Business Case for Establishing an IDSA Registry

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Executive Summary

This business case presents options, along with supporting rationale, to enable the IDSA Board of Directors to set the strategic direction for the society with respect to quality measurement for the clinical practice of infectious diseases.

There are two key facts that serve as the starting point for consideration:

1. Current ID Quality Measurement is nearly non-existent and, should it remain this way, **it will put ID physicians at risk for further payment penalties**.
    a. For the bulk of ID clinical practice which occurs in the inpatient setting, there is only one relevant clinical quality measure.[i] ID-relevant quality measures that apply to the outpatient setting are focused on HIV and HCV patients.
    b. For ID physicians who were eligible to participate in PQRS, approximately 35% received a payment penalty in 2015 and approximately 38% received one in 2016.
2. In the move from fee-for-service to performance-based payment, hospitals and physician groups will assume more financial risks through alternative payment models such as bundled payments as well as through penalties associated with poor patient outcomes (HAIs, readmissions).
    a. With a bundled payment arrangement, the payer is only concerned about patient outcome measures, and not the individual measurement of each provider involved. The onus of provider-level measurement falls to the entity who is ultimately at financial risk and who must distribute the bundled payment amongst providers (e.g. the hospital). **The distribution of this bundled payment will be driven by the quality of care demonstrated by the providers involved.**

This environment of increased financial risk will raise scrutiny from hospital administrators on the quality of care provided within their facilities which does not bode well for ID physicians who do not have sufficient relevant measures or a common mechanism by which they can report any measures.

This report draws on research conducted by IDSA staff and consultants from Hart Health Strategies that assesses the business aspects of implementing a clinical data registry. Through interviews with representatives of other medical societies, we are able to understand the challenges and limited successes involved with standing up a registry. Through this primary research, we conclude the following:

- Registries require significant financial resources to establish and sustain (as the revenue they generate does not cover the cost).
- Participation in the registry is low for at least the first 3-5 years, therefore establishing a registry should be seen as a long-term commitment in order to fully realize the potential benefits.
- Initially, the benefit of a registry for participants is as a tool for reporting to programs such as Medicare's PQRS. The benefits of producing national bench-marks for quality as well as using a registry for applied research purposes may be seen once the registry has broad-based participation.

- The ideal registry is one that receives data seamlessly from data sources (electronic health record systems). The current lack of interconnectivity between data sources requires custom-built interfaces that come with additional costs. As well, there is a significant amount of administrative work involved with identifying and securing access to data, requiring legal contracting and regulatory compliance oversight with hospitals and electronic health record systems vendors.

The underlying premise of this discussion is that IDSA creates the "intellectual property" derived from clinical practice guidelines and will therefore be recognized as the authority in defining electronic clinical quality measurement. As such, the responsibility to assist ID physicians to convey their value in a standardized and systematic manner through clinical quality measurement falls to IDSA. Recognizing the need for ID-relevant measures to enable ID physicians to demonstrate their value, there are two choices to consider:

1. **IDSA collects data from ID physicians in order to measure quality, report on their behalf when possible, and provide them bench-marking reports**. This would likely entail IDSA creating a registry that enables the reporting of measures that are both relevant to ID Physicians and to hospital administrators.

    a. Having a registry facilitates the creation of ID-relevant quality measures without having to go through the measure validation and endorsement process, which is a costly and time-consuming.

    b. This registry will initially focus only on ID conditions that are most common to bundled payment procedures (i.e. total knee, total hip, etc).

    c. Until interconnectivity between data sources improve, the registry will collect data via web-portal.

2. **IDSA provides the "intellectual property" that enables hospitals to measure the care that ID physicians provide within the hospital's electronic health record systems.** This would involve IDSA going to hospitals and health care systems with the offer of embedding fully-validated ID-relevant measures into their electronic health record systems to enable the measurement of quality

    a. This strategy may be well received by hospitals who face significant financial risk and would still enable ID physicians to demonstrate the quality of care that they deliver.

    b. The clinical quality measurement will be initially focused on ID conditions that are most common to bundled payment procedures.

These two options are put forth to the IDSA BOD so that a decision can be made as to what direction the society should proceed. Both would require financial support of approximately $200,000 to engage vendors, consultants, and/or bring talent in-house.

Background

The U.S. healthcare system has entered a new era of increased transparency and accountability in which clinical data registries can serve a critical role to promote safe, high quality care. Nevertheless, the vast majority of recognized medical specialties in the U.S. lack affiliation with a clinical registry and those that do exist tend to be substandard. A 2016 study of 153 U.S. clinical registries containing health service and disease outcomes data concluded that there is substantial opportunity to develop more specialty-specific clinical registries with publicly available data.[ii] The study found that among the 117 AMA specialty societies, only 16.2% were affiliated with a registry.

The ideal registry is able to find a balance between feasibility, scientific soundness, and clinical significance. For a medical specialty society weighing the pros and cons of establishing a registry, considerable due diligence is required to thoroughly understand the challenges that exist in trying to achieve that balance between feasibility, validity, and significance. Over the past year, IDSA's Quality Improvement Committee has studied the current regulatory environment as it relates to quality measurement and gained a deeper understanding of the IT-related issues that would inform the decision as to whether IDSA should invest in a clinical data registry that focuses on infectious diseases.[iii] This report lays out the business case for establishing a clinical data registry.

The Problem

Physician reimbursement is shifting from a fee-for-service to a value-based payment model that rewards high quality, cost-effective health care delivery that results in better patient outcomes. Payers such as the Centers for Medicare and Medicaid Services (CMS) utilize clinical quality measures (CQMs) relating to specific interventions, conditions, and/or patient outcomes to assess quality of care. To avoid payment penalties and receive full compensation for services provided, physicians are required to report on CQMs within the Physician Quality Reporting System (PQRS), soon to become the Merit-based Incentive Payment System (MIPS). This is problematic for infectious diseases (ID) physicians as there is a lack of appropriate CQMs to reliably assess the quality of care that ID physicians provide.

In the current PQRS program, the top five CQMs reported by ID physicians are[iv]:

1. Documentation of Current Medications in the Medical Record
2. Preventive Care and Screening: Tobacco Use: Screening and Cessation Intervention
3. Preventive Care and Screening: Body Mass Index (BMI) Screening and Follow-up
4. Preventive Care and Screening: Pneumonia Vaccination for Patients 65 or Older
5. Preventive Care and Screening: Influenza Immunization

This highlights the lack of relevant CQMs to accurately evaluate the care provided by an ID physician which then results in payment penalties.[v] From the PQRS Experience Reports published by CMS, 34.9% of eligible ID physicians participating in PQRS received a payment penalty in 2015 and 37.5% received a payment penalty in 2016. Furthermore, the use of CQMs tied to the reimbursement of physicians will be in place for the foreseeable future with the passage of the Medicare Access and CHIP Reauthorization Act of 2015 (MACRA) legislation. MACRA will subject physicians who treat Medicare patients to

payment adjustments based, in part, on a physician's performance on CQMs, with payment adjustments ranging from -4% to +4% starting in 2019 and increasing to -9% to +9% by 2022.[vi] Furthermore, as alternative payment models such as bundled payments become more prominent in the health care payment system, the ability to measure quality across an episode-of-care will be needed. Current measures on which ID physician are assessed are insufficient and new, more relevant measures are needed to allow ID physicians to demonstrate value.

Clinical data registries provide an opportunity to develop measures, derived from practice guidelines, as well as to collect data on validated measures from which a provider's quality may be assessed. Therefore, a clinical data registry will facilitate the development of more relevant quality measures the clinical practice of infectious diseases. Below, an in-depth analysis of the requirements and trade-offs involved in establishing a clinical data registry is provided as well as an exploration of alternative strategies.

Establishing a Registry

Business Purpose

The principal purpose of an IDSA established registry will be to improve the quality of direct and indirect patient care relating to infectious diseases. Achieving this purpose will in turn promote the value of the Infectious Diseases (ID) specialty and the ID physician within the healthcare system by associating patient and economic outcomes with best practices. A secondary purpose of this registry will be to assist IDSA members (those participating in the registry) with reporting requirements such as those that exist with PQRS/MIPS and some private commercial payer quality improvement programs. Finally, the registry could benefit further research in clinical infectious diseases, collecting data that can be used to inform clinical guidance.

