



OTA Registry: Review and Recommendations

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Executive Summary

OTA's Registry Project Team was charged with exploring options for updating current OTA registry software as follows:

1. Provide BOD with recommendations regarding how to update the OTA registry software to allow current members who use the platform to continue to do so.
2. Make recommendation as to advisability in staying with current software platform vs migrating to another platform such as REDCap, etc.
3. Consider the financial investment required for such an update – and consider the costs over time in short term – over 1-year, medium term – 5 years, and long term - > 5 years
4. If possible, in the update allow administrative access for BOD to identify how many OTA members are actively using the registry without compromising patient data

OTA reached out to .orgSource for assistance in meeting these charges and exploring the following:

1. Examples of how other specialty societies use their registries to support their mission.
2. Perspectives on how a registry could provide value to the OTA.
3. An assessment of the current technologies used to support the registry.
4. Suggestions on how to move forward

Since 2005, .orgSource has worked with associations, and particularly medical societies, to effectively plan and implement digital transformation, as well further the mission of your membership organization. The OTA selected .orgSource to develop this report given the work .orgSource has performed with OTA to select and implement a new AMS and web platform. Through conversations with the OTA Registry Project Team, OTA staff, the current OTA registry vendor, other specialty societies and ABOS, .orgSource has compiled data on how the OTA registry was developed, how it is being used, and considerations for moving forward.

Registries are used by other groups to aggregate data to determine treatment effectiveness, improve standards of care, reduce risk and provide ABOS Self-Assessment Examination and Practice Improvement credits, to name a few. In many instances, registries develop in strategic partnerships where visionary discussions take place over several years before the actual registry comes to fruition. Such strategic vision prompted the development of the OTA Registry twenty years ago when leaders embarked on a system to track treatment in a uniquely robust, complex and comprehensive database, involving a long list of fractures and sub-codes.

Now, eighteen years later with 27 institutional users, 50,000 patients, and multiple inputs for each patient, there is latent potential in harnessing the data submitted in the Registry. The data is not de-identified. This prevents it from being available for study to anyone outside of each participating institution without lengthy IRB processes and downloads for each approved study. OTA itself is blocked from harnessing its own data. New technologies permit the de-identification of some or all of the data, and with the permission of the participating institutions, the registry can become a rich source of shared information.

However, the current technology used for the OTA Registry was last updated in 2008. The user interface is outdated. The AO Foundation/OTA Fracture Codes most recently updated in 2018 are not reflected in the current database.

To preserve the integrity of the data in the current system, the Data Harbor system should be invested in. The cost of immediate upgrade is modest compared to the cost of identifying, implementing and migrating data to a new system. It should also be noted that newer registries are more focused and less relational than the OTA database, and to replicate what is currently in place, as is, would likely be cost prohibitive. Nor may that be what best serves OTA long-term.

The immediate update provides OTA time to develop a well thought out plan for moving its registry forward. Long term, OTA may want to add benchmarks and measures to its current system (typical of newer registries) and/or migrate some of its data into an altogether different registry while maintaining the current database.

.orgSource recommends that OTA takes the time to develop a well thought out plan, and as that plan is developed, research potential implications in terms of time and budget.

The following suggestions for moving forward are provided for OTA's consideration:

1. Make critical updates to the current registry platform in the near future (within 1 year). Estimated cost will be \$26,000-\$28,000.
2. Develop a short- and long-term registry vision (within 2 years).
3. Research options for implementing that vision, whether on the current platform and/or a new platform or both (within 2-3 years).
4. If the current Data Harbor platform is maintained long-term, budget for and implement regular updates to the platform to keep pace with technology (annually).
5. Search for seed funding to build an ABOS SAE and Practice Improvement credit organized and approved registry within the existing OTA Registry (Year 4-5).
6. Regardless of the path chosen, work on data de-identification (within 4 years)

Background

The OTA trauma fracture registry began eighteen years ago under initial board leadership and Julie Agel, MS, a statistician who helped structurally build it and continues to use it as an institutional user. According to John Harrast at Data Harbor Solutions, this was one of the first such registries in the country.

