

Donald W. Rucker, M.D.
National Coordinator for
Health Information Technology

Dear Doctor Rucker,

Background

The Veterans Health Information Exchange (VHIE) Data Quality Team is pleased to submit comments to the Office of the National Coordinator for Health Information Technology (ONC) on the 2020-2025 Federal Health IT Strategic Plan. We appreciate ONC's commitment to thoughtfully consider the comments it receives from stakeholders.

Since its initiation in 2016, the VHIE Data Quality team provides the nation's largest surveillance monitoring of the HL7 data exchanges. VHIE has over 200 partner connections (2,000 hospitals/ 32,000 clinics) and in FY20 as a result of the MISSION Act, National Network Expansion (NNE) initiatives and an expected connection to the CommonWell National Level Gateways Service (NLGS) will enable VA health information exchange with almost every clinician in the U.S.

Our extensive experience implementing national-level health IT interoperability projects, including our track record of supporting and operationalizing federal government and private sector interoperability initiatives provide a unique perspective on interoperability-related provisions of the 2020-2025 Federal Health IT Strategic Plan.

Overview of VHIE Data Quality Team Comments

Currently the adherence to HL7 standards documents is so variable that it causes many clinical data challenges. Our purpose in responding to the 2020-2025 Federal Health IT Strategic Plan is to facilitate the Vision and Mission to improve the health and well-being of individuals, families, and communities.

*"We're not just fighting an epidemic;
we're fighting an infodemic..."*
~ WHO Director-General Dr. Tedros
Adhanom Ghebreyesus

Overall

- Advocate that Focus on Value must include Best Practices
- Advocate that *clinical intention* must remain intact during data transmission
- Advocate there are ethical implications for needing a national-level program of data quality indicators
- Advocate that every phase in the data flow continuum is improved by sharing the responsibility for mitigation
- Advocate high-quality data from source through robust workflows
- Advocate for national-level clinical data-quality thresholds to support safe practices
- Advocate that everyone in healthcare IT must own a part of the solution
- Advocate clear and enforced data quality content standards
- Advocate vendor agile development lifecycles
- Advocate integrated data flow ecosystem that mirrors the patient ecosystem
- Advocate tighter and enforced HL7 standards and implementation guide(s), minimize need for transformation

- Advocate for the clinical intention being conveyed and the clinician trusting the data exchanged
- Advocate nationally, to implement and enforce a rapid, agile approach
- Advocate collaboration between stakeholders on data exchange implementation
- Advocate for national clinical data quality thresholds to be implemented
- Advocate for re-evaluation and continuous surveillance of clinical data quality exchanges

Conclusion

In the attached comments, we provide high-priority comments from our unique perspective on interoperability-related provisions of the strategic plan with the intention to help strengthen the final document. We share an overall aim to improve the health and health care of patients through a fully-connected health system that empowers patients, caregivers, and their healthcare provider to use and share electronic health information that is clinically fit for use.

We thank ONC for providing the opportunity to comment on the 2020-2025 Federal Health IT Strategic Plan. The VHIE Data Quality Team is ready, willing, and able to support ONC efforts with our metrics, scoring, and trending reports.

Respectfully,
Sandi Mitchell, RPh, MSIS, FASHP
Healthcare Data Quality Analyst SME
VA VHIE Data Quality Team

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Authors

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**Comments to The Office of the National Coordinator for Health Information Technology Regarding
2020-2025 Federal Health IT Strategic Plan**

