Venous Access: National Guideline and Registry Development (VANGuaRD) Demonstration Project Update

MDEpiNet Annual Meeting
October 1-2, 2015

VANGUARD Overview

Index patient:

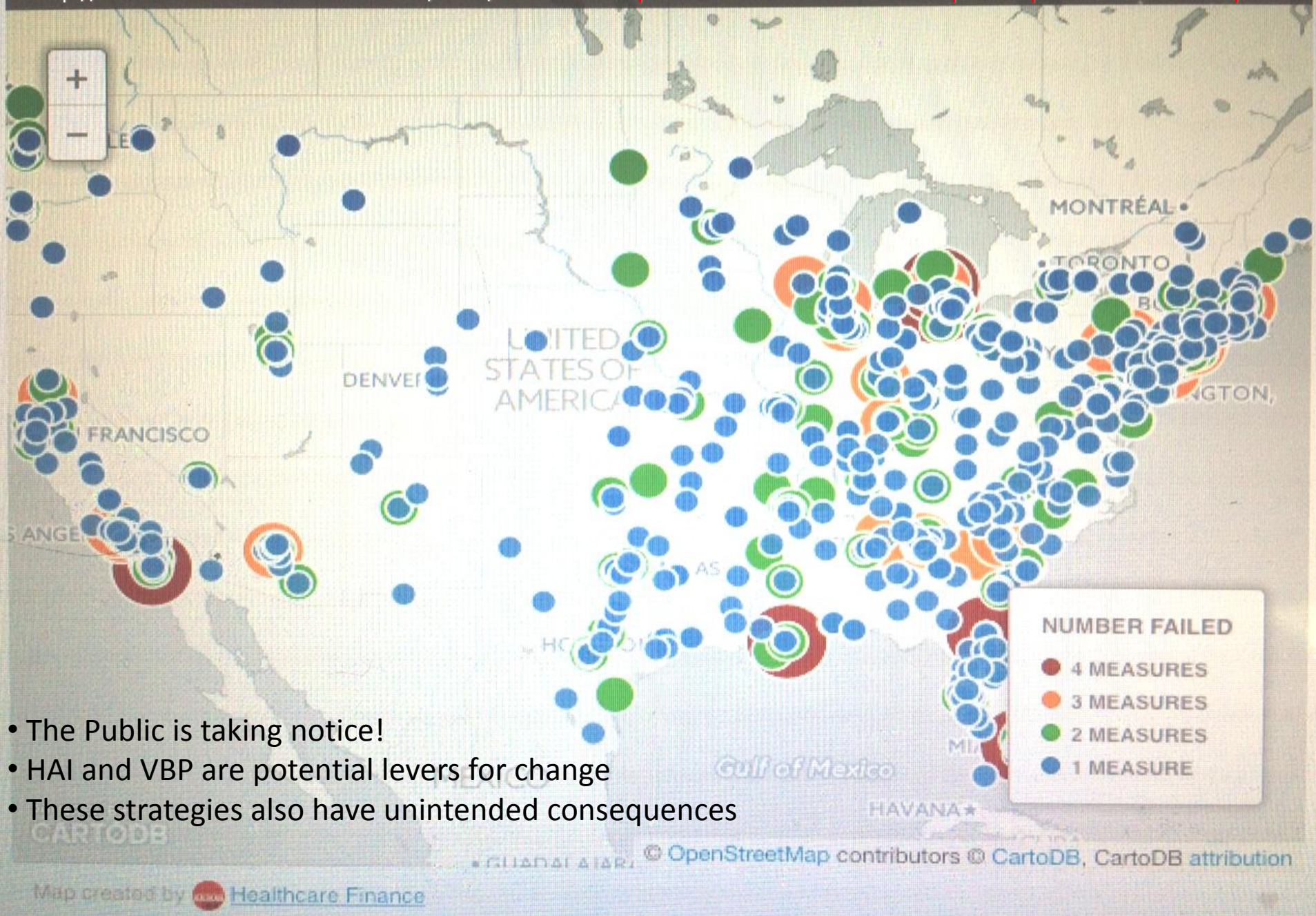
- 7-year-old, intestinal failure
- Never > 2 months without CRBSI
- With new catheter technology, 254 catheter days without infection
- Removed, port placed to allow “swimming”
- Port CRBSI at 2 weeks, removed at 2 months
- Midline placed at bedside, couldn’t advance
- Pathway selected known to be obstructed
- Information not available
- Midline CRBSI at 2 days with thrombosis

VANGUARD Overview

- 10 M central venous catheter insertions/year in US
- Complications add
  - Tens of billions to health care costs/year
  - Up to $127,000 per CRBSI in high risk patients
  - 12.5-25% mortality related to CRBSI
  - Up to 19 additional hospital days per episode
- Hospital-acquired infections are not reimbursed
- Value based purchasing assesses additional penalties
- Even modest success could save $billions annually!
- Who are the beneficiaries and how can we demonstrate the potential ROI to encourage support of VANGUARD?

