SPECIAL COMMUNICATION

Chronic Central Venous Access: From Research Consensus Panel to National Multistakeholder Initiative

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ABBREVIATIONS

CDC = Centers for Disease Control and Prevention, CLABSI = central line–associated bloodstream infections, CRBSI = catheter-related bloodstream infection, CVAD = central venous access device, FDA = US Food and Drug Administration, HL7 FHIR = Health Level 7 Fast Healthcare Interoperability Resources, ICU = intensive care unit, NHSN = National Health Safety Network, NLM = National Library of Medicine, ONC = US Office of the National Coordinator for Healthcare Information Technology, RCP = Research Consensus Panel, VANGUARD = Venous Access: National Guidelines and Registry Development initiative

Fifty years ago, the first central venous access devices (CVADs) intended for long-term use were used to deliver parenteral nutrition (1). The index patient required 16 catheters in 5 different locations over her first 22 months of life, encountering a range of clinical issues that remain prevalent today. Critical issues include catheter-related infections, venous injury, thrombosis, chronic inflammation, fibrosis, occlusion, and progressive attrition of central venous capital. The frequency and severity of these complications remain core issues that differentiate patients who require chronic venous access from those whose access needs are acute, temporary, or occasional.

It is unknown how many of the more than 8,000,000 CVADs placed each year in the US are for the purposes of chronic access (market data). Also unknown are the related health care costs and impacts on patient and caregiver quality of life. Estimates of added costs from related complications range from billions to tens of billions of dollars annually (2,3). Function, costs, and complications of acute access have been studied extensively over the past few decades. Challenges inherent in following patients and catheters across time and venues, including gaps in the medical record, have inhibited similar study concerning chronic

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access. Although many guidelines and standards have been published, they often reflect expert consensus within silos with minimal scientific evidence or participation across stakeholder specialties (4). Because multi-institutional multidisciplinary prospective studies are lacking, with large evidence gaps and lack of unified data element definitions, meaningful meta-analysis has not been possible (5).

To discuss critical issues related to chronic central venous access and opportunities for investigation, the Society of Interventional Radiology (SIR) Foundation sponsored a multidisciplinary Research Consensus Panel (RCP) meeting on October 20, 2014. RCP recommendations led to establishment of the VANGUARD initiative (Venous Access: National Guideline and Registry Development) through infrastructure development and stakeholder symposia held in 2015 and 2016, respectively. Through extensive stakeholder partnerships, the initiative now serves as a prototype strategic coordinated registry network as part of national efforts to improve evaluation of medical device safety and effectiveness, and as a sponsor of terminology development and research in the central venous access domain. The present paper reports the proceedings of the RCP and documents ongoing development of the priority projects recommended by the panel.

METHODS

Panel Membership

Twelve expert panelists took part in the RCP, including an anesthesiologist, a gastroenterologist, a hematologist, an interventional nephrologist, five interventional radiologists, two nurse practitioners, and a transplant surgeon, along with representatives of the US Food and Drug Administration (FDA), health care economists, health care agencies and medical societies, major CVAD manufacturers, and patients. In addition to the panelists, an infectious disease physician (L.A.M.), an interventional radiologist (S.M.T.) and an expert in strategic planning (J.C.C.) were integrally involved in project development.

Agenda Methodology

The panelists developed an agenda before the RCP meeting to establish common foundations and identify gaps in the current knowledge base. Twelve discussion topics were determined through consensus and presented by panelists with expertise in each area. Afterward, round-robin discussions elaborated on critical research questions, evaluated potential future research studies, and consolidated topics. Comments were invited from subject matter experts and other participants. Finally, a consensus was reached on priority research and infrastructure initiatives for multispecialty collaborative development.

RESULTS

Priority Research and Program Development

The RCP participants identified more than 25 potential studies and program development projects that could help to answer the most important clinical questions identified by the panelists, create pivotal multi-institutional registries, define promising pathways for future investigation, and develop critical fundamental alliances. These were compiled into 5 categories by the expert panel. Where appropriate, subsequent development of priority projects is described.

1) The highest priority was given to development of the VANGUARD initiative, including recruitment of a comprehensive multistakeholder group focusing on CVADs. Soon after the RCP, VANGUARD was adopted as a priority workgroup of the Medical Device Epidemiology Network public-private partnership, a national effort sponsored by the FDA and other agencies to strengthen post-market surveillance of medical device safety and effectiveness (6). VANGUARD symposia in 2015 (sponsored by First Databank, Indianapolis, Indiana) and 2016 (sponsored by SIR Foundation and National Library of Medicine [NLM]; Bethesda, Maryland) focused on the three major aims identified by the RCP:

a) *Define and publish universal (multidisciplinary) central venous data models and vocabulary.* Resulting data elements and outcome measures will be incorporated into a central venous access data dictionary (metadata registry) facilitated and hosted by the National Information Center on Health Services Research and Health Care Technology at NLM and the Cancer Data Standards Registry and Repository of the National Cancer Institute. This vocabulary will be used for registry construction (eg, the SIR/American College of Radiology Interventional Radiology Quality Registry (7)), standardization of reporting (eg, structured reports (8)), and data element transfer and reuse. These data element definitions will be certified through a transparent consensus process for use by all core stakeholder groups, curated by VANGUARD as the responsible expert group, and integrated with the Health and Human Services Office of the National Coordinator for Health Information Technology (ONC) Nationwide Interoperability Roadmap (9) and existing standardized medical ontologies.

b) *Specify structure, governance, and intended use of a comprehensive national or international multidisciplinary registry for central venous access.* This effort joins stakeholder medical specialties, government and private agencies, health care institutions, medical device and information technology industry representatives, and patient and family support groups to develop a strategic coordinated registry network within the framework of the National Evaluation System for Health Technology (10). This network is designed to support acquisition of prospective data from stakeholders and to provide infrastructure for multidisciplinary multi-institutional pragmatic trials. The intent is to collect post-market surveillance and comparative effectiveness data valued by regulatory