Antibiotic Resistance Information Exchanges: Interim Guidance



Centers for Disease Control and Prevention National Center for Emerging and Zoonotic Infectious Diseases

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Executive Summary

Antibiotic resistance (AR) is a major clinical and public health threat with potential to unravel more than half a century of human health advances offered by modern medical care. Unfortunately, modern healthcare delivery is notably contributory to the spread of antibiotic-resistant organisms, as patients who have become colonized with resistant organisms often receive care across multiple healthcare settings (e.g., ambulatory care, acute care hospitals (ACHs), and various long-term care (LTC) settings, including long-term acute care hospitals (LTACHs) and skilled nursing facilities (SNFs)).

Although the threat of antibiotic-resistant organism transmission from a colonized patient to physically proximate patients remains for the duration of colonization, the lack of information sharing between healthcare facilities often results in the colonized status of a patient being unknown to a receiving or admitting facility. When this occurs, the appropriate infection control precautions are less likely to be used from the start of patient care, which increases the likelihood that resistant organisms will spread to other patients.

The need for improved AR situational awareness is a major challenge to the U.S. Centers for Disease Control and Prevention's (CDC's) strategy to contain the most threatening forms of resistance and the genes responsible for such phenotypes. To fulfill their central role in implementing the CDC's containment strategy, some state health departments have developed systems (Multidrug-Resistant Organism (MDRO) Registries or MDRO Alert Systems, referred to herein as AR Information Exchanges (ARIEs)) that track patients previously colonized or infected with specific MDROs and then alert healthcare providers when these patients are admitted to a facility. The term AR Information Exchange emphasizes the importance of multidirectional information flow amongst healthcare facilities and public health authorities, as opposed to unidirectional data collection and storage. This document provides interim guidance for public health agencies and healthcare facilities developing ARIEs. Ideally, all ARIEs would align with a set of guiding principles and aspire toward interoperability and a standards-based system that benefits all stakeholders. An ARIE should:

- 1. Facilitate the timely sharing of relevant patient, facility, and pathogen information to trigger appropriate action in anticipation of or as soon as possible in a patient encounter.
- 2. Protect health information to maintain patient privacy and data security.
- 3. Minimize the implementation burden by:
 - a. Adhering to a parsimonious, well-defined set of data elements.
 - b. Facilitating interoperability and automating electronic data entry and transmission by aligning with existing data systems, health information technology (IT) standards, vocabularies, specifications, and messaging when possible.
- 4. Incorporate performance and engagement metrics for quality improvement.

CDC recommends that public health professionals leading the development of ARIEs prioritize timely delivery of accurate data to healthcare providers working at the clinical front lines. Timely and actionable AR data delivered when and where it is needed helps prevent the spread of AR. To make progress toward that operational goal, public health agencies can provide technical support, convene stakeholders, garner resources, and lead the charge for solutions that adhere to the guiding principles.

This interim guidance is intended for operational use by individuals and organizations responsible for developing or enhancing an ARIE; however, it does not constitute legal advice. Public health agencies should follow applicable laws, statues, and/or regulations when developing ARIEs with questions about directed to the entity's legal counsel.



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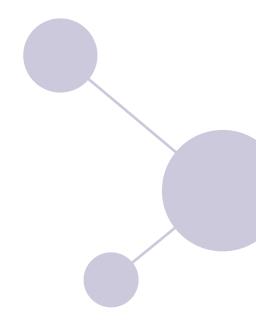
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Acronyms

- ACH Acute care hospital
- ADT Admission, discharge, and transfer
- **ANSI** American National Standards Institute
- APHL Association of Public Health Laboratories
- API Application programming interface
- **AR** Antibiotic resistance
- **ARIE** Antibiotic Resistance Information Exchange
- **ARSTF** Antibiotic Resistance Surveillance Task Force
- **CCD** Continuity of care document
- **CDC** U.S. Centers for Disease Control and Prevention
- CDA HL7 Clinical Document Architecture, Release 2.0
- C-CDA HL7 CDA® Release 2.0 Implementation Guide: Consolidated-CDA Templates for Clinical Notes (U.S. Realm)
- **CFR** Code of Federal Regulations
- **CP** Carbapenemase-producing
- **CRE** Carbapenem-resistant Enterobacteriaceae
- **CSTE** Council of State and Territorial Epidemiologists
- DOB Date of birth
- **DUA** Data use agreement
- eCR Electronic case reporting
- **EHR** Electronic health record
- eICR Electronic initial case reporting
- **ELC** Epidemiology and Laboratory Capacity for Prevention and Control of Emerging Infectious Diseases
- **ELR** Electronic laboratory reporting
- **EMPI** Enterprise master patient index
- EMR Electronic medical record
- EMS Emergency medical services
- ETL Extract/transform/load
- FERPA Family Educational Rights and Privacy Act
- FHIR Fast Healthcare Interoperability Resources
- HHS U.S. Department of Health and Human Services
- **HIE** Health information exchange
- HIPAA Health Insurance Portability and Accountability Act
- **HIO** Health information exchange organization
- HL7 Health Level Seven
- HMD Hierarchical message descriptor

IG	Implementation guide
IP	Infection preventionist
IPC	Infection prevention and control
ІТ	Information technology
LIMS	Laboratory information management system
LIS	Laboratory information system
LTACH	Long-term acute care hospital
LTC	Long-term care
MAR	Medication administration record
MDRO	Multidrug-resistant organism
MPI	Master patient index
MU	Meaningful Use
NND	Nationally notifiable disease
ONC	Office of the National Coordinator for Health Information Technology
PHI	Protected health information
PHIN	Public Health Information Network
PHL	Public health laboratory
PID	Patient identification
RIM	Reference Information Model
SNF	Skilled nursing facility
U.S.	United States
VA	U.S. Department of Veterans Affairs



Background

Multi-drug resistant organisms (MDROs) are an increasing concern in both public health and clinical care. MDROs can spread within and between patients and healthcare facilities and these pathogens are implicated in infections that are difficult to treat. Antibiotic-resistant organisms account for more than 2.8 million infections in the United States each year and more than 35,000 people die as a result.

The Centers for Disease Control and Prevention's (CDC's) antibiotic resistance (AR) containment strategy is designed to slow the spread of novel or rare AR mechanisms through aggressive response to one or more cases of a targeted organism. Effective containment strategy implementation calls for facilities to coordinate care between each other. This coordination includes timely and clear inter-facility communication when patients who are infected or colonized with an AR pathogen are transferred from one facility to another. Such communications enable the receiving facility to ensure appropriate Transmission-Based Precautions are initiated and maintained.

Public health agencies have a central role in coordinating the implementation of the containment strategy. These agencies are well positioned to assist healthcare facilities with early detection and quick actions aimed at thwarting spread of resistant pathogens. Timely provisioning of antimicrobial susceptibility laboratory test results indicative of AR and infection prevention recommendations to facilities and providers are key public health contributions to containment. With timely information exchange and appropriate actions taken, the implementation of the containment strategy can reduce the spread of antibiotic-resistant organisms, protect health-care providers, and improve patient safety.