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Federal Health Principles	5	Focus on Value: Promote and pursue activities that improve health and care quality, efficiency, safety, affordability, equity, effectiveness, and access.	<p>The <i>Focus on Value</i> must include Best Practice activities that completely capture and code the clinically impactful data element.</p> <p>The value proposition for Clinical Decision Support and AI, requires high-quality data to first train systems and then manage complex healthcare decisions. Research and protocol development projects have the clinical data quality of data elements captured.</p>
	5	Build a culture of secure access to health information: Support secure health information access, exchange, and use by individuals, caregivers, healthcare providers, and other stakeholders.	<p>Trust is key. The <i>clinical intention</i> needs to be effectively and completely conveyed between clinicians, including both local and external.</p> <p>For a clinician to trust, his external partner response matches his clear request for clinical data. Current state is often a mismatch of request and response, which frustrates the clinician and the patient and delays healthcare decisions.</p>
Opportunities in a Digital Health System	11	Achieving Interoperability Spurred by regulatory actions from ONC and CMS, it is increasingly using APIs to develop tools that provide patients and caregivers with their data and promote information sharing. Furthermore, the use of health information	Healthcare ethics points to requirements to evaluate the clinical data quality of each message during the exchange process and provide an indicator appended to the message.

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		exchanges and health information networks continues to grow. This signifies continued investment in collaboration and information sharing among stakeholders in this sector.	<p>Ethically it is imperative to indicate to both clinician and patient the quality of the data being displayed, this can be at a source-level, domain-level, or a data element-level.</p> <p>Transformations and aggregation can skew the data without an indicator being present. Most patients are not aware of data appropriateness and may not recognize that it's skewed. Need a national program.</p> <p>Interoperability is not just the exchange/technology handshake, but the secure transmission of the clinical intention that impacts the value of the data.</p>
Reducing Regulatory and Administrative Burden	12	Strategies to advance health IT should minimize burden by considering how best to incorporate technologies into existing workflows and reducing reporting requirements.	<p>Every phase of the data flow continuum can be better improved and supported by spreading around the mitigation.</p> <p><i>See Appendix A supporting document.</i></p>
Goals, Objectives, and Strategies	13	<p>Goal 1: Promote Health and Wellness Objective 1a: Improve individual access to health information Strategies:</p> <ul style="list-style-type: none"> • Enable individuals to access their health information by ensuring that they are able to view and interact with their data via secure mobile apps, patient portals, and other tools. • Promote greater portability of health information through APIs and other interoperable health IT that permits individuals to readily send and receive their data across various platforms. • Improve access to smartphones and other technologies needed to attain and use health information, especially for at-risk, minority, rural, disabled, and tribal populations. • Build the evidence base on the use of health information, including on the types of information that 	<p>There is a new work stream happening – when the patient displays one source of data that does not match the clinician’s local system data.</p> <ul style="list-style-type: none"> • Who triages those issues? • Who works with the patient to understand? • Who owns the fix for those problems with data? <p>All those workflows must be designed, developed, and implemented.</p> <p>Enabling access to healthcare data is one thing, but to educate the patients to understand the data is another.</p> <p>With multiple portals and patient reported data, the chance of having mis-matched data increases dramatically.</p>

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		will benefit individuals most and the best ways to present information to patients and caregivers.	Complete and high-quality data from the source will limit these issues from happening in the first place.
Goals, Objectives, and Strategies	14	<p>Goal 1: Promote Health and Wellness</p> <p>Objective 1b: Advance healthy and safe practices through health IT</p>	<p>Development and enforcement of national clinical data quality thresholds.</p> <p>The full potential cannot be realized as long as the industry remains in the “Garbage In Garbage Out” stage of development.</p>
Goals, Objectives, and Strategies	14	<p>Goal 1: Promote Health and Wellness</p> <p>Objective 1c: Integrate health and human services information</p> <p>... Additionally, there is almost no coordination between agencies in real-time, creating inefficiencies and inhibiting initiatives to address social determinants of health. Furthermore, community-based organizations providing health and human service (e.g., the aging and disability network funded by the Administration for Community Living) lack the requisite health IT infrastructure and adoption support that is needed in order to become fully integrated as part of the care continuum.</p>	<p>National data thresholds for the clinical quality of the data shall be established to support the safe practices through health IT.</p> <p>Beyond the secure data exchange, the clinical content of the data exchange needs to be defined and implemented at a tighter and more granular level.</p> <p>Healthcare is unlike any other industry, with a tolerance for wide adherence to standards and multiple code systems. That does not work in the finance, automotive, or the retail industries – so why is this tolerated in healthcare? – with even more critical implications to each of us.</p>
Goals, Objectives, and Strategies	15	<p>Goal 2: Enhance the Delivery and Experience of Care</p> <p>Objective 2a: Ensure safe and high-quality care through the use of health IT</p> <p>Healthcare providers can develop care plans and deliver high quality, safe, person-centered care when health systems and programs deploy tools that collect, store, and use health data that addresses the unique needs of each individual patient.</p>	<p>We need to recognize that all of us own part of the solution - vendor, data architect, network resources, builders, clinicians.</p> <p>With clinical decision support implemented from data capture to data sharing, the data will support personalized medical plans centered around the patient.</p> <p><i>See Appendix A supporting document.</i></p>