Hospital-acquired infection failures in U.S. hospitals

http://www.healthcarefinancenews.com/news/see-which-hospitals-failed-and-were-fined-hospital-acquired-conditions-map-list



- The Public is taking notice!
- HAI and VBP are potential levers for change
- These strategies also have unintended consequences

VANGUARD Overview

The VANGUARD mission:

Leverage multidisciplinary, multi-institutional evidence to improve the quality of care and reduce the costs and complications of care related to central venous access

- Develop a national collaborative registry network (CRN)
- Focused on central venous access (especially chronic)
- Integrated with workflow
- Integrated with other electronic data sources for relevant populations
- Centered on patient outcomes throughout the venous life cycle
- Provide a nexus for collegial action including research, quality assurance, regulation, certification, policy development, guidelines & standards

VANGUARD Overview

Focus I

- Semantically interoperable vocabulary
- Standard data element definitions
- Consensus building & conflict management
- Consortium of process & content stakeholders
  - Office of the National Coordinator for Health IT (HHS)
  - Nat'l Library of Medicine (LOINC, SNOMED-CT, UMLS, NCI, HL7, etc.)
  - NCI Center for Biomedical Informatics & Information Tech
  - MDEpiNet Data Learning Center
  - HL-7 Vocabulary Group
  - AHRQ
  - Catheter manufacturers
  - Health information technology vendors
  - Clinical content experts
- VANGUARD has established a working group of core stakeholders. An Advisory Panel meeting is planned for mid-January 2016.

VANGUARD Overview

Focus II

- Semantically interoperable vocabulary
- High level EHR "gateway" tool at decision-points of care
  - Integrate with workflow
  - Uniform reporting (structured reports) across disciplines
  - Proactively summarize venous access history
  - Right patient, right device, right conditions
  - Provide 'best practice' checklists
  - Meet patients & providers where they're at
  - Capture & archive central venous access transactions and outcomes
  - Durably link patients & medical devices across time and venue
- Plan Advisory Panel meeting for core developers mid-November 2015, hosted by First Databank, Inc.

VANGUARD Overview

Focus III

- Semantically interoperable vocabulary
- High level EHR "gateway" tool at decision-points of care
- Pilot registry of venous access
  - Comprehensive, innovative, multidisciplinary, multi-institutional
  - Use the unified standard venous access vocabulary
  - Automagically capture relevant events from the EHR
  - Follow patients across time and venues
  - Involve patients in care; patients input events and outcomes
  - Continuous prospective metadata analysis
    - Comparative effectiveness research
    - Learning research strategies
    - Continuous postmarket device surveillance

VANGUARD Overview

Focus III

- Semantically interoperable vocabulary
- High level EHR "gateway" tool at decision-points of care
- Pilot registry of venous access
  - VANGUARD will work toward proof of concept in a population at high risk for frequent catheter-related complications, and plan a comparative effectiveness study of available devices for prevention of CRBSI.
  - This gives VANGUARD an opportunity to "road test" GUDID and UDI coding, durable linkage to the patient and transmission to end users, data element extraction from EHR, and evaluation of safety and effectiveness measures.

VANGUARD Overview

- Semantically interoperable vocabulary
- High level EHR tool at decision-point of care
- Pilot registry of venous access
- Multidisciplinary, multi-institutional evidence
  - Develop non-siloed standards to guide care
  - Use principles of cognitive computing and big data
    - Natural language queries
    - Learn trends, proactively signal adverse events
    - Benchmark against similar communities of care
    - Find the drops of device characteristics in the outcome bucket
    - Align elective decisions, incentives and outcomes (PQRS, VBP, HAI)

VANGUARD Overview

- Semantically interoperable vocabulary
- High level EHR tool at decision-point of care
- Pilot registry of venous access
- Multidisciplinary, multi-institutional evidence
  - The ultimate goal of VANGUARD is to inform our future practice:
  - developing dynamic and context-sensitive standards and guidelines based on current strong data
  - delivering these best practice models to providers and patients at the decision points of care
  - and using them as benchmarks for regulation, compensation, and strategic resourcing for research, development, and quality assurance.

