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SPECIAL COMMUNICATION

An International Vascular Registry Infrastructure for Medical Device Evaluation and Surveillance

The Medical Device Epidemiology Network (MDEpiNet) is an innovative effort supported by the US Food and Drug Administration (FDA) that is committed to the development of a medical device science and surveillance infrastructure. Recently MDEpiNet sponsored a national medical device registry task force which developed a guidance document for 21st century medical device evaluation that highlights the importance of national and international registries, their linkages with other relevant data, and stakeholder involvement.[1] Two international efforts, the International Consortium of Orthopedic Registries (ICOR) and the International Consortium of Cardiovascular Registries (ICCR)[2] were launched in the past 4 years to study orthopedic and cardiovascular devices in this regard.

INTERNATIONAL CONSORTIUM OF VASCULAR REGISTRIES (ICVR)

In November 2014, the MDEpiNet Science & Infrastructure Center, In collaboration with the Society for Vascular Surgery Vascular Quality Initiative (SVS/VQI) and the VASCUNET registry collaboration (a working committee of the European Society for Vascular Surgery, ESVS, founded in 1997, including 12 vascular registries from Europe, Australia, and New Zealand) launched the ICVR[3] to build an innovative network dedicated to vascular surgery and device outcomes. The ICVR has both direct data sharing by multiple national registries and distributed systems for research and surveillance initially focusing on high priority questions related to the variation in device use and patient selection. It has access to data regarding hundreds of thousands of procedures performed to treat abdominal, carotid and lower limb arterial disease by both open and endovascular surgery. Many registries also have data on venous procedures, such as ileofemoral venous stents and inferior vena cava filters. Since 2014, the representatives of 13 registries have developed a governance structure for data sharing and held four major workshops in New York City, Uppsala, Sweden and Hamburg, Germany, to launch initial investigations.

International sharing of experience in quality improvement, desire to improve vascular care and evaluation of device performance are the three main motivations that have led to enthusiastic participation of national registries and clinician leaders. Importantly, most vascular devices are approved earlier in Europe than in the United States, but the United States population provides a larger cohort for device evaluation. Combining data from multiple registries accelerates the ability to detect device safety signals, to benefit patients worldwide.

CASE STUDY OF DEVICE USE

Initial ICVR studies will address variation in the use of technology and techniques for carotid disease, abdominal aortic aneurysms (AAAs), and peripheral arterial disease. Endovascular aneurysm repair (EVAR) for treating AAAs is an important case study that shows the value of international data. Since stent grafts were introduced for treating AAAs they have been increasingly used because of their less invasive nature and better early outcomes compared with open surgical repair.[4] However, high device costs and expenses related to post-implantation surveillance have led to different rates of utilisation between countries. The recently published ICVR data[5] indicate that while >70% of patients with AAA in the United States and Australia are treated by EVAR, this was the case in <40% of patients in Norway, Denmark, and Hungary.

International variation in the use of the EVAR indicates that there is still uncertainty about its benefit in various sub-populations of patients.[6] The variation also allows conduct of comparative studies of EVAR versus open surgery. A major advantage of international investigations is the inclusion of a much larger number of patients, making it possible to study subgroups of patients, and to assess rare adverse events that are difficult to study in individual national registries. There are interesting differences between countries regarding the proportion of intact AAA repairs, varying from 71% in Finland to 92% in the United States (Fig. 1), as well as the proportion of AAA repairs performed on patients with small diameter aneurysms.[5]

POTENTIAL FOR STAKEHOLDER COLLABORATION

The ICVR effort includes international registry owners, as well as manufacturers, the Center for Medicare and Medicaid Services, and the FDA. This stakeholder engagement has enabled a discussion not only related to device innovation and evaluation but also the potential registry

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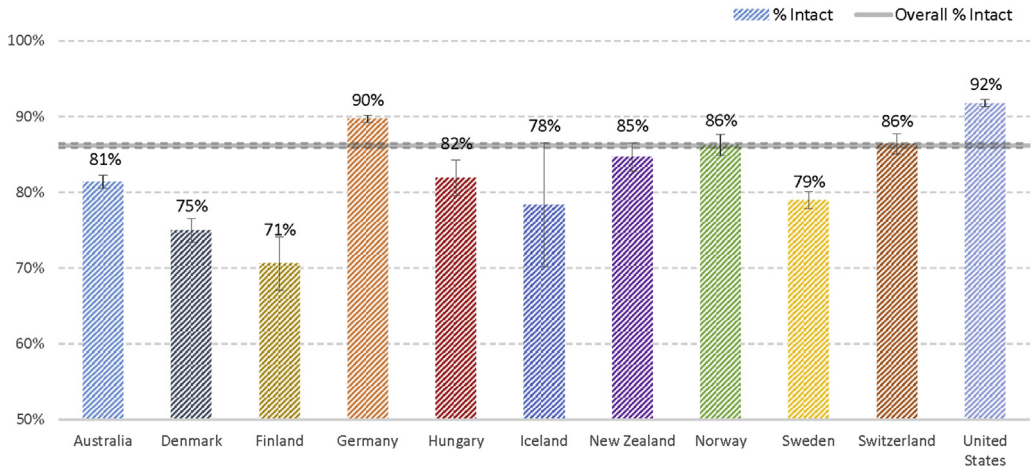

Figure 1. Abdominal aortic aneurysm repairs performed on intact versus ruptured aorta among ICVR participating countries 2010—2013. Data from Beck et al.[5]

role as an advanced surveillance system. The stakeholders recognise that the interest in creating a global registry consortium is sincere and has a substantial potential to make an international impact. From regulatory and industry perspectives, data from ICVR can be used for both pre- and post-market purposes including leveraging the data for labeling changes, creating global objective performance criteria or adverse event reporting, and hosting surveillance studies often required by regulators. The data can also help develop global risk prediction models for patient centred decision making. Finally, ICVR projects can lead to the development of new intellectual property and conduct of more efficient international clinical trials that leverage the global registry infrastructure.

The ICOR was the first major international initiative related to implantable devices and developed a model for collaboration.[7] However, there are major differences between ICVR and ICOR efforts in terms of scientific approach to data collection and aggregation. The ICOR orthopedic registries are able to evaluate failing devices within their own registry because device failure most often leads to re-operations conducted by orthopedic surgeons. When treating AAAs, however, this is not always the case, since device failure may cause rupture and death without additional surgery, which is not captured in the same registry. Hence, one of the challenges the ICVR is working out how to ensure long-term follow-up by linking with administrative databases without coming in conflict with data protection laws in the different countries. Sharing expertise for registry data linkages with other data sources, such as cause of death registries, will be an important aspect of international learning.

ICVR benefits from strong support of registry champions within each country who recognise the goals and requirements, and who enthusiastically endorse this worldwide effort. ICVR also recognised that while common definitions need to be adopted for core variables, the process should be pragmatic and performed simultaneously with conduct of projects so that data harmonisation is not disconnected from reality. An important challenge is uniform device identification within registries. The adoption of unique device identifiers (UDIs)[8] by manufacturers will enable more device specific surveillance efforts.

SUMMARY

Based on the successful template of ICOR, ICVR has rapidly developed global collaboration with potential benefits for patients worldwide. It is an innovative effort building on successes achieved in orthopedics and cohesion among international registries. ICVR will enable a collaboration of stakeholders to create a sustainable global system to evaluate the safety and efficacy of new and existing vascular devices and procedures, while promoting scientific evaluation, innovation, and quality improvement.

CONFLICT OF INTEREST

The authors declare no conflicts of interest.

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