What is ‘Observation Care’?

Any discussion of “observation care” runs immediately into the question of what is meant by the term. Even use of “observation care” is debated, as various other terms are employed to refer to the same concept, including observation unit, observation level of care, observation status, clinical decision unit, and emergency room observation or decision unit. For the purposes of this paper, the definition of observation care promulgated by the Centers for Medicare and Medicaid Services (CMS) will be used.

Specifically, CMS says observation care is “a well-defined set of specific, clinically appropriate services, which include ongoing short-term treatment, assessment, and reassessment, that are furnished while a decision is being made regarding whether patients will require further treatment as hospital inpatients or if they are able to be discharged from the hospital. Observation services are commonly ordered for patients who present to the emergency department and who then require a significant period of treatment or monitoring in order to make a decision concerning their admission or discharge.”

CMS also states, “In only rare and exceptional cases do reasonable and necessary outpatient observation services span more than 48 hours. In the majority of cases, the decision whether to discharge a patient from the hospital following resolution of the reason for the observation care or to admit the patient as an inpatient can be made in less than 48 hours, usually in less than 24 hours.”

Accepting CMS’ definition of observation care, the types of clinical situations that are most amenable to observation care are those in which neither discharge from the emergency department (e.g., mild acute viral illness in an otherwise healthy patient) nor inpatient admission (e.g., ST-elevation myocardial infarction diagnosed during initial evaluation) is routine.

The published literature on observation care is fairly consistent in finding that the most common diagnoses represented in adults in observation care are (not listed in order of frequency) findings consistent with an acute coronary syndrome (e.g., chest pain), abdominal pain, asthma, atrial fibrillation with rapid ventricular response, cellulitis, COPD, dehydration, headache, heart failure, hyperglycemia, pneumonia, pyelonephritis, syncope or near-syncope, and transient ischemic attack. Beyond these common diagnoses, there is a long list of other diagnoses that occur with lesser frequency. For pediatric patients, the most common diagnoses are abdominal pain, asthma, bronchiolitis, cellulitis, closed head injury, croup, gastroenteritis, and seizure. The seeming simplicity of observation care belies the complex and impactful “baggage” that gets thrust to the forefront of any attempt to describe its intended purpose, clinical ramifications, and related regulations. For example, there are high-stakes financial implications for both patients and providers that result from the decision to treat a patient in observation care instead of as a full inpatient admission. It is beyond the scope of this paper to detail the clinical indications or contraindications of observation care for a particular diagnosis; rather, this paper will outline some of the reasons observation care has become such an important element of care for payers, providers, and patients. In addition, some recent developments in the regulatory environment surrounding observation care will be discussed.
Recent Challenges and Controversies in Using Observation Care

It should be noted that the concept of observation care as a clinical entity and an option for a patient's initial disposition in the emergency department is not new. Since the 1980s there have been reports on the use and utility of what amounts clinically to observation care.

For example, alternatives to inpatient admission for patients presenting with symptoms consistent with acute coronary syndrome (ACS) have been extensively examined and reported in the literature for at least 25 years.

At the same time, if an alternative to the dichotomous option of admit vs. discharge from the emergency department is not new, one should be cautious in lumping together older descriptions and versions of observation care with more recently developed examples. Notably, recent incarnations of observation care have more prominent and significant financial implications for all involved stakeholders (i.e., payers, providers, patients). In fact, it would not be incorrect to conclude that the current reality of observation care is as much about third-party reimbursement consequences as anything else. This is not to say that clinical aspects, such as balancing the risk and benefits of hospital-based care (i.e., infection vs. inpatient treatment or monitoring needed) are not important, but much of the uncertainty, conflict, and rule-making concerns the financial aspect.

The nexus of the issue is whether or not a given patient's care will be paid for by a third-party insurer at the higher inpatient rate or at the lower outpatient rate. Many of the details vary by the third-party payer, but for illustrative purposes, we can examine the details as promulgated by CMS regarding Medicare fee-for-service patients, as CMS' rules are often adopted in whole or part by other payers.

