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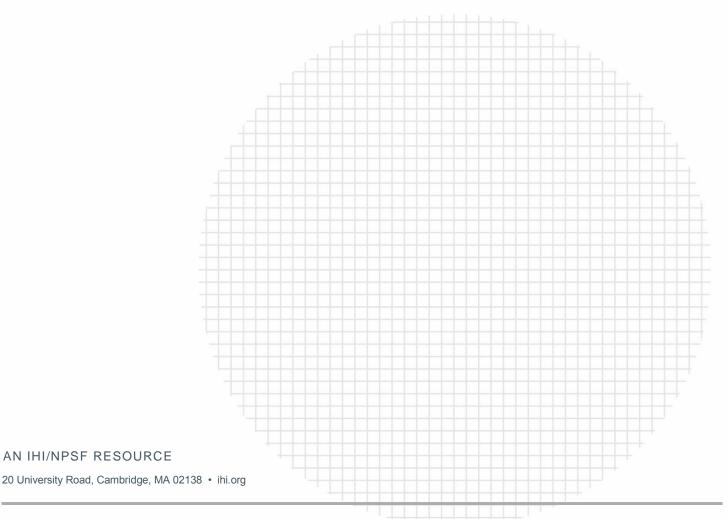
TOGETHER FOR SAFER CARE

# Patient Safety in the Home

Assessment of Issues, Challenges, and Opportunities

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The Institute for Healthcare Improvement (IHI) and the National Patient Safety Foundation (NPSF) began working together as one organization in May 2017. The newly formed entity is committed to using its combined knowledge and resources to focus and energize the patient safety agenda in order to build systems of safety across the continuum of care. To learn more about our trainings, resources, and practical applications, visit ihi.org/PatientSafety

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# Executive Summary

The health care system continues its shift away from its historically predominant focus on inpatient care, driven by economics, demographics, patient preference, and technology. Yet patient safety in the home care setting is less well understood than patient safety in other settings.

The Institute for Healthcare Improvement / National Patient Safety Foundation, with support from the Gordon and Betty Moore Foundation, contracted with Westat to evaluate research on patient safety in the home and identify gaps. Based on a scan of peer-reviewed and grey literature and subject matter expert interviews, the project examined safety issues in the home, including challenges, funding mechanisms to support safe home care, and conceptual frameworks that seek to structure these disparate issues.

Challenges related to patient safety in the home are wide ranging and include fragmentation of care; household hazards; ill-prepared family caregivers; limited training and regulation of home care workers; inadequate communication among patients, caregivers, and providers; and misaligned payment incentives. While a body of research is slowly emerging, these significant challenges require more research to fully understand, measure, and improve the safety of home care.

Patient safety issues in the home are multifaceted; we use four dimensions to organize them. The **physical dimension** involves the physical attributes of the home care setting, including environmental hazards such as home layout and infrastructure, clutter, and unsanitary conditions. Key **processes of care** that affect home safety — medication management, infection control, nutrition, fall prevention, complex clinical care, and care coordination — are also discussed in this category. The **emotional dimension** of home care safety involves stress, trauma, and discomfort related to receiving and providing care. Finally, the **social and functional dimensions** of home care safety involve the community and the network of support, and the effects of health conditions on activities of daily living.

The US health care system also influences home care safety through multifaceted financing arrangements, technological innovations, and regulations and standards that apply to home care providers. Efforts to improve patient safety in the home include programs aimed at conducting comprehensive health and safety assessments, improving caregiver education and training, and enhancing home-based care services (primary care, transitional care, and medication management).

This report concludes with opportunities for research to advance the science of patient safety improvement in the home. These include standardizing operational definitions and typology; improving measurement; developing assessments of caregiver needs, technology needs, and comprehensive patient-centered assessment processes; identifying promising practices; and ascertaining effective dissemination strategies to spread research findings.

# I. Purpose and Methods

The word "home" embodies safety, security, and comfort. However, for many people, particularly the elderly, the home environment poses risks for injury, declining health, and reduced quality of life. The Institute for Healthcare Improvement / National Patient Safety Foundation, with support from the Gordon and Betty Moore Foundation, contracted with Westat to evaluate the current state of research on patient safety in the home care setting and identify gaps in the available evidence. It sought to identify safety issues in the home, barriers and challenges to safe home care, and resources that address patient safety in the home. The project also explored how reimbursement affects patient safety and funding mechanisms that can support the safety of care in the home. This report reflects a synthesis of an environmental scan of peer-reviewed and grey literature, as well as subject matter expert (SME) interviews. (Appendixes A, B, and C provide details about the methods used in the literature review and the interviews.)

# II. Introduction and Background

The health care industry is rapidly increasing its capacity to care for patients outside of traditional hospital and outpatient settings. The Centers for Medicare & Medicaid Services (CMS) reported that 10,800 Medicare-certified home health agencies served nearly 3.5 million beneficiaries in 2010.[1] The US Department of Labor, Bureau of Labor Statistics, estimates the compound annual growth rate for home health care services from 2014 to 2024 to be nearly 5 percent, the highest among all industries.[2] Yet even as home-based care is on the rise, patient safety in the home is not as well studied and understood as patient safety in other care settings.[3]

## Factors Driving the Increase in Home Care

In the last 50 years, hospitals have been steadily discharging patients earlier. The average length of stay declined from 8 days in the 1960s to 6.5 days in the mid-1980s[4] to 4.5 days in 2012.[5] This trend reflects CMS's shift from fee-for-service reimbursement to the prospective payment system, which capped coverage based on patient diagnosis and thereby incentivized hospitals to implement cost-reducing strategies such as earlier discharge. With the implementation of associated penalties (the Hospital Readmissions Reduction Program can reduce Medicare payments by as much as 3 percent as a penalty for readmission), improving the quality and safety of home care so patients may remain at home is increasingly desirable for everyone.

Another key factor is the aging of the US population. By 2030, more than 20 percent of Americans will be age 65 or older, compared with 13 percent in 2010 and 9.8 percent in 1970.[6] According to a National Center for Health Statistics report, the number of Americans who will need some form of long-term care is expected to rise from 13 million in 2000 to 27 million in 2050.[7] Given these demographic factors, home health care in the US is expected to grow.[8] This will continue putting financial pressure on health care payers, who recognize that home-based care can provide a less costly alternative to inpatient care.

Patients and their families often prefer to receive care or recover at home, where they enjoy a quieter environment, sleep better, and are less vulnerable to hospital-associated infections. Factors contributing to increasing demand for home health care include the "aging in place" movement that calls for patients to have choices about where and how they live as they grow older, the increasing voice of patients (patient-centered care), the evolving view of patients as consumers, and the baby boomers' desire for autonomy.[9] In addition, patients and their families may find

home care more affordable than a long-term care facility or nursing home; as the population ages, this is likely to compel even greater reliance on home-based care.

Also facilitating the growth in home care is the ever-improving technology that enables patients to stay at home.[10] Internet-based programs, applications, and devices can contribute to improvements in the quality and safety of home care. Categories of these technologies include patient portals, online support networks, training/educational resources for caregivers, mobile apps for appointment scheduling and reminders, advances in telemedicine/telehealth, wearable sensors that remotely monitor patients, personal response systems that can be used to notify a call center when a patient falls, and automated medication dispensing systems that reduce medication errors. Other supportive programs can enhance the community infrastructure, such as locality-specific messaging that alerts neighbors of nearby home care patients' needs (e.g., more frequent visitors, grocery or drug store runs, rides to a doctor, respite care for a family caregiver); community center wellness programs (e.g., swim classes for mobility-impaired patients); and transportation innovations (e.g., Uber).

# Patient Safety Challenges Related to Greater Reliance on Home Care

## Complexity and Fragmentation

The increasing shift from acute care to home care brings with it concerns for patient safety. Ever shorter hospital stays, research suggests, result in patients coming home "quicker but sicker,"[11] contributing to increasing complexity of home care and related safety issues. Contextual factors, including the patient's unique clinical needs, particular home setting, socioeconomic situation, and availability of care further complicate home care safety. Experts repeatedly report that fragmentation of care is endemic among patients receiving care at home, making it difficult to consider the patient in a holistic, comprehensive way.

> *"Home care is quite fragmented. Home care providers are sent into the home for a certain reason... By only being paid to do that and only being told to look at that, [providers] miss the big picture... they don't go in there and assess what the major concerns are, what's going on with the caregiver, understanding how that's working together. [It] ends up leading everybody... into more complex situations, because those things were not taken into consideration."* — Researcher

Further, monitoring changes in health and disease progression over time is key to adapting clinical interventions. The concept of health over time is known as the health trajectory, which describes the longitudinal and dynamic changes of the course of health and disease.[12] In the hospital setting, providers have routine assessments and processes to detect safety issues. However, in the home setting, provider contact may be episodic and care delivery diffused among several providers, who may lack a reliable method (e.g., EHR) to communicate, and importantly, identify and track trends in safety issues over time.

> *"We're not treating body parts here. We're treating people who have lives outside the doctor's office. Knowing what those lives are impacts their health and safety. That kind of thing, I really do think, is important."* — Family caregiver

> *"Patient safety in home care is very different than patient safety in the hospital setting, and much more complex."* — Researcher

A related key challenge is that homes fundamentally are not structured for health care delivery. The "medicalization of the home" and concomitant burden on households and families can be daunting, especially without adequate clinical or community support. Young children may be particularly affected as they see family members receive painful dressing changes or discover the box of hypodermic needles.[13] Other household environmental hazards, such as inadequate electricity or limited space for medical equipment, also can pose safety issues.

## Caregivers as "Secondary Patients"

The availability, safety, and well-being of caregivers can be another challenge. An estimated 52 million caregivers care for someone over the age of 18 in the US, or roughly one out of every five households.[14] Sometimes referred to as "secondary patients," such caregivers usually do not receive adequate training, which can pose risks both to the patient and themselves.[15] Indeed, one seminal study noted that the "safety of the client, family, caregiver, and provider is inextricably linked… interconnected, interrelated, and influenced by one another."[16]

Caregivers are often responsible for supporting patients in activities of daily living, functional support (e.g., lifting patients), and other physical interactions that pose risks for both patients and caregivers.[17] Other common activities of family caregivers include complex tasks such as medication management (notably, 78 percent of family caregivers who manage medications administer intravenous fluids and injections), use of specialized medical equipment, wound care, food preparation to meet the patient's dietary needs, and care coordination.[18] Not surprisingly, many caregivers report high levels of stress — often related to fear of making medical errors — caregiver fatigue, and develop depression and other health problems.[18] They also suffer from isolation[17,19] and, particularly among family caregivers, guilt.[20]

> *"When these seniors take care of each other, sometimes it depends on the day who's the caregiver, and who's the patient. If we don't attend to that, we miss the boat."*
> *— Researcher*

> *"Family caregivers and the person they're caring for are intertwined like a double helix. We're completely intertwined, so what happens to me happens to [my spouse], and what happens to [my spouse] happens to me." — Family caregiver*

## Caregiver Training and Regulation

Similarly, there are training and competency issues related to personal care aides and direct care workers who provide support (bathing, dressing, and social) for the elderly and others with disabilities or chronic conditions. Personal aides held about 1.8 million jobs in 2014.[21] Most of them work in a home setting, are typically paid by the patients and family, have no formal education requirements, may not have background checks, and lack ongoing supervision — representing a "highly unregulated workforce."[22] Limited regulations on health care workers can be both a blessing and a curse for patients in home settings. It broadens the supply of affordable caregivers — enabling home care patients to access a level of care that might not otherwise be available — but also jeopardizes the safety of patients who rely upon unlicensed, uncertified, and untrained aides.[23]

> *"A nurse can come in from one agency. A physiotherapist might be in from another agency. A personal support worker could be there all the time from a different agency and [none of them] talk to one another." —Family caregiver*

## Communication and Care Coordination

Another complication involves the lack of communication and coordination among patients, caregivers, and multiple providers. In contrast to an inpatient setting, implementation of the home care patient's care plan is less controlled and structured. Hospitals have systems to support provider-to-provider communication, but in the home setting, the patient and/or family caregiver has the critical responsibility of reporting test results and clinician recommendations to other clinicians. This introduces opportunities for human error in reporting and further complicates care coordination.