To support implementation of the containment strategy, some health departments have developed systems (e.g., MDRO Registries or MDRO Alert Systems) that track patients colonized or infected with specific MDROs to alert healthcare facilities when patients with a history of antibiotic resistant infections or colonizations are admitted to the facility. CDC has supported MDRO registries launched and maintained by city, state, and federal partners (e.g., the U.S. Department of Veterans Affairs (VA)) via the Epidemiology and Laboratory Capacity for Prevention and Control of Emerging Infectious Diseases (ELC) Cooperative Agreement and other mechanisms. CDC continues to support some systems via the ELC Cooperative Agreement, and additional jurisdictions have expressed interest in or are already in the process of establishing such systems.

This Interim Guidance on the development and use of AR Information Exchanges (ARIEs) is provided by CDC for public health agencies and healthcare facilities that seek to establish or improve mechanisms for facilitating timely information about patients with MDROs. This Interim Guidance supports the goals of national and agency strategies, including the U.S. National Action Plan for Combating Antibiotic-Resistant Bacteria and CDC's Data Modernization Initiative.^{i,ii}

Public health agencies should follow applicable laws, statues, and/ or regulations when developing ARIEs and questions about applicability should be directed to the entity's legal counsel.

In this document, the term ARIE replaces MDRO Registry, as ARIE more accurately reflects the intended purpose and scope of the system and avoids the suggestion of unidirectional data collection and storage associated with registries. Use of Information Exchange emphasizes the functional importance of multidirectional information flows between healthcare facilities and public health agencies.



Methods

This interim guidance was developed to support CDC's Division of Healthcare Quality Promotion (DHQP) infection prevention and control (IPC) and MDRO containment efforts, including those implemented by health departments.

CDC DHQP reviewed existing MDRO registry (now called ARIE) efforts to determine if and how CDC should guide and support the development of these systems moving forward. Deloitte Consulting was contracted to complete a baseline assessment to provide information on existing systems. Seven jurisdictions and the U.S. Department of Veterans Affairs (VA) /VA Portland Health Care System were interviewed to learn about their capabilities, as well as the use cases that had propelled them to act. The interviews provided information on challenges faced, lessons learned, and other themes applicable to development of ARIEs in other jurisdictions. Additional landscape analyses were undertaken to understand other methods of MDRO tracking, both domestically and internationally, and to provide a depiction of areas where best practice guidance was needed.

These analyses identified several characteristics that are critical for ARIE success, including automation, systems integration, and clear data privacy and use policies. Additional information gathered that informed development of the interim guidance included:

- Pathogens tracked in an ARIE: Jurisdictions tracked different pathogens in their ARIE systems. These variations were driven by state reporting mandates and a desire to track and monitor emerging pathogens before they become endemic.
- Maturity of existing ARIEs: At the time of the analyses, ARIEs were at varying levels of maturity in terms of planning and implementation, indicating the need for interim guidance that could be useful to jurisdictions at varying stages of ARIE development.
- Leading practices: Jurisdictions regularly reached out to each other for guidance on best practices in ARIE development.

The analyses also identified several roles for CDC in supporting ARIE development and implementation, including development of standards and guidance, provision of technical assistance and financial resources, and conducting data analysis and evaluation.

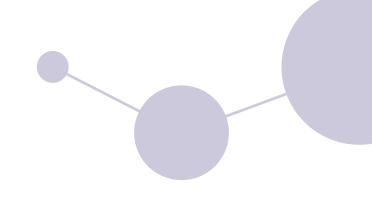
Based on the outcomes of the interviews and landscape analyses, CDC DHQP began development of interim guidance that identified guiding principles for ARIE development and provided information and additional resources that would be useful for both health department leadership and program implementers. A writing committee of subject matter experts from programs across CDC DHQP drafted the guiding principles and supporting content through a collaborative writing process. CDC DHQP leadership were briefed regularly on the development of the interim guidance and provided ongoing feedback on the content. The interim guidance is intended to support HHS, CDC, and DHQP strategic efforts, as noted in the Background section. Development of the interim guidance incorporated expertise and experiences in key areas, including epidemiology, surveillance, information technology, data standards, healthcare delivery system IPC and clinical workflows, policy, communication, and partner engagement, In addition, CDC's Office of General Council reviewed a draft of the document and provided input on protecting health information to maintain patient privacy and data security.

CDC DHQP sought feedback from numerous external partners and stakeholders throughout development of the interim guidance, including state health departments and professional organizations. The partners and stakeholders engaged are listed in the Acknowledgements section and the writing committee is grateful for all who contributed to development of this interim guidance.

In July 2019, CDC DHQP presented a summary of the information gathering and analyses conducted by Deloitte Consulting and shared an early draft of the guiding principles with leadership of the Council of State and Territorial Epidemiologists (CSTE). CDC DHQP continued engagement with CSTE, as well as the Association of Public Health Laboratories (APHL), through the CSTE – APHL – CDC AR Surveillance Task Force (ARSTF). CDC DHQP provided an overview of the ARIE interim guidance to the ARSTF in February 2020 and sought input on the content of the interim guidance from ARSTF leadership throughout the remainder of the drafting process.

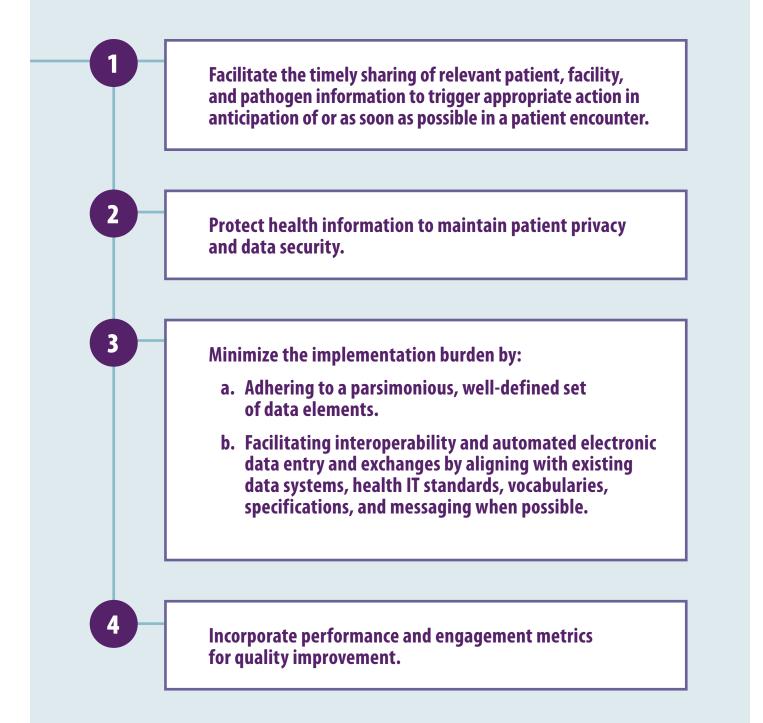
In November 2019, CDC DHQP presented an overview of the draft interim guidance and guiding principles during a breakout session of the 2019 Annual HAI/AR Programs Meeting in Atlanta, GA. The feedback received during that breakout session was incorporated into the document. Additionally, a small group of health department HAI/AR program representatives expressed interested in further supporting development of the interim guidance document; this small group reviewed drafts of the interim guidance and provided invaluable feedback.

The interim guidance document was reviewed through all standard CDC clearance processes, including cross-clearance by CDC's Center for Surveillance, Epidemiology, and Laboratory Services, prior to being made publicly available.



