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Module Creation Within the TOPS Registry: An Opportunity for Longitudinal Collection of Procedure-specific Clinical Outcomes

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Summary: The Tracking Operations and Outcomes for Plastic Surgeons (TOPS) data registry, first launched in 2002 by the American Society of Plastic Surgeons (ASPS) in collaboration with the Plastic Surgery Foundation (PSF), was designed to avoid the perceived shortcomings of other national data registries as they pertain to interests of the plastic surgery community. Given the diversity of plastic surgery practice, the ASPS and PSF sought to ensure that the TOPS registry platform would support detailed collection of data useful to plastic surgeons practicing in all subspecialties. Therefore, a key design element of the TOPS registry is its ability to incorporate custom-made modules that allow for focused collection of topic/procedure-specific information. Although the TOPS database has collected information on more than 1.6 million plastic surgery procedures and outcomes since its inception more than 20 years ago, only a handful of custom modules have been created. This article outlines the senior author's experience collaborating with the ASPS and PSF to successfully develop and implement a custom module within the TOPS registry. This information serves to promote further awareness, usage, and creation of TOPS modules, as these modules enable assessment of complex clinical conditions by leveraging data collection efforts through the single largest national plastic surgery organization. *(Plast Reconstr Surg Glob Open 2024; 12:e6397; doi: 10.1097/GOX.0000000000006397; Published online 19 December 2024.)*

INTRODUCTION

National medical registries are increasingly being leveraged to power research investigations related to patient outcomes, clinical practice patterns, and quality of care measures.[1] Related to plastic and reconstructive surgery, the American Society of Plastic Surgeons (ASPS) and the Plastic Surgery Foundation (PSF) worked to develop a national data registry tailored to the interests of the plastic surgery community. This registry, termed Tracking Operations and Outcomes for Plastic Surgeons (TOPS), was first launched in 2002 with the goals of serving as a practice management tool (eg, assessing clinical practice patterns and patient outcomes and identifying gaps in clinical care), facilitating reporting of data necessary for compliance with federal regulations, and enabling high-quality clinical research endeavors.[1,2] Information in this registry is also used to help generate the National Clearinghouse of Annual Plastic Surgery Statistics reports. Participation in the TOPS registry is made freely available to all ASPS members and candidate members practicing in the United States and has collected information on more than 1.6 million plastic surgery procedures and outcomes since its inception more than 20 years ago.[3] Several peer-reviewed research articles have been published using data acquired through the TOPS registry.[4–23]

The impetus for creation of the TOPS registry was, in part, based on the recognition that other national medical data registries failed to capture information that is of particular relevance to plastic surgeons.[1,4] Accordingly, the TOPS registry was designed to avoid the perceived shortcomings of other national data registries as they pertained to plastic surgery interests. Given the breadth of plastic surgery practice, the ASPS and PSF aimed to ensure that the TOPS registry platform would support collection of

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data that are specific and useful to plastic surgeons practicing in all subspecialties. Thus, a key design element of the TOPS registry is its ability to integrate "modules" targeted at collecting information pertinent to specific plastic surgery topics and/or procedures of interest. To date, only a handful of modules have been developed for and incorporated with the TOPS registry, including breast implant, lipoplasty, and postbariatric body contouring modules. Most recently, the senior author (A.K.G.) led an initiative to implement a custom cleft palate module aimed at providing TOPS registry users with straight-forward templates for inputting important patient data related to palatoplasty procedures and subsequent outcomes (eg, operative and speech). This is the first TOPS module to direct registry users to a series of sequential custom data entry forms, each corresponding to a clinically relevant time point at which clinicians are expected to assess particular postoperative outcomes.

The present article seeks to demonstrate the utility of the TOPS registry as a platform on which custom, procedure-specific modules can be built. These modules enable assessment of complex clinical conditions that are best understood through longitudinal collection of multicenter data. Although past reviews of such conditions have often relied on data originating from a single institution or a few selected institutions, national registries enable true multicenter contribution of longitudinal data, greatly enhancing the understanding of different treatment modalities and their long-term outcomes. The cleft palate module, which was made accessible to all ASPS/PSF members in July 2019, exemplifies these points and serves as an example of the process by which a TOPS module was successfully developed and implemented; the following sections of the article detail this process, and an overview, along with key points, is outlined in Figure 1. This review serves to promote further awareness of the value that specialized modules within the TOPS registry provide. We encourage subspecialty societies within plastic surgery to work with the ASPS/PSF to develop additional modules that aid in the understanding of complex clinical problems through longitudinal data input that is open to all plastic surgeons who treat patients with the selected condition(s).