## Financing

Financing and reimbursement may also present safety obstacles. Although high-quality home health care may prevent costly readmissions and emergency department visits, provider reimbursement systems are fragmented and not aligned to comprehensively support safe home care. In fact, the financial burden of providing care at home rests largely on the family and unpaid caregivers, who provide care for more than 90 percent of home care patients.[24]

In short, patient safety in the home is complex. Moreover, there is no systematic method to determine the extent of the challenges.[25,26] At-home adverse event rates have been estimated to range from 4.4 to 15 percent.[27,28,29,30,31] Yet despite such indicators of the deficiencies of home care, research that supports evidence-based practices to ensure the quality and safety of home care remains an emergent field. The heterogeneity of operational definitions, the lack of a taxonomy to describe home-based adverse events, and the absence of a universally accepted quality of care framework or quality metrics[32] pose significant challenges to building a body of research on patient safety in the home.

Deepening the complexity is that patients each have unique clinical care needs, household relationships and composition, community infrastructure, financial and health considerations, and access to licensed (and unlicensed) caregivers — all of which affect their safety in the home setting. The following section offers details about these factors.

# III. The Dimensions of Patient Safety Issues in the Home

Conceptual frameworks have emerged in recent years to capture dimensions of home care and patient safety. For example, the World Health Organization devised an international classification system of patient safety concepts for all care settings, including the home.[33] The Lang model, which categorizes home care safety concerns,[34] outlines four dimensions of safety: **physical** (environment, supplies, diversity and relationships with people involved to administer care); **emotional** (psychological impact of receiving and providing care); **social** (community settings and the network of support); and **functional** (how health affects activities of daily living/work). An *adaptation* of Lang's model (i.e., adding "key processes of care" to the physical dimension) provides an organizing framework to discuss the pressing issues related to patient safety in the home. Notably, not only are these issues important in understanding home care safety, but they indicate the importance of establishing mechanisms to assess and act on them over time.

# The Physical Dimension, Including Key Processes of Care

Lang's first dimension of home care safety focuses on the physical attributes of the home care setting, including the physical environment, as well as safety risks associated with the management, administration, and use of equipment and supplies.[35] This section discusses these safety concerns, ranging from key process of care issues that influence home safety to environmental factors associated with the physical dimension of the home.

## Key Processes of Care

Among the most common adverse events in the home setting are medication complications or errors, infections, and falls.[29] These events — along with other issues such as proper nutrition, the increasing care complexity of patients in the home, ineffective care coordination, and communication challenges — represent significant safety issues.

### Medication Management

Medication management is a significant patient safety concern across all health care delivery settings, but is particularly salient in the home. Research suggests medication errors or drug therapy problems occur in about 70 percent of home care patients,[36,37,38] with polypharmacy and potentially inappropriate medications being significant drivers.[39,40,41,42] These rates may be even higher among patients with chronic conditions who frequently visit the hospital.[43] Other medication-related safety issues include improper dosing, confusion about medication orders and names, and poor medication adherence due to economic, access, or social factors. Compounding these issues are additional medication management complexities inherent in the home environment. Challenges with safe storage is one example.[44] Safe disposal of medication is another. Moreover, medication management in the home largely becomes the responsibility of the patient or untrained caregiver. This can contribute to errors[45] and does not allow for visibility or oversight of medication management processes that are typical of inpatient settings.

> *"Medication safety in the home is a huge issue — either not taking medicines or over-taking them."*     *— Clinician*

Increased involvement of community pharmacists can address these issues and improve home medication safety. The pharmacist role in home care has been limited to monitoring intravenous drug therapy or serving as a consultant to patients and home care clinicians. However, the delivery of more intensive medication management services by community pharmacists is a growing trend.[46] Such services include activities such as educating the patient or caregiver about safe medication administration, counseling them about potential side effects or drug interactions, and assessing the frequency of refill requests to indicate if patients are taking their medications as prescribed.[47] In addition to these services, pharmacists also can provide comprehensive reviews of patient regimens to track high-risk medications, polypharmacy, and medication reconciliation. However, while community pharmacists have the expertise for these services, the challenges of productivity pressures in retail stores and the limited availability of physical space for consultation often prevents implementation.

> *"It's long been an issue for hospice agencies in maintaining the safety of their drugs for the individual as well as the community… Even if they're used appropriately, maintained safely, no one in the home environment has any interest in any redistribution… of those drugs, you still have the question of what happens when the patient dies. How do [the drugs] get disposed of? What's an appropriate*

*disposal route? Should they go down the toilet? Do they need to be crushed? Can you return them?" — Association interviewee*

This emerging role for pharmacists, particularly when conducted during transitions of care (e.g., at hospital discharge to home),[48] may improve patient outcomes, reduce hospital readmission rates, and improve medication adherence.[46,47,49] It may also help reduce medication errors for older adults in community settings, according to findings from a systematic review.[50] Other home-based approaches include pharmacist or pharmacy technician home visits, pharmacist-to-home health agency collaboration, and pharmacist participation on health care outreach teams (e.g., mobile-integrated health and community paramedicine programs). Regrettably, however, current financial incentives and regulations may pose barriers to widespread adoption of these strategies.

*"[Community pharmacists] are in the business of getting the right patients [the] right medications at the right dose with the right instructions. Anything beyond is where the tension is — productivity, efficiency, getting it right. What additional role can they play? It's not really been well articulated, by the pharmacy industry or trade organizations or community pharmacies, about expanding their role."*
*— Clinician*

Other evidence-based home care medication safety practices include using a medication-dispensing device,[51] community pharmacy services that prepackage and sort medications and deliver them to the home,[52] and in-depth medication education for patients and family members.[50] Improving collaboration and communication between physicians, home health clinicians, and other caregivers — particularly through health information exchanges or interoperable electronic health record systems — is another strategy. Finally, genetic testing and shifts toward "precision" medicine offer potential opportunities for advancing home-based medication safety.[53]

**Infection Control**
The home setting introduces distinct challenges for infection control. For example, the uncontrolled, nonclinical nature of the environment, coupled with the complexity of illnesses among home health patients, can increase a patient's risk of infection.[54] Care associated with invasive interventions for home care patients (e.g., central lines, urinary or hemodialysis catheters, ventilators, and even wound and pressure ulcer care) speak to the need for infection prevention strategies.[55] In one recently published study, approximately 3.5 percent of home care patients developed infections that led to emergency care or hospitalization; moreover, infections caused 17 percent of unplanned hospitalizations among patients receiving home-based care.[56] Infection control issues are further complicated when responsibility for clinical care falls to either untrained caregivers or to patients themselves. Increased education, therefore, is critical in preventing infections in the home care setting.[57, 58]

*"Being trained in the hospital is being trained in a safe environment. Oftentimes, the questions that [providers] have about a certain procedure don't become apparent until they're in the home. Then you have the dog and the cat, right? 'Is the dog allowed to jump on the bed when I do this wound care?' It's the uncontrolled environment that makes training in the home really important."*
*— Association interviewee*

Infection surveillance, a practice that is highly structured in inpatient settings, poses unique challenges for home care providers and patients. For example, the lack of standard definitions and surveillance methods for home care-acquired infections hinders efforts to collect and analyze valid data on infection rates, which in turn hampers efforts to analyze risk factors that lead to effective control efforts.[55] Other obstacles include a lack of trained infection control personnel in home care

settings, insufficient infrastructure to meaningfully capture clinical and laboratory data, and difficulties in obtaining numerator and denominator data.[59]

### Fall Prevention

Falls represent a significant and growing safety risk in home and community settings, threatening older adults' health and independence and leading to high health care costs.[60] Among older adults, falls are a leading cause of accidental injury and death: Medicare expenses resulting from falls exceeded $31 billion in 2014.[61] Fall-related deaths have increased 163 percent since 2000; this rate, and its associated costs, is expected to continue to rise.[61]

> *"One of the biggest gaps for people in thinking about home health safety is the bathroom. We tend to slip getting into, [getting out of, and while in] the tub. Yet there are all kinds of equipment out there, hand railings and things, that people just don't always consider necessary because they only fall once."* — *Patient*

Home care safety efforts tend to emphasize treatment of injuries rather than fall prevention;[62] efforts to engage caregivers in fall prevention activities have had limited impact. This may be due to patients' perception that falls are isolated incidents rather than a widespread safety issue. Studies show a lack of uptake of fall risk assessment by caregivers or home health care providers.[63,64] Other safety issues in the home, such as inadequate medication management or poor nutrition, also contribute to fall risk.[65,66,67]

The 2015 National Falls Prevention Action Plan released by the National Council on Aging identifies goals, strategies, and action steps around four key fall prevention domains, one of which is home safety.[60] Its fall prevention home safety goals focus on increasing older adults' knowledge of and access to home safety measures (e.g., assessments and home modifications) and educating caregivers, nonmedical service providers, and others about addressing and promoting safety concerns. Tactical strategies to achieve these goals include sponsoring awareness campaigns, identifying and bolstering community-based resources, supporting advocacy efforts related to home safety, disseminating evidence-based strategies, and enhancing cross-sector partnerships on prevention interventions.

The literature points to additional strategies for home-based fall prevention. For example, a systematic review found that home-based and group exercise programs delivered by an occupational therapist, consisting of balance and strength training exercises and home safety interventions, reduced the rate of falls.[68] Coordinated team-based home care interventions that focused on fall prevention also showed reductions in fall risk factors.[69] Moreover, one study found that an instructional DVD program targeting family caregivers increased caregiver knowledge about fall prevention and reduced the incidence of falls in the home.[70]

### Nutrition

In interviews, SMEs identified access to adequate nutrition for home care patients and caregivers as a safety issue. Whether due to immobility, lack of transportation to buy groceries, proximity to nutritious food (i.e., "food deserts"), or other factors, poor nutrition can lead to adverse events, such as pressure ulcers and falls. Even in the absence of issues related to nutrition access, home care patients can encounter challenges with food preparation.[71] Malnutrition can affect every bodily system, including decreased respiratory and cardiac function, gastrointestinal disorders, and weak physical function, all of which can prevent full patient recovery and may result in readmissions.[72] A related nutritional issue, especially in the elderly, is poor oral and dental health, which can cause chewing difficulties, affect chronic disease management, and reduce general quality of life.[73]

*"You walk in, and you look in the refrigerator, and there's no food. Then you look in the cabinets, and there's cans of green beans and that's it."* — *Clinician*

### Complex Clinical Care

Home care patients have increasingly complex care needs. According to one nationally representative survey, almost half of family caregivers performed clinical tasks for care recipients with multiple chronic physical and cognitive conditions, and more than three quarters of those caregivers were managing medications (including intravenous fluid and injection administration).[18]

*"Infusion therapy devices. Oh my goodness. How did that become something that you manage in your own home? That's crazy."* — *Family caregiver*

Safety risks associated with delivery of complex clinical care in the home are not fully understood. For example, some research suggests that infusion therapy in the home is both safe and more comfortable for patients,[74,75,76] while other research found that infusion therapy actually increases many safety concerns.[54,77] Parenteral nutrition — a complex therapy that can result in serious harm if not properly addressed — represents a particular safety challenge.[78] In the home setting, a systematic review found that parenteral nutrition is a risk factor for intravenous catheter-associated infections,[54] and total parenteral nutrition has been associated with increased 30-day readmissions and central venous catheter complications.[77]

*"The problem is [patients and family caregivers] are expected to operate this kind of stuff, which obviously, in years past, has been relegated to nurses and skilled professionals. Now, we're expected to do these things. No one wants to take the time to train us, and work side by side with us, until we have it down pat."* — *Family caregiver*

The lack of patient and caregiver training for performing multifaceted therapeutic activities is a ubiquitous conclusion. For example, studies conducted over the last decade found that the risk of injury from venous or nutritional tubes is directly related to lack of knowledge and clinical competence, according to the National Center for Biotechnology Information.[58] Nearly 40 percent of home-based caregivers, meanwhile, report a desire for additional training on such clinical activities as wound care.[18]

*"Everyone wants to do the right thing, but the caregiver is asked to do things they have no training in, for example [to administer eye drops to a patient] they need to wash their hands, and not touch the eye with the dropper… [the caregiver] didn't have good technique, and caused an infection in the patient's eye."* — *Researcher*

Interviews with SMEs identified additional safety challenges associated with complex care in the home, such as appropriate disposal of supplies and materials. Indeed, a systematic review found that home disposal practices of materials used in clinical procedures — including dressings or sharps — represented safety risks, particularly needle stick injuries.[17] Inappropriate use of medical supplies required for complex therapies (e.g., sharing insulin pens or reusing hypodermic needles) is yet another concern.