Areas of Interest	Objectives

Antimicrobial Stewardship (AS)	• Define and measure the value of AS programs
	• Patient outcomes attributed to processes of care
	  ○ Utilize process of care quality measures to examine the association with patient outcomes
	• Association with antimicrobial resistance (AR)
	  ○ Utilize microbiology lab data and examine the association with AR

Infection Control and Prevention (ICP)	• Measure the value of IPC programs • Patient outcomes attributed to ICP interventions ○ Develop measure concepts to examine the association of ICP processes and patient outcomes
Specific ID conditions and Complex Infections (CI)	• Documentation of entire consultation services for the treatment of CI • Patient outcomes
High-risk Patient Populations	• HIV • HCV

	• Cancer • Transplant

Registry Services for Primary and Secondary Markets

***Primary market**: Individuals and organizations whose use of information from the registry will be considered a part of the registry's regular workflow to include data collection and analysis*

***Secondary market**: Individuals and organizations performing other uses with the data such as users requesting use of registry data for studies*

The primary market for an IDSA registry will be the roughly 7,000 US-based ID physicians in clinical practice as well as US-based hospitals/health systems. The patient-level clinical data to be captured will assess performance on provider-level metrics related to AS, ICP, bio-preparedness, CI, and care of high-risk patient populations, as well as routine ID conditions. Providers reporting data to the registry will receive reports on their performance in order to improve aspects of care that may fall below performance benchmarks. The proposed collection of clinical data and near real-time sharing of analyzed data can create a continuous cycle of learning and process improvement, leading to better patient and economic outcomes. The actionable data that will be shared with physicians will also be of interest to hospitals and hospital systems as the clinical performance data can inform hospital administrators on the effectiveness of AS, ICP, and bio-preparedness programs and the performance of physicians involved with the mentioned programs as well as the physicians performance regarding the care of high-risk patients and patients with complex infections.

The secondary market for an IDSA registry will be researchers from academic institutions, health services research organizations, and public health entities. The analysis of registry data may result in publications that can be shared with the larger clinical communities.

Registry Population – Data Collection & Use

The registry population is defined by the sites-of-service where patients receive care. For the majority of ID physicians, this will be the inpatient setting in acute care hospitals and, to a lesser degree, outpatient clinic or office-based care. Patients that receive care in other sites-of-service such as long-term care facilities may be included in the registry population, depending on the interconnectivity of the electronic health record (EHR) system across different types of facilities.

It is important to note that because the main site-of-service for ID physicians is the inpatient setting and the main employment affiliation for IDSA members is employed by Hospital/Academic Medical Centers (AMCs), patient-level data collection will rely on established business agreements and database interfaces with the entities that hold the EHR data, (i.e. the hospitals/health systems). In other words, a registry that is designed to meet the needs of IDSA would need to be able to receive data from possibly thousands of facilities where IDSA members provide care.

Evaluating Registry Program Performance

There are many aspects on which to assess the performance of a registry program. Some of these aspects are listed below:

- Number of providers reporting data (this could be translated into percent of IDSA members participating in the registry)
- Number of patient cases
- Number of CQMs able to be collected and reported by registry
- Financial viability of the registry

The objectives of the registry influence its scope, which in turn, has bearing on the number of quality measures collected, sources of data as well as the range of participants and patients. Where other clinical registries maintained by other medical societies are able to focus quality measure development around procedures or specific diseases (i.e. plastic surgery procedures or Inflammatory Bowel Disease), an IDSA registry will likely start small with a few measures for Staph. aureus, antimicrobial stewardship, and possibly C. diff. Measure development for other ID conditions could then be added in overtime, particularly as guidelines are updated.

Participation in an IDSA registry will likely be low initially but may increase dramatically depending on the rate in which larger hospitals and health systems agree to share data from their EHRs. As mentioned above, many IDSA members are employed by hospital systems or AMCs and, when one of these large entities agrees to share data with the registry, then the data for many ID physicians as well as a large volume of patient cases will be collected through one data sharing agreement. The start-up costs associated with a clinical data registry are substantial, ($1 MM range) with significant annual maintenance costs. Structuring the financial model on a member participation fee will be complicated. Assuming a member is employed, the data from his/her facility would first have to be accessible before the member would be willing to pay to participate in the registry. Those members in private practice who own their electronic health record system would likely be more willing to participate as they can submit data directly from their EHR, although additional financial investment may be requiredto enable the data interface.

Learning from Others

There are many medical societies who have established registries to measure quality of patient care and provide reporting services for their members. The collective experience of these medical societies would inform IDSA's strategic decision-making about whether to invest in an ID-focused clinical data registry. IDSA engaged Hart Health Strategies, Inc. (HHS) to conduct primary research with multiple professional societies that have established registries or have seriously considered investing in a registry to better understand the range of internal and external considerations, the diversity of approaches, the benefits, and the most significant obstacles. HHS conducted in-depth discussions with stakeholders that share common characteristics with the IDSA membership—whether in terms of clinical focus, practice setting, or employment status- and with which there might be a potential for collaboration in the future. The table below lists the societies interviewed that share common features with IDSA.

Society	Description
American College of Emergency Physicians (ACEP)	Although ACEP has ~34,000 members, the specialty is primarily facility-focused with a strong interest in multiple clinical topics of relevance to IDSA (e.g. infection control, appropriate use of antibiotics, etc.).
American College of Rheumatology (ACR)	Similar in size to IDSA, but practices almost exclusively in the outpatient setting.
American College of Surgeons (ACS)	Significantly larger than IDSA, which around 80,000 members, but similar to IDSA in that members practice mainly in the inpatient setting, but also across other settings such as outpatient and post-acute. ACS also has an interest in infections due to its surgical focus.
American Gastroenterological Association (AGA)	Although largely outpatient-focused and has a slightly larger membership (~16,000) than IDSA, it shares some clinical priority areas with IDSA (e.g., HCV, C. diff)
American Society of Plastic Surgeons (ASPS)	Also has members that practice across settings (inpatient, outpatient, and post-acute care facilities) and has an interest in surgical site infections, but is more similar in size to IDSA than ACS (with about half its size with ~5,700 members).
American Urological Association (AUA)	About double the size of IDSA (~22,000 members), but members practice in both the outpatient and inpatient setting. Because urology is a surgical specialty, AUA also has an interest in infections.
Society of Hospital Medicine	SHM already conducted a similar environmental assessment on strategies to best meet the quality measurement needs of its hospitalist members and decided against investing in a registry at this time.

This primary research provides background information related to the development, implementation and ongoing operation of a registry based on first-hand experience. Furthermore, potential strategies for IDSA to pursue in regards to a clinical data registry are laid out including the feasibility, estimated cost, and potential impact of each of these options. Additional strategies are presented that might be pursued in conjunction with or as an alternative to investing in a registry.

COMPARATIVE REGISTRIES – OBJECTIVES AND SCOPE

As registries evolve from concept to actual implementation, objectives tend to shift based on external pressures and internal realizations about the limitations of resources. While the fundamental goal of most, if not all, professional society registries interviewed is to promote the highest quality of care for patients, providing participants with a tool to satisfy quality-focused reporting mandates-- including PQRS, but also MOC-- seemed to be the driving force behind the actual implementation of the registry. Therefore, for many medical societies, the registry mainly serves as a compliance tool for members to avoid payment penalties by reporting quality measure performance via the registry. For example, although the impetus for the American Academy of Allergy Immunology, (AAAAI) to invest in a registry was to improve the specialty's quality of care and find ways to differentiate it from primary care, its current registry focuses simply on providing a useful tool for its members. It is offered solely for the purpose of PQRS reporting and only targets practicing allergist groups (the vast majority of its membership). It is not available to immunologists or those involved only in research. It also is only available to physician members and not allied health professionals. Although AAAAI is considering expanding the registry to non-physician professionals in the future, its main priority right now is increasing physician participation rates. Other secondary and tertiary objectives for launching a registry include: research, development, tracking safety/harm/adverse events, and public reporting. Although still a top objective, demonstrating the value of the specialty was a lower priority for most specialties interviewed.

