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Hot topics in interventional cardiology: Proceedings from the society for cardiovascular angiography and interventions (SCAI) 2021 think tank

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Authors
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Abstract

The Society for Cardiovascular Angiography and Interventions (SCAI) Think Tank is a collaborative venture that brings together interventional cardiologists, administrative partners, and select members of the cardiovascular industry community annually for high-level field-wide discussions. The 2021 Think Tank was organized into four parallel sessions reflective of the field of interventional cardiology: (a) coronary intervention, (b) endovascular medicine, (c) structural heart disease, and (d) congenital heart disease. Each session was moderated by a senior content expert and co-moderated by a member of SCAI’s Emerging Leader Mentorship program. This document presents the proceedings to the wider cardiovascular community in order to enhance participation in this discussion, create additional dialog from a broader base, and thereby aid SCAI, the industry community and external stakeholders in developing specific action items to move these areas forward.

KEYWORDS

congenital heart disease, coronary artery disease, pediatrics, peripheral arterial disease, structural heart disease intervention

1 | INTRODUCTION

The annual Society for Cardiovascular Angiography and Interventions (SCAI) Think Tank brings together content experts, SCAI leaders, and key industry partners for a one-day session on timely topics within the four pillars of interventional cardiology—coronary, peripheral, structural, and congenital. The themes of this year centered on quality assurance of coronary and peripheral procedures, either at ambulatory surgical centers or in the hospital setting, the need to expand indications for minimally invasive structural procedures to meet the needs of an aging cardiovascular population, and the need to track implantable devices over time in our pediatric patients with congenital heart disease (CHD) who have now been able to achieve a longer life expectancy into young adulthood, middle age, and beyond. It is hoped that these discussions stimulate further initiatives within SCAI, our members, and our industry colleagues to meet these contemporary demands and help us achieve better outcomes for our cardiovascular patients.

2 | CORONARY: PERCUTANEOUS CORONARY PROCEDURES IN THE AMBULATORY SURGERY CENTER—WHAT DOES THIS MEAN TO THE PRACTICE, OVERSIGHT, VALUE, AND QUALITY OF PROCEDURAL AREAS?

Over the last 35 years, percutaneous coronary intervention (PCI) has evolved considerably in terms of device technology, pharmacologic options, and procedural techniques. In parallel with these scientific advancements by our members and industry partners, the rates of PCI-related complications have dropped precipitously despite the increasing anatomic and clinical complexity seen more routinely now in patients presenting with coronary artery disease. Accordingly, same-day discharge after PCI has been increasingly adopted and PCI has been expanded to centers without cardiothoracic surgical back up. With these developments in care processes and improved
outcomes, PCI is now in the early stages of being performed in non-
hospital outpatient facilities (e.g., ambulatory surgical centers [ASCs]).
While there are potential benefits to the performance of PCI in ASCs,
including cost-savings,5 wider access to care, a more gratifying patient
experience, and greater physician autonomy, there are no published
data on the safety of PCI performed in ASCs specifically. Hence, the
true risk of adverse clinical outcomes in this setting is unknown,
prompting concerns regarding quality and oversight.

As a national society comprising over 4000 members of the inter-
ventional cardiology community, SCAI is in a unique position to help
define the quality benchmarks for the evaluation of catheterization
laboratories and for the performance of PCI. In keeping with this role,
SCAI in 2020 proactively generated and published two complemen-
tary expert consensus statements detailing guidance for the optimal
performance of complex PCI as well as for the development of an
ASC-based PCI program.6,7 Notably, it was recommended that poten-
tially high-risk procedures, such as the treatment of unprotected left
main lesions, chronic total occlusions, and severely calcified lesions
be referred to a hospital-based setting.6 Nevertheless, with the
recent Centers for Medicare & Medicaid Services (CMS) decision all-
owing for the reimbursement of complex PCI procedures in ASCs, a
growing (albeit small) number of atherectomy procedures are now
being performed in these centers. As such, a group of key opinion
leaders from the interventional community, representing both physi-
cians and industry partners, convened at the 2021 SCAI Virtual
Think Tank to deliberate how PCI in ASCs should be performed,
especially when case selection falls outside of our initial recommend-
dations, and the role that SCAI should play in optimizing quality in
these settings.