Although some health care organizations are bolstering safety training for home-based patients and their caregivers around performing complex clinical tasks,[17] the inherent safety challenges of unlicensed caregivers performing this complex care persist.

**Care Coordination and Transitions**
The patient safety field has long recognized fragmentation in the US health care system, particularly during care transitions, as an important contributor to errors and patient harm.[79] Transitions are particularly problematic when patients leave the hospital to receive care in another setting or at home.[80] Many factors contribute to gaps in care during these transitions, including poor communication, incomplete transfer of information, inadequate education of older adults and their caregivers, and limited access to essential services in the new care setting.[81]

These gaps can lead to preventable safety incidents that waste resources, frustrate health care consumers, and endanger patients' lives,[82] particularly complex or chronically ill patients who experience multiple care transitions.[83] Home health care can help optimize outcomes after a transition home from the hospital, but family members and the patients themselves[84] often are insufficiently engaged in managing the transition.[85] Accordingly, The Joint Commission identified patient and family engagement as one of seven foundations to support safe, high-quality care transitions.[86]

> *"I don't yet see a lot of health systems coordinating with their local Meals on Wheels, or their local senior center, or local food bank, or personal care services. All those services of social stuff that social workers know about, but that doctors and most health care providers don't know how to tell people to access, including me."* — Clinician

Poor communication between clinicians and patients and families during care transitions is only one part of the care coordination dilemma; another safety risk for home care patients is the lack of formal infrastructure around provider-to-provider communication. While hospital patients benefit from systems that support sharing information across clinicians (e.g., nurse end-of-shift reporting), such infrastructure is less formal or nonexistent between hospital and outpatient providers. The home care patient and/or family caregiver takes on the critical responsibility of reporting clinical insights and care recommendations offered by one clinician to the patient's other clinicians. This creates new opportunities for human error in reporting and further complicates care coordination efforts.

## Environmental Hazards

The home environment is a key risk factor related to patient safety, especially among the elderly.[87] Common environmental hazards include issues related to the home infrastructure, physical layout of the home, clutter, and unsanitary conditions.

**Home Infrastructure and Physical Layout**
Home infrastructure and physical layout, as interviewed SMEs noted repeatedly, is a core issue in ensuring patient safety in the home. Preventive strategies to reduce safety hazards include securing area rugs and electrical cords,[88] replacing missing handrails and installing grab bars,[22] improving lighting,[88,89] fixing uneven or broken steps,[90,91] installing fire extinguishers and carbon monoxide and smoke detectors,[92] confirming safe water temperatures, and installing appropriate receptacles to dispose of used needles and other medical supplies.[22] Confirming appropriate temperature and humidity levels to operate electronic monitoring and other medical equipment is also critical.[93] A serious potential safety issue involves the use of oxygen therapy and potential fire hazards from smoking and other flammable sources.[94] Other factors, such as ensuring appropriate ventilation to filter mold and other particulate matter, replacing inadequate electrical infrastructure needed to operate durable medical equipment, and obtaining reliable communication capacity (e.g., Internet and telephone)[95] may be more costly to address. Patients who live alone tend to have less social support and may have limited ability to make needed home modifications.[92]

*"...with dialysis and respirators at home, nobody goes into the home to see if the electrical system of that house can support that piece of technology. People think you can just transport it."* — Association interviewee

*"From my perspective, safety isn't just about the environment. It's the interaction between what the person is able to do and what the environment requires. If someone, let's say, what they need is grab bars at their bathtub, but if they're also personally weak or in terrible pain, they're not going to be able to safely get into the bath."* — Researcher

Problems with a home's physical layout are even more challenging to tackle. For example, small rooms and narrow stairs and hallways may prevent individuals with disabilities from performing activities of daily living;[93] multilevel homes can create hazards, especially when critical spaces (e.g., front entry, sleeping area, and toilet) are not on the same floor.[22] Moreover, homes may lack adequate floor space to accommodate critical medical or communications equipment, such as devices that monitor and share health data with remote providers.[22]

### Clutter

Cluttered spaces in the home pose patient safety concerns.[96] Clutter may result in an increased risk of falls or injury related to falling items (especially among the elderly),[97] fire hazards,[98] and unsanitary conditions in the home (e.g., unmanaged garbage, poor air quality due to airborne bacteria).[99] Dust and animal dander may also collect in cluttered spaces, triggering allergies and asthma.[100] Extreme clutter is often the result of hoarding, a common mental health condition[99] that affects approximately 5 percent of adults.[99,101]

*"I had a patient who had sores due to extreme swelling in her feet. When I finally entered the home to provide her care, I found out that her house was so dirty and cluttered she did not even have a place to lay down to put her feet up... There was two to four feet of garbage everywhere in her apartment."* — Clinician

### Unsanitary Conditions

Providing sanitary conditions poses a particular challenge to patients in the home. "Home hygiene" refers to the prevention of pathogen spread in home settings. Poor home hygiene can lead to the spread of germs and disease, infection, and other safety problems. Sources of pathogens include contaminated food, domestic animals, vermin,[22] ill visitors, stagnant water accumulations,[102] inappropriate use of medical supplies (e.g., reusing hypodermic needles, improper disposal of medical waste), and poor personal hygiene (e.g., inadequate hand washing). Pathogen control may be particularly challenging when patients are too weak or are otherwise unable to disinfect areas contaminated with bodily fluids.[102] Patients with compromised immunity and/or certain conditions may be at particular risk.[103]

Many patient safety assessment tools designed to evaluate the home environment are available. For example, the *Household Safety Survey Checklist* allows caregivers to identify common household hazards related to falls, fire, electricity, hygiene, chemical, and other hazards found in the home.[104] (Appendix D provides additional tools and resources.)

## The Emotional Dimension

The second dimension of safety concerns identified in Lang's framework represents emotional issues, which develop in response to the psychological impact of receiving and providing care.

Emotions play a critical role in the safety of patients and caregivers. First, family members may find themselves "conscripted"[35, 44] into a role for which they are ill prepared. As noted earlier, caregivers are asked to perform complex medical tasks[105] with little training or oversight,[93] such as providing wound care,[106] operating specialty medical equipment, or managing complex medication regimens.[15,18,107] Nearly half of the country's unpaid caregivers provide assistance to a family member who has multiple physical and/or chronic conditions[18] or who has "substantial" care needs, such as those associated with dementia[108] or impaired self-care activities (e.g., eating, dressing, toileting).[109] The more responsibilities the caregiver takes on, the greater the stress and fatigue and thus the greater the risk to the caregiver's health.[16,18,110,111] Add a full-time job to these duties, which is the case for more than half of adult children who care for parents,[15] and an already challenging situation may become overwhelming.

> *"At age 54, my husband was diagnosed with a debilitating neurological disease, which has no treatment and no cure... Now he can no longer talk, walk, stand, or feed himself. He's totally incontinent and needs full-time assistance for daily living. I received no financial help and work full time to support his full-time home care. I am now a senior myself, but shoulder the entire household responsibility, from cooking, cleaning, and shopping to mowing the lawn and shoveling the snow. I am overworked and worn out... I feel very alone, constantly worrying about my husband's health. Life has been a struggle for me."* — Family caregiver

In addition to the emotional burden of providing care and keeping the patient safe, caregivers are at risk of being traumatized should an adverse event occur. One clinician interviewee recounted a story of a middle-aged man who had to give his mother insulin injections after her discharge from the hospital. Lacking sufficient training, the man caused an injury that landed his mother back in the hospital. She recounted, "This man — a tough guy — was crying his eyes out. He was saying, 'I can't imagine that I'm the one who hurt my own mother. How can this happen? How can they make me do this to her?'" Another researcher interviewee echoed this account, saying, "The families that I've worked with, when they've ended up making mistakes or harming the person in some way, it's devastating. It's a very difficult thing emotionally for them."

Less dramatically, but of equal concern for safety, patients and caregivers may be reluctant to "hospitalize" their home in a way that would create a safer environment for the patient. Moving rugs, installing handrails, or even moving a hospital bed into the home "could have emotional and social implications for the clients, family members, and caregivers."[13] One researcher interviewee concurred, noting that, ultimately, patient autonomy may win out: "When you go into somebody's house, you could tell them, 'Take away the carpet. You shouldn't do this, you should do that.' At the end of the day... Henry and Martha have to figure it out on their own, and they'll do what they want to do no matter what you tell them." Patients, she added, should be allowed the "dignity of risk," that is, accepting a level of risk that is consistent with their values.

> *"People think that the elder is just manipulating them, that [the elder] really could do it but they just want [the caregiver] to serve them. [This happens] all the time, especially with early cognitive impairment. People don't understand that mom or dad isn't doing this to them purposely, it's their capabilities at this point."* — Association interviewee

Finally, family relationships can affect the emotional well-being and safety of patient and caregiver. A challenging upbringing could lead an adult child serving as caregiver to question the ill parent's motivations. Ensuing perceptions — and misperceptions — can create additional risks for the patient and add pressure to an already emotionally fraught relationship.

## The Social and Functional Dimensions

Rounding out the dimensions of Lang's framework are social issues (related to the patient's family, support networks, and community) and functional issues (i.e., how health conditions affect activities of daily living, the ability to function independently). As Lang notes, patients may face increased risk to their safety simply because of the desire to remain at home "at any cost." Illnesses bring about inherent limitations in daily functioning, which may multiply as an illness progresses. However, the extent to which safety risks increase, and for whom, is a function of the patient's social matrix.

Importantly, family structures are very different from what they were 50 years ago: couples are having fewer (or no) children, family members are more geographically dispersed, and there is greater workforce participation by women.[109] No longer can parents expect that their children — particularly daughters — will be in a position to care for them at home. Thus, older patients who choose to remain at home increasingly must rely on their spouses, support networks (friends and neighbors),[112] and/or paid providers for their care and safety.

As noted previously, spouses are often the "go to" caregivers for patients, but too frequently are drafted into a role they may not be well positioned to fill.[44] Said one researcher interviewee, "Nobody says to them, 'Do you have time?... Do you want to look after this person?' It's just assumed that this person needs care and if there's somebody living at home they will be able to do that." Indeed, not all caregivers have the physical, cognitive, or emotional makeup to serve in this role. Moreover, when combined with insufficient training, this common scenario puts both the patient's and caregiver's safety in jeopardy. Caregiver fatigue has been characterized thematically to include symptoms of uncertainty, doubt, attachment, and strain,[113] which can ultimately affect the caregivers' physical, emotional, psychological and financial health.[18] Respite care, which Medicare defines as "short-term inpatient care provided to the individual... to relieve the family members or others caring for the individual at home" can provide support for caregivers.[114]

Fortunately, some seniors have extensive social networks and may be able to draw on these natural supports to ensure they are safe at home. Friends who live nearby can play several roles to maintain the patient's independence and safety, including picking up groceries or medications, dropping off hot meals, making regular wellness checks on the patient and caregiver, offering social interaction as a "normalizing" activity, providing transportation to doctors' appointments, and a host of other activities that formal social and medical service systems may not be able to provide. The neighborhood in which a patient lives also matters.

A patient interviewee affirmed the importance of neighbors: "[I was] trying to get to radiation therapy in the blizzard of 2010. My community association had somebody in my driveway every day to take me to therapy. You really need a good, strong support system, and a lot of people don't have that."

Patients who are socially isolated still may choose to remain at home, even when they are no longer able to manage activities of daily living. Their safety becomes dependent on the robustness of their local service infrastructure. For example, home care patients periodically need to see their physicians, but their safety may be at risk if they cannot drive or live in a rural area without public transportation. Yet even patients who live in an area with strong public transportation infrastructure may be at risk. Few of these services are free, and a patient may not be able to safely live independently because of an inability to pay for transportation to and from medical appointments.

*"The resources that are available in your local neighborhood, do they facilitate healthy activities that are beyond the home? Are there even sidewalks that you can walk on? Are there parks where you can meet other people? [Is] there access to transportation? These are home health care issues that extend beyond the home.... Your home is in a community, and the community in which you find yourself living has home health care implications."* — Regulatory agency interviewee

As noted earlier, adequate nutrition is fundamental to health and the ability to remain independent. One community resource is Meals on Wheels, which delivers hot, nutritious meals to homebound seniors five days per week without regard for the recipients' economic status. Drivers, who directly contact the patient or caregiver each weekday, can play an important role in ensuring that patients and their caregivers are safe. However, the service is not available in all communities (such as rural areas) and many seniors may be unaware that the service is available to them free of charge. Thus, patients and caregivers who are trying to remain on their own may lack access to healthy or sufficient food.

