Project title: **VANGUARD Strategic Coordinated Registry Network**

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**Formal team collaborators (updated)**:

VANGUARD CRN (Kevin Baskin, Richard Towbin, principals)

FDA-Sonrisa Consulting (Marti Velezis)

FDA/MDEpiNet (Danica Marinac-Dabic)

VANGUARD Medical Systems (Robert Lario)

Oley Foundation; patient advocate panel lead (Beth Gore)

TrackMy Solutions (Jeremy Elias)

PatientLink/MyLinks (Debi Willis)

National Association of Community Health Centers (Julia Skapik)

The Pasadalia Group (Jack Lewin)

PCORnet (Tom Campion)

PEDSnet (Charlie Bailey)

First Databank (Pat Lupinetti, Julie Suko)

PenRad (Richard Esmond)

AVATAR Group: Alliance for Vascular Access Teaching and Research (Claire Rickard)

WoCoVA: World Congress of Vascular Access (Ton Van Boxtel)

SIR: Society for Interventional Radiology (Jeremy Durack)

Perspecta Health Concourse (Bo Dagnall)

Cognitive Medical Systems (Emory Fry)

SHEA: Society for Healthcare Epidemiology of America (Len Mermel)

INS: Infusion Nurses Society (Lynn Hadaway)

VASA: Vascular Access Society of the Americas (Jeff Lawson)

American College of Radiology (Laura Coombs)

American Society of Diagnostic and Interventional Nephrology (Monnie Wasse)

American Society for Enteral and Parenteral Nutrition (Biren Modi)

American Society of Transplant Surgeons (Stuart Greenstein)

Infectious Disease Society of North America (Nasia Safdar)

International Society of Thrombosis and Hemostasis (Janna Journeycake)

Interventional Radiology Society of Autralasia (John Vrazas)

Phoenix Children’s Hospital (Carrie Schaefer)

Sick Kids, Toronto (Michael Temple)

Children’s National Medical Center (Karun Sharma)

Children’s Hospital, Dallas (Barbara Drews)

Children’s Hospital of Pennsylvania (CHOP)

Cincinnati Children’s Hospital Medical Center (Darcy Doellman)

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National Library of Medicine (Lisa Lang)

Agency for Health Quality and Research (Elise Berliner)

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University of Pittsburgh Strategic Management (John Camillus)

CMS Alliance to Modernize Healthcare (CAMH)/MITRE (Erin Williams)

Ryder Science, Inc. (Marcia Ryder)

**Project scope**:

As a strategic coordinated registry network, VANGUARD is building infrastructure, coordinating standards development, integrating patient engagement and conducting research to demonstrate the value of patient-centered interoperability for improving healthcare quality, delivery, meaningful data, and decision support focusing on venous and vascular access as a prototypical international multidisciplinary community of use cases around interventional procedures, maintenance and outcomes of invasive vascular access.

**Goals**:

I. Establish more accurate and reliable methodology, data infrastructure and reporting for the measurement, treatment and prevention of complications and outcomes related to invasive venous catheters and procedures with a specific focus on catheter-related bloodstream infections, quality of life and morbidity and mortality.

A. Search for indirect evidence of likely catheter-related complications, such as infection (e.g., fever, purulent discharge, concurrent catheter removal, concurrent antibiotic administration or prescription, and any concurrent blood, wound swab or catheter tip cultures; also within 30 day admission, readmission, admission to ICU, venous catheter insertion, sepsis, death). (Part of ONC-LEAP Proposal; data requested from PCORnet/PEDSnet)

B Checklist based system for highly reliable extraction and reporting of catheter-related complications from clinical workflow. (Part of ONC-LEAP Proposal)

C. Interactive "map" for documentation, review and registration of venous and venous access events. (Planning; anatomic vocabulary development in progress)

D. Anatomy of central and peripheral systemic veins and related structures. (anatomic vocabulary development in progress)

E. Signs or symptoms of infection in a catheterized patient, signs or symptoms of a source of infection other than a venous catheter, microbiologic evidence of catheter-related infection. (Part of ONC-LEAP Proposal; data requested from PCORnet/PEDSnet; part of multi-institutional pilot)

F. Signs or symptoms of catheter-related thrombosis or venous injury. (Second phase pilot)

G. Signs or symptoms of vesicant or other extravasation-related injury. (Second phase pilot)

H. Comparative effectiveness analysis of conventional open surgical AV fistula v. percutaneous endovascular AV fistula for hemodialysis access. (Research Summit on “Percutaneous AV Fistula Creation” held 9/12/19. Proceedings paper in progress.)

