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Impact evaluation using the translational science benefits model framework in the national center for advancing translational science clinical and translational science award program

Edited by
Pamela Davidson, Joe Hunt and Douglas Luke

Coordinated by
Anna La Manna

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Topic editors
Pamela Davidson — University of California, Los Angeles, United States
Joe Hunt — Indiana University, Purdue University Indianapolis, United States
Douglas Luke — Washington University in St. Louis, United States

Topic coordinator
Anna La Manna — Washington University in St. Louis, United States

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EDITED AND REVIEWED BY
Maximilian Pangratius de Courten,
Victoria University, Australia

*CORRESPONDENCE
Douglas A. Luke
✉ dluke@wustl.edu

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Editorial: Impact evaluation using the translational science benefits model framework in the national center for advancing translational science clinical and translational science award program

Pamela L. Davidson[1,2], Joe Hunt[3], Anna La Manna[4] and Douglas A. Luke[4]*

[1]CTSI-Evaluation, Clinical and Translational Science Institute (CTSI), University of California, Los Angeles, Los Angeles, CA, United States, [2]Department of Health Policy and Management, Fielding School of Public Health, University of California, Los Angeles, Los Angeles, CA, United States, [3]Indiana Clinical and Translational Sciences Institute (Indiana CTSI), Indiana University School of Medicine, Indianapolis, IN, United States, [4]Center for Public Health Systems Science, School of Public Health, Washington University, St. Louis, MO, United States

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translational science, Translational Science Benefits Model (TSBM), knowledge translation, CTSA program, impact

Editorial on the Research Topic
Impact evaluation using the translational science benefits model framework in the national center for advancing translational science clinical and translational science award program

Introduction

Over the past several years, a new discipline has emerged called *translational science.* Translational science, championed by the National Center for Advancing Translational Science (NCATS), is defined as "…the field that generates innovations that overcome longstanding challenges along the translational research pipeline. These include scientific, operational, financial, and administrative innovations that transform the way that research is done, making it faster, more efficient, and more impactful" (1). In this sense, translational science is quite similar to the discipline of implementation science, which studies how evidence-based scientific knowledge is translated, adopted, implemented, and maintained in communities and healthcare settings (2).

Knowledge translation is a critical dissemination activity that transforms research results into new products, practices, and policies to benefit health and society. Yet, effectively bridging the gap between clinical research and practical applications is challenging. The US National Institutes of Health (NIH) and NCATS address this challenge through the Clinical and Translational Science Award (CTSA) Program. The charge of the CTSA Program is to transform the organization and infrastructure of the academic research enterprise to accelerate the movement of discoveries from clinical science to the bedside and community.

Documenting the results of these efforts is a necessary component to assess outcomes, health and social impacts, and support continuous improvement. Within the CTSA program, more than 60 CTSA hubs, primarily located at academic health sciences research institutes across the nation, are beginning to systematically measure and evaluate the impacts of their activities. One model used to track and assess impact is the Translational Science Benefits Model (TSBM), introduced in 2018, [see Figure 1, (3)]. TSBM is one of the pioneering frameworks for standardized documentation and dissemination of data on outcomes and impacts of translational science and translational research. Although translational science is still in its infancy, much work is being conducted nationally within CTSA hubs, communities, and research partners.

The recent *Frontiers in Public Health* Research Topic (*Impact evaluation using the translational science benefits model framework in the national center for advancing translational science clinical and translational science award program*) included 11 articles, written by more than 60 co-authors based at a wide range of CTSA hubs, contexts, and settings. Based on these articles, this editorial presents three crosscutting themes for reflecting on the TSBM Research Topic and state of the evolving science: 1) Versatility and methodological insights of the TSBM, 2) Knowledge translation as a pathway to longer-term impacts, and 3) Advancing translational science.

Versatility and methodological insights of the TSBM

Articles in this edition demonstrate the versatility and methodological advancements of the TSBM. The TSBM began as a structured framework designed to assess the health and societal impacts of translational science. Over time, substantial advancements in methodology and operationalization have transformed TSBM into a dynamic tool for measuring the outcomes of translational science at multiple levels within the research enterprise, that also supports continuous improvement in scientific evaluation. This framework has been applied in various aspects such as setting strategic direction, operations management, continuous quality improvement (CQI), and tracking organizational contributions to advancing human health.

The integration of the TSBM framework has proven effective in eliciting recommendations for measures of significance on the contributions of the CTSA environment and consortium (Kane et al.). By integrating concept mapping with the TSBM framework, measures can be selected at both individual, organization and consortium levels, aiding strategic resource allocation.

For day-to-day management, the TSBM framework combined with the balanced scorecard and project management tools has supported organizational performance measurement at the program level, ensuring efficient allocation of resources and effective tracking of contributions to advancing priorities (Gholami et al.). Similarly, an adaptation of the TSBM framework in assessing performance has applied CQI tools to achieve performance improvements (Brimhall et al.). Methodological enhancements include real-time performance monitoring systems, balanced scorecards, and project management platforms, supporting frequent updates and comprehensive tracking aligned with strategic institutional goals (Swanson et al.).

Methodologies like Plan-Do-Study-Act cycles, inclusive leadership in team science, and automation through natural language processing (NLP) and artificial intelligence (AI) have further expanded the operational capabilities of the TSBM (Molzhon et al.). Concept mapping has aligned program goals with evaluation priorities (Manjunath et al.), ensuring diverse stakeholder perspectives are captured and consensus around evaluation metrics is formed (Kane et al.).

Overall, these advancements illustrate the evolution of the TSBM into a dynamic, methodologically robust measurement tool that effectively supports continuous improvement, providing standardized and comparative monitoring, and adaptive evaluation in translational science. This integration enables organizations to create and sustain a culture of impact, promoting awareness of the real-world benefits of their work (Davidson et al.).

Knowledge translation: pathway to demonstrated health and societal impact

Potential and demonstrated knowledge translation impact is measured using four domains and 30 indicators operationalized in the TSBM. In a novel research project, CTSA hub-county interorganizational collaborations were followed longitudinally to assess both knowledge translation impact and the longer-term health and societal benefits reported in impact stories (Davidson et al.). Similarly, a Northern Ohio CTSA hub demonstrated societal benefits in public health practice, highlighting enhanced healthcare access, improving health outcomes, informing policy, and generating economic benefits (Zhang et al.). Researchers at the Duke University CTSA, shared the value of integrating TSBM into multiple levels of the research enterprise to examine impact, using case studies, program area level (e.g., pilot studies), and cross-program and institutional monitoring of TSBM in an organizational database (Sperling et al.). VCU CTSA evaluators emphasized increasing focus on educating investigators on the importance of measuring impact and the longer-term broad reaching effects of their translational science research (Molzhon et al.).

Advancing translational science

As an impact evaluation framework, the TSBM is clearly relevant to translational science, given its goal of producing impactful scientific innovations. More specifically, a number of articles in this TSBM Research Topic feature one or more of the core principles of translational science (4). For example, the principle of *team science* is prominent in the article by Brimhall et al., who developed a logic model featuring inclusive leadership and other team science concepts. Methodological *creativity and innovation* were prominent in article which featured concept mapping (Kane et al.), innovative CQI methods

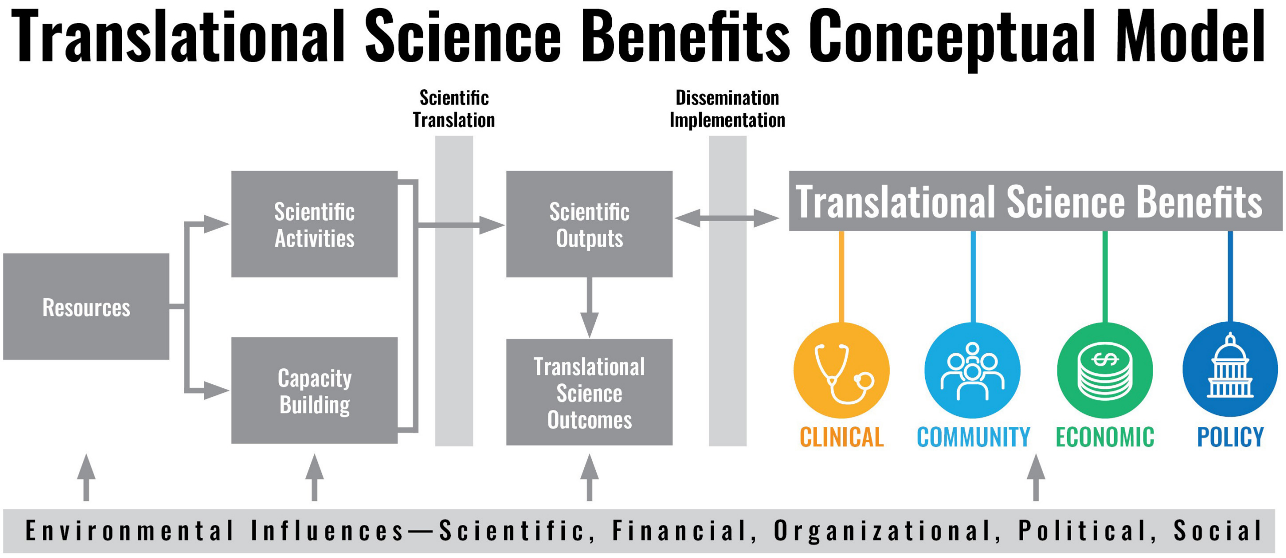

FIGURE 1
The Translational Science Benefits Model (TSBM) logic framework.

including real-time monitoring dashboards (Gholami et al.), and natural language processing of bibliometric data (Manjunath et al.). Finally, a number of articles featured *boundary-crossing partnerships* between academic and community organizations in Los Angeles (Davidson et al.), Wisconsin and Missouri (Manjunath et al.), and a consortium of rural states (La Manna et al.).

Conclusions

In summary, the CTSA Program, supported by NIH and NCATS, plays a pivotal role in transforming research into tangible health and societal benefits. The use of the TSBM has proven instrumental in systematically measuring and documenting these impacts. According to NCATS, "Translation turns observations in the laboratory, clinic, and community into diagnostics, therapeutics, medical procedures, and behavioral changes;" these are literally measured in the TSBM and are precursors to improvements in the delivery system and people's health.

Through advancements in methodology and versatile applications, the TSBM supports continuous improvement and adaptive evaluation, fostering a culture of impact within translational science. The Research Topic of articles in this edition reflects on the evolving state of translational science, underscoring its significance and the real-world benefits it provides.

Author contributions

PD: Conceptualization, Writing – original draft, Writing – review & editing. JH: Conceptualization, Writing – original draft, Writing – review & editing. AL: Conceptualization, Writing – original draft, Writing – review & editing. DL: Conceptualization, Writing – original draft, Writing – review & editing.

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EDITED BY
Douglas Luke,
Washington University in St. Louis,
United States

REVIEWED BY
Nasser Sharareh,
The University of Utah, United States
Emmanuel Tetteh,
Washington University in St. Louis,
United States

*CORRESPONDENCE
Cathleen Kane
✉ cathleen.kane@nyulangone.org

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Navigating the road ahead: using concept mapping to assess Clinical and Translational Science Award (CTSA) program goals

Cathleen Kane[1]*, William Trochim[2], Haim Bar[3], Andie Vaught[4], Heather Baker[4], Munziba Khan[4], Robin Wagner[4], Kristi Holmes[5], Keith Herzog[5] and Jamie Mihoko Doyle[4]

[1]New York University Langone Health, Clinical and Translational Science Institute (CTSI), New York, NY, United States, [2]The Brooks School of Public Policy, Cornell University, Ithaca, NY, United States, [3]Department of Statistics, University of Connecticut, Storrs, CT, United States, [4]Division of Clinical Innovation, National Center for Advancing Translational Sciences, National Institutes of Health, Bethesda, MD, United States, [5]Northwestern University Feinberg School of Medicine, Northwestern University Clinical and Translational Sciences (NUCATS) Institute, Chicago, IL, United States

Evaluating large-scale programs designed to transform public health demands innovative approaches for navigating their complexity and scope. The Clinical and Translational Science Awards (CTSA) Program, supported by the NIH's National Center for Advancing Translational Sciences (NCATS), represents a significant national investment with over 60 sites or "hubs" spread across the country. Assessing an initiative of this size and complexity requires measures that balance local flexibility with national coherence. To that end, this study used concept mapping, a mixed-methods approach integrating qualitative brainstorming and sorting with quantitative multidimensional scaling and cluster analysis. Participation across the CTSA was unprecedented. Over 100 evaluation stakeholders were engaged across the network of hubs, leading to the identification of more than 80 measures, which were then organized into thematic clusters that reflect a logical progression from CTSA activities to outcomes and impacts, as well as critical foundational factors such as collaboration and education. The results also revealed a pattern where long-term impacts were ranked among the highest in importance but among the lowest in feasibility, particularly for measures tied to the Translational Science Benefits Model (TSBM), a new evaluation framework gaining popularity across the CTSA. The findings of this study underscore the efficacy of concept mapping in incorporating wide-ranging perspectives, identifying areas of consensus, and informing leadership in the development of unified, data-driven evaluation frameworks —such as TSBM and/or a CTSA logic model— critical to maximizing the CTSA's transformative potential for public health.

KEYWORDS

Clinical and Translational Science Awards (CTSA), concept mapping, evaluation study, stakeholder participation, mixed-methods research, Translational Science Benefits Model (TSBM), longitudinal impact, National Institutes of Health (NIH)

1 Introduction

It has been over 17 years since the National Institutes of Health (NIH) launched the Clinical and Translational Science Awards (CTSA) Program, an ambitious set of bold initiatives (1) and national investments aimed at improving the process of transforming laboratory, clinical, and community-based discoveries into effective public health interventions (2). The CTSA program is a nationwide network of medical research institutions, referred to as "hubs", designed to synergize infrastructure and interdisciplinary, scientific expertise to advance clinical and translational science (CTS) research. CTSA hubs facilitate translational research through targeted pilot awards, research support services, community engagement, and multidisciplinary training. In Fiscal Year 2024, the National Center for Advancing Translational Sciences (NCATS) invested more than $629 million (3) to support more than 60 hubs.

Large biomedical research investments, such as the CTSA program, require rigorous process and outcome evaluations to determine whether the program is meeting its goals and if systematic modifications are needed over time. The Foundations for Evidence-based Policymaking Act of 2018 (also known as the Evidence Act) further underscores the need for federal agencies to build evidence in support of programs and decision-making, including the CTSA program and NCATS (4). However, the CTSA program's expansive goals, diverse institutional activities, and decentralized structure create a complex evaluation environment requiring an approach that balances local flexibility with consortium-wide coherence (5). Assessments of programs with this complexity present both practical and theoretical challenges. One practical challenge, for instance, centers on the number of CTSA institutions supported (>60) that are geographically disparate. Another challenge is building consensus among multiple evaluation stakeholders from different hubs that have a wide array of local contexts (rural vs. urban), varying financial resources, and differing roles at their CTSA (ex. CTSA Evaluators vs. Administrators).

Concept mapping is one approach to addressing these challenges by enabling stakeholders to define evaluation measures collaboratively through an asynchronous participatory platform, thereby fostering a quantifiable consensus and shared vision while respecting individual hub and institutional contexts (6–9). By design, this methodology is an example of participatory evaluation. This study utilized concept mapping to identify a comprehensive set of specific measures for evaluating the CTSA Program's success in meeting its goals. Input was gathered from a diverse range of perspectives and locations, spanning multiple hubs nationwide and involving over 100 key stakeholders, including CTSA Administrators, CTSA Evaluators, and NCATS staff. By engaging CTSA participants from a set of different but complimentary roles, the study sought to uncover areas of consensus or disagreement around key themes while ensuring differing perspectives were represented.

2 Materials and methods

Concept mapping is a mixed-methods approach that applies quantitative analysis to qualitative inputs. This methodology was chosen for this project as opposed to other analogous approaches such as the Delphi Method (10, 11) or Nominal Group Technique (NGT) (10, 12) because: multiple non geo-located stakeholders needed to asynchronously and collaboratively define and organize ideas; both qualitative and quantitative analysis was preferable for structuring a variety of concepts; visualization of conceptual relationships would be more useful than simple ranking; and group consensus-building was a key goal for the process overall. As Trochim describes it, concept mapping is "*…a unique integration of qualitative (group process brainstorming unstructured sorting interpretation) and quantitative (multidimensional scaling hierarchical cluster analysis) methods designed to enable a group of people to articulate and depict graphically a coherent conceptual framework or model of any topic or issue of interest*" [(13), p. 166]. This method has been used extensively in planning and evaluation since the 1980s (6, 9, 13, 14), and involves four essential components detailed below: Participant Selection, Data Collection, Analysis, and Interpretation.

Implementing this methodology required three waves of primary data collection and participant engagement to interpret findings. All waves of data collection involved soliciting volunteers at regularly scheduled CTSA Administrator and Evaluators meetings, and internal meetings of NCATS staff as well as sending emails directly to these targeted audiences for participation. These three groups of stakeholders—CTSA Administrators, CTSA Evaluators, and NCATS staff—were non-randomly sampled for heterogeneity. More specifically, they were also selected because of their direct and often complementary roles in designing, implementing, and utilizing evaluation data to monitor and convey the value-add and impact of CTSA-funded activities. Participation was voluntary and each participant did not need to participate in all three waves of data collection.

The first wave of data collection involved the brainstorming of measures where participants were asked to respond to a focus prompt with a data collection instrument that was created in REDCap. After providing the CTSA program goals, the data collection instrument included the following focus prompt to guide participants: "Please brainstorm as many measures as you can in response to the following prompt: *'One specific measure I think should be used in an evaluation of the CTSA program is….*" Data collection opened on February 8, 2022 and closed on March 8, 2022. A total of 320 statements were collected from participants. While the focus prompt specifically solicited measures, some participants gave statements about measures instead. Therefore, we refer to the raw data that was collected as "statements." It is interesting to note that select non-NCATS/NIH staff were invited to participate ($N = 3$), but ultimately did not participate in any waves of data collection.

The next step involves unitizing the statements, a content analysis methodology (15) that is part of the concept mapping process. Trochim et al. (16) describe "unitizing" as "…the process of dividing a continuous text into smaller units that can then be analyzed" (P. 67). For example, there were instances where responses were double-barreled (e.g., "Describe the impact of CTSA funding on community health or translation into clinical practice"). These responses were then parsed out by two of the authors (CK and JD) into single idea statements (e.g., "Describe the impact of CTSA funding on community health" and "Describe the impact of CTSA funding on translation into clinical practice"). Of the 320 statements originally submitted by participants, statements were then parsed into 499 single idea statements. Two authors (CK and JD) then iteratively and inductively combined these single idea statements into 81 final statements that were used for the remainder of the process and constitute the detailed content of the mapping exercise. More formally, the authors use an inductive and independent blind coding process where similarities between statements arose from the data itself (induction) rather than having a pre-determined list of categories, bins, or statements for which each of the 499 single statements would need to be combined (deduction). The process was also "iterative" in that the 499 single idea statements were exchanged iteratively with two authors until the final list of statements was obtained. This approach, which combines iterative and inductive processes, can be described as inductive content analysis (17). A flow diagram of the brainstorming data collection and arrival of the final statement set for sorting is available in Supplementary Figure S1.

The second wave of data collection involved soliciting the same three groups—CTSA Evaluators, Administrators, and NCATS staff—to sort the 81 measures. For the sorting, participants were given a macro-enabled spreadsheet (18) and asked to assign labels of their choosing next to each statement. The only restrictions that were given to the participant were as follows: (1) spreadsheets could not be reformatted in any way, (2) each statement could only be labeled exclusively in one group, and (3) all statements could not be put into a single group. It is important to mention that while the approach used involves having participants "label" each statement, this is functionally the same as having them physically sort similar statements into piles that are then labeled (ex. "Collaborations", "Translation Measure", "Success Stories", etc.). All submitted labels were later used in a subsequent wave of qualitative analysis to assign representative titles to the clusters in the concept map. Data collection for the sorting part of this activity opened on February 20, 2023, and closed on March 3, 2023. Three participants submitted their sorted statements after the due date (two NCATS staff and a participant from a CTSA hub), with the last submitted received on April 10, 2023. These late submissions were included in the analysis.

Shortly following the sorting activity, the groups were then asked to rate the 81 measures by their feasibility and importance using a REDCap form. More specifically, participants were asked to rate measures on a five-point scale according to their relative feasibility of collection and relative importance for assessing the extent to which the CTSA program is meeting its goals, where: 1 = Not Feasible/Relatively Unimportant; 2 = Somewhat Feasible/Important; 3 = Moderately Feasible/Important; 4 = Very Feasible/Important; and 5 = Extremely Feasible/Important. Participants were asked to spread out their ratings and try to use each of the five rating values at least several times.

The RCMap package in R was used to perform all analyses (19). The analysis begins with the construction from the pile-sorting information of an NxN binary symmetric matrix of similarities, $X_{ij,k}$, for each sorter. For a single participant (indexed by k) $X_{ij,k} = 1$ for any two statements i and j, if the two items were placed together in the same pile (category label) by the participant, otherwise a 0 is entered. The total similarity matrix is obtained by summing across all individual participants' matrices (20). Therefore, each cell in this total matrix indicates how many participants sorted the two statements together (regardless of what other statements they may have been sorted with). This total similarity matrix is the input for nonmetric multidimensional scaling (MDS) with a two-dimensional solution, which yields a two-dimensional (x,y) configuration/plot of the statements such that statements that were piled together more frequently are located closer to each other in this space while statements piled together less frequently are further apart (the "point map"). This x,y configuration is the input for hierarchical cluster analysis using Ward's method (21) which effectively partitions the x,y configuration of statements into non-overlapping clusters, called the "cluster map". The importance and feasibility rating data are averaged across persons for each statement and cluster in a second stage of analysis described below.

