SOCIETY to IMPROVE DIAGNOSIS in MEDICINE

Better outcomes through better diagnosis.

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U.S. Department of Health and Human Services

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Dear Dr. Rucker:

On behalf of the leadership and members of the Society to Improve Diagnosis in Medicine (SIDM), we thank you for the opportunity to share our comments on ONC's draft 2020-2025 Federal Health IT Strategic Plan (the "Plan"). We recognize the importance of the Plan in setting the agenda, direction and priorities of the nation's health IT infrastructure and ecosystem. The recent coronavirus COVID-19 crisis has only further highlighted the need for timely, accurate, and fully communicated diagnoses and robust, agile and comprehensive health IT policies and solutions to support the diagnostic process.

The Society to Improve Diagnosis in Medicine (SIDM) (https://www.improvediagnosis.org/) was founded in 2011 to catalyze and lead change to improve diagnosis and eliminate harm from diagnostic error, the leading source by far of serious medical harm in the U.S. Our work is generally grounded in the findings and recommendations of the 2015 National Academy of Medicine report, *Improving Diagnosis in Health Care*, part of the *Quality Chasm* series. We work in partnership with patients, their families, the healthcare community and every interested stakeholder. SIDM also sponsors the annual international Diagnostic Error in Medicine

conference series, and the peer-reviewed publication *DIAGNOSIS*. Our allied Coalition to Improve Diagnosis (CID) (https://www.improvediagnosis.org/cid/) includes the nation's premier health care systems, specialty societies, patient advocacy groups, certifying and accrediting organizations, risk management organizations and others that together represent hundreds of thousands of healthcare providers and patients working to raise awareness and stimulate action to improve diagnostic quality and safety. The Coalition also includes liaisons from mission-aligned federal agencies: CMS**,** AHRQ, the CDC and the VA.

We are pleased to offer recommendations to make ONC's Strategic Plan even stronger and more salient, specifically through reference to diagnostic quality and safety (as distinct from treatment and prescribing) as a top tier patient quality and safety concern, and acknowledgement of the crucial role that Health Information Technology can and should play in reducing risks and minimizing harms from diagnostic error.

About Diagnostic Error

The ECRI Institute has designated diagnostic error to be the #1 patient safety concern in the US today (and for the previous two years as well).[i] Diagnostic errors affect an estimated 12 million adult Americans each year just in primary care settings,[2] with as many as a third of those suffering serious harms, and account for 40,000-80,000 deaths in U.S. hospitals each year.[3] Diagnostic errors are not only the most common and catastrophic of medical errors, but also the most costly, with aggregate costs to the healthcare system likely in excess of $100 billion.[4]   In fact, the public health footprint of diagnostic error and its consequences likely dwarfs that of all other medical-related harms _combined_.   In its landmark report on the problem, *Improving Diagnosis in Health Care* (2015) the National Academy of Medicine concluded that each of us is likely to be affected by diagnostic error in our lifetime, and that addressing diagnostic error is an urgent national priority.[5]

Health IT and Diagnosis

The electronic health record (EHR) is at the very center of healthcare services in every setting and plays a major role in determining the quality and safety of diagnosis. The EHR has already improved diagnosis in any number of ways. Examples (see more in Appendix A) include the ability to organize and read legible notes, find diagnostic test results and consultation reports, and integrate the patient in the diagnostic process through OpenNotes and patient portals. At the same time, inefficiencies, unanticipated 'side

effects', and a host of design flaws in the EHR contribute to delayed and missed diagnoses,[6,7] and represent important contributory factors in the harm identified in medical malpractice suits.[8] Of direct relevance to the draft Strategic Plan, most current EHR systems typically lack many desirable features that have been recommended to enhance the efficiency, quality and safety of diagnosis.[6,9,10] These include features such as being able to capture symptoms, a differential diagnosis, level of certainty of the working diagnosis, reminders/triggers to follow-up on tests or necessary care, decision support for diagnosis, and fail-safes to ensure closed-loop communication of test and imaging results (See Appendix A for an expanded list).

Beyond the EHR itself, the broader health IT ecosystem and the rules that govern and drive it exert a powerful influence on the diagnostic process, which often involves multiple providers, settings, and tests distributed across multiple systems. The complexity of this process, the opportunities for lethal failure of information transfer – and conversely, the opportunities to radically improve diagnostic quality and safety -- was one of the foundational justifications for the HITECH Act a decade ago.

