

# Beyond Infection: Device Utilization Ratio as a Performance Measure for Urinary Catheter Harm

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Catheter-associated urinary tract infection (CAUTI) is considered a reasonably preventable event in the hospital setting, and it has been included in the US Department of Health and Human Services National Action Plan to Prevent Healthcare-Associated Infections. While multiple definitions for measuring CAUTI exist, each has important limitations, and understanding these limitations is important to both clinical practice and policy decisions. The National Healthcare Safety Network (NHSN) surveillance definition, the most frequently used outcome measure for CAUTI prevention efforts, has limited clinical correlation and does not necessarily reflect noninfectious harms related to the catheter. We advocate use of the device utilization ratio (DUR) as an additional performance measure for potential urinary catheter harm. The DUR is patient-centered and objective and is currently captured as part of NHSN reporting. Furthermore, these data are readily obtainable from electronic medical records. The DUR also provides a more direct reflection of improvement efforts focused on reducing inappropriate urinary catheter use.

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## BACKGROUND

Preventing catheter-associated urinary tract infection (CAUTI) is a national safety priority and has been adopted as a metric by the Centers for Medicare and Medicaid Services to optimize outcomes.<sup>1–3</sup> The risk of developing a CAUTI starts upon insertion and increases daily until catheter removal; this risk is also affected by patient characteristics.<sup>4,5</sup> In addition to urinary tract infection (UTI), the presence of the urinary catheter may lead to unnecessary urine cultures, associated inappropriate use of antimicrobials,<sup>6</sup> colonization and outbreaks of multidrug-resistant Gram-negative organisms,<sup>7,8</sup> and *Clostridium difficile* infection.<sup>9</sup> Noninfectious complications such as urethral and bladder trauma<sup>10</sup> and impaired mobility<sup>11</sup> are also salient patient harms related to the catheter. Our objectives are to discuss the current outcome measures used to evaluate CAUTI events and to address their strengths and limitations in the context of both clinical practice and healthcare policy. We conclude by emphasizing the benefits of using the device utilization ratio (DUR) as an additional performance measure that reflects the risk of both infectious and noninfectious harm associated with the catheter.

## Outcomes Currently Used to Evaluate CAUTI

Several different definitions of CAUTI are currently in use for epidemiological surveillance, clinical diagnosis, and billing (Table 1).

*Surveillance-based criteria for CAUTI.* The most frequently used surveillance definition of CAUTI comes from the Centers for Disease Control and Prevention (CDC) National Healthcare Safety Network (NHSN).<sup>12</sup> The NHSN CAUTI definition applies to patients with an indwelling urinary catheter in place for >2 calendar days on the day of the event and who have the catheter in place on the day of or the day before the event. The catheter-associated symptomatic UTI (SUTI) definition requires the application of different algorithms to identify CAUTI events that draw on a combination of clinical symptoms or signs, the result of the urine culture, and the temporal use of an indwelling urinary catheter. The algorithms rely on the presence of no more than 2 species of microorganisms in the urine, in addition to other elements such as fever (regardless of the cause) or localized findings. Starting in January 2015, the SUTI definition excluded urine analysis findings, nonbacterial

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TABLE 1. The National Health Safety Network and Infectious Diseases Society of America Claims-Based Definitions for Catheter-Associated Urinary Tract Infections (CAUTI) and Clinician Diagnosis

Source	Criteria	Catheter Types	Use	Advantages	Limitations
National Healthcare Safety Network (NHSN) 2015	Bacteriuria ( $\geq 10^5$ CFU/mL); algorithm-based including the presence of 1 of 3 clinical findings: fever, suprapubic tenderness, costovertebral angle pain or tenderness; if catheter is removed, urgency, frequency, dysuria are also options.	Indwelling	CAUTI surveillance for public reporting and performance metrics	Objective criteria, reproducible, universally used for quality improvement initiatives	Does not correlate with clinical CAUTI or clinician practice; heavily dependent on fever even if alternate source present; limited in evaluating improvements in reducing CAUTI events when efforts focus on avoiding device placement
Clinical Practice Guideline: Infectious Diseases Society of America (IDSA)	Bacteriuria ( $\geq 10^3$ CFU/mL); signs or symptoms of a urinary tract infection, and no other identified source of infection	Indwelling, suprapubic, external (condom), and intermittent	Clinical diagnosis; to distinguish CAUTI from asymptomatic bacteriuria	Clinical; independent of urinalysis results; the diagnosis by exclusion minimizes over-diagnosing CAUTI in patients with asymptomatic bacteriuria	Not easy for a clinician to follow or apply to a specific patient; runs counter to ingrained diagnostic biases (pyuria not used)
Claims-based	Administrative claims data for the purposes of identifying UTIs as hospital-acquired and catheter-associated	Indwelling	Billing; to identify hospital-acquired CAUTIs as a diagnosis that is ineligible for generating additional hospital payment as a comorbidity	Identified by diagnosis codes submitted by hospital coders routinely in the process of generating and submitting administrative data to request hospital payment	Low sensitivity to capture clinical CAUTIs (ie, many CAUTIs that occur are identified simply as UTIs but not CAUTIs in claims data)
Clinician diagnosis	Informal but common criteria based on presence of bacteriuria, pyuria, and many subjective findings	Unclear; physicians often are not aware of the presence of the urinary catheter or the type	Deciding whether to treat with antimicrobial agents; to explain clinical symptoms	Based on clinician evaluation; influenced by the type of organism; directly affects patient care	Subjective findings used for diagnosis, including urine color, smell and consistency; pyuria often equated to infection; high potential for inappropriate antimicrobial use

