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Perspective

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The National Healthcare Safety Network's digital quality measures: CDC's automated measures for surveillance of patient safety

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Abstract

Objective: This article presents the National Healthcare Safety Network (NHSN)'s approach to automation for public health surveillance using digital quality measures (dQMs) via an open-source tool (NHSNLink) and piloting of this approach using real-world data in a newly established collaborative program (NHSNCoLab). The approach leverages Health Level Seven Fast Healthcare Interoperability Resources (FHIR) application programming interfaces to improve data collection and reporting for public health and patient safety beginning with common, clinically significant, and preventable patient harms, such as medication-related hypoglycemia, healthcare facility-onset *Clostridioides difficile* infection, and healthcare-associated venous thromboembolism.

Conclusions: The NHSN's FHIR dQMs hold the promise of minimizing the burden of reporting, improving accuracy, quality, and validity of data collected by NHSN, and increasing speed and efficiency of public health surveillance.

Key words: National Healthcare Safety Network; fast healthcare interoperability resources; data modernization; automation; healthcare data exchange; application programming interface; digital quality measure; healthcare-associated infections; patient safety; medication safety.

The National Healthcare Safety Network

The Centers for Disease Control and Prevention's (CDC's) National Healthcare Safety Network (NHSN) is the nation's largest surveillance platform for healthcare event reporting, quality measurement, and public health response, serving over 38 000 US healthcare facilities with data for more than 47 million patients.[1] While ensuring the security, integrity, and confidentiality of data, NHSN enables healthcare facilities to report and to analyze data on healthcare-associated infections (HAIs) and other healthcare events, to share data with clinical and administrative leadership and quality collaboratives, as well as with state and local departments of health, and to meet Centers for Medicare and Medicaid Services (CMS) payment program requirements.[2] The NHSN conducts surveillance for HAIs, antimicrobial use and resistance, vaccination of healthcare personnel, and other healthcare events across a wide range of healthcare facilities, from acute care hospitals to dialysis centers.[3]

NHSN was launched in 2005 to expand upon the National Nosocomial Infection Surveillance System for the purposes of surveilling, analyzing, and reporting actionable data on HAIs.[4] In 2006, NHSN leveraged emerging interoperability pathways to create the first national standard for transmission of public health data from electronic health records (EHRs) via Health Level Seven (HL7) Clinical Document Architecture (CDA) standards.[5] However, challenges remain in timely public health surveillance of healthcare-associated harm. Following identification of a significant patient safety issue or area for quality improvement, today's processes for acquiring actionable healthcare data require years spent to translate measures into computer-readable definitions, to realize implementation of those measures by EHR vendors or third-party applications, and to validate results. In 2020, to address these delays and consistent with the goals of CDC's Data Modernization Initiative to improve electronic exchange and integration between public health and healthcare, NHSN leveraged the newer generation of interoperability standards to further automate data collection via Fast Healthcare Interoperability Resources (FHIR) digital quality measures (dQMs).[6,7] The NHSN's new approach aims to reduce burden of reporting by creating efficiencies in data collection, while simultaneously improving the quality of surveillance by providing patient-level, clinically relevant, and

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complete data for analysis and response. The thrust of this work is to shift the complexity of data curation and interpretation from widely distributed, relatively resource-limited healthcare personnel whose primary mission is patient care, onto centralized public health analysts with access to sophisticated analytic tools for providing risk-adjusted, benchmarked, actionable information back to facilities and decision-makers. This article describes how this approach is being implemented via an open-source FHIR application (NHSNLink), development of FHIR-based dQMs, and supported by a formal and persistent collaborative program for piloting and validation (NHSNCoLab); it concludes with status and remaining challenges.

