctor of Nursing Practice degree from Chamberlain University with a concentration in leadership. Her interests include chronic disease management, shared decision making, patient-centered care, and diabetes. She recently presented at the 2019 Northeast Ohio Nurse Practitioner Association on the topic of common cardiac presentations.

Implementation of risk assessment tools in psychiatric services

By Gary A. Chaimowitz, MB, ChB, MBA, FRCP(C), Mini Mamak, Ed.D, CPsych, Heather M. Moulden, PhD, CPsych, Ivana Furimsky, BScN, MN, CPMHN(C), CCRC, and Andrew T. Olagunju, MBBS, MSc, FWACP, FMCPsych ⓘ

Abstract: **Violence remains a major risk management concern in psychiatric services with implications on the safety and well-being of patients, staff, and the public. Serious physical and psychological consequences of violence involving property damage, bodily injuries, and threat to life have been reported in mental health services. Risk assessment tools are important safeguard measures; however, research on clinical implementation is presently limited. Structured professional judgment (SPJ) risk management tools that incorporate professional discretion with analytical understanding of evidence-based risk factors are widely accepted for risk assessment. However, clinical utility is suboptimal due to several barriers, including those related to the tool, the clinical setting, and resistance from health professionals. To better understand the challenges militating against optimal implementation of risk assessment tools, we reviewed and presented some lessons from the implementation of clinical practice guidelines on a general scale and our experience implementing an SPJ tool called Hamilton Anatomy of Risk Management across a variety of psychiatric services. In summary, the clinical utility of risk assessment tools improves if the tool is psychometrically sound, concise, consensus rated, time efficient, and practical for planning risk management. User feedbacks on the tool utility are also important to sustain implementation.**

INTRODUCTION

Violence remains a major concern in psychiatric services with serious implications on the safety and wellbeing of patients, staff and the public.[1,2] While the prevalence of violence tends to vary significantly depending on the study setting, there is agreement that violent incidents are relatively higher in psychiatric services, and higher still among forensic psychiatric services, when

compared to the general population. For instance, previous studies have reported as much as 22% and 48% prevalence rates for violence in civil and forensic psychiatric services, respectively, and noted that these rates are many-fold higher than the rates in the general population.[2]

The physical and psychological consequences of violence are substantial, as violent incidents involving property damage, bodily injuries, and threat to life have been reported in mental health services.[3,4] Earlier research works have linked violence with several adverse outcomes, including general distress, fear, anxiety, posttraumatic stress,[5-7] increased staff turnover rate, higher service costs, and lower quality of care.[8-11] Furthermore, violence does accentuate negative media attention and stigmatizing public opinion of people living with psychiatric disorders and psychiatric services.[3,12]

Overall, the management of violent incidents is critical in mental health services but poses a variety of challenges, such as limited predictive risk models, high variability in risk scenarios, and finite resources.[13-15] Risk assessment is an important safety measure, as it facilitates discussion about violence and other risk-associated behaviors, including aggression, escape/elopement, or reoffending, among others.[2,3]

Risk assessment for violence involves an appraisal of the degree to which harm is likely to occur in the future[16,17] and has progressively evolved from "stand-alone" use of either clinical judgment or actuarial tools (applies mathematical and statistical methods to assess risk) to the development of structured professional judgment (SPJ) tools.[18,19] SPJ tools are widely accepted for risk assessment as they allow an analytical understanding of risk factors and scenarios in a systematic fashion based on scientific evidence.[18] The SPJ approach to risk assessment was intended to reduce the perceived limitations of actuarial tools and unstructured clinical judgment by combining professional discretion and clinical judgment with analysis of risk factors and scenarios.[8]

SPJ risk assessment tools were introduced approximately two decades ago at about the same time evidence-based practice was promoted in clinical medicine.[18,20] It is therefore conceivable that SPJ tools would be widely used in psychiatric services given that these tools are derived from evidence-based processes; however, this is not the case. This is one of the rationales for the development of Hamilton Anatomy of Risk Management (HARM), which is an evidence-based SPJ tool that incorporates a team-based approach to risk assessment and management.[2,21]

Given that evidence-based clinical practice guidelines (CPGs) are designed to support translation of new evidence into clinical practice,[20,22] understanding the barriers to the uptake of CPGs can provide a perspective on the challenges of implementing SPJ tools in psychiatric services. In light of the above, this article addresses the

Highlights

- Risk assessment tools are an important safety measure in psychiatric services. While structured professional judgment (SPJ) tools are widely accepted for risk assessment, several barriers, including those related to the tool, the clinical setting, and health professionals, hamper their implementation.

- Lessons from the successful implementation of the Hamilton Anatomy of Risk Management, an SPJ risk tool, showed that clinical utility is strengthened if a tool is psychometrically sound, concise, consensus rated, time efficient, and includes practicable risk management plans.

- User feedbacks on tool clinical utility are important to sustain implementation of SPJ tools.

challenges militating against optimal implementation of risk assessment tools using the subsections described below. First, it outlines barriers to clinical implementation of CPGs and SPJ tools on a general scale; second, we present the strategy employed in the multisite implementation of the HARM across a variety of psychiatric services; and third, recommendations to improve clinical implementation of SPJ risk assessment tools are provided.

EXAMPLES OF BARRIERS TO CLINICAL IMPLEMENTATION OF CPGs

CPGs were introduced as essential tools to support evidence-based practice and standardize clinical care in order to prevent inappropriate variability or errors.[23] In medicine, adherence to CPGs has produced better outcomes and improved care. For example, good outcomes in stroke and myocardial infarction are linked to good implementation of evidence-based interventions in CPGs.[24,25] Notwithstanding, implementation of CPGs varies and is sometimes suboptimal.[26-28] Examples of common barriers to CPG implementation across several fields of medicine include poor accessibility, conflicts with professional practice, beliefs about evidence-based practice, and financial motives.[28,29] Concerns regarding maintenance of "intellectual independence" can also limit openness to novel clinical practice.[29] Finally, novel changes can be resisted because of frustrating previous experiences, where the science or research underpinning changes in standard of practice are debunked later.[10,20]