TOPIC SELECTION

Before initiating a proposal for development of a TOPS module, it is first necessary to identify a question/topic that is of substantial interest to the plastic surgery community. Ideally, researchers should choose a topic informed by 1 or more of the various plastic surgery subspecialty societies to target an area of greatest need. These topics may address clinical questions that have been previously unexplored or to which a consensus does not exist. Most importantly, though, exploration of the chosen topic should have the potential to significantly impact and improve clinical care provided by plastic surgeons. The topic of choice should also allow for adequate investigation via the use of registry-style data. Trackable, objective parameters are the preferred style of data recording within the TOPS registry, and one must ensure that the investigational topic and relevant data are compatible with this approach.

These considerations were used to identify the need for a TOPS module aimed at collecting longitudinal data for clinical, operative, and speech outcomes of patients undergoing cleft palate repair. This topic was selected by the American Society of Maxillofacial Surgeons (ASMS) as an area of significant clinical practice that lacked sufficient quality of research data necessary to effectively inform and improve practice patterns over time. Specifically, high-volume, standardized, and long-term data pertaining to cleft severity, chosen surgical repair technique, and subsequent palatoplasty outcomes beyond the initial postoperative period (eg, maxillary growth, speech development) were unavailable. Given that many of these variables have well-accepted and standardized classifications (eg, cleft severity: Veau/Randall classifications; hard palate repair technique: Bardach, Von Langenbeck, straight-line; soft palate repair technique: Furlow, intravelar veloplasty), a data registry is also ideally suited for capturing this information.

Takeaways

Question: The diversity of plastic surgery practice necessitates that data registries permit tailored collection of information for specific clinical problems.

Findings: This article outlines the senior author's experience collaborating with the American Society of Plastic Surgeons and Plastic Surgery Foundation to successfully develop and implement a custom module within the Tracking Operations and Outcomes for Plastic Surgeons registry.

Meaning: This information serves to promote further awareness, usage, and creation of tracking operations and outcomes for plastic surgery modules, as these modules enable assessment of complex clinical conditions by leveraging data collection efforts through the single largest national plastic surgery organization.

MODULE PROPOSAL AND DEVELOPMENT

Once an appropriate topic was identified, the proposal for creation of a clinical module within the TOPS registry was initiated via contacting the ASPS Research and Scientific Affairs Department (research@plasticsurgery.org). This proposal indicated the desire to create a subspecialty/topic-specific module within the TOPS registry that addressed a significant area of clinical practice and for which a current module did not exist.

After obtaining approval, the PSF provided examples of modules that have been successfully implemented in the TOPS registry to assist with development of the suggested module. These examples were very helpful, as there are a variety of methods by which data capture can be structured within the TOPS registry (eg, yes/no questions, checkbox options, open-ended responses); any combination of these options can be used in a TOPS module