During the discussion, the overarching theme was related to the
importance of ensuring optimal outcomes for patients undergoing PCI
at ASCs (Figure 1). In the spirit of patient transparency, there was a
strong sentiment that informed consent must include a clear acknowl-
edgement of the possible consequences of the absence of services
and equipment that are normally present in a hospital-based setting
(e.g., cardiac anesthesiology, mechanical circulatory support, and
cardiothoracic surgery) and that financial incentives (if any) for the physi-
cian to perform the procedure at the ASC should be made clear to the
patient. Additionally, while catastrophic complications are expected to
be rare if case selection is appropriate, transfer protocols in the event
of a major complication should be clearly communicated to the care
team and the potential need for emergency transfer made clear to the
patient prior to the procedure.

As was clearly defined in SCAI’s statement on ASC-based PCI
programs,6 certain standards for the facility itself, the equipment
available at the ASC facility, and the qualifications of all personnel
(e.g., nursing, technologist, and physician) practicing at the ASC were
felt to be of paramount importance. In particular, there was consid-
erable discussion regarding the use of intravascular imaging and physio-
logic testing. Multiple studies have demonstrated improved outcomes
with the use of these strategies when compared with angiographically
guided PCI alone.8–12 The availability of these technologies is neces-
sary to determine the need for revascularization and optimize PCI out-
comes. Nevertheless, given the lack of CMS reimbursement for
intravascular ultrasound and optical coherence tomography, there
was concern that monetary considerations could limit the use of these
evidence-based tools in an ASC setting. As such, it was felt that SCAI
needs to continue to actively advocate for additional CMS reimburse-
ment for these adjunctive procedures, and assure their availability and
use in ASC facilities, in order to promote best practices and decrease
the potential for inappropriate PCI not only in ASCs, but in any PCI
center.

In order to ensure that ASCs performing PCI adhere to best prac-
tices, there was further consensus that some form of data monitoring
would be necessary for ongoing quality assurance. In fact, since it is
expected that the majority of PCIs performed at ASCs will and should
be lower risk, it was proposed that a higher benchmark for safety out-
comes should be considered. While existing national cardiovascular
registries, such as the NCDR CathPCI registry, do provide a wealth of
information regarding volumes, outcomes, and procedural appropri-
ateness in the hospital setting, currently there is no existing registry
that evaluates metrics specific to an ASC site of service. Since the pri-
mary focus for monitoring ASCs would be to assess safety
(as opposed to a repository of data for research), it was agreed that
the development of a scaled-back registry, focused only on the essen-
tial measures of quality (including appropriate PCI, complication rates
and discharge protocols based on best practices), is needed and that
participation in such a registry should be tied to reimbursement in
order to guarantee ASC site involvement. The Outpatient Endo-
vascular and Interventional Society (OEIS) is currently developing a
cardiac module within their national registry, specifically focused on
cardiac interventions performed at ASCs and outpatient interventional
suites and may provide an opportunity in the near future to imple-
ment a quality assessment program for ASCs performing PCIs. It was
recognized that the major barrier to implementing this process would
be the cost involved and the need for a clinical director (e.g., cath lab
director) to provide physician and data oversight at the ASC, and it is
recommended that payers and ASC facilities take this into

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**FIGURE 1** Key recommendations for high-quality ASC-based PCI program. ASC, ambulatory surgical centers; PCI, percutaneous coronary intervention.
consideration when negotiating contracts and determining reimbursement policies for procedures performed in an ASC setting.

In summary, there was a general consensus that SCAI should continue to advocate that ASCs abide by the expert recommendations laid out in the recent position statement, supplemented by the updated 2021 Cath Lab Best Practices Consensus Document, on the performance of PCI at an ASC. In order to preserve patient safety and ensure high-quality outcomes, proper incentives to promote best practices (such as the use of intravascular imaging or physiology-guided PCI) and requirements to engage in the reporting of quality metrics are needed. By working together with state and federal governing bodies and agencies, SCAI has the opportunity to play a large and important role in the evolving landscape of ASCs performing PCI.

