March 9, 2020

Don Rucker, M.D.

National Coordinator for Health Information Technology

Office of the National Coordinator, U.S. Department of Health and Human Services

330 C ST SW

Mary Switzer Building

Washington, D.C. 20201

Re: 2020-2025 Federal Health IT Strategic Plan

Submitted electronically at <https://www.healthit.gov/topic/2020-2025-federal-health-it-strategic-plan>

Dear Dr. Rucker:

ECRI Institute appreciates the opportunity to submit comments to the Office of the National Coordinator for Health IT (ONC on the *2020-2025 Federal Health IT Strategic Plan*. ECRI Institute is a 52-year-old independent, nonprofit, 501(c)(3) that improves the safety, quality, and cost effectiveness of patient care across all healthcare settings. ECRI Institute’s work in patient safety, medical product testing and evaluation, evidence-based guidelines, accident investigation, and dissemination of alerts and recommendations aligns with the vision, mission, and goals of the Federal Health IT Strategic Plan. ECRI Institute’s Patient Safety Organization (PSO) is certified by the U.S. Department of Health & Human Services and is now one of the largest in the U.S.; ECRI is a designated Evidence-based Practice Center (EPC)—ECRI-Penn Medicine Evidence-based Practice Center—by the U.S. Agency for Healthcare Research & Quality. We do not accept gifts or grants from the pharmaceutical or medical device industries and our publications and informational products carry no outside advertising.

Since 2014, ECRI has convened and operated the *Partnership for Health IT Patient Safety* (*Partnership*), a multi-stakeholder collaborative that identifies and examines health IT-related safety concerns, develops evidence-based safe practices, provides tools and resources for implementation, and widely disseminates learnings and strategies for use. The *Partnership* brings together clinicians, healthcare organizations, professional societies, EHR and content developers/vendors, insurers, regulators, patient safety organizations (PSOs), human factor experts, researchers, patient advocates, and thought leaders to identify, address, and mitigate safety issues through recommendations and implementations. Reports on focused topics, available at [www.hitsafety.org,](http://www.hitsafety.org/) are relevant to the specific comments sought by ONC on the draft strategic plan.

We are very supportive of the draft plan and its emphasis on goals, objectives, and strategies. ECRI’s vision is in alignment with the draft plan as we strive to advancing effective, evidence-based healthcare globally. Given our extensive work in patient safety, and in particular health IT patient safety, and our curation of high quality evidence-based clinical recommendations, our comments focus on certain safety-related provisions of the draft strategic plan. With this focus, our detailed suggestions appear below.

**Detailed Comments**

Federal Health Principles

We appreciate and strongly support the inclusion of “safety” in the Focus on Value principle. Patient safety is central to our shared goals for health care and health IT use. It is essential to recognize that although health IT can enhance safe health care delivery it must also be developed and used in ways that improve and do not detract from patient safety.

We strongly support this goal and its objectives and strategies, especially Objective 1b: “Advance healthy and safe practices through health IT.” We also support the strategies identified for this objective and offer the following suggested refinements and comments:

* Leverage all levels of data (e.g., individual- and community-level) to predict epidemics, inform and monitor public health action outcomes, improve quality of life, enhance patient and consumer safety and quality of care, and address disease occurrence and preventable deaths.”

*Comment: This addition is consistent with the wording of the objective and reflects the role of data to support analyses that can help patients and consumers have safer experiences with the health care system while receiving the highest level of care. In addition, clinicians, healthcare organizations, vendor developers can advance healthy and safe practices through health IT, as exemplified by the Partnership’s work on patient identification, improving drug allergy communications and safer opioid prescribing.[[1]](#footnote-1)*