Guiding Principles

This document provides interim guidance for developing and implementing ARIEs. CDC recognizes that a one-size-fits-all approach to developing an ARIE is not feasible given the unique aspects of jurisdictions, including existing systems and infrastructure, the availability of resources, and the ARIE users and stakeholders. Ideally, all ARIEs align with the guiding principles and work toward interoperability and standards-based systems that benefit all levels of stakeholders. An ARIE should:



Facilitate the timely sharing of relevant patient, facility, and pathogen information to trigger appropriate action in anticipation of or as soon as possible in a patient encounter.

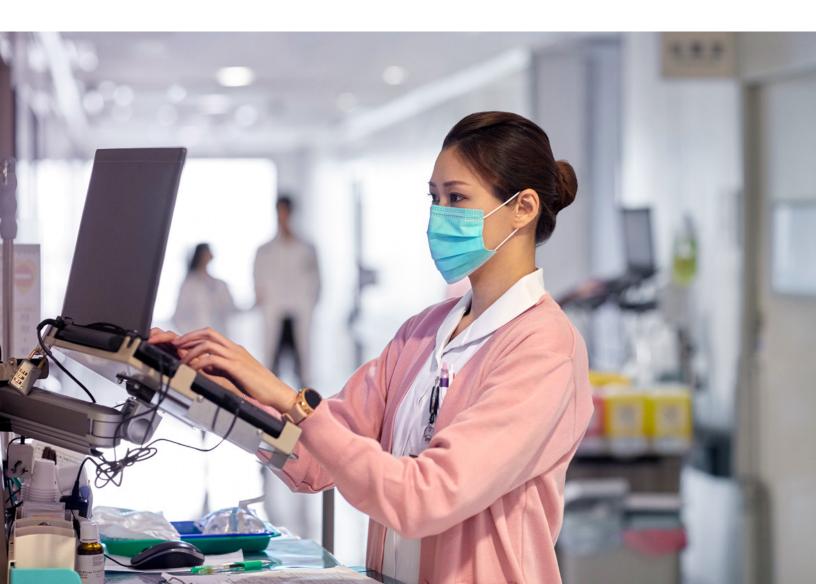
The colonization or infection of a patient with an MDRO is often not identified at the time of healthcare facility admission. A delay in initiating appropriate Transmission-Based Precautions can lead to AR pathogen spread to other patients and staff. Prompt notification and alerting can reduce the spread of MDROs. Therefore, the primary purpose of an ARIE is to capture relevant information to then trigger appropriate action (e.g., implementation of Transmission-Based Precautions, point-prevalence surveys) to contain and treat MDROs.

For example, healthcare facilities implementing specific infection prevention actions when a patient with an MDRO is transferred or admitted to their facility can help to slow or stop spread. ARIE systems administered by public health agencies can mediate an alert or communication to the healthcare facility, where the information can be used to trigger infection prevention safeguards and inform clinical decision-making.

When patients are transferred between facilities, key elements of patient and pathogen information (see Guiding Principle 3) should be delivered to the receiving facility in a timely manner as part of the standard process of health information exchange. Additional information, such as diagnostic microbiology laboratory results provided by public health and other clinical laboratories, could provide significant benefit to facility infection control efforts and clinical decision-making if the information is made readily available to healthcare providers and facilities.

When designing an ARIE, key components and capabilities to consider include AR data source systems, criteria for including or excluding patients and associated AR data, patient matching, event notifications, and data storage. Technological and workflow solutions will vary depending on participating entities' technical capabilities, support staff availability, and adoption of standards for workflows and health IT data. Appendix A provides additional guidance on the technology and workflows needed to support these efforts.

Notifications ideally occur during or within hours of patient admissions and can occur before admissions, for example during pre-admission evaluation (e.g., while patient is in the emergency department or an ambulatory setting). An ARIE that cannot routinely achieve notification within 24 hours of admission would not be sufficient.





Protect health information to maintain patient privacy and data security.

Meticulous handling of each patient's protected health information (PHI) is a primary concern of the ARIE. Therefore, adhering to all applicable laws (e.g., the Health Insurance Portability and Accountability Act (HIPAA) Privacy Rule and the Family Educational Rights and Privacy Act (FERPA)) related to patients' privacy and data security is vitally important.^{III,IV}

The HIPAA Privacy Rule sets the standards for who has access to PHI and generally requires that covered entities limit the use of PHI to the minimum necessary to accomplish the intended use of preserving and protecting the patient's and the public's health. Covered entities in the context of an ARIE include healthcare providers (e.g., laboratories, clinics, and other healthcare facilities).

ARIEs can utilize health information exchanges (HIEs) / health information exchange organizations (HIOs) as part of their infrastructure. HIEs can be run by a state, regionally- or community-based, private/ proprietary, or hybrids. The HIPAA Privacy Rule implications vary based on the status of a HIE. CDC recommends ARIE developers and users ensure all security requirements for the ARIE comply with appropriate federal and state laws governing information exchange in the HIE.

If an ARIE serves as a repository for storing and maintaining records rather than simply providing access to view records maintained by a source organization, CDC recommends development of policies regarding ownership and retention of the ARIE's data.

CDC recommends public health agencies and healthcare facilities consult with their entity's legal counsel to review plans for any ARIE. Additional resources regarding access and administration, data sharing, and data use agreements (DUAs) can be found in Appendix D.

Access and Administration

The federal privacy rule addresses who should have access to PHI, and the HIPAA Security Rule focuses on access controls to ensure only those who should have access are granted access. Administrative, technical, and physical safeguards are all required for compliance with the rule.^v ARIEs are operated and managed by regional, state, or local public health agencies; it is incumbent on those agencies to develop jurisdiction-specific systems and processes for authenticating ARIE users and limiting ARIE access to authorized users. ARIE operators should not use access credentials issued by systems outside their jurisdiction, such as a federal system, as a proxy method of establishing user credentials for their ARIE.

Data Collection and Data Use Agreements (DUAs)

Data sharing between ARIEs can add value within a single public health jurisdiction but calls for close attention to the legality of sharing PHI and steadfast assurances that data are securely transacted. Data sharing permissions and limitations are likely to vary from jurisdiction to jurisdiction and warrant careful analysis before implementing data exchanges between ARIEs. One suggested best practice is to obtain DUAs with relevant jurisdictions or users. ARIEs should consider patient flow volume (e.g., the number of patients that move across jurisdiction lines for care) when deciding whether and with whom to engage in a data sharing agreement. Another consideration is laboratory data system technical capabilities in adjacent jurisdictions that are necessary for effective and secure data exchange. Depending on jurisdiction-specific privacy regulations, jurisdictions can also consider connecting their information to another jurisdiction's ARIE instead of building their own.

3a. Adhere to a parsimonious, well-defined set of data elements.

ARIEs need a basic set of data elements to track patients, MDROs, associated conditions, and healthcare facility utilization. The minimum data elements recommended for a functional ARIE suggested in this interim guidance were selected from the United States Core Data for Interoperability (USCDI) as well as critical data elements needed for containment and outbreak response.^{vi,vii} These data are present in the Health Level Seven (HL7) Clinical Document Architecture (CDA)[®] R2 Implementation Guide: Consolidated CDA Templates for Clinical Notes – United States as well as the HL7 CDA[®] R2 Implementation Guide: C-CDA R2.1 Supplemental Templates for Infectious Disease, Release 1, STU 1 – US Realm.^{viii} These supplemental infectious disease templates were developed to standardize interfacility communications and make data more readily available to prevent the spread of MDROs.^{ix} Please see Appendix B for additional details on document exchange standards in use in healthcare IT.