The OTA trauma registry has been described by Ms. Agel as a library to allow users to identify the cases they are interested in (i.e., a given fracture pattern or implant). The MS SQL database relationally tracks individual patients through multiple admissions, with multiple injuries, and multiple surgeries per injuries, complications (orthopedic and systemic), and outcomes (patient reported). The AO Foundation/OTA Fracture and Dislocation Classification codes serve as the categorization for the OTA registry. John Harrast from Data Harbor Solutions has indicated that this level of relational tracking is extraordinary compared to more recently developed registries.

There are 27 institutions who utilize the OTA registry; currently the range of patient records in the registry for each institution is 100 to 10,000. There are about 50,000 patient records in the registry. Each institution who uses the registry can see only their own identified data. OTA as an organization does not have access to or ownership of any of the data held the registry. This was a decision that was made when the registry was established and is not a common approach to registry management today. Typically, registry sponsors have access to de-identified data within the registry.

There is no charge to institutions using the OTA registry. The annual cost to OTA to support the registry is \$3,600.

The OTA Board has deemed that it is at a crossroads as to how to best support the OTA membership and build member value in the OTA Registry. After 18 years of offering it as a member benefit, the board intends to circle back around to better understand how OTA members use the registry and how it can be modernized. At minimum, there is a hope to make the database more viable for the current users, as some user interface has posed challenges to using it.

How specialty societies value registries

Before discussing the current and future opportunities for use of the OTA registry, this report will address how other specialty societies use registries to support their mission, and how registries build value in examples of member organizations.

Use of registries

The **Multicenter Orthopaedic Outcomes Network (MOON)** has its roots in the Vanderbilt Sports Medicine-Cleveland Clinic Foundation ACL Reconstruction Registry from 1993. Starting with these two institutions in 2002, the MOON has expanded to seven institutions with data that forms the largest prospective longitudinal ACL reconstruction cohort in the U.S. Aside from collecting baseline information on each patient, institutions entering data into the registry submit follow-up questionnaires and risk factors at two-, six- and ten-years post ACL reconstruction. The emphasis on collecting enough follow-up data and performing sophisticated multivariate analysis of the complex data set has resulted in over 40 publications. The MOON group boasts of having an 80 percent follow-up rate with patients; this success is feasible as pain relief and functional improvement are often the factors to determine treatment effectiveness. The MOON Group has had a significant cascading impact on the development of other orthopedic specialty registries, showing the field that conducting multi-center, multi-surgeon research in orthopedics is possible.

An emphasis on patient-reported outcomes is one valued both by payers and funders, as well as the public, as shown in another example of the value of registries in pediatric sports medicine.

A multi-center project involving a benchmark registry started with initial conversations in 2014 at **Pediatric Research in Sports Medicine (PRiSM)**. After three years of fine-tuning a project plan, Henry B. Ellis, MD received the initial grant funding in 2017 from the American Academy of Orthopedic Surgeons (AAOS) and Pediatric Orthopedic Society of North America (POSNA) to initiate the pediatric sports medicine benchmark registry. Centered at Scottish Rite in Frisco, TX, the multi-center registry hosts

deidentified data from 12 sites on pediatric injuries and orthopedic conditions. Establishing standards of care, harnessing trends for patient education, and reducing risk to patients are the goals of the quality improvement registry. Aside from going through the IRB process with an additional 12+ institutions, the next step for this registry is to qualify iterative physician practice improvement and their data entry for ABOS Maintenance of Certification Part 4. Information gleaned from the registry data has also contributed to a patient education video which will launch only about 8 months after the data entry began in July 2018.

Brenda Kulp, a staff member at the American Board of Orthopaedic Surgery, shared ways in which orthopedic specialty societies **use approved registries to award ABOS Self-Assessment Exam and Practice Improvement credits**. Brenda pointed out that while many of the approved registries have a robust amount of data (e.g., The AAOS Registry Program), she encourages subspecialty groups (like OTA) to start with a smaller subset of data to adapt the key criteria for ABOS registries. For instance, metrics, patient outcomes and benchmarks (i.e., based on current data in the OTA registry or other resources) could be identified for a handful of lower extremity fractures. Then, a set of steps could be prepared in following with the key criteria for ABOS approved registries (see website: <https://www.abos.org/moc/cmeseae/self-assessment-examinations-and-practice-improvement/registries.aspx>).