Most registries are not initially set up in a manner that makes reporting on all patients a feasible option. Other registries remain satisfied with statistically valid samples. Participants in AUA and ACR's registries, for example, collect data on all patients because their systems can accommodate automated data entry and impose little additional burden on the participant. For the ACS, the amount of data reported to the registry is dependent on each surgeon's preference—there is no requirements set by ACS (except if a surgeon is using it for PQRS). ASPS prefers that users of its registries report on all patients, but imposes no specific requirements.

The scope of a registry often changes over time as priorities become clearer and operational challenges are remedied. Modules might be added, data elements broadened, and measures tweaked or expanded. ACS' Surgeon Specific Registry (SSR) originally offered only four measures, but within three years, had 62 measures, 12 of which were developed by the ACS. When AGA's QCDR was first approved in 2014, it only contained 12 measures. It now includes 19 measures to cover additional topics that are relevant to a broader swath of its membership and more cross-cutting measures, which make the registry attractive to participants beyond its own membership.

Regardless of the path chosen, all registries face the challenge of balancing the ultimate analytical power of the resulting with the burden of data collection so that physicians have reason to believe that participation in the registry is a worthy investment of their time and resources. This is not an easy task and many registries still suffer from low participation rates despite heavy investments. Among professional societies interviewed, most have participation rates hovering in the range of 2-5% of total membership, although a couple of more advanced registries have achieved participation rates as high as 20% of their membership (AUA).

Although ACR continues to sign up new participants, they expect interest in this registry to level off in the future since it will only ever appeal to a specific population (i.e., those who have more direct control and access of data). Ultimately, ACR would like to achieve a 25% participation rate. Participation rates for AAAAI's remained very low in the first couple of years (only 10 participants in year one) and if MACRA had not passed and been so registry focused, they might have scrapped the initiative. However, now three years in, the registry is finally starting to pick up participants. Although the number of participants still represents less than 1% of AAAAI members, it has increased five-fold since the registry was first launched three years ago.

The ACR is a good example of how shifting priorities influence the objective and scope of a registry. Although ACR's initial investment in the concept of a registry was driven by loftier quality improvement goals, its focus shifted to offering an administratively simple tool that members could use to easily and meaningfully comply with PQRS reporting requirements. The registry became simply a reporting tool and not the more robust quality improvement tool they wanted it to be. And although ACR always envisioned offering an EHR-based registry where data would automatically and seamlessly stream from the EHR to the registry, it took about five years to reach that goal. Instead, they initially launched a registry that relied on manual data entry. However, the utility of that registry quickly diminished as CMS continued to increase PQRS reporting thresholds, and the pressure for a more automated tool that could capture all patients increased. ACR again shifted focus and invested in the development of an EHR-enabled PQRS qualified clinical data registry (QCDR), which quickly supplanted its original registry. While ACR is hoping to move all members to this platform and eventually retire the original registry, it continues to maintain it for practices that still cannot connect or integrate with their EHRs.

Interestingly, the Rheumatology Informatics System for Effectiveness (RISE) Registry has evolved to such a user-friendly and robust tool that even those who initially signed up with only PQRS in mind now find that they can also easily use it for other broader internal tracking and quality improvement activities. RISE participants can easily submit data on all patients and users appreciate being able to see data on their entire patient population, rather than cherry picked patients. With access to this bigger picture, they often realize they are not actually doing things or performing at the level that they thought they were. Even physicians in larger group practices or systems who are not directly responsible for PQRS reporting still see value in the tool and use it for internal tracking purposes. It should be noted that ACR is an outpatient registry that caters mostly to solo and small private practices so they have not experienced the institutional hurdles shared by hospital-focused specialties.

Another example of shifting priorities is the American Association of Neurological Surgeons (AANS) Neurosurgery Quality Outcomes Database (QOD), which was first piloted in 2011 as a tool to help neurosurgeons better understand the quality of their care and demonstrate their value. Participation rates climbed slowly, largely due to a cumbersome platform that required an onsite data entry coordinator. Four years later, in response to evolving federal mandates and low participation rates, the QOD shifted focus and became a QCDR. Now in its second year of being a QCDR, it is yet again undergoing a transformation as it looks into contracting with a different vendor that can provide better data collection efficiencies. The intent is to significantly reduce the requirement for dedicated data coordinators and to develop solutions related to direct transfer of information from EHRs to the registry

platform. It also is in the midst of a complete overhaul of its data and internal quality systems, including stricter requirements on enrollment and follow-up, a re-construction of its site reports to increase the value of the reported data, and the development of a "vanguard" designation for centers that are performing at particularly high levels with respect to patient enrollment and data quality.

ACEP warned that when weighing decisions about the scope of a registry, professional societies must carefully and realistically consider their ability to take on such a project. ACEP expressed regrets about their approach of literally building the train as it was going down the tracks. They did not have adequate staff to respond to what was an unexpectedly overwhelming demand and fears they may have alienated some of their best customers.

REGISTRY COSTS AND FINANCING

Start Up and Maintenance Costs

The estimated start up and maintenance costs of running a registry depends on the scope of the registry and the range of its functionalities and uses. For most societies interviewed, particularly those with PQRS-centered registries and those contracting with FIGmd, start up costs were in the $1 million range and ongoing annual maintenance costs are also in the $1 million range. The ACR admitted it had a failed start and invested a lot more in upfront costs than necessary (about $2-3 million). ASPS' reported significantly lower start up costs were under $200,000 and annual maintenance costs are under $300,000, possibly due to a smaller expected number of participants. Another smaller group spent less than $500,000 over three years, although low participation rates continue to result in a relatively high cost to the society per participant.

Internal staffing contributes to about 30-40% of maintenance costs, while vendor costs contribute 30-50%. The remainder of the total is spent on miscellaneous costs, such as legal, marketing and other IT expenses. ACS, which has a significantly larger membership than the other interviewees, was unwilling to share start up and maintenance costs, but noted that the largest expense was contracting with a vendor (representing over 65% of total expenses).

Registry Financing and Support

None of the societies interviewed is profiting from their registry, and in fact, the ACR is losing money on its RISE registry. Charging participants a fee is the most common model and some practices even receive funding from their hospitals to do so. A couple of societies interviewed do not charge a fee for registry participants. However, they acknowledge that this model might not be sustainable over the long-run. For example, ACR's RISE is currently free to all ACR members and non-members and completely financed by the ACR. Although it does not plan to offer this free model forever, it hopes this strategy will help bring the registry up to scale by getting people comfortable with using it (although they hope to keep it free for ACR members). ACR also plans to eventually try to get external funding (e.g., grants), but feels it needs to build up the registry first before doing that. When conducting a similar environmental scan, all of the groups that ACR spoke with experienced several years of multimillion spending until they had something that was suitable for grants or other external funding.

Some societies only charge a fee to non-members, while those who charge a fee for all users typically offer members a reduced rate. Some groups rely solely on internal funding sources. ASPS' TOPS is funded through member dues, while GRAFT is funded through the society's reserve funds. Other groups rely on a mix of registry user fees and the society's general budget. 90% of ACS' SSR is funded from its general budget and membership fees, while another 10% comes from non-member registry participation fees. ACEP's CEDR is diversely funded through ACEP membership fees, a separate registry participation fee, the American Board of Emergency Medicine (which makes up about 20-25% of total funding), and a federal grant.

Industry support for registries is not common, but does occur. Besides internal funding, ASPS' GRAFT also has industry support. Although AGA's registries are not directly funded by industry, its Digestive Health Recognition Program, overall, has industry support.

PARTICIPANT RECRUITMENT STRATGIES AND BARRIERS

Common strategies for recruiting participants include direct member outreach (e.g., e-blasts, newsletters, other publications, and society websites) and promotion of the registry at annual meetings. ACR holds sessions and strategically places ads on RISE listing reasons why participation is important. Increasingly, abstracts based on the quality improvement data coming out of the RISE registry are getting picked up at annual meetings, which represents another way to showcase the value of its registry. AAAAI tries to tie its registry into news stories and advocacy briefs as much as possible.