In 2013, CMS put forth the “two-midnight rule.” CMS officials felt the rule was necessary, as it was concerning to them that the percentage of patients being treated with observation care for more than 48 hours (i.e., 3 or 4 days) was significant and might indicate a misuse or misunderstanding of how observation care should be applied according to CMS. Illustrating the point that observation care revolves around payment issues, the two-midnight rule states, in summary, that if two or more midnights of hospital-based care (i.e., care needed within a hospital) can be justified clinically, then a Part A (inpatient, higher reimbursement to hospital) bill can be submitted for this care. Conversely, if such care across 2 midnights cannot be clinically justified, is not documented sufficiently, or if care is provided for less than 2 midnights, a Part B (outpatient, lower reimbursement) bill should be submitted.

Considering the complexities of healthcare and the large numbers of patients, it is not surprising that even strict adherence to a given set of rules or guidelines is not a guarantee of a specific level of payment. However, simply ignoring the rules would likely result in more denials of Part A payments at the higher level of care, if only for the reason that auditors are specifically instructed to look for compliance with CMS regulations. Stated in other words, scrupulous compliance with any set of rules is no guarantee that auditors and payers will agree with a provider's decision-making, but failure to adhere to rules makes denial of payment much easier.
The Need for Clear and Accurate Documentation

Medical record documentation by the physician responsible for the admission decision is crucial in helping a reviewer assess the clinical judgment and decision-making that led to a conclusion of continued need for inpatient care. Specifically, this documentation has to be sufficient such that a review of the record alone (e.g., by an auditor) provides the necessary rationale to support the clinical decision. In the case of the two-midnight rule, CMS states that “… expectations for sufficient documentation will be rooted in good medical practice. Expected length of stay and the determination of the underlying need for … care at the hospital must be supported by complex medical factors such as history and comorbidities, the severity of signs and symptoms, current medical needs, and the risk of an adverse event.” (10) CMS also states that, “The decision to admit the beneficiary as an inpatient is a complex medical decision made by the physician in consideration of various factors including the beneficiary’s age, disease processes, comorbidities, and the potential impact of sending the beneficiary home.” (9) (10)

Despite these seemingly clear parameters, it often boils down to whether a reviewer will agree that it was “reasonable for the admitting physician to expect the beneficiary to require medically necessary hospital care lasting (at least) 2 midnights” by looking only at the physician’s documentation (e.g., plan of care, treatment orders, progress notes). (10) Given the way in which care usually unfolds, another way this requirement can be summarized is that the documentation must include a description of the severity of illness, what treatment/evaluations were performed, and how the patient responded to treatment.

An example may illustrate this point best. For a patient who presents with an acute exacerbation of heart failure, the clinical documentation should express the severity of the acute illness, and how this was assessed (e.g., exam findings, presence of tachypnea, new or worsened hypoxemia). It should also state what treatment was given (e.g., parenteral diuretics), how often it was administered, what the patient’s response to treatment was, and how this response was measured (e.g., continued hypoxemia, tachypnea).

Misconceptions about Observation Care

In light of these expectations for documentation, a few misconceptions about the rule can be appreciated. First, the mere passage of time cannot be used to justify submission of a Part A bill. Simply keeping the patient in the hospital is not enough; it has to be shown that the time in the hospital was medically necessary. (9) (10) Second, ongoing and progressive treatment should be applied during the period of observation care. Treatment should be instituted promptly and, importantly, reassessment of the patient’s clinical status and response to treatment should be made and followed by any needed adjustment and intensification of treatment. (9) (10) Considering the example of an exacerbation of heart failure, simply administering a standard dose of intravenous furosemide a few times over the course of observation care would not be sufficient to justify an inpatient admission. Rather, the record would be expected to show that appropriate doses of furosemide (i.e., doses exceeding the outpatient oral dose) were given and, depending on serial assessments of response, escalation of dosing as needed. (32) Finally, the patient’s clinical status at or near the end of the observation period should be described, along with the justification of either the need for continued treatment in a hospital (e.g., further treatments with parenteral diuretics needed) or suitability for discharge.
This documentation of justification for the need for more hospital-based treatment reveals how observation care can be of assistance to providers. Using the same example of a patient who presented to the emergency department in acutely decompensated heart failure, let’s suppose that the patient initially presented to the emergency department at 10 a.m. on a Monday and that initial emergency department treatment (i.e., 2-4 hours) was not sufficient to render the patient appropriate for discharge. Under the two-midnight rule, the physician is tasked with judging and documenting at 1 p.m. Monday whether the patient is likely to require hospital-based treatment and monitoring beyond midnight on Tuesday (35 hours hence). While it is possible this judgment would not be difficult for some patients (e.g., very severe underlying illness and presentation), for most patients this degree of prognostication is not feasible, or would be quite unreliable. This is when observation care could be appropriately used. This patient could be placed in observation care, treated, monitored, and reassessed as described above, with the clinician then being tasked with making this decision around noon on Tuesday (12 hours before the second midnight). The admit-vs.-discharge decision is now more easily and reliably made after the benefit of seeing how the patient responded to 23 to 24 hours of treatment, and with having to predict an ongoing need for hospital-based treatment within a much shorter timeframe.