Member value for registries

The examples of registries used by other specialty groups points out ways in which the OTA can build value of the OTA Registry for its members and for the orthopedic trauma field. The examples shared also point out how resolving the use and best value of the registry occurs over time, over several years, and possibly decades. The pace at which a registry develops depends much on the resources allocated (e.g., is there a grant available or home institution to sub), the agreement of leadership regarding direction and the value partnerships.

OTA Registry: Current Platform Assessment & Recommendations Moving Forward

An assessment of the current technologies used to support the registry.

The current technology used for the OTA Registry was last updated in 2008. Data Harbor uses SSL encrypted connections, a hardware firewall, has software framework security updates in place, and control access so users have access to their own data only. SQL has been updated four times since 2008, with each upgrade offering enhancements in functionality, user management, improved data encryption, security, backups, disaster recovery, cloud hosting, in-database advanced analytics and more. The current platform is dangerously outdated. An immediate update to SQL is critical. Updating SQL must occur hand in hand with the user interface update, thus making both critical updates.

Cost: \$1,000 (**Critical – Recommended**)

The user interface is outdated. The OTA registry is accessible via a web browser login (<https://zeus.dataharborsolutions.com/ota/wfLogin.aspx>) . User settings can be set up by the Site Admin at each institution. The current interface is not compatible with existing web standards which have evolved considerably since the last update. This is impeding usability. In addition, members have had issues with setting up multiple users at their sites due to the outdated interface. See **Appendix A. OTA Case Log Sys User Manual** for more details of the current registry.

Estimated Cost: \$20,000 (**Critical – Recommended**)

Note: Before investing the money, a very clear plan for what a new interface should look like must be agreed upon with Data Harbor Solutions. It is not clear to .orgSource from the limited information provided if this is a reasonable estimate.

The fracture codes are outdated. The AO Foundation/OTA Fracture Codes most recently updated in 2018 are not reflected in the current Registry. The current technology allows for the entry of patient data by institutional user via a web browser SQL database. In the current Registry, participating institutions enter and view their own data, as follows:

- a. Enroll patients with fracture records (updated as of 2008) and relational data for fracture and sub-fracture,
- b. Submission of follow-up visit data for patients (tracked by unique Patient_ID),
- c. Ability to download a CSV file of identified patient data. *After the download, the file requires much manipulation to make the data comparable.*
- d. Ability to search the registry library by fracture code.

Cost: \$3,000-\$5,000 (**Critical - Recommended**)

Lack of an image registry. Other medical society registries have options to upload images with the code (CPT or ICD) so that a broader picture of the patient case can be recorded. If the registry is de-identified, registry users can search codes to view similar cases, their treatment options and (potential) patient-reported outcomes entered by other institutions and users. In addition, the registry can serve as a catalog of fractures or other such codes to build awareness for residents and fellows in their field. Aside from capturing the patient treatment for particular fractures, the registry can also serve as an educational tool when de-identified.

An Image Registry would allow members to upload pre-op, intra-op, post-op, and follow-up images of their cases, de-identifying them as necessary. They would then be able to use the Registry to review and study fractures, treatments, and radiographic results of patient cohorts.

Estimated cost: \$15,000 *Not recommended unless OTA moves to a de-identified data model. See below.*

The data in the registry is not de-identified. Without de-identification, the data from the institutions cannot be easily accessed through the database nor shared for approved research or educational purposes. OTA is locked out of the database it supports. The data must currently be downloaded to be shared with other researchers/organizations, etc. Per Julie Agel, this was intentional: “The database was set up to allow the sharing of data across sites by allowing sites to have identical database structures

with the ability to add custom fields for a specific study if they wanted. The combining of databases would occur outside the registry so that any data sharing is done explicitly with full knowledge of the sites involved with their own institutional IRB.”

While this structure may have worked 18 years ago, the requirement to download data to share it is outdated. The more common route today is to: (1) establish data sharing or business agreements between participating sites and the organizing association and data management system (note: this step can take over 2 years), (2) institute an automated de-identification of data when data is entered into the registry, and (3) award permissions to roles at user sites to view (de-identified) individual case data by fracture code, as well as aggregate data comparisons in the registry.

Implementing technologies to de-identify the data would be relatively easy. A unique identifier would be created and PHI would be removed. The political/legal process would be more difficult, requiring OTA to reach out to each institution to seek permission to de-identify data so that it can be shared. Institutions would need to approve a new data use agreement. Once approved, the data would be de-identified and moved to an area where it would be accessible to those with permission to access the data (e.g. OTA, researchers, etc.)