In addition to promoting the registry through repeated communications to members, AUA also tries to promote its registry's QCDR status and that it can also be used to meet the specialized registry measure under the EHR Incentive Program. AUA also attributes its successful recruitment strategy to making the on-boarding process as easy and flexible as possible for practices. AAAAI also emphasizes the importance and value of its registry, promoting it as a tool that is real and approachable for members.

Similarly, ACEP's recruitment strategy is focused more on building awareness about potential PQRS, Value Modifier and forthcoming Merit-Based Incentive Payment System (MIPS) Medicare payment penalties and advertising that thus far, potentially 3 out of 4 MIPS categories can be covered by participation in its QCDR. ACEP also encouraged emergency practices to serve as pilot sites by allowing them to participate for free. To promote participation, AAO-HNS offered the first year free to the first 1,000 participants to sign up for its Regent registry.

Across the board, professional societies cited institution-specific hurdles regarding data access, privacy, and legal issues, particularly at academic and larger institutions, as the biggest barriers to participant recruitment. Many also cited lack of interoperability between registries, including EHR vendors' reluctance to facilitate physician participation in the registry (discussed in more detail below). ACS notes that the biggest barrier to participant recruitment is difficulty managing the work and financing registry changes due to constantly changing CMS requirements.

Only one society reported a retention problem. ASPS' TOPS has seen a decrease in enrollment over the past few years. Reporting sites claim they do no have the bandwidth to complete data entry. In order to combat this, ASPS is planning major registry enhancements and opportunities for EHR integrations that

hopefully will create a more meaningful and valuable user experience and increase participation in the registry.

MEASURE DEVELOPMENT

The societies interviewed offer a mix of process, outcomes, structural and appropriate use measures. AUA's AQUA is currently pilot testing a patient-reported outcomes (PRO) measure, and ACEP's CEDR hopes to do so in the future. ACEP also includes cost/resource use measures.

The timeline for measure development seemed to vary widely among respondents and depends on the measure. For ACS, some of their measures took only a few weeks to develop, while others took several years. It took ACR two to three years to develop their current set of eight non-PQRS measures, however, it warned that its process is very methodologically rigorous and includes many steps. For AUA and AGA it took only several months to develop their non-PQRS measures (11 and 10 respectively), although with AGA, measure development has required new and iterative work to address rapid changes in Hepatitis C treatment. For ASPS and ACEP it took about 1-2 years to develop each measure.

Obviously, not all measures are created equally. For AAAAI, some of their measures were developed before they even thought about a registry. Some had a more inclusive stakeholder-engaged process so it took longer just to agree on basic specifications. However, that occurred more often in the past when AAAAI had more time and no pressure of current mandates. Others were developed in one cycle because they assigned physicians to the task with 10+ years of experience developing measures through the AMA PCPI. AAAAI is currently in the process of developing immunodeficiency measures, which are taking longer than usual because the volunteers assigned to the project have never done this type of work before.

Unlike many other registries, ACR's RISE collects data on all patients, rather than a patient sample, which makes it a strong testing bed for measures. ACR also does not necessarily report to payers on all measures collected via the registry- it first incorporates them, sees if members find them feasible and valuable, assesses performance gaps, and then determines what opportunities exist for the measure. As ACR continues to build its database, it expects its internal measure development process to become more efficient. ACR is also working on developing an outcomes measure and will use RISE data to help with risk adjustment.

OUTSOURCING TO A REGISTRY VENDOR

Most professional societies have opted to outsource at least aspects of their registry to a vendor due to a lack of internal capacity to support the registry on their own and cost-benefit analyses that favored contracting out rather than keeping it in-house. The more reputable vendors have many years of experience building integrated registries and are more capable of efficiently addressing some, but not all, challenges related to acquiring, integrating, and repurposing health data for professional societies, researchers, and facilities. Most also have a firm understanding of regulatory requirements, such as what is required for PQRS.

The role and responsibility of the registry vendor can vary across specialties and even among specialties using the same vendor. However, for the most part, the vendor is responsible for collecting and storing data, and day-to-day registry operations, while society staff handles recruiting and marketing, contracting with participating practices, measure development. Some responsibilities are shared between the vendor and society, such as data analytics, ensuring data integrity, specifying data elements, data use issues, regulatory/legal compliance, and technical assistance.

In addition to a lack of internal expertise, ASPS' decision to outsource was largely driven by concerns about assuming Business Associate responsibilities. AAAAI also noted that a primary benefit of working with a vendor is that it assumes the role of Business Associate and takes care of data use and other legal agreements. While cost was a factor, ACEP's decision to outsource was driven mainly by ease of use for members since its vendor made it possible for users to avoid manual/ongoing data entry and to not have to employ data entry personnel in order to participate. ACEP's vendor provides members with a client account manager and a mapping analyst who works with the participant to obtain data for all 41 measures in CEDR. The individual physician or group administrator then decided which 9 of those 41 measures should be reported to CMS.

Data ownership is a critical issue that must be addressed in contract negotiations with a data vendor. AAAAI has found that its vendor, CECity, has impeded access to aggregate data. When it requested measure-specific data from its vendor in order to evaluate how the measures were working, the vendor had to go through a lengthy process of getting permission (since it was recently acquired by Premier), and when it finally released the data, it was in a format that was uninterpretable to AAAAI and essentially useless. Not only does this limit the utility of the registry, but AAAAI fears this could be a problem in the future if they have more specific data analytic requests. However, the experience of AAAAI seems to be the exception to the rule and might be a result of how its contract with the vendor was organized.

Switching vendors is also not uncommon as registries evolve and expand or modify their scope and desired functionalities. ASPS built both of their registries with a database vendor, but have since moved both registries to a different vendor that is better suited to meeting the needs of its programs. The AANS originally partnered with a lesser known university-affiliated registry vendor, but is now looking to switch to a vendor that can provide better solutions for data collection efficiencies in order to address participation barriers and the expanding scope of the registry.

CONTRACTING FOR DATA SHARING

Despite increasing standardization of EHRs, there are many obstacles to achieving full interoperability between EHRs and registries. These center around:

- Concerns about confidentiality, privacy, security and data access- namely, that the secondary use of data may violate patient privacy and that protections are needed before data access can be automated; and

- Limitations in the ability to use and exchange information due to an ongoing lack of enforced standards related to vocabularies, data elements, data sets and other technical standards.[vii]

A critical component of running a registry is ensuring that data collection and use comply with applicable privacy and security regulations, as well as secure and ethical guiding principles. Contractual obligations will depend on the nature of the data collected, the proposed data uses and disclosures of such data, and the applicable laws and regulations relative to such collection, use and disclosure.[viii] In general, participants of a registry typically sign a participation agreement that establishes a shared understanding regarding participation requirements and expectations. This agreement typically includes a Business Associate Agreement (BAA), signed between the Business Associate (the professional society or registry) and the participant (the "covered entity"), as required under the Health Insurance Portability and Accountability Act of 1996 (HIPAA) and updated by the Health Information Technology for Economic and Clinical Health Act (HITECH-part of the American Recovery and Reinvestment Act of 2009). It also includes a Data Use Agreement. These agreements are intended to safeguard identifiable patient information (Protected Health Information or PHI) and govern the transfer of both identifiable and de-identified data.

Negotiations related to these agreements can have varying results. For ACR, the registry has an agreement with each participating site to release data. These agreements are between ACR and practices (and not the EHR vendors) because it is the practice's data. ACR has an agreement with each participant site to release data, even if the facility, itself, does not need to be directly involved in the registry. As mentioned earlier, some registry vendors assume the role of BA.

At AUA, many practices have used its template Participation and BAA/Data Use agreements, but some have required modifications to these agreements and/or insisted that AUA use the practice's own template agreement. Reaching acceptable BAA/Data Use agreements with hospitals and universities has been challenging in some instances, as have requirements to complete lengthy data security questionnaires administered by these facilities.