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Goals, Objectives, and Strategies	15	<p>Goal 2: Enhance the Delivery and Experience of Care</p> <p>Objective 2a: Ensure safe and high-quality care through the use of health IT</p> <p>Strategies:</p> <ul style="list-style-type: none"> • Promote interoperability and data sharing through widely-accepted standards to ensure health information is freely available across care settings for patient care, public health, research, and emergency and disaster preparedness, response, and recovery. 	<p>Clear and enforced data quality content standards are needed to support the strategy to Promote interoperability and data sharing through widely-accepted standards.</p> <p>Quality care is often not supported with quality data. The clinicians extend themselves, using paper systems when interoperability fails. The frustrated patient does not have access to the same paper data. And the frustrated clinician has worked too hard to pull together what should have been a simple data aggregation.</p> <p>Understandable clinical content that is widely available to the patient supports the patient owning their wellness and the health strategies they develop with their clinical care team.</p>
Goals, Objectives, and Strategies		<p>Goal 3: Build a Secure, Data-Driven Ecosystem to Accelerate Research and Innovation</p>	<p>Vendor development cycles are measured in years, whereas, mobile cycles are measured in days/weeks. The information overload overwhelms systems today with bad quality data.</p> <p>The traditional vendor development cycles must be challenged with more agile-like fix cycles (e.g. mobile phone updates).</p> <p>Change must happen quickly. Traditional systems must step up and meet the new rapid fix cycles.</p> <p>An ecosystem realizes that both ends of the challenge need to be on the same page and working toward shared goals, not commercial business development lists.</p>
Goals, Objectives, and Strategies	17	<p>Goal 3: Build a Secure, Data-Driven Ecosystem to Accelerate Research and Innovation</p>	<p>Today's patient care team represents multiple clinical teams across multiple healthcare enterprises and uses multiple</p>

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		An integrated ecosystem that collects data from multiple sources is critical for these tools to unlock the power of data.	healthcare systems. The data flow ecosystem must mirror the patient ecosystem.
Goals, Objectives, and Strategies	17	Improve harmonization of data elements and standards by creating a common vocabulary set to improve the consistency, integrity, and quality of data and to enable data to be effectively shared between systems using APIs.	Quality of data, not just the quality of care, is required to optimize the interoperability paradigm. Tighter transformations and enforced HL7 standards and implementation guide(s) to minimize the need for any transformation. Any transformation process increases the patient safety risk. Data is always better coming directly from the source.
Goals, Objectives, and Strategies	18	Goal 4: Connect Healthcare and Health Data through an Interoperable Health IT Infrastructure Objective 4a: Advance the development and use of health IT capabilities Federal agencies can support greater health IT research and development by reducing barriers to entry for health IT developers. In addition, healthcare providers need clear and easy ways to keep up with the continually evolving digital health landscape, and all stakeholders need to have confidence and trust in health IT for wider use of new capabilities to be achieved.	For a clinician to trust the external Partner data and push the button to add to the local EHR, the <i>clinical intention</i> needs to be conveyed effectively using HL7 Standards documents and an implementation guide. To support frustrated clinicians, easy screen-grab functionality should be connected to online issue reporting tools.
Goals, Objectives, and Strategies	19	Goal 4: Connect Healthcare and Health Data through an Interoperable Health IT Infrastructure Objective 4a: Advance the development and use of health IT capabilities Strategies: <ul style="list-style-type: none"> • Adopt and advance nationally endorsed standards, implementation specifications, and certification criteria through continued collaboration across public and private sectors. 	We need a rapid, agile and <i>required</i> national approach to be implemented and enforced. Clinical content data quality thresholds shall be established for the exchange between healthcare enterprises. The certification criteria based on test records shall be augmented with continuous surveillance monitoring to ensure the high clinical content quality is maintained.