Recommended that OTA considers moving to a de-identified data structure. Cost in technology and legal support for new data use and data sharing agreements TBD.

Security. In regard to cyber security, Data Harbor utilizes SSL encrypted connections, employs a hardware firewall, has a software framework security updates in place, and controls access so users have access to their own data only. With the SQL server update, OTA would have the opportunity to implement technologies that require stronger passwords, automate password expiration (and prevention of re-use), and two-factor authentication. Although even these authentication methods can be subject to hacking, they would provide a greater level of data security. Options provided by Data Harbor include:

- Requiring stronger passwords - \$2,000
- Expiring passwords - \$4,000
- Two-factor authentication - \$8,000

Initial Cost: \$2,000 minimum **Recommended that OTA immediately implements a requirement for stronger passwords.** If OTA commits to the system long-term, then the additional security measures outlined above should also be considered.

Select enhancements and upgrades that are not high yield. The enhancements of mobile data entry interface, importing data from an EMR or exporting data to an Excel file are deemed unnecessary after discussions with stakeholders. The reasons for this lack of interest in these enhancements included that the registry would be cumbersome to use on a mobile device, and EMR importing would be highly customized for one EMR at one hospital/institution. An Excel file would be difficult to parse out due to the relational nature of the data.

Summary: In summary, .orgSource recommends the following investments be made to update the OTA registry software to allow current members who use the platform to continue to do so. The following are additional cost on top of the estimated \$3,600 for yearly hosting by Data Harbor.

• Update SQL	\$1,000
• Update user interface	\$20,000
• Update fracture codes	\$3,000-\$5,000
• Require stronger passwords	\$2,000
TOTAL	\$26,000-\$28,000

Advisability of staying with the current platform vs. migrating to a new platform.

As already discussed, the current database interface is poor and has not kept up with the evolution of technology in this area. Nor are the fracture codes up-to-date. As it exists currently, even committed users are finding the platform difficult to use, and the platform is not attractive to new users. Without basic and immediate technology updates as outlined in the prior section, even the short-term integrity of the database may be at risk.

On the other hand, the database holds information on 50,000+ patients and goes back 18 years. For each patient, multiple fractures may be tracked, and for each fracture, multiple procedures may be tracked. This complex database holds tremendous potential for research and study.

Should OTA determine to withdraw the \$3,600 annual cost to maintain the Data Harbor platform, there is not a way for individual institutions to continue their data entry via an individual contract. (Data Harbor would consider contracting the continued use of the 'as is' registry with a group (3 or more) of established institutions.)

There are new registry platforms that offer interfaces built on the latest technologies and incorporate benchmarks and measure tools not present in the current database. But it is unlikely that any of those platforms will be able to accommodate the complexity of OTA's relational data without significant customization. While costs to migrate the OTA database to another system were not obtained, anecdotally, the cost of migrating simplified (less relational) data from one registry to a new one cost upwards of \$100,000.

John Harrast has noted that it would take significant time to export all OTA data into a format which could be imported into another registry platform. Significant testing and data validation would have to be undertaken by each institution after such a migration took place. That means that migration costs would be incurred both on the side of the originating platform and the new platform, and testing would involve a commitment of resources from participating institutions. Add this to the cost of investing in and customizing a new platform, OTA is looking at a significant investment in both time and money.

To preserve the integrity of the data in the OTA registry, the Data Harbor system should be invested in. The cost of immediate upgrade is modest compared to the cost of identifying, implementing and migrating data to a new system to completely replace the current system. To replicate what is currently in place, as is, would likely be cost prohibitive. Nor may that be what best serves OTA long-term.

The immediate update provides OTA time to develop a well thought out plan for moving its registry forward. Long term, OTA may want to migrate some of its data into an altogether different registry while maintaining the current database.

For example, OTA may want to create a registry that focuses on high yield fracture codes for which there is evidence for an initial standard of care or benchmark of care. Identifying the high incident codes in the current registry by collaborating with the registry users will initiate a collaboration which can test the feasibility and interest of registry users in de-identifying and aggregating data. This data could be further developed into an ABOS SAE and Practice Improvement credit-awarding component of the OTA Registry. It is often the case that medical society members are looking for applied and realistic ways to meet their SAE and PI credits; this would provide one or eventually several ways to do this.