Health Information Exchange and EHR Interoperability

There are multiple mechanisms by which registry platforms can integrate with EHRs and take advantage of data that has already been collected for other purposes. The extent to which a registry can directly communicate with an EHR depends on the extent to which data access barriers have been addressed; data definitions developed; and data transfer, transformation, and other record linkage algorithms developed.[ix] According to the 2015 CMSS Vendor Survey, approximately 70% of the respondents indicated that their registry could accept data directly from an EHR. All but two of the societies interviewed for this report claimed their registries were interoperable with EHRs. However, it is important to distinguish between a registry's *capability* to seamlessly communicate with an EHR and their actual *ability* to do so. Although vendor products have become increasingly savvy, multiple barriers outside of their control, as discussed below, continue to stand in the way of this actually happening.

Ideally, a registry would rely on a direct export model, where the registry works with EHR vendors directly to certify their support for the registry's specifications. This model imposes the least amount of

burden on the registry participant in terms of prep-work, which is done directly between the EHR and registry vendors, and actual data entry, which requires no additional effort on the part of the clinician once the connection is established. Few groups have attained this level of interoperability. For AUA, work is pending with select EHRs to certify their direct support for AQUA's specifications.

The societies that have partnered with some of the more sophisticated registry vendors, such as CECity and FIGmd, seem to have the capacity to accommodate multiple data exchange models. For example, ACEP's CEDR is interoperable with EHRs via the data push and pull model, as is AGA's IBD Digestive Health Recognition Program Registry (DHRP). For DHRP, manual entry may also occur through a web-based data entry portal that includes an upload functionality. To upload data, participants must download two spreadsheets: a data template and definition file. The data template is an Excel spreadsheet that contains the correct column headings, which correspond to the data elements required to build a master patient list in the registry. Participants may manually enter the data into the spreadsheet template or, if able, generate a report from their existing system (which must be exactly the same as the template). The definition file is a resource to help users understand the data fields in the patient template. After completing the data template, it is uploaded to the registry.

AAAAI, which also uses CECity, relies on the data "pull" model in that data capture software is placed on the network at each participating site and periodically queries the EHR for data to transmit to the registry through an internet gateway. However, this semi-automated transfer only works with a single EHR vendor, which AAAAI cannot legally tell its members to use to connect to its registry since this would be an antitrust violation (although AAAAI is encouraged by the fact that CECity is currently working with six EHRs that it could potentially connect to in the near future). Even among practices that use this EHR, only those with dedicated IT teams to pull and upload their data can really make this happen. Because of these ongoing issues, the only people using the AAAAI registry are those using this particular EHR who are in larger groups/institutions. Over 80% of its members in small practices still have not participated in PQRS and see no need to invest in the platform.

Participants in ACR's RISE, which is managed by FIGmd, only have to enter data once-- whether in their EHR or other practice management system-- and the registry takes care of the rest.[1] RISE is unique in that it can be tailored to collect and analyze data from a variety of sources – both structured and unstructured – so participants do not need to change their work flow. RISE also does not require participants to pay for and develop custom interfaces. When a participant signs up with RISE, they provide information to FIGmd on which of the registry's data fields are currently captured in their EHR. Practices spend a total of 6-10 hours over several months to prepare for and successfully incorporate the RISE registry. During this time, FIGmd works with the sites to ensure they are mapping data correctly so it is an automatic and iterative process. Once it is set up, physicians and their staff do not have to spend any time inputting data into the registry. It is also acceptable if there are data points in the registry that a participant is not capturing in his/her EHR. In these cases, participants work with FIGmd, over a series of conference calls, to review and refine data mapping to the registry.

[1] The FIGmd model also is used by American Academy of Otolaryngology-Head and Neck Surgery, American College of Cardiology, the American Academy of Ophthalmology, the American Academy of Neurology, the American College of Emergency Physicians, the American College of Rheumatology, and the American Urologic Association.

Interestingly, ACR developed a separate module exclusively for pediatric rheumatologists, which have their own diseases and own measure needs, largely in response to a very targeted demand. There are only about 200 pediatric rheumatologists nationwide and they are all in academic centers. Although their centers take care of satisfying Medicare quality reporting requirements on their behalf, about 12 centers with a focus on pediatrics are so happy with the platform that they rely on RISE solely as a quality improvement tool. Most of them have to do a work around because of data access issues and rely on manual data entry through a case form on a website. Regardless, they still must have an agreement with the facility to release the needed data. ACR notes that the extra effort required of manual entry only really works in certain circumstances. ACR's pediatric-focused members are a very specialized group of clinicians that value this tool so highly because they treat such rare conditions that, to date, have never been tracked methodically. They also see much fewer patients than general rheumatologists and because their clinical scope is so focused, these workarounds to data entry end up being much more "low-tech."

Dealing with EHR Vendors

The willingness of EHR vendors to work with registries is an ongoing challenge. Some will simply refuse to connect to a registry and others will charge sites another $5,000-$15,000 to do so. While the workarounds discussed earlier are a way to overcome some of these challenges, they require an initial investment of effort by the participating site. The level of manual effort required largely depends on how sophisticated the IT staff is at a practice or facility. The task, itself, is not necessarily so difficult if the site has the right people available to help. But, even when these resources exist, they might not have the manpower to assist or view one specialty's connection as a priority for the larger group or institution. In other cases, the institution is simply beholden to the EHR vendor.

For example, an American Academy of Otolaryngology–Head and Neck Surgery (AAO-HNS) board member served as a champion at a prestigious large academic center. By speaking to the right people within the hospital administration and IT leadership, he eventually convinced them to sign a contract and secure permission to access the data that the registry needed, despite lengthy negotiations to quell concerns regarding HIPAA and potential uses of the data. Nevertheless, the EHR vendor used by the facility still posed a roadblock by prohibiting the facilities from installing FigMD's connector software. Despite the availability of a workaround, the EHR vendors required such a labor intensive process to extract data from their platforms and send it to the registry, including the submission of a massive list of data files in order to map all the data, that the institution's IT department decided it was too complex and not worth its time. This was a major blow to the champion because of all the effort put into getting the facility to sign off and the minimal work that would have been associated with using the connector. Although negotiations with these larger institutions has been difficult for AAO-HNS, it has not been insurmountable and it has made progress on many fronts. For example, they have had ten academic centers sign up for the registry to date, although most of them use a different EHR vendor than the one described above.

Similarly, ACR's RISE has very few large academic center participants, and it is not for a lack of trying. Rheumatologists at these centers have shown great interest in using RISE, but continue to run into road

block after road block. While ACR has had some success with larger integrated systems, the larger academic systems have been a real challenge—especially those using one specific EHR (the same one that posed a roadblock to AAO-HNS). AAAAI has experienced similar roadblocks, but thinks these might start to change as the financial ramifications of not using a streamlined data collection system increase and practices and facilities put more pressure on their EHR vendors to cooperate.

AAAAI expressed regrets about initially putting so much time and resources into the look of the registry's user interface and deciding what measures to incorporate rather than focusing more heavily on how to address these EHR connection challenges. AAAAI believes that if it would have started with more simple measures and data points, it could have possibly had the ability to connect to a larger number of EHRs. To remedy this, they recently spent $76,000 to develop electronic specifications for six existing PQRS measures to make it easier for EHR vendors to program, which AAAAI hopes will significantly improve the ability of EHRs to connect to its registry. Nevertheless, AAAAI acknowledges that no matter how easy it makes it for the EHR vendors, it is still a matter of how much work the vendors will take on themselves versus what they are going to charge to do. AAAAI staff now tell members that the most important thing they can do if interested in participating in the registry is to tell their EHR vendor that they need to connect to the registry.

Finally, interoperability remains the biggest hurdle for specialties with a larger portion of physician practices in smaller and private practice who have not yet adopted an EHR.

Roadblocks Imposed by the Facility

Facility-imposed obstacles come in various forms. For some specialties, data ownership agreements, IRB approvals, and other security/legal concerns, particularly at academic institutions, have been particularly challenging (even when a registry has overall IRB exemption). Another issue is hospital fatigue. Hospitals are required to track and report massive amounts of data, including a fair amount of what they often consider as junk and poorly associated with hospital quality. Hospitals are being asked to respond to their own panoply of measures, which they have to pull and scrub data for and figure out how to report accurately, which results in a subordination of specialty-focused physician-driven efforts.