It is true that “when the clock starts ticking” is an important variable. If this patient presented at 10 p.m. on a Monday, it may have been possible to judge with some precision whether care would be needed past midnight on Tuesday (26 hours). Even taking this to each extreme by considering initial presentation to the emergency department at 6 a.m. or 11 p.m., it is clear that the time of patient presentation plays a role in determining if observation care is needed. This is the price to be paid for selecting a common, clear endpoint against which to judge medical necessity (2 midnights). CMS admits that the time of presentation is a factor, but adds that over a long enough term and over enough conditions and patients, this sort of thing will balance out. (7) (8) (9) (10)

A second misunderstanding of the application of the two-midnight rule is that all that is needed to justify inpatient admission is an attestation by the physician along the lines of, “It is my expectation that the patient will require hospital care spanning at least 2 midnights.” Like most simple global fixes for complex problems, this is not a substitute for thorough documentation. (10)

Part of the language included in the two-midnight rule describes some specific reasons why simply spending two midnights in the hospital does not automatically equate to an appropriate Part A bill. The rule states that CMS and its reviewers will look for patterns of “systematic gaming, abuse or delays in the provision of care in an attempt to qualify for the 2-midnight presumption.” If it is determined that any of these patterns exist, a Part A bill can be denied even if 2 midnights were spent in the hospital. Moreover, these patterns could result in serious consequences beyond denial of payment (e.g., more intensive auditing, suspension of ability to participate in Medicare). (7) (8) (9) (10) Examples of what is meant by “gaming, abuse and delays” include incorrect Diagnosis Related Groups assignment (e.g., avoidance of Diagnosis Related Groups usually associated with inpatient stays of less than two days), inappropriate delays in the provision of medically necessary care (e.g., specific testing is needed but not performed in a timely manner), and provision of inpatient services that lack medical necessity (e.g., could have been appropriately performed in non-inpatient settings). (8) (10)
Implementation of Policies Related to Observation Care

Although Medicare may be seen as the standard-bearer concerning the details of observation care use, each payer-provider dyad can have its own fine-print details regulating the use of observation care for patients insured by these other payers. These details are often outlined in the contract between payer and provider. For example, in some instances the “yardstick” is not 2 midnights, but a certain number of hours (e.g., 24 hours).

There are also examples wherein the provider is instructed by a payer that in all or most cases, a patient has to “fail observation care” prior to authorizing inpatient admission. While this may be an attractively straightforward implementation, this is not how observation care is usually practiced. This sort of implementation, which may only be possible to alter contractually (i.e., different language in the next contract), ignores the clinical reality that some conditions do not carry any reasonable doubt of requiring admission as an inpatient (e.g., initial diagnosis of ST-elevation myocardial infarction, or severe upper gastrointestinal bleeding).

Although the details of each payer’s observation rules are beyond the scope of this paper (e.g., start and stop of the clock, who performs reviews, how many charts will be reviewed, if there are exceptions to a rule), a brief description of how the two-midnight rule is implemented may be helpful, if only because Medicare is the most common payer, and other payers often adopt Medicare rules.

