



Audiology
Dentistry
Medicine
Nursing
Occupational Therapy
Optometry
Osteopathic Medicine
Pharmacy
Podiatric Medicine
Psychology
Social Work
Physical Therapy
Speech and Language Therapy
Veterinary Medicine

Mark D. Stewart, MPH
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American Institutes for Research
6003 Executive Blvd, Suite 300
Rockville, MD 20852

Dear Mr. Stewart,

As a stakeholder health professional society, we believe that National Academies of Practice (NAP) can bring a unique perspective to this American Institutes for Research (AIR) project under contract to the Agency for Healthcare Research and Quality (AHRQ). The National Academies of Practice consists of fourteen distinguished healthcare professions committed to advancing interprofessional healthcare by fostering collaboration in practice and advocating for quality health care processes that best serve the individuals and communities we serve. NAP firmly believes that close collaboration and coordination among healthcare professions, aligned with a vision for quality healthcare can make significant progress toward quality outcomes while reducing regulatory and administrative burdens for all involved in the health care continuum.

The National Academies of Practice appreciates the opportunity to contribute to this project. Please find NAP's comments and considerations below and accompanying this letter. We share these through an *"interprofessional lens"* in partnership to improve our US healthcare system. The accompanying document provides specific edits NAP members would appreciate being considered for this document. Note that yellow highlight has been used to identify areas of particular concern. The following are general comments and recommendations to strengthen the tone and context of the guidance being provided:

Interprofessional Collaborative Practice

NAP endorses the use of the full spectrum of all professionals and service providers to be effectively used toward quality healthcare. There are several examples of omissions of care toward the end of the AIR draft that are appreciated by NAP members and these are reflective of the type of clarifications requested below.

- In lieu of the use of terms such as "clinical and non-clinical staff", consider the use of "administration" (or "administrators"), "staff" and/or "caregivers". Simply using "caregivers" or "care providers" or "service providers" throughout the document may also be considered.

This would support assorted titles and credential requirements in all nursing facilities and in every state.

- When addressing any and all service providers who may be responsible for the patient's care, a single and consistent term for all service providers would avoid confusion or scope of practice concerns, dependent on the location of service.
- When needing to reference the originator of orders and/or prescriptions, we recommend the use of the phrase "*professional responsible for ordering the service*" in lieu of naming or attempting to list all those who may be responsible for ordering care in a nursing facility.
- There appears to be an underlying hierarchy of what care is and what constitutes an omission in care. NAP appreciates the historical nature of this perspective while recommending the expectations of contemporary healthcare be reflected in this AHRQ document. Please consider for inclusion the following concepts:
 - The members of NAP respect the skills of every member of the care team and embraces the person-centered nature of the care needed.
 - Each member of the care team (whether licensed, certified, registered or without designated credentials) has a purpose and function toward the well-being of the patient.
 - When a patient is in a nursing facility, a plan of care is essential to placement in that facility.
 - It is the plan of care that needs to be implemented and fully executed through the collaborative efforts of all those involved. All caregivers/service providers are charged to work together toward the health and safety of the patient.

Functional Health

NAP recommends a holistic approach to care be clearly stated and emphasized throughout the document.

- There are multiple references to "medical" and "non-medical" distinctions. This then requires different definitions throughout the document. The World Health Organization's definition of health as "Health is the state of complete physical, mental, and social well-being and not merely the absence of disease or infirmity" could be helpful.
- This document addresses direct care issues as well as system issues such as a short supply of flu vaccine. The WHO's *International Classification of Functioning, Disability, and Health (ICF)* could be a useful framework. NAP recommends a holistic approach to care be clearly stated and emphasized throughout the document.

