

Realizing Patient-Centered Clinical Decision Support: A New Performance Measurement Framework

Prashila Dullabh, Courtney Zott, Nicole Gauthreaux, James Swiger, Edwin A Lomotan, Dean F Sittig

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Realizing Patient-Centered Clinical Decision Support: A New Performance Measurement Framework

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Abstract

Background: Patient-centered clinical decision support (PC CDS) exists on a continuum that reflects the degree to which its knowledge base, data, delivery, and use focus on patient needs and experiences. A new focus on value-based, whole-person care has resulted in broader development of PC CDS technologies, yet there is a limited information on how to measure their performance and effectiveness. This paper provides a new framework for measuring the performance of PC CDS technology and describes how the framework can be applied to illustrative use cases.

Objective: This paper presents a new framework that incorporates patient-centered principles into traditional health information technology and clinical decision support (CDS) evaluation frameworks to create a unified guide to PC CDS performance measurement.

Methods: We reviewed existing literature on health information technology, CDS, and PC CDS measurement and evaluation to develop the framework. We validated and refined the measurement framework through key informant interviews and input from an expert panel.

Results: The PC CDS Performance Measurement Framework includes six domains: safe, timely, effective, efficient, equitable, and patient-centered. Each domain contains subdomains with example measures and approaches to patient-centeredness. The framework also describes different levels at which effects can be measured, for example, at the patient, clinician, organization, and population level.

Conclusions: This framework can be used by researchers, health system leaders, informaticians, and patients to understand the full breadth of performance and impact of PC CDS technology. As the field of PC CDS matures, researchers and evaluators can build upon the framework to assess which components of PC CDS technologies work, whether PC CDS technologies are being used as anticipated, and whether the intended outcomes of delivering evidence-based, patient-centered care are being achieved.

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Keywords: patient-centered; measurement, health care; clinical decision support

Introduction

In response to a growing body of research on suboptimal health care quality in the U.S., ¹, ² organizations delivering healthcare are amid an unprecedented transition in how they approach patient care and reimbursement. The new focus is on value-based, whole-person care that prioritizes patient values, goals, needs, and preferences to achieve positive health outcomes. This new approach to care is reflected in the U.S. Department of Health and Human Services priorities, ³ which include advancement of health information technology (health IT) and promotion of personalized medicine, patient involvement in the clinical decision-making process, and treatment recommendations guided by evidence-based guidelines.

Clinical decision support (CDS) technology (e.g., electronic health record [EHR] prompts and alerts, diagnostic and treatment guidance for clinicians based on clinical guidelines) aims to achieve these priorities but has traditionally focused on supporting clinicians at the point of care. Technology that supports patients and incorporates patient-centered knowledge and patient-generated health data, known as patient-centered clinical decision support (PC CDS), holds promise for advancing value-based, whole-person care. Specifically, PC CDS encompasses a spectrum of decision-making tools that significantly incorporate patient-centered factors related to knowledge, data, delivery, and use. Knowledge refers to the use of comparative effectiveness research (CER) or patient-centered outcomes research (PCOR) findings. Data focuses on the incorporation of patient-generated health data, patient preferences, social determinants of health, and other patient-specific information. Use refers to directly engaging patients and/or caregivers across different settings. Finally, delivery focuses on facilitating bi-directional information exchange in support of patient-centered care, including shared decision-making.

CDS developers commonly use the five rights⁷ as a benchmark for what makes a successful intervention, and several recent assessments of the CDS field have been published. 8,9,10 However, less is known about the emerging field of PC CDS. 11 Measurement of performance is critical to understanding how PC CDS technology can achieve the five rights and improve clinical and other patient-centered outcomes, as well as what unintended consequences may exist. PC CDS performance measurement is a complex undertaking given the intricacies of interventions, variety of data sources (e.g., EHRs, remote devices, apps), and nascency of the field. Without understanding of what leads to a successful PC CDS intervention, PC CDS technology development, use, effectiveness, and scalability will remain limited. To ensure PC CDS technology is safely and effectively integrated into healthcare delivery systems, further research and measurement is needed to adapt to the goals of a patient-centered approach and facilitate understanding of the factors that lead to successful implementation.

Objective

This paper presents a new framework that incorporates patient-centered principles into traditional health information technology (health IT) and CDS evaluation frameworks to create a unified guide to PC CDS performance measurement.

Methods

We employed three methods in developing the new performance measurement framework: 1) literature review; 2) key informant interviews (KIIs); and 3) feedback from an Expert Committee (EC) (see acknowledgements for EC members). The study was submitted for Institutional Review Board (IRB) review and classified as exempt.

Literature Review

Our literature review aimed to identify existing measurement frameworks and types of measurements used to assess health IT, CDS, and PC CDS technology performance. We began with a snowball approach, using a starting set of 10 peer-reviewed health IT and CDS measurement frameworks and measurement-related publications compiled by one of the authors (DFS) with previous CDS measurement and evaluation experience. We conducted backward citation tracking of the starting set of papers, then conducted a title/abstract screening to determine whether each article met the eligibility criteria (see Table 1).

Table 1. Eligibility criteria for literature review

Inclusion Criteria*

Covered at least one of the following three areas:

- Technical components relevant to PC CDS interventions, such as hardware and software, clinical content, and computer interfaces.
- The full information technology (IT) lifecycle of PC CDS: Knowledge Generation, Design, Development, Implementation, and Use.
- Measurement considerations at different levels (i.e., patient/clinician, system, health IT level).