Any reviewer is supposed to assess the appropriateness of the decision to admit a patient for inpatient hospital care based upon the information, results, and clinical picture at the time this decision was made, not based upon “how the patient did” (i.e., “Monday morning quarterbacking” -- since the patient did well admission was not necessary). The 2-midnight clock starts when the patient first receives services following arrival at the hospital, meaning that wait times prior to treatment (e.g., in the emergency department waiting room) and during triage (e.g., routine vital sign assessment) do not count; only inpatient care that was medically necessary counts. Time spent in custodial care (e.g., “social admissions”), delays in testing due to convenience or availability (e.g., needed test not available over the weekend), or receipt of care judged to not require an inpatient level of care (e.g., testing or treatment that can be safely done in the outpatient setting) are not included in the 2-midnight accrual.

For example, consider a patient who presents to the emergency department on a Saturday at 8 p.m. and is appropriately treated over midnight to Sunday, but a certain test (e.g., stress testing) that is judged to be necessary and must be performed as an inpatient is not available electively on Sunday, so the patient gets the test on Monday and is discharged prior to midnight Monday. A Part A Medicare bill should not be submitted for this patient. Similarly, if the reason the patient wasn’t discharged on Sunday was that a family member was not available to receive the patient or that necessary outpatient services (e.g., home health care) could not be arranged, a Part A Medicare bill cannot be justified. If the patient was coincidentally due for an elective colonoscopy and was held over until Monday for his or her gastroenterologist to perform it, this is not eligible for Part A payment. Furthermore, patients who are “left in the emergency department” (e.g., elderly or demented patients) and cannot safely be discharged to home, need skilled nursing facility placement, or are homeless would not qualify for Part A payment regardless of the number of midnights spent in the hospital.
While hospitals may not have any clinically acceptable, legal, or ethical alternative to continued hospital care, they still cannot bill for inpatient services. The presence of signs, symptoms, or test findings that justify staying overnight in observation care (e.g., mild dehydration, urinary tract infection, intoxication) do not alter this decision, unless it can be documented that the patient had a clinically necessary reason to require hospital services across a second midnight.

However, the two-midnight rule does clarify that if a patient is expected to receive care that will pass two midnights, but leaves against medical advice, dies, or is transferred prior to completing 2 midnights in the hospital, a Part A bill would still be appropriate. Furthermore, if a patient recovers more rapidly than was reasonably expected and is discharged prior to the second midnight, a Part A bill may still be appropriate. The crux of this latter scenario is whether the original assessment and documentation supported a reasonable expectation of at least 2 midnights of care or, stated another way, that the patient’s recovery was truly unusual and unexpected. This sort of exception is uncommon.

An interesting and illustrative aspect of the two-midnight rule is that it is truly not about intensity of care, but whether or not 2 or more midnights of hospital-based care is justifiable and documented. For example, the clinical necessity for telemetry monitoring is not, by itself, a justification for Part A billing. Even the necessity and provision of intensive care services is not, by itself, sufficient for Part A billing. Although the vast majority of patients who require ICU care will spend two or more midnights in justifiable hospital-level care, one could imagine a scenario in which an otherwise healthy patient presents early on a Monday morning with a drug overdose or intoxication, requires ICU level monitoring and treatment, but recovers sufficiently such that discharge to outpatient follow-up is appropriate by Tuesday evening.

Perhaps in light of this last example, the original rule was amended by CMS such that an acute clinical need for intubation and mechanical ventilation is an exception to the two or more midnights requirement. Therefore, if the patient who rapidly recovered from a drug overdose required mechanical ventilation, a Part A bill would be appropriate. Of note, a need for noninvasive ventilatory assistance, by itself, is not an exception.