Along this path, OTA may want to consider an **in-kind Grant for Arthrex Surgical Outcomes System (SOS) Global Registry**. Arthrex, a device manufacturer in the field of orthopedics, has invested in a Global Registry with modules in shoulder and elbow, knee, hip, distal extremities and spine for members of select grantee medical society members to use at no cost. On a yearly basis, the Grant Committee of Arthrex awards an in-kind grant to a medical society whereby the members of that society have free access to submit data and obtain analysis of their data compared or benchmarked against de-identified aggregate data. The Grants Committee meets about every other month and just met in late February 2019.

Should OTA pursue a partnership with Arthrex SOS, a trauma specific data benchmarking module will need to be built based on content and fields per the AO Foundation/OTA fracture codes and best practice. It should be noted that Arthrex has access to the de-identified global measure dataset which is reported to payers across the world. The SOS is a sophisticated system with capabilities for benchmarking, navigable analytics, patient outcomes reporting and EMR integration. While the SOS has migrated data from other data systems into SOS modules, this data migration occurs at an additional cost (depending on the extent and volume of the data fields) to the medical society. The Feb 28 SOS demonstration provided an overview of the system. More time is needed to investigate benefits and limitations of the system.

In terms of REDCap or other systems, both in terms of functionality and cost, it is difficult to investigate other potential platforms without first understanding the long-term goals and vision of the OTA board. Systems and costs will be impacted by the amount of data that would need to be migrated, whether or not OTA wants to maintain the current relational structure, registry size and scope, and more.

The introduction to the manual “The Registries for Evaluating Patient Outcomes: A User's Guide” published by the Agency for Healthcare Quality and Research it is stated:

*There is tremendous variability in size, scope, and resource requirements for registries. Registries may be large or small in terms of numbers of patients or participating sites. They may target rare or common conditions and exposures. They may require the collection of limited or extensive amounts of data, operate for short or long periods of time, and be funded generously or operate with limited financial support. In addition, the scope and focus of a registry may be adapted over time to reach broader or different populations, assimilate additional data, focus on or expand to different geographical regions, or address new research questions. **While this degree of***

flexibility confers enormous potential, registries require good planning in order to be successful.

.orgSource recommends that OTA takes the time to develop a well thought out plan, and as that plan is developed, research potential implications in terms of time and budget.

A Path Forward

.orgSource suggests the following path for consideration.

1. Make critical updates to the current database platform in the near future **(within 1 year)**.
 - Approve the allocation of \$26,000-\$28,000 to perform the recommended immediate upgrades detailed above.
 - The current database is highly relational and broad in a way that newer registries are not. There are 18 years of data in this platform (50,000 patient records).
 - An investment today gives a voice of support to current institutions, who would not have individual access to the registry if OTA severed ties with Data Harbor.
 - These upgrades have been warranted for several years and can be seen as basic overdue maintenance on the registry platform.
 - This investment protects the data already collected, allows institutions to continue to use the platform, and buys OTA time to develop a well-thought out and carefully considered long-term registry strategy.
2. Develop a short- and long-term registry vision **(within 2 years)**
 - a. Seek input from current registry users in that decision.
 - i. The data within the registry is significant. Invest time in understanding how each institution is using the registry. Understand what impact, if any, this data has had on the field, and if so, in what ways. Understand what would be lost if this current platform were to go away.
 - ii. Also elicit input from individuals who may not be using the system but might be interested in doing so. Understand what they would want to see in a registry and probe how OTA members would have their needs (e.g., ABOS SAE or PI credit) or interests (e.g., multicenter research) satisfied in their use of a revised registry.
 - iii. Engage .orgSource and/or OTA staff to develop and administer a survey or focus groups with current users and potential stakeholders. Set a tight timeline on gathering data and decision making. Share this information at the board retreat this summer.
 - b. For a moment, step aside from what is.
 - i. If OTA were to decide to build a registry today, from scratch, what data would be collected and why. How would the field be impacted? What crucial areas of orthopedic trauma could be impacted by potential benchmarking via a registry? What do you want/need to know that you don't know? What other partners will provide helpful perspectives?