3 | PERIPHERAL: UNDERSTANDING THE VALUE ASSESSMENT OF PERIPHERAL TECHNOLOGIES IN ACUTE AND CHRONIC INFRAinguINAL INTERVENTIONS

The focus of the endovascular session was to discuss emerging issues related to device selection for endovascular treatment of peripheral artery disease, including critical limb ischemia. Stakeholders from the interventional cardiology community, industry, and SCAI leadership were in attendance. SCAI has a long history of prioritizing quality initiatives regarding best practices and the appropriate use criteria in peripheral vascular interventions (PVI). The society has provided several consensus guidelines (class of recommendation and level of evidence) for device selection in specific clinical or anatomic subsets, based on comparative device safety and effectiveness data. However, recent studies continue to show marked heterogeneity of treatment practices in real world settings, both when performed in hospital or at an ASC. The SCAI think tank provided a forum to discuss several interrelated issues pertaining to SCAI’s role in guiding hospitals and clinicians regarding utilization of peripheral endovascular technologies. It is hoped that standardization aligned with best practices will serve the wider community by minimizing disparities of care demographically and geographically.

There was uniform support for SCAI’s role in monitoring practice patterns, device utilization, and outcomes in PVI. Given SCAI’s mandate to promote and enhance quality care and physician education, these activities were deemed to be consistent with the mission of the society. In addition, given SCAI’s prior quality initiatives in publishing expert consensus statements and appropriateness criteria, there is precedent and expertise for these initiatives within the SCAI membership. Past lessons from highly publicized examples of rarely appropriate PCIs highlight the legal exposure to physicians and health care systems as well as the negative impact such cases can have on the reputation of the interventional cardiology community. For these reasons, it was agreed that SCAI, physician membership, and industry partners should be aligned in fostering transparency regarding practice patterns with an eye toward understanding and disseminating best practice guidance to the peripheral interventional community.

The Think Tank group agreed that SCAI should be involved in the study of practice variation and valuation of devices related to peripheral endovascular procedures. There was less agreement about how best to improve the quality of patient care and minimize costs. One barrier is the identification of operators and institutions that are outliers, with respect to quality and/or appropriateness of device utilization. It is not known how much practice variation should be expected, however. There was interest in joining resources with other physician groups and societies (e.g. Society for Vascular Surgery) on policy statements to broaden global impact of such initiatives. More generally, we should consider promoting ethical business principles such as the value agenda, which in this context might include evaluation of practices based on the following parameters: (1) improved organization and integration of care, (2) established measures to evaluate outcomes and cost of care, (3) process for bundled payments for patient care cycles, (4) integrated care delivery across separate facilities within a health care system, (5) expand or build services across a geographic region to improve access to care, (6) management with emphasis on value-based care, and (7) appropriate reimbursement.

One option to identify “at risk” operators or laboratories would be to put quality assurance metrics in place, including peer review for appropriateness of PVI, review of device selection and utilization, and review of adherence to guidelines and expert consensus documents. There was a debate about whether an outside review board could assist with oversight and accountability for operators and institutions, and whether there should be reimbursement for such reviews. There was moderate interest, but no consensus achieved, about how this could be financed and whether a SCAI-led, industry-funded mechanism could be put in place.

Another option offered to address practice variation and under- or overutilization of certain devices was organizing a peripheral laboratory certification or accreditation process through SCAI, which could certify or accredit laboratories after a comprehensive peer-based review. SCAI would provide guidance and issue accreditation to programs meeting specific requirements, such as a random peer case review program and QA/QI process. Accreditation for ASCs should not be based purely on adjusted complication rates, but also on short- and long-term outcomes, as well as procedure and device appropriateness.

There was general agreement that there should be awareness that proliferation of ASCs nationwide has occurred without proper professional societal quality/utilization/appropriateness evaluations in place. The office-based lab (OBL)/ASCs were not necessarily deemed to be the problem, and in fact, many patients seem to prefer to receive care in an OBL/ASC setting. However, the current financial incentives of OBL/ASC physicians and lack of oversight regarding appropriateness of procedures and device selection pose a potential concern. One topic, which was debated, was whether OBL/ASCs performing endovascular procedures should be required to be part of a PVI registry. Physicians in attendance and stakeholders from industry were keenly interested in a concept of a comprehensive registry that would include data on costs, procedural complications/outcomes, and patient reported short- and long-term outcomes. Mandatory participation would be necessary for full engagement, complete quality
metrics, and accountability. However, the feasibility of such a registry for ASCs might be limited since outpatient-based laboratories do not generally have an infrastructure for data collection, as already discussed in the coronary section above. Whether self-reported patient data would be accurate and impactful was also discussed.