NOTE. CFU/mL, colony-forming units per milliliter.

organisms, and any quantitated urine cultures with < 100,000 colony-forming units (CFUs) per milliliter.

*CAUTI as defined by clinical practice guidelines.* The clinical definition of CAUTI published by the Infectious Diseases Society of America (IDSA) is based on clinical and laboratory findings, with the exclusion of other sources of infection.<sup>13</sup> The IDSA clinical definition incorporates patients with a urinary catheter (including indwelling and non-indwelling catheters) or those who have had a catheter discontinued within 48 hours prior to signs or symptoms. The clinical definition has 3 components: (1) significant amount of bacteriuria defined as  $\geq 10^3$  CFU/mL; (2) signs or symptoms of a urinary tract infection (as defined below); and (3) no other identified source of infection.<sup>13</sup> Signs and symptoms that may be compatible with CAUTI include new fever, chills, altered mentation, or malaise with no other recognized cause. In addition, flank pain, costovertebral angle tenderness, acute hematuria, and pelvic discomfort are considered local findings compatible with the diagnosis. Urinary frequency, dysuria, and urgency are included if the catheter has been removed within 48 hours. Many of these signs and symptoms are non-specific and make the clinical CAUTI definition a diagnosis by exclusion.<sup>13</sup> Furthermore, the IDSA guidelines exclude both the urinalysis results and the type of organism from the diagnosis of CAUTI.

*Claims-based diagnosis of CAUTI.* CAUTI events are also defined using administrative discharge data, which are submitted as claims to request payment. These data are used to identify UTIs as hospital-acquired and catheter-associated and thus not eligible as payable comorbidities.<sup>14,15</sup> Administrative data-derived hospital-acquired CAUTI rates are much lower than expected (0.14% of hospitalizations) according to medical record reviews and epidemiologic surveillance for CAUTIs.<sup>16,17</sup> A recent systematic review on the accuracy of administrative code data reported low sensitivity but high specificity for diagnosing CAUTI.<sup>18</sup> Although UTIs are commonly listed as diagnoses in discharge data, very few are identified in administrative data as CAUTIs because the documentation generated by clinicians that hospital coders must rely upon for generating diagnosis codes rarely includes explicit descriptions of UTIs as being catheter-associated.<sup>19</sup>

*Clinician-based diagnosis of CAUTI.* In clinical practice, clinicians often obtain urine cultures based on findings that are not consistent with evidence or guidelines, such as urine color, cloudiness, and odor.<sup>13</sup> These findings are non-specific for the presence or absence of organisms in the urine. Furthermore, clinicians often do not distinguish between asymptomatic bacteriuria and symptomatic CAUTI in their catheterized patients.<sup>6,20</sup> Pyuria in particular often drives inappropriate antimicrobial use and misdiagnosis of asymptomatic bacteriuria as CAUTI.<sup>6,21</sup> Many clinicians treat patients with asymptomatic bacteriuria,<sup>6</sup> even in patient groups with high risk for developing *Clostridium difficile* infection.<sup>22</sup>

Results from the Medicare Patient Safety Monitoring System, which captures adverse events in a sample of patients

admitted to US hospitals, were recently reported regarding clinician-diagnosed CAUTI for patients with specific diagnoses or surgeries over the period 2005–2011.<sup>23</sup> Clinician-diagnosed CAUTI was defined as an event in a patient who either had an indwelling catheter or underwent intermittent catheterization during their inpatient stay, where the physician made the diagnosis of UTI and ordered antimicrobials.<sup>23</sup> Physicians diagnosed CAUTI in ~5% of patients exposed to urinary catheterization for different primary diagnoses, whereas the NHSN CAUTI rate in the medical–surgical units in acute care hospitals averaged <1.5 events per 1,000 catheter days during a similar time period.<sup>24</sup> With a national inpatient average length of stay of 4–5 days, CAUTI events are much more prevalent based on a clinician-diagnosis compared to the NHSN-based definition.