Once the basic map structure is determined it is possible to construct any number of pattern match graphs [also called "ladder graphs", and known in the field of data visualization as a parallel coordinates graph (22)] that either compare two ratings (for all participants or any subgroups) or two groups (for any rating). Groups were determined from the demographic data that was collected. A pattern match or ladder graph is a useful visual device for showing relationships and especially for highlighting the degree of relationship between the entities being displayed. A Bonferroni correction was applied to the differences in means tests reported in the ladder graphs due to the multiple hypothesis tests performed. Finally, a "Go-Zone" plot (13) was generated to visually summarize feasibility and importance measures across all raters. Quadrants for each Go-Zone were generated using overall mean ratings for feasibility and importance, respectively.

The final step of the Concept Mapping process requires engagement with representative stakeholders, which we refer to as the Interpretation Group, to respond to the general layout of the concept map and associated visualizations. This group is tasked with providing final high-level feedback on the graphic representations based on the analysis described above, as well as a review of the concept map cluster titles based on qualitative coding of label names aggregated across all sorting participants Given the hierarchical nature of the relationship between funders and grant recipients, we prioritized capturing this final wave of targeted feedback strictly from the perspective of the hubs (Administrators and Evaluators). A stratified random sample of 12 participants was taken from the list of raters, with role (CTSA Administrator vs. Evaluator) and CTSA hub size (Small, Medium, and Large according to budgeted direct costs of the hub award) as strata (6 evaluators and 6 administrators, with two from each hub size within each sub-strata). Of the 12 participants, 4 did not respond or declined to participate in the interpretation step (2 evaluators and 2 administrators from medium and large hubs). Hubs that already had a participant committed to interpreting the findings were removed from the rating list for resampling, and additional potential participants were then selected. These participants had characteristics that were the same as those who did not respond or declined. All 4 of the newly sampled participants agreed to attend the interpretation session, and only one did not attend the actual meeting (an evaluator from a large hub). NCATS staff did not participate in the interpretation session.

3 Results

Table 1 shows the descriptive statistics of participant characteristics, as well as participating hubs. During the study period, there were 61 active CTSA hubs during the first wave of data collection (i.e., Brainstorming) and 65 active hubs during the second and third waves (i.e., Sorting and Rating). For the

TABLE 1 Descriptive statistics of participants.

Hub characteristics	Phase 1: Brainstorming		Phase 2: Sorting		Phase 3: Rating	
	%	*N*	%	*N*	%	*N*
Size						
Large	30%	6	32%	14	34%	16
Medium	15%	3	18%	8	15%	7
Small	55%	11	50%	22	51%	24
Region						
Midwest	30%	6	25%	11	21%	10
Northeast	20%	4	27%	12	34%	16
South	40%	8	34%	15	26%	12
West	10%	2	14%	6	19%	9
Number of participants						
1	75%	15	66%	29	57%	27
2	25%	5	20%	9	21%	10
3	0	0	7%	3	9%	4
4+	0	0	7%	3	13%	6
Hub participant characteristics						
Size						
Large	28%	7	34%	23	29%	26
Medium	20%	5	22%	15	19%	17
Small	52%	13	44%	30	53%	48
Region						
Midwest	36%	9	29%	20	18%	16
Northeast	20%	5	32%	22	30%	27
South	36%	9	25%	17	23%	21
West	8%	2	13%	9	30%	27
Role						
Evaluator	76%	19	71%	48	51%	46
Administrator	20%	5	15%	10	15%	14
KL2 PI	0%	0	0%	0	1%	1
TL1 PI	0%	0	0%	0	3%	3
UL1 PI	0%	0	0%	0	2%	2
Community partner	0%	0	0%	0	1%	1
Other CTSA hub staff	4%	1	9%	6	16%	15
Other	0	0	6%	4	10%	9
Total hub participants only		25		68		91
NCATS staff		8		6		10
Total unique participants		33		74		101
Total unique hubs		20		44		47

"Other CTSA Hub staff" for brainstorming was a staff member in Informatics. "Size" is defined by hub award direct cost. "Region" is defined by the US Census (https://www2.census.gov/geo/pdfs/maps-data/maps/reference/us_regdiv.pdf).

PI, Principal Investigator.

Brainstorming stage of Concept Mapping, we had participants from 20 out of 61 hubs (33%) and 33 participants, which included 8 NCATS staff. Participation increased with subsequent waves of data collection, with 44 out of 65 hubs participating in the Sorting stage (68%), and 47 out of 65 hubs (72%) participating in the Rating stage. The number of individual participants also increased with each stage, with a 124% increase (from $N = 33$ to $N = 74$) in the number of participants from Brainstorming to Sorting and a 36% increase (from $N = 74$ to $N = 101$) from Sorting to Rating. Across all waves of data collection, nearly half of all participating hubs were small in size, which roughly reflects the proportion of total hubs in the portfolio of that size (23). The largest group of participants in the sample across all phases of data collection were CTSA Evaluators.

Figure 1 shows the concept map (specifically, the "cluster map"), a graphic depiction of the composite thinking of all participants based on the cluster analysis, and Table 2 lists all 81 measures represented in the plot. The number of clusters ($K = 8$) was chosen by examining an "elbow plot" of the within sum of squares by the number of clusters (24). All eight statements in Cluster 8, located in the middle of the map as a "weak center", were recoded to adjacent clusters based on manual review of the statements by the authors (CK and JD). Statements 27, 56, and 62 were recoded to Cluster 5 (Hub Processes and Operations); Statements 47 and 58 were recoded to Cluster 6 [*Diversity, Equity, Inclusion, and Accessibility (DEIA)/Underrepresented in Research (URiR)*]; Statements 17 and 55 were recoded to Cluster 4 (*Mid-Term Outcomes*), and Statement #33 to Cluster 1 (*Long-Term Impacts*).

Given the content of the focus prompt, this map suggests a structured, comprehensive framework to discuss and assess various potential measures to be used to evaluate whether the CTSA program is meeting its stated goals. Reading from left to right and moving clockwise on the map, the clusters can be described as follows:

- **Hub Process and Operations:** This cluster focuses on the operational aspects of CTSA hubs, including measures like time (in days) to complete consultations, the number and types of multi-center trials supported, and the quality of services.
- **Collaboration:** This cluster examines the collaborative efforts within and between CTSA hubs, including partnerships with community members, state and local public health entities, and other CTSA hubs. It also includes measures such as tracking qualitative data on community perceptions and experiences with research.
- **Diversity, Equity, Inclusion, and Accessibility (DEIA)/Underrepresented in Research (URiR):** This cluster includes measures around the integration of diversity and inclusion in clinical research, with examples such as the relative availability of research materials in different languages and the participation of underrepresented populations in clinical trials.
- **Clinical Translational Research (CTR) Training & Careers:** These measures focus on training and career development. This cluster includes measures such as the number of training programs, overall mentorship satisfaction,

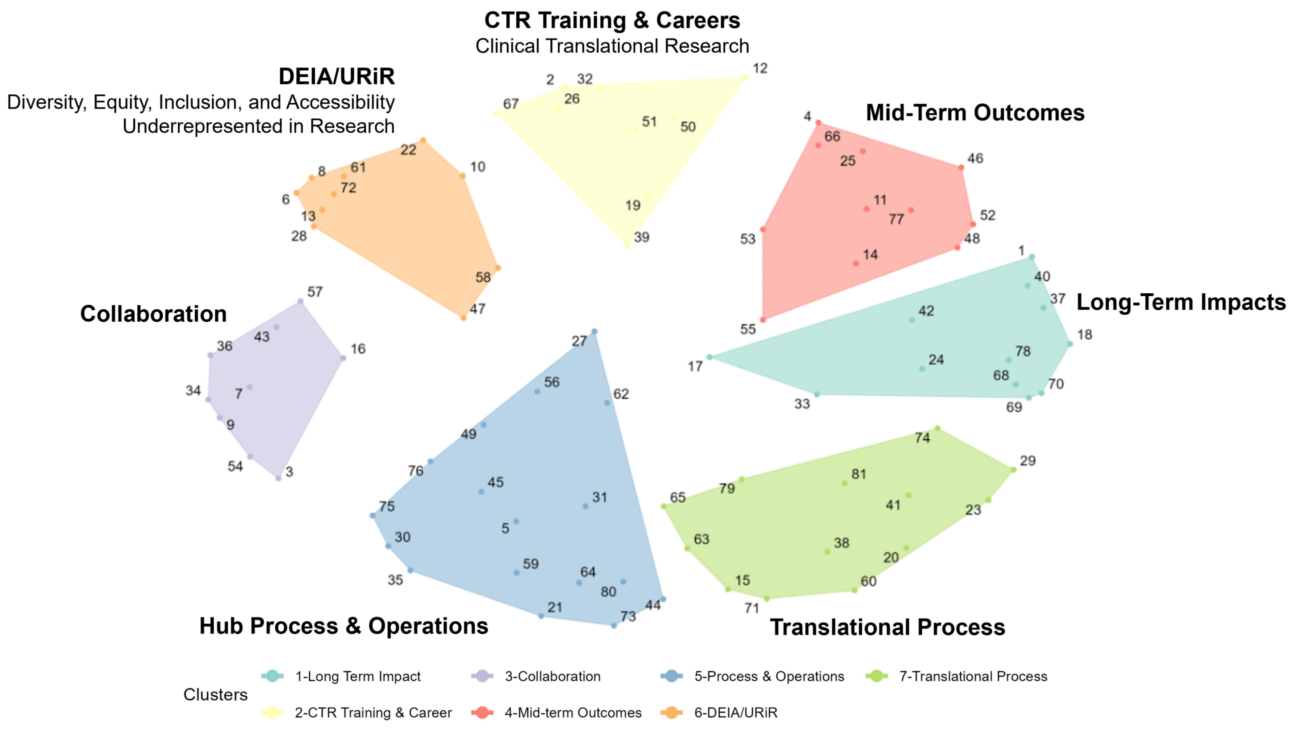

FIGURE 1
A concept map of CTSA measures.

ASSUMPTIONS:

- **Collaboration** is a part of all activities in this logical progression, acting as the conduit between "Hub Processes & Operations" and various types of participant measures ("DEIA/URiR, CTR Trainees")

FIGURE 2
CTSA evaluation concept map clusters arranged as a logical process model.

specific career outcomes, and the retention of trainees in research.

- **Mid-Term Outcomes:** This cluster aims to track mid-term progress such as the more proximal impact of hub-supported projects on subsequent publications or grants, bibliometric indicators or changes in promotion and tenure policies.
- **Long-Term Impacts:** This cluster includes measures for the broad, long-term effects of CTSA activities, such as the number of Food and Drug Administration (FDA) approvals, economic and community health benefits, and/or policy or legislative impacts. It also contains measures around systematic reviews and high-level success stories. Notably, all Translational Science Benefits Model (TSBM) measures (numbers 68, 69, 70, and 78) were sorted thematically into this cluster.
- **Translational Process:** This cluster concentrates on tracking the progression of research from the early stages of discovery to clinical application. Measures include the use of retrospective case studies, or the tracking of research across the translational spectrum (e.g., from bench to clinical trials).

Figure 2 shows a logical progression with the clusters from our map in Figure 1 "flattened" and listed in temporal order. Working clockwise from the bottom of the map in Figure 1, we begin the process in Figure 2 by first listing CTSA Activities such as *Hub Processes and Operations (5)* (how hubs carry out their work). We can compress the next two clusters in the map: *Diversity, Equity, Inclusion, and Accessibility (DEIA)/Underrepresented in Research (URiR; 6) and CTR Training & Careers (2)* into a single common phase in Figure 2 focused on key Participants, with *Collaboration (3)* as a critical component for all relevant participants in

TABLE 2 Concept mapping measures.

Statement	Cluster	Statement	GoZone category	Mean importance	Mean feasibility
1	1	Number and type of patents or trademarks filed and/or received (e.g., IP data, implementation science etc.)	High feasibility low importance	3	3.58
2	2	Number and type of trainings offered by Hub (e.g., courses, certificates, workshops, seminars, tracks, etc.)	High feasibility high importance	3.68	4.17
3	3	Institutional collaboration and commitment to clinical and translational science research (e.g., number of projects and protocols, in-kind support, $ and personnel)	Low feasibility high importance	3.59	3.07
4	4	Number of pilot grants advancing to clinical trial proposals and/or awards	High feasibility high importance	3.86	3.92
5	5	Median time to complete CTSA Hub-supported consultation and/or services (duration in days)	Low feasibility low importance	2.51	3.08
6	6	Number and type of measurable plans, policies or changes related to diversity, equity, and inclusion	Low feasibility high importance	3.74	2.68
7	3	Number and types of CTSA Hub interactions with state, local and public health entities	Low feasibility low importance	3	2.67
8	6	Qualitative data regarding how gender and racial diversity in clinical translational research can be achieved and/or what is needed	Low feasibility high importance	3.7	2.66
9	3	Number and types of new or ongoing collaborations with multiple CTSA Hubs and/or national consortium	High feasibility high importance	3.59	3.65
10	6	Number and percent of pilot awardees overall and by relevant demographics (e.g., women and underrepresented populations)	High feasibility high importance	3.64	4.23
11	4	For newly emerging health crises requiring a rapid response: Number of CTSA-affiliated investigators publishing relevant results within X period of time (in months or years)	High feasibility low importance	3.23	3.24
12	2	Relative familiarity with the term “translational science” among key indicator groups (healthcare providers, leaders of relevant community organizations and academic faculty in relevant fields)	Low feasibility low importance	2.69	2.36
13	6	Number and type of underrepresented populations in clinical trials tool	High feasibility high importance	4.14	3.34
14	4	Number and type of CTSA Hub supported services with subsequent grants and/or publications cited	High Feasibility High Importance	3.52	3.26
15	7	Number of different CTSA initiatives with a specific focus on >1 of the following: quality, safety, efficiency and effectiveness of clinical research	Low feasibility low importance	2.99	2.88
16	3	Number, type, duration, and quality of Hub-supported community engagement services and tools	High feasibility high importance	3.64	3.26
17	1	Number of datasets made discoverable as a result of Hub-supported Informatics resources	High feasibility high importance	3.28	3.29
18	1	The collection of high-level success stories (e.g., novel approaches or collaborations, mitigating translational science roadblocks)	High feasibility high importance	3.85	3.29
19	2	Number and type of changes in promotion and tenure policy as the result of Hub activities	Low feasibility low importance	2.87	2.37
20	7	Number of Hub supported opportunities created for novel care approaches for clinical research participants relative to other regional providers	Low feasibility low importance	2.87	1.96
21	5	Cost per participant enrolled in NIH-supported clinical trials	Low feasibility low importance	2.69	2.39
22	6	Scientific interdisciplinarity as measured by number and type of Doctoral/MBA/MPH degree types, scientific areas, and/or collaborations between and support of various departments, in Hub-supported work	Low feasibility low importance	2.86	2.77
23	7	Return on investment (ROI): The timing and magnitude of expected total gains relative to the timing and magnitude of expected total costs	Low feasibility low importance	3.2	2.24
24	1	Systematic reviews and/or meta evaluation (e.g., the Cochrane or Campbell Collaboration showing the reproducibility of results published in a discipline over a set time period)	Low feasibility low importance	2.75	2.64

(Continued)

TABLE 2 (Continued)

Statement	Cluster	Statement	GoZone category	Mean importance	Mean feasibility
25	4	Number and/or percent of Hub-supported Pilot projects with >1 subsequent publication	High feasibility low importance	3.16	4.15
26	2	Number of and satisfaction with formal mentors supported by the Hub	High feasibility high importance	3.3	3.53
27	5	Types of research projects supported by Hub (e.g., T1–T4, various disciplines)	High feasibility high importance	3.3	3.64
28	6	Proportion of CTSA-affiliated investigators who request or receive CTSA Hub-supported materials in a language other than English	Low feasibility low importance	2.42	2.73
29	7	The use of retrospective case studies	Low feasibility low importance	2.57	2.88
30	5	Number and type of active multi-center trials	High feasibility high importance	3.39	3.95
31	5	Qualitative measures of Hub services quality (satisfaction, reliability, responsiveness)	High feasibility high importance	3.43	3.27
32	2	Number and types of knowledge and/or skills attained by participants of trainings offered by Hubs	Low feasibility high importance	3.44	3.02
33	1	Number and type of new programs as a result of CTSA Hub activity (e.g., entrepreneurship, translational science.)	High feasibility high importance	3.4	3.31
34	3	Number and types of collaborative research projects and collaborators within a CTSA Hub	High feasibility high importance	3.52	3.19
35	5	Number and type of available infrastructure or resources for multi-site clinical trials per CTSA Hub (e.g., Access to underrepresented populations, Clinical Trials Management Systems/EHR, etc.)	High feasibility high importance	3.46	3.44
36	3	Number and types of Hub collaborations with community members, advisors or partner agencies	High feasibility high importance	3.85	3.37
37	1	CTSA Hub-level listing of scientific and operational innovations developed, demonstrated, and disseminated	Low feasibility high importance	3.82	2.88
38	7	Number and type of actions generated from RPPR review within a CTSA Hub	Low feasibility low importance	2.44	2.95
39	2	Number of CTSA hub website page views	High feasibility low importance	2.04	4.51
40	1	Number and type of award-winning innovations developed at CTSA Hubs	High feasibility low importance	3.13	3.24
41	7	Tracking Hub-supported research from one step to the next on the translational spectrum (T1, T2, T3, etc.) via operational markers (e.g., first in human, clinical trial phases, FDA approval, etc.)	Low feasibility high importance	3.47	2.28
42	1	Number of FDA approvals received by CTSA Hubs	High feasibility low importance	3.16	3.78
43	3	Qualitative data regarding community experiences with and perceptions of research (trust, community value, equity, researcher preparedness, and indicators of successful engagement) and perceptions of optimism regarding positive health outcomes	Low feasibility high importance	3.89	2.83
44	5	Duration (raw number or median) in days from start to finish of IRB application (Common Metric: Could also be applied for sIRB or eSRC)	High feasibility low importance	3.18	3.95
45	5	Number and type of CTSA Hub supported service consultations and services	High feasibility low importance	3.19	4.05
46	4	Frequency and reach of CTSA-affiliated personnel interviewed by the media	Low feasibility low importance	2.18	2.64
47	6	Number of researchers served by the CTSA Hub (overall and by percent of relevant demographics e.g., women and Underrepresented Populations)	High feasibility high importance	3.53	3.41
48	4	The Altmetric Attention Score (a weighted count of all of the online attention discoverable for an individual research output, including but not limited to social media, news, and policy documents)	High feasibility low importance	2.7	3.19

(Continued)

TABLE 2 (Continued)

Statement	Cluster	Statement	GoZone category	Mean importance	Mean feasibility
49	5	Tracking number of new Hub personnel (e.g., tracking key personnel changes over time, turnover rate)	High feasibility low importance	2.51	3.63
50	2	Number, type and percent of career impacts on participants in Hub-supported career development (e.g., promotion, subsequent funding, leadership)	Low feasibility high importance	3.69	3.02
51	2	Number and percent of trainees and scholars who remain engaged in research after training (Common Metric: Overall and by relevant demographics e.g. women, underrepresented populations, etc.)	High feasibility high importance	3.87	3.51
52	4	Bibliometrics, general (e.g., the wide range of bibliometrics used in academia such as the H-index or the Journal impact factor)	High feasibility low importance	2.97	3.75
53	4	Time from end of pilot grant to first subsequent grant and/or publication (duration in days)	High feasibility low importance	2.85	3.14
54	3	Team Science readiness regarding issues such as Authorship & Credit; Contingencies & Communicating; and Conflict of Interest (e.g., Checklist published by the National Cancer Institute)	Low feasibility low importance	2.98	2.41
55	4	Number and type of NIH institutes or programs (outside of NCATS) using CTSA resources or CTSA developed resources	Low feasibility low importance	2.99	2.39
56	5	Number and type of Hub-supported faculty involved in clinical research	High feasibility low importance	3.19	3.57
57	3	Number and type of community members trained by Hubs	High feasibility high importance	3.45	3.28
58	6	Number and types of CTSA Hub supported research studies (e.g., those involving health disparities or special populations)	High feasibility high importance	3.72	3.61
59	5	Number (and growth in number) of patients enrolled into Hub supported trials	High feasibility high importance	3.48	3.58
60	7	Measures of data quality including performance data readability, relevance, reliability, representative, and reproducibility in Hub supported research	Low feasibility high importance	3.39	2.3
61	6	Proportion of positions representing individuals from underrepresented populations in research across the biomedical workforce (i.e., coordinators, technicians, analysts, not just investigators, or Hub leadership)	Low feasibility high importance	3.57	2.58
62	5	Number of new and repeat investigators receiving CTSA Hub services	High feasibility low importance	3.06	3.9
63	7	Reduced number of deferrals in CTSA Hub-supported research projects	Low feasibility low importance	2.33	2.51
64	5	Time to activation of new clinical trials supported by the CTSA Hub (in days)	High feasibility high importance	3.26	3.42
65	7	Qualitative data regarding number and kinds of barriers faced by Hubs	Low feasibility high importance	3.57	2.87
66	4	Number and/or percent of Hub supported Pilot projects with >1 subsequent grant for extramural funding	High feasibility high importance	3.32	3.73
67	2	Number and percent of KL2 and/or TL1 applicants, participants and graduates (overall and by relevant demographics, e.g., women, underrepresented populations, etc.)	High feasibility high importance	3.93	4.4
68	1	Number and type of Clinical and Medical Benefits (from Translational Science Benefits Model. e.g. procedures, guidelines, tools, and products)	Low feasibility high importance	3.71	2.66
69	1	Number and type of Economic Benefits (from Translational Science Benefits Model. e.g., commercial products, financial savings and benefits)	Low feasibility high importance	3.43	2.35
70	1	Number and type of Community and Public Health Benefits (from Translational Science Benefits Model. e.g., health activities, care, and promotion)	Low feasibility high importance	3.68	2.51
71	7	Changes made at a Hub in response to Rapid Cycle Quality Improvement (RCQI) by theme and percentage change	Low feasibility low importance	2.69	2.25

(Continued)

TABLE 2 (Continued)

Statement	Cluster	Statement	GoZone category	Mean importance	Mean feasibility
72	6	Quantitative measures of CTSA leadership, staff, and supporting institution and/or catchment area by demographic diversity (Underrepresented populations, gender, early-career, socioeconomic status, etc.)	Low feasibility high importance	3.36	3.04
73	5	Clinical trial process quality (e.g., number of audits, monitoring or biorepositories, adherence to FDA requirements)	Low feasibility high importance	3.25	2.96
74	7	Number of outcomes and innovations of CTSA supported and/or funded clinical research (e.g., quality, safety, efficacy, clinical and behavioral innovations and/or outcomes, IND, etc.)	Low feasibility high importance	3.67	2.63
75	5	Number of CTSA Hubs integrating EHR data (i.e., feasibility, recruitment)	High feasibility high importance	3.37	3.52
76	5	Average time to fill clinical research professionals (CRP) positions relative to other, readily available staff positions (duration in days)	Low feasibility low importance	2.64	2.64
77	4	Number of publications by CTSA Hub-affiliated authors overall, and percent by authors demographics (e.g. gender and underrepresented populations, field...)	High feasibility low importance	3.17	3.43
78	1	Number and type of Policy and Legislative Benefits (from Translational Science Benefits Model. E.g., advisory activities, policies and legislation)	Low feasibility high importance	3.4	2.51
79	7	Proportion of phase 1 clinical trials (T1) to bench studies (T0) supported by the CTSA Hub	Low feasibility low importance	2.79	3
80	5	Number or percent of studies reaching the median accrual ratio (Common Metric: percent of participants accrued divided by percent of recruitment period to date)	Low feasibility low importance	3.16	2.97
81	7	Number of Hubs reporting on activities within a measurable period of time once an urgent public health need is identified for the national CTSA consortium (readiness/rapid response in days or months within specified categories, e.g., research, education, training, community engagement etc.)	Low feasibility high importance	3.47	2.8

the Activities phases. Continuing clockwise around Figure 1 to inform the process phases in Figure 2, we can next list clusters for Outcomes *Mid-term Outcomes (4)* (immediately observable intermediate results) followed by *Long-term Impacts (1)* (final consequences or effects) and finally *Translational Processes (7)* (the ultimate mission of the CTSAs, to move research from discovery to application). Thus, whether viewed clockwise on the concept map (Figure 1) or as a simplified linear progression (Figure 2), our project participants logically grouped the measures related to CTSA Activities (formative evaluation) in specific logical relation to those corresponding to Outcomes and Impacts (summative evaluation). In reviewing both graphic depictions, we can see that project participants showed agreement not only in a comprehensive list of measures in general, but in a rational thematic framework for where these measures belonged relative to the evaluation of the CTSA program.