NHSN FHIR digital quality measures: new measures, new approaches

Currently, surveillance in NHSN relies on a combination of automated and semi-automated EHR reporting.[8] While some healthcare events rely on manual entry of aggregated event rates into the NHSN application by healthcare personnel, other events, such as *Clostridioides difficile* infection events, *Methicillin-resistant Staphylococcus aureus* bacteremia events, as well as antimicrobial use and resistance, can be submitted via HL7 CDA-supported methods from EHR vendors or third-party applications. These methods have improved speed, accuracy, and credibility of patient safety reporting compared to other methods (eg, administrative data-based surveillance).[9,10] Although "electronic" in terms of method of data transmission, this first wave of EHR-based reporting remains heavily reliant on time consuming, manual interpretation of measure definitions and logic. This aspect was highlighted by the COVID-19 pandemic, which presented a significant challenge to data-gathering for all public health surveillance systems: how to radically shorten the time frame for acquisition of data while minimizing the burden of reporting on healthcare entities and maintaining data accuracy and quality.[11,12] Roadblocks to acquiring timely and accurate healthcare event data are known to include long vendor product cycles, reliance on manual data entry (burdensome and error-prone), limited application programming interface (API) deployment, and lack of access by public health to real-time and patient-level (vs aggregated) clinical data. The 21st Century Cures Act requiring adoption of APIs that support data access "without special effort" using HL7 FHIR API-enabled services catalyzed a path forward to automated healthcare data exchange.[13]

The groundwork for FHIR dQM-enabled reporting had been laid by vendors' adoption of standardized terminologies for structured data, supported by growing maturity and uptake of the HL7 FHIR API, and compliance with the Office of the National Coordinator for Health Information Technology United States Core Data for Interoperability (USCDI).[14] Surveillance using FHIR-based dQMs in the NHSN also aligns with CMS' digital measure transformation, including transition from electronic clinical quality measures (eCQMs) to dQMs in quality measurement programs.[15] CMS eCQMs and NHSN dQMs share criteria for evidence-driven measurement and may cover overlapping or identical domains and use cases. However, they differ in data architecture, transmission methods, and generate different levels of patient data (patient-level for dQMs vs summary or aggregate data for eCQMs).[16] In contrast to eCQMs, this second FHIR-based wave of NHSN dQMs are purposefully designed for automation.

NHSNLink: a FHIR application for public health reporting

NHSNLink is CDC's FHIR application for public health reporting to NHSN, published under the Apache 2.0 open-source license.[17,18] Initially piloted to leverage FHIR for access to clinical information on COVID-19 patients,[19] the application is now a permanent, secure application utilized for dQM-based surveillance. Housed behind the CDC firewall, NHSNLink has a multi-component architecture that uses an extensible and configurable query engine to connect NHSN to a healthcare facility's EHR securely via the FHIR API, extract data, and submit it to the NHSN's back-end analytic environment (Figure 1). NHSNLink is accessible to any clinical data application with a FHIR Release 4 (or later) API,[20] irrespective of EHR vendor or third-party application. It builds upon the vendor-neutral principles of NHSN and provides access across the heterogeneous landscape of US healthcare facilities and data sources. Because of its focus on FHIR-based acquisition of data, NHSNLink queries the EHR for the patient census, extracting the data required to calculate the measure for each reporting period. An alternate method where the facility or vendor pushes data to NHSNLink from the EHR is under exploration.

Once securely connected to the facility FHIR API, NHSNLink uses HL7 FHIR quality measure specifications to create a MeasureReport Bundle composed of a patient list and respective FHIR resources for those patients.[21,22] The MeasureReport bundle is then sent to the NHSN application, where the full suite of analytic tools is available for data quality processes and measure calculation, risk adjustment, stratification, and other operations. The measure results are provided back to the healthcare facility or state and local health departments via the NHSN web-based public interface, allowing NHSN users to further analyze and interpret their surveillance data to identify targets for quality improvement and patient safety. This promotes a single, centralized, consistent analytic framework that can be applied and adapted efficiently based on standardized source data. An example of NHSNLink deployment after connecting to the facility EHR is shown in Figure 2.

The design, development, and implementation of NHSNLink adheres to CDC security requirements.[23] As with all NHSN systems, data within NHSNLink are protected by administrative, technical, and physical security controls that safeguard the confidentiality, integrity, and privacy of personal information according to industry-standard policies and federal laws,[24–28] and it has flexible support for secure user access using industry-standard authentication processes.[29,30] Additionally, the FHIR framework supports flexibility in data access, allowing facilities to control data access vis configuration of FHIR endpoints to expose only selected, pre-specified FHIR-resources.