As stated above, the ability to accurately follow a medication regimen is critical to patients being able to remain at home safely,[36] and community pharmacists can play an important role in reducing medication errors among homebound patients.[47] As one clinical interviewee pointed out, "The pharmacist may be the only relationship that folks have with the medical establishment on an ongoing basis, in terms of [whom] they really trust." Patients who do not have access to community pharmacists, however, may be at greater risk of medication administration errors that could jeopardize their ability to maintain their independence.

Patients who are unmarried, have no children, or who lack a strong social network may be able to rely on paid providers to stay at home safely. However, assuming that the community has sufficient resources, this option may carry its own set of risks for the patient. The lack of on-site supervision, use of low-wage paraprofessionals, and lack of nearby colleagues for the home-care clinician's immediate consultation all contribute to the potential for medical mistakes. The risk of error is compounded when a patient has multiple providers coming into the home throughout the week.

*"If you have people that are not your family coming into help, how do you make sure the person isn't exploited, or that things aren't stolen, or the person isn't abused? Those are important questions."* — Researcher

One researcher described this phenomenon: "Home care nurses or providers... are sent into the home for a certain reason. [The patient] need[s] an IV, they need a dressing changed, they need a whatever. By only being paid to do that and only being told to look at that, they miss the big picture. By missing the big picture, meaning they don't go in there and assess what the major concerns are, what's going on with the caregiver, understanding how that's working together... leads everybody down into more complex situations, because those things were not taken into consideration." For example, if the providers and caregivers are not communicating well, they may miss signs of deterioration. Finally, although the vast majority of paid unlicensed and medical professionals are kind and caring individuals, when that is not the case, fragile patients or caregivers are vulnerable to theft, maltreatment, or other abuses.

# IV. Health Care System Considerations

In addition to the patient safety issues described above, substantial system-level challenges influence safety in the home, including complex financing arrangements and quality improvement activities, technology, and regulatory issues, as discussed below.

## Provider Reimbursement

As noted earlier, providing appropriate and safe care in the home can prevent readmissions and emergency department visits, and thereby avoid significant costs. Moreover, "aging in place" and providing care in the home can provide significant savings over institutional care. However, current provider reimbursement systems are fragmented and not aligned with coordinating effective, safe, and comprehensive home-based care.

Potential sources of funding for home care include:[115]

- **Federal and state support:**

  o Medicare fee-for-service reimburses skilled in-home care services (e.g., nursing/physical, speech, social, and occupational services), as well as supplies and equipment for a homebound patient's short episode of care, but typically does not cover personal care or meals.[116]

  o State Medicaid funding can provide for home services under waiver programs (e.g., Programs of All-Inclusive Care for the Elderly), provided income restrictions are met, but coverage varies significantly by state.[117] In 2014, 53 percent of Medicaid long-term services and supports funding supported home and community-based services,[118] which may include services such as medical care, adult day health and respite services, case management, health aides, personal care, and transportation.[119] As part of home and community-based services, self-directed personal assistant services (i.e., cash and counseling services) allow participants to hire relatives as paid caregivers.

  o Home care programs supported by the Older Americans Act and the Department of Veterans Affairs (e.g., the Veterans Affairs Home-Based Primary Care initiative) are designed for targeted populations and situations.

- **Health insurance:** Private health plans typically align coverage with Medicare (e.g., skilled, short-term, medically necessary care) and may authorize a limited number of home health visits per episode of care to reduce utilization.

- **Private payment:** Private out-of-pocket expenses and long-term care insurance are costly and challenging options for most families, particularly for at-risk populations.

Recent initiatives are addressing these issues through payment reforms and demonstration efforts, many of which incorporate new quality measures that may affect patient safety in the home. Among the most promising approaches are several CMS efforts. CMS's "pay for performance" structure evolved into value-based care (VBC). Driven by the Triple Aim to improve the experience of care, improve the health of populations, and reduce costs,[120] VBC programs "reward health care providers with incentive payments for the quality of care they give to people with Medicare."[121,122] Also, the Medicare Access and CHIP Reauthorization Act of 2015 (MACRA) established the Merit-based Incentive Payment System (MIPS) and Alternative Payment Models (APMs); these provide home safety-related measures.

## Value-Based Care

Of the seven current CMS VBC programs, two are particularly relevant for safety in the home. First, the 2012 Hospital Readmission Reduction Program facilitates processes to improve care coordination, discharge planning, patient education, and follow-up care to prevent readmissions, all of which could affect safety in the home. Similarly, the Home Health Value-Based Purchasing program, which began in January 2016 in nine states, tests home-health agency payment incentives and quality measures aimed at improving quality of care and reducing costs.[123] Metrics that are most applicable to safety at home include medication education for patients and caregivers on all of the patient's prescriptions, hospital and emergency department utilization, and advance care planning.[124]

## MACRA / MIPS

The Medicare Access and CHIP Reauthorization Act of 2015 (MACRA) established the Merit-based Incentive Payment System (MIPS) and Alternative Payment Models (APMs). For MIPS, clinicians receiving Part B payments must report their performance through four performance categories (i.e., quality, cost, improvement activities, and advancing care information). Individual performance determines the adjustment amount applied to a percentage of a clinician's payments.[125] Quality measures and improvement activities are based on clinical standards of care. MIPS quality measures, which may be endorsed by the National Quality Forum,[126] relate to several National Quality Strategy domains,[127] including patient safety.[128] These measures include Dementia Counseling Regarding Safety Concerns, Documentation of Current Medications in the Medical Record, Elder Maltreatment Screen and Follow-Up Plan, Falls: Risk Assessment, Falls: Screening for Future Fall Risk, and Use of High-Risk Medication in the Elderly. Improvement activities cover several subcategories (e.g., patient safety and practice), and include implementation of fall screening and assessment programs, as well as the use of patient safety tools. These quality measures and improvement activities may help incentivize patient safety in the home.[125]

## Comprehensive Primary Care Plus

Launched in January 2017, Comprehensive Primary Care Plus (CPC+) is a CMS multipayer initiative that aims to strengthen primary care medical homes. CPC+ offers an innovative payment structure that supports delivery of comprehensive primary care.[129] Depending on their care delivery and health information technology capabilities, participating practices across 14 regions follow one of two tracks. Track 1 participants focus on building capacity to deliver comprehensive primary care and better meet the needs of patients. Track 2 participants, having built this capacity, focus on comprehensive care delivery (e.g., assessing and managing patients with complex needs).[130] Practices in both tracks are expected to improve care delivery by increasing patient and caregiver engagement and enhancing care coordination — particularly during transitions of care. CPC+ also includes a performance-based incentive payment based on patient experience, clinical quality, and utilization measures (e.g., Use of High-Risk Medications in the Elderly and Screening for Future Fall Risks).[131]

## Alternative Payment Models

In recent years, CMS has established several APMs, or unique payment arrangements with rigorous quality components to move toward value-based care. Many APMs mandate that participating clinicians report quality measures related to home patient safety.[125] Clinicians, hospitals, and suppliers voluntarily come together to coordinate care and provide better services through accountable care organizations (ACOs).[132] For instance, the Medicare Shared Savings

Program ACOs Track 1 initiative requires clinicians to report quality measures (e.g., Medication Reconciliation Post Discharge and Falls: Screening for Future Fall Risk) to incentivize patient safety in the home.[133]

> *"There seems to be a groundswell for health systems, for responsible entities, to start paying attention to social determinants of health, many of which impact on home safety. As we collect better social data, you'll start to see ACOs, Medicare Advantage, pay more attention to social determinants. I don't think people yet think of home safety as a social determinant — and how home safety can have an astonishing effect on readmissions and total cost of care, which is really important to [payers]."   — Clinician*

The Independence at Home Demonstration is another home safety-related VBC initiative of the CMS Center for Medicare & Medicaid Innovation (CMMI). It calls upon selected medical practices to deliver comprehensive primary care services at home for Medicare beneficiaries with multiple chronic conditions. In the second year of the program, 14 participating practices saved $7.8 million in aggregate, representing an average of $746 per patient. By achieving quality standards, seven participating practices earned over $5 million in payment incentives.[134] These quality measures relate to reducing readmissions, performing medication reconciliation, and addressing patient preferences, all of which relate to safety in the home.

> *"I think it [reimbursement for home care] should be flipped on its head. If we want people to stay at home, have longer lives, and be more productive, then more money has to flow in that direction, versus inpatient settings."   — Researcher*

> *"My mom fell, had a severely broken arm, she was in our home recovering. We desperately needed in-home care. We had an organization calmly sit in our kitchen and tell us that would be $500 a day out of our pocket for the care that she needed. We ended up putting her in a rehab facility, which ended up costing Medicare far more than if we had had the support to keep her in our home."   — Family caregiver*

In summary, while promising initiatives have the potential to measure and support home safety, the need remains for stable funding that reimburses a comprehensive array of home care services aimed at ensuring a safe home environment.

# Technology and Equipment

### Technology

The trend toward home-based care is benefiting from — and driving — technological innovations. For example, technology can increase the length of time that patients are able to reside at home[10] and maintain a sense of security and safety.[135,136] Technologies that can support patient home care and reduce caregiver burden include: telemedicine/telehealth to deliver care to patients isolated by geography or mobility challenges; wearable sensing technology to remotely monitor patients; automatic medication dispensing systems to reduce medication errors; robotic caregivers to support daily living and mobility; and countless Internet-based supports, including patient portals, online social support networks, resources for training and education, and mobile apps for appointment scheduling, alerts, and reminders.

In turn, the demand for safe and effective home care has spurred significant investment in developing new technologies. In 2015, startups developing such technology received more than $80 million of funding.[137] Venture capital investment in technology-enabled home care has

exploded, with over $200 million invested in 2016,[138] and the market for "Internet of Things" technology — a network of devices that collect and exchange data via the Internet (e.g., monitoring systems) — is expected to grow 38 percent by 2020.[139]

A 2016 survey assessed US health care consumers' reactions to telemedicine, remote monitoring and sensors, and robotics in the context of home care.[140] Results indicated that caregivers and heavy users of the health care system are keenly interested in these technologies. Consumers prioritize those that are high quality, provide individualized care, and protect personal information. Telemedicine was identified as particularly important, especially for postsurgical and chronic care management. Indeed, the field of telemedicine is growing rapidly,[141] and research has demonstrated its contribution to patient satisfaction, specifically in treating dementia[10] and heart failure[142] in the home setting. Recently enacted Federal legislation, such as the 20th Century Cures Act and the Expanding Capacity for Health Outcomes (ECHO) Act, contain telehealth-friendly language and may further promote this technology.[143]

> *"We have far more technology these days than we have people who understand it and can use it… We have wearables, sensors, medication dispensers, GPS devices. All of these can have a very positive impact on patient safety. [But] most people can't afford them… We have a ton of technology that is just waiting in the wings to help support people, but it's not free. The people that need it most just can't get it."*
> *— Family caregiver*

Despite the interest in technological supports, a survey of caregivers revealed that only 6 percent of respondents reported using technology; much of what they used was limited to scheduling, tracking, and managing medication refills or delivery. Barriers to the use of technology included lack of awareness; high out-of-pocket costs; perception of insufficient value (i.e., added cost versus improvement); lack of evidence that the tools promote patient safety; insufficient time to learn about, understand, and select from the many offerings; lack of technical support; lack of confidence in their ability to use the technology; and insufficient training and experience.[144,145]

Further, consumers and providers ask whether such products were designed with the end user in mind. They specifically question the degree to which developers incorporate human factors principles during development,[146] as well as the extent to which designers considered the unique context of the home care setting.[147] For example, caregivers seek integrated and coordinated technologies to minimize having to learn many new applications,[144] but the technology has not yet caught up to demand.

> *"I'm a senior… do people realize that you're talking to somebody who wasn't raised with technology, who doesn't know all this stuff?"* — Patient

Even telemedicine, despite its growth, faces many barriers to more widespread use, including the lack of reimbursement, cost-effectiveness concerns, safety-related issues (e.g., potential for fragmentation),[148] lower quality of the patient-physician relationship, and legal issues (e.g., licensure laws).[141] Lastly, many of these new technologies have not produced evidence that they work; there is a paucity of literature evaluating effectiveness or safety of these technologies. Many of the studies that do exist lack scientific rigor and have not applied quantitative methods within their evaluations.[149]

In summary, technological innovations offer great promise to improve the safety and effectiveness of home-based care and support safety in the home; however, that promise cannot be realized until many barriers are addressed.