Another central topic discussed was whether observational/registry data would change physician practice patterns. There was moderate pessimism that such data would impact practice patterns since, for instance, even high-quality randomized controlled trials have not resulted in large-scale utilization of drug-coated balloons. There was consensus that given the strong influence of reimbursement on physician behavior, SCAI members and industry should strive to work with payers to realign payment structure, with an emphasis on evidenced-based outcomes-based metrics. There was a view that consensus documents may not help to change physician behavior unless they can be enforced. Thus, linking registry participation to reimbursement by payers was discussed.

In summary, there was general agreement that issues related to PVI procedural appropriateness, heterogeneity in device selection, variance in cost and practice patterns were all linked in complex ways and are important priorities for SCAI to be engaged in. The expansion of OBL/ASCs was recognized as an opportunity to create SCAI-led quality assurance metrics, such as peer review for appropriateness of PVI and review of device selection/utilization. Several options, such as development of a SCAI-led certification or accreditation process for operators and laboratories and participation in PVI registries were identified as discussed above. There was a consensus that SCAI should advocate for realignment of financial incentives with an emphasis on outcomes-based metrics.

### 4 | STRUCTURAL: ENHANCING INNOVATION IN STRUCTURAL HEART PROCEDURES—EMERGING INDICATIONS FOR VALVES, CLIPS, AND PLUGS

As more cardiovascular patients survive to an advanced age, with inherent comorbidities including frailty, cardiac procedures will need to continue to evolve to treat diseases via percutaneous (rather than open surgical) methods. The current era of minimally invasive devices for structural heart disease (SHD) interventions presents clinicians with a toolbox to develop creative solutions. As expected, these solutions involve permutations of utilizing medical devices in methods novel to their intended purpose, or in the United States device regulatory framework, outside of their approved “labeled” indication.

For example, transcatheter valves are approved for transcatheter aortic valve replacement (TAVR) in patients with severe aortic stenosis. However, there are complex patients for whom adjunctive procedures have evolved to overcome challenges to successfully performing TAVR that are not part of the food and drug administration (FDA) labeling for the procedure (e.g., BASILICA). Furthermore, given that there are no similar valves approved for replacement of the mitral valve, operators have utilized the available aortic valves to perform transcatheter mitral valve replacement (TMVR). While such “off-label” use of a product may gain traction within the interventional cardiology community through podium presentations, case reports, and social media, a presentation bias occurs as operators are reluctant to share deaths or serious complications. Thus, quality and safety remain a concern regarding appropriate case section, technical skillsets, complication management, and post-procedure care. In addition, the medical device industry, charged with assuring proper use of their products through operator training, support, and guidance, are unable to assist to assure optimal procedural outcomes when the devices are used off-label. While measurement and communication of quality within the interventional community and to the public remains a challenge already for FDA-approved procedures, it is exceedingly difficult for off-label device procedures.

### TABLE 1  Practice variation in device selection in PVI procedures

<table>
<thead>
<tr>
<th>Practice variation in peripheral vascular interventions (PVI)</th>
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</thead>
<tbody>
<tr>
<td>Lessons learned and emerging challenges</td>
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<tr>
<td>• PVI and device selection can be affected by financial incentives</td>
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<tr>
<td>• Financial incentives can lead to:</td>
</tr>
<tr>
<td>• Unnecessary procedures, adverse outcomes, and harm to patients</td>
</tr>
<tr>
<td>• Healthcare disparities</td>
</tr>
<tr>
<td>• Additional expense to payers and health care systems</td>
</tr>
<tr>
<td>• Patient and societal mistrust</td>
</tr>
<tr>
<td>• Identifying “at risk” operators/outliers is challenging</td>
</tr>
<tr>
<td>• OBL/ASCs expansion is occurring without a mechanism to evaluate appropriateness, quality, and safety</td>
</tr>
<tr>
<td>• Consensus/guideline documents are not being followed and do not lead to higher quality care</td>
</tr>
<tr>
<td>• Physician behavior is strongly linked to reimbursement</td>
</tr>
<tr>
<td>• Reimbursement is not necessarily linked to best PVI practices</td>
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</table>