**Approach** :

Develop workflow documents (BPMN), clinical data models, mapping to existing codes and value sets\*, development of any necessary new SNOMED-CT and LOINC codes (SOLOR), and FHIR IG specification to include reuse of WHT CRN IG, existing FHIR profiles, extensions and implementation guides. FHIR IG will be implemented via connect-a-thon with available resources (note – pending appropriate resources). This work will leverage the existing and ongoing work around UDI and augmented unique device identifier (AUDI) metadata for the class of venous and vascular access devices, automated search strategies and validation, decision support systems, CRN registry infrastructure, structured reports, and integration of patient-centered daily workflow interfaces with a platform that links patients to their complete medical records.

\* Initial FHIR IG content will use exemplar vocabulary bindings if the necessary value sets are not available at the time of ballot.

**Value proposition**

Achieving necessary registry infrastructure, standard interoperable vocabulary, structured reports, documentation interfaces and checklist-based bi-directional decision support permits the generation, recovery and automated extraction of high-quality data meaningful to the domain. This is essential for sustained growth of the project and appropriate ROI for collaborators.

**Project team**: Multidisciplinary team of clinicians, informaticists, terminologists, researchers, public health regulatory bodies, and patient and patient advocates. Some but not all are already experienced in the registry and HIT domains. Our team has international partners in the same clinical space in Australia.

Patients:

A major patient-reported outcome vendor, PatientLink, is a core partner and they work with advocacy organizations to bring patient perspective. Patients will have improved access to their own health records, will be able to readily integrate experiential data with clinical data, will gain ability to participate meaningfully in care decisions with their clinicians, and will have improved ability to self-advocate with high-quality relevant data regarding best practices and patient-important outcomes.

Clinicians:

The clinical leadership is driven by members of the Society for Interventional Radiology, American Society for Infectious Disease, and general pediatric and internal medicine clinicians. Clinicians should obtain mission-critical data and data analytics and decision support that enable them to deliver improved care of the right kind at the right time to the right patient without increased workflow burden.

Healthcare networks and institutions:

The PCORnet and the Patient Safety Network have a variety of clinical delivery organizations represented and these in turn will contribute the data for the initial effort. Healthcare institutions will obtain reliable and meaningful data of sufficient granularity to support excellence, identify and remediate gaps in care, make purchasing decisions informed by relevant outcomes data instead of restricting themselves to cost-per-unit and other substandard metrics, with decreased uncertainty and risk.

Payers:

We are in discussions with multiple payer groups targeting improved data quality around CLABSI (or better, CRBSI). Payers will gain ability to relate payment and incentives to patient-important outcomes, to identify and support successful care strategies, and to test innovative strategies with real-time outcomes data. We need help engaging groups like DaVinci.

Industry:

Device manufacturers can obtain regulatory grade data from workflow that permits shifting resources from arbitrary pre-clinical RCTs to post-market surveillance, markedly decreasing costs of innovation, expanding indications, and providing sufficient granularity to appropriately focus on areas of competitive advantage and to identify gaps consistent with their resources. (AUDI is especially important to these market, R&D, and regulatory functions and to link patients – and patient-generated data – to their devices over time and across venues. AUDI and FHIR have not yet been fully introduced to each other, so we are working on a generalizeable solution to this component of the VANGUARD FHIR IG.) The FDA in public private partnerships has demonstrated that there is many-fold ROI for post-market surveillance based on registries for vendors. Health IT vendors will have the value of secure health data exchange demonstrated for timely access to critical data and for access to higher quality, interoperable data.

Government:

Infrastructure proposed for this registry could further the CDC and other agencies’ approaches to surveillance and this project is in communication with these stakeholders. Regulators will obtain continuous, high-grade, sensitive surveillance data on device safety and public health, permitting earlier detection of adverse signals, allowing identification of safety signals related to specific device characteristics within a class, and relating support of innovation to specific patient-important outcomes.

National health surveillance networks will gain ability to link patients (and patient-provided data) and outcomes through use of unique patient and device identifiers, and to identify health risks associated with discrete clinical practices, device characteristics, health and payer policies, and access to care.