Figure 3 shows the parallel coordinates plots, or "ladder graphs", which describe the relationship between feasibility and importance for the 81 measures. Bonferroni corrected p-values indicate that the mean feasibility and mean importance for all seven clusters were statistically different except for CTR Training and Careers ($p = 0.009$); but the magnitude of the difference varied by cluster. On average, more than half of the seven clusters of measures were rated as appreciably more important than feasible, with lower averages overall on the feasibility side of the figure. *Translational Process (7) and Long-Term Impacts measures (1)* stood out as the least feasible relative to their importance. Notable exceptions were *Mid-Term Outcomes (4)* and *Hub Processes and Operations (5)*, which were the only clusters rated as less important than feasible on average. Interestingly, these clusters are more closely tied to the daily activities of CTSA hubs and are frequently utilized for external reporting as well as for internal review by hub leadership.

Subgroup heterogeneity by participant type is evident when the data were disaggregated, as seen in Figure 4. Figure 4 ("ladder graphs") stratifies average ratings for Mean Importance (left) and Mean Feasibility (right) by the three primary participant roles: CTSA Administrators, CTSA Evaluators, and NCATS staff. Here the pattern of high importance and low feasibility regarding *Long-Term Impacts (1)* can be seen in more relief when broken out by participant type. On the left of Figure 4, in regards to relative average importance, the steep angle of *Long-Term Impacts (1)* illustrates Administrators ranking this cluster in the bottom third, whereas Evaluators and NCATS staff ranked the same cluster in the top third. *Mid-term Outcomes (4)* and *Long-Term Impact (1)* represent the most pronounced, statistically different discrepancies in average importance ratings between CTSA Evaluators and Administrators. Moreover, both NCATS staff and CTSA Administrators had average importance ratings that were not statistically different from CTSA Evaluators on these two clusters. In contrast, NCATS staff rated almost all measures as more important on average than their peers in Administration and Evaluation in terms of the magnitude of their means, but were only

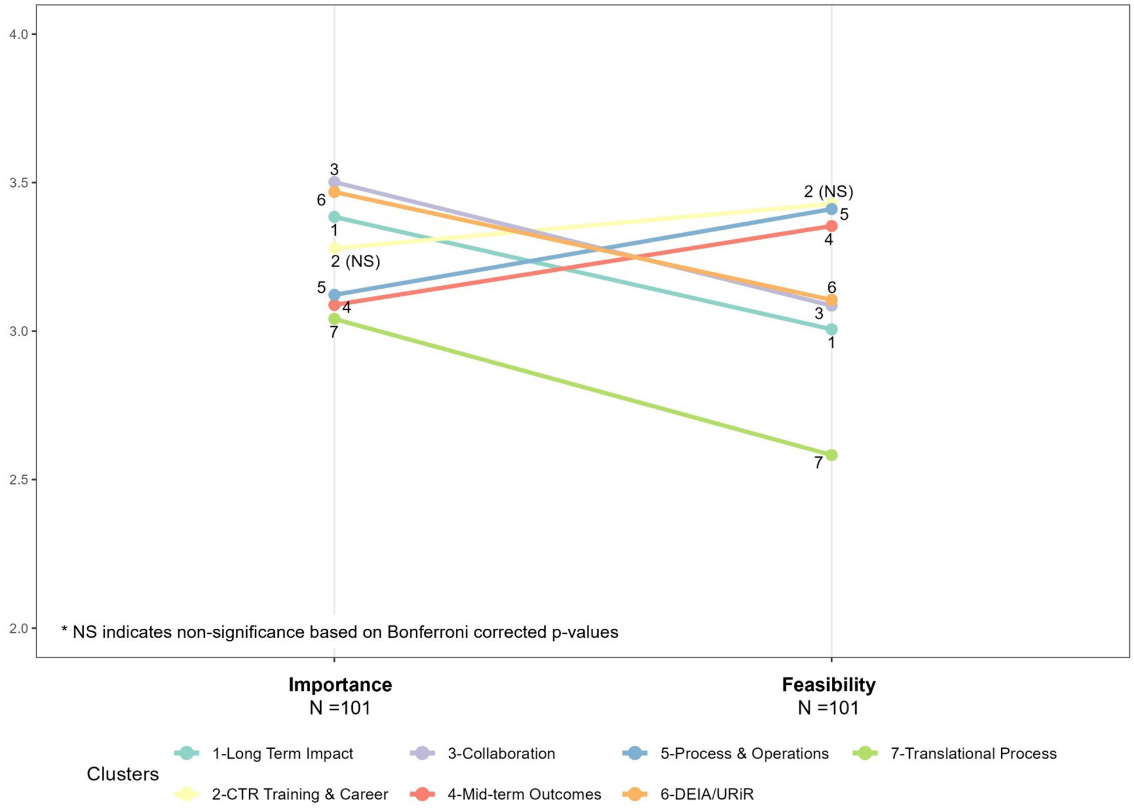

FIGURE 3
Parallel coordinates plots (or "ladder graphs"), mean feasibility and mean importance.

statistically different from CTSA Evaluators on *Collaboration (3)*. On the right of Figure 4, regarding relative average feasibility, there are more steep lines illustrating differences observed by cluster between CTSA Administrators and NCATS staff, and a pattern of more agreement between the feasibility ratings of CTSA Evaluators and NCATS staff. The mean feasibility ratings between CTSA Evaluators and NCATS staff are not statistically different across nearly all clusters of measures except for *Translational Process (7)* shown at the bottom of the graph. Overall, these trends in Figure 4, along with low Bonferroni-corrected *p*-values—show the most measurable disagreement in the feasibility ratings for CTSA Administrators vs. the other two subgroups (CTSA Evaluators and NCATS staff). The Significance Tests for Ladder Graphs by Group are shown in Table 3.

Figure 5 visually represents all measures as single points based on their average Feasibility and Importance ("GoZone plot"). Measures with highly rated importance and feasibility can be seen as points in the upper right side of the Figure, whereas measures with relatively low importance and feasibility can be seen as points on the lower left. High Feasibility-Low Importance and Low Feasibility-High Importance measures appear in the upper left and lower right, respectively. The lower right quadrant—Low Feasibility-High Importance measures—is of particular interest with respect to the differing rating levels between Administrators, Evaluators and NCATS staff especially in regard to *Long-Term Impacts (1)* and TSBM. For instance, measures 68 (Number and type of Clinical and Medical Benefits), 69 (Number and type of Economic Benefits), 70 (Number and type of Community and Public Health Benefits), and 78 (Number and type of Policy and Legislative Benefits) directly reference the full scope of the TSBM, a framework gaining popularity across the CTSA consortium (25, 26). *Translational Processes (7)* is also well-represented in the lower-right quadrant, with measures such as data quality (Statement 60), CTSA hub-level listing of scientific and operational innovations developed, demonstrated and disseminated (Statement 37), tracking hub-supported research from one step to the next on the translational spectrum (Statement 41), the number of outcomes and innovations of CTSA supported and/or funded clinical research (Statement 74) rated, on average, as having high importance but low feasibility.

4 Discussion

The purpose of this study was to conduct a comprehensive analysis of the range of measures for assessing the CTSA program's goals and to identify areas of consensus and differing perspectives. This effort resulted in three main findings. First, the concept mapping activity yielded a broad range of measures ($N = 81$). In terms of the overall volume of statements per themed cluster, *Process and Operations* had the greatest number of measures (>50% larger than the median). However, it stands to reason that in any large and complex program such as the CTSA, it is likely that causality will operate through many multiple pathways (the

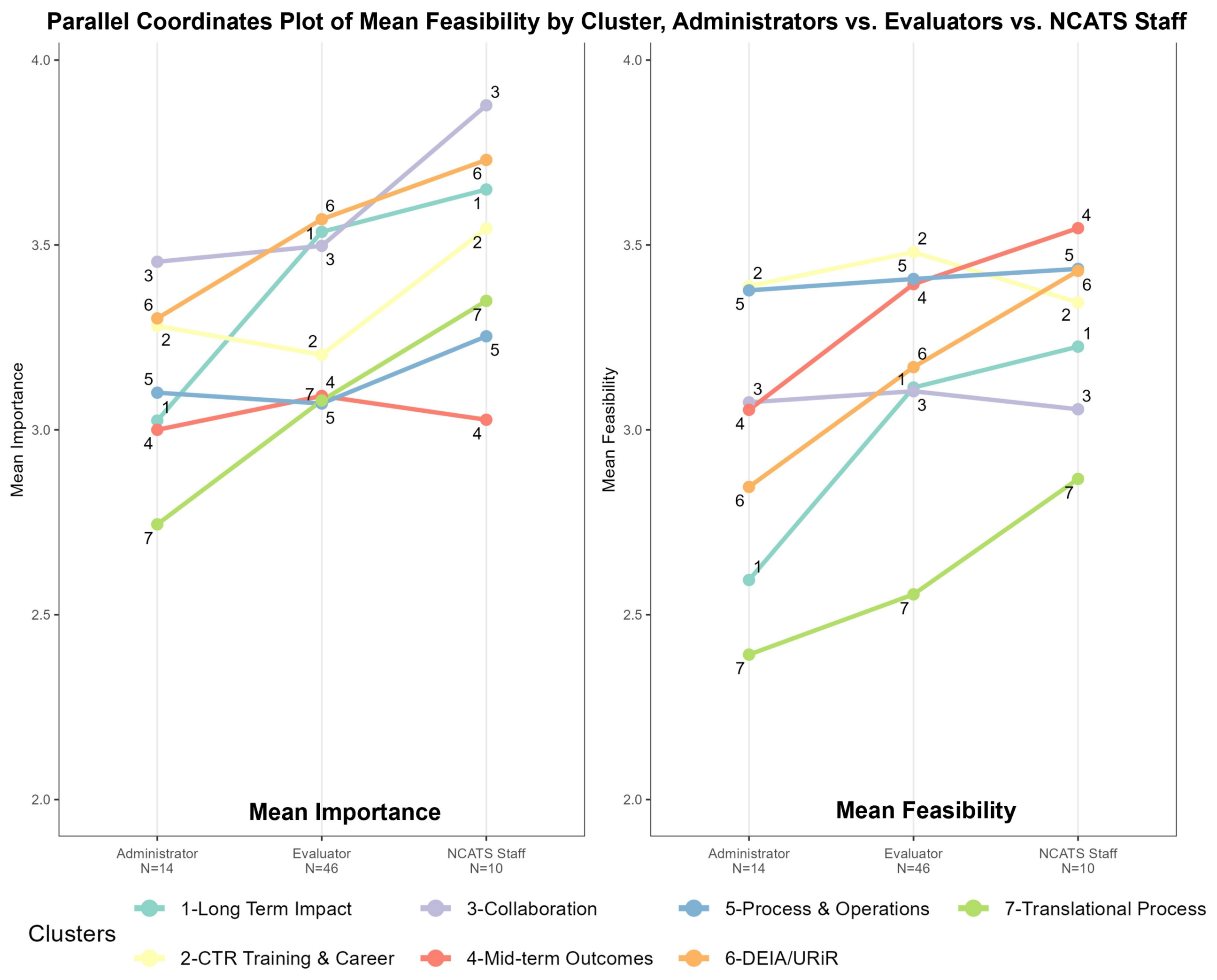

FIGURE 4
Feasibility vs. importance "ladder graphs" by primary participant type: CTSA administrators, CTSA evaluators, and NCATS staff.

intentional use of multiple processes) toward a common goal (a smaller focused set of desired outcomes and impacts). Second, the clusters in our concept map corresponded with the components of a traditional logic model, illustrating the expected progression from actions to outcomes. Measures focused on CTSA activities and processes are included in the clusters represented on the left side of the map, and progress to measures associated with outcomes and impacts on right side of the map. A related finding was the TSBM measures were arrayed in a tight configuration on the far-right side of the map. This spatial placement and consolidation suggest that many participants classified the TSBM measures similarly. Third, the analyses stratified by role (in Figure 4: "ladder graphs") showed diverging views on importance and feasibility by participant role (CTSA Evaluator vs. CTSA Administrator vs. NCATS staff), particularly regarding *Long-term Impact* measures, which included the TSBM (four out of nine measures in the cluster). There was also a striking and widespread consensus on the overall *importance* of the long-term impact measures. Evaluators and NCATS staff in particular showed marked consensus on the importance of long-term measures, However, this agreement sharply contrasted with the pronounced disagreement regarding the *feasibility* of implementing these measures in practice, revealing a substantial divide among key stakeholders. Interestingly, the vast majority of long-term impact measures ranked with both highly importance and low feasibility centered almost exclusively on the TSBM (in Figure 5: GoZone plot).

The patterns in these findings could be due to several factors. The discrepancies in perceived feasibility and the heavy representation of processes and operations measures could reflect functional differences in day-to-day responsibilities and scopes of work across roles. For example, *Hub Processes and Operations* was the cluster with the largest number of measures. Many of these measures are linked to narratives reported in annual progress reports (Measure #45: "Number and type of CTSA hub supported service consultations and services") and continuous quality improvement activities routinely conducted at most hubs [Measure #64: Time to activation of new clinical trials supported by the CTSA hub (in days)]. These measures lie at the

TABLE 3 Significance tests for ladder graphs by group.

Group	Importance			Feasibility		
	Evaluators vs. NCATS	Evaluators vs. administrators	Administrators vs. NCATS	Evaluators vs. NCATS	Evaluators vs. administrators	Administrators vs. NCATS
1	0.24	$p < 0.0001$*	$p < 0.0001$*	0.24	$p < 0.0001$*	$p < 0.0001$*
2	0.01	0.54	0.12	0.28	0.49	0.79
3	0.0001*	0.70	0.00	0.65	0.81	0.90
4	0.54	0.39	0.84	0.17	0.004*	0.001*
5	0.04	0.73	0.16	0.75	0.74	0.61
6	0.13	0.02	0.002*	0.02	0.01	0.0001*
7	0.02	0.001*	$p < 0.0001$	0.001*	0.09	$p < 0.0001$*

*Significance thresholds are based on Bonferroni-corrected p-value threshold of 0.007.

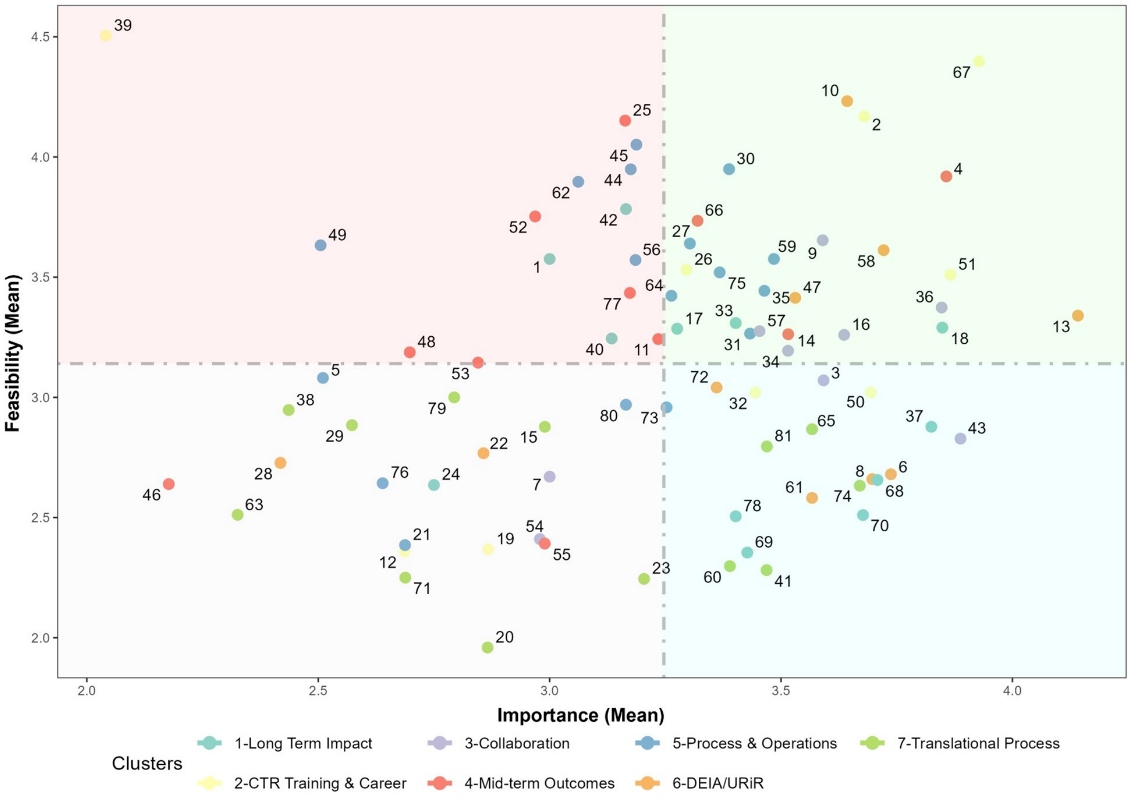

FIGURE 5
Feasibility vs. importance "go-zone" plot for all concept mapping measures.

intersection of work that CTSA Evaluators and Administrators perform each year. However, Administrators, specifically, must prioritize proximal process measures aligned with hub operations, whereas Evaluators often find themselves balancing short-term programmatic reporting and deliverables with broader, hypothesis-driven questions NCATS staff are required to monitor program performance and across the consortium. Another consideration is that the contrasting views on feasibility by roles may reflect overall familiarity with measures and their implementation. For instance, in the concept mapping interpretation group, one CTSA Administrator expressed concern that measuring "*Number and Type of Economic or Public Health Benefits*" in their catchment area would be challenging. They wondered how to access economic data and grappled with the complexities of attribution vs. contribution. Meanwhile, in the same meeting, an Evaluator shared how their team already used several TSBM survey questions, collected through trainee applications, exit interviews and alumni surveys to gather high-level self-reported data. This highlighted a contrast: one side believed they needed sensitive, detailed financial measures in order to operate within the TSBM framework, while the other had already integrated straightforward self-reported surveys to capture essential data. In this short meeting, the Administrators learned that *both* types of data could be used within TSBM; broad economic indicators and individual success stories both fit in this flexible framework for measuring impact.

It should be noted that this concept mapping study had several limitations that must be considered when interpreting its findings. First, the concept mapping process relied on voluntary participation across the CTSA consortium, which may have introduced self-selection bias, as participants with stronger opinions or familiarity with evaluation practices may have been more likely to contribute. Second, the majority of participants were drawing on the perspective of a single hub (Evaluators and Administrators), and the total number of NCATS staff was relatively low. This means that the greater part of the feedback stemmed from a hub-specific rather than a consortium level perceptions and experiences. Third, all participants were part of the CTSA program in some manner, which may have introduced additional bias based on the preponderance of internal perspective. Fourth, while the RCMap package provided robust analytical tools for clustering and visualizing participant input, the manual reassignment of certain measures to specific clusters introduces a degree of subjectivity, potentially influencing the final cluster configurations. Fifth, given the rapidly evolving nature of translational science and the specific goals outlined in the NCATS Strategic Plan (27), the measures identified here may require regular updates to remain aligned with emerging priorities, technological advancements, and evolving program goals. Finally, in the specific context for this discussion, it is also important to note that concept mapping is a tool for illustrating the composite thinking of a diverse group at a single point in time, rather than a means for providing incontrovertible or static answers. For example, the feasibility and importance ratings illustrated in the Go-Zone charts and ladder graphs are based on subjective assessments at a single point in time, which may be influenced by respondents' individual experiences, familiarity with particular measures, and role-specific priorities.