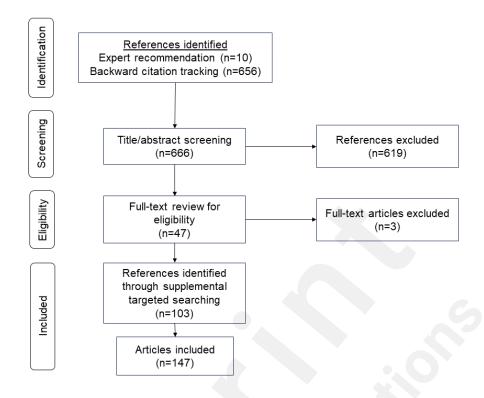
Published as a peer-reviewed research article (i.e., not abstracts, viewpoints, commentaries, editorials, or protocols)

Full text available in English or Spanish

The team reviewed the full text of each source and extracted information according to three predetermined data abstraction domains: 1) whether the source was a formal evaluation or measurement framework, 2) if the source was an evaluation or measurement framework, whether it was validated, and 3) whether the source's findings specified the following: levels of measurement (e.g., organization, individual), measure domains, measure subdomains, and specific measures

The team extracted the subdomain definitions from the full text of each source. In cases where definitions or descriptions were not explicitly stated, we conducted supplemental searches to find more specific information. We also conducted supplemental searches to describe the relationship of each domain and subdomain to PC CDS interventions. Given that PC CDS is a relatively new term, we used search terms encompassing key areas of CDS, such as "digital health" and "shared decision-making", in combination with the relevant measurement concept. We screened titles and abstracts and excluded publications that were not peer-reviewed research articles, were not available in English or Spanish, did not involve a PC CDS technology, and did not measure the appropriate measure domain. This yielded an additional 103 peer reviewed articles. The final search included 147 sources (see Figure 1).

Figure 1. Flow diagram for literature review



Key Informant Interviews

Using the network of the Clinical Decision Support Innovation Collaborative, ¹² we identified a convenience sample of 8–10 potential informants to ensure interviews provided diverse understandings of PC CDS performance measurement. Ultimately, we recruited 6 key informants—which included CDS developers, clinicians, informaticians, patient representatives, and measurement experts—to seek feedback on the framework and validate the measurement domains and subdomains. Informants received the draft framework in advance of the KIIs, and in the 60-minute interviews were asked to focus feedback in three areas: 1) perspectives on how we organized the domains and subdomains, 2) any gaps in the domains and subdomains, and 3) any refinements to the existing domains and subdomains. Transcript-style notes were created after each interview. We analyzed information from the KIIs using qualitative thematic synthesis, ¹³ employing an inductive approach with simultaneous phases of data collection and analysis. Two senior staff reviewed the transcript-style notes to refine the themes identified in each interview and map them to the domains and subdomains identified in the literature review.

Expert Committee

The research team operates a seven-member EC comprising informaticians, clinicians, CDS developers, and patient advocates. The EC validated the idea and need for a unified measurement framework for PC CDS performance, provided input on the organizing structure and measure domains for the framework, and reviewed the final framework.

Results

We identified 6 measurement and evaluation frameworks and two systematic reviews of such frameworks (Table 2). These frameworks and systematic reviews cover general health IT as well as CDS-specific

evaluation.

Table 2. Identified Frameworks and Systematic Reviews

Framework or Systematic Review	Description
Human, Organization, and Technology-fit framework (HOT-fit) ¹⁴	Building on previous models of health information systems (HIS) evaluation, HOT-fit proposes 8 dimensions for evaluating HIS and numerous evaluation measures within those dimensions. The framework incorporates the concept of "fit" among human, organization, and technical factors (i.e., not only does performance matter on individual dimensions and measures, but these factors must be in alignment for HIS to be successful).
Behavior and Acceptance Framework (BEAR) ¹⁵	BEAR is an integrated conceptual framework that bridges the gap between behavioral change and technology acceptance aspects of CDS implementation. BEAR presents "constructs" that are "determinants of behavioral change and acceptance of CDS" and groups them into domains.
Evaluation in Life Cycle of Information Technology (ELICIT) ¹⁶	ELICIT is an evaluation framework for EHR-integrated innovations to support evaluation activities at each of 4 IT lifecycle phases: planning, development, implementation, and operation. The framework also proposes three levels at which evaluations can be conducted—society, user, and IT—and provides measurement exemplars within each level.
Health IT Reference Evaluation Framework (HITREf) ¹⁷	HITREf builds on a prior systematic review to propose 4 evaluation concepts comprising 12 evaluation components to assess health IT.
Measures of success of computerized clinical decision support systems: an overview of systematic reviews ¹⁸	This overview is the first to focus on evaluation metrics of CDS, which were mapped according to the updated DeLone and McLean Information Systems Success Model. ¹⁹
Handbook of eHealth Evaluation: An Evidence-Based Approach ²⁰	This handbook provides a systematic overview of the different evaluation approaches to IT, with case examples that have been applied and reported for a wide range of healthcare systems and settings.
Health information systems evaluation frameworks: A systematic review ²¹	This paper analyzes studies on the evaluation of health information systems by applying a content, context, and process framework to address the 'who,' 'what,' 'how,' 'when,' and 'why' of the evaluation processes used.
Clinical, Human and Organizational, Educational, Administrative, Technical, Social (CHEATS) Framework ²²	CHEATS is an IT evaluation framework for healthcare that proposes six areas for assessment: 1) clinical, 2) human and organizational, 3) educational, 4) administrative, 5) technical, and 6) social. The framework recommends both qualitative and quantitative approaches to measuring the assessment areas.

Each framework offered several areas and concepts for measurement. Most began with an organizing construct for measurement and offered example measurement subcategories. However, the nature and specificity of the constructs and subcategories varied. Some frameworks were structured around broad ideas and concepts; others began with a narrower focus. Due to the variation, we chose to categorize measurement concepts into two types: domains and subdomains. This enabled us to define domains as broad yet actionable measurement areas, within which more specific areas (subdomains) can be measured. We first employed an inductive approach to identify the measure domains and subdomains for our framework. Specifically, two

members of the research team mapped similar domains and subdomains within the literature to identify the most mentioned concepts. Two senior members of the research team then reviewed the mapping, discussed disagreements, and agreed on modifications to arrive at final domains and associated subdomains. We found that the proposed measure domains and subdomains most commonly discussed in the literature focused on diverse aspects of quality measurement. We then conducted a targeted literature review to identify any existing healthcare quality frameworks that covered our identified domains. As a result of this review, we identified the National Academy of Medicine's (NAM) six domains of healthcare quality: safe, timely, effective, efficient, equitable, and patient-centered and we selected this as the organizing construct for our framework.²³ We also found that the measure domains and subdomains include the structures, processes, and outcomes²⁴ associated with the PC CDS interventions, i.e., measures related to the PC CDS technology and how it is performing; measures related to the impact of the PC CDS technology on patient and clinician behavior; and measures reflecting the impact of the PC CDS technology on clinical and other outcomes.