Consistent Use of Terminology and Clarifications

It is difficult to ascertain who or what is being referenced in parts of the document (see comments and recommendations via Word markup). NAP suggests a Glossary of terms be used for the many acronyms used throughout this document. The following are offered as examples of our concern:

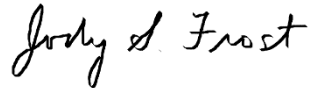
- Consistent with the concerns expressed regarding service provider titles and associated responsibilities (see above), the "Explanation of concepts and terms" differentiates between "medical and non-medical care". For the patient in a nursing facility who has significant mobility challenges and/or cognitive deficits, "bathing or dressing" may be integral to the overall patient care plan and the essential reason for the placement in the facility. Through the use of collaborative planning and practice, we recommend the interprofessional plan for the patient be considered essential and all caregivers be collaboratively responsible for the care that is provided.
- Throughout the document the definition of Omissions of Care is inconsistent. On page two there is a global statement that appears to define the types of situations identified as omissions

in care. On page three, the definition changes to include “increased risk of any harm”. To assure understanding and clearly defined parameters, we recommend a comprehensive definition be provided initially and referenced throughout.

- Please note there are several comment items to request clarification of the statement being made. It’s unclear regarding to whom or what the statement is referencing.

These comments and recommendations are respectfully submitted in anticipation of ongoing collaboration and future research that is interprofessionally planned and collaboratively provided.

Respectfully submitted,

A handwritten signature in black ink that reads "Jody S. Frost". The signature is written in a cursive, flowing style.

Jody S Frost, PT, DPT, PhD, FAPTA, FNAP
President, National Academies of Practice (NAP)

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Revised Draft Definition of “Omissions of Care”

Version 10, June 2019

Intended uses for the definition:

We propose a definition of “omissions of care” in U.S. nursing homes to guide further research and quality improvement activities. The intended audiences include researchers, health professionals, providers, nursing home residents and family members, and policy makers. This definition is not designed or intended for regulatory purposes, enforcement actions, or accountability measures such as public reporting or payment programs.

The definition is intended to support:

- a) Research on the nature, frequency, and impacts of omissions of care in nursing homes. A concise, uniform definition can help researchers consistently address relevant factors in their work and decrease uncertainty about whether studies focused on omissions of care have defined the concept in the same way.
- b) Quality improvement planning. Before evaluating root causes or developing interventions, researchers, providers and policymakers need a consistent way to determine if an omission occurred. A concise, uniform definition that encompasses all forms of omitted care in nursing homes is needed.
- c) Quality improvement activities. These may include improving policies and procedures, QAPI programs, communications, staffing, or resource management to prevent or respond to omissions of care. A concise, uniform definition may help all stakeholders to consider and apply the same principles, seeking alignment of policies and practices, in designing and implementing quality improvement interventions.
- d) Training and education. The definition could be included in professional or in-service continuing education for nursing staff, administrators, and clinicians. A concise, uniform definition that encompasses both clinical and non-clinical care and associated outcomes can help providers better understand and communicate with each other, as well as interpret and apply differing regulations, measurements, guidelines, or policies relevant to omissions of care.

Because many omissions are related to systems rather than individual actions, the definition does not include causes and attributions, which could serve to codify specific ideas about how and why omissions occur. Rather, cause and attribution are considered as part of how stakeholders respond to omissions that occur. We believe this approach can help stakeholders think more comprehensively about what care has been omitted and determine how to respond to those omissions.

Working Draft Definition:

Omissions of care in nursing homes encompass situations when care, ~~either clinical or non-clinical~~, is not provided for a resident that and results in, or increases the risk of, additional monitoring or intervention or an undesirable or adverse physical, emotional, or psychosocial outcomes for the resident.

It is the act of “not doing” something that defines an omission of care. The definition purposefully does not include the following:

- the reason for the omission
- the individuals or entities responsible for its occurrence, which may include but not limited to administrators, staff and/or caregivers such as organizational leadership, residents or family members, or other caregivers
- the type of care omitted
- the magnitude of the results or risk that the omission creates

However, these factors are extremely important in considering methods to identify or avoid omissions, understand root causes, or determine how to address them when they occur.

Explanation of concepts and terms:

Care, either clinical or non-clinical: “Care” encompasses:

- care the resident needs, expects, requests, or wants, which is often called “whole person care” and includes non-medical care such as e.g. bathing or dressing, helping with recreation or leisure activities, or providing comfort or companionship.
- the formal, medical care plan for the resident
- written or verbal physician orders for the resident, such as prescriptions
- applicable policies, guidelines, standards, and regulations or laws related to provision of care or to proper documentation and record-keeping, communication with family members and health care providers, and management of the resident’s care coordination or transition of care needs.