Abbreviations: ASC, ambulatory surgical centers; OBL, office-based lab; SCAI, society for cardiovascular angiography and interventions.
The specialty of interventional cardiology has historically been at the forefront of innovation and improved patient care by generating the data to support novel procedures (e.g., randomized controlled trials, well-conducted observational studies). Furthermore, carefully designed registries are used to examine off-label device use and supplements the research on approved products beyond the randomized data. To date, these innovations have principally been in the areas of coronary and peripheral vascular procedures, however. Notably, and in contrast, the field of SHD has developed with unique challenges that necessitate a different pathway for meeting deficiencies in patient/procedural care. These include: (1) The mandate of the “Heart Team” approach with the physical presence of both cardiac surgeons and interventional cardiologists to evaluate and treat patients cooperatively; and (2) National Coverage Decisions that closely associate FDA labeling of devices, clinical trial data, and reimbursement for structural heart procedures. In essence, enhancing treatment for patients with SHD now involves the complexity of the medical device industry, federal government, cardiac surgery, and interventional cardiology. The mission of SCAI is to lead the global interventional cardiology community in education, advocacy, research, and quality of patient care. Clearly, to achieve all of these aims, SCAI must endeavor to enhance and improve the treatment of patients with SHD moving forward.

**4.1 Alignment of operators, industry, and regulators**

To allow iterative expansion of labeled indications for devices and/or procedures, SCAI has the unique ability to unite operators, the medical device industry, and the FDA to devise acceptable next steps to achieve this result (Figure 2). SCAI think tank consensus was to consider single-arm studies and more specific device/procedure registry data that could be utilized for this goal and SCAI could be the organizing “sponsor” to facilitate the process. In this way, multicenter industry sponsored studies would still be undertaken to expand indications and procedures (e.g., TAVR in patients with moderate aortic stenosis) as has been the current and accepted standard. However, leaflet altering procedures such as BASILICA preceding TAVR would not require such randomized trial data to become “on-label” for appropriate patients. Furthermore, single arm studies and appropriate registry data would be large enough to develop standards for patient outcomes that should be acceptable for such procedures. Lastly, reimbursement for these procedures continues to be an issue for operators, and SCAI would be appropriately empowered with this type of data to pursue opportunities to appropriately affect reimbursement and payment decisions.

**4.2 Organization of education and training**

Education and training are ongoing needs with continued procedural innovations and SCAI is ideally suited to fulfill this need. Previously, SCAI has developed position statements, training requirement statements and supported e-book learning for interventional procedures. All of these avenues should be considered for training in the structural heart arena with a focus on adapting the best available media and computing resources to support training programs. Likewise, there is a need for “expert consultative” services in which “experts” in the field could be consulted for procedural advice prior to an operator taking on an advanced procedure. These could be facilitated by SCAI by organizing and publicizing an available “expert panel” of individuals agreeable to providing such a service as well as by providing the optimal method of communication between parties. The concept of “virtual proctoring” was also brought forward given the rapid development in hardware and software (e.g., augmented reality and virtual reality) to allow such interactions currently and in the near future, although there are multiple potential liability concerns that would have to be considered prior to implementation.

**4.3 Partnership with congenital interventionalists**

It was recognized that a great deal of symmetry exists between these structural heart treatment issues proposed and those faced by our colleagues in the CHD arena. Thus, moving forward, the proposed efforts by SCAI should not occur specifically to the structural heart arena or specific procedures, but rather be developed as more general templates and pathways to allow for iterative expansion of indications.

To summarize, clearly innovation and meeting the needs of an aging population require that our tools and techniques expand significantly in the structural heart space. Alignment of relevant stakeholders and agreement on a process to facilitate appropriate FDA approvals, potentially orchestrated by SCAI, together with organization of novel educational and training initiatives, will all be pivotal to expand treatment options in a safe and efficacious manner.

**FIGURE 2** SCAI as the intermediary to align structural operators, the medical industry, and the food and drug administration. SCAI, society for cardiovascular angiography and interventions
## 5 | CONGENITAL: HOW CAN THE PEDIATRIC INTERVENTIONAL COMMUNITY EFFECTIVELY TRACK IMPLANTABLE DEVICES FROM CHILDHOOD TO ADULTHOOD?