Overview of the PC CDS Performance Measurement Framework

Our results begin with a high-level overview of the PC CDS performance measurement framework domains. We then provide further detail about each domain and its subdomains, as well as illustrative measures. Given that PC CDS is a type of CDS, each domain and subdomain includes and builds on traditional CDS measures. To account for the unique features of PC CDS we also specifically describe how to integrate patient-centered principles into each domain and subdomain to evaluate PC CDS performance. We conclude the section with an overall description of the framework and the different levels of measurement (e.g., individual patient, organization) that can be used when applying it to real-world evaluations.

The NAM's six healthcare quality domains²⁵ are as follows:

- *Safe:* Avoiding harm to patients or users from the use of the system or recommendations provided that is intended to help them.
- *Timely*: Reducing waits and sometimes harmful delays (e.g., due to technology malfunction) for both those who receive and those who give care, and ensuring care is provided at the time it is needed.
- *Effective:* Providing functional, accessible systems and services based on scientific knowledge to all who could benefit and refraining from providing systems and services to those not likely to benefit (avoiding underuse and misuse, respectively).
- *Efficient:* Avoiding wasted or unnecessary effort, ensuring integration into clinician and patient workflows, and reducing burden on the intended user, support the intended goal.
- *Equitable*: Providing interventions, advice, and care that accounts for social determinants of health (SDOH) and does not vary in quality because of personal characteristics.
- *Patient-Centered:* Providing interventions, advice, and care that is respectful of and responsive to individual patient preferences, needs, and values and ensuring patient values guide all clinical decisions.

Safe

PC CDS technology has the potential to improve patient safety by preventing adverse events. However, such technology can also cause adverse events (e.g., when patient or clinician-facing alerts

are inappropriately overridden) if not designed, developed, or implemented correctly. ^{26,27,28,29,30,31,32} Concerns around patient safety and quality also prompted the U.S. Food and Drug Administration (FDA) working with others in the federal government to develop a proposed strategy and recommendations for a risk-based framework for health information. ³³, ³⁴

While not intended for legal compliance, the safety of PC CDS technology can be appropriately assessed by developers and implementers through measuring three subdomains: 1) error quantification, 2) system quality, and 3) completeness of data or other information.

Table 3. Safe Subdomain Definitions

Subdomain	Definition	Example Measures
Error Quantification	The degree to which a specific intervention leads to patient risks and safety-related reportable adverse events, including any unanticipated consequences to the patient, clinician, or healthcare organization. ^{35,36} When evaluating PC CDS interventions, measures of errors should both: 1) ensure patients are not experiencing negative clinical impacts (e.g., adverse reaction to a drug due to an inappropriately overridden alert ³⁷), as well as 2) pay particular attention to symptoms patients may be experiencing. For example, measures related to drug-drug interactions or adverse drug events could use patient-reported data about symptoms. ³⁸	 Appropriateness of screening reminders Occurrence of severe/life threatening patient safety events Patient-reported symptom burden or volatility Patient-reported adverse events
System Quality	The degree to which the information and functions provided by the system meet the user's needs or expectations and give user satisfaction; the degree to which the system is free from deficiencies or defects ^{.39,40} As the number of alerts sent directly to patients increases with PC CDS technology, system quality will inevitably become ever more important. Measures of patient centeredness should focus on ensuring the PC CDS technology can retrieve, as needed, patient-contributed data accurately to drive alerts. ⁴¹	 Knowledge accuracy, reliability, and validity Alert accuracy Algorithm accuracy Data retrieval accuracy Patient-reported issues with system functionality
Completeness	The degree to which the system provides all the information required by the user to make the intended decision or to perform the intended behavior. 42,43,44,45,46,47,48 When evaluating PC CDS technology, completeness should account for unique patient characteristics—patient-reported outcomes, and/or patient preferences—that may impact care decisions. For example, when discussing treatment options for a patient on chemotherapy, the PC CDS technology needs to account for adverse patient-reported outcomes such as peripheral neuropathy, which can be minimized by stopping one or more of the chemotherapy agents. 49	

Timely

PC CDS interventions aim to reduce delays for care teams and patients in providing or receiving care. Properly implemented, PC CDS interventions have been shown to improve the ability of clinicians to deliver care at the right time,⁵⁰ and for patients to better manage their health. However, the CDS literature has documented numerous challenges to achieving this goal, including relevance of clinical recommendations, currency of clinical guidance, reliability of CDS tools, data availability, and more.⁵¹

The timeliness of PC CDS interventions can be assessed by measuring five subdomains: 1) computer processing time, 2) whether information is up to date, 3) availability of the PC CDS technology, 4) whether information is provided when the user needs it, and 5) whether the patient receives care at the right time. Measurements in each subdomain should consider and/or be adapted to patient lifestyles, new patient-generated data types, different methods of delivery (e.g., apps, patient portals), and patient preferences, to form an adequate assessment of a PC CDS intervention's impact on care timeliness. Patient preferences and experiences are critical to include in addition to standard measurements (e.g., for care timeliness, a patient-centered measurement approach should examine both the time to care delivery and patient preferences around timing of treatment).

Table 4. Timely Subdomain Definitions

Subdomain	Definition	Example Measures
Computer Processing Time	The degree to which the time required for the computer to complete the work required to gather data, run the CDS algorithm and generate an intervention is reduced. ⁵² For PC CDS technology, developers might be interested in how long it takes the PC CDS engine to gather data and run the algorithm necessary to process patient-generated health data (PGHD) from remote devices and arrive at a recommendation.	Time for alert to fire Time for PC CDS artifact to incorporate relevant patient contributed data
Information Provided is Up to Date	The degree to which the information presented by the system is based on up-to-date input. 53,54,55,56 For PC CDS technology, use of PGHD including patient-reported outcomes (PROs), makes timeliness important to measure. The volume and pace of data collected from biometric devices requires nuanced consideration of timeliness (e.g., a patient's most recent blood glucose reading may not be the most relevant for long-term clinical decision-making).	 Information resource includes the most current patient provided information. The artifact is updated with the latest evidence-based guidelines.
Availability	The degree to which a system can be used when the user needs to use it. 57,58,59,60 Patient-centered evaluations of availability should assess whether the patient encounters any technical issues when accessing the system. 61,62	 Patient feedback on system glitches Patient-reported technical issues
Information is Provided when the User is Making the Decision	The degree to which the necessary information presented by the PC CDS technology is available at the time it is needed. Patient-centered evaluations of availability should assess whether the PC CDS technology fires at the right time to support the patient in evidence-informed decision-making. Patient "workflows" or lifestyles are also key	 Alert frequency (compared to patient' expressed routines and preferences) Tool customizability (to enable patients to customize

	considerations for this subdomain.	alerts to schedules)
Care Timeliness	The degree to which the system can provide care in a timely manner after a need is recognized. 66, 67 To ensure a patient-centered lens, measures should incorporate patients' preferences regarding when a specific intervention or type of care should be delivered (e.g., if the patient desires medication first or prefers to try lifestyle changes).	 Time to care delivery Care team response time to patient inquiries submitted via PC CDS technology Care team response time to alerts