Not provided: Care is “not provided” when it is:

- never delivered
- incomplete
- delivered but delayed beyond the appropriate or necessary timeframe for the care

The frequency of care omission is not included in the definition, but could play a role when determining a response to omissions. An omission of care may be attributable to multiple factors but neither the cause nor the attribution is part of the definition of omissions.

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Commented [TT1]: There is an emphasis early in document that will not give reason for omissions, discuss magnitude, or specific risk yet later in the document discuss such important issues. Perhaps should state up front that this is an exploratory document that will hopefully lead to evaluation tools to improve health care by looking at reasons, magnitude, and other crucial issues.

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Physical, emotional, or psychosocial outcome: In nursing homes, all health, well-being, and quality of life outcomes are relevant. These include traditional clinical outcomes of physical well-being, such as blood pressure, mobility, skin integrity, or pain; emotional ~~or mental~~ outcomes, such as self-esteem, ~~depressed~~ mood, loneliness, or anxiety; and other psychosocial outcomes, such as ability to participate in social activities, isolation, autonomy, or positive relations with others.

Individuals or entities responsible: A wide variety of individuals or entities may be ultimately responsible for an omission of care or for responding to omissions that occur. However, the definition excludes considerations of causes or responsible entities so that it may flexibly encompass *all* possible causes and agents. For example, a flu vaccine may be omitted for a resident because of any of the following:

- the nurse does not administer it
- the physician fails to order the vaccine to be given
- the nursing home administration orders insufficient vaccine supplies
- there is a nationwide shortage and no vaccine doses are available.

In all these scenarios, the result is the same omission of care, but the accountable party, and thus the response required, varies. If these causes were written into the definition, however, this could potentially discourage stakeholders from considering other causes that might arise. For example, an insurer might refuse to pay for the vaccine or the pharmacy might fail to deliver an order on time. When a resident refuses care, however, this is not an omission because the care is no longer something the resident expects, requests, or wants.

~~Increases the risk of additional monitoring or intervention, or undesirable outcome.~~ An omission of care need not result in actual harm or an adverse outcome for the resident. **If failure to provide care increases the risk of any harm or adverse outcome, it is an omission of care.** Further, when failure to provide care causes no harm but does result in additional testing, monitoring or treatment, it is an omission of care. The magnitude of the increased risk is not included in the definition but is critical to consider when prioritizing quality improvement efforts and developing strategies to prevent the omissions from occurring.

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Principles for operationalizing the definition

These five principles guide researchers, health professionals, providers, and policy makers in thinking about how to ~~make this use this~~ definition ~~work for them~~.

1. Consider care the residents wants, requests, or expects in addition to care ordered by health professionals or facilities, included in best practice guidelines, or required by law.

- Consider the full spectrum of care needs, both medical and non-medical, such as psychosocial and spiritual care or activities of daily living (ADL and IADL).

- Engage the resident, or designated family members, in determining care needs. While health professionals often define “needed care” by what they order or provide as a matter of routine or requirement, residents should play a critical role in defining what constitutes their own care. However, this does not mean that any and all care a resident wants must be provided on demand to avoid being considered an omission requiring a response. Rather, contextual factors such as the frequency and magnitude of impact that omissions have on residents’ physical, emotional, and psychosocial well-being must be taken into account. For example, a resident may strongly desire a specific brand of coffee that the nursing home does not purchase. Failing to provide that brand could be considered an omission under the proposed definition but is unlikely to meet any criteria for causing or increasing risk of harm or adverse outcome. By contrast, failing to provide meals that meet a resident’s religious requirements, such as Kosher or halal meals, would be an omission of care that could have a considerable impact on the resident’s well-being.
- Consider and respect the resident’s right to refuse care recommended by health professionals or practice guidelines. Refusals should be documented, and the refused care should not be considered an omission as long as the risks and benefits of the refusal are explained.