The minimum recommended data elements listed to the right are a subset from these documents. The minimum recommended data should be sufficient to facilitate accurate patient matching, facility identification, and pathogen identification. Additional details are provided in Appendix B.

Appendix B lists optional data elements that could be included to provide additional information that might inform inter-facility communication, patient care, and public health. These optional elements are not necessary for a basic ARIE but are recommended to assist in making clinical decisions or informing public health. Minimum recommended data elements for patient, facility, and MDRO identification:

- Name
- Date of birth (DOB)
- Sex
- Address
- Phone number
- Unique patient ID
- Event type (patient movement (admission, discharge, or transfer) and/or new MDRO identification)
- Facility name (facility with the current encounter) of triggering event
- Facility address (facility with the current encounter) of triggering event
- MDRO (e.g., name of organism and type/category of resistance)¹
- Mechanism of resistance²
- Specimen collection date corresponding to first positive laboratory result
- Specimen collection date corresponding to most recent positive laboratory result^{3,4}
- 1 This is the data element that qualifies a patient's entry into the registry. If patient is infected or colonized with more than one MDRO, the information should be provided for each MDRO.
- 2 Mechanism of resistance as a required data element may depend on the specific MDRO. For example, some MDROs are only considered a public health threat requiring containment if resistant by a specific mechanism (e.g., carbapenemase-producing *Pseudomonas aeruginosa*). Mechanism of resistance is a recommended data element if only some MDRO genotypes are under surveillance.
- 3 Date of most recent isolation of MDRO in question.
- 4 The date of first and last positive laboratory result would be the same if there is only one result to report.





3b. Facilitate interoperability and automated electronic data entry and exchanges by aligning with existing data systems, health IT standards, vocabularies, specifications, and messaging when possible.

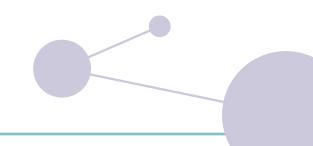
The availability of electronic clinical and laboratory data in standardized, electronic form facilitates information exchange tasks associated with ARIE operations, including record searches, data analysis, and data quality control. Standardized data also assist with automation scripts, patient record matching, and interoperability with outside data systems. Aligning with existing data systems, health IT standards, standard terminologies, and message specifications is necessary to support interoperability and automation of electronic data entry and transmission in ARIEs.

When a functional health information exchange (HIE) is available and accessible, it may enable ARIE integration with existing healthcare information systems such as laboratory information systems (LISs) and electronic medical record (EMR) systems. ARIEs connected to an HIE can leverage existing infrastructure, workflows and user agreements and avoid duplicative user interfaces and platforms, which can interfere with clinician workflows.

Automated data feeds into the ARIE and automated alerts are key usability features. While start-up efforts often rely on manual data entry, migrating to automated data feeds can increase performance, timeliness of data delivery, user satisfaction, and capacity of an ARIE. Additional information about source systems and alerting is available in Appendix A. Avoiding stand-alone ARIE development is a pragmatic strategic objective. Regional interoperability can enhance inter-facility communication regarding patients with MDROs. This is especially valuable for jurisdictions that have a constant flow of patients seeking care across jurisdictional borders. When developing an ARIE, existing infrastructure (e.g., regional HIEs), needs to be evaluated for feasibility as partners. DUAs, as discussed in section 2, would be pursued as appropriate. Appendix B highlights the main components of an ARIE to facilitate interoperability.

Standard Infection Definitions

National and jurisdictional reporting requirements, as well as local, state, and regional epidemiology data, are key factors to consider when deciding which MDROs to track in an ARIE. This includes case definitions and criteria specified for reporting. CDC and CSTE are two common sources for standard definitions.



Assessing Functionality and Accuracy

The clinical and public health priority placed on curbing AR transmission in healthcare facilities, coupled with the resource commitment to build and maintain an ARIE, place a premium on systematic assessment of ARIE function. ARIE architects, developers, and implementers would benefit from employing a continuous quality improvement plan, with at least annual assessment, that identifies opportunities to improve exchange performance and implementation early, plan for improvements, and execute these improvements. Optimally, quality assessments for program improvements and metrics should be established before ARIE development begins, and the metrics should be a mainstay of quality assessment and improvement throughout the duration the ARIE is operational. Domains of assessment include:

- 1. Functionality and Accuracy
 - a. Assess the initial build for core functionality and accuracy in exchanging patient infection or colonization status from an identifying facility (i.e., facility in which patient colonization status was detected) to an admitting facility, with accurate delivery of minimum data elements.
 - b. Determine proportion of infected or colonized patient transfer or admission events that are accurately reported across each of the minimum data elements.
- 2. Data Protection
 - a. Perform regular security scans, audit log reviews, and system vulnerability assessments for vulnerabilities.
 - b. Encrypt data at rest as well as in transit.
- 3. Burden
 - a. Assess the time required to perform any manual processes of reporting into the exchange or accessing information from the exchange.
- 4. Utilization of the Exchange
 - a. Review the proportion of all MDRO-infected or -colonized patient transfers or admissions, as determined by health record audit, that are reported into the exchange, along with the proportion of exchange-reported events accessed by receiving/admitting facilities (see Appendix C).
- 5. Timeliness
 - a. Determine the time after admission or transfer receipt by which MDRO infection or colonization status becomes accessible to receiving facility.
 - b. Determine the time after admission or transfer receipt by which an order for appropriate Transmission-Based Precautions is placed at a receiving facility.

Data Analysis and Delivery

Producing reports or information from the data available in an ARIE serves a variety of purposes. These reports can provide timely updates of specified information at the facility and public health levels. Data analysis of the ARIE and data delivery can improve the visibility of MDRO detection, identify potential outbreaks, serve as measures of MDRO burden on healthcare facilities, provide actionable feedback to facilities, and enable assessments of prevention and treatment methods. Robust reporting and feedback to facilities enables health departments to strengthen their communication and relationships with healthcare facilities, as well as facilitate future innovation, research, and prevention opportunities. Appendix C lists some sample report types.



Appendix A. Components and Capabilities to Consider Supporting an ARIE

Source Systems for an ARIE and Populating the Registry

Primary data source feeds for an ARIE include laboratory information systems (LIS), laboratory information management systems (LIMS), public health laboratories (PHLs), public health surveillance systems, EMRs, other clinical records, and/or HIEs.

Some relevant results, primarily from commercial laboratories, may be distributed through electronic laboratory reporting (ELR). ELR implementation may vary, especially in hospital laboratories with onsite diagnostic microbiology. EMRs and HIEs have increased their ELR adoption with meaningful use (MU) incentives but not all hospitals have ELR in production. Therefore, to ensure adequate coverage of both inpatient and outpatient facilities both ELR- and EMR- (or HIE) sourced data may be required in some jurisdictions.

Source systems will send results and messages to an event or encounter notification service provider, a function which may be performed by the ARIE itself or a regional HIE. The message specifications (including requirements for specific data fields) are legislated by individual territories and states.^{x, xi} Additional data sourced from clinical documentation in EMRs may provide value to stakeholders (see Appendix B).