### Equipment

As noted earlier, the increasing complexity of care in the home has resulted in many life-critical pieces of equipment being used in the home — ventilators, infusion devices, home dialysis, and telemonitoring systems. The hospital standards, regulations, inspections, and overall culture of safety surrounding equipment do not typically translate to the home setting.

> *"Any device that's being deployed in a hospital these days, you'll see them at home as well — infusion pumps, ventilators, [other] assistance devices — but you don't have someone who can necessarily fix them if they break, or figure out if there's a problem. There's a potential of a safety issue if a device malfunctions. It may not be recognized."*    — *Researcher*

A 2013 Summit on Healthcare Technology in Nonclinical Settings, convened by the Association for the Advancement of Medical Instrumentation and the US Food and Drug Administration, noted several barriers in safe use of equipment, including limited coordination among health care prescribers and equipment providers; poor assessment of home readiness risks (space, infrastructure support, caregiver and patient abilities); varied user interfaces, lack of intuitive design; inadequate training, ongoing support, and maintenance; and lack of data about equipment errors and malfunctions.[147]

Recommendations to reduce these barriers included improving stakeholders' understanding of the variability across settings; coordinating transitions in care; adopting a systems approach in workflows, therapies, technology, and payment; simplifying and standardizing regulations, data, and testing; and designing equipment that incorporates the patient perspective and is easy to use in the home setting.[147]

## Relevant Regulations and Standards

US regulations on home care providers, including home hospice staff and home care aides, vary by state. Yet unregulated care providers (UCPs), by definition, have no mandatory training requirements or practice standards. Evolving provider roles blur lines between UCPs and licensed providers; however, research suggests that relying on educated, experienced nurses over UCPs for home care delivery results in improved patient outcomes. However, little is known about the relationship among skill mix, cost, and patient outcomes, nor about how delegation occurs between regulated and unregulated providers in the home care setting.[150]

CMS manages regulations regarding home health agency participation in the Medicare and Medicaid programs that provide skilled home care. In January 2017, CMS issued new rules (with a proposed delay until 2018[151]) for conditions of participation, designed to improve care for Medicare and Medicaid patients and align incentives to improve safety in the home. The standards focus on patient rights and education, an expanded comprehensive assessment of all aspects of the patient's well-being, integrated communication and care coordination systems, and data-driven improvement programs.[152,153]

CMS also requires home health agencies to report performance data for eligible adults through the Outcome and Assessment Information Set (OASIS),[154] which is the basis for the publicly available Home Health Compare tool. Home health-related quality measures include potentially avoidable events, which may help address safety in the home. These measures include emergent care for fall injury, wound infection, and improper medication administration and side effects; developing urinary tract infection; increase in pressure ulcers; decline in activities of daily living; decline in

managing oral medications; and discharge to the community with needs of wound care, medication assistance, toileting assistance, behavioral problems, or unhealed pressure ulcer.[19]

Recognizing the importance and growth in home care,[155] The Joint Commission established National Patient Safety Goals to improve patient safety in the home. These goals focus on problems in home care safety and how to solve them. For 2017, the goals include correct patient identification, safe use of medications, infection prevention, falls prevention, and identification of safety risks.[156]

# V. Resources, Promising Approaches, and Programs

This section presents selected approaches and programs that serve as exemplars for promising practices to improve patient safety in the home. Several of these programs aim to prevent the need for higher levels of care (e.g., hospitalizations, emergency visits) while improving outcomes relevant to patient safety issues in the home (e.g., medication management, falls, infection, environmental safety). Both SME interviews and the literature review served as sources for these exemplars. Due to the wide range of models and approaches, a comprehensive analysis of all existing programs is beyond the scope of this report. The programs described below are indicative of promising approaches in three general areas: comprehensive health and safety assessments, caregiver education and training, and home-based care services (primary care, transitional care, and medication management).

## Comprehensive Health and Safety Assessments

### Community Aging in Place: Advancing Better Living for Elders (CAPABLE) Program

CAPABLE is a home-based intervention that aims to keep low-income older adults functioning as independently as possible in their own homes to enhance their capacity to "age in place." Participants in the program, which was recently studied as part of a demonstration project funded by CMMI, receive home-based patient-centered nursing care, occupational therapy, and handyman services. Home repairs and modifications, such as installation of stair railings, grab bars, improved lighting, assistive devices, and raised toilet seats, allow participants to navigate their homes more easily and safely. The intervention is designed to reduce health care utilization by improving medication management, home safety, and functional status while decreasing isolation, depression, and fall risk. Several studies found that the model is effective at reducing nursing home and hospital admissions, improving functioning and quality of life, and reducing health care costs.[157,158,159] Results of the demonstration project showed that 75 percent of participants improved their performance of activities of daily living after completing the program.[160] A more recent evaluation of the program noted that it was associated with reduced total Medicare expenditures.[161] CAPABLE has received funding to expand the program to three cities in Michigan as part of Michigan Medicaid's pilot program to deliver home and community-based services to help keep nursing home-eligible adults in the community.[162]

### Queen Anne's County, Maryland, Mobile Integrated Community Health (MICH) Program

In 2014, the Queen Anne's County, Maryland, Department of Emergency Services (EMS) launched an innovative program to improve outcomes among the county's most vulnerable, medically complex residents. The first of its kind in Maryland, MICH targets high-risk patients who frequently call 911 and provides intervention-based health care services, home safety assessments, and referrals to community services. A field team (paramedic, nurse practitioner, and behavioral health professional) performs a comprehensive, in-home assessment that examines the patient's physical, social, and behavioral health. As relevant, a pharmacist conducts a televisit for medication management. The team uses evidence-based tools to assess safety risk, including the Hendrich II Fall Risk Model and the Physical Environment Assessment Tool (PEAT). According to MICH leadership, the program has served a total of 116 patients and has achieved successful outcomes, reducing 911 usage by 23 percent and avoiding an estimated 132 emergency department visits over a 12-month period.[163] By leveraging EMS workforce and infrastructure, the program represents an efficient approach to improving outcomes among a high-risk population.

In fact, community paramedicine (the use of paramedics beyond their customary emergency transport roles) is a model of community-based health care that is emerging as a national trend. In Arizona, several pilot programs that focus on fire service-based community paramedicine are indicative of models that show promise for improving health outcomes among medically underserved populations[164] through home-based assessment and care, patient education, home safety assessments, and referrals to social services. EMS providers in Arizona have partnered with the state's health department to develop a formal "treat and refer" program; the initiative leads national efforts in the area of reimbursement by offering cost recovery for EMS agencies providing community paramedicine services.[165]

# Caregiver Education and Training

### Home Alone Alliance[SM] Family Caregiver Instructional Videos

In December 2012, the AARP Public Policy Institute and United Hospital Fund published a joint report, *Home Alone: Family Caregivers Providing Complex Chronic Care,*[18] describing the challenges of family caregivers who provide medical and nursing tasks in the home such as handling prescriptions, wound care, assisting with mobility, and operating medical equipment. Despite frequent contact with health care professionals, family caregivers often do these tasks with no preparation or training, and can experience stress about performing such tasks safely and correctly.

To address this problem, the United Hospital Fund held a series of family caregiver discussion groups designed to hear from family caregivers about their experience. Discussion groups focused on a series of themes including the emotional impact of caregiving, problems with medication management, and lack of training on wound care. The findings were detailed in the 2016 report *It All Falls On Me,*[106] which informed the development of a series of instructional videos aimed at helping train caregivers to manage complex caretaking tasks.

In 2015, AARP launched the Home Alone Alliance[SM] in collaboration with the United Hospital Fund, the Family Caregiver Alliance, and the Betty Irene Davis School of Nursing at the University of California at Davis, to bring together partners in various sectors to create solutions that support family caregivers. Alliance members developed an initial video series for caregivers on medication

management, followed by a series instructing family caregivers how to perform mobility-related tasks. These videos are freely available on the AARP website.[166]

# Model Programs for Home-Based Care Services

### MedStar Medical House Call Program

This Washington, DC–area house call program provides home-based medical care and chronic disease management services for high-risk seniors with multiple chronic conditions, who are often too ill, frail, or disabled to visit health care provider offices. The program targets patients at the greatest risk of incurring high health care costs. A geriatrician completes a comprehensive at-home assessment to ascertain the patient's clinical and psychosocial issues and potential safety hazards. The program then provides 24/7 access to an interdisciplinary care team including the geriatrician, a nurse practitioner, and a social worker, with on-call telephone coverage and frequent home visits. Clinicians make urgent house calls when needed to prevent avoidable hospitalizations, and social workers coordinate needed support services, focusing on the educational and emotional support needs of family caregivers as well. A study found that participation in the program resulted in 9 percent fewer hospitalizations, a 20 percent reduction in emergency department visits, a 27 percent reduction in skilled nursing facility stays, and a 75 percent reduction in end-of-life hospitalizations compared to a control group.[167] Overall, the program reduced Medicare costs by 17 percent, with a total savings of $6.1 million over two years. MedStar's program is one of several models being evaluated in the Center for Medicare & Medicaid Innovation's Independence at Home (IAH) demonstration program, which examines the impact of house call models on outcomes and costs.[168]

### The Care Transitions Program® (CTP®)

CTP is a four-week program in which a specially trained "transitions coach" works with patients and family caregivers to ensure a smooth transition to home from either a hospital or short-term skilled nursing facility.[169] The transitions coach, usually a nurse or social worker, encourages patients to take a more active role in their care, providing health education and self-management strategies, performing medication reconciliation, and facilitating communication with clinicians. The model is unique in that it uses adult learning principles to enhance patient self-management. The four "pillars" of the intervention are medication self-management, use of a patient-centered personal health record, follow-up care, and patient knowledge of "red flags." Multiple studies provide evidence that the model is effective at reducing hospital readmissions and costs.[170,171] A randomized controlled trial found a 30 percent lower 30-day readmission rate, a 26 percent lower 90-day readmission rate, and 19 percent lower per-patient costs of care after six months.[172] More than 900 organizations in 43 states have adopted the intervention.[173]

### Community Care of North Carolina

Community Care of North Carolina (CCNC) is a statewide, community-based program for establishing access to a primary care medical home for vulnerable populations and providing those medical homes with the multidisciplinary support needed to ensure comprehensive, coordinated, high-quality care.[174] CCNC relies on a network of primary care practices, as well as 14 nonprofit "regional networks" of physicians, nurses, pharmacists, hospitals, health departments, social service agencies, and other community organizations.[174,175] Central to these efforts are community pharmacists who partner with CCNC to provide enhanced medication management services in community settings. The services that these pharmacists provide are diverse, consisting of, for example, transitional care and behavioral health interventions. CCNC's overall efforts produced

nearly $1 billion in costs savings between 2007 and 2010.[175] Those who received CCNC transitional care services were 20 percent less likely to experience a readmission during the subsequent year, with benefits being greatest among patients with the highest readmission risk.[174]

# VI. Research Opportunities

In concluding this environmental scan, including an extensive literature review and interviews with experts and stakeholders regarding patient safety in the home, we are left with remaining questions. Based on recommendations identified through the scan, the following areas represent opportunities for research to advance the science and practice of patient safety improvement in the home.

> *"A good taxonomy to define safety in the home and all the chief domains associated with that... [is] one of the first-order tasks... Once you have taxonomy then you can start to see what's out there, you could start to understand where the gaps and opportunities really are."* — Researcher

## Standardizing Operational Definitions and Typology

As noted from literature and experts throughout this effort, perhaps the greatest challenge to building a body of research on safety issues in home care is the heterogeneity of operational definitions.[22,176,177] In part, the challenge in even determining adverse event rates to document the scope of the safety problem stems from a lack of consensus of universal definitions of patient safety and adverse events in the home, and this gap hinders efforts to clearly document the incidence and prevalence of such events.[178] Quality indicators (e.g., patient experience, safety culture, patient outcomes) as operationalized in hospital settings do not directly translate to the home setting. Developing a common vocabulary and taxonomy of home-based adverse events and establishing a universally accepted quality of care framework represent key opportunities to advance the field of patient safety in the home.