2. Care provided outside the appropriate “care window” may still be an omission.

Care that is delivered to the resident may still constitute an omission if it is not delivered in a timely fashion. To assess omissions, providers must ascertain mandatory requirements, use evidence-based guidelines, or establish facility standards for a “care window,” or timeframe within which care must be provided, for each form of care. For example, if the resident’s medications are to be given between 8 am and 10 am, the resident is to receive a shower every other day before dinner time, or a flu vaccine is to be administered during the month of September. Care that is delivered outside those “care windows” would be omissions.

Similarly, providers must determine how to integrate care the facility does not provide in-house. For example, residents requiring periodic care off-site may need different care windows for in-house care on those days. Or, if the nursing home is not capable of providing certain forms of care (e.g., ventilators), then a care window should be determined for the resident’s transfer to an appropriate alternate facility.

3. Consider omissions that increase risk of harm or adverse outcome as well as those that definitely cause harm or adverse outcomes.

- Ascertain mandatory requirements or establish facility standards for assessing whether if omitting care leads to harm or increased risk of harm. Harm may occur in many domains, ranging from including for example resident safety, physical and emotional comfort, or social and mental well-being. For example, if the care addresses resident preferences or respects the person’s dignity, then omitting this care may increase risk of harm in domains such as self-esteem or happiness.

Commented [MOU4]: Does this also need to be documented?

Commented [TT5R4]: Need at least brief statement here about decisional capacity and sometimes needing someone else for such difficulty decisions.

Commented [MOU6]: Can you give a more practical example of this

- Engage the resident, or designated family members, in determining relevant harms or adverse outcomes. Harms and adverse outcomes have historically been defined by health professionals, but residents or family members may have valuable perspectives on relevant physical, emotional and psychosocial well-being outcomes. Residents or family members can help:
 - define the omission
 - investigate root causes
 - determine the response, including both immediate mitigation and long-term quality improvement efforts
- Determine what screening for resident risk factors or surveillance of health and well-being might be needed. Consider how these activities may themselves result in or increase risk of an omission of care.

Commented [MOU7]: I would suggest the need to be consistent in the use of all three aspects you identified within the definition

4. Consistently ~~separate-detach causes or attributions from~~ the process of determining whether an omission occurred ~~from, potential causes or attributions~~

- **Determining whether an omission occurred should be restricted to considering whether care was needed, requested, wanted, or expected and whether the care took place at the appropriate time.** Adding attributions or causes may distract stakeholders from clearly and consistently determining whether an omission has occurred. Further, including attribution when defining omissions potentially decreases stakeholders' capacity to detect omissions that indicate broader opportunities for improvement or system change.
- Determining the cause and attribution of an omission should be the first step in responding to omissions, developing quality improvement efforts, or identifying strategies to prevent future omissions. Causes and attribution should also be considered across a broad spectrum that encompasses both proximate and distal contributors. For example, an omission may result from nursing home staff action, or it may be the result of actions by external entities, policies, or availability of community resources. By limiting omissions of care to those attributable to the nursing home organization and its staff, ~~causes and may result in~~ contributing factors outside of the facility ~~could be~~ ing ignored or remaining undetected. For example, an omission may occur because the community does not have equipment to perform a needed diagnostic test. This may indicate that the community needs to determine if investing in such equipment ~~would~~ may be a ~~beneficial~~. If a laboratory does not perform an ordered test, or ~~the~~ pharmacy does not deliver ordered medication, both represent ~~an~~ omissions that are not attributable to the nursing facility or health professionals within the facility. By incorporating attribution, these omissions might be overlooked or ignored in quality improvement efforts.

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Commented [MOU8]: Consistency of use of care not received, care incomplete, and care delayed as described on page 2 "not provided"

5. Develop interventions or quality improvement plans that account for the type of omission, the types of harms or, causes and attribution, and considers whether incidence of omission is isolated or systemic.