A central master patient index (MPI)⁵ of patients colonized or infected with an MDRO included within a jurisdiction would be used. The MPI is foundational for identity integrity at the individual patient level. If facilities in a region use an existing HIE they should consider use of an MPI. Patient identifiers on incoming messages can be compared to this MPI to determine if there is a match to an existing patient or if a new patient needs to be added. If there is a match, the record is updated to reflect new results and/or patient facility transitions. If there is no match for a positive result, then a new patient record may be created. In either scenario, based on system requirements, an alert may be generated. See Appendix B for more details about managing patient identification.

Notification of an Eligible Event

Health conditions for which data are included in an ARIE should be defined by the public health agency responsible for the ARIE. Conditions included are likely to reflect reporting laws, statutes, and/or regulations, as well as local, state, and regional epidemiology.

Timely and accurate alerts and results management are key elements of ARIE functionality that support inter-facility communication and public health activities. Alerts are ideally automated and targeted to the correct care team, including the infection prevention staff, for a given patient and facility. Alerts can provide varying levels of detail and automated alerts are triggered when an eligible event occurs. An admission, discharge, transfer (ADT)⁶ notification and/or applicable ELR laboratory reportable result created by the admitting and/or discharging facility EMRs or laboratory LIS is sent securely to an event notification service provider for processing. This function could be provided by the ARIE or a regional HIE/HIO could play this role.

Triggering an Alert

The trigger to populate the ARIE and generate an alert may be a positive MDRO laboratory result and/or an ADT event at a participating facility. It should be noted that some facilities (and HIEs) do not have real-time laboratory and/or ADT information exchange and, instead, they send a daily batch feed, which will impact the timing of alerts.

Alerts can be delivered in a variety of secure ways with varying degrees of detail. Collaboration with laboratories, healthcare facilities, and providers is essential to ensure alerting and information retrieval integration into the workflow of staff responsible for managing alerts and results. Proper routing of alerts is critical for patient safety, as well as containment and response efforts.

Facilities may receive and manage electronic alerts in a variety of ways depending on their workflow needs. Alerts may be "asynchronous" (i.e., in-box type format), managed by staff members not involved in direct patient care, and be processed as a batch (e.g., a nurse managing messages for an entire cohort of patients). Alerts can also be in context and targeted to specific healthcare providers, "synchronous" with clinical care (e.g., an alert that is displayed to a provider while placing orders on a specific patient). Healthcare facilities utilizing off-site commercial laboratories (with non-integrated LISs) may have different needs from healthcare facilities with onsite microbiology and fully integrated EMRs with LISs.

⁵ A registry, database, or list of individual patients in a healthcare record system, HIE, or another database/registry.

⁶ An event that occurs when a patient is admitted to a facility, discharged from a facility, or transferred from one facility to another. An ADT notification is an electronic notification of an ADT event.

Regardless of the approach used to implement an ARIE, key activities for healthcare facilities and public health agencies that receive alerts include: review of alerts for accuracy; result review and accept if appropriate; documentation in the receiving medical record as appropriate; and facilitation of appropriate outreach and action. Collaboration between public health agency staff, healthcare facilities and providers, and other stakeholders is critical.

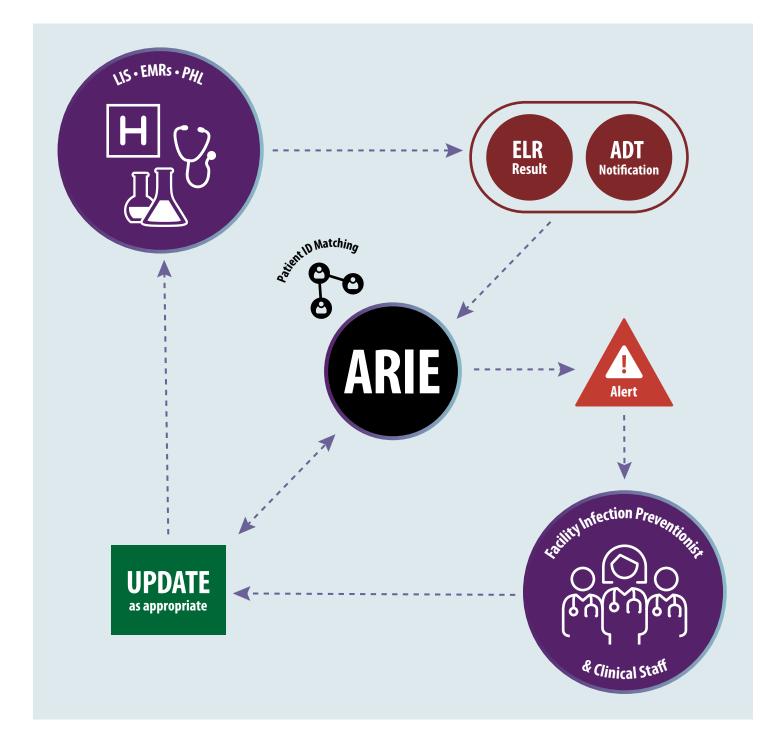
A simple notification of a possible match is one possible implementation approach. The infection preventionist (IP) at the facility receives a message containing no PHI, such as: "A patient

Figure 1. Examples of Information Flow in an ARIE.

admitted in the past (x) hours is a potential match. Please review the ARIE." Match notifications trigger additional actions such as patient match verification and results viewing through secure delivery.

More advanced system-to-system integration and implementation could provide patient level, in-context alerts and/or results viewing and delivery into the receiving EMR, visible to both providers and infection control personnel.

A high-level example of how information could flow in an ARIE is displayed in Figure 1.



Appendix B. Data Requirements

Optional Data Elements

Listed below are optional data elements that can inform inter-facility communication, patient care, and public health action. These data elements are not necessary for a basic ARIE but could assist in making clinical decisions or informing public health.

- Patient information
 - Medication allergies
 - Race
 - Ethnicity
 - Preferred language
 - Sex
- Patient travel history
 - Last date of travel outside of the United States (including country(ies) visited)
 - Last date the patient received healthcare outside the United States (including which country(ies))
- Past infectious diseases
 - Past infectious disease diagnosis⁷
 - Past infectious disease diagnosis date
- Current Diagnostic information
 - Diagnosed infectious condition(s)⁸
 - Date(s) of diagnosis(es)
- HAI information
 - Does the patient have a healthcare-associated infection? (Y/N)
 - Is the patient on Transmission-Based Precautions?
 - If yes, what type of precautions?
- Pathogen information
 - Specimen source⁹
 - Phenotype¹⁰
 - Genus and species name
 - Current pathogenic carrier state (e.g., infected versus colonized)
- Diagnosing laboratory information
 - Laboratory reporting the MDRO
 - Date(s) of specimen collection

- Treatment information
 - Antibiotic(s) indication
 - Antibiotic(s) start date
 - Antibiotic(s) dosage
 - Antibiotic(s) route of administration
 - Antibiotic(s) intended duration
 - Facility information
 - For all relevant facilities (e.g., admitting, transferring, discharging, ambulatory): Name, address, unit number, phone number, unique facility ID, and point(s) of contact
- Procedures
 - Procedures¹¹
 - Current or recent invasive medical device
 - Location of invasive medical device

ARIE HL7 Document Specifications

Healthcare data exchange standards undergird EMR interoperability. The HL7 Clinical Document Architecture, Release 2.0 (CDA® Release 2 (R2)) is a document exchange standard that is the most widely used for clinical documents in healthcare. It is a flexible standard that is both human and machine-readable. C-CDA is a specific Implementation Guide (IG), built on CDA R2, that includes a variety of documents intended for use by U.S. EMRs for exchange of data. Electronic case reporting to public health using the electronic initial case report (eICR) utilizes a CDA format. There are many CDA IGs, many of which are public health related that are built on CDA, and reuse parts of C-CDA (including eICR) but are not considered part of C-CDA. A subset of CDA IG's are intended to be Supplements to C-CDA. These IG's are consistently identified by HL7 as: HL7 CDA® R2 Implementation Guide: C-CDA R2.1 Supplemental Templates for [X] where X is the subject area. The Infectious Diseases IG identified in section 3a is one such supplement to C-CDA. Developers of an ARIE are encouraged to determine which C-CDA document types their participating facilities have implemented as they design their information exchange.