In general, barriers to optimum adoption or implementation of CPGs are often categorized into those related to the quality of guidelines, characteristics of health care professionals, the practice setting, incentives, regulations, and patient factors.[24,26] While some barriers to implementation may be unique to CPGs, several are generalizable to other areas of clinical practice,[22,24] thereby

providing an empirical perspective as to why clinicians may not adhere to evidence-based practice, such as the clinical utility of risk assessment tools.[22,24,26]

In addition to the above-mentioned barriers, psychiatry as a field suffers unique issues that may undermine clinical implementation of CPGs or other evidence-based processes. For instance, there are ongoing discussions about the face validity of psychiatric diagnoses.[30] Experts in psychiatry recognize that diagnostic classification is heterogeneous (partly responsible for "dimensional classification" in the Diagnostic and Statistical Manual of Mental Disorders, Fifth Edition), and patients may not always be defined by a single diagnosis as psychiatric illnesses or clinical features tend to vary in severity and course.[31,32] It is also sometimes difficult for clinicians to follow new treatment or management approaches exclusively as statistical advantages of one approach over another may not always be clinically meaningful.[33,34] All these issues speak to the uniqueness of clinical implementation of evidence-based practice in psychiatric services.

SOME BARRIERS TO IMPLEMENTING STRUCTURED PROFESSIONAL JUDGMENT RISK ASSESSMENT TOOLS

Many SPJ tools are developed to conduct formal risk assessment; however clinical implementation is limited, especially in nonforensic settings due to some barriers.[2,7-9] For instance, the panel of experts developing SPJ tools may be small, tend to come from the same location, have apparent ownership, and may benefit from the adoption of the tool. In addition, developers of risk tools may also be less familiar with the imperfections of clinical practice settings, especially as clinical teams may see the use of risk tools as additional work, rather than a time-saving process. While the science may be embedded in the tool, research evidence may not usually be as visible or strong. It is also possible that the well-purported benefits and risk reduction will not be apparent, or be impossible to quantify in each clinical encounter practically.[35-38]

IMPLEMENTATION OF HARM: LESSONS AND RECOMMENDATIONS

The HARM is an SPJ tool developed by a forensic psychiatrist (GAC) and psychologist (MM) who both had an academic interest and were directly involved in patient care, including risk assessment, prediction, and management. The tool was constructed to be psychometrically sound, brief, easy to use, and comprehensive in recording acts of aggression and to guide the management of violence risk.[5]

The HARM includes an embedded measure of aggression, called the Aggressive Incidents Scale (AIS).[21,39] The AIS is a scale that defines increasing levels of severity of

aggression for the purpose of accurately measuring and communicating about aggression within the risk assessment process. The construction of the HARM-AIS program ensured that assessment of aggression and management of risk are well integrated within a variety of clinical environment. In fact, the wide applicability of the HARM-AIS for risk assessment in general psychiatric services was highlighted as an example of leading innovative best practice when Accreditation Canada recognized the tool in 2009 and 2011. Now, the HARM-AIS is currently available in multiple languages, including English, Spanish, French, Mandarin, German, Italian, Russian, and Arabic, to facilitate clinical implementation.[40] Additional resources and materials that describe the development, clinical applications, electronic versions, and access to digital copies of the tools are available online through the Hamilton Anatomy of Risk Management (e-HARM) website (https://www.ais-harm.com/). They are open source, and the tools are free.[41] (See Appendix A for eHARM copy.)

As part of the development of these tools in 2006, evidence from the literature was synthesized to standardize the recording of aggressive incidents and allow structured discussion of risk to inform immediate management, including making decisions on the patient's liberty. The HARM was developed for conducting structured consensus and multidisciplinary team-based risk assessment that guides short-term prediction and management of risk. The findings from the ratings are incorporated directly into the determination of patient privileges and management recommendations.[39] Generally, the administrative process has evolved over time to require that professional teams conduct a risk assessment, predict and produce a management approach, and then document before signing off on privileges.

The team meeting was considered the clinical "rock face," thus the targeted forum where the HARM tool was first introduced. In preparation for the introduction of the tool implementation, general training by way of workshops in risk assessment, prediction, and management was conducted. At the training, the presence of the developers to answer questions, provide explanations, and navigate the trainees through the completion of the tools was helpful. Senior management of sites where the tools are used were engaged to ensure that the psychiatrists were also champions of the tool, an essential component of the implementation. In the course of using these tools, user focus groups at the development site helped define the tool so that it would be relevant clinically, easy to use, and concise and to encourage ownership. It took approximately 3 months for adoption and several years longer for sustained implementation. The tool developers were open to and incorporated new ideas, adaptions, and changes.

The tools were first introduced to an inpatient forensic setting in 2006. Currently, the HARM-AIS is used in a variety of settings including community, general, and forensic psychiatric services. Overall, introduction of

HARM to additional settings (including general, outpatient, youth corrections, and community psychiatric services) was much more carefully planned and efficient given the clinical experience from the first developmental iterations. Generally, the process of introduction in new services included engagement of local champions who understood the importance of risk assessment and a selection of high-functioning teams as early adopters. Didactic lectures were planned to address theoretical concepts on violence among psychiatric populations, and interactive workshops were arranged for hands-on skill transfer on risk assessment, prediction, and management before the tools were introduced. Once the HARM-AIS was introduced, the value of the tools was discussed locally, and follow-up evaluation and dialogue with the local team continued.

Feedback and auditing following introduction in a new service allowed improvement of these tools and their clinical utility. The implementation plan across different psychiatric services from preimplementation phase and staff training for integration of HARM into daily workflows was iteratively revised in keep with the Plan-Do-Check-Act (PDCA) cycle model.[42] Similarly, the tool evolved overtime to become user friendly such that, in current form, it is completely electronically interphased and allows real-time data extraction on risk factors during team-based discussion of patient management. Additional features were added to enable data analysis, and graphical representation of patient-risk analytics or aggregator to observe trends in risk and treatment patterns across multiple patients (see Appendices B and C). Over time, staff began to "own" the tools, with the team producing process fidelity by keeping team members faithful to the tool. Finally, it is expedient for management to buy in on the benefits and clinical translation of the tools.

IMPLEMENTATION OF RISK ASSESSMENT TOOLS: TIPS AND RECOMMENDATION

The adoption and implementation of SPJ tools in clinical settings and the process of clinical-based risk assessments can improve by the recommendations described below.