General Observations

We have some observations about the Strategic Plan which motivate more specific recommendations below. **First and foremost**, **the Plan severely underweights the urgency of addressing diagnostic error and striving to improve diagnostic quality, particularly in light of the statistics presented above.** Accurate and timely diagnosis is the very *foundation* of high-value care: If the diagnosis is wrong, all treatment that follows is either harm, or waste, or both. Yet "diagnosis" is only mentioned once in the entire Strategic Plan, and that is within the narrow scope of precision medicine on page 15. Failure to include a focus on improving diagnosis misses one of the most significant opportunities that Health IT policymakers, and the stakeholder collaborations envisioned in this Plan, have to markedly improve health care safety, quality, and value. Diagnosis is a process, often a long and multi-component one, with both cognitive and systems dimensions that are subject to failure, but the most common failures also are, or are likely to be, amenable to well designed, evidence-based HIT enabled supports and safeguards.

Second, given the focus on health IT technology, **the Plan only weakly conveys the notion that health IT can have a positive impact on reducing diagnostic error and improving diagnosis**. In numerous places, the Plan connects health IT to better treatments and therapeutics but, other than for precision medicine, at most only implies or hints at the connection between health IT and diagnosis.

We ask that the plan explicitly designate the improvement of diagnostic quality and safety as a health IT priority. Diagnostic error should be called out as one of the "Challenges in Health Care", and the relevancy of health IT should be its own category in the section on "Opportunities in a Digital Health System". Health IT and the EHR have already achieved transformative progress in this direction. This needs to be recognized, built upon, and the current flaws that undermine diagnostic quality and safety need to be addressed. There are numerous ways in which health IT policy and technology innovation can improve diagnostic quality and safety and reduce harms from diagnostic error. ***Appendix A*** contains a list of recommendations well supported in the literature and lived experience of clinicians and patients. Moreover, the recent ONC and CMS actions to implement the CURES and CPR Supplemental have made significant inroads to advance interoperability, reduce documentation burden, and expand access via electronic communication, all of which lower significant barriers to diagnostic accuracy and timeliness. The Strategic Plan should build on these to make HIT actually *work better* for diagnosis. For example, while reducing documentation associated with billing for E&M services is resoundingly welcomed, the next operative question should be: what does ideal clinical documentation look like from a diagnosing, treating, covering, referring, or consultant clinician's perspective, and how can ONC work with the medical profession and the developer community to bake that into the next generation of certified EHRs and related technologies?. Health IT capabilities, policies and infrastructure could massively impact diagnostic accuracy and timeliness, and save tens of thousands of lives each year through this effort. The NAM/IoM report concluded that improving diagnosis is not only possible, but is a "moral, professional and public health imperative" and it is a timely one that ONC should grab with both hands to lead in the framing of this report.

Specific Comments and Recommendations

We share these comments and recommendations in the spirit of bolstering the Strategic Plan and the signals that it will send to HIT developers and the broader stakeholder community about the importance of optimizing HIT/HER systems to reduce harms from diagnostic error:

- **Letter from the National Coordinator (page 3-4)**
  - We urge more specific mention of diagnosis, diagnostic error or improving diagnosis in the Coordinator's important stage-setting letter. Perhaps (underlined text represent suggested modifications or additions to passages in the Plan), ***"The Plan will decrease***

provider burden, <u>improve both diagnosis and treatment</u>, and open up entirely new business models throughout the health app economy."