At the CHD Think Tank discussion, members of the pediatric/congenital interventional cardiology community met with corporate representatives of CHD device manufacturers and discussed the current status of device-tracking from childhood into adult life, identified gaps in this process, and offered possible strategies and solutions to fill these gaps. The discussion revolved around how SCAI can engage the various stakeholders including physicians, industry, and patients together to establish an improved system for device tracking.

Survival of children born with CHD into adulthood has steadily improved over the past three decades. This has brought about several new challenges in the management of adult survivors of CHD. One of these involves tracking of devices implanted during infancy and childhood into adult life. Tracking poses unique challenges, as infants and children who are treated can now outlive the physicians implanting the devices, device-tracking registries, the manufacturer, and even currently available technology. Further, CHD patients often require reoperations where devices may be explanted or modified. Repeat interventions may alter the original implanted device or additional devices may be implanted superimposed onto previously implanted devices. Clearly, then, details of the type, medical device manufacturer, model, size, and number of devices implanted previously, along with the implant dates, procedure notes, and potential procedural challenges encountered are vital for the proper transfer and continued care of pediatric CHD patients transitioning to adult care. However, this effort will require a standardized device tracking mechanism, collaboration of all stakeholders, and addressing of concerns over potential HIPAA violations to enable proper transfer of information.

### 5.1 Gaps in the current device-tracking practices for CHD patients

There are no standardized tracking systems currently available for devices implanted to treat CHDs and the gaps are multifactorial (Table 2). Industry tracks certain devices as mandated by the FDA, which include devices that have the potential to result in a serious adverse health consequence in the event of a device failure, are implanted for more than one year, and whenever the device is intended to be a life sustaining or life supporting device outside of a hospital setting (e.g., implantable pacemakers). However, this process is not universally applied to all permanently implantable medical devices (e.g., vascular stents and plugs) and active surveillance in some cases. In addition, when it does occur, the tracking process is typically not beyond a few years post-implant. One of the pitfalls for industry tracking devices is that the company can track only those devices that are registered, and tracking is dependent on the operator to submit the device registration information. Furthermore, industry has no standardized methods of tracking of devices used off-label, which is a common practice across the CHD interventional community. The FDA also does not require all implantable devices to be registered. For example, there is no requirement to register stents, which are often used for treatment of vascular stenoses in CHD. Moreover, follow-up for CHD patients is frequently not streamlined during the transition to adult congenital cardiology care.

Most hospitals typically have an internal device-tracking system for patients within the health care system. Currently, most electronic medical records (EMR) are not built with any robust device-tracking platform. In addition, the EMRs of distinct hospital systems most typically do not communicate with each other. Therefore, as pediatric patients’ age and move out of parental care and insurance, details of their implanted devices are often lost. National registries such as the NCDR (National Cardiovascular Data Registry), and the CCISC (Congenital Cardiovascular Interventional Study Consortium) are neither built specifically for device-tracking, nor are they kept active or updated regarding long-term device related issues such as late device malfunction, device explantation, device reintervention, or change in the patient’s clinical situation.

### Table 2  Summary of tracking of implantable devices in CHD: gaps and strategies for improvement

<table>
<thead>
<tr>
<th>Gaps</th>
<th>Strategies to streamline device tracking</th>
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<tbody>
<tr>
<td>No tracking system currently available</td>
<td>Prioritization of certain devices for tracking throughout the lifetime of CHD patients</td>
</tr>
<tr>
<td>Industry tracks devices only if FDA mandated</td>
<td>Backfilling into currently available registries and device-tracking systems within industry</td>
</tr>
<tr>
<td>Tracking can only occur if device registration is submitted</td>
<td>Develop a system to track off-label use of devices</td>
</tr>
<tr>
<td>Lack of active surveillance</td>
<td>Establishment of a SCAI registry specifically for device tracking for CHD patients</td>
</tr>
<tr>
<td>Off-label use of devices for CHD prevents tracking</td>
<td>Partnering with EMR systems to develop electronic device registration and tracking algorithms</td>
</tr>
<tr>
<td>Transition of care is not streamlined into adulthood</td>
<td>Development of patient specific, health passports</td>
</tr>
<tr>
<td>Gaps in transfer of EMR between hospital systems</td>
<td>Regulatory agencies/insurance carriers to mandate device registration/tracking</td>
</tr>
<tr>
<td>Complexities in allowing patient access to medical records</td>
<td></td>
</tr>
</tbody>
</table>