**Deliverables**

1. Interoperability

Domain specific vocabulary harmonized across disciplinary, agency, and territorial lines, including clinical data models, mapping to existing codes, development of new SNOMED-CT and LOINC codes, and specification of FHIR profiles, data elements, extensions and implementation guides. **This process is currently underway, and a first HL7 ballot is planned for January 2021.** This demonstration of concept can be scaled within the domain and translated to other domains, consistent with the goals of USCDI, and mitigating the risk of non-interoperable silos of interoperability. This stands in stark contrast to the current situation with irregular vocabulary usage, low quality data, disharmony even within silos and data blocking by entrenched data stewards. A segmented Delphi consensus process across stakeholder groups is planned for the coming year with FDA support. The first phase will involve vocabulary necessary for transmission of data regarding intravascular catheter-related infection, with first HL7 ballot by 2021. Vocabulary related to other aspects of venous and vascular access devices and care and to underlying anatomic nomenclature are expected in subsequent phases, as well as granular metadata for clinically relevant device characteristics, through development of an AUDI database. **We do need help from the HL7 and Logica communities to accomplish these tasks. CIC calls with VANGUARD CRN updates and discussion have been occurring regularly, and Logica community participation is welcomed and encouraged.**

2. Structured reports

Structured reports are currently available from SIR for vascular access procedure reports. Reports in formats usable by other clinical specialties are expected in the first phase, as well as structured reports focused on continuing care and device salvage. In near-term phases structured reports are expected via a patient-facing application for patient-provided data.

3. Integrated Medical Management and Educational Gateway (IMMEG) interactive FHIR-based graphics-oriented data capture and retrieval. The goal is an interactive venous map where venous events can be captured at the time of service, providing an easily accessible hyperlinked summary of the patient's history. As a part of continuing care documentation, the resource would follow the patient. As a high-level alert (akin to allergy alerts), interaction with the resource could be required prior to related orders (e.g., prior to insertion of a new device). As an atlas tied to defined registration points, data would be computable across patients and devices. The concept is translatable and scalable to other systems, that can also be linked through co-registration. This is not an early-phase deliverable, but development of required underlying anatomic nomenclature is.

4. Workflow diagrams. An initial draft BPMN+ workflow diagram for the VANGUARD-MDEpiNet demonstration project is attached. Workflow diagrams are anticipated for all major phases of project development. Modular elements of these diagrams may be translatable to similar projects, and may be useful for associated APIs and other programming.

5. Infrastructure for secure exchange of health data. We (VANGUARD and the Pasadalia Group) are currently working with FDA-HIVE to explore a meta-CRN to facilitate mapping of existing and emerging COVID-19 registries to permit broader access to data so that analysis and modeling can work beyond silos. Patient-authorized access to patient-aggregated health data to pool resources in a person-centered network is also desirable model. The associated privacy network and proof of trust blockchain resources are specifically intended as proof of concept for translation across the healthcare domain and broadly scalable. The demonstration project is intended for delivery in a first phase RADx project.

6. Automated queries of aggregated health data. VANGUARD intends to work with Perspecta, PEDSnet, and PCORnet to develop automated mechanisms for sampling longitudinal databases to answer high-value clinical questions. With PCORnet and PEDSnet, VANGUARD intends a first phase search for evidence of gaps in care related to central line associated bloodstream infection (CLABSI) diagnosis in high-need high-cost patients, a national public health priority. With Perspecta, the VANGUARD demonstration project intends a first phase search for similar gaps in care from authorized access to high-risk-patient-downloaded medical records, for comparison of data quality. Strategies that integrate patient engagement with large-n data sharing are inherently highly scalable. This is a second or third phase project.

7. Interoperable Coordinated Registry Architecture for Networked Enterprises (iCRANE) and checklist-based diagnostics. VANGUARD expects to develop a transparent clinician interface for transactions involving venous and vascular access events that sits on top of and is evoked from the EHR. The initial phase aims to develop a checklist-based cognitive support system for diagnosis of venous catheter-related infection - to fill the gap in care identified in the demonstration project for automated searching of aggregated health data (above). This is part of our current ONC-LEAP proposal. Such systems are routinely used in other industries, such as aviation, and are applicable across a broad range but a particular class of healthcare use cases. Success will require complex cultural and organizational change efforts, not just the checklist itself. iCRANE is a longer term project and will not be part of first phase development, although much of early phase work will be preparatory for development of this system.

8. Decision-support. The cognitive support in iCRANE (above) will be augmented with decision support systems that perform one of three functions, as outline below. Again, this is anticipated as a later phase project.

a. Data extraction, cleaning, and analysis. The interactions of the responsible clinician and the critical data points related to the patient history, clinical presentation, laboratory findings and outcomes will be organized and presented to the clinician and other relevant stakeholders (including the patient) as the basis for iterative decision-making during patient assessment and care, and will be consumed as part of documentation (including coding and billing), aggregated with data from other institutions for national health outcomes surveillance (e.g., CDC National Health Safety Network), and integrated into the VANGUARD CRN (below) as components of third-phase development.

b. Order sets appropriate to the diagnostic pathway and patient results will be pushed to the clinician for discretionary decisions to aid timely and efficient workflow.

c. Context-sensitive aggregate data appropriate to the patient history and presentation and aligned with existing best practices, guidelines, standards and policies will be pushed to the clinician and other relevant stakeholders (including the patient) as a cognitive aid at critical decision points of care.