### Limitations of the Outcomes Currently Used to Measure CAUTI

The optimal definition for CAUTI used in quality improvement efforts is one that only captures true instances of disease for which treatment is recommended, thus serving both clinical and surveillance needs. At present, all of the available definitions suffer from substantial limitations. For example, the IDSA definition is based on excluding other sources of potential infection and relies on subjective criteria.<sup>13</sup> Clinician practice often does not follow these guidelines and may be driven instead by perceived risks, such as patient characteristics (older age), types of organisms (Gram-negative organisms on urine culture), and the presence of pyuria.<sup>6,21</sup> Clinicians often treat asymptomatic bacteriuria as a UTI,<sup>6,20</sup> as a positive urine culture is a strong trigger for antimicrobial use even without evidence of infection.<sup>25</sup> Claims-based CAUTI is associated with very poor sensitivity, underestimating the number of events. Only the NHSN definition, a national measure used for quality improvement initiatives, is based on objective criteria, which makes it attractive for public reporting and comparison over time.

*Limitations of the NHSN CAUTI definition, criteria, and summary measure in evaluating outcomes.* Although the NHSN CAUTI measure is the measure most widely used to evaluate CAUTI nationally, it also has several limitations. First, case finding, using the previous NHSN CAUTI definition, is restricted by low positive predictive value when compared with clinical CAUTI diagnoses.<sup>26</sup> In one study, only 35% and 62% of cases fitting the NHSN definition were considered CAUTIs when evaluated by infectious diseases specialists and treating physicians, respectively.<sup>26</sup> Moreover, some NHSN-defined CAUTIs may not merit clinical treatment, particularly those diagnosed on the basis of fever alone, as the fever might actually be caused by a nonurinary etiology. Refinements in the NHSN criteria enacted January 2015, excluding funguria and lower urine-culture colony counts, may improve the positive predictive value of the definition for detecting clinically relevant events. A more clinically relevant NHSN

definition will be more accepted and thus support efforts to reduce CAUTI.

A second limitation of the surveillance definition is the potential for underreporting of CAUTI events. Validation of reported CAUTI outcomes by CMS is also in progress, a process that has its own constraints,<sup>27</sup> but may result in improved compliance by hospitals reporting these to NHSN. The Healthcare Infection Control Practices Advisory Committee (HICPAC) acknowledges the limitations of surveillance definitions when evaluating clinical disease and recommends that reported data be systematically validated.<sup>28</sup> Developing electronic means to capture NHSN CAUTI would reduce reporter subjectivity and also eliminate the inherent bias of self-reporting.<sup>29</sup> An electronically accessible definition could be based upon urinary catheter presence, associated bacteriuria, and fever; such a definition would capture more than 90% of the currently identified NHSN CAUTI cases.<sup>26</sup>

Third, NHSN-defined CAUTI events may be influenced by the prevalence of fever and the frequency of urine culture collection in a given location, both of which are critical elements for case identification.<sup>26</sup> For example, the NHSN reported that the pooled mean CAUTI rate for neurosurgical intensive care units (ICUs) (high fever prevalence) is 5.3 per 1,000 catheter days, 3 times greater than the mean CAUTI rate of medical–surgical ICUs with >15 beds.<sup>30</sup> Furthermore, seasonal influenza, often associated with admissions to ICUs for febrile patients with severe infection, may lead to an increase in NHSN-defined CAUTI rates. In addition to patient-specific risk factors (eg, fever prevalence or duration of catheter use), provider- or facility-specific practices (eg, reflex urine culturing triggered by fever or abnormal urinalysis) may result in higher NHSN-defined CAUTI rates.<sup>26,31</sup> The presence of fever leads clinicians to obtain urine cultures,<sup>32</sup> resulting in an increase in detection of patients with asymptomatic bacteriuria who may not have clinical CAUTI.

Fourth, the NHSN reliance on catheter days as the denominator for CAUTI rates makes it challenging in some situations to measure the impact of specific quality improvement efforts focusing on reducing device use. Interventions mainly focusing on device avoidance, such as an intervention in the emergency department to prevent inappropriate placement,<sup>33</sup> may lead to selecting a smaller population with higher risk for infection, resulting in a paradoxical increase or no change in NHSN CAUTI rates.<sup>34,35</sup> A population-based CAUTI rate (calculated as the number of CAUTI events divided by the total number of patient days multiplied by 10,000) factors in the effect of catheter avoidance on the entire population and may better reflect the success of such efforts, especially for the same unit or facility over time, as it accounts for both the change in device use and the change in device infection risk.<sup>35</sup>

Despite the limitations of the NHSN measure, this measure is especially useful for evaluating CAUTI over time, particularly for units with stable device utilization and urine culturing practices. This measure is enhanced by using the standardized infection ratio, which adjusts for patient mix by type and size of patient

care location, and hospital affiliation with a medical school. However, following trends nationally over time has been challenged by successive definition modifications, refinements, and clarifications as well as uptake in reporting as a result of state and national reporting mandates. Further refinements to the NHSN CAUTI measure to improve standardization of reporting, along with implementation of electronic surveillance, will facilitate monitoring of infectious complications associated with the urinary catheter. In addition to monitoring CAUTI, monitoring a device-use performance measure might serve as a useful way to capture the broader potential for catheter harm.