Recommendation for tool-related barriers

With respect to the quality of risk assessment tools, there is a relative advantage when the tool is perceived as better than the current state and compatible with the values and practices of the local organization. On the other hand, the tool may face additional barriers if it is perceived as difficult to understand and use. Clinical auditing of implementation and feedback on utility and performance of the tool do enhance support for sustained use. It needs to be both easy to use and quick and work.

Recommendation for health professional–related barriers

An understanding of health care professional characteristics and attitude to change is important. Openness to change, concerns about autonomy, and training on use of the risk assessment tool should be addressed. If these proimplementation measures are not addressed, the tool will likely not be implemented, and failure can be wrongly attributed to the tool rather than implementation. Physician support and engagement greatly enhance the implementation process and uptake of a specific tool.

Recommendation for practice setting–related barriers

The practice setting is important, such that implementation is enhanced if use of risk assessment is beneficial and aligns with the organization's mission. Importantly, the local standard of care needs to be in line with the new practice. Organizational support to provide sufficient resources to implement the risk assessment tool cannot be overemphasized. There is evidence to suggest that regulation from accreditation or licensing bodies can influence the implementation of tools. For example, evidence-based practice selected by accreditation or licensing bodies tends to be more readily adopted.[43] There is also the role of incentives, especially if the risk assessment tool does affect incidents of malpractice or has financial impacts. Senior leadership requiring implementation is an additional recommendation, but only if the other factors have been addressed.

General recommendations and tips for implementation

There are implementation strategies shown to be effective for introducing a new clinical practice. The use of traditional continuing education, printed material, and meeting clinicians in their practice setting are generally considered weak strategies. Effective strategies include the use of concurrent audit and feedback targeted at specific providers and delivered by peers or opinion leaders. Successful implementation strategies have included use of reminder systems through verbal, paper, or computer cues; interactive educational meetings or workshops; and multiple interventions over time. Sustainability of new practice is ensured in settings with a supportive organizational climate that espouses a long-term commitment to training and resources. Organizations that are interested in research lead to improvement and sustainable tool utilization. Continued engagement with local champions and face-to-face interactions with stakeholders are important. Creating incentives for use, networks and communities of practice, and Web-based information that can be accessed anytime can lead to ongoing sustainability.

CONCLUSION

Implementation issues tend to be underestimated but may be more complex with respect to risk assessment tools. Lessons from clinical implementation of CPGs and the HARM-AIS across a variety of psychiatric services described in this article are important to developing an efficient implementation strategy. Overall, implementation is enhanced if the tool is concise, efficient to administer, and accessible for consensus rating and has a practical risk management impact (ie, useful product). The introduction of consensus-based risk assessment needs careful planning, and stakeholders' engagement should be sustained. It is pragmatic to develop indicator measures to track implementation, audit clinical utility, and organize update trainings or workshops. Employing the PDCA cycle tool during implementation can facilitate a structured framework for integration into clinical workflow and on-going quality improvement.

[Corrections added July 9, 2020, after first publication online. The article category was updated from Research to Clinical/Patient Safety.]

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Patient eHARM - Forensic Version

| Home | New HARM Report | Patient Analytics | Print |

Patient Name

Hospital:

Date of Birth: DD-MMM-YYYY

Record Date: DD-MMM-YYYY — 18-Dec-2017

Date of Last HARM:

Gender: ○ Male ○ Female

Diagnosis 1:

Diagnosis 2:

Diagnosis 3:

Independent Risk Ax.
Low ○ ○ ○ ○ ○ High
○ Not Completed

Date Completed: DD-MMM-YYYY

Index Offences and Prior Convictions
Please select all that apply:

Offence		
Arson	☐	☐
Attempt Murder, Assault & Related Offences	☐	☐
Homicide	☐	☐
Kidnapping & Related Offences	☐	☐
Robbery & Related Offences	☐	☐
Sexual Offences	☐	☐
Weapons Related Offences	☐	☐
Treason/Terrorism	☐	☐
Criminal Harassment, Utter Threats & Related Offences	☐	☐
Driving Related Offences	☐	☐
Fraud & Related Offences	☐	☐
Obstruct Justice/Breach/FTC/Escape Custody Offences	☐	☐
Property Offences	☐	☐
Substance Related Offences	☐	☐
Mischief/Miscellaneous Offences	☐	☐

Enter Comments Here:

Record	Date(s)	# Charges

*Past Gender Target

*Past Victim Target

*Historical Risk Factors
Please select all that apply: Details:

Factor		Details
Major Mental Disorder	☐	
Personality Disorder	☐	
Substance Use	☐	
Cognitive Deficits	☐	
Other	☐	
Other	☐	
Other	☐	

*AIS Totals

Week of 20-Nov (four weeks ago)

	N	P	V	PC
9				
8				
7				
6				
5				
4				
3				
2				
1				
	0	0	0	0

*Risk Factors

Risk Factor		Risk Factor Status	Change
Rule Adherence	☐		
Insight-Illness	☐		
Mood Symptoms	☐		
Psychotic Symptoms	☐		
Impulse Control	☐		
Program Participation	☐		
Substance Abuse	☐		
Med Non-Adherence	☐		
Attitude/Cooperation	☐		
Stress Management	☐		
Anger Management	☐		
Family Support	☐		
Peer Influence	☐		
Other	☐		

Protective Factors   Please identify 1 or 2 protective factors:

Comments:

Potential Behaviours	Primary Rationale	Potential Gender Target	Potential Victim Target		Duty to Protect?
▼	▼	▼	▼		○ Yes ○ No
▼	▼	▼	▼		**Action Taken?**
					○ Yes ○ No
					☑ History of Escape?