Nevertheless, these findings suggest that there is no shortage of available measures to assess the CTSA programmatic goals, but there may be a lack of consensus on how to implement them effectively and efficiently. This opens opportunities for future work. These concept mapping results could support multiple complimentary frameworks such as a consortium-wide logic model and the TSBM. While individual CTSAs may have developed logic models to address local needs and individual grant aims (28), a logic model for the consortium has not yet been developed. Using the results of this concept map as a foundation for this model would have the benefit of being a "bottom up" and data-driven exercise representing the thinking of the wide range of participants as opposed to a "top down" exercise with authorship and buy-in limited to a minority of stakeholders. Simultaneously, these same findings highlight that while TSBM measures are currently recognized as highly important, there are significant challenges around perceptions on feasibility. This provides a focused starting point for developing strategies to address and overcome these barriers to evaluation implementation.

This project also revealed practical opportunities for NCATS to provide strategic leadership by integrating the interdisciplinary insights of Evaluators and Administrators. The concept mapping process and results from this analysis create a starting point for future collaborative evaluation activities centered on assessing the CTSA program and its progress toward achieving its goals. Just as there are many roads to Rome, there are many ways to support translation in clinical research. As reflected in the concept map, on the activities side of the logical progression we have numerous interventions and collaborations to support clinical translational research. By the time we get to the outcomes side of the logical progression we are essentially listing impact measures that revisit the central mission of the CTSA program: To increase the pace of development and availability of treatments; to enable more individuals and communities to contribute to and benefit from translational science; and to identify and address inefficiencies in translation that slow and even stop research efforts (27). To fully leverage the strengths of CTSA Evaluators, Administrators, and NCATS staff, it is essential to embrace their distinct roles and responsibilities. Administrators focus on monitoring their own hub's operations, NCATS oversee consortium-wide outcomes and impacts, and Evaluators bridge these perspectives, balancing program-level reporting with broader questions of long-term effects. These differences are not limitations, but integral features of the system's structure, presenting opportunities for collaboration to enhance the full breadth of evaluation of the CTSA program.

Ultimately, the most difficult and pressing work will not lie in the selection of measures, but in driving coordinated CTSA evaluation across the consortium. Frameworks like concept mapping, logic modeling, and TSBM offer concrete signposts on the "many roads to Rome"; but their utility in this navigation depends on coordinated direction. Of all three roles represented in this study, only NCATS has the unique perspective and operational authority to endorse a unified CTSA logic model associated with a specific set of impact measures. They are also the only contributors with the level of access and critical resources necessary to collect and analyze aggregated data for a program of this complexity, scale and importance. By using data from these findings to guide their ongoing efforts, NCATS can strengthen its ability to assess whether the CTSA is meeting its goals and demonstrate the program's broader value. If we are to overcome the roadblocks on the path to evaluation, there is an opportunity ahead to harness and align the unique perspectives and strengths of CTSA Evaluators, Administrators and NCATS consortium leadership. By setting a course centered around a shared vision for the way forward, these frameworks can guide us in the effective evaluation of the long-term impact of the CTSA Program.

Data availability statement

The raw data supporting the conclusions of this article will be made available by the authors, without undue reservation.

Ethics statement

Ethical review and approval were not required for the study on human participants in accordance with the local legislation and institutional requirements. Written informed consent from the (patients/participants or patients/participants legal guardian/next of kin) was not required to participate in this study in accordance with the national legislation and the institutional requirements. The research was conducted in accordance with ethical principles for integrity, transparency, and responsible scholarship.

Author contributions

CK: Conceptualization, Formal analysis, Methodology, Project administration, Visualization, Writing – original draft, Investigation, Supervision, Resources. WT: Writing – review & editing, Methodology. HBar: Data curation, Formal analysis, Methodology, Resources, Software, Validation, Visualization, Writing – review & editing. AV: Writing – review & editing. HBak: Writing – review & editing. MK: Writing – review & editing. RW: Formal analysis, Writing – review & editing. KHo: Data curation, Methodology, Resources, Writing – review & editing. KHe: Data curation, Methodology, Resources, Writing – review & editing. JD: Conceptualization, Data curation, Formal analysis, Methodology, Project administration, Resources, Software, Supervision, Validation, Visualization, Writing – original draft.

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Conflict of interest

The authors declare that the research was conducted in the absence of any commercial or financial relationships that could be construed as a potential conflict of interest.

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The author(s) declare that no Gen AI was used in the creation of this manuscript.

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EDITED BY
Joe Hunt,
Indiana University, Purdue University Indianapolis, United States

REVIEWED BY
Jiban K. Pal,
Indian Statistical Institute, India
Carolynn Thomas Jones,
The Ohio State University, United States

*CORRESPONDENCE
Maryam Gholami
✉ mgholami@health.ucsd.edu

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Modernizing CTSA hub evaluation: an integrated system for performance monitoring and translational science impact assessment

Maryam Gholami[1]*, Elizabeth Johnson[1,2], Kera Swanson[1], Carlos Rojas[1] and Daniel Bouland[1]

[1]Altman Clinical and Translational Research Institute (ACTRI), University of California San Diego Health, La Jolla, CA, United States, [2]The San Diego Center for AIDS Research (CFAR), University of California San Diego Health, La Jolla, CA, United States

Background: The Evaluation Unit at the Altman Clinical and Translational Research Institute (ACTRI) implemented a balanced scorecard model in conjunction with a project management tool to consolidate data collection for progress monitoring, strategic alignment, and impact assessment. This approach aims to streamline communication and enhance information accessibility for all partners. We developed an efficient system for collecting, analyzing, and reporting key information on unit progress, impact, and alignment with institutional goals. The Translational Science Benefits Model (TSBM) was proposed as a framework to evaluate the broader impact of our translational research, beyond immediate scientific advancements, across clinical, societal, economic, and policy domains.

Methods: The ACTRI Evaluation Unit initially adapted the balanced scorecard (BSC) to the research environment, substituting business perspectives with research grant aims. In its second iteration, the BSC was integrated into Monday.com, a project management platform, to create customized, real-time monitoring dashboards for each unit within the institute. The Evaluation Unit's 3.0 version further adapted the TSBM to assess the broader impacts of unit activities. Quarterly data collection was implemented, and partners were trained in impact assessment and dashboard usage. This process began in early 2023 and is ongoing.

Results: Eleven monitoring dashboards were developed and successfully implemented across the institute. The new system facilitated more efficient data collection and reporting, reducing communication overhead and increasing the frequency of updates. The data collected were utilized to draft annual reports as well as inform strategic planning and executive sessions.

Conclusions: Integrating the TSBM into our existing BSC framework, combined with a project management tool, effectively streamlined impact assessment and progress monitoring. This approach not only enhanced data collection and reporting efficiency but also encouraged units to align their goals and activities with desired impacts, thereby strengthening the institute's overall strategic focus.

KEYWORDS

impact assessment, progress tracking, process monitoring, evaluation, translational science benefits model

Introduction

In the rapidly evolving landscape of clinical and translational science, effective evaluation, impact assessment, and strategic alignment have become increasingly crucial for research institutions (Trochim et al., 2013). The University of California San Diego (UCSD) Altman Clinical and Translational Research Institute (ACTRI) has recognized this need and implemented an innovative approach to address these challenges.

The Evaluation Unit at the ACTRI plays a pivotal role in supporting program and unit leaders in planning, executing, and monitoring their activities. This support ensures that all efforts are aligned with organizational goals and contribute to continuous performance improvement. To facilitate this process, the Evaluation Unit identified the need for a robust measurement system that would enable the ACTRI units to assess their progress and develop targeted improvement plans (Croucher et al., 2018; Himanen and Puuska, 2022).

In 2012, building upon the success of the Balanced Scorecard (BSC) implementation in the academic department of medicine (Bouland et al., 2011), the ACTRI's Evaluation Unit adopted an electronic version of the BSC for strategic management purposes (Hoyo and Bouland, 2022).

The Balanced Scorecard (BSC) functions as a strategic management framework that enables organizations to translate their vision into measurable objectives (Kaplan and Norton, 1992).

Rather than focusing exclusively on financial metrics, the BSC provides a multidimensional approach to performance assessment. The framework facilitates the conversion of strategic goals into actionable initiatives with clear performance indicators. By monitoring progress across multiple perspectives—financial performance, customer relationships, internal processes, and organizational learning—leadership teams gain comprehensive visibility into organizational effectiveness. This integrated approach to performance measurement allows executives to develop a holistic understanding of operations and make data-driven decisions that support long-term strategic objectives. The BSC thus bridges the gap between strategic planning and operational execution, ensuring alignment throughout the organization.

In 2022, to further enhance efficiency and streamline progress management, the Evaluation Unit migrated the BSC to Monday.com, a widely used project management platform (Monday.com, n.d.). It was noted that customization of the BSC required more costly programming resources. Monday.com offered a visual and collaborative workspace where teams could create and customize workflows, manage tasks, track projects, and collaborate in real-time. This migration provided a more flexible and adaptive platform to meet the unique needs of the ACTRI's various units and workflows.

Complementing this approach, the ACTRI has incorporated the Translational Science Benefits Model (TSBM) to evaluate the broader impact of translational research beyond immediate scientific advancements (Luke et al., 2018). The Translational Science Benefits Model (TSBM) provides a structured framework for understanding and measuring how scientific research creates tangible value beyond academia. This model maps the progression of knowledge from laboratory discoveries to real-world applications across four distinct domains:

Clinical benefits: Improvements in patient care, treatment protocols, diagnostic capabilities, and health outcomes resulting from research implementation in healthcare settings.

Community benefits: Enhanced public health practices, increased health literacy, improved access to care, and strengthened community partnerships that collectively improve population health.

Economic benefits: Financial returns including cost savings, efficiency gains, new commercial opportunities, job creation, and broader economic development stemming from scientific advances.

Policy benefits: Evidence-based changes to regulations, guidelines, standards, and public policies that improve systems and structures affecting health and wellbeing.

The TSBM helps researchers, funders, and stakeholders systematically identify, track, and communicate the diverse impacts of their work. By providing a comprehensive evaluation framework that extends beyond traditional academic metrics (like publications and citations), the TSBM enables more accurate assessment of research's societal value and helps justify continued investment in scientific enterprise.

By integrating the BSC model with Monday.com and the TSBM framework, the ACTRI has developed a comprehensive system for data collection, progress monitoring, strategic alignment, and impact assessment. This integrated approach was developed with the goal of serving multiple purposes:

1. Streamline communication processes across the organization.
2. Enhance information accessibility to units, operations, and center leaders.
3. Provide a robust framework for evaluating the broader impact of translational research.
4. Allow for real-time tracking and management of projects and tasks.
5. Facilitate the continuous quality improvement plans based on data-driven insights.

This paper will describe the implementation of this unified system at the ACTRI, evaluation plans for its effectiveness in streamlining processes, strengthening strategic alignment, and providing a more comprehensive assessment of research impact. We will discuss the challenges encountered, the solutions developed, and the potential implications of this approach for other research institutions seeking to improve their evaluation and management processes.

Methods

In version 1.0, the process began with the ACTRI Evaluation Unit adapting the traditional BSC to suit the research environment. Instead of using standard business perspectives, we substituted these with research grant aims, aligning the scorecard more closely with our institutional goals (Bouland et al., 2011; Hoyo and Bouland, 2022). This initial adaptation laid the groundwork for the subsequent iterations of our evaluation system.

BOX 1 Streamlining multiple processes using the information collected by the ACTRI Evaluation Unit.

RPPR tables and narratives: These dashboards serve as a valuable resource for populating NIH Research Performance Progress Report (RPPR) tables and crafting accompanying narratives.

Grant proposals: The information collected is instrumental in formulating comprehensive grant proposals.

Annual external advisory committee meeting presentations: We rely on the data to create compelling presentations for our annual external advisory committee meetings.

Internal executive committee meetings: The dashboards facilitate productive discussions and decision-making during internal executive committee meetings.

Administrative and financial analyses and management: We utilize the data for in-depth administrative and financial analyses, aiding effective management practices.

The BSC provided a more robust tool for linking management to strategy. Our primary objective was to create a centralized hub offering a comprehensive solution for all partners involved in our research activities (Kaufmann and Kock, 2022; Santos et al., 2022).

In the second phase, version 2.0, we integrated the adapted BSC into Monday.com, a versatile project management platform, where multiple individuals can have access to each dashboard to import and export information. This incorporation allowed us to create customized, real-time monitoring dashboards for each unit within the institute (Monday.com, n.d.). The synergy between the BSC framework and Monday.com's functionality provided a robust foundation for our evaluation and monitoring efforts.

The widespread adoption and success of Monday.com within the ACTRI led to a strategic decision to integrate the BSCs with this platform. Monday.com was familiar to users for project management efforts, time tracking functions, process flows, and as a general go-to place for file storage and communication consolidation.

We designed the Monday.com dashboards with the specific goal of capturing only essential information to meet the needs of our hubs strategic planning goals. Our main objective is to use this data effectively for various purposes. Box 1 outlines the purposes for which we collect information through the dashboards.

Building on this foundation, the third version (3.0) of our evaluation system further incorporated the Translational Science Benefits Model (TSBM; Luke et al., 2018). This addition enabled a more comprehensive assessment of the broader impacts of unit activities across various domains, enhancing our ability to capture and communicate the full value of our research outcomes (Miovsky et al., 2023; Sperling et al., 2023). This integration creates a powerful system that not only tracks operational metrics but also captures the multidimensional societal value of our research initiatives. By implementing this framework through the accessible Monday.com platform, we've created an intuitive, centralized solution that supports strategic decision-making while reducing administrative burden. This approach enables ACTRI to demonstrate accountability to stakeholders, optimize resource allocation, and ultimately accelerate the translation of scientific discoveries into meaningful benefits across clinical, community, economic, and policy domains. Box 2 details specific information that we collect in the centralized dashboards.

BOX 2 Information collected by ACTRI Evaluation using the integrated system.

Specific aims: Clear and concise articulation of the unit's specific objectives and goals.

Metrics for each aim: Quantifiable measures or key performance indicators (KPIs) that allow for objective assessment of progress toward the specified aims.

Strategies for achieving the aims: Detailed actionable plans outlining the steps and methods to be employed in order to attain the stated aims.

Connect boards: Linking project-specific Monday dashboards to the relevant units' BSC dashboard provides easier access to a comprehensive view of each project.

Alignment with overall ACTRI goals: Demonstrating how these aims and strategies contribute to our overarching ACTRI goals.

Impact assessment based on TSBM: Evaluation of the anticipated or observed impacts of the aims and strategies in alignment with the TSBM.

Additional columns (added based on feedback): These columns were introduced based on suggestions from unit leaders and project managers, addressing specific needs and enhancing the utility of the platform.

Implementing Monday balanced scorecards

To ensure the effectiveness of the integrated system, we implemented a quarterly data collection schedule. The quarterly data collection schedule serves as the operational backbone of our streamlined evaluation system, establishing a consistent rhythm for information gathering and analysis across the institution. This structured approach ensures that leadership has access to current metrics, enabling responsive management decisions based on the latest available data. Our training program complements this schedule, focusing on building capacity among partners to not only utilize the Monday.com interface but also to develop critical analytical skills for meaningful impact assessment.

We provided one-on-one training sessions in conjunction with the implementation of the new system. The dual focus of our training—impact evaluation methodology and technical platform proficiency—has proven essential for successful deployment. By equipping unit leaders with both conceptual understanding and practical skills, we've fostered organizational buy-in and created a sustainable culture of evidence-based decision making. The guidelines outlined in Box 3 provide a replicable framework that addresses common implementation challenges. This comprehensive approach to system adoption has been instrumental in transforming our evaluation framework from a theoretical model into an embedded institutional practice that drives continuous improvement and demonstrates the full value of our translational research efforts.

The resulting integrated platform serves multiple functions, creating a versatile tool for our institution. Unit leaders and project managers can directly input data into the system, ensuring real-time updates on project progress and outcomes. The Executive

BOX 3 Implementation strategies to integrate the BSC-Monday.com at the ACTRI.

Board introduction: Initially, we created customized dashboards for all 11 units across ACTRI, populating them with specific aims, strategies, and metrics in alignment with the grant proposal.

Guided orientation: We then conducted comprehensive walkthroughs with unit leaders and project managers, elucidating the purpose behind the dashboards and providing a detailed explanation of each column's role. This included clarifying what needed to be added to the dashboards.

TSBM training: We provided translational science benefits models training for all unit leaders and project managers and shared learning materials with them.

Open dialogue: We actively engaged in discussions, welcomed questions, and actively sought feedback regarding the complexity and feasibility of the task. This collaborative approach led to the inclusion of additional columns, based on valuable input from unit leaders and project managers.

Continuous support: Throughout the dashboard completion process, we offered ongoing support and maintained open lines of communication.

Deadline setting: We established deadlines, allowing a 2-week timeframe for the initial phase of tasks. Subsequently, we revisited the dashboards, collaborating with unit leaders and project managers to ensure all missing elements were addressed.

Strategic communication: We leveraged upcoming milestones, such as the annual RPPR, grant proposal preparations, and the impending EAC meeting, as opportunities to communicate the importance of completing the dashboards. This strategic approach ensured that the dashboards would serve as invaluable resources for these critical events.

Committee can monitor unit progress through customized dashboards and reports. Furthermore, the system facilitates the extraction of information for various purposes, including National Institute of Health (NIH) Research Performance Process Reports (RPPRs), grant applications, Executive Advisory Committee (EAC) presentations, and various internal applications and reports (Trochim et al., 2013).

Results

Prior to implementing our integrated system, our evaluation process faced significant operational challenges. Data collection relied heavily on email communications, requiring multiple follow-up messages to unit leaders to gather necessary information. Responses were often unstructured, inconsistent, and frequently delayed. The annual Research Performance Progress Report (RPPR) preparation was particularly problematic, characterized by last-minute data gathering, incomplete information, and a rushed compilation process due to the absence of systematic tracking throughout the year. This reactive approach led to potential omissions and increased stress on both unit leaders and evaluation staff.

Implementing our integrated BSC and Monday.com system, along with the TSBM, led to significant improvements in the institute's monitoring and evaluation processes. The outcomes of this implementation fall into three domains for ongoing quality improvement: system deployment, operational efficiency, and strategic impact.

System deployment

We successfully developed 11 monitoring dashboards across the institute. These dashboards were tailored to the specific needs and functions of different units within our organization, ensuring comprehensive coverage of all key areas of our operations. The widespread adoption of these dashboards demonstrates the scalability and adaptability of our combined approach to diverse research contexts within the institute. One common challenge that we experienced across most units was initial skepticism that was overcome with the ease of use.

Operational efficiency

The new system led to marked improvements in operational efficiency, particularly in the areas of data collection and reporting:

1. Data Collection: The integration of Monday.com with our adapted BSC framework streamlined the data collection process. Unit leaders and project managers were able to input data directly into the system, leading to more timely and accurate information gathering.
2. Reporting Efficiency: The centralized nature of the system significantly reduced the time and effort required to compile and generate reports. This efficiency gain was particularly notable in the preparation of annual reports, where the readily available, well-organized data expedited the drafting process.
3. Communication Overhead: We observed a substantial reduction in communication overhead. The real-time nature of the Monday.com platform, combined with the structured data input, minimized the need for frequent follow-ups and clarifications.

Strategic impact

The application of this new evaluation system shows several promising impacts on our strategic planning and decision-making processes.

The following examples are in the process to be realized:

1. Informed Strategic Planning: We will use the information gathered for the 2025 strategic planning retreat. The system's comprehensive and up-to-date data provided by will provide leaders with a valuable resource for making informed decisions, grounded in accurate insights on the performance and progress of various units.
2. Executive Committee: The system proves to be an invaluable tool during Executive Committee sessions. The ability to access real-time data and generate on-the-spot reports enhances the quality and depth of discussions, leading to more informed decision-making at the highest levels of institute leadership. We are currently scheduled for periodic presentations at Executive Committee meetings and plan to use the system as our data source.

The following impacts of our integrated system have been realized:

TABLE 1 Evaluation plan for the system designed to track progress and impact at the ACTRI.

Evaluation component	Metrics/methods	Data collection method
Data quality		
Completeness	Percentage of fields completed	Automated audit
Timeliness	On-time submission rate	System timestamps
Accuracy	Error rate in reported data	Random verification
User experience		
System usability	User satisfaction scores	User surveys
Training effectiveness	Training completion rates	Training records
User engagement	Dashboard access frequency	Usage logs
Operational efficiency		
Report generation	Time saved in report creation	Time tracking
Communication efficiency	Reduction in data-related emails	Email analytics
RPPR preparation	Time spent on RPPR compilation	Time tracking
Strategic impact		
Decision making	Use of data in strategic decisions	Strategic review
Executive discussions	Presentations in Executive meetings	Meeting minutes
Cross-unit Collaboration	Number of collaborative projects	Project tracking

3. Holistic Impact Assessment: The incorporation of the TSBM into our monitoring system allowed for a more comprehensive assessment of our research activities. This broader perspective on impact helped align our strategic goals with the wider benefits of our translational science efforts.
4. Adaptive Management: The regular influx of data and the ease of generating reports allowed for more adaptive management practices. Leaders were able to identify trends, challenges, and opportunities more quickly, enabling timely adjustments to strategies and resource allocations.

While initial observations suggest improvements in operational efficiency and strategic capabilities, we plan to rigorously evaluate the full impact and effectiveness of our integrated approach through a comprehensive evaluation plan (see Table 1). This systematic assessment will help quantify the system's contribution to data-driven decision-making and impact assessment across the institute, providing evidence-based insights into its value and identifying areas for optimization.

Evaluation plan

Our evaluation of the amalgamated BSC, Monday.com, and TSBM system will employ a mixed-methods approach to assess both the implementation process and outcomes. This comprehensive evaluation framework (Table 1) will help ensure continuous improvement and maximize the system's value for all partners.