Effective

Effectiveness requires monitoring whether the PC CDS technology is benefiting those for whom it is intended. A landmark 2012 systematic review found that CDS interventions were generally effective at improving healthcare process measures, but evidence for effectiveness in areas such as improving clinical and economic outcomes was lacking. Similarly mixed findings on patient outcomes have been documented in more recent systematic CDS reviews in all healthcare settings. Reviews of CDS effectiveness that focus on specific interventions or disease states (e.g., medication-related CDS interventions) have also shown inconsistent results.

Effectiveness of PC CDS interventions can be assessed by measuring six subdomains: 1) user satisfaction, 2) acceptability; 3) patient health outcomes, 4) usability, 5) clinician performance, and 6) transparency.

Table 5. Effective Subdomain Definitions

Subdomain	Definition	Example Measures
User Satisfaction	The degree to which a user is satisfied with their experience in using the system and with the system's potential impact. This subdomain captures several concepts (such as user attitudes toward the system or perceptions of usability, quality, timeliness, and usefulness) that, taken together, provide an overall evaluation of the user's experience and satisfaction with the impact of the PC CDS technology.	 Willingness to recommend the PC CDS technology to others Satisfaction with data quality Satisfaction with content and extensiveness of reminders
Acceptability	The degree to which the user perceives the PC CDS technology is appropriate, adequate, and relevant, and that both clinicians and patients see the CDS as helpful. ⁷⁷ Measuring acceptability of PC CDS technology should involve attention to user subgroups who have different preferences and needs regarding guidelines and alerts.	 Sustained use of PC CDS technology Perceived benefit for patient case/complexity User perceptions of impact on performance
Patient Health Outcomes	The degree to which change in health status is attributable to PC CDS interventions. 78, 79,80,81,82,83,84 Measurement of patient health outcomes involves examining changes in health status (e.g., morbidity) relevant to the disease or condition attributable to CDS. 85 When evaluating PC CDS interventions, as with many other subdomains, measures should also consider the outcomes patients desire, in addition to traditional clinical indicators helpful for clinicians	 Life expectancy Quality of life Morbidity Mortality Burden of disease Changes in PRO scores due to intervention

	and healthcare organizations.	Changes in patients' self-reported symptoms and/or symptom burden
Usability	The degree to which the system enables users to carry out their tasks safely, effectively, efficiently, and enjoyably. 86 Usability assessments need to account for the different methods and settings in which PC CDS technology will be delivered to patients and/or clinicians. 87,88,89,90,91,92,93,94,95,96,97,98,99,100 Measures include the quality of a user's experience when interacting with the PC CDS technology, and concepts such as fit with workflow/lifestyle, learnability, and use. 101 Also encompassed is the ease with which a system can be used by the intended actors to achieve specified goals. 102 Relevant usability aspects of PC CDS technology: • Fit with workflow/lifestyle: For clinicians, the degree of fit between organizational work practices and how PC CDS can be integrated into the clinician tasks and processes is important. 103 For patients, anticipating how the PC CDS tool fits into the patient "workflows" or lifestyles is a key consideration. • Learnability: This includes extent of feature use, help desk requests, and rate of uptake. 104 • Use: This includes the degree to which users log in and use the technology, as well as persistence of use of alternatives/workarounds. 105 106,107,108,109,110	 Perceived ease of use Rate of usability errors Extent of feature use Help desk requests Rate of uptake Extent of uptake Persistence of use of alternatives/workarounds Perceptions of alignment with patients' daily lives
Clinician Performance	The degree to which the clinician improves diagnosis, or provides more complete preventive care, better disease management, more accurate drug dosing, and/or drug prescribing. When evaluating PC CDS interventions, evaluators should include assessing whether the technology fosters greater rates of patient-centered decisions among clinicians.	 Changes in clinical practice Alert follow-up actions taken by care teams Clinician medication prescribing patterns Workflow efficiency Degree of shared-decision-making
Transparency	The degree to which descriptions of the guideline source, updates to the guidelines (if applicable), and the artifact author(s) are clear; and that relevant metadata like potential conflicts of interest and disclosures of interest related to its development and use are available. To be patient-centered, this information also needs to be detailed enough for general understanding of the subject and available in a clear and readable manner to promote patient trust in the system and empowerment to make better informed decisions. 113	 Updates to the guidelines Artifact author Potential conflicts of interest Sources of information provided Feedback on success and error/failure cases

Efficient

PC CDS technology should support the intended goal of the intervention, while enabling clinicians

and patients to complete tasks without wasted or unnecessary effort. PC CDS technology holds promise for increasing the efficiency of the clinician effort and other resources needed to care for patients. But PC CDS technology can increase workload and burden when not designed or implemented properly. Interventions should be monitored to ensure they do not contribute to clinician burnout and are an efficient use of organizational resources. Similarly, PC CDS technology needs to fit into patient lifestyles without adding net burden for patients and their caregivers.

Efficiency of PC CDS interventions can be assessed by measuring six subdomains: 1) relevance/appropriateness, 2) interoperability, 3) cost, 4) reuse/scalability, 5) service utilization, and 6) cognitive workload.