Goal 2: Enhance the Delivery and Experience of Care

We strongly support this goal and its objectives and strategies. We especially highlight and support “Objective 2a: Ensure safe and high-quality care through the use of health IT” and its focus on “safe, person-centered care,” “improved patient matching” and “patient safety solutions.” *It is essential to address all care settings and models as we seek to ensure safety and high-quality care using health IT. Practices like screening for behavioral health and other issues, clinical documentation, and standards-based information sharing and exchange (e.g., communication, interoperability) will help to ensure safe, quality care. ECRI continues to collaborate to identify evidence-based practices to facilitate the safe use of technologies.* We support the strategies identified for this objective and offer the following suggested refinements and comments:

* Optimize care delivery by applying advanced capabilities like machine learning, evidence-based clinical decision support, and smart dashboards and alerts in ways that reflect evidence-based best practices and principles of safe software development and use.

*Comment: It is essential that advanced capabilities such as machine learning, clinical decision support, and alerting are developed using safety-focused software development and implementation methods and best practices (e.g., applying robust* *development, verification and validation standards and guidelines*) *and used in ways that enhance and do not detract from clinical workflows. The Partnership has emphasized that trustworthy, evidence-based CDS at the appropriate time in the workflow is an essential component to optimal care delivery (e.g., drug allergies, safer opioid prescribing[[2]](#footnote-2))*

* Continue efforts to establish identity solutions that improve patient matching within and across data systems.

*Comment: As reflected in an ECRI Partnership report[[3]](#footnote-3) on this issue, accurate patient matching is essential within as well as across health care organizations, providers and those support organizations that help to inform care (e.g., Prescription Drug Monitoring Programs, and Health Information Exchanges).*

* Support expanded use of health IT for promoting safer clinical practices by automating patient safety and rapid reporting features into the health IT infrastructure to prevent and address adverse events, including overprescribing of controlled substances, and by implementing provisions of the 21st Century Cures legislation that enable health IT developers to participate effectively with Patient Safety Organizations (PSOs).

*Comment: We urge HHS to work with the Agency for Healthcare Research and Quality (AHRQ) and other HHS agencies to implement this critical provision of 21st Century Cures (Section 4005(c)).*

* Use electronic clinical quality measure (eCQM) data, including measures of safe health IT use, to optimize healthcare providers’ and researchers’ abilities to assess quality and outcomes.

*Comment: As demonstrated by a recent National Quality Forum report[[4]](#footnote-4), measures of safe health IT play an important role in the portfolio of clinical quality measures.*

* Implement mechanisms of data governance and provenance to promote safety, security, and accountability through all stages of care and uses of health IT.

*Comment: We applaud the recognition that data governance and provenance are essential for effective data use and exchange, patient safety and safe use of health IT and safe healthcare decision-making.*

* Promote interoperability and data sharing through uniformly developed and implemented widely-accepted standards to ensure health information is freely available across care settings for patient care, public health, research, patient safety enhancement, and emergency and disaster preparedness, response, and recovery.

*Comment: Based on our extensive experience, it is essential that standards are developed in a uniform fashion by recognized Standards Development organizations, using accepted principles (e.g., the ANSI Essential Requirements[[5]](#footnote-5)). Increased data liquidity will greatly enhance the ability of PSOs and other authorized users to pursue evidence- and data-based patient safety improvement activities.*

Goal 3: Build a Secure, Data-Driven Ecosystem to Accelerate Research and Innovation

We strongly support this goal and its objectives and strategies. We especially highlight and support Objective 3b: “Support research and analysis using health IT and data at the individual and population levels.” We support the strategies identified for this objective and offer the following suggested refinements and comments:

* Increase use of new technologies and analytic approaches like ML and predictive modeling to harness the power of integrated data for improving quality, safety, outcomes, and decision making.

*Comment: Based on our own experience, especially with machine learning, we believe that such new technologies and analytic approaches can play an important role in using data to evaluate safety issues and suggest enhancements. At the same time, we see an urgent need for standardization of both data and algorithm conventions so that ML and other algorithms can consistently pull the same information regardless of the system being used*.