Discussion

The implementation of our BSC and Monday.com system, integrating the TSBM, marks a significant advancement in the ACTRI's evaluation and management practices. Preliminary results indicate promising improvements in operational efficiency, data accessibility, and strategic decision-making capabilities. These outcomes support the broader goals of the Clinical and Translational Science Award (CTSA) program to improve the efficiency and impact of translational research (Center for Advancing Translational Sciences Institutes of Health, 2025).

The creation of this centralized system has streamlined our evaluation and reporting processes, improved data accessibility, and enhanced our ability to assess and communicate the broader impacts of our research activities. Initiated in early 2023, this ongoing process of integration, data collection, and training continues to evolve to meet the changing needs of our institution and the broader landscape of clinical and translational science.

Our approach builds on previous efforts within the CTSA consortium to create robust evaluation frameworks (Rubio, 2013; Selker, 2020). While the Common Metrics system did not employ the same technological platform, it shared our goal of fostering a more responsive, data-driven research environment. Our assimilation of the BSC with Monday.com offers a novel solution to challenges identified in earlier CTSA evaluation efforts, particularly enhancing real-time data accessibility and maximizing the value of invested efforts (Rubio, 2013; Welch et al., 2021).

The incorporation of the TSBM into our evaluation framework is particularly noteworthy. This model, developed by Luke et al. (2018), provides a structured approach to assessing the broader impacts of translational science across clinical, community, economic, and policy domains. By incorporating the TSBM with our BSC and project management tool, we've created a system that not only tracks operational metrics but also captures the wider societal benefits of our research. This aligns with the growing emphasis within the CTSA program on demonstrating the real-world impact of translational science (Ruiz et al., 2022).

Our success in implementing this system across 11 diverse units within our institute demonstrates its scalability and adaptability. The reduction in communication overhead and increased frequency of updates observed in our results address a common challenge faced by CTSA hubs: the need for timely and accurate data to inform decision-making (Ruiz et al., 2022). Our system's ability to facilitate more efficient data collection and reporting is particularly valuable in the context of the annual RPPR required by the National Center for Advancing Translational Sciences (NCATS).

The potential strategic impact of our system, particularly its role in informing executive sessions and strategic planning, aligns with the CTSA program's emphasis on data-driven leadership (Center for Advancing Translational Sciences Institutes of Health, 2025).

By providing real-time, comprehensive data on both operational performance and broader impacts, our system enables a more agile and responsive approach to managing translational science initiatives. This capability is increasingly important as CTSA hubs are called upon to demonstrate their value and adapt to changing research priorities (Center for Advancing Translational Sciences Institutes of Health, 2025).

Limitations

While our preliminary results are promising, it's important to acknowledge some limitations. The implementation of such a comprehensive system requires significant investment in terms of time, resources, and organizational change management. Future research could explore the cost-effectiveness of this approach compared to other evaluation strategies employed across the CTSA consortium. Additionally, longitudinal studies will be necessary to fully assess the long-term impact and effectiveness of this system on strategic management, research outcomes, and translational efficiency.

Future directions

To further enhance our understanding of ACTRI's broader contributions to building capacity in translational science, we plan to expand the evaluation system in future iterations. Upcoming versions will incorporate additional metrics and domains that reflect evolving priorities of translational science. For instance, we will assess workforce development impacts, including researcher training, mentorship outcomes, and diversity within research teams. Additionally, we plan to evaluate the effectiveness of community partnerships by tracking engagement levels, collaborative outcomes, and the impact of community-driven research.

Conclusion

Our integrated approach to evaluation and management represents a significant step forward in addressing the complex challenges faced by CTSA hubs. By combining established frameworks like the BSC and TSBM with modern project management tools like Monday.com, we've created a system that enhances both operational efficiency and strategic capabilities. As the CTSA program continues to evolve, such innovative approaches to evaluation and management will be crucial in maximizing the impact of translational science investments.

Data availability statement

The original contributions presented in the study are included in the article/supplementary material, further inquiries can be directed to the corresponding author.

Author contributions

MG: Conceptualization, Methodology, Writing – original draft, Writing – review & editing. EJ: Writing – review & editing. KS: Writing – review & editing. CR: Writing – review & editing. DB: Writing – review & editing.

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Conflict of interest

The authors declare that the research was conducted in the absence of any commercial or financial relationships that could be construed as a potential conflict of interest.

Generative AI statement

The author(s) declare that no Gen AI was used in the creation of this manuscript.

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Who benefits? Health equity and the Translational Science Benefits Model

Anna La Manna[1]*, Julie Heidbreder[1], Shannon Casey[2], Kat Phelps[3], Mia LaBrier[1], Laura Brossart[1], Ella Clark[1], Emmanuel Tetteh[1], Sara Malone[1], Douglas A. Luke[1] and Todd Combs[1]

[1]Center for Public Health Systems Science, Washington University in St. Louis, St. Louis, MI, United States, [2]School of Medicine and Public Health, University of Wisconsin-Madison, Madison, WI, United States, [3]School of Nursing, University of Wisconsin-Madison, Madison, WI, United States

EDITED BY
Milton "Mickey" Eder,
University of Minnesota Twin Cities,
United States

REVIEWED BY
Clara M. Pelfrey,
Case Western Reserve University,
United States
Beth Tigges,
University of New Mexico, United States

*CORRESPONDENCE
Anna La Manna
✉ lamanna@wustl.edu

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Introduction: Evaluating the impacts of translational science is crucial for demonstrating the quality, relevance, and societal benefits of research. This paper presents current results of efforts to expand the Translational Science Benefits Model (TSBM), a framework and toolkit originally developed at Washington University in St. Louis with 30 specific, real-world benefits across clinical, community, economic, and policy domains. In response to a growing emphasis on health and social equity, we have refined the TSBM to better address and integrate ideas of fairness and justice.

Methods: Our methods included a literature scan to identify health equity gaps in the framework, community listening sessions in St. Louis, MO, and Madison, WI, and thematic analysis to incorporate equity into the TSBM.

Results: The results introduce new dimensions within the existing TSBM domains that include 10 new benefits, all emphasizing themes of trust, power, and access.

Discussion: Our aim is to enhance the relevance and utility of the framework and tools to researchers, practitioners, and those affected by implementations of findings from translational science and research. The integration of equity into the TSBM supports continued growth in the number of users and uses of the framework and toolkit to demonstrate health and social impact.

KEYWORDS

community engagement, translational science, health equity, impact evaluation, framework

Introduction

Evidence of the broader health, social, economic, and policy impacts from clinical and translational science is key in demonstrating the quality, usefulness, and relevance of empirical research to society. Individuals and communities meant to benefit from interventions, programs, or scientific discoveries, organizational staff and leadership, funders, and governments all have interests in downstream outcomes from science and research. Evaluation efforts – specifically those focused on impact – can demonstrate accountability from science and research to many different groups. More broadly, impact evaluation highlights the value that interventions create (1). Translational science and research exist to accelerate the realization of these impacts (2), from the development of research innovations through the implementation and sustainment. We define translational impacts of science and research as the advances that demonstrably increase health and well-being or health equity for individuals, families, communities, populations, regions, or systems. We conceptualize health equity as a continuous process of expanding the principles of fairness and justice in opportunities for all persons to achieve the best possible health outcomes.

The Translational Science Benefits Model (TSBM) is a framework for evaluating the downstream health and social impacts of clinical and translational research. It was created as part of the broader evaluation of the Institute of Clinical and Translational Sciences (ICTS) at Washington University in St. Louis (WashU). The ICTS is one of over 60 "hubs" awarded by the National Clinical and Translational Science Awardees (CTSAs) program at the NIH (3). First published in 2018, the TSBM originally included 30 specific benefits of translational science comprising four domains: clinical, community, economic, and policy (4). These translational benefits from science do not replace more traditional indicators of scientific contributions such as publication and research funding metrics but rather reflect further downstream impacts of science in society. The 30 benefits are available online at https://translationalsciencebenefits.wustl.edu/benefits/. Methods and strategies used to develop the TSBM framework are published elsewhere (4).

Our team continues to refine the framework and has developed the complementary *Translating for Impact Toolkit* to help scientists, programs, and institutions apply the TSBM to their work by integrating impact throughout the research process and intervention implementation (5). Individuals and groups can use any of this set of nine free web-based tools to plan, track, and demonstrate the impact of their work. Planning for impact tools include the *Road Map to Impact*, *Benefits 2×2, Pattern Mapper,* and *Team Manager* tools which help ensure that multiple and necessary points of view and areas of expertise are represented. The *Impact Tracker* helps to organize milestones toward specific benefits, and tools like the *Product Navigator, Case Study Builder, Impact Profile,* and *Dissemination Planner* help to demonstrate impact by conceptualizing, creating, and disseminating translational products for different purposes and audiences. Using the provided dissemination product templates and guides, teams can specify whether each benefit claimed is potential or demonstrated, allowing applications for projects at all phases, from projects in development to others that have formally ended. Multiple other CTSA hubs, along with other educational, scientific, and research institutions and programs across the US and internationally, use the TSBM framework and toolkit for planning, training, and evaluation.

While health equity has been studied for decades (6), major contemporary socio-cultural and health events, such as the COVID-19 pandemic, have brought to light the deeply entrenched inequities within communities and health systems around the world (7, 8). There has been increased attention on issues of social and health equity in all aspects of life, and a growing emphasis on health equity in research and practice reflects this (9–14). The recommendations of Healthy People 2030 included achieving health equity with the overarching goal to improve health and well-being for all (15). In line with these shifts, we systematically examined the extent to which the TSBM framework and toolkit clearly spoke to equity. TSBM case studies have demonstrated how several of the 30 benefits we originally identified can highlight increases in equity, for example improving *Healthcare Delivery* to better serve food-insecure communities of color (16), tailoring existing *Therapeutic Procedures* to better address drug use in students facing adversity (17), and developing and implementing new *Guidelines* for treating physical health risks of adults with serious mental illness in outpatient facilities (18). Additionally, all nine of the tools for TSBM have components that explicitly address equity considerations in research and implementation projects. That being said, there is much room for improvement in how the TSBM explicitly includes health equity.

Here we describe our approach to update the TSBM to clearly include explicit, community-vetted, health equity benefits and present current findings. For these efforts, our team includes the TSBM group from WashU and colleagues from the University of Wisconsin-Madison (UW) Institute for Clinical and Translational Research. We first explain our data collection and methodological strategies, followed by a presentation of proposed new benefits that focus on equity. We conclude with a discussion of how the updated TSBM can help scientists and organizations demonstrate the positive impact of their work on addressing health equity in society.

Materials and methods

We set out to explicitly integrate health equity into the TSBM. We began by searching the scientific and gray literature to help identify gaps in the originally identified 30 benefits of the framework and engaged community members and groups from communities to gain different perspectives on health and healthcare. After synthesizing findings from all these efforts, we developed new benefits for the framework in an iterative process that included presenting and getting feedback from community groups and members. The new health equity benefits were presented to the ICTS Translational Research Program Officer, the ICTS Associate Director of Operations, and other members of the ICTS Evaluation team for review. The new health equity benefits were then presented to members of the ICTS External Advisory Board during an annual meeting. Currently, we are gathering additional feedback from groups of researchers and scientists to further study how these updated benefits can be applied in research and practice. As this work is ongoing, input from these researchers will be included in future papers.

Literature scan of equity impacts

We conducted a literature scan to assess how equity impact is expressed and measured in health research and evaluation. Specifically, we searched for peer-reviewed articles and existing toolkits, frameworks, and other templates that included health equity in assessments of the broader impacts of science and research. We used a semi-structured approach to search PubMed, Google Scholar, and Olin PRIMO, a search tool that scans multiple databases developed at WashU. Key search terms included: health disparities, health equity, measurement, monitoring, social determinants of health, and surveillance. We also used the following combinations of terms: unjustness or discrimination or inequality or disparity or equity or inequity or equality or (social and determinant) plus health plus evaluation or indicator or measurement or monitoring or assessment or outcome. Additionally, we specifically searched journals in implementation science, translational science, public health, and evaluation (e.g., *Implementation Science*, *Clinical and Translational Science*, *American Journal of Evaluation*). Key concepts from the literature scan were compared to the original TSBM benefits to identify gaps and opportunities in the framework related to health equity. This comparison and its findings were the basis for discussion with community members.

Community listening sessions

Near the end of the literature and TSBM reviews, we conducted a total of three community listening sessions. We recruited new and existing partners consisting of individuals and representatives of community groups with lived experiences of health and healthcare inequities from St. Louis, Missouri, and Madison, Wisconsin. In St. Louis, we invited community groups that were previously engaged with the ICTS at WashU as participants in *community studios*. Community studios are not focus groups, and therefore they do not collect demographic information. They serve to inform researchers with community or patient input for research development or implementation. For our community studio, participants were required to be community implementers of evidence-based programs and involved in policy and/or advocacy. For Madison, we recruited individuals from the Community Advisors on Research Design and Strategies (CARDS) Program, a group in existence for 15 years through the Wisconsin Network for Research Support (19). CARDS members were recruited by staff at local community centers as people who live in under-resourced neighborhoods and regularly used their services, such as food pantries, senior meals and educational programs. The CARDS group consists of 24 members with diverse demographic backgrounds. The majority of members (75%, $n = 18$) identify as Black or African American, while 16.7% ($n = 4$) identify as White, and 8.3% ($n = 2$) identify as Other. Of the 24 CARDS members, 66.7% ($n = 16$) identify as female and 33.3% ($n = 8$) identify as male. The age of CARDS members ranges from 23 to 81 years, with a mean age of 51 years. While direct income data is not collected, 50% ($n = 12$) of members self-identify as low-income, and 50% ($n = 12$) identify as not low-income. A total of 20.8% ($n = 5$) of members identify as having a disability, while 79.2% ($n = 19$) do not. Our goal for the sessions was to develop a better understanding of how to maximize the relevance and usefulness of equity considerations in the TSBM. We convened one session in St. Louis in person and two virtual sessions from Madison.

For the St. Louis session, we gave a brief presentation to introduce participants to the TSBM and summarize our literature scan findings. Prior to the session, we prepared three key questions to stimulate thinking about how the TSBM benefits could better recognize, describe, and demonstrate increases in health equity as translational impacts. The three questions were: (1) What is the one largest equity impact that your work has had?, (2) What equity benefits should we consider adding to the TSBM?, and (3) Take a look at the current TSBM benefits, are there any equity considerations that we should attend to? If so, what are they? We readied additional probes to elicit more conversation and details if needed and followed our discussion by asking about dissemination strategies (e.g., audiences, media and modes for sharing) and for overall reflections. This session was 90 min long and led by an expert facilitator. The WashU TSBM team provided an introduction, posed the questions to participants, and guided discussion as needed.

The input gathered from the St. Louis session was synthesized using an inductive thematic analysis approach. While formal transcripts were not created, detailed notes were taken during each session, capturing key discussion points, participant insights, and emergent themes. The research team reviewed these notes collectively to identify recurring patterns and concepts.

For the first Madison session, we repeated the presentation and revised the questions from insights gained during the first one in St. Louis. We wanted to more directly ask about and capture not only the direct lived experiences of participants but also their impressions about what equity looks like in their communities. The revised questions included: (1) What specific benefits are absolutely essential to you from health research or health care? and (2) How do you know the impacts have been fairly distributed so that all people can benefit from research? Both sessions from Madison were 90 min long. In the second session, we presented a set of proposed benefits developed iteratively after the St. Louis and first Madison session and solicited final feedback from participants.

Madison sessions were recorded, transcribed, and de-identified. Those transcripts were reviewed by members of the UW-Madison team for themes related to TSBM equity themes. In addition, team members aggregated their written notes with staff person notes taken during the meetings. After both Madison sessions, 10-page reports summarized outcomes and recommendations, including quotes that supported findings. While no special software was used, a reflexive thematic approach was used, with researchers generating themes through meaningful engagement with the data, the ability of themes to deepen with multiple reads of transcripts, and reflections upon our own experiences as researchers that brought assumptions and priorities into our work (20). Braun and Clarke (20) note six recursive phases: "familiarization; coding; generating initial themes; reviewing and developing themes; refining, defining and naming themes; and writing up (p. 39).

Synthesis

Following the literature scan, TSBM review, and listening sessions, we compiled findings and continued refinement of the health equity benefits for the TSBM framework. To synthesize and organize key insights from the literature review and two community listening sessions, the team employed a digital collaboration tool, MURAL. This platform facilitated the structured visualization of diverse perspectives, allowing for the categorization and synthesis of themes and ideas. This approach supported the identification of key themes and facilitated a shared understanding among team members.

With these findings and through discussions, formal meetings, and email communications, we worked through several rounds of editing and feedback from the team and community collaborator colleagues to produce the benefits described here.

Results

Many themes emerged from our efforts to explicitly include health equity considerations in the TSBM framework. We learned from existing literature and relevant materials how others formally describe, categorize, and operationalize concepts of equity. Community listening sessions provided opportunities to hear about the lived experiences of healthcare participants and users. We held the first session in St. Louis and the other two virtually for Madison. We hosted 8 community organization leaders in St. Louis and 8 and 14 CARDS (21) members in the first and second Madison sessions. Half (7) of the participants for the last session had attended the first one for Madison and the other half were new to the project but all were experienced CARDS members. Using the information gained through the literature scan and listening sessions we developed 10 additional benefits to update the original list of 30 published with the TSBM framework.

Preliminary findings

In the literature scan, we identified and reviewed 58 peer-reviewed articles and four gray literature sources. Through reviewing the abstracts or introductions, 15 sources were selected for full review (Appendix A). We found multiple examples that fit directly into one of the 30 original TSBM benefits and could be easily added to the longer descriptions of existing benefits. For example, adding routine screenings for the social determinants of health under the Diagnostic procedures benefit or adding the removal of racialized or economic barriers to care under the Healthcare accessibility benefit.

Many of the themes we identified from existing sources, however, did not fit neatly into existing benefits, and we used them as a starting point to develop both the materials for the first listening session and initial sketches of potential new benefits. In the first listening session, the group shared general insights about increasing equity in healthcare and health outcomes and provided guidance on how to expand existing benefits. For example, they suggested including community members as deliverers of health education programs and developers of "Health education resources." The group also identified the retention of diverse healthcare professionals as a potential benefit. Specifically, participants noted that healthcare providers from marginalized groups often experience racism in the workplace, which contributes to increased turnover. They suggested that addressing such racism could improve workplace culture and increase retention.

In the first session for Madison, community members followed up with explications of barriers to health and healthcare. In most cases, they cited scarcity or absence of essential resources or conditions and shared lived experiences with health and systems of healthcare. Among the missing or lacking components were transportation, access to quality care, insurance, affordable care options, and trust and understanding. Table 1 summarizes findings from the literature scan and the first two listening sessions, organized by the four TSBM domains (clinical, community, economic, policy). More quotations from the Madison session are available in Appendix B.

The team compiled information from the literature scan, the St. Louis session, and the first Madison session into a digital collaboration tool to visualize the relations between the identified inductive concepts. Three overarching themes were identified to organize the health equity concepts: trust, power, and access. These themes guided our adaptations to the framework. Initial conversations yielded approximately 20 health equity benefits. At that point, the UW-Madison team met for multiple hours to review, discuss, and refine the list of indicators down to 14, with quotes that reflected or summarized those indicators. An additional series of meetings brought both campus teams together to reflect and refine, seeking to avoid overlap with existing benefits, to create discrete categories that were broad enough to allow for customization and operationalization, and to select the benefits that had the strongest evidence for inclusion across all groups consulted. This resulted in 10 proposed benefits for the TSBM.

We took those working benefit titles and definitions back to community members in Madison for feedback. Specifically, we asked if each the 10 benefits across the four TSBM domains was important, if it was clear, and if it made sense to them. CARDS members were united in expressing that all 10 benefits felt relevant and important for improving health equity. Many stressed how important the benefits were. They also shared that the benefits all seemed connected, noting their inter-relatedness. As for clarity, participants agreed that most of the benefit titles made sense and were easy to understand. The three exceptions were called "Trusted decision-making," "Equitable systems and structures," and "Policy engagement" at the time. CARDS members emphasized that decision-making first and foremost should be *shared*. They found "systems and structures" too vague, expressing that features of the *built environment* for health and healthcare – like transportation, location, accessibility – were most important after talking through examples, and that "engagement" in policy was too broad.

Participants found about half of the 10 definitions straightforward, and others unclear, remarking that while the titles made sense, many phrases in the definitions as presented were sometimes too academic, unnecessarily complex, or vague. Examples include *co-creation*, *dismantling structures*, *service inequities*, and *economic activities*. Throughout the course of discussions, CARDS members expressed sentiments that the definitions should "just say that then" after asking for more information. There were also discussions about the terms *historically underrepresented* and *underserved*. Reflecting larger concurrent societal-level struggles with myriad terms used to describe groups with less or no power, no consensus was reached in the listening sessions, though some made suggestions of using *minorities* or *minoritized*, or explicitly stating the groups to whom statements refer. In our conversations with community members, and as colleagues, we were reminded that these benefits will be operationalized within studies as variables. As an example, a single research study could not "provide access to health resources where all people need them." Rather, a team or teams might collectively research best responses to a community need, and in aggregate many studies working together will create shifts that build Community Resource Access.

The importance of the previously identified overarching themes of trust, power, and access were confirmed by the community input from the second Madison session. The members highlighted the importance of trust, power, and access in addressing and increasing attention to health equity in the TSBM. This trust is between patients and providers as well as communities and researchers. Participants agreed enthusiastically when others said things like:

> *"If you don't have trust, the other benefits will never happen."*
>
> *"There are more ways to build trust than just explaining benefits and risks [to patients]."*
>
> *"…trust builds when providers encourage patients to be part of the decision-making process."*

TABLE 1 Themes, insights, and quotations from existing sources and initial listening sessions.