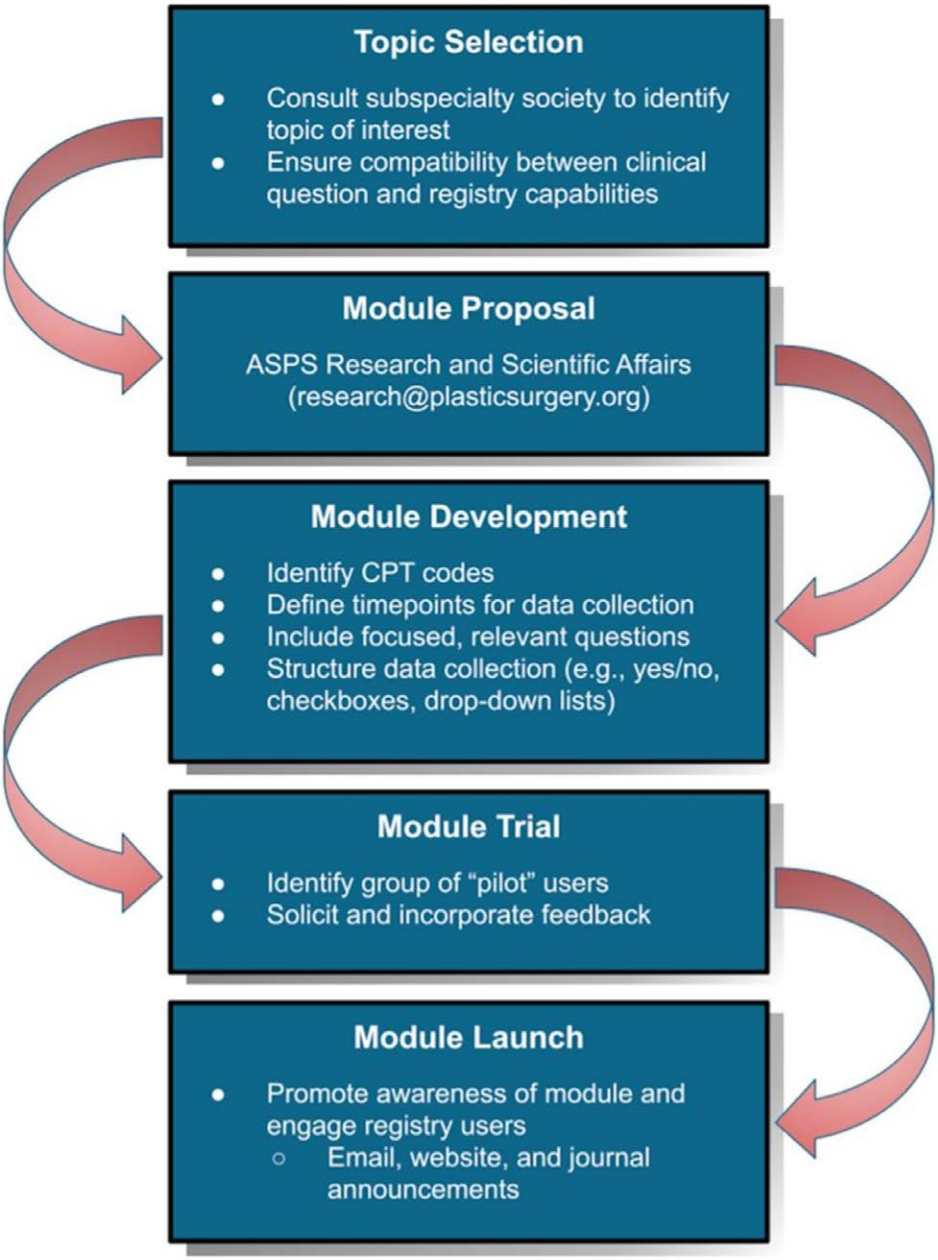

Fig. 1. Overview and key points of the process by which the TOPS cleft palate module was developed and implemented. CPT, current procedural terminology.

to facilitate tailored and complete data collection. Still, the module should be designed in a manner that avoids collection of information unrelated to the intended clinical focus to prevent an overly burdensome data entry process for surgeons. Entry into a specific module within the TOPS platform is triggered through input of Current Procedural Terminology codes associated with the procedure of interest, and the collected data should concisely reflect this focus. Throughout this development process, the authors of the module must work closely with the PSF to optimize efficiency of data entry at key time points in the progress of the clinical condition.

To ensure that the cleft palate module met these criteria, a subcommittee of 3 plastic surgeon members of the ASMS was founded. This subcommittee was tasked with creating a module template focused on capturing pertinent data in a concise manner that could be presented to the ASPS/PSF Registry Steering Committee. Of particular help with this endeavor was the prior experience of 1 member in developing a template for another national data registry. Together, all subcommittee members worked to draft and revise an initial module template that they felt addressed key data points relevant to surgical outcomes in the most succinct manner possible.

For example, selected Current Procedural Terminology codes for the cleft palate module were limited to 3 (4200, 42205, and 42235) and information collected through the use of branching logic, a process whereby presentation of follow-up questions is dependent on the chosen answer to a prior question, to prevent users from being directed to questions that were not applicable to their inputted data (Fig. 2).

Following the initial draft, an additional input was garnered from other pediatric plastic surgeons who had significant experience using and creating data registries to further refine the questions and optimize data collection methodology. This feedback helped to ensure uniformity between the data classification systems currently proposed and those used in other registries focused on cleft palate. This standardization would allow data collected across different registries to complement each other rather than compete. Thus, a subsequent evaluation of other registries collecting information related to cleft palate outcomes was performed to identify and incorporate the most appropriate classification systems into the TOPS cleft palate module. For variables where many different classification systems are in use (eg, speech scoring scales), the ability to specify and input data for multiple classification systems was implemented.