**Impact of Observation Care on Patients**

Thus far, the financial implications of observation care under the two-midnight rule have been discussed from the perspective of the hospital. However, being treated in observation care rather than as an admitted inpatient can have significant financial consequences for the patient as well. Specifically, Medicare fee-for-service patients experience a different level of deductibles and coinsurance when care is rendered in observation care. For these patients, Part B benefits are quite different than Part A benefits. The precise differences experienced by Medicare patients are beyond the scope of this discussion and depend on whether the patient has supplementary coverage to cover some of the gaps in Part B coverage, and if they have exceeded their annual deductibles (for Part A, Part B, neither, or both). One crucial difference is that Part B does not cover the costs of “self-administered” medications (i.e., medications usually taken at home) that are given to the patient while an outpatient (e.g., observation care). Furthermore, some hospitals do not permit patients to bring their medications from home, causing patients to incur substantial financial liabilities when treated in observation care. Similar to how hospital billing is handled, time spent in observation care (e.g., first midnight) is considered as inpatient care (Part A eligible) for billing purposes.
purposes if the patient is admitted as an inpatient after the initial observation care stay (e.g., they are admitted after their first midnight during the same episode of care). (21) (23) (24)

It is not always safe to assume that patients incur higher personal costs after an observation care stay that did not result in inpatient hospital admission. In an article in the *Journal of Hospital Medicine*, the authors used the 20% sample of Medicare patients to examine the cumulative financial liability incurred under varying assumptions. Limiting analysis to Medicare fee-for-service patients who had Part A and Part B coverage, the authors found that, considering an annual inpatient deductible of $1100, the median (interquartile range) patient liability for a single observation stay of $334 ($216-$530) meant that an observation care stay costs less for most patients than if they were admitted as an inpatient. Conversely, they found that for the small percentage of beneficiaries with multiple observation stays within a 60-day period, their financial liability was greater than $1100, meaning that inpatient admission may have been less expensive. (21)

In response to patient confusion and consternation, the NOTICE Act was enacted, which requires hospitals to provide written and oral notification to a patient when he or she has been treated in observation care for more than 24 hours. (33) This notification has been standardized and communicates that observation care is not considered inpatient care -- even if the patient is in a hospital bed and stays overnight. The notification also outlines some of the differences between Part A and Part B coverage in broad strokes, and reiterates that Medicare only covers skilled nursing facility care if the patient is sent to a skilled nursing facility after at least 3 days of inpatient care. (34) This notice must be delivered in oral and written forms to the patient within 36 hours of initiation of observation services, upon discharge from observation care, or when admitted as an inpatient. (33) It is not entirely clear when the requirements of this act will go into effect, which has been the cause of concern and frustration. (35)

Considering the likely negative reaction this notice may engender in some patients and recalling Medicare’s language in the two-midnight rule that observation care can usually be completed within 24 hours with a decision of discharge or admission, the most prudent plan would consist of two aspects, at the least for Medicare patients (and other patients if similar rules are adopted by other payers).

First, observation care should be utilized judiciously; that is to say, striving not to use observation care for patients who could be discharged directly from the emergency department, or for patients for whom it can be reasonably prognosticated within the emergency department care phase of treatment (e.g., 2-4 hours) that the patient will require 2 or more midnights of hospital-based care. The second aspect would entail striving to make the clinical decision to discharge from observation care to home or to admit the patient within 24 hours of observation care. This practice would rely upon balancing the need to have enough time to observe how the patient responds to treatment, and the wish to not unnecessarily admit patients for inpatient care.

While beyond the scope of this paper, it is important to understand the mechanics of the audit/review process by Medicare (or any payer), the appeals process, and the expected financial impact of payment regulations, benchmarks, and updates. (9) (10) These details should be seen as being potentially fluid, necessitating repeated review of amendments and rule adjustments. For example, one of the more confusing and controversial aspects of the two-midnight rule is that while “midnights” spent in emergency department or observation care do
count toward the 2 midnights (i.e., the decision after one midnight spent in observation care is whether one more is necessary), this is not the case for the “3-day skilled nursing facility rule.” Briefly, this rule states that in order for a patient to have Medicare cover skilled nursing facility treatment, the patient must be directly discharged from an inpatient hospital stay spanning at least 3 days. In contrast to the fact that midnights crossed in observation care count toward a 2-midnight stay, this same midnight in observation care cannot be included as part of the 3-day pre-skilled nursing facility requirement. This obvious and seemingly inexplicable conflict has been a common subject of comment and complaint, and could conceivably be revised in the future.