* Build the evidence base on use of health IT for improving quality and safety through research that investigates the impact of health technologies on patient care, safety, and outcomes, including standardized analyses of health IT systems data.[[6]](#footnote-6)

*Comment: We strongly support the need to improve the evidence base on health IT to improve patient safety and suggest that safety be added as a fundamental to achieving this goal.*

Goal 4: Connect Healthcare and Health Data through an Interoperable Health IT Infrastructure

We strongly support this goal and its objectives and strategies. We especially highlight and support Objective 4a: “Advance the development and use of health IT capabilities.” We support the strategies identified for this objective, as well as the clear focus on privacy protection in this and Objectives 4b and 4c, and offer the following suggested refinements and comments:

* Follow health IT safety and user-centered design principles in the development and design of solutions to ensure tools are safe, accessible, usable, and address the needs of the users for whom they are developed.

*Comment: This is an essential strategy. We urge the federal government to make full use of the health IT safety principles and best practices reflected in the work of the ECRI Partnership for Health IT Patient Safety[[7]](#footnote-7) and the excellent “Safer Guides”[[8]](#footnote-8) (developed with ONC funding).*

We also highlight the importance of Objective 4b. “Establish transparent expectations for data sharing.” We support the strategies identified for this objective and offer the following suggested refinements and comments:

*Comment: Based on our experience working with health care data on projects like the above- mentioned “systems data” project, it is essential that implementation of this objective and the strategies to “develop resources and communications plans” and “promote data liquidity” address specifically the availability of data to support a learning healthcare system.*

**Conclusions**

ECRI Institute looks forward to continued collaboration with ONC. For questions, please do not hesitate to contact me at kschoelles@ecri.org. ECRI Institute welcomes further discussion on this topic. Our website is  [www.ecri.org.](http://www.ecri.org/)

Sincerely,

 

Karen Schoelles, MD, SM, FACP

Vice President, Clinical Excellence and Patient Safety

1. <https://assets.ecri.org/PDF/HIT-Partnership/ECRI-Implementation-Guide-Patient-Id.pdf>, <https://assets.ecri.org/PDF/HIT-Partnership/ECRI-Implementation-Guide-Drug-Allergies.pdf>, <https://assets.ecri.org/PDF/HIT-Partnership/EHRA-ECRI-Implementation-Guide-Final.pdf> [↑](#footnote-ref-1)
2. <https://assets.ecri.org/PDF/HIT-Partnership/ECRI-Implementation-Guide-Drug-Allergies.pdf>, <https://assets.ecri.org/PDF/HIT-Partnership/EHRA-ECRI-Implementation-Guide-Final.pdf> [↑](#footnote-ref-2)
3. <https://assets.ecri.org/PDF/HIT-Partnership/ECRI-Implementation-Guide-Patient-Id.pdf> [↑](#footnote-ref-3)
4. <http://www.qualityforum.org/Publications/2016/02/Identification_and_Prioritization_of_HIT_Patient_Safety_Measures.aspx> [↑](#footnote-ref-4)
5. [https://share.ansi.org/Shared%20Documents/Standards%20Activities/American%20National%20Standards/Procedures,%20Guides,%20and%20Forms/2020\_ANSI\_Essential\_Requirements.pdf](https://share.ansi.org/Shared%20Documents/Standards%20Activities/American%20National%20Standards/Procedures%2C%20Guides%2C%20and%20Forms/2020_ANSI_Essential_Requirements.pdf) [↑](#footnote-ref-5)
6. <https://www.ecri.org/hit/identifying-potential-new-data-sources-for-safety> [↑](#footnote-ref-6)
7. <https://www.ecri.org/solutions/hit-partnership> and <https://www.healthit.gov/topic/safety/safer-guides> [↑](#footnote-ref-7)
8. <https://www.healthit.gov/topic/safety/safer-guides> [↑](#footnote-ref-8)