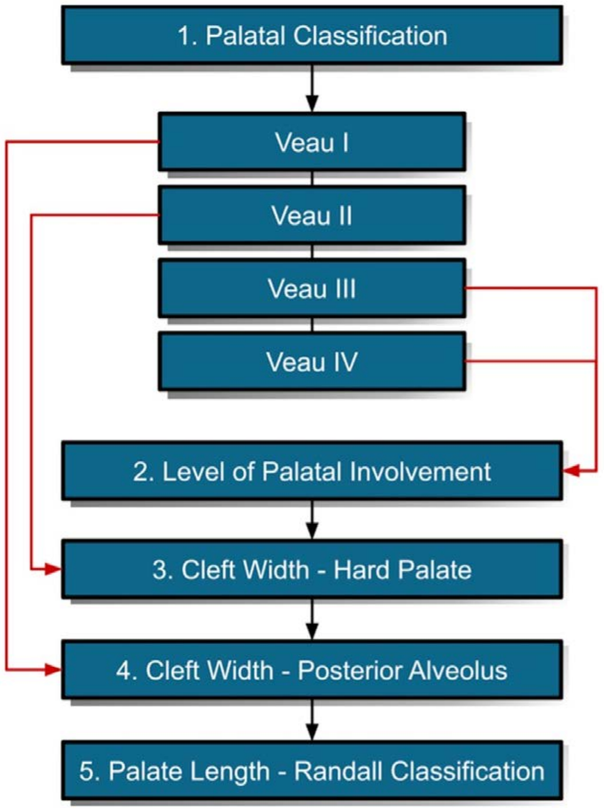

Fig. 2. Example of branching logic implemented in questions of the TOPS cleft palate module. Registry users are directed to only those questions which are applicable based on their answer to question 1 (palatal classification).

In addition to these efforts made toward standardization between registries, care was also taken to develop the TOPS cleft palate module in such a way that clearly distinguished its purpose as compared with other existing registries collecting information related to cleft palate procedures and outcomes (eg, National Surgical Quality Improvement Program, American Board of Plastic Surgery, International Consortium for Health Outcomes Measurement, Americleft). Although many of these other registries are limited by the length at which follow-up data is collected, the TOPS registry platform enabled unique design of the cleft palate module to track outcomes in children from the time of initial cleft palate repair through their late teenage years so that meaningful data regarding fistula formation, speech development, and maxillary growth could be obtained. To facilitate this longitudinal data collection, module "sections" were created to accommodate data entry at clinically important time points corresponding to expected patient visits/follow-up. For example, section A of the module collects baseline patient/procedure information and was designed to be completed at the time of each patient's cleft palate repair; subsequent sections pertaining to fistula, speech, and maxillary development evaluations for each patient do not become available to registry users until the baseline section is complete. The registry then functions to "flag" each patient record when input of new data for each section is due (eg, age 3 years and annually thereafter for speech evaluations and surgical management of velopharyngeal insufficiency; ages 8, 12, and ≥16 for evaluations of maxillary development) so that registry users are prompted to complete these sections at appropriate time intervals. This cleft palate module design was presented to the ASPS/PSF Registry Steering Committee for refinement before its trial launch. At this time, the PSF provided a demonstration of the trial "workflow" of similarly structured modules to enable a better understanding of how users would interact with the registry once implemented.

MODULE TRIAL AND REVISION

Upon completion and approval of module design by the ASPS/PSF, trial of the module was initiated. This trial primarily functioned to gauge the module's ease of use among a small subset of registry users, as well as to identify any areas of the module which could benefit from revision before making it available to all TOPS registry users. Plastic surgeons with significant experience and clinical practice related to the topic were invited to serve as "pilot" users of the module. Access to the TOPS registry and associated modules is obtained through the Plastic Surgery Registries Network registration portal (https://psrn.plasticsurgery.org/signup/login.aspx); free registration is available to all active ASPS members. Users must also submit proof that their institution allows contribution of data to national registries, as some institutions have been reluctant to permit national registry participation among their physicians due to concerns over protection of patient information and related data-sharing policies. Importantly, patient data inputted into the TOPS registry are de-identified at the time of entry and is only able to be tracked to a specific patient through the host institution. Although many institutions are becoming increasingly receptive to registry participation given their use in informing clinical advances through evidence-based medicine, the PSF has also been successful in soliciting approval for registry participation from those institutions which were initially disinclined to do so and guiding them in the mechanisms by which they can participate.

Feedback from pilot users was used to further modify the module before making it more broadly available. Once the module had been sufficiently trialed and necessary design changes implemented, the PSF expanded access to all TOPS registry users. Advertisement of the new module ensued, assisting in promoting awareness and interest in the topic.

The cleft palate module was first trialed with members of the ASMS Board of Directors. This group was chosen to trial the module based on their vested interest and expertise in the topic, likelihood for responsiveness to participation, and association with several different medical institutions. These characteristics assisted in promoting multi-institutional contribution and collaboration in assessing long-term outcomes and developing further clinical solutions based on these outcomes.