- ii. Consider engaging an outside facilitator, if necessary, to lead a brainstorming session through this process.
 - c. Envision what OTA could do with the data already collected. Consider de-identification of current and/or future data.
 - d. Determine if development of a smaller registry is warranted.
 - 3. Research options for implementing that vision, whether on the current platform and/or a new platform or both **(within 2-3 years)**.
 - a. Further investigate the in-kind grant opportunity with Arthrex SOS.
 - i. Transition the OTA Registry Project Team volunteers to develop a grant application for Arthrex SOS with the support of OTA Staff.
 - ii. Liaison with SOS staff to obtain an estimated cost of migrating current OTA Registry data into a proposed Trauma Module in Arthrex SOS.
 - iii. Further investigate the user experience and any limitations of the SOS modules.
 - iv. Pros:
 - 1. Several of the modernizing elements (improved usability via mobile, addition of patient reported outcomes collection, de-identification of data, robust analysis and benchmarking) are taken care of by transitioning to SOS from the current Data Harbor registry.
 - 2. Not only will the potential Trauma module support OTA members (at no specific cost to them other than membership dues), other physicians will also enter data into the module, thus building awareness of orthopedic trauma best practice.
 - 3. See **Appendix B. Arthrex – SAMPLE AOSSM SOS Program Agreement_7.6.2018** for the starting point of the agreement which Arthrex has negotiated with other medical societies.
 - v. Cons:
 - 1. Given that the registry is bound to a grant award on a yearly basis, the OTA could be vulnerable to changes in the scope and trends in which Arthrex is responding. Thus, in-kind grant support could be removed.
 - 2. There is an uncertain cost and process to migrating the 18 years of data from Data Harbor to SOS. Before this can be accomplished, OTA would need to determine which data it wants to keep. In addition, if the data is to be de-identified legal costs will be incurred in re-negotiating contracts with participating institutions.
 - 3. Arthrex is a commercial entity and involvement in its global registry could cause misperceptions among OTA members and leaders.
 - b. Consider other platform options.
4. If the current Data Harbor platform is maintained long-term, budget for and implement regular updates to the platform to keep pace with technology **(annually)**.
5. Search for seed funding to build an ABOS SAE and Practice Improvement credit organized and approved registry within the existing OTA Registry **(Year 4-5)**.
 - a. Pros:

- i. With a proven track record in establishing one of the first registries in the orthopedic field, it will possible to build a case for funding with various partners (e.g., other medical societies, payers).
 - ii. Building collaborative mechanisms for improving practice, keeping costs down and building quality patient outcomes is a trend in medical society management.
 - iii. It is often the case that medical society members are looking for applied and realistic ways to meet their SAE and PI credits; this would provide one or eventually several.
 - b. Cons:
 - i. The funder may insert commercial support to persuade the trauma fractures or codes which would be first implemented for ABOS SAE and PI credit.
- 6. Regardless of the path chosen, work on data de-identification (**within 4 years**).
 - a. This is where OTA will get value from its investment.
 - b. Pursue examples of data use agreements, business agreements and other contracts used by other medical societies and associations with de-identified data in registries.
 - c. Initiate conversations with 2-3 current institutions' IRB who use the OTA registry to vet the needs for de-identified data collection.
 - d. Pros:
 - i. These initial steps will yield an understanding of how much of an administrative undertaking the de-identification of data is.
 - ii. The information gathered will support a decision point before going down the path of full de-identification of data.
 - e. Cons:
 - i. Potential cost of staff time to perform this work, follow-up and analysis.

Financial Investment

Year 1	Make critical updates to current registry	\$26,000-\$28,000
	Annual fees / Data Harbor	\$3,600
	Total Year One	\$29,600-\$31,600
Year 2	Annual fees / Data Harbor	\$3,600
	Budget for enhancements to current registry.	\$10,000
	In kind volunteer and stakeholder time to dedicate time to envisioning the future value of the Registry	In kind