NHSN FHIR digital quality measures

The NHSN has identified 5 initial areas of focus for FHIR dQMs: (1) medication safety, (2) improved HAI definitions, (3) respiratory pathogen surveillance, (4) adult sepsis events, and (5) healthcare-associated venous thromboembolism. Table 1 lists the measures farthest ahead in development and implementation status within the NHSNCoLab.[31] These

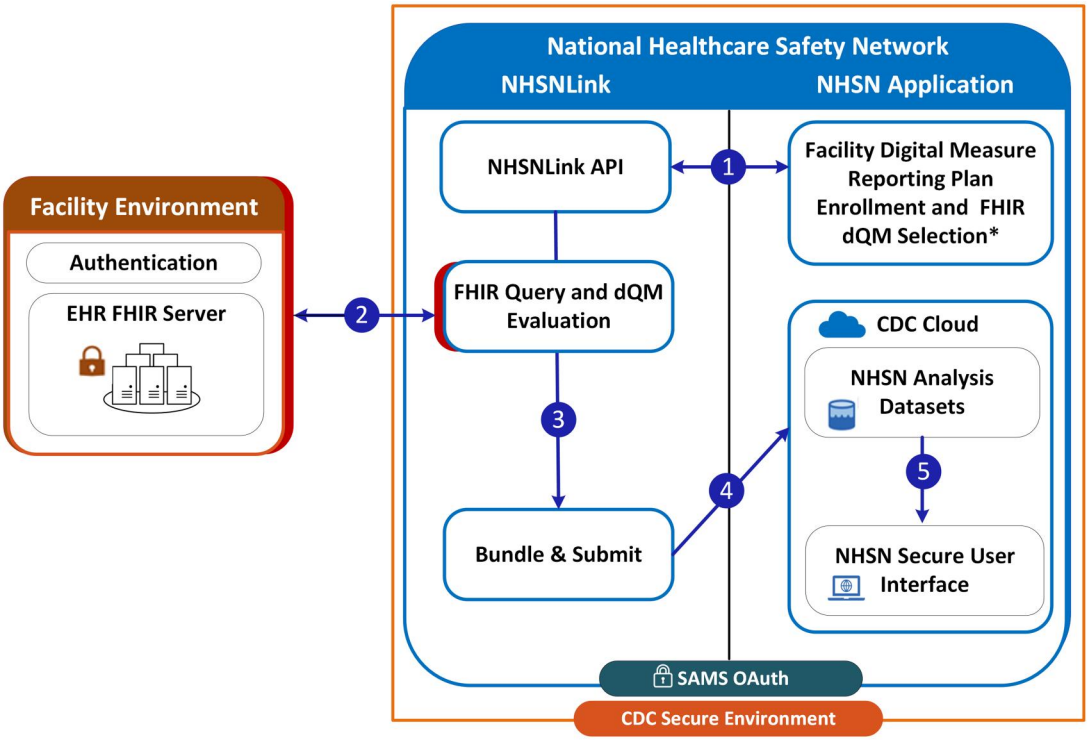

Figure 1. Data flow of NHSNLink, the NHSN application for FHIR digital quality measure reporting. 1. Confirm facility enrollment in digital measure reporting plan; request and receive NHSN FHIR dQM 2. Request and receive patients of interest and query data defined by dQM; 3. Evaluate and filter data as defined by dQM; 4. Submit MeasureReport Bundle for patients meeting dQM definition; 5. NHSN ingests and analyzes MeasureReport Bundle; NHSN makes data reports available via secure NHSN user interface. *Signals facility readiness to report digital quality measure and that facility has signed NHSN data-use agreements for secure data-sharing, including "NHSN Agreement to Participate and Consent" and "NHSN Facility/Group User & Administrator Rules of Behavior."[24,32] Red color represents FHIR API or other secure data exchange endpoint. Abbreviations: API = application programming interface, CDC = Centers for Disease Control and Prevention, dQM = digital quality measure, EHR = electronic health record, FHIR = fast healthcare interoperability resources, NHSN, National Healthcare Safety Network, SAMS = secure access management services.

measures were chosen based on clinical importance, amenability to prevention or quality improvement, feasibility of capture by automated data exchange, and alignment with CMS quality-reporting mandates. Other dQMs under evaluation for development by the NHSN include neonatal late-onset sepsis and meningitis, opioid-associated adverse events, acute kidney injury, patient-level antibiotic use, and antibiotic-associated adverse events.