	Themes from literature	Concepts from St. Louis session	Quotes from Madison (session 1)
Clinical	• Data equity	• Believe people’s own experiences • Fair access to services regardless of clinical study participation • Center patients in research process • Practice shared decision-making • Use understandable language	• *“…within our community, it’s hard for people to trust health care providers. It’s hard for people to also understand what they are talking about.”* • *“… with a lot of African American women, you know, we have been gaslighted.”*
Community	• Built environment • Community capacity • Community engagement • Education access and quality • Health impact assessment • Partnerships	• Increase attention to building relationships • Increase agency in people’s own health outcomes	• *“…And there are people that miss appointments simply because it’s just like it’s too much of a struggle to have to load up your two kids on a bus…”* • *“…they wanted me to go travel all the way to Milwaukee to get my tooth pulled… so I ended up [going to a closer dental place…along with that came not as good service or you’d be waiting 2 h…”* • *“…what I need, for instance, is access to an emergency room immediately if I’ve been hurt.”*
Economic	• Affordability of care • Economic stability • Hiring diversity • Sustainability • Workforce development	• Reallocate resources • Hiring diversity	• *“I do not feel like parents should have to pay for meal tickets and like, you know, to eat while [their] kids [are] staying there at the hospital. You know, they expect parents to be able to have the funds to go back and forth and then feed themselves”* • *“The health care system seems more to me like a corporation because it seems like if you do not have health insurance, that you are not going to get the best treatment.”* • *“…to have the opportunity to go to any health care center that specializes in said health concern. We need that world, do not we?”*
Policy	• Equitable policy enforcement • Power sharing	• Redistribute power • Close gaps between standards or policies and practice	• *“…ears that are willing to hear the morality of it all…anybody that has any effect on budgets at the federal level… So, I guess that’s top-level politicians, business leaders.”*

> *“Doesn't it take time to build trust? And usually in these research things, if you go in there, you don't know the researchers. They don't know you.”*

Different aspects of power were also central in the sessions. One participant mentioned that “*anybody that has any effect on budgets at the federal level*” (Table 1) needs to hear the session discussions, and multiple CARDS members pointed out that using superlatives in the benefits implies that somewhere, someone holds the power to decide. Phrases like delivering health services *to those who need them* ***most*** or *to the* ***most*** vulnerable populations do not imply universal agreement on who or where those communities or individuals are. Participants also expressed the need for the power that comes with options, to avoid, for example, hours of travel, waiting, or childcare and cost-prohibitive incidental expenses of healthcare like family expenses for room and board. Closely related to power is access. Beyond but not excluding usually cited barriers to health and healthcare like cost and proximity, fairer access to specialists and earlier access to innovative treatments are also important, for example.

Equity benefits in the TSBM

Using all the feedback and knowledge generated through our discussions with community organizations and members, along with our previous work, we have developed 10 benefits. The new benefits, along with definitions are highlighted in Table 2, where the rightmost columns highlight the running themes.

New equity benefits in the Clinical domain are patient-centered, in both healthcare and research settings. Those in the Community domain focus on collaborations and increased support for all people and groups where they are needed. The new benefits in the Economic and Policy domains consider fair opportunities and inclusive policies and practices that address various types of existing disparities.

Finally, the equity additions are shown in context with all the TSBM benefits in Table 3. The new expanded TSBM framework now has 40 benefits spread across the four domains of clinical, community, economic, and policy impacts. Each domain now has three or four subdomains, that now include equity increases.

Discussion

To demonstrate and evaluate the translational impacts of science and research it is necessary to consider how research advancements affect opportunity, fairness, and justice – the cornerstone principles of equity. With equity comes trust, power, and access; we designed the new TSBM benefits to reflect these themes. Assisted by community organizers, patients, and societal representatives, we amended the TSBM to include 10 new benefits in Equity Increases domains. Those in the clinical domain focus on fair access, voices that are heard, and the active participation for patients in care, the planning of care, and new lines of research and discovery. The community benefits are advances that level the playing field between people – as patients, families, and community members – and providers and researchers. Inclusive representation, opportunity, and income distributions across

TABLE 2 TSBM equity benefits.

Domains and benefits	Definitions	Trust	Power	Access
Clinical				
Clinical innovation access	Timely access to clinical advances for all	✓		✓
Patient-guided research	Research that engages patients throughout and aligns with patient priorities	✓	✓	
Shared decision-making	Interactions between providers and patients that are clear, understood, and create trust	✓	✓	
Community				
Community power & partnerships	Relationships between people, researchers, and providers built on power sharing	✓	✓	
Healthy built environment	Services, spaces, and places that support everyone's well-being		✓	✓
Resource access	Access to health resources when and where all people need them		✓	✓
Economic				
Diverse healthcare workforce	Expanded opportunities for all people in healthcare and health research		✓	✓
Equitable healthcare economies	Broadened distribution of income and wealth in healthcare		✓	✓
Policy				
Community-guided policy	Community perspectives are clear, apparent, and drivers of the policymaking process	✓	✓	
Social justice through policy	Policies address, decrease, or erase health disparities and build social justice		✓	✓

TABLE 3 Equity increases subdomains and benefits in context.

Clinical	Community	Economic	Policy
Equity increases • Clinical innovation access • Patient-guided research • Shared decision-making	Equity increases • Community power & partnerships • Healthy built environment • Resource access	Commercial products • License agreements • Non-profit or commercial entities • Patents	Advisory activities • Committee participation • Expert testimony • Scientific research reports
Procedures & guidelines • Diagnostic procedures • Investigative procedures • Guidelines • Therapeutic procedures	Health activities & products • Community health services • Consumer software • Health education resources	Equity increases • Diverse healthcare workforce • Equitable healthcare economies	Equity increases • Policy engagement • Social justice through policy
Tools & products • Biological factors & products • Biomedical technology • Drugs • Equipment & supplies • Software technologies	Health care characteristics • Health care accessibility • Health care delivery • Health care quality • Health promotion • Disease prevention & reduction • Life expectancy & quality of life • Public health practices	Financial savings & benefits • Cost effectiveness • Cost savings • Societal & financial cost of illness	Policies & legislation • Legislation • Policies • Standards

roles in healthcare underlie the economic benefits. And policy efforts – both small "p" organizational and large "P" governmental policies – that demonstrably integrate perspectives from the communities they will impact and diminish barriers to health and well-being for all are highlighted in the policy domain.

Through our efforts to infuse considerations of equity into the TSBM, we also critically reviewed the original benefits to explore whether and how they could be understood through an equity lens. We found that multiple TSBM users had already done this through case studies of their own work. We also found many instances where issues of equity fit naturally in the definitions, longer descriptions, rationales, and examples and can use these as opportunities to update the framework. Along with the new benefits, these updates will make a renewed TSBM itself more accessible and applicable in more areas of research, evaluation, policy, and practice.

Issues of power and trust are not new ideas when thinking about equity. It is perhaps unsurprising that they rose as overarching themes of our efforts, and community member input in particular. This could be perceived on one hand as affirming of our efforts, and on the other as issues that bear repeating. Power has many faces – political, social, economic – and comes with control over rules and other institutions and practices, both formal and informal. The new TSBM benefits focus on sharing these types of power among all people, and highlighting when efforts are successful. Power, or the lack of it, is also found in more everyday aspects of life, like access, choices, and opportunities. The new benefits also draw attention to points when people get more of these.

Power goes hand-in-hand with trust. Built over time, trust in patient-provider and community-researcher relationships comes with more than just explaining benefits and risks of treatment or handing out pamphlets, decision aids, or financial incentives. It comes with sustained engagement, across clinical visits and providers, and long-term, mutually beneficial community-researcher partnerships. Trust develops when patients and people are listened to, heard, and believed, with awareness that their experiences and perspectives matter, and that all these have mattered in previous interactions and play a part in shaping their future. The new TSBM benefits also reflect this, and as in instances where power is fairly distributed, serve as mechanisms to emphasize when trust is mutually shared.

Though the primary users of the TSBM are scientists and researchers, the motivation driving it and its *translational* rationale imply the need for accessibility for various audiences. While they may seem simple, changes to wording and purposive definitions serve to broaden the framework's accessibility and understanding for more people, including our own team. Following up with CARDS members after the initial listening sessions and initial development of the new benefits to get more thoughts and reactions was crucial to this process and cannot be underestimated. We are tremendously appreciative of the time and input all the community members gave to the project and look forward to sharing back the updated TSBM with them. In addition, planning for, using, and demonstrating the new TSBM benefits will require more input from evaluators in CTSA hubs, patients, people, and communities throughout the research process. Concepts like power and trust are not easily inferred secondhand and necessitate evidence, testimonials, and stories from the people who feel impacted in a positive way. This will require training for scientists and researchers beyond those whose work focuses mainly or explicitly on issues of equity.

In addition to sharing updates with partners and gathering feedback from researchers, next steps include continuing to update the TSBM by developing longer descriptions and examples for the new benefits and refreshing the original ones with new examples. We are actively working to flesh out the new benefits to make them more distinct and ensure that each category is clearly defined. This ongoing process, which includes gathering feedback from stakeholders and deeply reviewing existing benefits, aims to clarify the specific benefits being addressed and to minimize any ambiguity. We have developed and continue to refine language for the rationale behind each new benefit to further explain why each is an important impact of translational science and research. The rationale, along with a detailed description that includes examples, guidance for finding and collecting information to demonstrate each benefit, and a curated list of relevant resources and publications, will complete this work and mirror the supportive elements provided for the original 30 benefits on the TSBM website (22). As the new health equity benefits are integrated into web-based TSBM tools, there will be more detail regarding each of the benefits and how they are distinct. This process has not been completed and therefore not included in this paper.

This work has several implications for research, evaluation, and practice. The TSBM framework has been in use since 2018, and the toolkit since 2021. The number, diversity, geography, and substantive areas of uses and users continue to grow. The additional focus of health equity and 10 benefits that explicitly centralize how the impact of science and research can improve well-being for all people and communities expands the relevance and application of the TSBM. Rather than an "evaluation checklist" for impacts of science and research, the TSBM offers a "menu of potential benefits" for communities and society. Increases in its reach and visibility can inspire those in research to integrate health equity considerations earlier in their research planning and inspire those in clinical practice to share successful strategies that result in mutual trust and openly shared decision-making. The updated TSBM can also encourage its adaptation to new arenas and further facilitate its use in and beyond educational, health, healthcare, and public health programs and institutions. Work and evaluation in physical and social sciences, social work and public policy, political-, social-, economic-, and community-based programming along with international development efforts can more readily take advantage of the TSBM to systematically design, document, demonstrate, and disseminate progress and downstream impacts for individuals, communities, and society.

Data availability statement

The raw data supporting the conclusions of this article will be made available by the authors, without undue reservation.

Author contributions

ALM: Conceptualization, Formal analysis, Supervision, Writing – original draft, Writing – review & editing, Data curation, Investigation, Methodology, Project administration. JH: Data curation, Formal analysis, Investigation, Writing – original draft, Writing – review & editing. SC: Data curation, Formal analysis, Investigation, Methodology, Writing – original draft, Writing – review & editing. KP: Data curation, Formal analysis, Investigation, Methodology, Writing – original draft, Writing – review & editing. ML: Data curation, Formal analysis, Investigation, Methodology, Writing – original draft, Writing – review & editing. LB: Supervision, Writing – original draft, Writing – review & editing. EC: Formal analysis, Investigation, Writing – original draft, Writing – review & editing. ET: Conceptualization, Formal analysis, Supervision, Writing – original draft, Writing – review & editing. SM: Conceptualization, Formal analysis, Supervision, Writing – original draft, Writing – review & editing. DL: Conceptualization, Formal analysis, Funding acquisition, Methodology, Supervision, Writing – original draft, Writing – review & editing. TC: Conceptualization, Formal analysis, Investigation, Methodology, Supervision, Visualization, Writing – original draft, Writing – review & editing.

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Conflict of interest

The authors declare that the research was conducted in the absence of any commercial or financial relationships that could be construed as a potential conflict of interest.

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EDITED BY
Douglas Luke,
Washington University in St. Louis,
United States

REVIEWED BY
Robet L. Drury,
ReThink Health, United States
Anna La Manna,
Washington University in St. Louis,
United States

*CORRESPONDENCE
Maggie Padek
✉ mpadekkalman@kumc.edu

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Examining rural health equity and impact through the translational science benefits model: outcomes from the CTSA Consortium of Rural States (CORES)

Maggie Padek[1]*, Rebecca Butcher[2], Rebecca deLacerda Allen[3], Hilary L. Surratt[3], Maran Subramain[4], Beth Tigges[5], Alyson G. Eggleston[6], Jessica H. Presley[7], Trent Matheson[8] and Nasser Sharareh[8,9]

[1]Frontiers Clinical and Translational Science Institute, University of Kansas Medical Center, Kansas City, KS, United States, [2]Dartmouth SYNERGY Clinical and Translational Science Institute, Geisel School of Medicine, Lebanon, NH, United States, [3]Center for Clinical and Translational Science, University of Kentucky College of Medicine, Lexington, KY, United States, [4]Institute for Clinical and Translational Science, University of Iowa, Iowa City, IA, United States, [5]University of New Mexico Health Sciences Clinical and Translational Science Center, Albuquerque, NM, United States, [6]Clinical and Translational Science Institute, Pennsylvania State University, Hershey, PA, United States, [7]The Translational Research Institute, University of Arkansas for Medical Sciences, Little Rock, AR, United States, [8]Utah Clinical and Translational Science Institute at the University of Utah, Salt Lake City, UT, United States, [9]Department of Population Health Sciences, Spencer Fox Eccles School of Medicine, University of Utah, Salt Lake City, UT, United States

Introduction: Rural communities often lack access to healthcare, have limited resources and infrastructure, and may experience suboptimal translation of evidence-based interventions into practice or measurement of translational research impact. The Consortium of Rural States (CORES), comprising eight Clinical and Translational Science Award (CTSA) hubs, is a research consortium that focuses on clinical and translational research impacting rural health.

Methods: Utilizing the Translational Science Benefits Model (TSBM) framework, each CTSA hub's evaluation lead co-created an inventory of rural-focused activities, projects, and initiatives that occurred at their respective site during the funding period 2021–2023. Variables included program area; activity type and description; target population; activity status; outputs; and short-term outcomes. The evaluators then mapped site outcomes according to the four TSBM domains (clinical, community, economic, policy) and 30 subcategories (benefits).

Results: 184 rural-focused activities, projects and initiatives were identified across the hubs. All rural-focused efforts involved impacts in the Community and Clinical domains of the TSBM, with >60% focusing on Community impacts. These results suggest an opportunity gap to better define Economic and Policy-level impacts in the context of rural-focused initiatives.

Discussion: This work demonstrates a novel mapping of the TSBM to rural health research settings and explores the nuances of using the concepts and domains of the TSBM as a coding tool. This work gives the Consortium insight on the types of projects and impacts that are supported and how to prioritize more exploration of the full range of translational science benefits in rural health initiatives going forward.

KEYWORDS

rural health, translational science, TSBM, impact evaluation, CTSA

Introduction

Disparities in health outcomes between urban and rural settings are well documented within the scientific literature (1–3). Overall, rural residents, who account for 14% of the U.S. population, experience significantly higher rates of mortality and chronic diseases than urban residents (4, 5). Differential health outcomes in rural communities are largely attributed to a variety of social determinants of health, such as poverty, limited access to healthcare, inadequate resources and infrastructure for health services (6, 7), and reduced educational and economic opportunities (6, 7). Rural communities may also experience suboptimal translation of evidence-based health interventions into practice.

Moreover, there are several challenges in both conducting rural health research and describing associated impacts. Challenges range from agreement on how rurality is defined to dealing with methodological issues unique to recruiting and studying health issues in socially and culturally diverse and geographically dispersed populations (8, 9). Over the last decade, a number of frameworks to measure research impacts have been developed (10) with attempts to create specific frameworks to measure rural health research impacts (11) but it is unclear the degree to which these frameworks are widely accepted and utilized. Disseminating rural health research findings have additional challenges ensuring that results are accessible to non-researchers and presented in a way that resonates with communities that have grown increasingly culturally, socially and economically diverse (8, 12).

These challenges led the National Center for Advancing Translational Science (NCATS) at the National Institutes of Health (NIH) to present a report in 2019 emphasizing the need for translational science to address rural health inequities (13). Since then, there have been research and dissemination initiatives focused on improving equitable care access in rural communities but limited attention on the impact of this focus on rural health (13). In 2012, the Consortium of Rural States (CORES)[1] formed as an informal working group of academic medical institutions, funded by smaller Clinical and Translational Science Awards (CTSAs) from NCATS, with a shared public health focus on rural populations (14, 15). CORES institutions collaborated to reduce the burden of illness and mortality within rural populations through inter-institutional pilot funding and sharing best practices. The membership of CORES includes hubs with current or recent CTSA grants in the G and T funding tiers (small to small-medium CTSAs). The limitation of CORES members to small to small/medium CTSA hubs is intended to bring together hubs with similar resources and with a similar impact on their respective institutions. By 2024, the Consortium had grown to eight institutions: Dartmouth SYNERGY Clinical Translational Science Institute (CTSI), Pennsylvania State University CTSI, Translational Research Institute at the University of Arkansas for Medical Sciences, University of Iowa Institute for Clinical Translational Science (ICTS), Frontiers CTSI at University of Kansas, University of Kentucky Center for Clinical and Translational Science (CCTS), University of New Mexico Health Sciences Clinical and Translational Science Center (CTSC), and University of Utah CTSI. The Consortium has funded over 34 pilot projects totaling more than $2.1 million since its inception. CORES convenes annually at a rotating host institution to share advancements and best practices from their respective institutes and to collaborate on initiatives within smaller workgroups. Despite the longevity of CORES, prior to 2023, there had been no collective effort to study shared and divergent rural public health initiatives and challenges, nor to quantify the impact domains of rural research activities within these hubs.

The Translational Science Benefits Model (TSBM) was developed in 2016 by Luke et al. at Washington University in St. Louis (16, 17) to characterize the impacts of translational science activities from CTSA-funded projects across four domains: Clinical and medical (clinical), Community and public health (community), Economic, and Policy and legislative (policy). Within those four domains, the authors identified 30 health and social benefits that serve as intermediary benchmarks to assess health and social impact. Together, these domains and intermediary benchmarks provide a framework for understanding the long timespan between initiating translational science activities and measuring realized health and social benefits. The TSBM has been widely adopted by evaluators across CTSAs and there are multiple calls in both the literature (18, 19) and at the federal funding level (20, 21) to utilize the TSBM in varied ways to describe the impacts of translational science research. Although the TSBM has been utilized in logic model planning (22), capacity assessments (23), project assessment (24, 25), and case study development (17), few efforts have utilized the framework to study health impacts in rural contexts (26, 27). The TSBM is poised to describe research impacts in rural settings as its framework is anchored in descriptive definitions that are meant to be understood by the lay public (8, 17). The aim of this collaborative study was to apply the TSBM framework in a novel way to inventory and classify the activities and outcomes of the rural-focused research and scholarship initiatives supported by the CORES hubs to (1) explore the range of benefits across the Consortium, (2) identify any gaps in utilizing the TSBM framework, and (3) contribute to advancing methods grounded in translational science benefits for use across the wider CTSA community.

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[1] https://www.ctsacores.com/

Abbreviations: CCTS, Center for Clinical and Translational Science; CTSC, Clinical and Translational Science Center; CORES, Consortium of Rural States; CTSA, Clinical and Translational Science Award; CTSI, Clinical and Translational Science Institute; ICTS, Institute for Clinical and Translational Science; NCATS, National Center for Advancing Translational Science; NIH, National Institutes of Health; NOFO, Notice of Funding Opportunity; TSBM, Translational Science Benefits Model.

Methods

The CORES evaluation workgroup consisted of at least one evaluation representative from each hub. The study was confined to the eight CTSA hubs represented by each CORES institution in the workgroup, which ensured availability of data aligned with the rural focus of the project. The group met monthly from September 2023 to September 2024 to develop project aims and to achieve consensus on study design, review methods, inclusion criteria, and data points to be gathered. Smaller working groups formed throughout the project to accomplish specific tasks such as finalize the data collection inventory tool, conduct data analysis, and synthesize results. Hubs submitted the requisite information to their respective Institutional Review Boards, and all were designated as not human subjects' research and exempt from IRB approval.

Sampling and data collection

Hubs independently compiled relevant data for the 2021–2023 inventory over a four-month period utilizing prior years' Research Performance Progress Reports (RPPRs), data from pilot program awards with rural foci, as well as surveys of local staff, scholars, and faculty and/or querying relevant investigators at local team meetings. Since each hub engages in unique activities and captures output data differently, the representative evaluator selected source documents best positioned to contain the data needed to inform the inventory. Activities and projects were included in the inventory if they met the following criteria: (a) demonstrated focus on rural health settings and populations; (b) were funded through the CTSA; and (c) project status was 'in progress' or 'completed' during the analysis time-period. Projects and activities were excluded if they had not yet started or were limited to brief, transactional activities (e.g., one-time assistance on a project such as statistical consultations).

Because each hub was on a different timeline for their current grant cycle (Figure 1), the team restricted the analysis to activities and projects occurring during 2021–2023, as seven of eight CORES sites were actively funding pilot projects and programs during this overlapping time window. All hubs contributed data apart from Dartmouth as they were unfunded during the time period defined. Their evaluator was still an active contributor in the study design, data cleaning and data analysis. Data were compiled in the inventory, a shared Microsoft Online Excel spreadsheet hosted on a restricted access Microsoft Teams channel with each hub having a standardized worksheet to complete. Fields were defined with a codebook, and dropdown menus and other data validation were used to standardize data entry. Monthly meetings with all evaluators were held to ensure data entry consistency and to resolve and troubleshoot any discrepancies in how data was entered and interpreted.

