In 1993, the US Supreme Court ruled that an essential component for a treatment to be considered standard practice is acceptance from the relevant scientific community. Yet, how the medical community comes to embrace new treatment options is not always clear. The largest determinant of whether physicians agree on a treatment's efficacy is likely the results of scientific studies. However, questions remain as to which kinds of studies and what volume of investigations are required to move a treatment from experimental to validated. Additionally, there may be numerous external forces that contribute to an innovation's pace and process. Pressures from the lay community, regulatory rulings, and funding sources are examples of factors that could play a role in the evolution of a new idea. All are components worthy of study. Considering the wide implications of which treatments become designated as acceptable, further investigation of how a therapy moves from conception to acceptance is warranted. This is particularly important in fields in which treatment development is less standardized. For many new drugs, the developmental pathway in the United States is laid out from preclinical studies through Phase 3 randomized controlled trials by FDA regulations. Other countries use their own processes. But for other treatments, particularly surgeries, the progression of a procedure to community acceptance is less clear. A significant challenge for investigating treatment development is the selection of an applicable end point that represents community acceptance for procedures that did not develop along a standard drug-based path. This report aims to demonstrate the theory, method, uses, and limitations of a new model for measuring new metric that the authors term “progressive scholarly acceptance.” A model was developed to identify when the scientific community has accepted an innovation, by observing when researchers have moved beyond the initial study of efficacy. This model could enable further investigations into the methods and influences of treatment development. http://thejns.org/doi/abs/10.3171/2015.1.JNS142661

KEY WORDS science; innovation; standard of care; surgery; idea

Theory

Progressive scholarly acceptance is a new metric that attempts to identify when an idea or medical innovation moves from the experimental fringe to the academic mainstream. It is based on a view of surgical innovation as continually building on past innovations.

Riskin et al. explored historical patterns of surgical innovation and, through the lens of the plentiful research on business innovation, created new nomenclature to categorize contributions based on clinical impact. They argued for two phases of surgical innovation: an “expand-
ing period” and a “refining period.” An expanding period occurs when a significant innovation spurs rapid change that considerably alters patient care. A refining period is a time when new developments merely improve the existing method with relatively modest clinical impact. These refinements increase efficiency, decrease costs, or moderately improve outcomes, but do not have a huge bearing on patient care. The authors described surgical history as having an “ebb-and-flow” pattern, where an expanding technology leads to rapid clinical change followed by a period of refinement when those changes are moderately improved.9

In their work, Riskin et al. use this theory to describe development of whole fields over centuries, but the concepts of expanding and refining innovations can also be applied to a narrower perspective.9 In fact, depending on the focus, a single innovation could be considered an expanding or refining technology. One example is stereotactic radiosurgery in neurosurgery. When viewed in a broader context, the invention of radiosurgery is the enabling technology and new applications that arose over the subsequent decades, such as its use for trigeminal neuralgia (TN) or brain metastases, were new refinements. But from a narrower perspective, the use of radiosurgery for TN could be considered an expanding innovation, as it had significant impact on certain patients’ care and enabled considerable research into even further refinement. Examples are its application in certain TN subpopulations, such as patients with multiple sclerosis, and in technical refinements such as radiation dose.

In this view, broader innovations give rise to refining innovations that themselves result in more narrow refinements. An appropriate visual representation of this repeating pattern is a diagram of a branching tree, where each branch is a new innovation (Fig. 1). Any branch could be selected and viewed as the broad innovation, and the innovations branching from it viewed as the refinements.

Key to the PSA theory is the recognition that prior to refinement comes acceptance of the broad, initial innovation. That is, before an investigator begins to study a refinement, he or she believes in the procedure they are building upon. Additionally, when a report is published, it reveals the views of more than just its authors, as the journal reviewers must acknowledge the appropriateness of the idea for study. As studies diffuse, more investigators are likely to accept the procedure and begin their own refinements, further publishing and perpetuating the procedure’s usefulness. At some point, assuming continued procedural success, the volume of reports focused on refinements will eclipse the number of studies testing the initial question of efficacy. This is an indication of community acceptance, and what we term PSA. Progressing—or moving beyond the initial question—is a signal of acceptance from the relevant community.

It is crucial to point out that community acceptance of a certain procedure does not mean it is objectively efficacious; it only means that the community at large believes in its efficacy at some level. There are many examples, such as autologous bone marrow transplantation for breast cancer,11 of a treatment initially being accepted by the scientific community and considered to be an optimal therapy, and then additional studies demonstrated its ineffectiveness.