Each FHIR dQM is developed based on the clinical measure specifications from an NHSN protocol and follows the HL7 FHIR quality measure implementation guides to define the population evaluated for meeting measure criteria.[20,21] The dQM development process maps NHSN protocol concepts to dQM data elements in FHIR resources, building on new and already-existing standardized value sets (eg, NHSN's terminology standard for inpatient locations). Administrative, demographic, and clinical concepts such as medication orders and laboratory results, along with their attributes (eg, date/time a medication was ordered or date/time a lab was resulted), are translated into HL7 Clinical Quality Language (CQL) to create the measure logic (rules that define the measure). The NHSN FHIR dQM is comprised of metadata and CQL required for identification of the measure numerator and denominator, as well as data required to support surveillance (eg, for measure stratification, risk adjustment, or facility benchmarking). An HL7 Implementation Guide to support facility transmission of accurate (eg, using standardized terminologies) and complete (eg, containing all the required FHIR resources) NHSN FHIR dQM data is under development.

NHSNCoLab: alpha and beta deployments

Configuration and deployment of NHSNLink has been alpha and beta piloted at selected healthcare facilities, as part of the NHSNCoLab (Figure 3).[31] The goal of the NHSNCoLab is to support the feasibility and validity of new NHSN measures and innovative approaches to healthcare event data collection. On-going, close collaboration defined by standing institutional agreements accelerates testing and validation, and better integrates NHSN user perspectives into surveillance. At the time of this report, there are 14 health systems participating in the NHSNCoLab that are piloting FHIR dQMs. These facilities are operating FHIR (Release 4 or later) APIs that conform to the US Core standard and that can be used for public health or regulatory reporting. Additionally, the facilities have information technology resources to deploy FHIR APIs, clinical informaticist expertise, and staff with NHSN reporting experience. In alpha piloting, NHSNLink queries the facility's FHIR endpoint in non-Production (eg, Sandbox) EHR environments. This stage tests the interaction between NHSNLink and the EHR, executes the criteria for the patients of interest, and produces a MeasureReport bundle for test patients. In beta piloting, NHSNLink connects to a facility's Production environment to demonstrate the end-to-end feasibility of a complete MeasureReport bundle for real-world patient data, while ensuring authentication and