		Immediate (days)				Short-Term (weeks)				
ⓘ	Clinical Likelihood Of Violence	*with professional support	Low	○○○○○○	High	*with professional support	Low	○○○○○○	High
		*released & no professional support	Low	○○○○○○	High	*released & no professional support	Low	○○○○○○	High
ⓘ	*Escape Risk	Immediate (days)	Low	○○○○○○	High	Short-Term (weeks)	Low	○○○○○○	High

Risk Management & Transition Planning

ⓘ   ⓘ

Risk Factor	Treatment Plan / Intervention	Program information	Team Member	Response	Privileges

*Stressors/Destabilizers ⓘ _____   HARM Reporting Frequency _____

	Class of Medication	Medication	Route	Frequency	Start Date DD-MMM-YYYY	Dose
1*						
2						
3						
4						
5						
6						

*Risk Scenario Updated   ○ Yes   ○ No   ○ N/A

❗ Last Update: -

General Team Comments

*Completed By _____

Physician Signature _____

V3 Hamilton Anatomy of Risk Management-Forensic Version (HARM-FV)

Indicates Mandatory Inputs · When copying and pasting, please paste-values only by right-clicking and selecting 'Paste Special' - 'Values' - 'OK'

Submit

Patient ID:	JohnS12345	Record Date: DD-MMM-YYYY	23-Aug-2016
Hospital:	St. Joseph's Healthcare Hamilton	Date of Last HARM:	
*Date of Birth: DD-MMM-YYYY	1-Feb-1970	*Gender:	● Male ○ Female

*Diagnosis 1: Schizophrenia Spectrum and Other Psychotic Disorders

Diagnosis 2:

Other:

*Independent long-term Risk Ax

Low ○ ○ ○ ○ ○ High

● Not Completed

Date Completed: DD-MMM-YYYY

*Diagnosis 1:

Diagn

- Neurodevelopmental Disorders
- Schizophrenia Spectrum and Other Psychotic Disorders
- Bipolar and Related Disorders
- Depressive Disorders
- Anxiety Disorders
- Obsessive-Compulsive and Related Disorders
- Trauma and Stressor-Related Disorders
- Dissociative Disorders

> Drop-down menus, required fields, and embedded definitions allow for consistent reporting and increased reliability

Index Offences and Prior Convictions

Please select all that apply:

	*Index Offences	Prior Convictions
Arson	☐	☐
Attempt Murder, Assault & Related Offences	☐	☐
Homicide	☐	☐
Kidnapping & Related Offences	☐	☐
Robbery & Related Offences	☐	☐
Sexual Offences	☐	☐
Weapons Related Offences	☐	☐
Treason/Terrorism	☐	
Criminal Harassment, Utter Threats & Related Offences	☐	☐
Driving Related Offences		
Fraud & Related Offences	☐	☐
Obstruct Justice/Breach/FTC/ Escape Custody Offences	☐	☐
Property Offences	☐	☐
Substance Related Offences	☐	☐
Mischief/Miscellaneous Offences	☐	☐

Enter Comments Here:

Record	Date(s)	# Charges

*Past Gender Target

*Past Victim Target

Past (side label)

Historical Risk Factors

Please select all that apply: Details:

Major Mental Disorder	☐	
Personality Disorder	☐	
Substance Use	☐	
Cognitive Deficits	☐	
Other (Please Specify)	☐	
Other (Please Specify)	☐	
Other (Please Specify)	☐	

Current / Past

*AIS Totals

Week of	01-08-16	08-08-16	15-08-16	22-08-16
	three weeks ago	two weeks ago	last week	this week

Severity scale: 9, 8, 7, 6, 5, 4, 3, 2, 1

Columns: N P V PC (for each week)

Total: 0 0 0 0   0 0 0 0   0 0 0 0   0 0 0 0

*Risk Factors — *Please select all that apply:*

Risk Factor	Risk Factor Status	Change
Rule Adherence ☐		
Insight-Illness ☐		
Mood Symptoms ☐		
Psychotic Symptoms ☐		
Impulse Control ☐		
Program Participation ☐		
Substance Abuse ☐		
Med Non-Adherence ☐		
Attitude/Cooperation ☐		
Stress Management ☐		
Anger Management ☐		
Family Support ☐		
Peer Influence ☐		
Other ☐		

Protective Factors — *Please identify upto 1 or 2 protective factors:* — Comments:

Potential Behaviours	Primary Rationale	Potential Gender Target	Potential Victim Target

Duty to Protect? ○ Yes ○ No

Action Taken? ○ Yes ○ No

---

*AIS Totals

Week of	29-08-16	05-09-16	12-09-16	19-09-16
	three weeks ago	two weeks ago	last week	this week

Columns: N P V PC (for each week)

Severity: 9, 8, 7, 6, 5, 4, 3, 2, 1

6 - Push/Shove - Clearly aggressive push or shove, e.g. push has significant force and the target falls to the ground.

Total: 0 0 0 0   0 0 0 0   0 0 0 0   0 0 0 0

Future

Clinical Likelihood Of Violence

	Immediate (days)		Short-Term (weeks)	
*with professional support	Low ○○○○○ High		*with professional support	Low ○○○○○ High
*released & no professional support	Low ○○○○○ High		*released & no professional support	Low ○○○○○ High

Escape Risk

*Immediate (days) — Low ○○○○○ High   *Short-Term (weeks) — Low ○○○○○ High

---

* Risk Management & Transition Planning

Risk Factor	Treatment Plan / Intervention	Program Information	Team Member	Response	Privileges

*Stressors/Destabilizers _____   ***Date of Next HARM Ax** _____

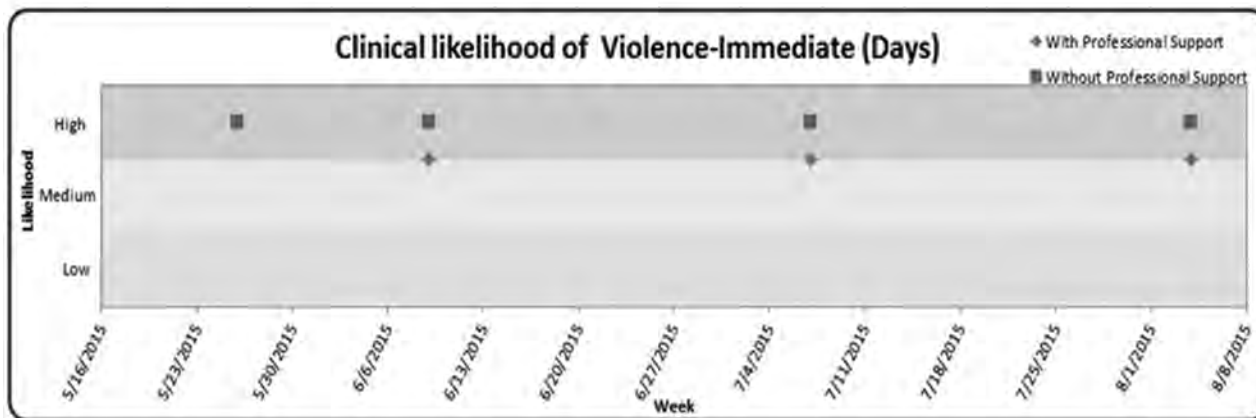| Class of Medication	Medication	Route	Frequency	Start Date	Dose
1					
2					
3					
4					
5					
6					