Table 6. Efficient Subdomain Definitions

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Subdomain	Definition	Example Measures
Relevance/ Appropriateness	The degree to which recommendations are relevant for the clinical context, 115,116,117 and appropriate for patient care. 118 A patient-centered approach to measuring appropriateness takes a more holistic view and accounts for patient outcomes, preferences, and costs versus focusing solely on clinical safety and efficacy. 119	 Alert appropriateness Prescription appropriateness Appropriateness of treatment Patient perceptions of appropriateness
Interoperability	The degree to which two or more systems or elements are able to exchange information and use the information that has been exchanged. 120, 121,122,123 Interoperability in the context of PC CDS technology means ensuring patient data such as patient-generated health data (i.e., data from medical devices and wearables and PRO data) can be seamlessly shared between parties (e.g., sent from patient to clinician) and technologies (e.g., device to EHR) using data exchange standards. 124 Interoperability can also apply to assessing the speed with which Fast Healthcare Interoperability Resources (FHIR) application programming interfaces (APIs) are integrated into EHRs and can be retrieved for PC CDS technology.	Time to write data from patient app to EHR Time to view data from EHR using an app
Cost	The amount of money required to design, develop, implement, and use the system and paid recurrently to use the system. Traditional cost-effectiveness analyses offer thresholds for determining when an intervention is cost-effective (i.e., when benefits outweigh costs). But evaluators should also determine their own thresholds for determining whether interventions perform "well" in this subdomain, based on their organizational context. A patient-centered perspective would involve examining benefits that are most important to patients and determining costs to the patient, not only clinicians and healthcare delivery systems.	 Development cost Implementation cost Maintenance cost Hardware/software cost Personnel cost Cost/benefit ratio Financial burden on patient
Reuse/Scalability	The degree to which the deployment of CDS capabilities is expanded with the centralized management of machine-executable knowledge resources, which are then leveraged across multiple care settings by CDS engines interfaced with different health information systems. 130,131 Developing PC CDS	 Site uptake of PC CDS technology Accessibility Organizational perspectives on sustainability

	artifacts often requires specialized clinical and informatics knowledge that not all health systems have. It is important to measure how artifacts are being adopted, such as through PC CDS technology uptake (number, proportion, or duration of use) or clinician and patient perspectives on accessibility.	Degree of decision task automation
Utilization of Services	The degree to which patients interact with healthcare, the types of care they receive, and the timing of that care. 132, 133 When evaluating PC CDS interventions, measurements should account for the patient's perspective on accessibility, continuity, and coordination of care. 134	 Use by setting (e.g., emergency department, inpatient) Duplicate lab tests Time until next appointment Test appropriateness
Cognitive Workload	The degree to which the demands placed on a person by mental work are balanced with the person's mental capacity. 135, 136,137 PC CDS technology design should carefully consider how information is presented to both clinicians and patients to account for different levels of health literacy. When evaluating PC CDS technology, patients and caregivers are typically the primary users, so evaluations should consider the cognitive workload of tools and information for patients.	 Patient workload Alert fatigue Think time Cognitive overload Desensitization

Equitable

A plethora of research indicates the persistence of inequities in U.S. healthcare based on personal characteristics and SDOH; yet few studies have examined the impact of health IT on equity. ^{138,139, 140} We consider two means by which PC CDS technology could impact equity in healthcare delivery: 1) by unintentionally increasing the digital divide, and thereby who benefits from PC CDS technology¹⁴¹; and 2) by incorporating SDOH data into decision support, thereby ensuring delivery systems are offering guidance to patients and caregivers that accounts for their specific needs in an equitable way. Given this, key informants emphasized the importance of designing and developing PC CDS interventions with equity in mind. For example, organizations should take into account differing levels of education and health literacy in designing technologies. Additionally, care should be taken not to use biased clinical algorithms (e.g., algorithms that "correct" for race but ultimately lead to undertreatment or overtreatment of minority populations ¹⁴²). ¹⁴³

Equity is complex to measure and involves assessing the relationship of group characteristics with the structures, processes, and outcomes of health care delivery. Therefore, to measure overall impact of PC CDS technology on equity, we provide factors in six SDOH subdomains that can be used to assess relationships to performance in the framework's other subdomains. These factors are: 1) social context, 2) economic context, 3) health literacy, 4) digital health literacy, 5) physical infrastructure, and 6) healthcare context. Equity measurement applies both at the individual and organizational levels and across phases of the PC CDS lifecycle (i.e., whether usability differs by social context is important to identify in the Design and Development phase as well as the Use phase).

Table 7. Equitable Subdomain Definitions

Subdomain	Definition	Example Measures
Social Context	The degree to which factors that influence a patient's social and community supports, including demographics, social cohesion, and discrimination are included. 146 PC CDS technology needs to carefully factor in social context factors when delivering decision support to both patients and clinicians. Additionally, social context factors can be used to conduct analyses for other subdomains. For example, patient satisfaction with PC CDS technology can be segmented by patient demographics such as age, race, ethnicity, sexual orientation, gender identity, education status, disability status, to ensure technology is satisfactory regardless of demographic differences.	 Patient satisfaction with PC CDS technology by preferred language Degree to which PC CDS technology incorporates social context
Economic Context	The degree to which factors related to financial status such as employment, income, and poverty are included. To optimize patient use of PC CDS technology, specific measurements should consider the digital divide among PC CDS technology users. 148,149,150	 Use of PC CDS technology by household income Degree to which PC CDS technology incorporates employment context
Health Literacy	Organizational: The degree to which organizations equitably enable individuals to find, understand, and use information and services to inform health-related decisions and actions for themselves and others. Personal: The degree to which individuals have the ability to find, understand, and use information and services to inform health-related decisions and actions for themselves and others. Evaluators may wish to examine whether performance in other domains and subdomains is impacted by these factors to help understand how their organization is performing on health literacy and how PC CDS technology can be designed for patients with different literacy levels. For example, a practice managing patients with depression might periodically ask patients to fill out PHQ-9 questionnaires—but unless these questionnaires are made available in different languages, patients who do not speak English are less likely to fill them out than their English-speaking counterparts.	 Patient engagement with PC CDS technology by education level Literacy level of information provided by PC CDS technology Languages/translations offered by PC CDS technology
Digital Health Literacy	The ability to seek, find, understand, and appraise health information from electronic sources and apply the knowledge gained to address or solving a health problem." ¹⁵³ Similar to health literacy, evaluators should examine whether performance in other domains and subdomains is impacted by digital health literacy, such as engagement and use of PC CDS technology.	 Digital health literacy level of information provided by PC CDS technology Patient engagement with PC CDS technology by digital health literacy level
Physical Infrastructure	The degree to which factors related to the community in which the patient lives (e.g., housing, transportation, and food availability) are included. 154 Although accessing and collecting this information is challenging, PC CDS technology that can do so will be better able to tailor interventions to the specific needs and circumstances of patients. For example,	 Patient engagement with PC CDS technology by housing status Degree to which recommendations of PC CDS technology incorporate access to transportation

	recommendations to a patient on frequency of doctors' appointments may need to account for patients access to transportation and make available other options like telemedicine as well.	
Healthcare Context	The degree to which availability of, use of, and attitudes toward healthcare services that may impact participation in PC CDS interventions and behaviors after the intervention are included. Evaluators should include whether the care is high-quality, culturally and linguistically appropriate, and health-literate; access to insurance; rurality; and attitudes towards healthcare, and service use in their assessment of healthcare context. 155	Use of PC CDS technology by attitudes toward health care Patient engagement with recommendations of PC CDS technology by health insurance status Degree to which PC CDS technology incorporates healthcare context