## Improving Measurement

"We cannot improve what we cannot measure" is a universal adage in quality improvement circles. To support the trend toward value-based care, determining what processes are effective to ensure safe care requires valid measures. Although recent work by the National Quality Forum is an important first step,[176] more can be done to establish nationally recognized and patient-centered quality indicators and metrics around patient safety.[24,29] There are other sources and existing measure sets to leverage in developing patient safety measures (e.g., OASIS avoidable events).[32] With well-defined consensus metrics, including patient and caregiver perspectives, we can address another broadly recognized research opportunity: better determining the prevalence and incidence of patient safety-related events in the home.[32,54,179]

> *"I would like to know the prevalence of unsafe polypharmacy [and] unsafe physical conditions in the home... I would really love to get a handle on how many people are overusing opioids to manage pain, because I think that's a huge health and safety issue... Only [when] we know how prevalent [these are can we] come up with a solution."* — Payer

## Understanding Caregiver Characteristics and Needs

A better understanding of the range of caregivers and their needs is critical to improving home-based patient safety.[15,18,24,180] The literature and SMEs identify a broad range of caregivers in home settings — ranging from licensed clinicians to family members (e.g., adult children, parents, and elderly spouses — many of whom may have significant other family responsibilities) to paid or unpaid aides and unregulated care providers. There is inconsistency in the process for delegation of tasks from licensed professionals to others. Caregiver categories and subcategories vary in skill level and education regarding safety issues, including such core strategies as proper care techniques, medication administration, and infection prevention. Deepening our understanding of caregivers' physical and clinical capabilities, as well as their range of skills, can help in development of tailored training efforts designed to help caregivers improve outcomes.

> *"Among the older adults who need functional support with day-to-day activities, how many of those are receiving private care aides, and what are the characteristics of those aides? Are they similar to those of home health aides in training or certification? I haven't seen any literature on that topic."*
> *— Association interviewee*

## Assessing Technology

Experts recognize a need for technology assessments that meaningfully attend to human factors principles and patient and caregiver needs.[10,93,140,144,145] While critical to ensuring patient safety in home care, many technologies currently used in home-based patient care are not perceived as user-friendly. Consumers question whether manufacturers adequately incorporate human factors principles during development[146] or if products are designed with the end user or the unique home care setting in mind.[147] Research into appropriate use of technology in the home, and how it can be used to improve care team coordination, can be instrumental. Factors influencing technology abandonment is another gap, as is the absence of both a systematic assessment of household technological capacity (e.g., percentage of households with access to modern telecommunication mediums such as wireless or broadband) and usability research and evaluation of home-based technologies.[181] Moreover, cost-effectiveness studies are needed to improve uptake and ensure affordability by patients.

> *"As an opportunity, I think there's a tremendous disconnect between the people who are designing devices and the people who... they think their technology is addressing. The potential consumers of that technology, whether it's real people and caregivers or physicians and other people who order services, there's a complete disconnect in what they think is important."* *— Researcher*

> *"[We need to] understand the impact of human factors on the ability of a health care consumer to either adopt or reject technology or care. That would be tremendous. That's a gap... What are the human factors that drive behavior, particularly when somebody is ill?"* *— Regulatory agency interviewee*

## Developing Standard, Comprehensive Patient-Centered Assessment Processes

Many screening and risk assessment tools are available, but most focus on environmental hazards in the home setting (e.g., fall prevention) or specific risk factors (e.g., medication management).

Other complex, multidimensional issues inherent in addressing patient safety in the home (e.g., psychosocial determinants, personal functional capacity, safety culture, and financial issues) may be overlooked. Therefore, another research opportunity is to synthesize and evaluate available assessments in service of developing a comprehensive process to assess all safety domains related to patients and caregivers, and importantly over time reassess and monitor for changing circumstances and needs. Another priority is provider training that focuses on how to systematically assess safety domains, incorporate the values and goals of patients and caregivers, and offer guidance on seeking help from community resources.

*"We're not looking through the patient's eyes, if you will, because if you talk to the family they say, 'Oh, everything's fine at home,' because they're well. They can manage whatever risks there are. But if you're debilitated from being in the hospital or you have some kind of disability, the world looks completely different at home. We need [to] go in and look through the eyes of the patient's current state, debilitative. Maybe they will be fully well again, but when they come home, they are not well and don't have the same capacity to manage things they managed before. That's when home becomes a risk."* — Payer

*"There's no attempt that I know of, where the [organization] has a process where they take a look at these issues that have happened and say, what are we doing to prevent this in our [organization]?... and then put the guidance or requirements to address them, rather than wait until the next patient gets hurt."* — Clinician

*"I think using podcasts and videos, where real people are talking about safety challenges they had in their own home, or in the home of someone they care for, and how they solved those challenges would be great."* — Family caregiver

## Identifying and Disseminating Proven Models and Best Practices

Finally, there is a need to identify successful and replicable strategies to improve patient safety in the home. Spreading innovative approaches in care coordination and provider-to-provider communication will help support a culture of home care safety. Downstream from assessing patient and caregiver knowledge to identify knowledge gaps, disseminating specific training and educational materials to address those gaps represents an important opportunity. Moreover, there is a well-documented need to help hospital staff and primary care providers understand the challenges that patients face at home (e.g., environmental barriers such as staircases, access to services such as transportation or grocery delivery). However, the practices that are possibly most in need of identification and spread relate to evaluating financing models that seek to better align cost-saving incentives and appropriate reimbursement.[13,93,182]

*"At this point in time, I think you need dissemination to policymakers... I think that's the big challenge, is how to get the people who could make those changes [to home care financing], the policymakers, how their ear can be bent to understand what this means, and the long-term implications of not attending to it."* — Researcher

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# Appendices

## Appendix A: Literature Review Methodology

This report captures, in part, results from a literature review of peer-reviewed and grey literature. The literature review aimed to identify sources that collectively document the current state of patient safety in the home setting and gaps in relevant research and information. The literature review methodology was a multipronged approach designed to be both structured and nimble based on inputs throughout the course of the project. This appendix briefly summarizes the methodology.

### A. Initial Review of Published and Grey Literature

The foundational step in the literature review was a broad search of published literature to get a sense of the scope and central themes of patient safety in the home setting. To construct this initial search, two Westat senior researchers identified key search terms and collaborated with a team of Westat librarians to develop and execute a search strategy. After reviewing the strategy, IHI/NPSF staff requested targeted exploration of infusion therapy, the role of community pharmacists, and practical assessment tools.

The published literature searches were conducted in PubMed, Cochrane Database of Systematic Reviews (via PubMed), CINAHL (Cumulative Index to Nursing and Allied Health Literature), PsycINFO, ASSIA (Applied Social Science Index and Abstracts), Social Services Abstracts, Joanna Briggs Institute Database, HAPI (Health and Psychosocial Instruments), Business Source Premier, and WorldCat. Results were limited to English language articles published from 2005 through 2016. The terms used in the initial search where chosen from those appearing in Table A-1 below. The two Westat researchers independently reviewed all abstracts identified during the search to select those in scope for the review based on the research questions and discussions with IHI/NPSF (e.g., omitted articles related to Occupational Safety and Health Administration standards for home health employees). The researchers did not assess or exclude any articles based on the quality or rigor of research methods.

The researchers discussed and determined which articles were in scope. One researcher read all identified articles, eliminating any that fell out of scope after thorough review. Reference Manager® 12 was used to manage the search results and remove duplicate citations.

Concurrent with the initial published literature search, Westat's team of librarians conducted an initial grey literature search using similar search terms to discover additional patient home safety resources geared toward researchers, the workforce, and consumers. Sources of grey material included the websites of US and Canadian government agencies and relevant stakeholders from health, patient safety, home care, and consumer organizations. The types of grey material uncovered included reports; studies, surveys, statistics; guidelines, handbooks, workshops, tools; conference presentations; and booklets and fact sheets.

**Table A-1. Search Terms Used in the Initial Published Literature Review**

| Home Health Terms | Safety Terms | Infection Control Terms | Instrument Terms | Other Terms |
|---|---|---|---|---|
| Home care services[mh] | Safety[sh] | Infection control[mh] | Questionnaires[mh] | Home infusion therapy[mh] |
| Home care agencies[mh] | Safe* | Infection[mh] | Instrument* | Home intravenous therapy[sh] |
| Home care[sh] | Patient safety[mh] | Infection* | Measure* | Infusion, intravenous[mh] |
| Home health care[sh] | Patient safety[sh] | Wound* | Tool* | Pharmacists[mh] |
| Home visiting programs[sh] | Safety measures[sh] | Ulcer* | Toolkit* | Pharmacy service[sh] |
| Home care personnel[sh] | Safety management[mh] | Sore* | Psychometrics[mh] | Reimburse* |
| Home health aides[mh] | Safeguards[sh] | Hygiene* | Psychometrics[sh] | Payment* |
| "Home health" | Accident prevention[mh] | Sanitary/unsanitary | Reproducibility of results[mh] | Cost* |
| "Home healthcare" | Accident prevention[sh] | Clean/cleanliness | Test validity[sh] | Direct service costs[mh] |
| "Home care" | Accident* | | Test reliability[sh] | Insurance, health, reimbursement[mh] |
| Home-based | Accidental falls[mh] | | | Pilot* |
| Homebound | Fall* | | | Pilot projects[mh] |
| In-home | Injury/injuries | | | Model* |
| Home | Hazard* | | | Models, organizational[mh] |
| Community | Medical errors[mh] | | | Quality management[sh] |
| Community health nursing[sh] | Medication errors[mh] | | | Professional competence[mh] |
| | Medication errors[sh] | | | Competent* |
| | Error* | | | Telemedicine[mh] |
| | "Adverse event*" | | | Telemedicine[sh] |
| | Risk management[sh] | | | Telehealth |
| | Risk factors[sh] | | | Telemonitor* |
| | Risk* | | | |

[mh]=indicates a medical subject heading in PubMed

[sh]=indicates a subject heading in any database other than PubMed; * indicates truncation

## B. Additional Targeted Searching of Published and Grey Literature

Westat also undertook periodic targeted searches and obtained specific articles and resources in response to feedback and recommendations from subject matter experts (e.g., a program evaluation of innovative models published March 2017) and to themes that emerged from the initial published and grey literature. These targeted searches (using the Google search engine) focused primarily on grey literature related to fall prevention, medication management, community pharmacy, infection control, telemedicine, and legislation/public policy/payment initiatives that apply to the home setting.

Westat's team of librarians also performed targeted searches of 1) all relevant databases for trade journals or magazines; 2) CINAHL specifically for articles from Home Healthcare Now; 3) PubMed, PsycINFO, CINAHL, ASSIA, Social Services Abstracts, and Sociological Abstracts for cost and reimbursement issues in the home setting; and 4) PubMed specifically for reviews, systematic reviews, meta-analyses, and evidence-based results. These targeted searches used similar limitations with regard to publication date and English language.

Finally, Westat used a "snowball" approach, also known as "citation mining," in which reviewers searched reference lists of the articles uncovered during the initial literature review to identify additional articles germane to patient safety in the home.

# Appendix B: Qualitative Analysis Methodology

The subject matter expert (SME) interviews conducted for this report aimed to obtain perspectives about key safety issues in the home setting; effective models, resources, and approaches to keeping patients safe at home; trends and opportunities for improvement; and potential areas for future research. Westat's Institutional Review Board (IRB) reviewed the study description and interview guide, and approved both in January 2017. Appendix B describes: 1) our methods for SME recruitment; 2) the interview process, including the interview protocol (Appendix C); and 3) the qualitative analysis, including the NVivo codebook.

## A. SME Recruitment

Westat identified and recruited participants for the SME interviews between January and April 2017 using a multipronged approach. The iterative identification process included: reviewing lists of known stakeholders in the patient safety and home care community; identifying researchers who had published on home safety; following up on recommendations from IHI/NPSF and the Moore Foundation; and asking SMEs to recommend other experts within their professional networks. Using an IHI/NPSF-approved script that described the project, Westat invited potential interviewees via email; staff made follow-up phone calls to those individuals who did not respond to the initial invitation. Ultimately, Westat scheduled and conducted 60-minute telephone interviews with 25 SMEs. Table B-1 lists the number and type of SME participants recruited.

**Table B-1. Subject Matter Experts by Type**

| SME Type | Number |
|---|:---:|
| Clinician | 4 |
| Association / Regulatory Agency / Payer | 12 |
| Researcher | 5 |
| Patient / Caregiver | 4 |

## B. Interview Process

All SME telephone interviews were conducted between February and April 2017 using a structured guide that Westat's IRB approved. At the outset of each interview, interviewees were informed about the purpose of the study. With interviewees' permission, all interviews were audio-recorded and transcribed to facilitate analysis and ensure the accuracy of the findings. Each interview lasted approximately 60 minutes, during which the interviewers asked the SMEs a series of open-ended questions (with relevant probes as needed) focused on safety issues in the home, barriers and challenges for safe care, identification of safety resources and infrastructure, and areas for future research. The guide underwent minor modifications throughout the interviewing process to improve interviewee comprehension of the questions and to ensure that the interview remained within the 60-minute timeframe. Appendix C presents the full interview guide.