Feedback from this group resulted in creation of a user guide for the cleft palate module. This guide was made available on the TOPS homepage and details the instructions/timeline for data entry related to fistula management, speech evaluation, surgical management of velopharyngeal insufficiency, and maxillary development. The instructional guide also includes detailed information on classification systems (eg, Veau, Randall) and proper measurement techniques for cleft anthropometry (eg, cleft width), ensuring consistent methodology among module users.

Upon final revision and launch of the cleft palate module, it was important to engage as many surgeons as possible in registry use. The ASMS leadership approved and sent e-mail correspondences to all members of the society, informing them about the creation of the TOPS cleft palate module. Similarly, announcements were added to the ASMS website and the society's associated journal (*FACE*). To further facilitate registry use, the members were reminded that participation satisfies the Practice Improvement Activity of Continuous Certification for the American Board of Plastic Surgery.

TIMELINE

The timeline, encompassing proposal, development, trial, revision, and final launch of the cleft palate module, totaled 34 months and involved contributions from 8 plastic surgeons. Approximately half of this time period was devoted to the foundational steps of module development and design in preparation for its trial launch, with the remaining time used for longitudinal (ie, >1 year) trial and iterative improvements based on user feedback. Of note, the time investment required to complete these processes is highly dependent on several factors such as module complexity, number of contributors, and timely communication with key parties.

MODULE USE

Since being made available to all TOPS registry users in July 2019, plastic surgeons from 13 institutions have logged data for more than 250 patients using the cleft palate module. (**See appendix, Supplemental Digital Content 1**, which displays the current TOPS cleft palate module user interface, **http://links.lww.com/PRSGO/D711**) Although still in its infancy, this module holds significant promise for developing into a robust and comprehensive data repository that practicing plastic surgeons across the nation may contribute to and use for improving the surgical care delivered to patients with cleft palate. The few other custom TOPS modules (Table 1) have demonstrated striking success since their implementation, having captured data on thousands of patients. For example, information collected through the TOPS Breast Implant module, first implemented in 2007, was used to power a research study with a cohort of nearly 85,000 patients.[14] Additionally, the Lipoplasty module has enabled research studies with cohorts of several thousand patients.[15,16]

DATA ACCESS

TOPS registry users may request registry data for research purposes by submitting the TOPS Research Data Application Form (available at https://form.jotform.com/81266036735155). This form requires that users provide basic information regarding the purpose of the data request, specific endpoints/data elements being requested, and the intended use of any data that is released. The TOPS Steering Committee reviews all data requests and determines their approval. Individuals with approved requests are able to purchase the requested data for a fee as determined by the PSF and their registry vendor.

CONCLUSIONS

The TOPS database provides plastic surgeons with an opportunity to engage in national efforts aimed at improving the quality of surgical care delivered to patients. The database was intentionally built on a versatile platform that supports incorporation of custom modules, which can be developed by plastic surgeons to investigate procedure-specific clinical interests. These modules can amass high-quality and useful information on a large number of patients by leveraging data collection efforts from members of the ASPS, the largest national plastic surgery organization. Only a small number of custom modules have been created thus far, indicating that few plastic surgeons have taken advantage of this unique feature

Table 1. List of All Former and Current Modules Implemented Through the TOPS Registry

TOPS Module	Year Implemented	Status
Breast implant	2007	Retired*
Lipoplasty	Before 2011	Active
Bariatric	Before 2011	Active
Cleft palate	2019	Active

*TOPS Breast Implant module was retired due to its duplicative nature with the National Breast Implant Registry.

residing within the TOPS infrastructure. To promote further usage of the TOPS registry and awareness of its ability to collect targeted data, we have outlined the process by which a custom module was successfully developed and implemented. This information may serve as a general guide by which plastic surgeons in all subspecialties may work with the ASPS/PSF to develop additional modules that aid in the understanding of surgical procedures and clinical conditions through longitudinal collection of multicenter data. However, it is important to note that the TOPS registry platform is continually evolving and the step-by-step process by which modules are created will also change accordingly. We encourage plastic surgeons who feel that there are complex clinical questions of relevance that would benefit from data collection through national clinical registries to work with their respective subspecialty societies to propose future module formation within the TOPS registry. Subspecialty societies should then work with the research arms of the ASPS/PSF to develop and implement these modules within the TOPS registry platform. Such efforts will allow for complex clinical questions that are pertinent to plastic surgeons to be addressed through level I and II reports, as opposed to the preponderance of level IV and V reports in our present literature.

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DISCLOSURE

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