Variables

Using the TSBM conceptual framework as a guide, the team identified the key variables that were (a) descriptive of the projects/activities, (b) relevant for impact measurement, (c) tracked by hubs, and (d) feasible to compile and report in the collection period. Variables included the activity title and description, the population of focus, status of the project, and judgments on the perceived benefit of each project according to TSBM definitions. The table included in the Supplementary materials provides a thorough outline and description of each variable along with how evaluators categorized and scored them. Benefits were also defined as either "potential" meaning there was no demonstrated evidence of achieving that benefit, but the evaluator believed the research could generate the outcome in the future and "demonstrated" meaning there was documented evidence that the benefit was already achieved by the research (usually through completion report of study or publication).

Data analysis

Once all data were entered into the shared spreadsheet, a subcommittee of three members (MP, RB, RDA) cleaned and checked the data, identified any missing data, and developed a data analysis strategy. Each hub's data was double coded by two different coders as a form of investigator triangulation. Coders did not code their own hub's data. Coders met over three separate meetings to align coding approach, discuss any discrepancies in the data, and reach consensus on final scoring. Some hubs were not tracking TSBM variables during the defined time-period and did not have data available for variables such as "potential" or "demonstrated" and "level of impact." Missing

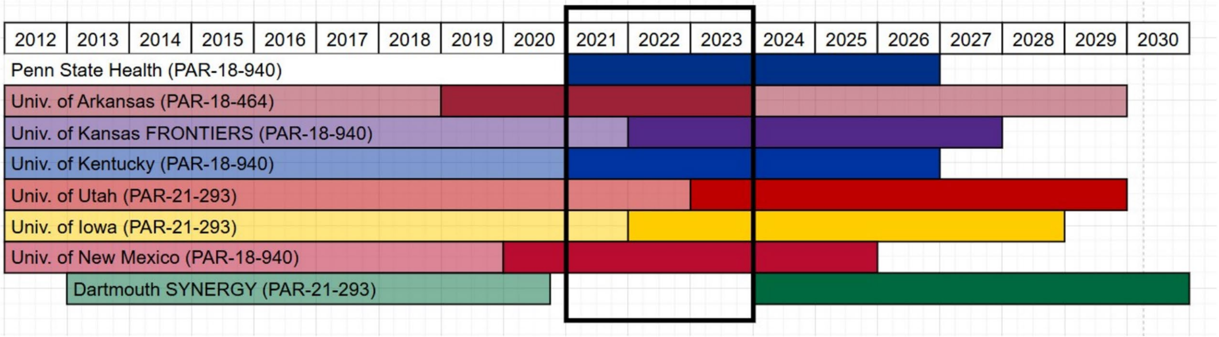

FIGURE 1
Period of analysis (2021–2023) relative to CORES' current CTSA funding.

data and questions were directed back to the relevant hub evaluator to resolve, if possible. Not all missing data could be identified, and missing data were excluded from analysis. A new variable was created to code primary and secondary target populations from the free text entry to standardize population focus. Counts and averages were calculated for TSBM benefits per project/activity. Variable counts were calculated across all hubs together and for each hub independently, and averages were computed when relevant. Program areas associated with the projects were identified by hub and thematically analyzed across all hubs. Differences in program area terminology were observed across hubs, mostly attributable to the language used in the Notice of Funding Opportunity (NOFO) under which each hub was operating (PARs are shown in Figure 1). The team used inductive analysis to create thematically common program area categories for summarization. Final coded data were recorded in a separate worksheet designated for each coder, and one coder (RDA) compiled all data into a final analysis worksheet.

Results

Across the seven included hubs, a total of 184 projects and activities focusing on rural health and populations met the inclusion criteria. On average, there were 26 projects per hub (range: 19–48). Projects spanned 10 different programmatic areas including pilot funding programs, K & T scholar programs, quality improvement activities, research capacity and methods support, workforce development, and community engagement activities. Table 1 presents the hub-level and aggregate counts of rural-focused research activities, translational science (TS) benefits and level of impact, and associated target populations collected and scored with the TSBM inventory.

Figure 2 summarizes the distribution of TSBM benefits by domain associated with the research activities of each of the seven hubs in the analysis. On average, there were 2.4 (range 1.2–4.4) TSBM benefits per project per hub and three times as many *potential* TSBM benefits reported as *demonstrated* TSBM benefits (five hubs reporting). Across all hubs, 65% of the projects mapped to Community benefits, 51% mapped to Clinical benefits, 5% mapped to Economic benefits and 4% mapped to Policy benefits. The largest proportion (48%) of projects focused on patients or individuals as the population of benefit, followed by projects which focused on community organizations as the population of benefit (41%). Most projects or rural research activities across the seven hubs achieved state level impact (59%), followed by regional impact (42%) and impact at a national level (34%). Importantly, most projects' impacts (66%) were still considered "potential," as the TSBM benefits were not yet demonstrated at the time of data collection.

Discussion

Overall, the results showed that the TSBM offered a useful framework to code and analyze a wide variety of rural-focused projects and enabled a cross-site exploration of demonstrated and potential outcomes, which to our knowledge has not been done before. It was expected that rural focused projects would largely map to the Clinical or Community TSBM domains. This finding is consistent with other studies that have mapped the TSBM to outcomes (28); rural-focused initiatives are typically designed to impact under-resourced communities with clinical and community-based interventions. For instance, a Clinical domain study that took place in rural New Mexico focused on prescriber uptake of the innovative biomedical technology of the ECHO program to treat opioid use disorders (29). An example of a Community domain study was the expansion of genomic testing services into rural Kansas primary care clinics to improve healthcare accessibility and healthcare delivery (30). These projects highlight how rural CTSAs impact rural healthcare by improving access and capacity in rural areas, and how these activities are aligned with the TSBM framework.

However, very few projects mapped onto the Economic and Policy domains. This may be because the benefits within Economic and Policy domains are typically actualized several years after a project has concluded and may not be the typical target outcomes for projects focused on rural health (31). Further compounding this issue, very few hubs have established evaluation measures to track economic or policy impacts (32) and investigators may not even consider what future economic and policy outcomes they expect to see in initial project designs. Many CTSAs and investigators do not have the capacity or expertise to measure economic benefits such as cost savings, cost effectiveness, and the societal and financial cost of illness, three of the Economic subdomains. Economic analyses could be encouraged and included in CTSA-funded projects, and CTSAs could offer economic analysis as core services for investigators.

The skewedness of the observed benefits toward Clinical and Community TSBM domains may also stem from how the economic and policy benefits are defined, as the definitions may lack sufficient detail. The noted benefits within these two domains of the TSBM are broad and more distal as research outcomes (e.g., policies, legislation, patents, license agreements, cost savings). Future work is needed to better define and potentially expand the TSBM benefits within the Economic and Policy domains to characterize a wider range of economic and policy outcomes relevant to underserved populations like rural communities—areas that have been historically marginalized and excluded from economic gains and lacking advocates among policymakers. Similarly, further clarification of policy benefits could help researchers understand appropriate targets for systems and population health research (33). This has been noted as an area of need specific to rural health services research (34).

Unfortunately, policy changes take time and can be difficult to track—as the market demand for a product like Overton (35) proves. Overton is a cloud-based application that aims to identify influences of research on policy through real-time tracking of state and federal policy actions linked to scientific research citations which may be useful for tracking how research activities impact policy. However, legislative, and even many policy statements rarely include exhaustive lists of scientific references as the basis for their scientific decisions, often making it difficult to track these linkages even if they do exist. Local policy impacts may be difficult to detect if not reported by investigators or scientific results are undervalued by policy makers.

Although there were fewer Economic and Policy benefits than Community and Clinical, all four domains are critical for fulfilling the promise of translational science. To increase the Economic and Policy benefits, better upstream consideration and integration of these benefits and the pathways to achieve them are needed. Better operationalization of the specific activities involved in such benefits would be an important first step to understanding the potential Economic and Policy benefits of translational science along with

TABLE 1 Hub-level and aggregate counts of CORES rural research activities (TSBM inventory results).

Variable	Total count across all sites	Average across all sites	Hub 1 totals	Hub 2 totals	Hub 3 totals	Hub 4 totals	Hub 5 totals	Hub 6 totals	Hub 7 totals
# of CTSI program areas with rural research activities	N/A	6.6	3	8	10	4	5	10	6
# of rural research activities or projects	184	26.3	48	23	24	19	19	31	20
# of completed projects to date	62	8.9	18	1	4	3	10	17	9
# of projects in progress	119	17.0	30	22	19	15	8	14	11
Avg # of TS benefits per project/site*	14.14	2.4	1.29	1.23	1.57	3.78	1.9	^	4.37
Total # of Clinical Domain projects	94	13.4	22	16	10	13	7	14	12
Total # of Community Domain projects	120	17.1	28	10	23	12	18	16	13
Total # of Economic Domain projects	9	1.3	2	0	1	1	2	0	3
Total # of Policy Domain projects	8	1.1	1	1	3	2	0	1	0
# of POTENTIAL benefits (across all domains)	107	21.4	^	23	25	21	29	^	9
# of DEMONSTRATED benefits (across all domains)	37	7.4	^	2	10	5	7	^	13
Population focus of the CORES projects									
Patient/Individuals	89	12.7	40	7	2	9	14	7	10
Providers/Clinical Staff/ CHWs	46	6.6	8	5	9	2	9	5	8
Researchers/Res Admin & Staff	49	7.0	5	6	11	6	2	17	2
Community Org	75	10.7	7	12	12	7	1	23	13
Level of impact of CORES rural research activities									
# of individual-level impacts	8	1.6	^	0	1	7	0	^	0
# of local-level impacts	10	2.0	^	2	1	1	6	^	0
# of organization-level impacts	9	1.8	^	8	1	0	0	^	0
# of state-level impacts	58	11.6	^	4	6	15	12	^	21
# of regional-level impacts	42	8.4	^	5	24	8	3	^	2
# of national-level impacts	34	6.8	^	8	5	2	16	^	3

^ Data missing from Hub.
* Each project could align with more than one translational science benefit (there are 30 benefits in the TSBM).

discussion of how these may differ between rural and urban settings and to what extent definitions capture beneficial activities in varying communities. Currently, beneficial activities and outcomes include patents, technology transfer, and workflow/procedural enhancements. Other activities could include cost–benefit analyses, legislative or advocacy efforts, and social media efforts to extend health impacts. Consideration of all activities and benefits and their applications to rural health research will also be important as the field progresses.

However, there were challenges applying the framework as a coding tool when the benefits within each TSBM domain lacked sufficient specificity. While Luke et al. have provided the definitions of each TSBM benefit, there is little guidance on what documentation is necessary for an impact to align with a benefit and what constitutes a benefit as "demonstrated" (36). Most of the CORES' institutions had not previously applied the TSBM to their own assessment of rural projects prior to this study, leading evaluators to retrospectively code TSBM domains and benefits for each research project. This resulted in instances of subjective coding decisions which required multiple rounds of review and discussion among the analysis subcommittee to reach standardization of coded benefits across projects and sites. However, this work demonstrates that the TSBM can be utilized as a coding tool rather than strictly for case study development. It has also been suggested that the TSBM should be expanded to integrate more health equity concepts (37, 38). If broadening the scope of the TSBM to include health equity concepts, it will be important to consider rural populations. The current inclusion of healthcare access in the Community domain likely does not fully encompass a wider range of health equity impacts on rural populations, such as health literacy, food availability, transit options, and place-based environmental impacts on health.

Limitations

Although this project was intentionally designed as a cross-hub analysis using data from multiple CTSA hubs, there were some limitations to our approach. First, hubs varied in administrative, funding and evaluation structures which resulted in a relatively narrow timeframe and inclusion criteria for the data. The analysis period was limited to 3 years, although some hubs had been collecting data for much longer than others. Sampling decisions were compounded by

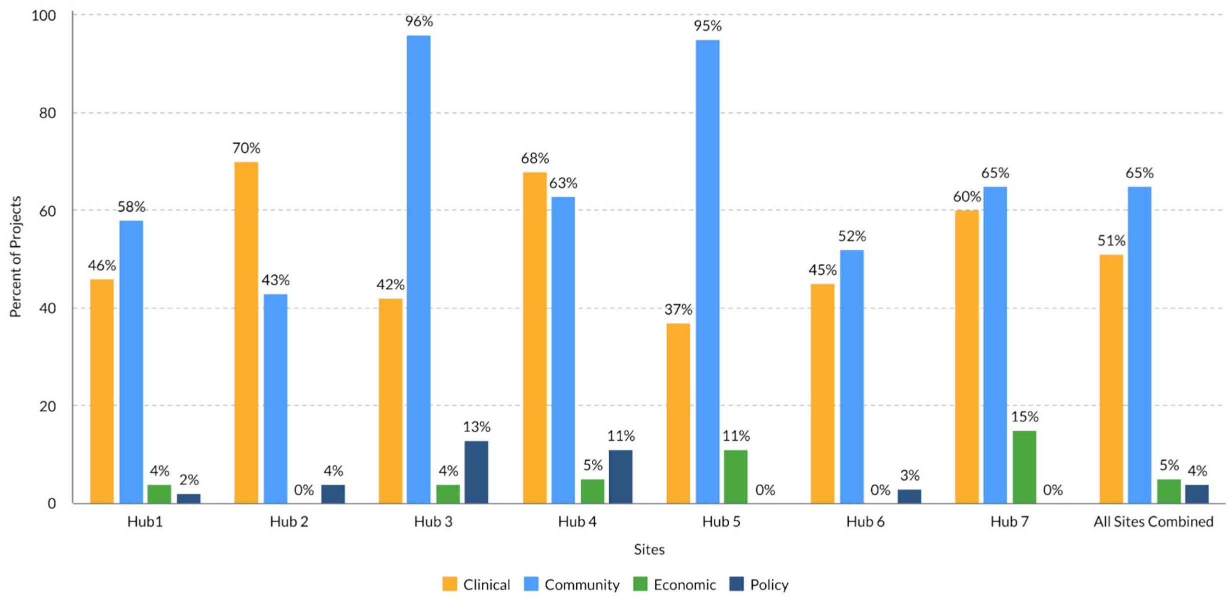

FIGURE 2
CORES site projects by TSBM domains.

whether to include the full range of CTSA-funded activities or only those where potential translational science benefits could be tracked and recorded. We decided not to include brief t*ransactional* activities, such as informatics or methodology consultations to ensure more consistency in data across the hubs, although some hubs provided such services to rural-based providers or in settings that clearly benefited from new data knowledge and access. Documentation of demonstrated benefits was subjective to each hub and was not included in this analysis. Future applications of the TSBM inventory will benefit from potentially broader inclusion criteria.

For this study, each site collected data in an Excel spreadsheet. In the future, a more structured format of data collection (e.g., REDCap project) would help standardize the process, validate fields, and reduce missing data and non-valid free text entries. Additional changes to the data fields may also be warranted, including allowing the entry of multiple benefits per domain and allowing multiple populations within the same subgroup (e.g., different providers, different patient populations). As noted previously, there is also a need to increase understanding of when a benefit has been 'demonstrated' rather than still considered a 'potential' benefit. Future alignment of evaluation and metric tracking will provide more robust data than the current retrospective analysis. A final limitation is the potential impact of the COVID-19 pandemic on the study timeframe (2021–2023). Because the pandemic negatively impacted many research projects by disrupting activities, data collection, and timelines, it is possible that research occurring proximate to the pandemic had limited reach and outcomes resulting in fewer observed TSBM benefits.

Implications for rural health projects

Despite some of these limitations, the application of the TSBM in this study was valuable in providing a shared framework for identifying and describing health research impacts among distinct and regionally diverse institutions. It was particularly useful as an initial approach to examining rural health impacts, as this study was the first recorded attempt to explore translational science impacts in rural communities across multiple states. The TSBM provides a basis for identifying what is currently known and highlighting gaps that need additional study. With additional research, there can be a holistic evaluation of the impact of rural-focused research on the greater public health that is informed by the TSBM and other complementary approaches (39).

Next steps

Further refinements of the TSBM as described above will enable easier and more robust applications of the model to assess impacts of future projects within the Consortium. Indeed, better defined inclusion criteria coupled with 'real-time' tracking of the TSBM benefits and, enhanced data collection methods will strengthen cross-hub data analyses in the future. In addition, using examples of economic and policy benefits emerging from this and future analysis, new measures and evaluation processes can be developed to better track these impacts, even while recognizing the variability in actualization time. It will be important moving forward to have collaborations in standardizing measures and compiling data with non-rural focused hubs, which would afford a better understanding of differences between rural-serving and urban-serving hubs. Finally, the use of cutting-edge tools, such as Overton or other artificial intelligence or machine learning tools, could supplement current practices in identifying and defining not only policy benefits within and across projects but facilitate more efficient identification of demonstrated outcomes from these projects in the literature (40). An additional future step is further exploring these demonstrated outcomes through qualitative analysis to align our work within the original application of the TSBM through case study development.

Conclusion

The TSBM is a compelling framework for describing impacts of translational science research. However, the application of the framework in impact assessments is still in development and being tested by many groups and in many different research settings. The CORES Consortium wanted to test the applicability of the TSBM to rural health research settings and explore the nuances of using the domains and benefits of the TSBM as a coding tool rather than a case study tool. This work highlights where refinement of the tool is still needed in applying the model to assess within-and across-hub impacts. But this work also gives the Consortium insight on the types of projects and impacts that are currently supported and how to prioritize more exploration of the full range of translational science benefits in rural health initiatives going forward. The CTSAs can be influential drivers of research focus and priorities at their respective institutions. While CTSAs are specific research infrastructure to the United States, we believe this application of the TSBM framework to rural research projects can be applied to other assessments of research impacts in rural settings both within the United States and across international settings. By demonstrating the impact of hubs' work on rural health, together the CORES hubs can push toward alleviating health disparities within these communities.

Data availability statement

The raw data supporting the conclusions of this article will be made available by the authors, without undue reservation.

Author contributions

MP: Conceptualization, Data curation, Formal analysis, Methodology, Project administration, Writing – original draft, Writing – review & editing, Investigation, Validation, Visualization. RB: Conceptualization, Formal analysis, Methodology, Visualization, Writing – original draft, Writing – review & editing, Validation, Data curation. Rd: Conceptualization, Data curation, Formal analysis, Methodology, Writing – original draft, Writing – review & editing, Validation, Investigation. HS: Conceptualization, Investigation, Writing – original draft, Writing – review & editing, Project administration. MS: Conceptualization, Investigation, Methodology, Writing – original draft, Writing – review & editing, Project administration. BT: Conceptualization, Investigation, Writing – original draft, Writing – review & editing, Project administration. AE: Conceptualization, Investigation, Writing – original draft, Writing – review & editing, Project administration. JP: Conceptualization, Investigation, Visualization, Writing – original draft, Writing – review & editing, Project administration. TM: Data curation, Investigation, Writing – original draft, Writing – review & editing. NS: Writing – original draft, Writing – review & editing.

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Conflict of interest

The authors declare that the research was conducted in the absence of any commercial or financial relationships that could be construed as a potential conflict of interest.

Generative AI statement

The authors declare that no Gen AI was used in the creation of this manuscript.

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Supplementary material

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EDITED BY
Joe Hunt,
Indiana University, Purdue University
Indianapolis, United States

REVIEWED BY
Kevin Fuji,
Creighton University, United States
Denise Daudelin,
Tufts University, United States

*CORRESPONDENCE
Kim C. Brimhall
✉ brimhall@bu.edu

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Building on the Translational Science Benefits Model to include team science: a practical and theory-based approach to continuous quality improvement and impact evaluation for Clinical and Translational Science Award programs

Kim C. Brimhall[1,2]*, Kayla Kuhfeldt[1], Darrell N. Kotton[1,3,4] and Matthew R. Jones[1,3,5]

[1]Clinical and Translational Science Institute, Boston University, Boston, MA, United States, [2]Department of Health Policy, Law, and Management, School of Public Health, Boston University, Boston, MA, United States, [3]Center for Regenerative Medicine, Boston University and Boston Medical Center, Boston, MA, United States, [4]The Pulmonary Center, Boston University Chobanian and Avedisian School of Medicine, Boston, MA, United States, [5]Department of Medicine, Boston University Chobanian and Avedisian School of Medicine, Boston, MA, United States

Introduction: Clinical and Translational Science Award (CTSA) programs seek to improve the quality and impact of clinical and translational science. CTSA evaluation teams implement structured, evidence-based continuous quality improvement (CQI) processes to enhance activities and outcomes, ultimately benefiting public health. The Translational Science Benefits Model (TSBM) provides a framework for assessing translational science's health and societal impact, yet additional tools are needed to integrate CQI with impact evaluation. Addressing this gap requires combining CQI methodologies with team science approaches. Building on TSBM, CQI theories (e.g., Plan-Do-Study-Act cycles), and team science principles (e.g., inclusive leadership), we propose a theory-driven, evidence-based logic model to enhance CTSA programs. Using our TL1 Regenerative Medicine Training Program (RMTP) as a case study, we demonstrate its practical application for CTSA evaluation teams.

Methods: We conducted a literature review on impact evaluation, CQI, and team science to develop a theory-based approach for CTSA evaluation teams. Using case study methodology, we analyzed RMTP data (2015–2023) through: (a) Interviews with RMTP leaders, mentors, and trainees to explore program implementation and outcomes; (b) Document analysis of program materials, meeting notes, and reports; (c) Bibliometric and policy analysis of publications, citations, and policy documents to assess impact; and (d) Surveys to capture trainees' perspectives on program quality and leadership. This mixed-methods approach provided a comprehensive assessment of RMTP's impact and demonstrated the utility of our team science-based approach to CQI and evaluation.

Results: Our sample included RMTP directors ($N = 2$), mentors ($N = 24$), and trainees ($N = 38$). Among trainees, 68% identified as female, and 21% were from underrepresented groups in medicine. Of 34 graduates, 31 continued in regenerative medicine research. Qualitative data highlighted CQI strategies, such as embedding evaluation into advisory meetings to enhance program functioning. Inclusive leadership fostered a climate where diverse perspectives informed improvements. Quantitative and document analysis further demonstrated how RMTP activities led to positive health and societal impacts within the TSBM framework.