- o **Federal Health Principles (p 5): Designating Diagnostic quality and safety as a HIT priority is not only consistent with, but would exemplify the Federal Health Principles:**
  - o ***Focus on value*** – An accurate, communicated and timely diagnosis ("ACT" diagnosis, for short) is the *sine qua non* of high-value care: if the diagnosis is wrong, **all else that follows is either harm, waste, or both**.
  - o ***Put individuals first*** – Diagnosis is the ultimate example of person-centered care and it requires synthesis of many inputs: the patient's expressed problem; history and physical exam findings; lab and imaging investigations; co-morbidities; medications; and the patient's social, cultural and economic context.
  - o ***Put research into action*** – Research should not only inform better therapeutics and treatment, but also better diagnostic tools, practices and policies. The SaferDX framework provides the socio-technical guidance needed to organize this effort for diagnosis,[10] and the SaferDX Guides[11] represent a model example.
  - o ***Encourage innovation and competition –*** there are rich opportunities for HIT to drive competition and innovation in diagnosis – indeed we already are seeing that in a proliferation of apps and crowdsourcing experiments. In the growing value-based, risk-based payment market, clinicians and health systems would benefit from HIT vendors innovating to enable better diagnostic performance (and thus better outcomes, fewer unnecessary readmissions, etc) through smart screens and user- and workflow- friendly decision support at multiple points along the diagnostic process.

- o **We suggest adding language to the Introduction (page 7):**
  - o "Individual patient can use health IT (e.g., patient portals and patient-facing apps) to *<u>describe and/or image symptoms to their providers and participate in establishing a diagnosis, receive recommendations</u>*, access their health information, track and manage treatment of their health conditions."
  - o "Healthcare providers and healthcare organizations can use health IT to input and reference their patients' health information *<u>to home in on or adjust a diagnosis,</u>* make clinical decisions, create a care plan.."

o **Challenges in Healthcare (pages 8-9)**

   o ***Poor Health Outcomes*** – We suggest adding to the end of the section: ***"In addition, more than twelve million diagnostic errors occur each year, disproportionately victimizing underserved populations and communities,[4] and leading to at least 40,000-80,000 deaths each year,[2] and by some estimates, many more[12]."***

   o ***Access to Technology*** – As the COVID-19 coronavirus crisis reminds us, health IT technologies such as telehealth are increasingly critical to timely and accurate diagnosis in an effort to reduce burden and risks to both patients and clinicians. We suggest appending to the second paragraph in this section ***"For example, an inability to access telehealth technology can make it more difficult for individuals in rural and underserved areas to receive a timely and accurate diagnosis compared to those who do have access."***   That said, the benefits and risks of telehealth in diagnosis are understudied and such work needs to happen.

o **Opportunities in a Digital Health System (pages 10-12)**

   o ***Patient Empowerment*** – Suggest modification: **"***This more active role for patients includes responsibilities such as improving healthy behaviors, self-management of chronic conditions, and engaging in shared decision-making with healthcare providers in the course of diagnosis and treatment*"

   o ***Movement to Value-Based Care*** – We suggest a modification: "*These shifting incentives place greater importance on achieving accurate and timely diagnosis, addressing social determinants of health and patient health behaviors, and engaging in preventive care, population health management, and disease management.*"

   o ***New Technologies and Available Data*** – We suggest this modification: "*Collecting, organizing, analyzing, interpreting, and applying this 'big data' to diagnosis, treatment and patient engagement is both a challenge and a significant opportunity.*"
   In addition, big data must be accurate data and include relevant contextual information in order to actually improve care.   For example, patients often complain about incorrect

information in their medical records which could lead to incorrect diagnoses and patient harm, and social determinants information can contribute importantly to building a differential diagnosis. It is imperative that there be mechanisms to address such inaccuracies in EHRs and other health IT systems. Hence, we suggest adding the following to the end of this section: ***It is also critical to develop mechanisms to evaluate and improve the accuracy and completeness of the data sets upon which algorithms run and learn."***

- o **Goal 1: Promote Health and Wellness (pages 13-14)**
  - o *Objective 1a: Improve individual access to health information* – We whole-heartedly agree with the importance of this objective and suggest strengthening the language: ***"It allows patients to become more engaged in their <u>diagnosis, and the care</u> and management of their conditions…".***

  - o *Objective 1b: Advance healthy and safe practices through health IT –* we suggest: "***Health IT can be further leveraged to promote access to care for preventing, <u>diagnosing</u>, or addressing existing health needs, as well as to identify and respond to public health threats***."