### What is the Ideal Performance Measure to Assess Potential Catheter Harm?

To date, the majority of interventions leading to a successful reduction in CAUTI (with different definitions used) have focused on reducing urinary catheter use, either by shortening duration or avoiding placement.<sup>36</sup> The main outcome focus has been CAUTI reduction, rather than avoiding catheter-associated harm. Other infection-related events (eg, inappropriate antimicrobial use, antimicrobial resistance, and *Clostridium difficile* infection) and noninfectious complications,<sup>10</sup> such as urethral damage, pain, or inadvertent catheter removal, have received limited attention. Importantly, the catheter may act as “a 1-point restraint,” limiting the patient’s mobility.<sup>11</sup>

While the urinary catheter use measure has traditionally been regarded as a process measure when evaluating CAUTI risk, it serves as a performance measure (both process and outcome measure) for potential “catheter harm” (Table 2). The urinary catheter device utilization ratio, calculated by dividing the number of indwelling catheter-days by patient days on the same unit, may be adjusted for variables currently reported to NHSN, including hospital demographics, such as size and teaching status, as well as unit type. The CDC is evaluating methods for risk adjustment of the device utilization ratio in an effort to develop a quality metric that may be amenable to interfacility comparisons. These efforts may also facilitate development of target device utilization ratios for different patient care locations. The device utilization ratio provides additional benefits in evaluating the population at risk for device-related infection.<sup>34,35</sup> The current NHSN defined CAUTI rate uses catheter days for a denominator and does not distinguish between a hospital with a low or a high device utilization ratio for the same rate. A unit with a high device utilization ratio may have the same CAUTI rate as one with a lower ratio, despite having more CAUTI events. Finally, the device utilization ratio is easily obtainable from electronic medical records<sup>37</sup> and is less susceptible to reporting bias. The device utilization ratio is the most patient-centered measure (in contrast to being event centered) because it has the potential to evaluate the overall risks to the patient associated with the catheter.

TABLE 2. Infectious and Noninfectious Harms Associated with Urinary Catheters

Immediate Complications	Downstream Consequences
<b>Infectious Complications</b>	
Catheter-associated urinary tract infections (lower urinary tract involvement)	Complicated infection (upper urinary tract involvement, bacteremia)
Asymptomatic bacteriuria associated with inappropriate antimicrobial use	Multidrug-resistant organisms (infection, reservoir, and transmission) <i>Clostridium difficile</i> infection Antimicrobial side effects
<b>Non-infectious Complications</b>	
Trauma	Urethral trauma with insertion or manipulation Hematuria Bladder injury including perforation Pressure ulcers, device related
Immobility (1-point restraint)	Pressure ulcers related to immobility Deconditioning, frailty Venous thromboembolism Falls
Patient suffering	Discomfort, pain Loss of dignity
Societal loss	Increased length of stay Unnecessary resource use

While device utilization provides a global measure of potential catheter harm, it does have limitations. The device utilization ratio does not distinguish between the number of catheter insertions and the duration of catheterization. The risk of urinary tract infection is likely not evenly spread throughout the life cycle of the catheter,<sup>5</sup> with a greater risk the longer the catheter is in place. The incidence of bacteriuria is related to duration of catheter use<sup>38</sup>; for example, the risk of bacteriuria in a patient with an indwelling catheter for 10 days may not be the same as the risk to 5 patients with catheter use of 2 days each. A potential complementary measure, also easily captured using data entered into electronic medical records, is to assess the rate of catheter insertions per patient admission. Furthermore, the device utilization ratio does not predict the proportion of appropriately used catheters, although a reduction over time is likely correlated with improvement.<sup>39</sup> Prior to implementation, evaluation of a proposed risk-adjusted device utilization metric with regard to usability as a quality metric and association with appropriateness is needed.

With all of the changes in the national approach to patient safety, it is important to consider a measure that reflects the multiple risks and harms associated with urinary catheters, including CAUTI. Expanding beyond traditional surveillance that is event-specific to additional performance measures may enable the evaluation of multiple risks to patient harm and is consistent with the statement by Fridkin and Olmsted: "Surveillance systems must be able to evolve in response to ever changing needs of the communities and society they serve."<sup>40</sup> A standardized measure of device utilization can serve as a performance metric that is objective, amenable to electronic reporting, and correlates with risk of both infectious and non-infectious harms associated with the urinary catheter.

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