- 7 See HL7 CDA® R2 Implementation Guide: C-CDA R2.1 Supplemental Templates for Infectious Disease, Release 1, STU 1 US Realm. Section 3.20 Past Infectious Disease Diagnosis.
- 8 Related to the MDRO in question (may need to pull the most recent diagnosis code stream). See HL7 CDA® R2 Implementation Guidance: C-CDA R2.1 Supplement Templates for Infectious Disease, Release 1, STU 1 – US Realm. Section 3.10 Infection Disease Sign/Symptom for implementation guidance. This template is based on the C-CDA Problem Observation Template.
- 9 Consider instituting a standardized set of sources for mapping.
- 10 Resistance that defines the MDRO.
- 11 SNOWMED-CT codes for high-risk procedures relevant to MDRO in question (e.g., duodenoscopy).

Newer standards and resources (such as Fast Healthcare Interoperability Resources (FHIR)) are used increasingly and many vendors and health systems are rapidly adopting FHIR today. Within the HL7 Standards development community, most new standards development activity is occurring within the FHIR standard, not the older Version 2 and CDA standards. Broad efforts are underway, spearheaded by public and private organizations, to encourage the use of FHIR in the United States. As part of the Cure's Act Final Rule, the Office of the National Coordinator for Health Information Technology (ONC) has identified HL7 FHIR as the application programming interface (API) solution EHR's must adopt for certification purposes. In the Centers for Medicare & Medicaid Services Interoperability and Patient Access final rule, HL7 FHIR has also been identified as the technical standard for patient API's and many payer/provider interactions. As evidenced, regulatory authorities at the national level are driving the healthcare industry towards broad adoption of FHIR.

As ARIE developers design their systems and future roadmaps, the capability to use FHIR resources should be strongly considered. ARIE developers are encouraged to collaborate with submitting facilities and plan for any future upgrades to their source systems which may enable additional functionality. Since it is widely used by healthcare organizations in the United States and internationally, HL7 has committed to ongoing maintenance support (such as errata, technical corrections, and minor updates) of CDA and Version 2 even as FHIR rapidly expands in adoption.^{xii} Use cases for new HL7 Implementation Guides should focus on the use of FHIR instead of CDA or Version 2 standards.^{xiii}

Patient Matching

Accurate patient matching and facility identification is a critical component of any health IT system. Without proper matching, incorrect records can be viewed, redundant records created, improper decisions made for individual patients, and under- or over-representation of cases in public health analysis can occur. Patient record matching is challenging and becomes much more complex as multiple stakeholders are networked and sharing information across a larger geographic footprint to support a jurisdiction's ARIE. Although ARIEs may contain a relatively small population of patients in each jurisdiction, they may receive ADT messages requiring evaluation for a patient match from many local facilities representing all ADT events. To partially mitigate this risk, best practices include development of a robust patient matching process.

National data element standards and best practice workflows have not been established for patient matching in healthcare IT. Currently, HIO/HIEs and EMRs use various solutions and techniques such as basic algorithms (name, sex, and DOB) to advanced statistical models. Data requirements for suitable matching may vary by region. Cultural and geographical variation may impact the stability of data attributes. Rural areas have reported address and phone number to be more reliable than urban providers.^{xiv} The HL7 patient identification (PID) segment is found in all ADT messages and is used for applications as the primary source for patient identification. The PID segment can include up to 30 different fields including patient sex, address, and an option for a patient ID. Similarly, HL7 v2.3.1 and 2.5.1 messages supporting ELR contain a PID message segment which contains patient identifying and demographic information.

Healthcare organizations use a variety of methods and technologies to manage their MPI and may vary in their ability to automate a patient match when receiving an incoming message. Some facilities will have cross-platform solutions (e.g., enterprise master patient index (EMPI))¹²capable of managing patient identification and information exchange with external systems (e.g., HIEs, external laboratories, and public health agencies). Since demographic data can be outdated, incomplete, or incorrect there will often be a list of records that do not match and will require an MPI clean up.

When developing a patient matching algorithm, receiving and sending system requirements need to be considered, and users should ensure they outline not only the necessary data elements but also the workflow and staffing requirements to consistently and accurately match patients. Developers are encouraged to review published frameworks for cross-organizational patient identity management.^{xv}

ARIE Interoperability

Components of an ARIE that facilitate interoperability include:

- Minimum recommended data elements: These elements are the foundation of information needed for a functional ARIE to ensure patient, facility, and pathogen identification.
- Standard infection definitions: Epidemiologists in public health agency infectious disease programs are authoritative sources on definitions in use in their jurisdictions.
- Bidirectional data flow with triggered alert capabilities (ELR and/or LIS, EMR (or HIE) integration): ARIEs should evaluate the extent that ELR is utilized by inpatient facilities in their region and consider the need for both ELR and EMR sourced data. An ADT data feed from regional facilities will enable tracking of patient movement and enable jurisdictions to receive timely MDRO matches and alerts. Standardization across jurisdictions will reduce the amount of education needed to onboard users to the ARIE.
- Use of HL7 messaging and document standards: Standardization of document types and messaging in the ARIE will enable integration with LIS, HIEs, EMRs, and neighboring jurisdiction ARIEs.
- Data access controls and patient matching standards: A standard level of security and patient matching across jurisdictions may assist in DUAs and jurisdiction agreement with sharing data. In some scenarios, neighboring jurisdictions may consider using the same user authentication service to reduce the number of login credentials for users.

¹² A unique number issued by the health institution to its various facilities and their information systems to enable access to patient's information across facilities' information systems.