  - o *Objective 1c: Integrate health and human services information* – We suggest adding diagnosis: "*Capture and integrate social determinants of health data into EHRs to assist in care processes, such as clinical decision support, **<u>diagnosis</u>** and referrals, integration of medical and social care, and address health disparities in a manner that is ethical and consistent with routine patient care.*"

- o **Goal 2: Enhance the Delivery and Experience of Care (pages 15-17)**
  - o *Objective 2a: Ensure safe and high-quality care through the use of health IT* - Suggest modification of this Strategies bullet: **"***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 **<u>and abnormal diagnostic lab and imaging results lacking follow up</u>**."*

- Diagnostic errors typically involve both cognitive- and system-related root causes,[13,14] but identifying and analyzing these elements is difficult from the currently-available data in the EHR. This barrier significantly limits the ability to develop effective diagnostic decision support and valid metrics of opportunities to improve diagnostic safety. Therefore, we recommend highlighting this need through adding the following new strategy/bullet following the bullet on eQMs: *"**Promote efficient capture of all accurate and high-value information necessary to support and assess the diagnostic process and treatment decisions.**"*

- *Objective 2c: Reduce regulatory and administrative burden on providers* – Suggest modification: *"It leaves healthcare providers feeling burned out, and it reduces the amount of time they have to **make proper diagnoses and formulate optimal treatment plans for patients.**"*

- **Goal 3: Build a Secure, Data-Driven Ecosystem to Accelerate Research and Innovation (pages 17-18)** The experience with and efforts to resolve diagnostic uncertainties re: COVID-19 we believe make this point:
  - Objective 3a: *Access, exchange, and use of data using secure, standardized-based APIs is key to building an integrated ecosystem that can support research, **diagnosis**, clinical decision making, population health management, and individual access to quality and cost information.*
  - A critical issue is the necessary interoperability and standardization of data to be able to share outcome event data regionally or nationally, across health systems. Without such information, it is impossible to accurately track the most important adverse events from diagnostic errors.[15] Objective 3a: *Bolster secure access to large datasets of health information for use in quality improvement and outcomes research **for both diagnosis and treatment**.*

o **Goal 4: Connect Healthcare and Health Data through an Interoperable Health IT Infrastructure (pages 18 – 20)**

  o Objective 4c: Enhance technology and communications infrastructure – We suggest modification to this Strategies bullet: ***"Promote adoption of infrastructure needed for telehealth to reach patients outside of traditional care settings<u>, enabling broader access to better and more timely diagnoses and treatment plans</u>."***

We appreciate this opportunity to contribute our observations and recommendations to ONC's 2020-2025 Strategic Plan, and we look forward to working with you alongside other HIT stakeholders and policymakers to realize a health IT ecosystem that better supports patients and clinicians in achieving accurate, timely and communicated diagnosis. Please do not hesitate to reach out to leslie.tucker@improvediagnosis.org if you have any questions or would like clarification or expansion on any of the recommendations above. Thank you for all you are doing to inject transformative tools and resources into health care.

Sincerely,

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David E. Newman-Toker, MD., PhD
President

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APPENDIX A

From: Graber et al, The Impact of Electronic Health Records on Diagnosis.
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Table 1: How Health IT Improves Diagnosis

Table 2: How Health IT Degrades Diagnosis

Table 3: EHR and health IT functionality that would improve diagnostic quality and safety

Table 1: How Health IT Improves Diagnosis

How Health IT Improves Diagnosis	Examples
Enhances access to care	**Using portals that link patients to their physicians and their medical records, diagnosis can take place without face-to-face contact.**
Provides access to patient information	**EHR's provide easy access to prior medical records, even if remote, and facilitate information sharing.**
Augments obtaining a reliable history and accurate physical examination	**Templates ("smart forms") ensure all appropriate questions are asked and relevant aspects of the physical exam are completed.**
Enhances the organization and timely display of information	**Well-organized records; readable and searchable content; immediate access to test results**
Provides decision support	**Web-based differential diagnosis generators**
Provides tools and calculators to assist in clinical decision making	**Pre-built tools to determine the need for appropriate screening or testing**
Supports the intelligent selection of a testing strategy	**Online guides to help select most appropriate imaging modality**
Facilitates access to key reference information and guidelines	**Web-based access to textbooks, Medline, peer-reviewed literature**
Helps ensure reliable follow up	**Reminders for patients about scheduled follow-up; reminders for providers to check on pending test results; patient registries**
Supports screening for preventive measures	**Population-level reports to identify who is due for screenings**
Facilitates collaboration for diagnosis, for example, with subspecialists	**Ability to share notes and images and to communicate asynchronously**
Facilitates communication with the patient	**Open notes allow patients to see their test results and progress notes**