Observation Care for Surgical Patients

The discussion of using observation care for patients undergoing surgery or procedures first begs the question of whether surgical patients can also be placed in observation care. A common usage of the term “observation” is to refer to surgical patients who are “observed” postoperatively to monitor their recovery course (e.g., tolerating liquids, out of bed, mental status, urination, bowel function) and assess when they may be safely discharged. For surgical patients, the key determination -- continuing with our use of CMS’ two-midnight rule as the prime example, is not whether they are called inpatients, but if they require 2 or more midnights of postoperative or post-procedural hospital-based care. Similar to how it works for medical patients, if a patient does not require clinically necessary hospital-based care across 2 postoperative midnights, a Part B bill submission is appropriate. However, if it can be documented that such care is necessary across 2 midnight then a Part A bill is appropriate.

For the surgical patient, the determination of such need is usually focused on postoperative recovery to a level of function and stability such that care can be safely continued in a setting other than a hospital. For example, if a patient had a laparoscopic cholecystectomy that was completed at 4 p.m. on Monday, the pertinent clinical decision is if the patient is ready for discharge (e.g., tolerating oral intake, able to walk, pain is controllable with oral medication) before midnight on Tuesday. Whether or not the patient spends one night in the hospital after surgery is immaterial to whether the procedure is considered ambulatory or outpatient (less than 2 midnights) or inpatient (2 or more midnights). This serves to effectively remove the distinction, at least from an insurance reimbursement standpoint, between surgeries that are day cases (e.g., patient goes home the day of the procedure) or overnight cases (e.g., patient spends the night in the hospital, but is discharged before midnight the next day). Either of these surgeries would be appropriate for a Part B bill and can be called “ambulatory” or “outpatient.” Similar to medical patients, the location within the hospital where this postoperative care is provided is not a factor; surgical patients can be located in a specific dedicated location, such as a particular post-anesthesia care unit, or placed throughout the hospital and still be considered outpatients (i.e., in observation care).

One difference in application of the two-midnight rule to medical and surgical patients is that CMS maintains what is called an “inpatient-only list.” This is a list of surgeries, identified by CPT code, that are only paid under Part A as an inpatient procedure, meaning, the patient must be an inpatient. This list is updated annually and almost exclusively consists of procedures that necessitate a patient receiving at least 2 midnights of hospital based care in all at the most unusual of circumstances. For example, in a laparoscopic hysterectomy, only one of the associated CPT procedure codes is on the inpatient-only list: laparoscopy with radical
hysterectomy, with bilateral total pelvic lymphadenectomy and para-aortic lymph node sampling, with removal of tubes(s) and ovary(s). This is clearly a complex, major surgical procedure. CMS' policy concerning surgery is that, "We believe that it would be rare and unusual for a stay of 0 or 1 midnights, for patients with known diagnoses entering a hospital for a specific minor surgical procedure or other treatment that is expected to keep them in the hospital for less than 2 midnights, to be appropriately classified as inpatient and paid under Medicare Part A." (10)

Analogous to how indeterminate medical patients are handled (i.e., placed in observation care and reassessed the next day), for surgical patients undergoing procedures in which it is not routine to expect a 2-midnight postoperative stay, CMS states “… if the physician cannot determine whether the beneficiary prognosis and treatment plan will now require an expected length of stay spanning 2 or more midnights, the physician should continue to treat the beneficiary as an outpatient. [Ed. Note: meaning outpatient from a billing standpoint.] If additional information gained during the outpatient stay subsequently suggests that the physician would expect the beneficiary to have a stay spanning 2 or more midnights, including the time in which the beneficiary has already received hospital care, the physician may admit the beneficiary as an inpatient at that point.” (10)

Similar to how the first midnight spent in observation care is handled for medical patients, the first postoperative midnight counts toward meeting the 2-midnight threshold. For the patient who completed laparoscopic cholecystectomy at 4 p.m. on Monday, a slow postoperative recovery or development of complications that make it clear the patient will not be discharged until at least sometime on Wednesday (e.g., not tolerating oral intake, postoperative infection), a Part A bill (inpatient) is appropriate, assuming that it is supported by adequate documentation and reasonable clinical judgment.