Cost is yet another reason why registries have trouble recruiting hospitals. While the biggest costs are usually associated with setting up the data feed, the institution must also often outlay resources for scrubbing and checking the data. Despite regulatory pressure to move toward a value-based healthcare system, hospitals will not prioritize investing in registries if there is no obvious business case for doing so. They are particularly hesitant to invest in tools that track their data and compare their performance to national benchmarks, when the current system is driven by penalties, rather than positive incentives to harness data and evaluate performance.

Physicians that practice in medium and large facilities or health systems also have little to no control over their choice of EHR. Making things more complicated, these practices tend to have highly individualized EHRs, which makes connectivity at the clinician or practice level even more challenging. The more modified and specialized these systems are, the more difficult it is to set up a standardized data upload. Representatives from the Society of Hospital Medicine (SHM) noted that if a registry only

required working with a single hospital, going through the process of setting up the data feed might be manageable. But when one considers the need to work with 100+ hospitals, that requires having a unique conversation hundreds of times with hospitals that the specialty might have varying relationships with. Solutions may only be unique to individual hospitals. It is not as simple as, "if this registry vendor works with EPIC, then this could be applied to all EPIC systems." The registry has to get into the weeds with each institution's individualized system and create unique mapping patterns.

Another interesting issue raised by SHM is that hospitals are concerned about the fidelity of EHR data, particularly when used for measurement, and that it might not accurately or comprehensively reflect who is actually providing what services (e.g., for a measure of discharge, who is the patient attributed to?). Bearing in mind that many EHR systems were initially designed to facilitate hospital billing, one should be concerned over the manner in which providers are attached (or not attached) to certain types of information, thereby complicating efforts to ensure appropriate attribution of a provider to a patient case.

COLLABORATIONS WITH OTHER SPECIALTIES AND STAKEHOLDERS

While many societies expressed a desire to collaborate with other stakeholders and possibly expand the reach of their registry beyond their own specialty in the future, most are singularly focused on increasing participation rates among their own members at this point in time. Nevertheless, most do not limit participation to members only and welcome non-members. Often, the measures offered by a registry will determine the extent of interest by non-members. For example, ACR does not have many rheumatology-specific measures so they have included a mix of more general, primary-care measures and rheumatology-focused measures. This has resulted in a lot of interest from generalists and internal medicine specialties who find that RISE's selection of measures is relevant to their practice. AAAAI is experiencing a similar uptick in physicians from outside the specialty signing up for the registry (primarily family physicians and internal medicine) since the measures offered work for them. This was not planned, but AAAAI is pleased that people are using it and is now looking at ways to differentiate data from these different sources.

More official collaborations include:

- AGA collaborates with other gastro-focused societies (ASGE, ACG), as well as American Association for the Study of Liver Diseases (AASLD)
- The AANS recently partnered with the American Academy of Physical Medicine and Rehabilitation (AAPM&R) to create a comprehensive spine care module using FigMD. Although the AANS is a surgical specialty society, this strategic decision was driven by increased payer attention to bundled payments and the need to take a leadership role over the spine care episode.
- ACEP collaborates with the Society for Emergency Medicine PAs and the Emergency Nurses Association.
- ACS relies on input from other surgical specialty societies, as needed. It also collaborates with the American Board of Surgery (ABOS) for MOC reporting requirements.

Interviewees were asked whether they would consider a future partnership where another specialty society, such as IDSA, "piggy-backs" off its existing registry by contributing and tracking infectious disease-specific measures. While ACEP Board approval would be required to approve collaboration with another specialty, ACEP staff expects that the Board, which is partly composed of hospitalists, would be very interested to engage with IDSA or any other hospital-based specialty. They already have had conversations with the SHM and others to potentially develop a hospitalist registry since most of the larger ED groups in the country now have a hospitalist business line, as well, and the number one question that ACEP receives from most of their large groups and best customers is "can I enroll my hospitalists too?" Although clinical cross-over with IDSA might be limited, the ACR also would be "really open" to adding measures of other specialties. They have had a lot of interest from other registries just in the rheumatology space, and are really open to exploring those and other strategic conversations, which if anything signals that this is something that specialty societies are, in fact, interested in. The AUA also would consider collaboration with other specialties in a potential "piggy-back" fashion, but it may not happen in the near-term since its main focus at this point is to solidify its core registry and expand urology-specific metrics. Because they started out by focusing on a specific aspect of urology (prostate cancer), they still have a fair amount of work to do to broaden their scope to include other urologic conditions. The AANS also recently expanded the scope of its registry by creating a non-surgical spine care QCDR module, which will help to expand its participant base beyond surgeon members and eventually allow it to look more comprehensively across the entire episode of a spine care patient, including post-acute care, indicating interest beyond their surgical specialty. ACS is another potential valuable partner. Although it did not comment on future collaborations, ACS noted that they are undergoing a huge investment in their suite of registries to stream data from each specific ACS registry into one "clearinghouse" registry, which would then perform aggregation, analytics, and report to CMS. This larger registry will be fed by not only its SSR, but by its bariatric, cancer, NSQIP, and other registries. As this project solidifies, there might be an opportunity for IDSA to collaborate with ACS.

GOVERNANCE/OVERSIGHT/STAFFING

Specialty societies most often incorporate a registry directly into the functions of their organization and are entirely owned by the specialty society (e.g., ACS' SSR and ACEP's CEDR). However, in some cases, a registry may be established as a separate non-profit organization for improved legal or tax protections (e.g. the American Association of Neurological Surgeons' NeuroPoint Alliance, which oversees its Quality Outcomes Database). In addition, some registries have developed a separate governance structure that allows for the engagement of multiple stakeholders including patient advocates, related medical specialties and providers, and industry.

Some governance structures are more formal than others. ACEP has a Registry Oversight Committee, which is appointed by and makes recommendations to ACEP's Board. It includes the following five subcommittees: Data Integrity and Research, Quality Measures, Data Standards, Member Education/MOC, and Participant Recruitment and Engagement. The AQUA Registry is directed by the AUA Science and Data Advisory Group and the AUA Data Committee. A Registry Advisory Work Group was utilized to determine strategic direction and scope for the registry, and a Registry Advisory Panel, with nationally recognized leaders in prostate care, was created to provide guidance and support to the

development of the registry. AUA also employs a Senior Physician Advisor who provides clinical guidance to the development of the registry and participates in all activities from registry design to implementation. The physician champion is also engaged to aid in the marketing of the registry to urologic practices, physicians and other urological associations

Responsibilities are often split and shared between society staff and the registry vendor. The budget and financial operations of the registry are usually managed internally. The registry vendor is typically responsible for data analytics, development of feedback reports, assisting with extracting data from other information systems, and submitting data to outside entities (e.g., CMS). Society staff and the vendor will often collaborate on marketing, user technical assistance, data use/publication requests, and ongoing technical maintenance of the registry platform/portal. Staff work with member volunteers (and sometimes the registry vendor) to specify data elements and develop measures and data analytic methodologies. The vendor, staff, and member volunteers all work together on data quality assurance and ensuring data integrity, as well as on the management of regulatory and legal compliance.

All professional society registries are operated by a full-time team. Some are as small as 1-4 staff, while others are as large as 60-100 staff. The AUA's registry team consists of six FTEs, hired in a phased manner. For ACS, running the SSR requires about 5 FTE employed by the ACS (a more specific breakdown of these roles is available if needed), as well as 5.5 FTE employed by the registry vendor.

ACEP only had .75 FTE in direct support when the registry first launched, which it now views as a mistake. It recently hired a consulting firm at considerable cost to dedicate approximately 10 full time consultants and staff to the contracting process alone, which does not include measures, data dictionary or technology. Looking back, ACEP believes that hiring the necessary staff in advance of the project launch would have been significantly more cost-effective for the budget and better in terms of building relationships between ACEP members and the registry. It recommends hiring a consultant, plus a minimum of three staff to initially test the project with a registry vendor and then potentially two or three more FTEs one year after the technology has been tested. ACEP also specifically highlighted the importance of a hospital-based registry having dedicated legal resources to handle an anticipated large number of legal questions. Not only does this work require the attention of an in-house General Counsel (plus another staff attorney, if possible), but ACEP also recommended spending time with an external counsel to understand the nuances of HIPAA and data use agreements.