Helps measure diagnostic performance and provide feedback	Tools to detect patients with red flag conditions not yet followed-up; identifying earlier providers who may want to know that an earlier diagnosis has changed

Table 2: How Health IT Degrades Diagnosis

How Health IT Degrades Diagnosis	Examples
Inaccurate documentation	Copy-paste note that contain wrong or misleading information; incomplete problem lists
Inadequate and missing information	Information lacking because of interoperability problems, or internal information sources that don't link to the EHR; erroneous entries that are never corrected; misplaced data; structured formats that obscure information
Information overload	Note bloat (excessive note length); alert fatigue
Usability issues that contribute to inefficiency and errors	Pick list errors; billing requirements that promote selecting a diagnosis before it is confirmed;
Impairs communication with the patient	The 'e-patient' problem
Impairs communication with other clinicians	Communicating through the EHR discourages direct communication
Consumes too much time	Burdensome documentation requirements

Lack of out-of-network follow-up for necessary diagnostic performance feedback	Interoperability and data sharing failures across hospitals or health systems prevents recognition of diagnostic errors or associated adverse events (misdiagnosis-related harms)

Table 3: EHR and health IT functionality that would improve diagnostic quality and safety

Access to care
Provide communication portals to patients at home; support bidirectional secure communication; Support OpenNotes
Support telehealth and mobile e-health applications with appropriate clinical and ethical safeguards
Patient-Physician encounter
Provide smart templates for patients to enter static (family and social history) and dynamic data (reason for the visit, past history, medications, review of symptoms)
Provide decision support to assist physicians in asking all the right questions and gathering all of the relevant data in the history and physical examination, for the most common complaints
Support team-based diagnosis
Improve ways to capture documentation and preserve face time with the patient
Clinical reasoning
Develop ways to organize data and present it optimally at the point of care
Incorporate decision support functionality to aid in calculations
Incorporate decision support functionality to generate an appropriate differential diagnosis; facilitate documentation of the differential diagnosis
Allow free text entry to document clinical reasoning
Provide access to relevant medical knowledge at the point of care
Facilitate data searching (e.g. finding all notes, visits, and tests in reference to a patient's cardiovascular problems)
Improve the problem list; be able to designate uncertainty about a diagnostic assignment; use decision support to optimize problem list accuracy
Diagnostic testing and consultation
Provide decision support for appropriate selection of diagnostic tests
Facilitate communication to appropriate expertise at the point of care (consultants, librarians, radiology and clinical lab liaisons)
Display time-based data graphically (lab tests, disease activity, medications utilization, etc) and in relation to other selectable clinical information
Follow-up

	Support clinicians being able to generate their own reminder list of items needing follow-up, and registries for patients who need follow-up (e.g. cancer screenings; abnl X-rays)
	Support complete imaging/test-result communication with mechanisms to ensure the loop is closed with both the ordering clinician and the patient.
	Develop functionality to automate feedback to patient's prior/referring clinicians on changes in diagnosis and/or harm
Diagnostic safety functionality	
	Facilitate use of trigger tools to identify patients at risk for harm
	Support true interoperability so that all relevant medical information can be gathered and used effectively at the point of care
	Be able to capture presenting complaints and descriptors as structured data elements, or extracted from free text by natural language processing
	Discourage entry of a diagnosis prematurely solely for billing, which can "anchor" succeeding providers inappropriately and leads to error. Allow as-yet-undiagnosed problems to be designated as such (e.g. NYD = not yet diagnosed) with supporting notes and working differential.
	Facilitate ways to monitor diagnostic performance (timeliness, accuracy), including access to out-of-EHR-network health events (e.g., hospitalization for adverse events following on a missed diagnosis in another health system) via health information exchanges
	Support high-quality clinical documentation as established by the profession (in process); preclude inappropriate copy-paste and discourage inappropriately long notes.
	Combat information overload with smart features/user centered design interfaces
	Develop predictive analytic approaches to suggest likely diagnoses not considered, and identify inconsistencies between assigned diagnoses and existing data