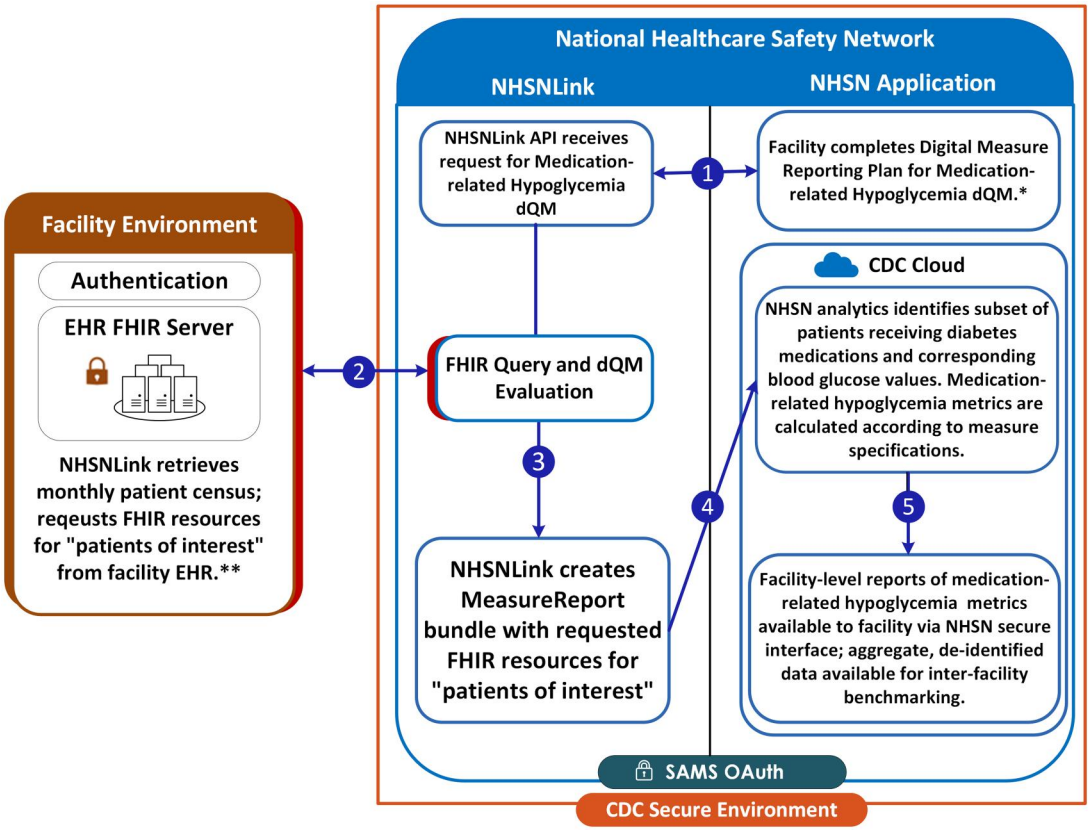

Figure 2. NHSN medication-related hypoglycemia digital quality measure: example of data flow from the healthcare facility EHR to the NHSN user interface. *Signals facility readiness to report digital quality measure and that facility has signed NHSN data-use agreements for secure data-sharing, including "NHSN Agreement to Participate and Consent" and "NHSN Facility/Group User & Administrator Rules of Behavior."[24,32] **Refer to Table 2 for a list of FHIR resources and corresponding data elements requested. Red color represents FHIR API or other secure data exchange endpoint. Abbreviations: API = application programing interface, CDC = Centers for Disease Control and Prevention, dQM = digital quality measure, EHR = electronic health record, FHIR = fast healthcare interoperability resources, NHSN, National Healthcare Safety Network, SAMS = secure access management services.

Table 1. Overview of NHSN FHIR digital quality measures in development, piloting, and implementation stages.

Measure[a]	Description	Measure development status and measure piloting status (EHR environment)
Glycemic control, medication-related hypoglycemia	Various rates of hypoglycemia events (severe, moderate, mild) among hospitalized patients treated with diabetes medications	Measure development completed Alpha Pilot (Sandbox), 2 sites Beta Pilot (Production), 4 sites Anticipated release to early adopters in 2024
Healthcare facility-onset, antibiotic-treated *Clostridioides difficile* infection (HT-CDI)	Various rates of hospital-onset, antibiotic-treated CDI events among hospitalized patients as measured by a combination of laboratory findings and medication treatments	Measure development completed Alpha Pilot (Sandbox), 4 sites Beta Pilot (Production), 2 sites Anticipated release to early adopters in 2024
Hospital-onset bacteremia and fungemia (HOB)	Various rates of hospital-onset bacteremia and fungemia events among hospitalized patients as defined by microbiology findings (irrespective of pathogen or device)	Measure development completed Alpha Pilot (Sandbox), 4 sites Beta Pilot (Production), 2 sites Anticipated release to early adopters in 2024
Respiratory pathogen surveillance (RPS)	Confirmed positive events of influenza, respiratory syncytial virus, or COVID-19 among hospitalized patients	Measure development completed Alpha Pilot (Sandbox), 3 sites
Adult sepsis	Various rates of adult sepsis events and sepsis outcomes	Measure in development Alpha Pilot (Sandbox), 1 site
Healthcare-associated venous thromboembolism (HA-VTE)	Various rates of inpatient VTE prophylaxis and HA-VTE outcome events	Measure in development Alpha Pilot (Sandbox), 2 sites

[a] All measures will be calculated for a 1- to 3-month period, except for respiratory pathogen surveillance, which is planned as a daily measure. In the future, it is anticipated that glycemic control measurement will also include reporting of inpatient hyperglycemia events.
Abbreviations: EHR = electronic health record, FHIR, fast healthcare interoperability resources, NHSN, National Healthcare Safety Network.