*Completed By _____

Physician Signature _____

*Risk Scenario Updated ○ Yes ○ No ○ N/A

General Team Comments

Risk Factor Performance – Impulse Control

Clinical likelihood of Violence-Immediate (Days)
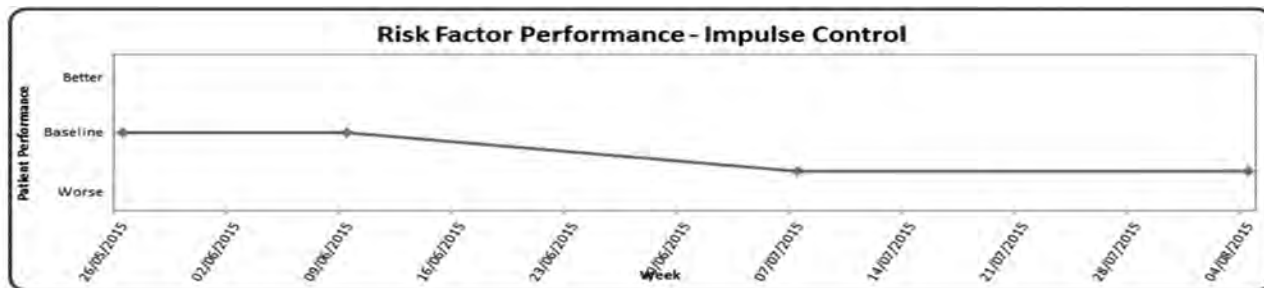
Note : AIS Total Charts will capture data for records entered in past 12 months only
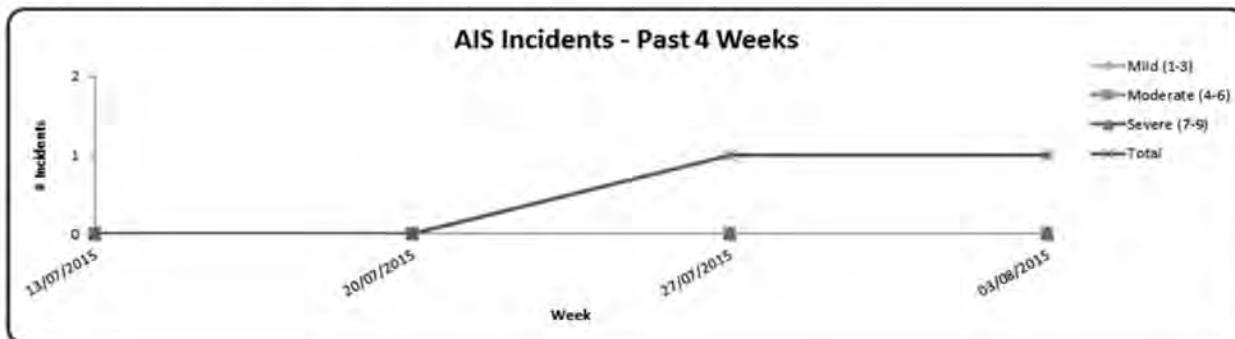

AIS Incidents - Past 4 Weeks

% Patients Started on each Treatment / Intervention

Operations
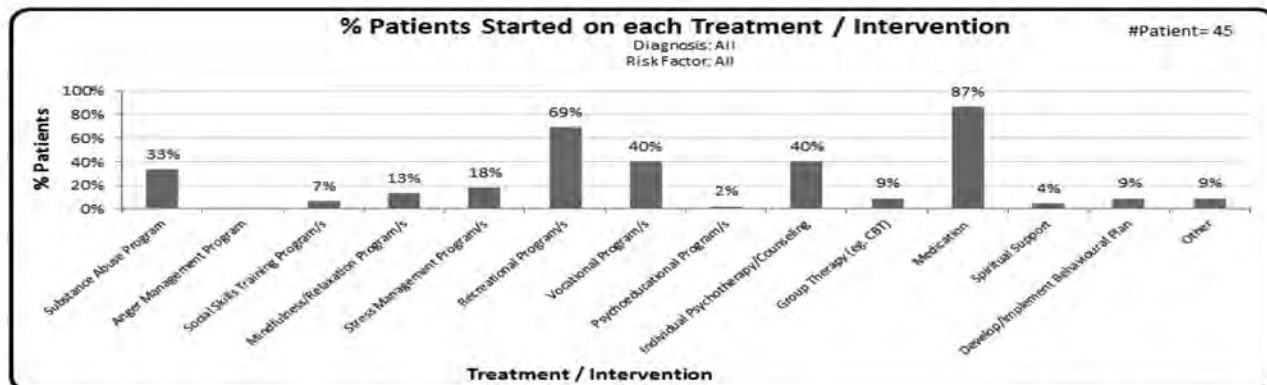
Design and implementation of the infection prevention program into risk management: Managing high level disinfection and sterilization in the outpatient setting

By Wendy Sweet, RN,
MSN, CPHRM,
Dayna Snyder, RN,
and Matthew Raymond,
CRCST

Reusable, invasive medical devices within the outpatient setting pose a risk for patient harm. Ineffective disinfection of medical devices can potentially lead to transmission of pathogens between patients; and improper handling can lead to patient injury. A risk assessment was conducted, and the results strongly supported the necessity to develop a robust infection prevention program within the risk management department. This exclusive program was a proactive approach to preventing patient exposure within our healthcare system. Designing and integrating an Infection Prevention program into the Risk Management Department presented challenges, especially with the magnitude of devices and lack of standardization throughout our 33 clinics. Key components of the program included: capturing an accurate inventory of devices throughout the system, hiring a sterile processing expert, engaging support from senior leadership, adhering to rigorous auditing processes, and establishing a staff competency training structure. Since the program was launched 2 years ago, outcomes include: identification of high-risk practices with immediate resolution, increase in average clinic compliance to device reprocessing standards from 88% to 99%, elimination of 71% of scope reprocessing and 39% of instrument sterilization by clinic staff with allocation to central sterile processing departments, and development of a staff competency training structure.