Appendix C. Sample Report Types

Sample ARIE report types include:

- Number of new MDRO cases
 - Frequency: weekly or monthly
 - Potential uses
 - Helps both healthcare facilities and public health departments understand MDRO burden and trends
 - Could identify an outbreak
- Matching
 - Frequency: as needed
 - Potential uses
 - Identifies potential matches between patient records
 - Used for manual review and confirmation/rejection of proposed matches
- Performance report
 - Frequency: weekly or monthly
 - Content may include:
 - Number of alerts sent
 - Number of alerts confirmed received
 - Number of alerts sent but not confirmed
 - Facilities with alerts not confirmed
 - Number of patients put on contact precautions
 - Percent of new cases identified and alerts sent within 24 hours

Appendix D. Additional Resources and Tools

Background

Containment Strategy Responding to Emerging AR Threats (<u>https://www.cdc.gov/hai/containment/index.html</u>)

Multidrug-resistant Organisms Management (https://www.cdc.gov/infectioncontrol/guidelines/mdro/index.html)

Guiding Principle 1: Facilitate the timely sharing of relevant patient, facility, and pathogen information

Laboratory Capacity: Antibiotic Resistance Laboratory Network (AR Lab Network) (https://www.cdc.gov/drugresistance/solutions-initiative/ar-lab-network.html)

Electronic laboratory reporting (ELR): ELR is a generic term referring to several formats for laboratory reports for reportable conditions transmitted electronically from laboratories to public health departments or between public health departments. ELR formats include the following:

- Laboratory reporting via HL7 2.3.1 or 2.5.1 compliant messages.
- Web-based entry from the laboratory into a public health system. Reports entered manually by public health departments are not considered to be ELR.
- Proprietary extract/transform/load (ETL) processes that automatically move data from a laboratory system to a public health system.
- In addition to the public health benefits, eligible hospitals that use ELR to fulfill public health requirements for MU receive financial incentives if they successfully attest under Stage 1 or Stage 2.

Guiding Principle 2: Protect health information to maintain patient privacy and data security

The Office for Civil Rights has oversight and enforcement responsibilities for the Privacy Rule. This website contains the text of the HIPAA Privacy Rule, comprehensive guidance, and answers to hundreds of questions:

Office for Civil Rights (<u>https://www.hhs.gov/ocr/index.html</u>)

CDC and the U.S. Department of Health and Human Services (HHS) published guidance on the HIPAA Privacy Rule and public health:

 HIPAA Privacy Rule and Public Health: Guidance from CDC and the U.S. Department of Health and Human Services (https://www.cdc.gov/mmwr/preview/mmwrhtml/m2e411a1.htm)

HIPAA disclosure for public health activities:

Office of Civil Right HIPAA Privacy: Disclosures for Public Health Activities (<u>https://www.hhs.gov/sites/default/files/ocr/privacy/hipaa/un-derstanding/special/publichealth/publichealth.pdf</u>)

HIPAA frequently asked questions:

- HIPAA FAQs for Professionals (<u>https://www.hhs.gov/hipaa/for-professionals/faq/index.html</u>)
- May covered entities disclose facially identifiable protected health information, such as name, address, and social security number, for public health purposes? (<u>https://www.hhs.gov/hipaa/for-professionals/faq/296/may-covered-entities-disclose-facially-identifiable-protected-health-information/index.html</u>)

Modifications to the HIPAA Privacy, Security, Enforcement, and Breach Notification Rules Under the Health Information Technology for Economic and Clinical Health Act and the Genetic Information Nondiscrimination Act; Other Modifications to the HIPAA Rules (<u>https://www.federalregister.gov/documents/2013/01/25/2013-01073/modifications-to-the-hipaa-privacy-security-enforcement-and-breach-notification-rules-under-the</u>)

Guiding Principle 3: Minimize the burden of implementation and use

HL7 Version 2: HL7's Version 2.x (V2) messaging standard is in the clinical domain and is widely implemented. This messaging standard allows the exchange of clinical data between systems. It is designed to support a central patient care system as well as a more distributed environment where data resides in departmental systems. Note: Nationally notifiable disease (NND) guidance aligns to HL7 v2.5 as outlined in the Public Health Information Network (PHIN) specification document. See Appendix Information Sources for reference URLs.

- For overview information: HL7 International (<u>http://www.hl7.org/</u>)
- HL7 Version 2 Product Suite (http://www.hl7.org/implement/standards/product_brief.cfm?product_id=185)

HL7 Version 3: The Version 3 Normative Edition represents a new approach to clinical information exchange based on a model driven methodology that produces messages and electronic documents expressed in XML syntax. The V3 specification is built around subject domains that provide storyboard descriptions, trigger events, interaction designs, domain object models derived from the Reference Information Model (RIM), hierarchical message descriptors (HMDs), and a prose description of each element. Implementation of these domains further depends upon a non-normative V3 Guide and normative specifications for: data types; the XML technical specifications or message wire format; message and control wrappers; and transport protocols.

HL7 Version 3 Product Suite (<u>http://www.hl7.org/implement/standards/product_brief.cfm?product_id=186</u>)

HL7 Version 3 Clinical Document Architecture (CDA): The HL7 Version 3 Clinical Document Architecture (CDA®) is a document markup standard that specifies the structure and semantics of "clinical documents" for the purpose of exchange between healthcare providers and patients. It defines a clinical document as having the following six characteristics: 1) persistence, 2) stewardship, 3) potential for authentication, 4) context, 5) wholeness, and 6) human readability. A CDA can contain any type of clinical content. Typical CDA documents would be a discharge summary, imaging report, admission and physical, pathology report, and more. The most popular use is for inter-enterprise information exchange, such as is envisioned for a U.S. HIE.

CDA® Release 2 (<u>https://www.hl7.org/implement/standards/product_brief.cfm?product_id=7</u>)

Consolidated-Clinical Documentation Architecture (C-CDA): Defines a set of CDA documents. The HL7 Consolidated CDA is an IG which specifies a library of templates and prescribes their use for a set of specific document types.

 C-CDA (HL7 CDA® R2 Implementation Guidance: Consolidated CDA Templates for Clinical Notes – US Realm (http://www.hl7.org/implement/standards/product_brief.cfm?product_id=492)

HL7 Fast Healthcare Interoperability Resources (FHIR): The newest version of HL7 provides another option for representing and exchanging clinical content as either XML or JSON (JavaScript Object Notation syntax) objects. FHIR is built around the concept of resources which are basic units of interoperability are defined for most clinical content and can be assembled with as much or as little as is needed to fulfill a particular use case. While FHIR is simpler to use than any other data representations, it is not widely in use and still needs to be consistently deployed among data trading partners to ensure compatibility.

- HL7 FHIR Release 4 (http://www.hl7.org/implement/standards/fhir/)
- Project Summary for FHIR Electronic Case Reporting (eCR) (http://www.hl7.org/special/Committees/projman/searchableProjectIndex.cfm?action=edit&ProjectNumber=1366)

Reference Information Model (RIM): The RIM is the cornerstone of the HL7 Version 3 development process. An object model created as part of the Version 3 methodology, the RIM is a large, pictorial representation of the HL7 clinical data (domains) and identifies the life cycle that a message or groups of related messages will carry. It is a shared model between all domains and, as such, is the model from which all domains create their messages. The RIM is an American National Standards Institute (ANSI) approved standard.

HL7 Reference Information Model (<u>http://www.hl7.org/implement/standards/rim.cfm</u>)

Electronic Initial Case Reporting (elCR): elCR is the automated identification and transmission of reportable health events from EMRs to public health authorities. Because elCR uses a consensus set of trigger events and a standardized format, EMR vendors can incorporate automated case reporting into the medical record systems consistently across the nation, minimizing development time and simplifying disease reporting for providers. Because the EMR is the data source for case reports, elCR will improve the completeness of patient contact, clinical, and epidemiologic information to jump start case investigations. Like ELR, elCR seeks to reduce the reporting burden for providers while improving the timeliness and accuracy of surveillance data at the local, state, and national levels.