Patient-Centered

Patient-centeredness involves facilitating active partnerships among patients, families, patient representatives, and health professionals that are effective within the context of the larger healthcare delivery system. Successful PC CDS technologies require a concerted effort to create accessible and targeted communication based on patient characteristics (e.g., health literacy and demographics), including finding an appropriate balance between providing needed information and overwhelming people with interruptive alerts. It also means extending decision support beyond merely providing information to identifying resources for patients and their caregivers. As one key informant noted: "CDS isn't always thought of as an educational intervention, but when it comes to patients it's worth considering if patients took away a somewhat lasting knowledge about the situation."

As PC CDS technologies continue to expand, it is crucial that they are effective in helping patients and caregivers make informed choices about their care and engage, as needed, in shared decision-making discussions with their clinicians and care teams. Measures in the patient-centered domain should be made from the patients' perspectives as much as possible.

Patient-centeredness of PC CDS technology can be measured with eight subdomains: 1) patient activation, 2) patient engagement, 3) patient satisfaction, 4) shared decision-making, 5) patient decision-making, 6) patient-relevant outcomes; 7) decisional quality and 8) patient knowledge acquisition.

Table 8. Patient-Centered Subdomain Definitions

Subdomain	Definition	Example Measures
Patient Activation	The degree to which the patient: 1) believes their role is important, 2) has the confidence and knowledge necessary to take action, 3) actually takes action to maintain and improve their own health, and 4) stays the course even under stress. ^{159,160} For PC CDS technology, what is relevant is patients having the knowledge, skills, and confidence to manage their own health, as related to health outcomes, due to the technology. ¹⁶¹ Patient activation is an indicator that patients are not only using or satisfied with a technology, but are being activated by it to manage their health. To gain an accurate understanding in this area, it is important to consider the influence of behavioral determinants such as existing patient attitudes, intentions, and norms or usual habits related to PC CDS technology and their health.	in making decisions about their

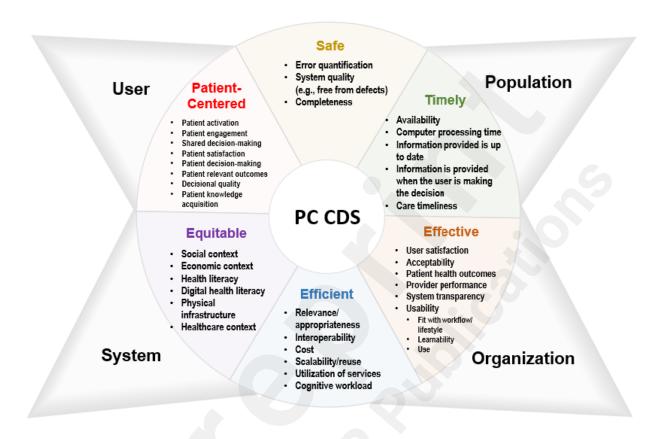
Patient Engagement Patient Satisfaction	The degree to which patients, families, their representatives, and health professionals work in active partnership at all levels across the healthcare system—direct care, organizational design and governance, and policy making—to improve health and healthcare. Patient engagement should be measured as the extent to which patients are engaged in the processes required to design, develop, implement, and use PC CDS technology. The patient's experience in using the system and the system's potential impact. 164,165,166,167,168 This is a subset of user satisfaction that focuses on patient preferences and expectations. This can be assessed even if the patient is not	 Extent of participation in technology design processes Extent of use of PC CDS technology Degree of behavior change due to technology Ease of decision Adherence to decision made Patient satisfaction with clinical encounter
Shared Decision- Making	the main or only user of the system. The degree to which a clinician communicates to the patient personalized information about options, outcomes, probabilities, and uncertainties of available options; and a patient communicates values and the relative importance of benefits and harms. This can occur through conversation between patient and clinician or through the PC CDS technology. Assessment relies on access to the latest evidence regarding treatment options, direction on how to weigh pros and cons, and a clinical culture that is supportive of patients. To	 Patient trust in PC CDS tool Decisional conflict Decision regret Decision readiness Use/effectiveness of decision aid
Patient Decision- Making	The degree to which a patient: 1) wants to be involved with CDS, and 2) makes choices on test, treatment, or outcome options based on their values, experiences, and assessments of benefits and harms. 171,172,173 Patient decision-making can occur with or without clinician involvement (i.e., shared decision-making). Measures should be selected based on what matters to the patient, how much it matters, and perceptions of risks and benefits for their lives. 174	 How decision was made Desire to make medical decisions Desire to seek information
Patient-Relevant Outcomes Decisional Quality	The degree to which patients can choose the outcomes that match their desires, beliefs, goals, and circumstances. This is particularly salient for outcomes related to quality of life. 175,176,177 The degree to which patients feel satisfied during and after the decision-making process. 178,179	 Symptoms Adverse events/complications Survival/mortality Pain Informed choice Weighing risks/benefits
Patient Knowledge Acquisition	Measurements of decisional quality should be sensitive to the preferences of patients, i.e., account for the relative importance a patient attaches to various outcomes. 180 The degree to which the patient comes away with lasting knowledge about their medical situation due to the PC CDS tool/intervention. This subdomain should measure the extent to which patients gain knowledge about their medical situations by taking part in the decision support activities. 181,182,183	 Confidence in decision Trust in information provided Quality of health information provided Change in knowledge about medical condition

Overall Framework

The overall measurement framework can be seen in Figure 2. The framework accounts for the impact of the PC CDS intervention occurring at multiple levels (e.g., individual user [patient or clinician], population of users, organization, and health IT system). The different levels at which the domains and subdomains can be

measured surround the framework, to indicate that the measurement perspective may change based on the goals and scope of the intervention, as well as on who is doing the measuring and/or interested in the outcome.