INTRODUCTION

The Scripps Medical Foundation (SMF) part of Scripps Health, a nonprofit nationally recognized health care system in southern California, consists of 33 outpatient clinics throughout San Diego County. SMF performs approximately 2000 different invasive procedures in the office setting, and has 400,000 patient encounters annually. In 2018, SMF Clinical Risk launched a proactive approach to prevent potential risk exposure to clinic patients. The risk team identified the lack of standardized processes regarding instrument reprocessing at the clinic level, which could put patients at risk for potential exposure. SMF Clinical Risk developed an innovative partnership between sterile processing, infection prevention, and risk management. The partnership between risk and infection prevention has created a proactive, integrated, risk deterrent program.

IMPORTANCE OF INFECTION PREVENTION WITHIN A RISK PROGRAM

The Joint Commission found that 74% of all immediate-threat-to-life declarations were due to sterilization and disinfection equipment breaches.[1] While Scripps had no exposure events related to improper equipment reprocessing, there were several events nationwide to support the importance of developing an infection control program into risk management.

In 2012, there was an outbreak of severe group A Streptococcus infections among persons undergoing tumescent liposuction at two outpatient cosmetic surgery facilities. These facilities were not subject to state or federal regulation. There were four confirmed and nine suspected cases, with one case resulting in death. Facility assessments and patient reports indicated substandard infection prevention, including errors in equipment sterilization and infection prevention training.[2]

In 2018, the California health department had concerns over cleaning issues with a hospital's surgical equipment. The problem was serious enough for the state to declare "Immediate Jeopardy" at the UC San Diego Hillcrest campus hospital. The deficiency was found in the way the hospital staff was processing instruments for surgeries. The deficiency was discovered during a routine compliance check conducted by the California Department of Public Health in March. Officials noted that "surgical instruments were not cleaned and processed according to nationally recognized infection control standards." The report declared the hospital had "failed to ensure they had an effective, active system wide infection control program … ." Deficiencies found included:

- trays with surgical equipment that had brown staining,

- sterilizing machines reportedly had large amounts of dark rust color,

- exterior machines were covered with dirt,

- instruments apparently had red stains in a postoperative room.[3]

In 2014, UCLA Medical Center experienced an outbreak of carbapenem-resistant Enterobacteriacea (CRE). The antibiotic-resistant strain of CRE killed three people and infected many others before a team of professionals tracked the superbug to a dirty duodenoscope used during an Endoscopic Retrograde Cholangiopancreatography (ERCP) procedure. The hospital had purchased the new scopes, priced at $40,000, only 7 months prior. The doctors followed the standard protocol provided by manufacturers. The UCLA infections drew attention from the Food and Drug Administration (FDA) and helped regulators and health care professionals to understand the dangers of endoscopy infections. However, UCLA was not the first hospital to deal with scope contamination. Dirty scopes spread antibiotic-resistant infections. They have been the cause of 11 deaths at Virginia Mason Hospital and Medical Center in Seattle, four infections at Cedars-Sinai Medical Center, and 281 exposures of *Escherichia coli* at Hartford Hospital further confirmed that ineffective scope sanitation was not an isolated issue.[4]

HISTORY

The journey began in 2017, when SMF Leadership identified a patient exposure risk within the clinics involving the handling and reprocessing of medical devices, such as endoscopes and sterile instruments. At the time of the discovery, there was limited oversight and no consistent regulation of the clinic's infection prevention practices. Initial risk assessment revealed that there was a lack of supervision at the 28 clinic sites performing reprocessing of multiuse devices. These findings identified that it was imperative that SMF urgently develop a comprehensive infection prevention program to mitigate patient harm.

As the first step in development of our program, an infection prevention Registered Nurse (RN) ("Clinical Risk Specialist") was hired into the Clinical Risk department to perform initial site assessments and document her findings. Four key challenges for this specialist were as follows:

- No centralized inventory of SMF scopes and equipment.

- No standardized procedures for reprocessing of scopes and equipment.

- No documented evidence of infection prevention training for the staff.

- No accountability or tracking of site reprocessing compliance.

Identification of these key challenges and recognizing that high-level disinfection (HLD) requires highly specialized

skills, it was identified that there was a critical need to add a full-time sterile processing (SPD) expert to partner with the infection prevention nurse. Once in place, the team designed an outpatient clinic infection prevention program from conception to implementation which included:

- baseline risk assessment,

- detailed scope and equipment inventory,

- review of current infection prevention processes

Engagement of senior leadership was vital to the initial build and future success of this risk infection prevention program. The team held biweekly meetings to communicate field findings, risk concerns, compliance issues, and identification of barriers to successful implementation.

OBTAINING A BASELINE RISK ASSESSMENT

Endoscopes were identified as the equipment posing the highest risk for exposure. Clinics were also struggling with maintaining an accurate inventory and tracking scopes that were out for repair. The team began by contracting with a scope inspection and repair technician to assess the current state. This was the first time SMF conducted a system-wide scope inventory using a contracted service. During this inventory, the team identified several issues throughout the clinics that included improper storage of scopes and critically damaged scopes that were still in use.

The results were vast; we discovered that seven departments were still using manual HLD to process 149 flexible endoscopes. These findings demonstrated the lack of consistency in reprocessing standards. The infection prevention team was able to meet with clinic managers and supervisors to assist them with obtaining needed equipment and addressing identified risk for potential exposure. This included promptly retiring critically damaged scopes, repairing moderately damaged scopes, and properly maintaining and storing all scopes.

DISCOVERING DEVICES BEYOND SCOPES

The Spaulding classification[5] categorizes medical devices into the following four categories:

1. *Critical items* (eg, surgical instruments) are objects that enter sterile tissue or the vascular system and must be sterile prior to use.

2. *Semicritical items* (eg, endoscopes for upper endoscopy and colonoscopy, vaginal probes) are objects that contact mucous membranes or nonintact skin and require, at a minimum, high-level disinfection prior to reuse.