Remaining Questions Surrounding Observation Care

Looking past all the rules, regulations, and definitions, some basic questions concerning observation care remain, but have not yet been satisfactorily studied and reported in the medical literature. One simple, yet fundamental, question is whether or not observation care is clinically beneficial to patients. One could envision that if an elderly, frail patient is spared an unnecessary inpatient hospital stay (assuming an equivalent clinical outcome), this could reduce the likelihood of adverse events such as delirium, hospital-acquired infection, or falls. Conversely, observation care could have a negative impact on patients, such as an increase in return visits to the emergency department or worsening clinical status due to an incompletely treated primary condition. Observation care may also have no clinical impact, as some facilities do not care for these patients in a central unit, but directly alongside inpatients throughout the hospital. Of course, a likely answer may be that it all depends on the patient and the details of the clinical situation; for some it may be a benefit, while for others it may be either neutral or harmful.

A related question is should the variety of observation care settings and arrangements be standardized. There is some evidence that the model of having a physically separate location dedicated to observation care is beneficial, at least in terms of efficiently making a disposition decision within 24 hours. (14) However, it is not known if having a closed unit where assigned physicians care for the patients or an open unit where there aren’t specific, dedicated physicians, and many doctors may have one of their patients in observation care, influences outcomes or the balance of benefits and harms.
The vast majority of the published literature that examines observation care is observational with little to no adjustment for confounding variables. These studies are susceptible to bias (e.g., confounding) and suffer from low statistical power (e.g., in the ability to detect harm) such that any reported benefits should be interpreted with caution. In addition, the vast majority of studies analyze primary outcomes such as cost, length of stay, and inpatient admission rates, not patient-centered clinical outcomes.

With these qualifications noted, most studies have found some benefit to observation care in terms of admission rates, lengths of stay, or costs, even if these findings are scattered over many diagnoses, patient groups, institutions, and varieties of observation care (e.g., dedicated vs. virtual).\(^{(1)}(4)(5)(17)(22)(38)(39)(40)\) A systematic review including 10 randomized controlled trials of adults compared care provided with or without the availability of a short-stay unit. Considering only results based upon studies published after the 1990s, 2 studies (215 patients with suspected acute coronary syndrome) found a 4- to 5-hour shorter length of stay with short-stay units, and 1 study (105 patients with suspected acute coronary syndrome) found a lower readmission rate (8% vs. 23%) with short-stay unit use.\(^{(41)}\)

**Conclusion**

Despite the lack of clear evidentiary support, observation care will continue to expand and be of importance, if only because of the significant financial ramifications contingent upon its use. At the same time, taking into account various financial incentives, complex and changing rules, and non-uniform implementation, it should not be surprising that there is still quite a bit of confusion, as exemplified by the seemingly concurrent underuse and overuse of observation care. A report by the Office of the Inspector General delivered to CMS concerning observation care and the two-midnight rule reported that in fiscal year 2014 about 3.5 million Medicare patients were treated in observation care and not admitted as inpatients (during that episode) and approximately 9.1 million were admitted as inpatients with or without an observation care stay along the way.\(^{(16)}\) Highlighting the continued inconsistency and confusion surrounding the two-midnight rule, about 750,000 observation-only patients (22%) were treated over 2 or more midnights. While this is lower than the 37% found in a similar analysis performed on 2012 Medicare data, which spurred development of the two-midnight rule, this indicates a significant proportion of potentially misclassified patients. The subset of these patients who could have had their hospital stay justified as inpatient represents potential lost revenue for the hospital and possible overuse of observation care services.\(^{(16)}(42)\)

Conversely, of Medicare patients admitted to inpatient care (with or without observation care), 12% did not have care that spanned at least 2 midnights (i.e., discharged before the second midnight). It is estimated that 39% of these patients (totaling over 423,000 patients) may have been inappropriately admitted as inpatients. This underuse of observation care represents almost $2.9 billion dollars in potential overpayments by Medicare in one fiscal year.\(^{(16)}\)

Despite open questions concerning the role of observation care from a purely clinical standpoint and confusion about some of the regulations, observation care will continue to be of considerable importance to payers, providers, and patients in the foreseeable future. Even if we restrict our perspective to the balance sheet of one payer (Medicare), with billions of dollars in play every year, observation care will remain an important aspect of patient care to understand and employ appropriately.
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