



The Society of Thoracic Surgeons

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Danica Marinac-Dabic, MD, PhD, MMSC
Center for Devices and Radiological Health
Food and Drug Administration
10903 New Hampshire Ave., Bldg. 66, Rm. 4110
Silver Spring, MD 20993-0002

Re: **Medical Device Epidemiology Network Registry Task Force Report**

Dear Dr. Marinac-Dabic,

On behalf of The Society of Thoracic Surgeons (STS), I write to provide comments on the Medical Device Registry Task Force's (MDRTF) report titled, "Recommendations for a National Medical Device Evaluation System: Strategically Coordinated Registry Networks to Bridge Clinical Care and Research." Founded in 1964, STS is an international not-for-profit organization representing more than 7,000 cardiothoracic surgeons, researchers, and allied health care professionals in 90 countries who are dedicated to ensuring the best surgical care for patients with diseases of the heart, lungs, and other organs in the chest. The mission of the Society is to enhance the ability of cardiothoracic surgeons to provide the highest quality patient care through education, research, and advocacy.

The Society is encouraged by the MDRTF's pragmatic approach to create a flexible infrastructure that would accommodate both existing data sources and emerging technologies. While STS appreciates the high-level strategic concepts introduced in the report, we seek greater clarification about what concrete steps are necessary to create, implement, and navigate a Coordinated Registry Network (CRN) system. Our comments below address the CRN's overall scope, participation, governance, several issues relating to data collection, use, and dissemination among participants, and proposed pilot projects.

CRN Scope and Participation

The MDRTF suggests the CRN will initially be developed for device surveillance but promotes the possibility of creating a robust infrastructure that includes all types of data on patients and the care they receive. STS believes the development of a nationwide network to link data across data sources is important and could help paint a fuller picture of a patient's clinical condition. However, the surveillance system should also ensure that clinical data registries and other data sources participating in the CRN are independent so they can continue to help providers improve health care quality, enhance patient outcomes, and facilitate innovation.

STS believes the CRN should establish incentives in order to foster network participation by entities that are being asked to integrate and adopt new system requirements. Clinical data registries like the STS National Database, Electronic Health Records (EHRs) vendors, and other data sources may be more inclined to participate if the CRN governing body can reduce the administrative burden as well as solidify potential funding sources to support proposed changes. While the STS understands and appreciates the MDRTF assertion that money alone will not develop and grow a medical device evaluation system, the Society will be extremely limited in our ability to take on significant technological changes to our database infrastructure without corresponding funding to support the CRN architecture. In addition, any modification of the STS National Database infrastructure in support of a CRN would require substantial review and evaluation to ensure alignment with the Society's goals and objectives. We would anticipate that other potential CRN participants would have similar constraints.

CRN Governance

The report indicates that resolving stakeholder differences on responsible data use and dissemination should be a key responsibility of governing entities. STS believes our experience in the collection, analysis, and dissemination of data from the STS National Database and the STS/ACC TVT Registry™ would make us an asset to CRN governance. In fact, the STS/ACC TVT Registry™ is cited throughout the report as a critical example of how a medical device registry can facilitate meaningful data collection that can be used for post-market surveillance, quality improvement, and comparative effectiveness research. In addition, the Society supports MDRTF's emphasis on patient participation in the overall governance structure as we have long been a proponent of patient education, empowerment, and shared decision-making throughout the care continuum.

Data Collection and Use

The MDRTF report highlights the fact that data-sharing between complimentary electronic information sources could allow the CRN to leverage the strengths and overcome the limitations of the individual participating components. The report also encourages owners of electronic health information systems to view the development of the CRN architecture as an inclusive opportunity for stakeholders to shape decisions that impact resource use and data access. The Society appreciates the opportunity to develop a CRN but we are concerned about potential confusion over data ownership, usage, and rights. We would like greater clarification about how registries could provide information without losing ownership rights once the data is accessed by other CRN partners.

If the CRN is to be successful, it must get buy-in from those entities that have experience with data collection and analysis. STS and other participants should be actively involved in CRN development and maintain ownership over the use of their data. If these steps are not taken, data within the CRN could be misused or misinterpreted, and the value of the data submitted to the STS Database could be diminished. In addition, participants in the STS National Database sign a contract with STS wherein the Society pledges not to share the participant's data with any other

entity without permission. If sharing across the CRN violates these participant contracts as written, STS would be faced with a substantial administrative burden in renegotiating contracts in order to join the CRN. Furthermore, many current registry participants may not renew their contracts knowing that their data will be shared.

As a condition of the Health Insurance Portability and Accountability Act (HIPAA), the STS National Database maintains business associate relationships with various vendors and health care entities which clearly define how data will be shared and how personal health information (PHI) will be managed. The MDRTF and/or the CRN governance body will have to clarify how HIPAA and the Common Rule for human subjects' research would apply in this new setting. Also, the report does not explain how de-identified data will be linked to other de-identified data to get a complete picture of a patient, or how such data would be protected and secured. STS is interested in learning more about how data would be shared and used across the CRN, and how data sharing and data use would be structured to maintain existing ownership rights and ensure the protection of PHI.