VANGUARD and UDI

Finding the Fit

- BUILD on emerging foundation for longitudinal data extraction and management
- RAPIDly identify devices in the venous access domain
  - Many access devices: ports, PICCs, TCLs, dialysis, apheresis, etc.
  - Devices used in venous and access salvage (crossover with RAPID)
  - Devices used in continuing care and management
  - Intravenous medications and other agents
- VANGUARD creates a ripe platform for testing and development of UDI and other EHR tools on compelling implantable medical device problems associated with high volume, high cost and high morbidity events, with rich opportunities for collaboration and convergence on success with other SMART Think Tank initiatives.

VANGUARD and UDI

Finding the Fit

- Connect the need for devices with their supply
- Assure device choice informed by indications & conditions
- Currently, UDI elements are “attached” to the device
- Should we encourage search for a ‘best fit’ UDI?
- UDI identifies device characteristics for devices that are implanted, but also offers a concise and searchable compendium of choices relevant to pre-implant decision-making that may ultimately have a greater impact on patient outcomes than issues related to the device alone.

VANGUARD and UDI

Patient-centered care:

- Could wrong procedures have been avoided?
- Could right devices have been promoted?
- Could venous capital have been preserved?
- Could relevant data have been archived?

Better care, lower cost:

- Need to integrate UDI into care pathways
- Use UDI attributes proactively

AccessGUDID is in beta!
Contact us with your comments and suggestions for the site.

ACCESS GUDID
IDENTIFY YOUR MEDICAL DEVICE

DEVICE: Cook Spectrum Turbo-Ject (00827002345515)

DOWNLOAD: XML | JSON PRINT

VIEW ALL SECTIONS | CLOSE ALL SECTIONS

DEVICE IDENTIFIER (DI) INFORMATION

Brand Name: Cook Spectrum Turbo-Ject
Primary DI Number: 00827002345515
Version or Model: G34551
Issuing Agency: GS1
Catalog Number: UPICS-4.0-CT-40NT-ABRM-1111
Device Count: 1
Company Name: Cook Incorporated
Device Description: Cook Spectrum Turbo-Ject PICC Set Minocycline/Rifampin Impregnated Power jectable Polyurethane Peripherally Inserted Central Venous Catheter

CLOSE

DEVICE CHARACTERISTICS
DEVICE STATUS
ALTERNATIVE AND ADDITIONAL IDENTIFIERS
CUSTOMER CONTACT [?]

Mission-critical attributes not included in device characteristics
Need to “attach” these attributes uniformly & reliably

VANGUARD and UDI

Finding the Fit

- Mechanical and physical characteristics determine failure
- Clinically relevant characteristics determine outcomes
- Where do the missing elements go?
- How do we integrate missing elements with workflow?

VANGUARD and UDI

Finding the Fit

- Durably link patient and device over time & across venues
  - UDI provides essential but not sufficient linkage
  - "Forced choice": an ICD-10 problem?
    - Can devices become a problem type in the problem list?
    - Key UDI events (like removal) and data (reason for removal) then become trackable outcomes in claims data
  - UPI: a unique *patient* identifier is crucial for linkage
  - Universal access
    - Downstream providers, patients, investigators, regulators all need to be clear that they are correctly interpreting which device they are discussing

VANGUARD and UDI

Finding the Fit

- Durably link patient and device over time & across venues
  - We will not learn about device safety and effectiveness outside the hospital where the device is implanted until we can achieve this objective: durable linkage of patient, device, decisions and outcomes over time and across venues.

VANGUARD and UDI

Finding the Fit

- Link patient-centered outcomes with UDI

For implantable medical devices, we hope most of the benefits will accrue outside the hospital, where much of care and outcomes are relatively unmonitored by anyone but the patient and family. We need a way to connect valid patient-centered data with the registry. UDI-derived attributes must be accessible to and unequivocally interpretable by the patient and family through a secure portal.

VANGUARD and UDI

Finding the Fit

- Link patient-centered outcomes with UDI

Patient-centered care:

- Patients know when and where events occur
- They may not characterize correctly
- Need to “curate” patient-UDI interaction
- Need to validate patient input format
- UDI a point of contact for
    - Education
    - Communication
    - Warning

Current Status of VANGUARD

- Seeking grants and broad stakeholder support
  - SIR Foundation, other medical societies & agencies
  - First Databank, Inc., other process experts
  - Device manufacturers and health care IT vendors
  - Philanthropic stakeholders
  - Private payers and healthcare institutions (beneficiary stakeholders)
  - Others (PCORI, CDC, ONC, AHRQ, NIH, NLM, CMS, JCAHO, etc.)
- Next step is Advisory Panel meetings to concretely plan
  - Development
  - Governance
  - Responsibilities & deliverables
  - Funding
  - Timeline
- Finalize Statements of Work
- Anticipate completion of initiative in 3 years
  - Vocabulary over 18 months
  - Venous Access EHR Gateway Tool over 18 months (parallel)
  - Pilot registry projects and data analysis over years 2-3