Figure 2. PC CDS Performance Measurement Framework



Application of the PC CDS Performance Measurement Framework

Implementers and evaluators need to work diligently to include patient-centered measures in their assessments, to ensure their measures account for a range of patient-centered considerations such as usability, patient digital and health literacy levels, and integration into patients' daily lives. To contribute to the field given its nascency, we provide two illustrative user scenarios for applying patient-centered measures across different phases of the PC CDS lifecycle and levels of measurement (see Table 9). To demonstrate the versatility of the framework the use cases were drawn to highlight different patient populations (i.e., post-partum patients and patients over 75); different potential duration of symptoms (i.e., acute and long term); different condition acuity; and the different types of PC CDS technology (e.g., patient-facing and clinician-facing). The use cases provide only a subset of potential measures from each domain; implementers and evaluators may choose different measures depending on the goals and context of the project.

Use Case 1. Hypertensive disorders of pregnancy (HDP) can pose serious health complications and increased risk of maternal mortality. Post-partum patients with HDP will need to monitor their blood pressure and hypertensive symptoms. To assess the design and development of a patient app to manage HDP, an evaluator could assess the *usability* of the app through user-centered design principles, to ensure the app is easy and intuitive to use. Additionally, *patient activation* could be assessed in the design phase, to explore if the app provides patients with the confidence and skills to manage their hypertension or if additional functionalities are needed, such as an education component. Other important subdomains to measure the system quality of the app include care timeliness, cognitive workload of interpreting blood pressure data, and health literacy considerations in the design of the app.

Use Case 2. Patients over age 75 with atrial fibrillation need to weigh the risks and benefits of taking oral anticoagulants. Anticoagulants can prevent blood clots that cause strokes but can also increase the risk of morbidity and mortality from gastrointestinal and intracerebral bleeding, particularly for older adults at greater risk of falls. The CHA₂DS₂-VASc tool provides estimates of the risk that patients with atrial fibrillation will have a stroke in the absence of treatment, and additional CDS tools provide estimates of a patient's risk of stroke and bleeding on various treatments. These estimates can help patients and their clinicians decide whether to initiate anticoagulation therapy. To assess the use of this tool post-implementation, an evaluator could consider measurements of *shared decision-making* to assess the patients' engagement with their clinician when deciding to take anticoagulants, and *patient health outcomes* to measure the impact of the decision on the patient's lifestyle, physical activity levels, and other outcomes important to the patient. Other important subdomains to consider would be unintended consequences in terms of adverse events, whether information is provided when user makes the decision, relevance/appropriateness of the recommendation provided, and social context of the population using the tool.

Table 9. Example Use Cases for Applying the PC CDS Performance Measurement Framework

Use Case Scenario	Relevant Domain and Subdomains to Measure	Measurement Level
Design and development of an app for managing hypertensive disorders of pregnancy (HDP) for post-partum patients	 Safe: System quality to check if the app has glitches or if it meets users' needs, such as ability to add notes to explain high or low readings Timely: Care timeliness to assess how quickly patients receive care after reporting clinically significant data Effective: Usability of the app to ensure it is easy and enjoyable to use Efficient: Interoperability to measure the time it takes to build the app and the amount of effort to integrate with the EHR Efficient: Cognitive workload to assess how the patient and care team uses and interprets large volumes of patient blood pressure and symptom data Equitable: Health literacy to ensure the app uses accessible language and the health system addresses barriers to accessing/using smartphones or blood pressure monitoring devices Patient-Centered: Patient activation to explore if the app provides patients with confidence and skills to manage their hypertension 	 Individual user: patient and clinician Population: post-partum patients with HDP Organization: the healthcare system where the app will be used and the company building the app Health IT system: the healthcare system's EHR platform

Use of a stroke risk assessment tool (e.g., CHA₂DS₂-VASc¹⁸⁷) to help clinicians and patients over age 75 with atrial fibrillation (afib) decide whether to initiate anticoagulation therapy

- Safe: Error quantification to assess whether the tool safely reduced the patient population's risk of stroke or adverse events from anticoagulants
- *Timely: Information provided when user is making the decision* to see if the assessment is taken when the patient is diagnosed with a-fib rather than after treatment has started or after the patient experiences adverse events
- Effective: Patient health outcomes to measure the impact of the decision on the patient population's overall lifestyle, physical activity levels, number of adverse events, number of strokes, and other outcomes important to patients
- Efficient: Relevance/appropriateness to ensure the recommendations produced by the tool are based on the clinical condition and context of the patient, such as whether they are physically active and at greater risk of falls
- *Equitable: Social context* to assess how the tool performs for patients over age 75 by sex category and race/ethnicity
- Patient-Centered: Shared decision-making to measure the patients' engagement with their clinician when deciding to take anticoagulants

- Individual user: patient and clinician
- *Population:* patients over age 75 with a-fib
- Organization: the healthcare system where the tool is implemented and used
- Health IT System: the clinical notes or EHR platform where the tool is hosted and calculated

Discussion

In this paper, we describe a new measurement framework that can be used by researchers, operational leaders, and patients to understand the performance and impact of PC CDS technology. The framework incorporates constructs from previously developed health IT and CDS evaluation frameworks and organizes them into measure domains and subdomains. We highlight five key considerations for this framework and their relevance.

Covers the entire PC CDS lifecycle. Domains and subdomains described in this paper address the entire PC CDS lifecycle—from the generation of Knowledge (which includes creating evidence-based guidelines based on patient-centered outcomes research), to the Design, Development, and Implementation of PC CDS, ¹⁸⁸ to the Use (i.e., healthcare delivery) of PC CDS. Some outcome-focused subdomains are more relevant to later stages of the lifecycle; for example, patient health outcomes and healthcare utilization are most relevant during the Use phase, after the technology has been implemented and these outcomes can be observed. On other hand, subdomains related to the performance of the technology (e.g., error quantification, system quality) are relevant across phases but are ideally addressed to the extent possible in the Design and Development phases. Thus, this framework provides the foundation for a more holistic evaluation of PC CDS technology that cover structure, process, and outcome measures.