- Consider the magnitude of an increased risk when determining quality improvement efforts and developing strategies to prevent omissions ~~from occurring~~. Also, should regulatory, legal and law enforcement entities choose to adopt this definition, the frequency of omission and magnitude of risk must be considered. For example, omitting a single dose of a Synthroid for a resident with hypothyroidism has an extremely low risk for undesired outcomes, and does not require additional monitoring or testing, but would constitute an omission of care. In contrast, forgetting to conduct a laboratory test for a resident on coumadin, may not detect an abnormal INR that may cause some increased risk of bleeding or clotting, if the INR was out of range. Failure to administer the first dose of an antibiotic for a resident with sepsis would have an ~~even greater~~ increased risk of an undesirable outcome. More importantly, all three of these examples occurring in a single facility in the same week may represent a broader systemic problem with consistent administration of medication. As such, each represents an omission of care, but the cause and magnitude will dictate the response.
- Create a process for responding to omissions of care that considers the spectrum of possible harms and underlying causes. While magnitude of risk or contribution to patient safety is critical, the frequency of occurrence, alignment with regulations or quality goals, or association with evaluation or reimbursement requirements are also valid considerations in developing and executing responses to omissions of care. A single failure to reposition a resident at risk of pressure ulcers is an omission requiring response. The type and extent of the response should be aligned with the associated potential harms or increased risks and should take into account root causes and attributions for the omission. However, responding to infrequent omissions while overlooking consistent, facility-wide failures, such as providing adequate oral care to multiple residents on multiple occasions, may reflect a process for responding to omissions that does not adequately address relevant potential harms or causes.

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Causes of omissions of care attributable to the nursing home

A wide variety of factors may cause, or contribute to ~~the cause of~~, omissions of care that are specific to nursing homes. While the definition explicitly excludes ~~cause~~, and is intended to encompass omissions caused by factors or entities both inside and outside of the nursing homes, ~~we conducted~~ a literature review focused on long-term care ~~that~~ resulted in the following list of potential nursing home causes:

- Time constraints for staff, including:
 - Inadequate time allowed or increased workload
 - Increased time required for nursing interventions
 - Poor response times
- Insufficient staff, including:

Commented [WJ10]:

Commented [WJ11R10]: Structural factors in particular are excluded here. Is it an omission of care not to provide needed services because they are not covered? For example, Medicare does not generally cover dental services and Medicaid coverage of dental services varies state by state, with some states offering no coverage. If an individual does not receive a needed and wanted dental extraction of an infected tooth that should be considered an omission of care.

Commented [MOU12]: Is it possible to sub categorize these causes. E.g. Workforce (training, skills, staffing levels), Management/leadership, infrastructure, resources, resident characteristics etc.

Commented [TT13R12]: Agree

Commented [MOU14]: For what?

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- Inadequate numbers of staff
- Temporary staff shortages or unexpected absences
- Poor resident/staff ratio
- Insufficient staff of specific types (e.g., RN, infection preventionist)
- Poor use of staff, such as inconsistent staff assignments
- Staff turnover
- Rationed nursing care
 - Explicit, or rationed through policies that limit care or prioritize care processes inappropriately
 - Implicit, or rationed through habit or individual staff decisions to, for example, leave care undone at the end of a shift
- Insufficient staff knowledge or training
- Complex or complicated resident needs
- Poorly designed workflow
- Poor teamwork, including poor definition of roles and responsibilities
- Poor communication, including
 - Poor communication within the care team
 - Lack of communication with, or failure to listen to, residents or family, particularly regarding care preferences
 - Lack of communication about risk factors or at-risk residents
 - Lack of interprofessional collaboration
- Ineffective delegation of tasks
- Inadequate or inconsistent documentation practices, including:
 - Lack of written plans for palliative care, advanced care directives
 - Lack of adequate screening or surveillance of at-risk patients
 - Lack of systematic medication reviews and reconciliations
- Denial that there is an issue or that omitted care has an impact, lack of transparency about omissions and their impacts
- Urgent or unanticipated situations that interfere with standard care processes
- “Busy days” where there are multiple admissions, discharges, or transfers
- Resident’s level of acuity
- Lack of or inadequate material resources, including
 - Medications
 - Supplies
 - Equipment
 - Technological infrastructure
- Resident or family member preferences or decisions
- Lack of physical skills
- Lack of personal or organizational accountability for resident’s care needs and safety

Commented [WJ16]: This does not fully highlight the complexities of informed refusal. The definition of refusal should consider capacity, competency, assent, consent, how to recognize refusal, what constitutes informed refusal, and surrogate decision making.