	Investigate platform options to meet the vision. Consultant fees.	\$15,000-\$50,000
	Consulting and/or legal fees to investigate and pursue data de-identification agreements.	\$10,000
	Total Year Two	\$38,600-\$58,600
Year 3	Annual fees / Data Harbor	\$3,600
	Budget for enhancements to current registry	\$10,000
	In kind volunteer and stakeholder time to dedicate time to envisioning the future value of the Registry	In kind
	Data migration (if moving to a new platform partially or completely). Depends upon amount of data to migrated.	TBD – Estimate \$20,000-\$100,000 for migration of some data
	Cost of implementation of a new platform	TBD - \$0 for Arthrex - ??? for other platforms
	Annual platform fees	TBD
	Total Year Three	\$33,600-\$113,600
Year 4	Annual fees / Data Harbor	\$3,600
	Budget for enhancements to current registry	\$10,000
	In kind volunteer and stakeholder time to dedicate time to envisioning the future value of the Registry	In kind
	Ongoing platform fees/new platform	TBD (If Arthrex is chosen, there would likely be no platform fee. Other platforms may have yearly maintenance fees. A budget should also be set for upgrades if these are not automatic.)
	Offset from grants	TBD
Year 5 and Beyond		TBD

Conclusion

As noted initially, there is latent potential in harnessing the data submitted in the OTA Registry. Selecting a handful of outlined options now, implementing those options, then reporting back, and continually circling back to the value of the OTA Registry will pay dividends to the great investment of data provided by users to date.

To circle back to the goals from the OTA Board:

1. Provide BOD with recommendations regarding how to update the OTA registry software to allow current members who use the platform to continue to do so.

The \$26,000-\$28,000 estimated expense outlined in the Assessment Section will update the registry to a safer, more complete library for users to retain fracture cases.

As stated in the report, Data Harbor does not have a single use opportunity for sites/institutions to continue to use, access and add to the current OTA registry. There is no one-off opportunity for registry engagement **without** the support of the OTA; there must be a small group (~5) of institutional users to set up a contract for continued use.

2. Make recommendation as to advisability in staying with current software platform vs migrating to another platform such as REDCap, etc.

.orgSource suggests considering doing both – staying with the current platform (with necessary upgrades) and its very complex data structure, rich patient history, and 15+ years of data AND migrating *some* of the data into an altogether different registry, such as a selection of high yield fracture codes.

While costs to migrate the OTA registry to another system were not obtained, anecdotally, the cost of migrating simplified (less relational) data from one registry to a new one cost upwards of \$100,000. Only after OTA decides what it wants to move where can a true estimate be developed.

Any decision is ultimately contingent upon the vision the board develops on managing a registry or registries long-term. This is the next step, before a final decision can be made on future platforms.

Note: Moving any data will require participant buy-in to data de-identification.

3. Consider the financial investment required for such an update – and consider the costs over time in short term – over 1-year, medium term – 5 years, and long term - > 5 years

Fee estimates will vary based upon the direction that OTA wants to go with the registry. At a very minimum, OTA should budget ~\$15,000 annually to maintain the current registry and provide ongoing maintenance and improvements. Data migrations costs for moving some, basic data could range from

\$20,000-\$100,000+. Moving all data in its current relational state to a new platform could exceed \$200,000. OTA also needs to budget for legal fees and expenses for updating agreements with participating institutions to de-identify data. Beyond this, expenses could include indirect costs to market the registry and provide information and indirect support to registry participants.

Grant funding or raising funds specifically to underwrite the registry could offset ongoing expenses.

4. If possible, in the update allow administrative access for BOD to identify how many OTA members are actively using the registry without compromising patient data.

There are 27 institutions who utilize the OTA registry; currently the range of patient records in the registry for each institution is 100 to 10,000. There are about 50,000 patient records in the registry. Each institution who uses the registry can see only their own identified data. OTA as an organization does not have access to or ownership of any of the data held the registry. This was a decision that was made when the registry was established and is not a common approach to registry management today. Gaining access to the data will require each participating institution to agree to de-identifying the data.

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APPENDIX

Consulted websites

<https://consultqd.clevelandclinic.org/the-moon-group-and-acl-surgery-a-decade-of-research-redefines-what-a-cohort-can-achieve/>

<https://scottishrithospital.org/news-items/sports-medicine-team-awarded-grant-for-multi-cente>

https://www2.aofoundation.org/AOFileServerSurgery/MyPortalFiles?FilePath=/Surgery/en/_docs/AOOTA%20Classification%20Compendium%202018.pdf

<https://www.ncbi.nlm.nih.gov/books/NBK208631/>

<https://www.abos.org/moc/cmesea/self-assessment-examinations-and-practice-improvement/registries.aspx>

Appendices

- A. Orthopedic Trauma Association Case Log System, User Manual
- B. Arthrex – SAMPLE AOSSM SOS Program Agreement_7.6.2018

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