Abbreviations: CHD, congenital heart disease; EMR, electronic medical records.
There are two other gaps in the mechanisms for transfer of medical records—the patient having personal access to their medical records in a passport-like file so that they can easily transmit it to a new physician without requiring institution to institution transfer of medical records, and a registry system to contain this passport. This is much more complicated, obviously, and risks breaches in privacy.

5.2 Strategies for SCAI to develop a streamlined device tracking process for CHD patients

There exists a great opportunity for SCAI to engage physicians, industry partners, regulatory bodies, and insurance carriers to develop a simple, easy to use, and streamlined device tracking system for patients with CHD that can be updated periodically with follow-up patient and device related data while ensuring that patient privacy is protected. The following points were made during the group discussion and summarized in (Table 2):

1. There is common agreement among the stakeholders of the importance of tracking devices used to treat CHD.
2. The CHD and industry representatives are enthusiastic to engage and collaborate with SCAI in developing a process for device tracking throughout the lifetime of children born with CHDs.
3. Specific strategies for device tracking can include but are not limited to:
   a. Prioritization of implantable devices for tracking throughout the lifetime of the CHD patient, depending on long-term complications, impact on future surgeries or other medical care (i.e., MRI compatibility of certain devices).
   b. Backfilling of missing patient and device related information into currently available registries and device-tracking systems within the device industry.
   c. Develop a system to track off-label use of devices.
   d. Establishment of a national registry by SCAI specifically for CHD device tracking which includes tracking of multiple device implants, explants, and device reinterventions in a single patient.
   e. Partnering with EMR systems to develop electronic device registration and tracking algorithms for implantable devices, which allows sharing of HIPAA compliant device information among various EMR platforms.
   f. Development of a patient specific, health passport. With the widespread use of smart phones throughout the United States and around the world, these patient health passports can be created as a cellphone/tablet application (Apps) that can be constantly updated through the internet “cloud.” Voluntary patient participation and “opting-in” within these Health Passport Apps can obviate health privacy concerns.

While there remain financial costs to developing such dependable tracking systems, there are also potential financial benefits. For example, tracking of off-label use of devices may provide important retrospective data that can be used to gain eventual FDA approval for the off-label indication to treat CHD as well as to develop proper CPT codes and valuation for the procedure.

Compliance to register an implanted device can be a challenge. However, strategies involving regulatory agencies and insurance carriers to mandate registration of implanted devices by the hospital or implanters prior to reimbursement can improve compliance. Some of these rules are already in practice for SHD. Alliance with insurance carriers could also ensure reputation incentives for transparent, self-reporting, and improved ratings for hospitals to participate in device tracking registries.

In summary, the SCAI CHD Think Tank group of CHD physicians and industry representatives had a very fruitful discussion regarding tracking of devices throughout the lifetime of patients with CHD. There was group consensus that there is a need for establishing a simple pathway for continuous tracking of these devices. There exists a great opportunity for SCAI to engage physicians, industry partners, regulatory bodies, and insurance carriers to develop a robust device-tracking system not just for CHD, but for other types of interventional cardiovascular procedures with permanent implants. SCAI has an opportunity to play an important role and can have a significant impact in the progress of interventional therapies by tracking of medical devices for patients with CHD.

6 CONCLUSION

SCAI is committed to enhancing safety, quality, and efficacy of percutaneous procedures. The current topics highlight areas of growth within our field, including the move to ambulatory surgical centers, providing more uniformity and standardization of care across geographies and demographics, following our pediatric congenital patients as they age and move through life, and rapidly evolving technology and techniques in the structural arena to meet the needs of a diverse, aging population. Hopefully, this initial discussion fuels attempts at collaboration to meet these challenges, and we welcome any further discussion from important stakeholders and the wider cardiovascular community.

CONFLICTS OF INTEREST

No conflicts of interest.

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