Direct focus on the patient. The framework's domains and subdomains center on patient aims and specifically include equity and patient-centeredness as key components of successful PC CDS technology. Additionally, each subdomain is a patient-centered concept (e.g., patient engagement) or has potential measurements that incorporate patient-centered principles (e.g., consideration of patient preferences for when decision support is delivered). So far, the emergence of PC CDS technology has revealed a gap in the frameworks, models, and methods commonly used for CDS evaluation,

particularly in understanding the effect of including patient data into PC CDS technology and the effectiveness of PC CDS technology. For example, patient engagement is critical to PC CDS interventions, yet few studies have focused on the factors that improve and sustain patient engagement, or what types of engagement lead to improved clinical or other outcomes. ¹⁹⁰

Covers measurement at different levels. Many frameworks also describe different aggregation levels at which performance metrics can, or should, be most appropriately assessed—depending on the goals of the PC CDS intervention, the nature of the domain and subdomain, and/or the differing perspectives of user groups (e.g., clinicians versus patients). The measurement framework introduced here accounts for the impact of the PC CDS technology occurring at the level of the individual user [patient or clinician], user population, organization, and health IT system level. For example, population-level impacts may be important to evaluators trying to understand effectiveness of PC CDS interventions on the overall health of the community; individual level impacts may be important to evaluators attempting to correlate individual-level use and engagement measures with specific clinical outcome measures to identify the optimal method of PC CDS intervention delivery.

Encompasses six independent but related domains. Our performance measurement framework provides a balanced methodology to assess the extent of use and the quality of PC CDS interventions. As such, it provides six relatively independent domains in which measurements can be made and leaves the decision to the user on how to synthesize or prioritize the diverse measurements. An evaluator of an intervention does not need to assess every subdomain in the framework. Rather, they should work to assess one or more components of each domain most relevant to the evaluator's particular PC CDS intervention or research focus. Additionally, while we have mapped the measurements and subdomains according to their most common applications, the context and goals of an evaluation may require applications to different or multiple subdomains and domains, respectively. Subdomains and measures may also be closely related and/or influence each other (e.g., patient activation and patient engagement). Given that PC CDS technology implementation occurs in many different contexts that may require departure from a standard framework, our intent is for the framework to serve as a foundation for users as they design their own evaluation plans.

Requires additional research and development. We propose this framework as a starting point for PC CDS measurement, but further testing for usability and completeness of the framework is needed to inform refinements as appropriate. We recognize that there has been more work in some of the NAM quality domains than in others. As a result, some domains are better understood and more fully characterized than others as they pertain to PC CDS technology, including the equitable and patient-centered domains. Similarly, some phases of the PC CDS lifecycle have been more thoroughly explored than others (e.g., the Clinical Decision Support phase has more work done on measurement than the Knowledge Generation phase, which is a newer area for PC CDS measurement). More work is also needed to define and develop measures for our six domains (safe, timely, effective, efficient, equitable, patient-centered), as well as newer domains that have been added to NAM's framework to support a learning health system. ¹⁹¹ This work will need to consider the emerging use of artificial intelligence (AI) in the generation of knowledge and/or patient-specific advice.

Conclusion

Taken as a whole, the new, unified PC CDS Performance Measurement framework we present here provides a firm foundation upon which researchers can build as the field of PC CDS matures. Clearly, more work must be done to better understand what is working, whether the specific PC CDS technology is being used as anticipated, and whether the intended outcomes are being achieved. In addition, we anticipate we will see further development in which measures are prioritized for evaluations and of the relevant patient-centered measures as PC CDS technologies become more

broadly available. We expect much progress to be made in PC CDS and its evaluation over the next decade, as our understanding of the needs of patients and clinicians evolves and our ability to collect and interpret more data improves.

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Abbreviations:

AI: Artificial intelligence

APIs: Application programming interfaces BEAR: Behavior and Acceptance Framework

CDS: Clinical decision support

CER: Comparative effectiveness research

CHEATS: Clinical, Human and Organizational, Educational, Administrative, Technical, Social

Framework

EC: Expert Committee

EHR: Electronic health record

ELICIT: Evaluation in Life Cycle of Information Technology

FDA: U.S. Food and Drug Administration

FHIR: Fast Healthcare Interoperability Resources

HDP: Hypertensive disorders of pregnancy Health IT: Health information technology

HITRE-f: Health IT Reference Evaluation Framework

HOT-fit: Human, Organization, and Technology Fit Framework

IRB: Institutional Review Board IT: Information technology KIIs: Key informant interviews

PC CDS: Patient-centered clinical decision support

PCOR: Patient-centered outcomes research PGHD: Patient-generated health data PHQ-9: Patient Health Questionnaire-9 PROs: Patient-reported outcomes

NAM: National Academy of Medicine SDOH: Social determinants of health

Data Availability: The data sets generated during and analyzed during this study are not publicly available due to possible re-identification but are available from the corresponding author on reasonable request.

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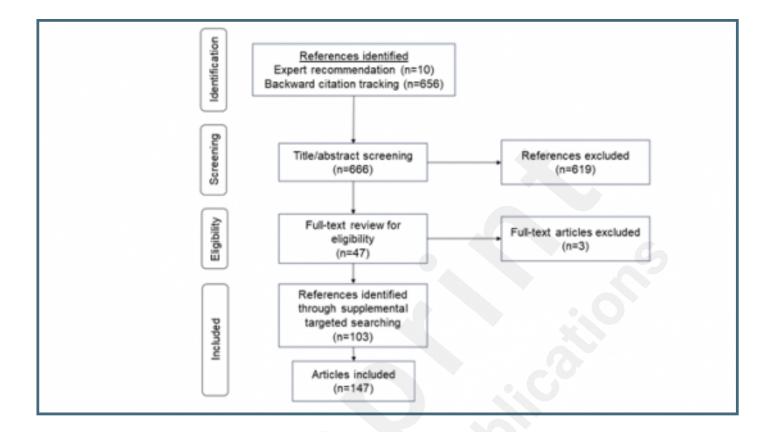
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Supplementary Files

Figures

This diagram presents the number of references identified and excluded at each stage of the literature review.



This figure presents the PC CDS Performance Measurement Framework domains and subdomains, as well as the four levels of measurement.