TIMELINE

Timelines also vary depending on the scope and objectives of the registry. ACEP's CEDR took only 6 months from initial concept to initial public launch. It took AAAAI 20 months from concept to signing a contract with a vendor. It regrets not spending more time testing the platform and the measures. A major complicating factor were the deadlines set by the federal government and the fact that rules change every year. The ACS' SSR took about two years to launch and continues to undergo modifications on an annual basis. The planning/design stage contributed the most to its overall timeline. For the AUA, it took over three years to implement its registry, and AGA about two years, with implementation (and associated modifications) contributing most to the overall timeline. For ASPS,

GRAFT took nearly four years to implement, with the initial planning and design being the most challenging stage.

PREPARING FOR THE ROAD AHEAD

In terms of what registries are now doing to prepare for newly revised federal mandates authorized under the Medicare Access and CHIP Reauthorization Act (MACRA), these mostly center around tweaking measures, expanding the scope of the registry to include more clinical scenarios and measures, and working on ways to more easily and directly capture EHR data to better accommodate what is expected to be higher reporting thresholds. They are also focused on strategies to allow participants to meet the Advancing Clinical Information (i.e., meaningful use of EHRs) and Clinical Practice Improvement Activities (CPIA) aspects of MIPS through use of the registry.

Some are also starting to think about how they can use the registry's data to support the development of specialty-focused episode-based bundles and other alternative payment models, although ACEP noted it would need access to additional claims data beyond what CMS currently makes available to make use of its registry here.

Summary of Primary Research

Summary Table of Specialty Society Interviews				
Society	**# of Members**	**Size of Registry**	**Cost (start-up, maintenance)**	**Funding**
American College of Rheumatology	- 9,500 members	- 660 users - 3 million patient encounters	- $2-3 million start-up - $1 million annual maintenance	- Funded by ACR - ACR is currently losing money from the registry
American Academy of Allergy, Asthma, and Immunology	- 6,500 members	- Less than 55 users	N/A	- Funded by AAAAI budget
American College of Surgeons	- 80,000 members	- 6,000 users - Includes 7 million surgical cases	N/A	- Funded by ACS general budget/membership fees and non-member registry participation fees
American Urological Association	- 22,000 members	- 2,390 users - 1.8 million patients captured	- $2-3 million total from 2014-2016 including start-up and maintenance	- Funded by AUA - Seeking other funding sources
American Gastroenterological Association	- 16,000 members	- 350 users across 3 registries for 2014 and 2015 - 3 registries captured a total of 15,500 patients in 2014 and 2015	N/A	- Funded by AGA and registry user fees - AGA's Digestive Health Recognition Program has partial industry support
American Society of Plastic Surgery	- 5,700 members	**TOPS Registry** - 300 annual users - More than 1.6 million procedures captured **GRAFT Registry** - 165 users - 1,900 patients captured	**TOPS** - $166,000 start-up - $260,000 annual maintenance **GRAFT** - $185,486 start-up - $125,000 annual maintenance + 1 FTE	- **TOPS** is funded by member dues - **GRAFT** is funded by ASPS reserve funds and corporate support
American College of Emergency Physicians	- 34,000 members	- 2,000 users - By end of 2016, 690,000 patients captured	- $1 million start-up - $1 million annual maintenance	- Funded by a combination of membership fees, separate participation fee, a federal grant, and the American Board of Emergency Medicine

From this primary research conducted with representatives from other medical societies, one is able to grasp the range of challenges and the depth of complexity involved in establishing a clinical data registry. From the perspective of a medical society, considerable financial resources are needed to cover start-up and maintenance costs (IT, staffing); administrative support is needed for the governance structure, BAA/Data Use agreement negotiations as well as potential dealings with EHR vendors. Growth in registry participants can be slow and registries will need to be continually adapted as a result of any regulatory changes. As well, if there is a model where a registry produces a revenue stream such that it becomes financially self-sufficient and allows a medical society to offer products or services to stakeholders outside of its members, it has yet to be discovered. Nonetheless, these medical society-sponsored registries seem to be fulfilling an important need for at least a small portion of members to sustain the continued commitment for the foreseeable future.

For IDSA, should it pursue establishing a clinical data registry, the key take-aways from this primary research are as follows:

- Given the inpatient-centric practice setting and the hospital/AMC employment affiliation of the majority of IDSA members, there will be considerable effort needed to successfully engage the hospital community and secure access to EHR data
- Given the current staffing structure within IDSA, the most efficient way to proceed would be to carefully vet a registry vendor, as opposed to building the in-house capabilities to establish the registry
- Current measure development efforts will need to be greatly enhanced to expand the portfolio of ID measures to include several relevant ID conditions
- The estimated time for IDSA to establish a registry is between 1.5 and 3 years
- The estimated start-up cost for the registry is $1-2 million dollars with annual maintenance costs in the range of $250,000 to $500,000

Strategic Options

Listed below are future strategies for IDSA to consider based on the research and background provided thus far.

INVESTING IN A REGISTRY

1. **Invest in an ID-focused, IDSA-led Registry**

The most practical and least risky strategy would be to start basic by offering a tool to facilitate PQRS/MIPS reporting for IDSA members and/or only focusing on a core data set for a particular condition. While institutional roadblocks are likely inevitable, IDSA could minimize this risk by partnering with a registry vendor that is widely used among hospital-based specialties. As part of the agreement to share EHR data with the registry, the hospital will receive a feedback report that displays the performance of the ID physicians on the measures collected. To solicit volunteers to test pilot the platform, IDSA could waive fees, offer enhanced technical assistance, and promote the opportunity to shape future iterations of the registry.

Pros	Cons
No specialty-wide infectious disease registry at a national level has been developed to date	The time and resources needed to collect and process data in a registry can be substantial, for both the specialty society and participants. This endeavor will require significant financial investment and a multi-year commitment.
An IDSA-led registry will ensure that ID physicians, rather than other parties, have control over the best strategies for identifying gaps in clinical care and how to most appropriately close those gaps.	Registry participation rates still hover in the 5% or less range for many specialties, therefore IDSA should expect low participation in the first 3-5 years.
Most quality programs use easily obtainable claims or billing data, which are limited, inconsistent and not ideal for measuring quality. A registry that draws more granular and clinically relevant data from the EHR will enable more meaningful quality measurement.	Access to EHR data for physicians, particularly at larger institutions, remains variable

A single data capture can potentially fulfill the requirements of multiple programs relevant to ID physicians, including Medicare quality reporting mandates, private payer requirements, MOC, and other facility-focused accreditation standards. This is particularly important now that the federal government has enhanced the importance of registries in regards to alternate value-driven payment models and CMS recognizes registry participation as a condition of Medicare reimbursement.	
Ensure that ID physicians are more uniformly engaged in value-based care. For a variety of reasons, most ID physicians might not be strategically engaged in tracking patients and evaluating the value of their care. By increasing the availability of more comprehensive data to ID physicians, including better data and analyses for performance improvement, IDSA can turn its members into more engaged healthcare stakeholders who are interested in more than simply absolute requirements and static performance measurement targets associated with programs such as the PQRS.	
Internal quality improvement: By providing access to detailed and aggregate data, as well as benchmarks, an ID-focused registry could be used for rapid-cycle quality improvement. ID physicians could more easily investigate treatment successes and adverse event patterns, which ultimately leads to better treatment decisions and improved patient outcomes	
Demonstrating the value of ID care: Over the long-run, IDSA could use aggregate data to demonstrate the value of the ID physician and advance the role and importance of the specialty among critical stakeholders, such as lawmakers, policymakers, CMS, and insurance	

companies.	
Despite institutional hurdles, registries can be a valuable tool for academic and health services researchers interested in retrospective observational studies, patterns of care analyses, comparative effectiveness research, outcomes assessments, or identifying specific patient cohorts to support study or trials designs.	