The Society is also interested in knowing if the FDA considered the extent to which the Freedom of Information Act (FOIA) would impact the CRN, and whether participating stakeholders would be comfortable with potential FOIA requests. It is our understanding that if the CRN uses federal funds, then CRN information could be subject to FOIA, and the Society would likely want to ensure our data is exempt from mandatory disclosure under FOIA.

Data Harmonization

STS appreciates the report acknowledges that standardizing and harmonizing data definitions is critically important to the infrastructure of the CRN. We encourage the CRN governing board to create a working group that develops standard definitions aimed at creating an electronic infrastructure capable of supporting a functional and interoperable system among data contributors. STS would like to participate in such a group, because we understand having one set of definitions for the STS National Database and another for the CRN would create a barrier to interoperability.

According to the report, the CRN will function by linking various data sources to fill the information gaps among CRN participants. However, one of the major challenges going forward will be establishing a broader understanding of the difference between a clinical registry and an EHR, as well as the barriers and expense of integrating information across these data sources. EHR vendors have not yet achieved interoperability among the various systems. In most cases, communication between EHRs and clinical data registries remains aspirational. A clinical data registry has highly structured, standardized data definitions and strict control over the accuracy and integrity of the data. On the other hand, EHR data may lack specific data definitions or controls over who enters the data and how data are entered. The data sets are very different, and while it is possible to link some data elements between EHRs and clinical registries, for many other data elements it is currently impossible to establish proper links. Interoperability amongst various data sets will require significant and on-going testing to demonstrate that data collected in EHRs can be integrated and validated against the gold standard of clinical registries.

The other group tasked with providing recommendations to FDA toward development of a national medical device system, known as the Planning Board, encouraged integration of unique device identifiers (UDIs) into electronic health information. Similar to our comments on the Planning Board recommendations, STS applauds the promotion and integration of UDIs. By linking clinical data registries with UDIs and claims information, medical device evaluation can be accomplished in the general population with greater specificity. This will improve our collection of long-term outcomes data and our ability to understand the comparative risk and therapeutic benefits of devices. Incorporating UDIs could also yield new insights into research and personalized medicine. However, this may come at a considerable expense. In order to overcome significant hurdles of UDI adoption in claims forms and EHRs, mature registries will need to re-engineer their data elements and infrastructure according to national IT standards. These changes will require a significant investment of resources. Therefore, STS encourages the CRN governing body to develop funding opportunities to incentivize and support CRN participants that want to adopt technological enhancements to support UDI integration and other system reforms.

Longitudinal Data

STS agrees that a significant benefit of a CRN would be facilitating greater access to longitudinal data. Because surgeons typically provide a single episode of care, the STS National Database does not currently collect longitudinal health information on the patients treated by STS members. In order to fully track patients over time in the health system, it is critical that we know if and when they have passed away. Prior to November 2011, when the Department of Commerce interpreted existing law as precluding public access to death data submitted to the Social Security Death Master File (SSDMF) by the states, STS was able to purchase complete SSDMF data so that we could confirm a patient's life status. Research based on this information helped to improve surgical outcomes, inform shared decision-making with patients and their families, and enhance the quality of patient care. We have pursued other avenues to obtain death information, but a complete SSDMF continues to be the most reliable source. We are mindful of significant concerns for the security of personal information found in the SSDMF, and are willing to provide all necessary assurances that the STS National Database is subject to rigorous privacy protocols that comply with HIPAA, the Federal Information Security Management Act, and other privacy and security regulations. We remain committed to enhancing patient safety by improving care in the operating room and protecting patient privacy and security.

We also believe current statute allows the Social Security Administration to share death data with the registry community. The recently enacted Medicare Access and CHIP Reauthorization Act allows QCDRs to access claims information from the Centers for Medicare and Medicaid Services for purposes of quality improvement, which is essential to our disease management and quality improvement efforts. In addition, a provision of the Social Security Act permits the Commissioner of Social Security to enter into an agreement with the Secretary of Health and Human Services for the purpose of matching data from the Social Security Administration and the Department of Health and Human Services. However, the authority granted under each

statute has not been exercised, and without linking death data to claims information, we are still missing a critical source of information for our important research.

CRN access to the complete SSDMF would enable the Society and other CRN participants to gain a more thorough understanding about the effectiveness of certain treatments. Moreover, patients, their families, and their physicians will be better equipped to make informed decisions regarding their health care needs.

Pilot Projects

STS is encouraged by the MDRTF's proposed pilot projects, and urges the CRN to provide adequate incentives for participation. The Society also suggests the CRN governing body allow for the development of other pilot projects by entities who may wish to participate in the CRN.

Thank you for considering our comments regarding the planning and implementation of a robust CRN system to ensure regulatory decisions consistently serve stakeholders across the medical device innovation environment. We look forward to working with the FDA and other stakeholders to launch a robust network that can monitor the safety and effectiveness of medical devices in the marketplace. Should you have any questions or like to discuss our comments further, please contact Courtney Yohe, STS Director of Government Relations, at (202) 787-1222 or by email at cyohe@sts.org.

Sincerely,

A handwritten signature in cursive script that reads "Mark S. Allen".

Mark S. Allen, MD
President