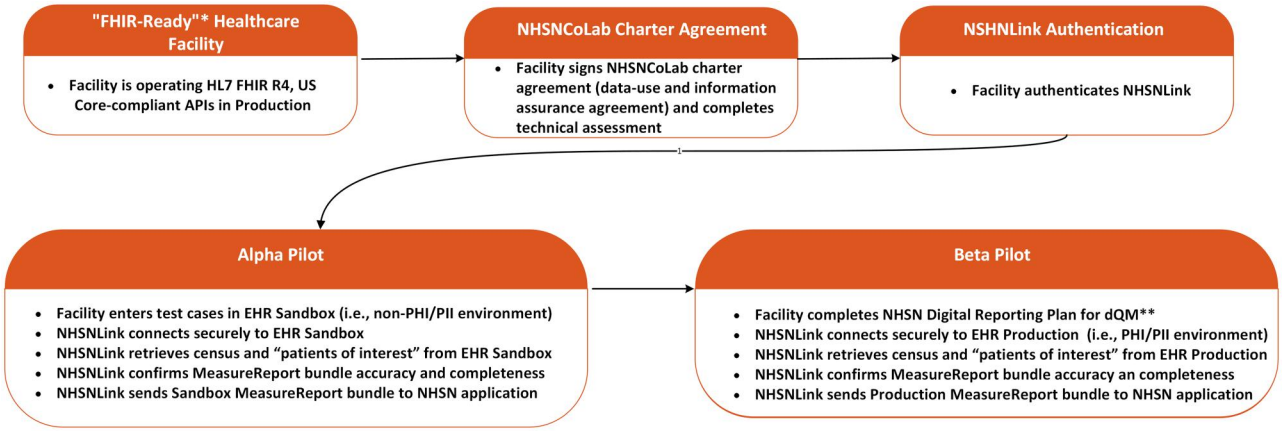

Figure 3. Workflow for alpha and beta deployments of NHSN FHIR digital quality measures within the NHSNCoLab. *"FHIR-Ready" indicates facility is operating HL7 FHIR Release 4 (or later release) and compliant with HL7 FHIR US Core Implementation Guide STU3 Release 3.1.1.[20,21] **Signals facility readiness to report digital quality measure and that facility has signed NHSN data-use agreements for secure data-sharing, including "NHSN Agreement to Participate and Consent" and "NHSN Facility/Group User & Administrator Rules of Behavior."[24,32] Abbreviations: API = application programing interface, dQM, digital quality measure, EHR = electronic health record, FHIR = fast healthcare interoperability resources, NHSN = National Healthcare Safety Network, R4 = Release 4, PHI = protected health information, PII = personally identifiable information.

Table 2. Examples of FHIR resources requested for NHSN FHIR digital quality measure reporting.

FHIR resource	Present in HL7 FHIR US Core profiles?[a]	Example data elements informed by the resources	Data elements requested from the resource[b]
Condition	Yes	Patient's diagnosis list at the time of admission	All
Coverage	No	Patient's insurance coverage	All
Device	No	Implantable devices (eg, central venous catheters) Mechanical ventilation status	All
Encounter	Yes	Patient's encounter with the healthcare facility (eg, emergency department visit or inpatient admission)	All
Location	Yes	Patient's location in the hospital at the time of healthcare event	All
Medication administration	No	Date/time medication was administered	All
Medication request	Yes	Date/time medication was ordered	All
Observation	Yes	Laboratory or microbiology test and result	All
Patient	Yes	Patient demographics (eg, date of birth, sex at birth, gender), race/ethnicity	Selected
Specimen	No	Laboratory or microbiology order	All

[a] Based on HL7 FHIR US Core Implementation Guide STU3 Release 3.1.1.[21]
[b] "All" indicates that all the data elements within that FHIR resource will be initially retrieved by NHSNLink from the EHR. "Selected" indicates that only selected data elements within that FHIR resource will be initially retrieved by NHSNLink from the EHR. Further filtering of data elements occurs during the execution of the dQM logic to select the data elements needed for measure calculation, stratification, and risk-adjustment.
Abbreviations: HL7 = Health Level Seven International, FHIR = fast healthcare interoperability resources, NHSN = National Healthcare Safety Network.

security conditions between NHSNLink and the facility's Production environment.