3. *Noncritical items* (eg, blood pressure cuffs) are objects that may come in contact with intact skin but not mucous membranes and should undergo cleaning and low- or intermediate-level disinfection depending on the nature and degree of contamination.

4. *Single-use devices* (SUD) are labeled by the manufacturer for a single use and do not have reprocessing instructions. They may not be reprocessed for reuse except by entities that have complied with FDA regulatory requirements and have received FDA clearance to reprocess specific SUDs.

Using the Spaulding classification, we began to assess clinical equipment by prioritizing critical and semicritical instruments. The team returned to the clinic sites expanding their assessments to include all items and devices in the Spaulding classification categories. This revealed the presence of other previously unidentified high-risk devices, including stainless steel instruments, vaginal probes, and ophthalmologic lenses. Key considerations included identifying how these devices were being used, how they were being reprocessed between patients, and determination of disposable alternatives.

MEASURING COMPLIANCE

After completion of the baseline assessment and inventory, an audit tool was developed using the CDC HICPAC bundle.[6] 2018 Baseline reprocessing audits were completed based on the following four categories to measure compliance to reprocessing standards.
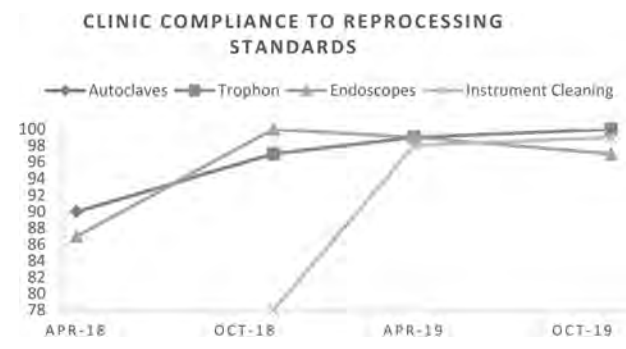
2018 (Baseline) audit results for clinic compliance to reprocessing standards:

1. Sterile instrument sterilization via autoclave (90% compliance).

2. Intracavity ultrasound probe HLD (97% compliance).

3. Endoscope reprocessing HLD (87% compliance).

4. Sterile instrument precleaning (78% compliance).

The above baseline audit confirmed that there were many variations in equipment reprocessing, including timeliness of bioburden removal. Prompt bioburden removal from devices is crucial for effective disinfection and sterilization. It has been shown that as time elapses, bioburden is increasingly linked to biofilm formation and pathogen survival.[7]

The use of correct brushes and enzymatic cleaners varied from site to site, which can decrease the effectiveness of the cleaning process. Staff protective equipment was underutilized, putting staff at risk for chemical exposure and/or injury. Chemical temperatures were not being

CLINIC COMPLIANCE TO REPROCESSING STANDARDS

monitored, potentially deeming the disinfectant solutions ineffective.

Completed SMF Infection Control audit results were reported to directors with immediate action items assigned. Senior leadership made all audit results transparent across the system for accountability. The risk team returned to the sites weekly until 100% compliance was achieved (*Image* 2).

Eighteen months after implementation of the infection prevention program, clinic compliance to reprocessing standards has increased significantly.

2019, 18 Months postprogram implementation, audit results for clinic compliance to reprocessing standards:

1. Sterile instrument sterilization via autoclave (99% compliance rate).

2. Intracavity ultrasound probe HLD (99% compliance rate).

3. Endoscope reprocessing (99% compliance rate).

4. Sterile instrument precleaning (97% compliant).

ESTABLISHING STAFF COMPETENCY, EDUCATION, AND RESOURCES

High-level disinfection and sterilization is a highly specialized skill, requiring that only trained and competent staff perform. Other than initial competency validation upon hire, and an online learning module annually, there was lack of hands-on return demonstration.

Once standards were established, a rigorous competency structure was established, using "champions" from each site. Champions are required to attend a skills lab annually, hosted by the risk infection prevention team and device vendors. The skills lab is where the champion's competency is validated by the risk team via hands-on demonstration and renewed annually. The skills lab was so

well received, we incorporated other infection prevention training into it as well, such as hand hygiene.

After competency validation the champions are deemed qualified to train all new staff coming into the department throughout the year. Expectations of the champion role required being a highly engaged leader in the infection prevention program, being present for site audits, and disseminating updates to their teams as needed.

Scripps Medical Foundation strictly prohibits staff from performing high-level disinfection or sterilization without a valid competency on file. Leadership is held accountable by signing a yearly attestation confirming:

- My site has an accurate inventory list of scopes, autoclaves, and HLD equipment.

- I can identify my department champion for HLD and sterilization.

- All my staff have completed their required training for HLD and sterilization.

- All my staff have completed hands-on demonstration of competencies to the site champion within the last 12 months.

- I can provide documentation of my staff's initial and annual HLD sterilization competencies upon request.

An online "tool kit" was posted on the Scripps Internal intranet. It is a "one stop shop" for staff to access all HLD-related policies, supplies, and standard work.

HANDLING OF HARMFUL DISINFECTANTS

Ortho-phthalaldehypde ("OPA"), a disinfectant chemical, was being used in seven clinics. Aside from the staff injury risk, OPA has a delicate operating margin. It must be maintained at a precise temperature to assure effectiveness. Out of range temperatures were noted; one clinic was measuring the room air temperature, rather than the chemical temperature. OPA was noted in several urology clinics for cystoscope disinfection, despite posing anaphylaxis risk for bladder cancer patients. The highly toxic OPA was even being used in a gastrointestial (GI) clinic to disinfect a reusable glass suction canister.