## C. Qualitative Analysis

Three Westat staff analyzed the interview data for this report using NVivo ([http://www.qsrinternational.com](http://www.qsrinternational.com)), a software package designed to support the management and analysis of qualitative data. The analysts began by creating a provisional coding scheme that covered the main study objectives, including safety issues in the home, barriers and challenges for safe care, identification of safety resources and infrastructure, and areas for future research. Using this provisional scheme, the analysts independently read and coded three SME transcripts. The team members then met to discuss their respective findings and resolve any differences in how they used the codes. The coding scheme was subsequently revised and team members developed definitions for each code to reduce ambiguity regarding application of the codes. After the interview transcripts were uploaded into the database, each team member was assigned a set of SME transcripts to code. The team met approximately once per week while coding the data to discuss emerging themes and to make any necessary adjustments to the coding scheme. As data were extracted for various nodes, team members reviewed the content to again ensure the consistency of the coding. Team members also reviewed the interview findings against the literature review to determine if the coding had overlooked any critical topics. (For example, the coding scheme did not capture one safety issue — the risk of pressure sores among patients in the home. However, a review of the transcripts indicated that SMEs raised this issue only in passing.) Table B-2 presents the final codebook.

**Table B-2. NVivo Codebook for SME Interviews**

| Name | Description |
|---|---|
| **Definitions** | **This larger category represents patient safety and home definitions.** |
| Definition of Patient Safety in the Home | General references of patient safety in the home setting |
| Definition of the Home | How the patient or caregiver defines the home setting |
| **Dissemination** | **References to how to best disseminate information to patients, caregivers, and providers about patient safety in the home setting** |
| **Key Issues** | |
| Ability | Covers cognitive, functional, and emotional abilities to provide care at home |
| Abuse | Financial, physical, emotional — any way that a caregiver could abuse the patient |
| Community Resources | References to the larger community context in which the patient resides. This may include community pharmacies, community members who stop by, Meals on Wheels, being checked by the postal carrier, etc. References may also be positive or negative (i.e., a dearth of resources in the community should be coded to this node as well as the presence of some of these supports). Finally, support groups should be subsumed under this code. |
| Environmental Hazards | Dust, cats, poor lighting, guns |
| Falls | Discussion of falling as a home safety issue |
| Infection Control | Concerns about infection control in the home. This may be double-coded with Environmental Hazards if the hazard appears to affect the caregiver's ability to maintain a sterile environment for the patient (or others, e.g., VRE infection). |

**Table B-2. NVivo Codebook for SME Interviews (continued)**

| Name | Description |
|---|---|
| **Medication Safety** | This larger category represents respondents' comments regarding challenges to safe medication dispensing |
| Adherence | Concerns about patient adherence to treatment. Lack of adherence may be the result of challenges with medication delivery, or the patient chooses to forego the recommended treatment. |
| Errors | Commentary about medication errors (dispensing the wrong dose, wrong pills, etc.) |
| Home Infusion | Specific references to home infusion |
| Medication Reconciliation | Models of reconciliation |
| Polypharmacy | Patient is on multiple medications |
| **Nonlicensed Caregivers** | This larger category refers to any nonlicensed caregivers, including family and paid caregivers. |
| Conscription and Assignment of Caregiver | Clinical team assumes the family member will provide care and s/he is volunteered into service for the patient. Also references indicating that most home care is done by the family caregiver. |
| Financial Difficulties | References to the fiscal impact on a caregiver who may have to quit working or reduce his/her schedule |
| Impact on Caregiver's Health | Respondent comments about how taking care of a family member can adversely affect the caregiver's health |
| Lack of Understanding | References to the caregiver not understanding the issues behind the patient's behaviors (e.g., misinterpretation of lack of initiative due to frontal lobe involvement as "laziness") |
| Motivations and Preferences | Discussions of caregiver's emotional motivations or choices related to providing home care. Can be either a facilitator or barrier. |
| Paid Unlicensed Caregivers | References from respondents about paid unlicensed caregivers |
| Second Victim | Respondent states that they make an error on a patient and they feel the emotional aftereffects of the error. |
| Nutrition | References to the need for home care patients (and possibly their caregivers) getting adequate nutrition |
| Patient Caregiver Dyad or Family System | Respondent says that home care must account for not just the patient, but the primary caregiver and/or other family members in the household. |
| **Patients** | This is a larger category that encompasses issues that are unique to patients. |
| Autonomy | Emerges as its own category in the literature review and some of the SME interviews as a patient preference. Important to note both isolation and autonomy — two different sides of the same coin. |
| Education | References to the need to provide education to the patient so s/he can make an informed decision or know how to do a particular procedure at home |
| Emotional Health | References to the emotional health and stability of the patient |
| Functional Decline | References to the patient's functional decline, usually as a result of his or her medical condition progressing |
| Living Alone and Isolation | References to patients who do not have family nearby or whose social networks may be limited |
| Patient Values and Preferences | References to what patients prefer, or values that may impact their care and safety at home |

**Table B-2. NVivo Codebook for SME Interviews (continued)**

| Name | Description |
|------|-------------|
| **Professionals** | This is a larger category that encompasses issues related to professional caregivers that may be assisting with home care. |
| Fear of Losing License | Providers may be concerned about professional implications of providing home care. |
| Fragmentation | All references to fragmentation in home-based services, such as multiple professionals coming into the home, a patient's multiple physicians prescribing treatments without good communication among themselves, etc. |
| Isolation | References to the licensed professional working without colleagues in the immediate caregiving environment. This could be a problem that needs to be addressed, but may also be discussed in terms of solutions (e.g., video conferencing capabilities that allow professionals to reach out to colleagues). |
| Jack of All Trades | References that home care providers need to master lots of different clinical tasks |
| Not in Charge | Recognition that clinicians working in the home environment are the guests in a guest-host relationship. Providers have less "say so" in this setting than they might believe they have in a structured care setting. |
| Professional Training and Education | References to the need for training of licensed providers in home care issues |
| Relationship Building | References to licensed professionals forming holistic relationships with the patients and their families |
| Task-Based Care | References to home care providers coming into the home and focusing solely on their own clinical task |
| Time | Interviewee discusses the amount of time each provider has to spend with the home-care patient and the implications of that. |
| Reluctance | Patient or caregiver may not be amenable to taking steps needed to be safe at home (e.g., having someone help with cleaning and cooking or ADLs, adjusting the environment to be safe). |
| Rural Areas | Discussion of some of the unique challenges in rural areas |
| Strengths | Comments about the strengths that nonlicensed caregivers bring to the home care setting. This can include the patient if s/he is taking care of him or herself. |
| **Training** | All references to training either the patient or the caregiver (professional training is covered under a separate code) |
| Assured Competence | The need to make sure caregivers are competent with the administration of some of the assigned tasks. That is, a person can be trained, but importance of assuring the caregiver is really doing everything properly. |
| Contingency Protocols | What is Plan B if something goes wrong? One aspect of training that's being emphasized by interviewees. Should also include emergency care. |
| Different Kinds of Equipment | Any discussions about training caregivers on different kinds of DME (e.g., train on one piece of equipment in the hospital, but get a different piece of equipment once home) |
| Knowing What to Expect Clinically | Discussions about the need for anticipatory training (e.g., what things look like when they're going wrong, or how long a procedure may take - so that the patient and caregiver can plan their time) |
| Lack of training | References to any lack of patient/caregiver/provider training |

**Table B-2. NVivo Codebook for SME Interviews (continued)**

| Name | Description |
|---|---|
| Skilled Care | References to caregivers and patients needing training in procedures that are usually performed by licensed professionals (infusion, injections, etc.) |
| Wounds and Pressure Ulcers | Emerging in the literature review more than the SME interviews, but use this code for any reference to the potential for a patient to experience breakdown as a result of poor home care |
| **Models of Care** | **Encompasses all references to models of home-based care** |
| **Needs** | **This overarching category encompasses areas that respondents indicate need to be addressed to improve home care.** |
| **Assessment** | This larger category encompasses all references to the kinds of assessments that are needed for optimal home care. |
| Caregiver | Discussions about assessing the capabilities and needs of the family member providing the care |
| Financial | Assessing the patient's/family's financial situation. Can be a critical component in determining the level of care that they receive (or what kind of DME). |
| Home Environment | Assessment of the home environment for trip hazards, electrical support for technology, adequate heating and cooling, etc. |
| Patient Holistically | Assessment of the patient as a whole person, not just a person with a disease |
| Temporal Changes | The need for ongoing assessment of the patient, caregiver, home, etc. for change over time |
| Funding-Reimbursement | Funding streams have not kept up with the service requests and needs |
| Patient, Caregiver, Family Engagement | Patients and caregivers need to be brought into the clinical team more than previously |
| Shared Decision Making | All references to the importance of determining the needs of the patient, caregiver, and others to create optimal home care |
| Standardization | Comments regarding the importance of standardizing home care |
| Support | References to the kinds of supports patients and caregivers need to maintain safety |
| Transitions | Any comment by respondents about the need to pay attention to hospital-to-home transitions *or* home-to-hospital transitions (e.g., something that goes wrong at home and that requires the patient to return to the hospital). |
| Workforce Capabilities | Comments regarding the kinds of capabilities the clinical workforce needs to have for home care |
| **Recommendations** | **Respondent recommendations** |
| **Research Gaps** | **This category encompasses gaps in the research literature noted by respondents** |
| **Resources** | **General code for all resources named by interviewees** |

**Table B-2. NVivo Codebook for SME Interviews (continued)**

| Name | Description |
|---|---|
| **Trends** | **This overarching category encompasses references to "here's the direction in which things are moving."** |
| Awareness of Family Caregiver | Increasing recognition that family members are bearing a lot of the burden of home care |
| **Clinical** | This larger category encompasses all clinical trends mentioned by respondents. |
| Accredited Home Care Agencies | Comments regarding the move toward home care agencies that have accreditation |
| Managing Acute Care at Home | References to the acuity level of patients who are being managed at home |
| Outcome Measures and Data | How is the effectiveness of home-based care being assessed? |
| Risk Reduction Not Elimination | References to clinicians learning to become comfortable with the idea that not all risks can be eliminated (patient preferences). Focus has to be on reduction of risk. |
| **Payments and Policies** | This larger category includes all references to systems of payment (which may reflect needed policy changes) that will support home care. |
| Aligning Payments With Home Care Needs | Discussions about movement toward appropriate coverage of home care. This includes coverage of procedures, clinicians, DME, etc. |
| Legislation | Any references to current or desired legislative efforts around home care |
| Regulations | Discussions about the need for regulation within the home care industry |
| Value-Based Payments | References to how value-based payment structures can support home health care |
| **Technology** | This overarching category encompasses respondent discussions around technology and home care. |
| Assistive Technology | Assistive devices that allow people to stay at home (range from Hoyer lifts to smart phone apps) |
| Communication | References to the use of technology as a way for either the licensed or unlicensed caregiver to communicate with others (e.g., treatment team, support persons) |
| Equipment | DME, O2 tanks, infusion pumps, etc. |
| Health IT | Very specific references to ways in which health IT may support safer care at home |
| Infrastructure to Support | References to infrastructure supports that are needed in the home relative to a particular technology (e.g., adequate electrical capability for certain machines; high-speed internet access for telemedicine) |
| Monitoring Devices | Any technology that allows the clinical team or a family member to ascertain the patient's level of adherence to the treatment regimen |
| Smart Technology | Discussion of some of the new smart technologies as adaptive "devices" that can promote the safety and independence in home care |

# Appendix C: Interview Discussion Guide

Thank you for agreeing to participate in the interview today. My name is [interviewer's name] and also on the call is [note taker name] who will take notes of our conversation.

As you know, we work for Westat, a private research organization in Rockville, Maryland. We are calling you on behalf of the Gordon and Betty Moore Foundation and the National Patient Safety Foundation (NPSF) about a research project entitled "*Patient Safety and Risk Assessment in the Home Setting*." We are conducting in-depth interviews with subject matter experts to describe the current state of patient safety in the home setting and to identify relevant research gaps.