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- Lack of management support for resident’s care needs and safety

Selected examples of omissions of care

- 1. A nursing home resident does not receive a flu vaccine at the appropriate time of year. Flu vaccine is not medically contra-indicated for the resident.**
 - a. This is an omission.
 - b. Possible cause 1: The nursing home administrator ordered insufficient doses of vaccine. Attribution: Nursing home
 - c. Possible cause 2: There is a nationwide shortage of flu vaccine due to failures in manufacturing and facility orders are not being fulfilled. Attribution: Supplier
- 2. Bed-bound residents at risk for developing pressure ulcers do not consistently receive appropriate preventive care such as repositioning.**
 - a. This is an omission.
 - b. Possible cause 1: The nursing home owner reduced facility staffing to minimal levels during evening, nighttime, and early morning hours, which increases resident/staffing ratios. Available staff therefore have difficulty completing all required tasks during these hours and residents are not repositioned on schedule as ordered. Attribution: Nursing home
 - c. Possible cause 2: Some nursing staff who work intermittently at the facility are not aware of which residents are at risk for pressure ulcer and how to reposition bed-bound resident’s heels. Attribution: Nursing home
- 3. A resident is prescribed a medication not in accordance with professional standards or guidelines (e.g. McGeer criteria for antibiotics).**
 - a. This is not an omission of care. This is the provision of care that is not needed, or a “commission of care.”
- 4. A resident is given the wrong dose of coumadin because the facility forgot to conduct a laboratory test to monitor the INR.**
 - a. Forgetting to do the test is the omission of care.
 - b. Giving the wrong dose of coumadin is not an omission; this is a commission of care.
 - c. Possible cause 1: The nursing home used a confusing process to track when monitoring tests are done and to record physician orders. Attribution: Nursing home
 - d. Possible cause 2: The nursing home uses agency nurses who are not familiar with the facility policy and procedure on ordering tests. Attribution: Nursing home
- 5. A resident would like to be groomed and dressed nicely when friends or family members come to visit but does not consistently receive the assistance needed to achieve this goal.**

Commented [MOU18]: These are really clear examples that highlight the different potential causes and attributions very well

Commented [TT19R18]: Agree, these are good examples

- a. This is an omission of care
 - b. Possible cause 1: The nursing home’s care policy does not prioritize this form of care. Attribution: Nursing home
 - c. Possible cause 2: Staffing shortages result in nursing staff not having sufficient time to assist the patient with grooming beyond complying with regular hygiene requirements. Attribution: Nursing home
- 6. A resident is misdiagnosed, or staff fail to detect and diagnose a condition.**
- a. This is not an omission of care. The misdiagnosis is not a failure to provide care. Misdiagnosis may be the *cause* of omissions of care when it results in a failure to supply care the resident needs. However, when misdiagnosis is the result of a failure to follow guidelines—for example, a policy for conducting screening tests or performing resident assessment—then that failure is the omission of care. In that case, the attribution could be the nursing home or the physician.
- 7. A resident is allowed to self-administer a medication; however the resident forgets to take the medication within the designated time period.**
- a. This is an omission of care.
 - b. Possible cause 1: Resident was distracted and forgot to take the medication. Attribution: Resident
 - c. Possible cause 2: Nursing home lacked protocol to confirm that patient took the self-administered medication. Attribution: Nursing home
- 8. A resident needs and does not receive assistance with performing oral hygiene activities (e.g. brushing teeth, denture care).**
- a. Not receiving needed assistance with performing oral hygiene activities is an omission of care.
 - b. Possible cause 1: The nursing home does not have a workflow for how and when assistance with oral hygiene activities is provided
 - c. Possible cause 2: The nursing home does not have training for staff on providing assistance with oral hygiene activities

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