- Case Reporting to Public Health Agencies (<u>https://www.healthit.gov/isa/case-reporting-public-health-agencies</u>)
- HL7 CDA® R2 Implementation Guidance: Public Health Case Report, Release 2 US Realm the Electronic Initial Case Report (eICR) (http://www.hl7.org/implement/standards/product_brief.cfm?product_id=436)

CDC PHIN Specification of HL7 v2.5 Implementation for National Notifiable Disease: CDC National Notifiable Diseases Surveillance System – Message Mapping Guide Related Documentation (https://wwwn.cdc.gov/nndss/case-notification/related-documentation.html)

Current Procedural Terminology - code set used for outpatient and office procedures: Current Procedural Terminology (<u>https://www.ama-assn.org/amaone/cpt-current-procedural-terminology</u>)

LOINC: Logical Observation Identifiers Names and Codes (https://loinc.org/)

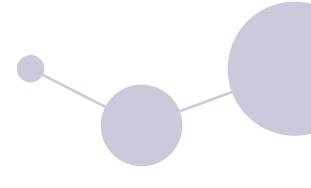
SNOMED CT: Suite of standards for exchange of clinical health information (https://www.nlm.nih.gov/healthit/snomedct/index.html)

Public Health and Promoting Interoperability Programs (formerly known as EHR MU)

https://www.cdc.gov/ehrmeaningfuluse/index.html

Guiding Principle 4: Incorporate performance and engagement metrics for quality improvement

Resources may be added in a future version.



Appendix E. Case Study

Transfer From a Long-Term Care (LTC) Facility to an Acute Care Hospital (ACH)

Mrs. Z is an 85-year-old female with a history of dementia, stage 4 sacral ulcer, chronic urinary catheter, and diabetes mellitus type 2. She resides in a LTC facility. Because of a fever and altered mentation, a urine culture is sent.

The laboratory that resulted her specimen is a commercial laboratory and is not part of the LTC facility or local ACH. The results are sent to the ordering provider and the LTC facility. In parallel, the isolate from the commercial laboratory is sent to state PHL that is part of the AR Laboratory Network for carbapenemase testing and antimicrobial susceptibility testing.¹³ Carbapenemase-producing (CP) carbapenem-resistant Enterobacteriaceae (CRE), *Klebsiella* spp. is isolated from the urine culture.

The commercial laboratory sent the result via ELR to the jurisdiction's ARIE and the patient was entered into the ARIE as a new patient and new MDRO event. Her name and other identifiers (e.g., the date of the culture, specimen source, and results) were included in the entry.

Treatment is initiated because Mrs. Z shows signs of infection related to the MDRO.

Five days after her culture was sent, Mrs. Z experiences unrelated symptoms of chest pain that require transfer to an emergency room and she is then admitted to the ACH. The nursing staff at the LTC facility speak with the emergency medical services (EMS) team providing transport to the ACH, and later they are called by the ACH nursing staff for nursing hand-off and the MDRO is mentioned during verbal hand-off and hand written in the nurses notes.

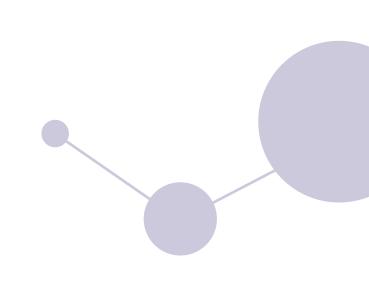
A large envelope of clinical documentation travels with Mrs. Z. The packet includes approximately seventy-five pages printed from the EMR of the sending facility. This includes face sheet with administrative data, medication administration record (MAR), nursing notes, advanced directives, recent laboratory results, and physician progress notes. Documentation of the MDRO is present in text of the physician note, nursing note, and microbiology results from outside commercial laboratories that were faxed to the LTC facility and copied for the transfer notes.

A continuity of care document (CCD) is automatically generated by the LTC EMR system, sent electronically to the receiving facility, and is also printed and sent by fax. The ADT messages sent from the LTC facility and the accepting ACH are received by the ARIE indicating a patient transfer event. The PID segment on the ADT message identifies Mrs. Z, the ARIE patient matching process reviews the MPI, locates her record, and her record in the ARIE is updated to reflect a new patient transfer event.

Because the patient has a record in the ARIE and has a new transfer event with additional PHL laboratory results of positive carbapenemase, an alert is generated and sent to the ACH which manages the alert based on their own user defined workflow. Appropriate actions such as implementing Transmission-Based Precautions and notification of clinical staff are taken, if indicated. ADT messages may be sent in real-time or as a daily batch of messages which may impact the timeline for the receiving facility.

In this example, the ARIE provides information not available to the healthcare facilities through traditional exchange of clinical information and facilitates the timely implementation of recommended infection control interventions to prevent further spread. Although specific discharge procedures and forms often exist, admitting facilities do not always receive this information or, more often, it is buried in a large physical or electronic file of medical information that is unstructured. Indications for antimicrobials are not always clear in the medical record. PHL results may impact clinical decisions but timely availability to healthcare providers will vary. The use of ARIE in this scenario is intended to supplement existing communication flows and assist with delivering relevant information to contacts at the admitting facility.

The health department is an important advisor and can provide guidance, information, and resources that may improve clinical care. Information relayed through the ARIE to the facility will be based on the data elements available to the health department. Depending on jurisdiction-defined workflow and data elements included in the ARIE, the health department can act as an advisor for treatment (e.g., communicate mechanism of resistance, susceptibility, and how to proceed with treatment if indicated). However, it should be noted that the ARIE does not serve as a legal medical record and any information provided via an ARIE should be verified by a secondary information source and/or the patient. Based on their own policies, healthcare facilities would choose which results to accept and include in their own legal medical record.



¹³ The AR Laboratory Network has established capability and capacity to detect carbapenemases in fifty-five PHL in the United States.

References

- i. U.S. National Action Plan for Combating Antibiotic-Resistant Bacteria (https://www.cdc.gov/drugresistance/us-activities/national-action-plan.html)
- ii. DC Data Modernization Initiative (https://www.cdc.gov/surveillance/surveillance-data-strategies/data-IT-transformation.html)
- iii. Health Insurance Portability and Accountability Act of 1996 45 Code of Federal Regulations Parts 160 and 164 (https://www.hhs.gov/hipaa/for-professionals/index.html)
- iv. U.S. Department of Education Family Educational Rights and Privacy Act (<u>https://www2.ed.gov/policy/gen/guid/fpco/ferpa/index.html</u>)
- v. Health Insurance Portability and Accountability Act of 1996 Security Series: Security 101 for Covered Entities (<u>https://www.hhs.gov/sites/default/files/ocr/privacy/hipaa/administrative/security101.pdf</u>)
- vi. United States Core Data for Interoperability (https://www.healthit.gov/isa/united-states-core-data-interoperability-uscdi)
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- x. ELR Meaningful Use (https://www.cdc.gov/elr/elr-meaningful-use.html)
- xi. Surveillance/Informatics: ELDR (https://www.cste.org/members/group.aspx?code=ELDR)
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- xiv. Patient Identification and Matching Final Report (https://www.healthit.gov/sites/default/files/patient_identification_matching_final_report.pdf)
- xv. The Sequoia Project: A Framework for Cross-Organizational Patient Identify Management (https://sequoiaproject.org/wp-content/uploads/2018/06/The-Sequoia-Project-Framework-for-Patient-Identity-Management-v31.pdf)