The information gathered in this interview will help inform an assessment of current safety trends in the home setting and potential areas for research for NPSF.

We would like to record the interview for note taking purposes; do I have your permission to record?

IF YES, turn on recorder, and capture their permission.

*NOTE: These questions serve as a guide for the discussion/interview. Not all questions will be asked, and many tailored to meet the expertise of the interviewee. Potential/optional probes are provided to prompt more in-depth discussion.*

As I mentioned before, we are conducting this interview with you to understand your perspective of the current state of patient safety in the home setting and to identify relevant gaps in care delivery and potential areas of research.

**I. BROAD OPENING QUESTION. FOCUS ON HOW INTERVIEWEE IS INVOLVED IN THIS TOPIC, INDIVIDUALLY AND ORGANIZATIONALLY.**

    a.   We've reached out to you because of your expertise in [NAME]. Can you tell us a little bit about how you/your organization are involved in home care and patient safety?

**II. VIEW OF CURRENT LANDSCAPE AND EMERGING TRENDS.**

    a.   When you think of health care in the home setting, what kinds of health care do you include?

    b.   How would you define patient safety in the home setting?

    c.   How does patient safety in the home setting differ compared to other health care settings (e.g., hospital)?

    PROBE AS NEEDED:

        o   How do environmental factors (e.g., the layout of the home) contribute to patient safety in the home setting?

        o   How do community services (e.g., pharmacies, senior services) contribute to patient safety in the home setting?

    d.   What do you think are the most common patient-safety-related problems in the home?

PROBE AS NEEDED:

- o Which of these patient safety problems do you think are the most critical to address?

- o (For Patients/Caregivers) Can you describe the patient safety issues or challenges that you have personally experienced in the home setting?

e. What are the barriers to addressing these problems?

f. What are the advantages of health care being provided in the home? Disadvantages?

g. To what extent does family support or caregiving impact patient safety in the home? Does it have both positive and negative impact?

PROBE AS NEEDED:

- o In terms of patient safety in the home setting, are there specific support services that are more important than others?

h. How does market competition, including availability of independent home care companies, affect patient safety in the home?

PROBE AS NEEDED:

- o (For Patients/Caregivers) Did you have problems getting home health or other support services at home. How did these services affect patient safety in home care?

i. What do you think are current and emerging trends related to patient safety in the home setting?

j. (AS APPROPRIATE) How are trends in payer reimbursement likely to affect patient safety and home care?

PROBE AS NEEDED:

- o Can you describe the major payers in this space?

- o How does/will reimbursement for home care services impact patient safety?

- o How do increased alternative payment models (e.g., transitional care services/coordination of care) impact patient safety in the home care setting?

- o What payment structures/methods/services could improve the safety of care in the home setting?

- o How will the changing reimbursement landscape impact safety (Medicare, Medicaid, private payers)?

## III. MODELS OF CARE

a. Are there specific interventions or models of care that enhance patient safety in the home?

PROBE AS NEEDED:

- o Do you know of any specific programs that are designed specifically to ensure patient safety in the home setting (e.g., Community Health Worker Model, community pharmacy models)?

b. Can you describe how technology, including medical devices affect patient safety in the home care setting?

PROBE AS NEEDED:

- o Are there specific devices that are more common than others?

- o How do specific devices impact patient safety in the home care setting?

- o How does durable medical equipment, such as [infusion therapy devices, oxygen therapy] affect patient safety in the home setting?

- o Are there specific devices that pose more safety risks than others? Are there specific patient/caregiving training requirements that would be beneficial to mitigate these safety risks?

- o How do health care professionals affect patient safety in the home setting?

- o Are there any forms of technology that increase patient safety (e.g., Personal Emergency Response Systems (PERS), remote monitoring devices)?

IV. **RESEARCH GAPS**

a. Based on your experience, what are particular gaps in research in patient safety in the home?

V. **INFORMATION AND ADDITIONAL RESOURCES**

a. What information about patient safety in the home setting do you find most useful for patients?

b. Are you aware of any organizations that are involved in patient safety issues in the home setting?

PROBE AS NEEDED:

- o What do you think is the best way to disseminate information about patient safety in the home care setting?

c. Where do you/your colleagues in your professional networks go for information or resources around this topic?

PROBE AS NEEDED:

- o Are there particular conferences, meetings, associations where conversations about home care and patient safety occur?

- o Are there other networks for patient and caregivers?

VI. **INNOVATIVE ORGANIZATIONS AND INDIVIDUALS**

a. NPSF seeks to identify specific innovations, health delivery systems and researchers who are working in this area.

Are there particular individuals/groups/organizations that you can point us to who are actively implementing new ways of improving patient safety in the home setting?

PROBE AS NEEDED:

- o What are the specific angles they are exploring?

- o What makes their approach unique?

- o What are challenges that they are missing or struggling to address?

**VII.    VISION FOR THE FUTURE**

a.   If you had all the resources at your disposal, what is your vision of how health care organizations, payers, patients, and caregivers could ideally improve patient safety in home care?

PROBE AS NEEDED:

- o Can you describe any current or potential regulations or policies that would improve patient safety in the home care setting?

- o How would you prioritize these?

**VIII.    REQUESTS AND THANKS; REQUEST FOR OTHER ORGANIZATIONS**

a.   We've covered quite a bit of ground today, thank you for your input and ideas. Are there other people or groups that come to mind that you haven't mentioned that you feel we should explore?

[RECORD NAME AND CONTACT INFORMATION]

**IX.    CLOSING**

I want to be mindful of your time, and we are close to the one-hour mark. I appreciate you sharing your thoughts with us today. If we have additional areas for follow up or clarification, we hope you are amenable for us to follow up with you.

If you have any additional information you would like to share with us, or any questions about the NPSF Patient Safety and Risk Assessment in the Home Setting project, please contact me at [email address and/or phone number].

Thank you.

# Appendix D: Tools and Resources

**NOTE:** *The tools and resources listed below were identified through the literature review and interviews; this appendix is not intended as an exhaustive listing of all available tools and resources.*

## General Home Safety

Bielaszka-DuVernay C. The "GRACE" model: In-home assessments lead to better care for dual eligibles. *Health Aff (Millwood)*, 2011;30(3):431–434. doi:10.1377/hlthaff.2011.0043

Cougar Home Safety Assessment (version 2.0):
> Baker A, Koval, D, Lishok C, Stine E. Cougar Home Safety Assessment - Version 2.0. 2004. https://www.misericordia.edu/uploaded/documents/academics/ot/ot_research/home_safety/ot_version2.pdf
>
> *Literature on above tool:* Fisher GS, Baker A, Koval D, Lishok C, Maisto E. A field test of the Cougar Home Safety Assessment (version 2.0) in the homes of older persons living alone. *Aust Occup Ther J*. 2007;54:124–130.

Minnesota Safety Council. Fall Prevention Home Safety Checklist: What YOU Can Do to Prevent Falls. http://www.minnesotasafetycouncil.org/seniorsafe/fallcheck.pdf Published 2004.

National Institute on Aging. Home safety for people with Alzheimer's disease. August 2010. NIH Publication No. 02-5179. https://www.nia.nih.gov/health/home-safety-and-alzheimers-disease

National Research Council. *Health Care Comes Home: The Human Factors*. Washington, DC: The National Academies Press; 2011. doi:10.17226/13149.

Physical Environment Assessment Tool (PEAT)©:
> Hendricks C. The PEAT scale: An EMS tool. *Emergency Medical Services*. 2004;33(11):47–48.

The Household Safety Survey Checklist:
> Gershon RR, Dailey M, Magda LA, Riley HE, Conolly J, Silver A. Safety in the home healthcare sector: Development of a new household safety checklist. *Journal of Patient Safety*. 2012;8:51–59.

## Caregivers

The Family Caregiver Activation in Transitions (FCAT) Tool:
> Coleman EA, Ground KL, Maul A. The Family Caregiver Activation in Transitions (FCAT) tool: A new measure of family caregiver self-efficacy. *Joint Commission Journal on Quality and Patient Safety*. 2017;41(11):502–507.

Sense of Security in Care — Relatives' Evaluation (SEC-R):
> Krevers B, Milberg A. The Sense of Security in Care — Relatives' Evaluation (SEC-R) instrument: Its development and presentation. *Journal of Pain and Symptom Management*. 2015;49:586–594.

## Falls

Anemaet WK, Krulish LH. Fall risk assessments in home care: OASIS-C expectations. *Home Health Care Management & Practice*. 2011;23:125–138.

Alliance for Home Health Quality and Innovation. *Improving Care Transitions Between Hospital and Home Health: A Home Health Model of Care Transitions*. Washington, DC: Alliance for Home Health Quality and Innovation; January 2014.
http://ahhqi.org/images/uploads/AHHQI_Care_Transitions_Tools_Kit_r011314.pdf

*Preventing Falls: A Guide to Implementing Effective Community-Based Fall Prevention Programs*. Atlanta, Georgia: Centers for Diseases Control and Prevention; 2015.
https://www.cdc.gov/homeandrecreationalsafety/pdf/falls/fallpreventionguide-2015-a.pdf

Gallagher R, Stith N, Southard V. Evaluation of the Missouri Alliance for Home Care Fall Risk Assessment Tool and Home-Based "Balanced Approach" Fall Reduction Initiative. *Home Health Care Management & Practice*. 2013;25:224–228.

Missouri Alliance for Home Care Fall Risk Assessment (MAHC-10):
> Missouri Alliance for Home Care; 2012.
> http://www.homecaremissouri.org/projects/falls/documents/Oct2012FINALValidatedFallriskassessmenttool.pdf

> *Literature on above tool:* Calys M, Gagnon K, Jernigan S. A validation study of the Missouri Alliance for Home Care Fall Risk Assessment Tool. *Home Health Care Management & Practice*. 2013;25:39-44.

Potter P, Olsen S, Kuhrik M, Kuhrik N, Huntley LR. A DVD program on fall prevention skills training for cancer family caregivers. *Journal of Cancer Education*. 2012;27:83–90.

Steven JA, Burns E. *A CDC Compendium of Effective Fall Interventions: What Works for Community-Dwelling Older Adults*. Atlanta, Georgia: Centers for Disease Control and Prevention; 2015. https://www.cdc.gov/homeandrecreationalsafety/pdf/falls/cdc_falls_compendium-2015-a.pdf

## Specific Health-Issue Safety

Barstow BA, Bennett DK, Vogtle LK. Perspectives on home safety: Do home safety assessments address the concerns of clients with vision loss? *American Journal of Occupational Therapy*. 2011;65(6):635–642.

> *Tools discussed in above literature:*

> Safety Assessment of Function and the Environment for Rehabilitation (SAFER). Chiu T, Oliver R, Ascott, P, et al. *Safety Assessment of Functional and the Environment for Rehabilitation-Health Outcome Measurement and Evaluation (SAFER-HOME), Version 3 manual*. Toronto, Ontario, Canada: COTA Health; 2006.

> Westmead Home Safety Assessment (WeHSA)

Baumgarten K, Hale Y, Messonnier M, McCabe M, Albright M, Bergeron E. Bridging the gap: A collaborative to reduce peripherally inserted central catheter infections in the home care environment. *Ochsner Journal*. 2013;13:352–358.

Kelly R, Puurveen G. Pressure ulcer risk assessment: A "proxy braden" scale in the Resident Assessment Instrument-Home Care (RAI-HC). *Home Health Care Management & Practice*. 2013;25:264–273.

*Preventing Central Line-Associated Bloodstream Infection (CLABSI) in the Home Care Setting*. New York: United Hospital Fund; 2016. https://www.uhfnyc.org/publications/881133

**Other**

Agency for Healthcare Research and Quality. All papers, briefs, and other resources on the PCMH. AHRQ Patient Centered Medical Home Resource Center site. https://pcmh.ahrq.gov/page/papers-briefs-and-resources

Agency for Healthcare Research and Quality. Transforming the organization and delivery of primary care. AHRQ Patient Centered Medical Home Resource Center site. https://pcmh.ahrq.gov/

Mistreatment of Older Adult Risk Factor Tool:
> Lindenbach JM, Larocque S, Lavoie AM, Garceau ML. Older adult mistreatment risk screening: Contribution to the validation of a screening tool in a domestic setting. *Canadian Journal on Aging*. 2012;31:235–252.

The Community Clutter and Hoarding Toolkit:
> Chater C, Shaw J, McKay SM. Hoarding in the home: A toolkit for the home healthcare provider. *Home Healthcare Nurse*. 2013;31:144–154.