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			<p>Clinical content data quality encompasses the complete data capture for each clinical domain and all the data elements are using HL7 standards value sets which support the receiver being able to ingest and display the external data in the local system.</p> <p>The VHIE Data Quality team experience is that once the interoperability technical handshakes succeed, and the one-time certification is achieved, nobody looks at or reevaluates the Production data. The VHIE DQ continuous surveillance of Production data has identified that the missing, misplaced and miscoded data are not reviewed. Out of sight, out of mind.</p> <p>Data standards are continually enforced in the automotive industry, the food industry, the financial industry and more. And yet not in healthcare.</p>
Goals, Objectives, and Strategies	19	<p>Goal 4: Connect Healthcare and Health Data through an Interoperable Health IT Infrastructure</p> <p>Objective 4b: Establish transparent expectations for data sharing</p> <p>...</p> <p>Stakeholders can support better understanding and transparency by sharing user-friendly compliance resources and by continuing to encourage collaboration between stakeholders on implementation of industry best practices that leverage existing privacy and security principles and frameworks.</p>	<p>Healthcare must demand collaboration between stakeholders on data exchange implementation. Healthcare does require best practices within healthcare enterprises by incentivization and public availability of clinician healthcare dashboards.</p> <p>But the healthcare IT industry is not part of that public availability of healthcare application dashboards for clinical content data quality.</p> <p>Clinical content data quality thresholds are key to improving healthcare for both the patient and the clinician. And will be cost-saving too.</p>
	19	<p>Goal 4: Connect Healthcare and Health Data through an Interoperable Health IT Infrastructure</p>	<p>Develop and publicize clinical content data quality thresholds. An idea whose time has come.</p>