Fortunately, in 2015 Scripps began diverting OPA out of the clinics. Starting in 2016, all intracavity ultrasound probes were transitioned to HLD via hydrogen peroxide vapor units. These HLD devices vaporize highly concentrated hydrogen peroxide, killing 99.9% of microbes in a 7-minute automated cycle, including HPV.[8,9]

Scripps converted many cystoscopes and nasopharyngeal scopes to correlating microbial barrier ("sheath")

Image 3:
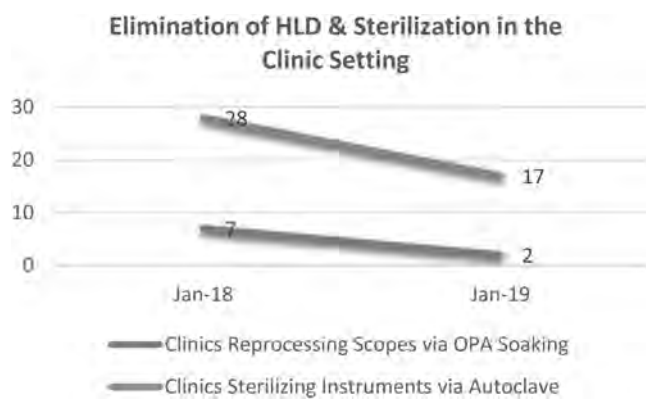
technology in 2016. These sheaths largely eliminated the need for HLD when used correctly. While extremely rare, the sheaths could fail or break with improper installation, which would result in the need for HLD. The risk team was able to identify this vulnerability and establish standard work with staff education.

CENTRALIZING TO STERILE PROCESSING DEPARTMENTS

A 2014 study showed employee compliance to HLD recommendations was observed as only 1.4% for manual methods versus 75.4% for an automated process.[10]

Of the 28 Scripps clinics performing HLD and sterilization, 20 were within a 10 mile radius to a Scripps Hospital. A centralized dedicated sterile processing department, with licensed technicians, was far superior to processing at the clinic sites. We relocated 39% of instrument sterilization and 71% of scope HLD from our clinics to a centralized SPD for automated reprocessing (*Image 3*).

CONTINUING REVIEW OF QUALITY STANDARDS

In order to achieve a sustainable program within an expanding health care system, the infection control team attends the Scripps system wide sterile processing committee and the Scripps system wide infection control committee. The team then provides infection control updates to clinic leadership.

As technology changes, along with the addition of new devices, the team facilitates education to the staff regarding proper reprocessing guidelines. The team partners with Scripps Biomed to maintain an accurate inventory of all critical devices within the clinic system.

Scripps continues to contract annually with the scope inspection and repair experts to examine all scopes in the system. Their detailed report includes inspection, damage, and life expectancy of the equipment. Based on recommendations, scopes are repaired, sequestered, and retired as needed.

The 2019 scope inspection identified multiple leaking cystoscopes. As a result, we implemented an additional scope leak testing step. This additional testing prior to patient use drastically increased the detection of leaks allowing for those scopes to be sequestered and repaired. Early leak detection significantly decreases the risk of patient exposure due to fluid invasion. As a precautionary measure, scopes whose manufacturers do not require leak testing are being tested to confirm the absence of a leak.

An additional benefit of conducting site audits is that it fosters the ability of the staff to establish a relationship with the risk team. One example is that staff disclosed to the team that the courier service that was transporting devices between clinics and hospitals lacked competency and accountability for safe handling. The team established safe handling guidelines, courier competency, infection prevention expectations, and accountability for damages incurred en route.

ONGOING MONITORING OF CLINIC INFECTIONS

In 2019, ATP testing was incorporated into the SMF Infection Control audits. Adenosine triphosphate (ATP) detection technology is a rapid test in which a surface swab identifies the presence of residual organic material (blood, mucous, virus, bacteria) remaining on a device after reprocessing. Staff and leadership were immediately notified of ATP results. An ATP result of greater than 200 was considered a test failure and required immediate device reprocessing. The ATP visual testing was well received by the staff, who eagerly awaited their swab results, assumed ownership of the process, and took pride in a zero ATP reading.

All identified infection clusters result in additional inspections by the team. Surgical site infections, contagious disease exposures, and all infection control concerns are now directed to the risk team for guidance. Data are tracked, trended, and escalated as needed.

The risk team continues to audit compliance biannually, and as indicated in order to ensure program sustainability, and adherence to the reprocessing standards. All departments with a score of <100% compliance are:

- provided immediate action items to managers and staff,

- reaudited until 100% compliance has been achieved,

- provided with ongoing education.

CONCLUSION

Achieving disinfection and sterilization through the use of standardized practices is essential for ensuring that medical and surgical instruments do not transmit pathogens to patients. This proactive approach has uncovered disparities that were resolved accordingly. The clinics were held to the highest infection prevention standards. Expectations and standards are gathered from Joint Commission, CDC (Center for Disease Control), AAMI (Association for the Advancement of Medical Instrumentation), and AAAHC (Accreditation Association for Ambulatory Healthcare). The clinic staff now reaches out to the risk team whenever there is an infection prevention concern or question. They now welcome our audits and are highly engaged in protecting our patients against infections.

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ABOUT THE AUTHORS

Wendy Sweet, RN, MSN, CPHRM, *joined the Quality/Risk Management Department at Scripps Foundation in 2011. She was the Manager of Risk and Patient Relations for Scripps Foundation from September, 2014 through November, 2019. She was awarded Recognition of Outstanding Contribution by the San Diego Association for Health Care Risk Management in 2013. She also received the Hero Award for Outstanding Achievement in Health Care by the Southern California Association of Health Care Risk Managers in 2018. Mrs. Sweet is involved with creating innovative risk prevention programs. These proactive programs focus on best practices in risk management including practitioner and staff education, departmental investigations, coordinating root cause analysis, and implementing an infection prevention program for Scripps Ambulatory Care Clinics.* ***Dayna Snyder, RN,*** *joined the Quality/Risk Management Department at Scripps Foundation in 2017. She is the Clinical Risk Specialist for Scripps Medical Foundation, specializing in high level disinfection, and management of clinic exposures. Dayna has been a registered nurse since 2005 and her awards include Nurse of the Year at Scripps Green Hospital 2011, and Nurse of the Year in a Supporting Role at Scripps Foundation in 2019.*
Matthew Raymond, CRCST, *brought his SPD (Sterile Processing Department) Expertise to our Risk Team in 2018. He is a content expert in scope reprocessing and sterilization. He is certified as an SPD Technician via International Association of Healthcare Central Service Materiel Management (IAHCSMM) SPD Scope processing via The Certification Board for Sterile Processing and Distribution (CBSPD). His 39-year SPD background includes, SPD Manager, SPD Scope coordinator, SPD Educator, and Operating Room Buyer.*

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