Data completeness and validation

The list of patients and all requested patient-level data retrieved in the MeasureReport bundle are reviewed manually to ensure the data needed for calculation of the measure are present. This includes ensuring capture of the correct patient population and data elements, conformance to HL7 FHIR specifications, and use of appropriate terminology standards, including, use of standardized value sets rather than local codes to represent data elements such as locations and laboratory values. If all required data are present, the MeasureReport bundle is transmitted to the NHSN application. If required data are missing, the facility is manually notified so that the MeasureReport bundle can be regenerated; automation of this process is planned for future releases. In the NHSN application, the MeasureReport data are validated against NHSN business rules. Future phases of the NHSNCoLab will pilot additional dQMs and establish ongoing processes for validation against primary EHR data sources (eg, clinician medical record review) to ensure the dQMs are providing information that is accurate for national public health surveillance and accountability programs.

Challenges and opportunities

Alpha and beta piloting have identified 3 primary areas for further NHSNLink development. First, the process for patient list acquisition requires further automation and scalability for widespread adoption. In our initial vendor implementation, a request for a list of patients using the FHIR API must be made to define the initial cohort of patients and

builds the list of patients of interest over time; this could be more amenable to automation. Second, some facilities' administrative and clinical data in the FHIR bundle deviates from industry-standard coding, such as use of local codes instead of Logical Observation Identifiers Names and Codes (LOINC), for representing laboratory tests, posing a challenge to data normalization. NHSNLink is exploring use of alternative methods (eg, FHIR ConceptMaps) to translate and normalize local codes into the appropriate standards. Third, NHSN FHIR measures rely heavily on data elements specified in USCDI (Table 2); however, there remain gaps in USCDI that are critical for public health surveillance, especially medication administration, mechanical ventilation, and radiology concepts, which can impede accurate measure calculation.

Conclusion

For nearly 20 years, the NHSN has promoted innovation in patient safety surveillance by measuring risk-adjusted HAI outcomes and other healthcare-associated events via standards-based electronic data exchange. By adopting the newer FHIR data exchange standard and supported by open-source tools, the NHSN dQMs will accrue patient-level data in an automated fashion enabling significant advances in NHSN risk-adjustment and benchmarking of healthcare-associated events. The data elements required for public health and quality improvement should be evaluated continually for inclusion in minimum healthcare data standards defined by USCDI. The NHSN is taking critical steps toward fulfilling the promise of EHR-based automated public health surveillance and rigorously benchmarked quality reporting. With a concurrent commitment from both the private and public sectors to secure information sharing of comprehensive and accurate patient-level data, the industry can achieve fully automated surveillance for healthcare events and continue to drive measurable, positive impact on patient care and public health.

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Author contributions

All authors (Nadine Shehab, Liora Alschuler, Sean McIlvenna, Zabrina Gonzaga, Andrew Laing, David deRoode, Raymund B. Dantes, Kristina Betz, Shuai Zheng, Sheila Abner, Elizabeth Stutler, Rick Geimer, Andrea L. Benin) have met the ICMJE criteria for authorship and contributed to the article in the following areas: made substantial contributions to the conception or design of the work; or the acquisition, analysis, or interpretation of data for the work; and drafting the work or revising it critically for important intellectual content; and final approval of the version to be published; and agreement to be accountable for all aspects of the work in ensuring that questions related to the accuracy or integrity of any part of the work are appropriately investigated and resolved. The findings and conclusions in this report are those of the authors and do not necessarily represent the official position of the Centers for Disease Control and Prevention (CDC).

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Conflicts of interest

The authors have no competing interests to declare.

Data availability

There are no new data associated with this article.

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Perspective