2. **Registry "Piggyback" Option**

Rather than invest in a brand new platform, IDSA could seek out a partnership with an existing clinical data registry. Depending on the interest of the partner, IDSA could help to refine existing measures or help to develop new ones offered by the registry that are more relevant and responsive to ID physicians. Ideally, IDSA would want to collaborate with a specialty that captures data from a hospital. For example, the ACS has a suite of physician and hospital-level registries that are relevant to hospital-based physicians. It is currently in the process of trying to bring all of these registries onto one common data platform with a common data warehouse strategy so that they can better populate data from EHRs and other data sources (including financial data), which will be a great benefit to patients and remove a large burden from physicians and could present an opportunity for IDSA. The ideal arrangement in partnering with another medical society would be to develop a separate data collection module or product line that responds specifically to the needs of ID physicians, rather than simply embed more ID-focused measures into existing modules that are not completely relevant to ID physicians.

Pros	Cons
Many specialties interviewed for this project expressed interest in a potential future collaboration.	Diminished control over potentially critical decisions regarding the registry's main objectives, the platform, and the range of measures and data points offered. Would create a potentially awkward relationship where one society is a vendor to another society.
Could be more cost effective and expedient by taking advantage of an existing infrastructure that has already been tested and updated to maximize functionality and feasibility. These platforms also already have some buy-in from EHR vendors and institutions.	Although many specialties expressed interest in a future collaboration, many viewed that as a longer-term goal since their more immediate goal is to expand the registry among their own membership.

3. Invest resources in assessing the feasibility of a developing a single platform that could be shared by hospital-based specialties (IDSA, Society of Hospital Medicine, Critical Care, etc.) that share similar challenge related to data access.

Pros	Cons
Could help to solve many of the obstacles hospital-based physicians now face in regards to data access limitations, particularly those related to hospital fatigue and resource prioritization since facilities would be more willing to sign off on a single platform versus multiple, disparate contracts.	In reality, implementation would be very challenging since there is a lot of variability and fragmentation among hospital-based specialties. Some have been in the registry space for 20+ years (e.g. some surgical specialties), others have already invested in QCDRs, and still others, like IDSA and SHM, have only dabbled in measure development and are still in the earliest stages of registry planning. SHM believes the task of getting all of these disparate provider groups to agree would be like herding cats given the provincial "turfiness" of specialties, particularly those with established registry platforms. Nevertheless, SHM would be "absolutely" open to exploring such a project if it were to evolve.

Alternatives to Investing in a Registry

Listed below are alternative strategies that IDSA could pursue, in addition to or as an alternative to pursuing a registry.

1. **Continue to invest in the development of physician-level measures.**

IDSA could continue to develop ID-relevant measure concepts, with numerator, denominator, and exclusion statements, and seek out partners to test and implement them.

Pros	Cons
This option poses a very small risk to IDSA in terms of investment, while letting the society remain in the driver's seat.	Without a registry, IDSA would be limited in its ability to generate data to inform measure development and to comprehensively test measures. This could limit the utility of the measures and would require collaboration with stakeholders to conduct feasibility, reliability, and validity testing. Questionable long-term value of individual measures - While there will always be a role for individual metrics for internal quality improvement purposes, CMS seems intent on moving to more population-focused models that focus on the coordination of care across the health care and not as mush on individual actions. For certain aspects of quality, it is questionable whether individual-level metrics are even meaningful.

2. **Utilize existing data sources, particularly data being collected by hospitals.**

In the absence of a registry, IDSA could take advantage of data that is already being collected and used by the federal government at the facility level-- whether for CMS quality reporting mandates, national data collection initiatives such as the CDC's National Healthcare Safety Network (NHSN), or The Joint Commission accreditation requirements.

This strategy can be pursued in a variety of ways. Since most ID physicians practice in the hospital setting are to some extent responsible for care decisions captured by facility-level metrics (e.g., readmissions, mortality rates, infection rates length of stay), IDSA might want to invest in strategies to harness data that are already being collected to assess individual physician performance for accountability purposes. IDSA also could use established national data collection networks, such as the NHSN, to test IDSA measure concepts and provide data back to IDSA or back to physicians at these facilities.

Similar to the strategy discussed above, another option would be for IDSA to piggy-back on a facility-focused registry, such as ACS' National Surgical Quality Improvement Program (NSQIP), which is a hospital-level registry that collects data to help surgeons and hospitals better understand their quality of care compared to similar hospitals with similar patients. The registry is unique in that it collects preoperative through 30-day postoperative data. Despite being a facility-level registry, NSQIP also provides blinded site-specific physician outcomes reports.

Pros	Cons
CMS has shown increasing interest in aligning hospital and physician measures to address existing measure gaps for hospital-based specialties and take advantage of data that is already being collected. This includes modifying facility-level measures so that they are pertinent to the individual physician or giving physicians credit for the performance of their hospital.	SHM remarked that although their members are extremely comfortable with measurement, within the membership there is a broad lack of understanding about the difference between what hospital receives as its facility-level Value-Based Purchasing score, what the hospital is actually holding the physician accountable for, and what physician-level reporting and measurement actually entails. Members press the leadership on why they are not investing more in things like a specialty-focused registry, but when SHM actually explains the nuts and bolts of how this would actually works, they say "Oh, we couldn't do this."
The CDC has already begun to engage IDSA on topics such as surveillance, how to most accurately define cases (e.g. C. diff), and general inquiries about what data IDSA would like the CDC to collect.	Also, under this scenario, IDSA would not own the data and the extent to which they can utilize existing data would still be subject to the discretion of facilities and other external stakeholders.

Piggy-backing onto NSQIP, in particular, could provide ID physicians with multiple opportunities to demonstrate their value by helping hospitals to prevent and most efficiently manage infections, reduce lengths of stays and preventable readmissions, and manage other costly complications. While hospitals can often easily track *how often* infections occur, they do not necessarily have good data on why they occur and what targeted quality improvement efforts will bring the number down. Data from NSQIP is used by hospital quality committees as the basis for quality improvement action plans, re-engineered workflows, fostering and improve internal education, and developing clinical performance improvement initiatives. This is particularly important as CMS moves in the direction of episode-based and other bundled payment models. Infection-related complications are among the costliest for hospitals and institutions can save millions of dollars by reducing infection and complication rates, reducing lengths of stay, preventing avoidable re-admissions, and overall better performance on federal pay-for-performance mandates.	

3. **Leverage EHR data to drive better outcomes.**

As EHRs take on increasingly sophisticated functionalities and can more easily integrate with other data sources, there is speculation (and even some indication from specific EHR vendors) that EHRs might become the clinical data registries of the future.

Pros	Cons
As real-world evidence hubs, EHRs can bring together communities of patients, providers, and payers and provide clinical, economic, and observational data to support clinical care optimization.	This strategy does not provide ID physicians with a tangible, immediate tool to respond directly to federal regulatory mandates facing physicians, although as MACRA rules are finalized, we expect CMS to increasingly recognize the value of both registry and EHR use.

Given the shifting focus to population health and accountable care organizations, innovative tools are being introduced, such as Cerner's HealtheIntent which was recently adopted by Geisinger Health System. These tools focus on patient management across the care continuum, but facilitate health and care at a patient and provider level. By establishing a relationship with these vendors either at the national level or local level, IDSA can position itself to ensure that data elements and functionalities are reflective of ID practice and responsive to member needs.	

4. Influence Efforts to Develop Data Definitions and Standards

Work with diverse stakeholders, such as the Council of Medical Specialty Societies (CMSS), the American Medical Association's National Quality Registry Network (NQRN), the American Medical Informatics Association (AMIA), the Health Information Management System Society (HIMSS), and standards development organizations such as Health Level 7 (HL7), who are working to maximize efficiencies in data elements across specialties by enabling health care organizations to collect a limited set of critical data that can support the automated population of multiple specialty registries.

Pros	Cons
Given the cross-cutting nature of the ID specialty, IDSA might be able to position itself well here to not only ensure well-informed standards and definitions, but to help to develop a more efficient infrastructure that responds to the current concerns of hospitals, IT staff, and EHR vendors.	As noted above, this strategy also does not directly respond to the immediate regulatory pressures facing ID physicians.

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