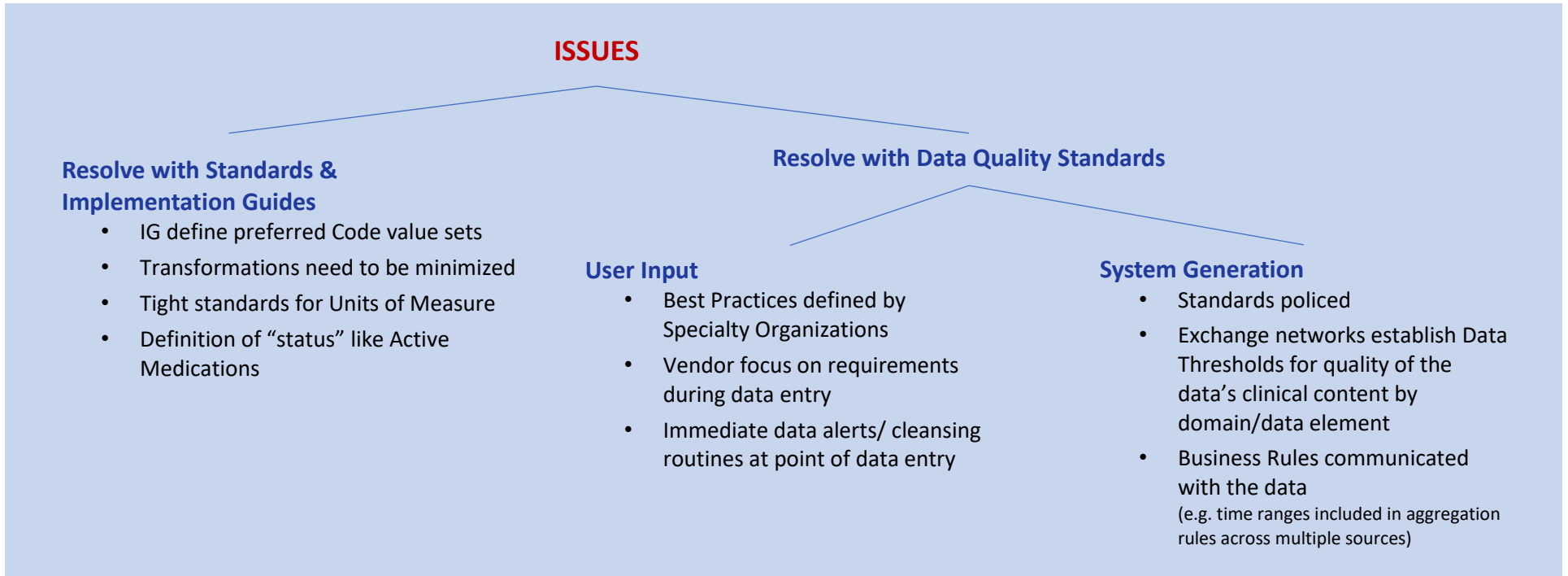
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		<p>Objective 4b: Establish transparent expectations for data sharing</p> <p>Strategies:</p> <p>...</p> <ul style="list-style-type: none"> • Promote data liquidity by working with developers, healthcare providers, payers, and state and federal entities to eliminate unnecessarily restrictive data sharing practices and to use endorsed standards, implementation specifications, and certification criteria. 	<p>The public awareness is critical. Without good clinical content, the sophistication of CDS or AI cannot be met, and the public needs to be aware of the barriers.</p> <p>How many patients are missing their Clinical Research opportunity? All because the data is in different systems and the interoperability currently in place does not support anyone having a full picture of the patient – not even the patient themselves.</p> <p>How many lives could be changed? How many more opportunities have to be lost?</p>
Goals, Objectives, and Strategies	20	<p>Goal 4: Connect Healthcare and Health Data through an Interoperable Health IT Infrastructure</p> <p>Objective: 4d: Promote secure health information that protects patient privacy</p>	<p>We agree with the Objective and its purpose.</p>
Appendix	22	<p>Appendix B: Measuring and Communicating Progress</p>	<p>The recommendation is for the continuous surveillance monitoring with communication of data quality content issues to the source and vendor with the requirement to address and fix the issues rapidly.</p> <p>The VHIE Data Quality team experience is that once the interoperability technical handshakes succeed, and the one-time certification is achieved, nobody looks at or reevaluates the Production data. The VHIE DQ continuous surveillance of Production data has identified that the missing, misplaced and miscoded data are not reviewed. Out of sight, out of mind.</p> <p>The VHIE DQ communication strategy is applied to the Vendor, Partner, and HIE actors with clinical data quality</p>

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			<p>metrics and scoring, including easy to use deliverables to resolve outstanding issues.</p> <p>Most commercial healthcare applications are designed for the financial tract, requiring the clinician to provide additional data, extraneous data to the clinical needs.</p> <p>The VA clinicians have always appreciated that VistA was designed and focused on patient care, not the financial needs.</p>

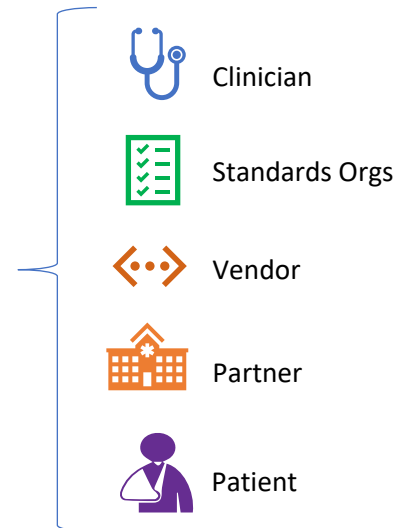
Owning the Fix



Channels of Opportunity

- Source Enterprise
 - Data Capture Process
 - CCD Configuration
 - Transformation
- Systems
 - Aggregation
 - Transmission
- Receiver Enterprise
 - Received CCD
 - Transformation
 - Storage
 - Display

Every actor has a role to play



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Location in the data flow Channels that Actors can act:

Source (Actors) of Data Quality Issues and Opportunities to Fix								
Data Capture Process	Source CCD Config	Source Transformation	CCD Aggregation	CCD Transmission	Requestor Receives CCD	Receiver Transformation	Receiver Storage	Receiver Display
<div style="border: 1px solid black; padding: 2px; margin-bottom: 5px;"> Data Missing <ul style="list-style-type: none"> Best Practice Training </div> <div style="border: 1px solid black; padding: 2px; margin-bottom: 5px; background-color: #FFD700;"> Data Capture Design </div> <div style="border: 1px solid black; padding: 2px; margin-bottom: 5px; background-color: #008000;"> Code Value Sets </div> <div style="border: 1px solid black; padding: 2px; margin-bottom: 5px; background-color: #FFD700;"> Use of Local Code Value Sets </div> <div style="border: 1px solid black; padding: 2px; background-color: #FFD700;"> Consumption of Interface messages / Population into native system </div>	<div style="border: 1px solid black; padding: 2px; margin-bottom: 5px; background-color: #FFD700;"> CCD Templates Available to Populate </div> <div style="border: 1px solid black; padding: 2px; margin-bottom: 5px; background-color: #008000;"> CCD Version </div> <div style="border: 1px solid black; padding: 2px; margin-bottom: 5px; background-color: #FFD700;"> CCD Config </div> <div style="border: 1px solid black; padding: 2px; margin-bottom: 5px; background-color: #FFD700;"> CCD Setup Decisions </div> <div style="border: 1px solid black; padding: 2px; background-color: #FFD700;"> CCD – Select Appropriate Domain for Data Elements </div>	<div style="border: 1px solid black; padding: 2px; background-color: #008000;"> Transform to Standardized Code Value Sets </div>	<div style="border: 1px solid black; padding: 2px; margin-bottom: 5px; background-color: #FFD700;"> CCD Version </div> <div style="border: 1px solid black; padding: 2px; margin-bottom: 5px; background-color: #FFD700;"> CCD Aggregation Config Rules </div> <div style="border: 1px solid black; padding: 2px; background-color: #008000;"> CCD Templates Available </div>	<div style="border: 1px solid black; padding: 2px; margin-bottom: 5px; background-color: #FFD700;"> Network Selection </div> <div style="border: 1px solid black; padding: 2px; margin-bottom: 5px; background-color: #FFD700;"> Aggregation Rules for Network or HIE </div> <div style="border: 1px solid black; padding: 2px; margin-bottom: 5px; background-color: #FFD700;"> Domain and Data Element Consumption of configuration / Data Rules </div> <div style="border: 1px solid black; padding: 2px; background-color: #FFD700;"> Identification of "Gold Standard" data source when multiple </div>	<div style="border: 1px solid black; padding: 2px; background-color: #FFD700;"> CCD Templates Available to Populate </div>	<div style="border: 1px solid black; padding: 2px; background-color: #008000;"> Transform to Standardized Code Value Sets </div> <div style="border: 1px solid black; padding: 2px; margin-bottom: 5px; background-color: #008000;"> Standardize data elements (e.g. Units of Measure) </div> <div style="border: 1px solid black; padding: 2px; background-color: #FFD700;"> Design of aggregating data from different sources </div>	<div style="border: 1px solid black; padding: 2px; margin-bottom: 5px; background-color: #FFD700;"> Decision on Storage - XML </div> <div style="border: 1px solid black; padding: 2px; background-color: #FFD700;"> Decision on Storage - Repository </div>	<div style="border: 1px solid black; padding: 2px; margin-bottom: 5px; background-color: #ADD8E6;"> Data Missing <ul style="list-style-type: none"> Where is the Data? </div> <div style="border: 1px solid black; padding: 2px; background-color: #ADD8E6;"> Clinician Frustration <ul style="list-style-type: none"> Display design Training </div>
							<p style="text-align: center; margin: 0;">KEY OPPORTUNITIES</p> <p style="margin: 0;"> Blue = Clinicians Best Practice Green = Standards Orgs Orange = Vendor; Vendor Implementation Teams; Vendor Ongoing Support </p>	