The goal of the PSA model is not to assess effectiveness but to use quantifiable, literature-based documentation to determine when the community accepts a procedure. Second, it can be used to study how the community accepts a procedure. This has significant value for studying development. PSA can be used as an end point for acceptance, and then the scientific characteristics of studies, the norms of a specific community, potential societal factors, and other variables can be described to identify how each influences innovation and movement toward acceptance.
Methods

The PSA model uses the scientific literature to assess how a topic is proposed, evaluated, disseminated, and adopted. The model is a bibliometric analysis (i.e., a measurement of texts and information) but is distinct from other well-known bibliometric tools such as impact factor and the h-index, which focus on the citation impact of the article or authors. The PSA model assesses the progression of a topic over time, similar to a literature review, but instead of selecting key articles, all literature found in selected databases is included in the analyses.

It may seem counterintuitive for a model that assesses the spread of acceptance to not differentiate article quality, as higher-quality articles in more renowned journals are likely to be more widely read and the findings perhaps accepted by more physicians. But instead of weighting articles with a metric such as journal impact factor, the influence of an article (as well as ancillary forces that are harder to measure, such as conference meetings/proceedings, personal correspondences, and related writings) is predicted to present itself when it instigates more investigations on the topic by more investigators. These subsequent publications are included in the PSA model. This will allow for observing the topic’s reception: Procedures will be evaluated. This will depend on the research question, though the annual numbers of articles assessing efficacy, as seen in the compounding plot (Fig. 2 upper). This analysis allows for more time-sensitive review of publication patterns, which is best used to assess changes following specific incidents (e.g., a regulatory ruling). But the annual changes tend to be more fickle, changing rapidly from chance and varied influences, and the change when the annual number of refining publications surpasses the annual number of initial studies may not be the best measure of acceptance. A more conservative measure for acceptance is found using the compounding analysis. In the compounding analysis, the total number of initial and refining publications is compounded each year as time passes (Fig. 2 lower). The year when the compounded number of refining articles surpasses the compounded number of initial articles is the best measure of PSA. This is the point when the total volume of articles written on refining innovations surpasses the volume of articles assessing basic efficacy. Reaching this point requires sustained refinement, with the rate of publication of refining articles remaining higher than that of initial efficacy reports. This means that the majority of research has moved on to refining research, implying the scientific community has accepted the answer to the initial question of efficacy.

For TN radiosurgery (Fig. 2), it can be seen that the annual study of refinement grew considerably and surpassed the study of initial efficacy in 2000. From then on, refinement investigations were sustained at higher levels, and by 2002, the total number of articles written on refinement for TN radiosurgery had eclipsed the number of articles assessing efficacy, as seen in the compounding plot (Fig. 2 lower). This is the point of PSA, and that year is the end point for community acceptance in the PSA model.

For TN radiosurgery, the community belief in efficacy aligns with the objective assessment of efficacy. The National Institute of Clinical Excellence in the United Kingdom released a systematic review endorsing radiosurgery for TN in 2004, with all of the evidence for Gamma knife.
radiosurgery published in 2002 or earlier. But another major value of PSA will be in investigating when acceptance does not agree with objective reviews of efficacy and which factors outside of scientific evidence change the community’s belief in efficacy.

Limitations

There are several limitations to the PSA model. The first is the time-intensive nature of producing the model. Currently, each report must be manually assessed to characterize the investigation as initial or refining. With wider utilization, this limitation could be overcome if authors were to declare which areas they were building on, similar to entering a keyword. This would allow for automated analysis.

Another problem is the delay from author acceptance until publication. Gathering data and completing a study takes time, and the PSA model does not register acceptance of the author until those studies are published. This is a real delay between the work performed and the publication.

Another timing issue is how well acceptance from academic medicine corresponds to clinician utilization. Clinicians that participate in clinical research are more likely, by profession, to be early adopters, and may accept and begin refining an innovation before noninvestigative clinicians accept it. The PSA model is clearly an assessment of scholarly views, and the correspondence between PSA and clinical use requires further investigation.

The model also fails to take into account published reviews and editorials. This is because they are not original studies, and cannot be readily classified as initial efficacy or refining investigations. Additionally, the timing of release of these types of articles does not necessarily correspond with the most up-to-date science. For example, a review may detail the results from older efficacy studies to remind readers about effectiveness long after investigators have moved onto refinement topics. But still, these methods of publication are part of the scientific conversation and surely have a role in demonstrating community perspective, so their absence is relevant.

Conclusions

The PSA metric fills a vital role as an end point for...
community acceptance of science. Despite its limitations, the PSA model we propose has considerable use in enabling investigators to further study how clinical medicine (or other science) evolves in different circumstances, and how varying factors influence societal acceptance of that science. These types of investigations will be critical to understanding treatment development and could inform strategies aiming to reform or regulate medical innovation.

References


Author contributions

Conception and design: both authors. Acquisition of data: Schnurman. Analysis and interpretation of data: both authors. Drafting the article: both authors. Critically revising the article: both authors. Reviewed submitted version of manuscript: both authors. Approved the final version of the manuscript on behalf of both authors: Kondziolka. Statistical analysis: Schnurman. Administrative/technical/material support: Kondziolka. Study supervision: Kondziolka.

Supplemental Information

Companion Paper


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