9. Patient-centered daily workflow interface. VANGUARD plans to work with MyLinks.com and MITRE to integrate the MITRE Patient Toolkit into MyLinks to provide patients with a structured mechanism to track daily symptoms, medications, schedules, and other events of interest that can be shared with clinicians and included in cumulative health records and in data analytics. This interface will also permit active and passive queries, provision of educational materials, fora for interaction with support communities, etc.

10. Strategic coordinated registry network infrastructure. The purpose of the VANGUARD CRN is to make high-quality data available to the patient-clinician partnership for informed decision-making at the critical decision points of care, and to repurpose this data interoperably to assist and strengthen the efforts of the many stakeholders in this domain so as to improve care quality and delivery and to control cost. **Development of a FHIR-based, triple store architecture is currently underway. VANGUARD anticipates standing up a pilot version by January 2021.** Details are outlined in the attached powerpoint stack. Development should be purposeful and should anticipate the desired use cases outlined above. The effort and lessons learned should be memorialized to benefit others with similar aims, and modular success will be shared where possible with the broader healthcare community, while respecting the fiduciary integrity of key stakeholders.

**Implementation**

Implementation plan is to work with PCOR-NET, PEDSnet, Children’s Hospital Association, the Healthcare Transformation Group and other partners to implement the data elements designed for the registry into their systems this includes:

\*Phoenix Children’s Hospital (Carrie Schaefer)

\*Sick Kids, Toronto (Michael Temple)

Children’s National Medical Center (Karun Sharma)

Children’s Hospital, Dallas (Barbara Drews)

Children’s Hospital of Pennsylvania (CHOP)

Cincinnati Children’s Hospital Medical Center (Darcy Doellman)

Cleveland Clinics (Gordon McLennan)

Miami Cardiac and Vascular Institute (Brian Schiro)

Intermountain Health (Stan Huff)

Mercy Health

Others

Largely this will involve the mining of existing data for registry submission. Optimally the content will also be implemented in Australia with the VANGUARD partner registry AVATAR, a CRBSI/central line registry across Australia. We are collaborating with CDC and hope to incorporate this into the National Healthcare Safety Network.

Sites may later be involved in implementation of clinical decision support in the form of identifying patients at risk for CRBSI and providing clinicians support in the form of electronic versions of the guidelines that are currently being finalized at IDSA.

**Relationship to existing work**

The VANGUARD registry will require a significant amount of existing data elements/models. These will be referenced from USCDI where a formal specification occurs or from existing models through Logica, such as the LOINC 2000 most common laboratory values. Unless there is an evidence-based reason to create a new or different data element from one that currently exists, we will reuse data. Where an existing element is not specific enough, we will elaborate on the existing element.

**Resources**

The project has to date been funded by volunteer clinician and partner time but there is limited PCOR-TF funding for a vascular coordinated registry network which is planned to be used to support some of the implementation guide development and registry infrastructure. The VANGUARD team have partners in Australia with a registry known as AVATAR and they have separate funding and may put some resources into the development as well. We expect there to be international collaboration on the modeling approach and content.

Ideally additional resources would be obtained to further develop registry infrastructure and clinical decision support tools—the VANGUARD team has been working with some technology vendors on the plan for the additional work. AHRQ and other agency funding will also be pursued as appropriate. **We would appreciate guidance and advice from the Logica community regarding assistance and direction to available resources.**

**Sustainability**

The registry will provide ongoing stewardship of the content because it will receive ongoing data from clinical sites and will perform ongoing research and surveillance using this data. It is the goal of this work that it may be incorporated into the coordinated registry network mentioned above. Initially the team will apply updates and feedback as often as is feasible across the implementation partners. In the formal registry updates would be more likely to occur no more than annually.

The steward is planned to be the VANGUARD CRN. The team plans to apply this content for the USCDI once it is considered mature.

**Licensing of intellectual property**

The registry content will be available through open source and the IG will be available with test and other supporting content through FHIR/Github. There may be future projects that may contain IP but these would be add-on software tools outside of this scope of work (like a vascular mapping and history tool).

**Project documents** - upload

If you have project documents you'd like to share with CIIC, please upload them here.

Vanguard PSS from Patient Care

Project documents - links

If you have project web or document links you'd like to share with CIIC, please include the URLs here.

<http://mdepinet.org/vanguard/>