Discussion: CTSA evaluation teams must integrate CQI and impact evaluation, yet few theory-based approaches exist. Our evaluation and CQI framework merges TSBM, CQI, and team science principles, providing a practical tool for guiding evaluation teams in continuous improvement while maximizing translational science impact.

KEYWORDS

Clinical and Translational Science Award, continuous quality improvement, evaluation, Translational Science Benefits Model, logic models

Introduction

Clinical and Translational Science Award (CTSA) programs have been tasked with improving the quality and impact of clinical and translational science (1–3). This involves implementing a well-structured, theory and evidence-based, continuous quality improvement (CQI) process that enhances CTSA activities and outcomes (3). Continuously striving to improve CTSA activities and outcomes helps increase the likelihood that these activities and outcomes have a beneficial impact on public health (4). The Translational Science Benefits Model (TSBM) provides a valuable framework for documenting translational science health and societal impact (5); however, more tools are needed to provide evaluation teams a theory-driven approach for simultaneously implementing CQI and impact evaluation. Although notices of funding opportunities require CTSA programs have a CQI program and measuring and evaluating CTSA public health impact, there is limited guidance on how to accomplish both CQI and public health impact evaluation (3).

Several CTSA programs have recently engaged in efforts to implement CQI processes along with impact evaluation activities. For example, Fishman and colleagues recently published their approach to CQI, highlighting the need for data collection around strategic goals to improve systems and processes (i.e., CQI) rather than solely collecting data to prove the effects of systems and processes (i.e., evaluation metrics) (3). This article provided a valuable distinction between methods and data used for CQI purposes, and those used for impact evaluation purposes. We extend and build on these efforts to provide a CQI approach that incorporates team science principles and impact evaluation using the TSBM (5). More specifically, we draw from theories on CQI (e.g., Plan-Do-Study-Act) (6–8), team science [e.g., inclusive leadership (9) and climate of inclusion (10–12)], and the TSBM framework (5) to develop a theory-driven evidence-based CQI and evaluation approach. We employ case study methodology using our TL1 Regenerative Medicine Training Program (RMTP) to demonstrate the practical application of our method and logic model. This example offers evaluation teams a concrete and adaptable framework for enhancing the quality and impact of clinical and translational science initiatives.

Literature review

In 2011 the National Institutes of Health established the National Center for Advancing Translational Sciences (NCATS) to support CTSA programs that advance translational science. Translational science aims to address urgent public health needs through developing rapid innovations and producing effective solutions to longstanding systemic bottlenecks that slow the translational process (i.e., translating research into practice so that new treatments and health solutions reach people faster) (2). To measure the effectiveness of the overall CTSA program, NCATS launched the Common Metrics Initiative in 2015 (13). This initiative aimed to develop and implement a standardized set of Common Metrics across CTSA programs to assess the overall impact of CTSAs. These common metrics included measures on CTSA outcomes of research process efficiency (e.g., median Institutional Review Board review duration), career development (e.g., retention and diversity of CTSA scholars/trainees in clinical and translational research), and scientific productivity (e.g., pilot and grant funding awards, publications) (5). While these metrics may provide insight into CTSA operational effectiveness, they are less informative on how CTSA activities can be improved and CTSA's long-term impact on translational science (5). In response, CTSA programs have been recently tasked with ensuring their activities and outcomes effectively lead to meaningful public health benefits (3, 5), suggesting CTSA evaluators need to implement CQI of CTSA activities and evaluate CTSA outcomes for public health impact. Research demonstrates the positive effects of implementing CQI processes as a way to enhance the efficiency and effectiveness of various CTSA activities (3), with the goal of increasing the likelihood these activities have a beneficial impact on societal and public health.

Translational Science Benefits Model

The Translational Science Benefits Model (TSBM) provides a valuable framework for documenting translational science health and societal impact (5). This relatively new framework identifies four main domains of how clinical and translational science can benefit health and society: clinical and medical, community and public health, economic, and policy and legislative. These domains provide a way of organizing how clinical and translational science can have an impact on public health and well-being (14). The clinical and medical domain refers to procedures, guidelines, tools, or products that were developed from clinical and translational research and implemented in clinical and/or medical practice. The community and public health benefits domain refers to the enhancement of health care, community, and/or population well-being as a result of clinical and translational research (e.g., improvements in health activities and products, health care characteristics, and/or community health promotion). Economic benefits of clinical and translational research can refer to developed commercial products, financial savings and benefits, and increased economic mobility of trainees and scholars. The fourth main benefit domain refers to policy and legislative benefits, including the ability of translational science to influence advisory activities and the decision-making process of organizational or public policies, legislation, or governmental standards. This can include how translational research informs policymaking and is used in formal adoption of policies and legislation, such as organizational guidelines and internal agency decisions as well as formal laws or rules enacted by governmental bodies (5, 14).

The TSBM framework can be a valuable tool for providing a common language around tracking the public health impact of clinical and translational science; however, more tools are needed to provide evaluation teams a theory-driven approach for simultaneously implementing CQI and impact evaluation. Given that CTSA programs have been tasked with accomplishing both, CQI and impact evaluation, we strived to create a theory-based framework that brought together CQI, impact evaluation using the TSBM, and team science.

Continuous quality improvement

Table 1 provides a summary of common CQI approaches. Rooted in the scientific method, CQI methods have been used to iteratively improve health care (8, 15) and more recently encouraged to enhance CTSA efforts toward translational science (1–3). The Plan-Do-Study/Check-Act (PDSA/PDCA) cycle of CQI is one of the most widely used methods within health care and considered a key foundational approach to quality improvement (6–8). The first stage in the PDSA/PDCA is "plan" or the prediction/hypothesis of testing a particular change. The "do" part of this cycle refers to implementing the planned change, whereas the "study" or "check" portion of the cycle refers to analyzing the effects of the change (hypothesis testing). The "act" part of the cycle generally refers to reaching a conclusion with another prediction of what to do next in the "plan" stage of the PDSA/PDCA (16).

A successful CQI process is learning (16). Learning may come from achieving quality improvement goals (the tested change in a CQI approach worked). Learning can also come when quality improvement goals are not achieved, often uncovering unanticipated constraints that need to be addressed and/or identifying new problems central to the originally identified challenge. In other words, a well-conducted CQI approach promises learning, not that specific quality improvement goals will achieve their desired outcomes (17). The task of CQI methods, such as the PDSA/PDCA, are to translate ideas for improvement into action, evaluate that action to encourage learning, and then ultimately improve the quality of what's done. Several CQI frameworks have been developed to expand upon the PDSA/PDCA approach.

The FOCUS-PDCA cycle enhances the PDSA/PDCA process by adding steps to find and improve a specific process, organize a knowledgeable team, clarify the selected process, understand variations in the selected process, and choose possible process improvements (18). The FADE approach is more of a linear CQI process that involves identifying a problem, understanding it through data analysis, developing solutions, and then implementing the solution plan (18). Similarly, lean CQI approaches follow more linear and data-driven steps (e.g., value stream mapping and root cause analysis) to quality improvement. The Lean 5S approach focuses on five ordered steps (sort, set/straighten, shine, standardize, sustain) to help reduce workplace waste by enhancing organization and efficiency (18, 19). The Kaizen approach focuses on more incremental and practical improvements through empowering employees to problem-solve, using data to drive change, acknowledging process defects, reducing variability and waste, and maintaining a disciplined workplace. Lean Six Sigma involves five steps that define (D) and measure (M) the problem, analyze (A) root causes, develop (D) or improve (I) solutions, and control (C) or verify (V) process stability (19). DMAIC is used for current process improvement whereas DMADV is used for developing new processes for improvement. Another CQI approach which incorporates data-driven methods and root cause analysis is the Logic Framework. This approach involves brainstorming to identify improvement areas, conducting root cause analysis to develop a problem tree, logical reasoning to create an objective tree, formulating the framework, and executing improvement projects (20). A more collaborative CQI framework includes the Breakthrough Series, which requires CQI teams to meet in quarterly collaborative learning sessions, share learning experiences, and continue discussion by telephone and cross-site visits to strengthen learning and idea exchange (18). A collaborative community-driven CQI approach is the 5 C-cyclic model (consultation, collection, consideration, collaboration, and celebration). This approach was originally designed for volunteer dental services in Aboriginal communities to improve quality of care based on community needs (18).

Many of the CQI frameworks were developed for specific organizational or programmatic quality improvement purposes and may not yield the flexibility needed for quality improvement in more complex multi-team systems, like CTSAs. For example, some of the most common challenges to CQI efforts involve individual resistance to change, discomfort with inter-professional collaboration, and failing to create a positive organizational climate conducive to CQI. Literature indicates possible solutions to common CQI challenges, such as qualified leadership that can foster collaborative workplace cultures (18), however, more research is needed on specific leadership approaches and organizational climates that support and engender CQI, particularly in complex interdisciplinary multi-team systems. Thus, using evidence-based and theory-driven team science approaches we developed a framework for CQI and evaluation to help mitigate common barriers to successful CQI. Our framework incorporates PDSA/PDCA's iterative improvement cycle, aligns with the Breakthrough Series and Kaizen approaches by emphasizing collaborative learning, team-based reflection, and valuing incremental and practical improvements, and uses the Logic Framework by incorporating logic models to support structured problem-solving. The unique and novel contributions of our

TABLE 1 Overview of continuous quality improvement (CQI) models.

CQI model	Key steps		Unique features
PDSA/PDCA	1. Plan 2. Do 3. Study 4. Check/Act		Foundational model for iterative continuous improvement.
FOCUS-PDCA	1. Find process 2. Organize team 3. Clarify process 4. Understand variations 5. Select improvements	then apply: 6. Plan 7. Do 8. Study 9. Check/Act	Extension of PDSA/PDCA to enhance process efficiency.
FADE	1. Focus (identify problem) 2. Analyze (data analysis) 3. Develop (solutions) 4. Execute (implement plan)		Linear process for problem identification, analysis, and execution of solutions; Ideal where clear problems exists & one-time solutions needed.
Logic framework	1. Identify improvement areas 2. Conduct root cause analysis 3. Create problem & objective trees 4. Formulate framework 5. Execute projects		Logical reasoning for structured problem-solving; Uses structured analysis tools like problem & objective trees.
Breakthrough series	1. Team collaborative learning sessions 2. Share experiences 3. Discuss progress		Emphasizes team learning, knowledge sharing, & cross-organizational collaboration.
Lean 5S	1. Sort 2. Set/Straighten 3. Shine 4. Standardize 5. Sustain		Focuses on workplace organization, efficiency, & reducing waste.
Kaizen	1. Continuous small improvements 2. Problem-solving 3. Employee empowerment		Encourages incremental, practical, low-cost changes & process discipline.
Lean Six Sigma DMAIC/DMADV	1. Define 2. Measure 3. Analyze 4. Improve 5. Control	1. Define 2. Measure 3. Analyze 4. Design 5. Verify	Data-driven process optimization; Reduces variability & waste while ensuring process stability (DMAIC used for current processes; DMADV used for new processes).
5C Cyclic Model	1. Consultation 2. Collection 3. Consideration 4. Collaboration 5. Celebration		Community-driven quality improvement; Designed for volunteer healthcare services in Aboriginal communities.
WE-CQI	1. Collaborative planning 2. Shared action 3. Team reflection & learning		Combines team science, TSBM, & PDSA/ PDCA, Kaizen, Breakthrough Series, & Logic Modeling into a simplified 3-step approach.

framework is that it simplifies these multiple CQI approaches, incorporates principles of team science, and applies the TSBM into a streamlined three-step process (collaborative planning, shared action, and team reflection/learning). Unlike CQI models with more rigid and linear steps (e.g., FADE, DMAIC), our approach is designed to be flexible and adaptive to dynamic team environments, such as multi-team complex systems like CTSAs. In essence, our framework applies team science principles, integrating collaboration, knowledge sharing, and iterative learning into a simplified yet comprehensive improvement model designed to promote TSBM impacts.

Team science

CTSA programs are multi-team systems wherein multiple groups of individuals (often diverse and multidisciplinary team members) must work together to accomplish CTSA objectives. This means individuals must work effectively within their respective teams and across multiple teams within the CTSA to accomplish program objectives. This requires a novel approach to quality improvement and evaluation methods that incorporates team science. Team science is a translational science core principle and one of NCATS's strategic goals

(21, 22), as it focuses on best practices for engaging multidisciplinary team members around shared objectives, such as implementing quality improvement and impact evaluation processes. Below we describe our evaluation and CQI approach grounded in team science theories that strive to create an inclusive organizational climate. Inclusion has been shown to be an effective organizational management and team science approach for creating environments wherein teams can openly share ideas with one another around complex challenges (23, 24) and generate new methods for quality improvement (9).

Theory-based framework

Wisdom-driven evaluation and continuous quality improvement

Drawing from theories of team science and several CQI frameworks, we develop a team-based quality improvement process designed to provide a theory-driven approach to CQI and impact evaluation for CTSA programs. More specifically, we draw on team science theories of inclusive leadership (9) and climate for inclusion (10–12) as best practices for implementing wisdom-driven evaluation and CQI (WE-CQI). We define WE-CQI as the ability to use collective knowledge and experiences to make shared decisions on measuring the quality and impact of something, including CQI efforts and evaluation of these efforts. There are three phases: collaborative planning, shared action, and team reflection and learning (see Figure 1).

Collaborative planning

The first phase, collaborative planning, involves engaging a representative group of team members who are involved in accomplishing the specific CTSA program objective. Sometimes this requires bringing together team members from the same program who focus on a specific CTSA objective and sometimes this involves bringing together multiple teams from different programs within a CTSA that partner to accomplish the CTSA objective. The CTSA evaluation team facilitates the WE-CQI meeting(s) focused on collaborative planning and decision-making around best practices for accomplishing the objective and generating ideas for quality improvement. During the collaborative planning phase, evaluation team members strive to use principals of inclusive leadership. Leader inclusiveness has been defined as the “words and deeds by a leader or leaders that indicate an invitation and appreciation for others’ contribution” (9). When leaders engage all team members by seeking input from others in decision making, encouraging everyone to take initiative in organizational processes (e.g., quality improvement and evaluation processes), and expressing equal value for the contributions of others, individual participation and engagement efforts increase (25). This type of leader inclusiveness goes beyond simply sharing decision making; it strives to foster intergroup contact by helping members feel valued and appreciated for their unique perspectives, regardless of individual job positions within the CTSA or personal educational backgrounds. The leader’s ability to encourage the participation of all members and expressing value for their unique perspectives aligns with the theoretical foundation for creating an inclusive climate (10–12, 26).

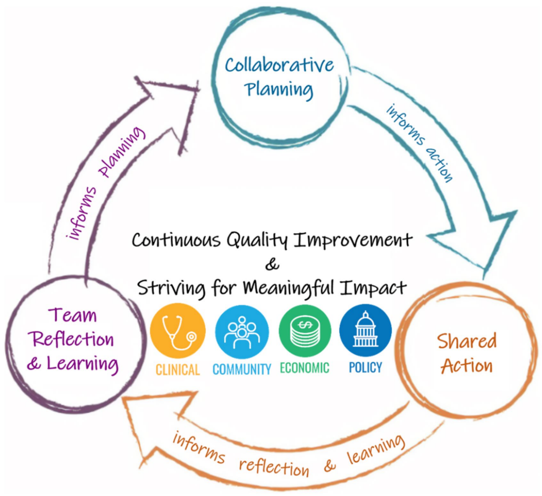

FIGURE 1
Wisdom-driven evaluation and continuous quality improvement (WE-CQI). TSBM icons: The Translational Science Benefits Model and Translating for Impact Toolkit© 2017–2023, created by the Institute of Clinical and Translational Sciences at Washington University in St. Louis and available at *translationalsciencebenefitsmodel.wustl.edu*, is licensed under *Attribution-NonCommercial-ShareAlike 4.0 International (CC BY-NC-SA 4.0)*.

Optimal distinctiveness theory suggests that individuals feel included when they are valued for their uniqueness while also experiencing a sense of belonging within the group (12, 26). When leaders demonstrate inclusiveness by acknowledging and appreciating team members’ unique perspectives, they reinforce the value of individual uniqueness. For example, when CTSA leaders or evaluators seek feedback and publicly recognize a team member’s contributions, they signal that the team member is a valued part of the group (27, 28). This, in turn, encourages other CTSA members to appreciate their contributions, fostering a stronger sense of belonging (26). Leader inclusiveness ensures that each team member feels valued, and by fostering both uniqueness and belonging, it creates an environment where individuals feel comfortable sharing their ideas with one another (29, 30).

Leader inclusiveness has been linked to increased psychological safety, which enables team members to take interpersonal risks, such as speaking up and sharing their ideas, experiences, and knowledge (31). This open exchange is essential during the collaborative planning phase of WE-CQI meetings, as team members must feel valued and engaged in developing the collaborative plan. However, if team members believe the perspectives they shared were not valued (not acknowledged, discussed, or incorporated), the quality improvement plan fails to reach a level of collaboration and instead may be viewed by team members as a performative exercise (an illusion of inclusion). For a collaborative plan to truly be collaborative, team members need feel a sense of empowerment and responsibility for the creation of the plan (team members are full partners in the plan’s creation).

Shared action

Once the collaborative plan has been created, team members responsible for accomplishing the CTSA objective share responsibility in the implementation of the collaborative plan. Leadership research suggests a narrow to medium span of control for CTSA leaders yields optimal results for team member satisfaction and performance (32, 33), suggesting CTSA leaders have ideally up to 10 team members they supervise (34). Thus, we have designed a proactive leadership structure to ensure CTSA program team members feel supported in the implementation of the collaborative plan. This structure includes quarterly WE-CQI meetings with the CTSA evaluation team and members of the CTSA program involved in the collaborative plan for quality improvement and evaluation of the specific CTSA objective. The purpose of the quarterly WE-CQI meetings is to provide consistent time to review the collaborative plan implementation and problem solve unanticipated barriers or challenges to implementation (these WE-CQI meetings are also scheduled as needed if major unanticipated barriers arise). In addition to quarterly WE-CQI meetings, the evaluation team holds bi-weekly WE-CQI meetings with program staff and managers. Each CTSA program has at least one manager (some programs have multiple managers depending on team size to ensure an optimal span of control) who are primarily responsible for the day-to-day implementation of program activities. These bi-weekly WE-CQI meetings are designed to be proactive in nature by providing training for managers in best practices for quality improvement and evaluation activities, reinforce a culture of inclusion and partnership in the shared action of the collaborative plan, and reserve time for staff to check-in and problem solve for minor unanticipated challenges with collaborative plan implementation [major barriers or challenges are brought to the quarterly (or as needed) WE-CQI meetings where all program team members are present].

Team reflection and learning

Once the collaborative plan has been implemented through shared action from members of the CSTA program, the evaluation team facilitates team reflection and learning through quarterly WE-CQI meetings. Similar to the collaborative planning phase, principles of inclusive leadership (9, 25) and inclusion (10–12) are used to facilitate team reflection on the implementation of the collaborative plan and evaluation of the tested quality improvement change implemented. Through open team dialogue, team members reflect on data collected on the implementation process, quality improvement change, and ultimately TSBM potential (or realized) impacts. A climate of psychological safety (35) is critical for successful team reflection and learning (36), particularly when discussing potentially sensitive topics, such as when quality improvement efforts fail to yield anticipated results. Inclusive leadership and climate for inclusion are critical antecedents to (25, 36) open and honest communication which enables learning from quality improvement processes and creating new avenues to further improve (31, 36). Thus, an open and honest discussion among all team members is needed to promote meaningful reflection of quality improvement efforts, determine whether continued changes are needed to effectively meet CTSA objectives, and evaluate the health and societal impact of CTSA activities. The team reflection and learning phase then informs the next collaborative planning phase in the WE-CQI framework for CQI and striving for meaningful impact.

Application and case study

Building on the TSBM framework (5) we develop a logic model that incorporates our theory-driven and team science-based approach to CQI and impact evaluation. We utilize a case study approach to demonstrate how our logic model can be applied with our TL1 Regenerative Medicine Training Program (RMTP), providing a practical approach for CTSA evaluation teams striving to improve the quality and impact of clinical and translational science (see Figure 2; Table 2).

WE-CQI logic model

Logic modeling refers to the process through which evaluators discern, represent and utilize program theory to design and implement each stage of evaluation (37). As a standard evaluation practice, logic modeling can enhance alignment and efficiency between data collection for CQI and evaluation and program activities and objectives (37). In the WE-CQI framework, logic modeling is used as part of the collaborative planning phase to co-design how CQI and evaluation activities are embedded within the CTSA program objectives. Members of the CTSA program and evaluators co-create the WE-CQI logic model to: (a) represent how program resources, activities, and outputs lead to short-and long-term outcomes and TSBM impacts; (b) design program CQI and evaluation activities; and (c) clarify shared roles and responsibilities of CTSA team members in the implementation of program activities, CQI, and evaluation. It is important to note that while all TSBM domains (i.e., clinical, community, economic, and policy) are represented in the WE-CQI logic model, not all CTSA programs will have equal impacts in each of the TSBM domains. For example, some CTSA programs, like the Community Engagement program may have more TSBM impacts in the community domain as opposed to the economic domain, and the RMTP program may have more impacts in the TSBM economic domain relative to the community domain. The overall goal of developing WE-CQI logic models for each CTSA program is to highlight which programs lend to specific TSBM impacts, with the ultimate goal of the entire CTSA having impacts in each TSBM domain.

To illustrate the WE-CQI's logic model application, we use the RMTP program as a case study. First, we listed all the resources (CTSA and other) that support the RMTP in the far-left column. Resources directly influence the activities the RMTP is able to perform and thus RMTP activities are listed in column two. Activities are then linked to anticipated outputs along with how these outputs are being measured (appear directly under each output description in the output column). Outputs are linked to short-term outcomes along with how short-term outcomes are being measured (appear directly under each short-term description in the short-term outcomes column). Short-term outcomes are then linked to long-term outcomes along with their associated methods which appear directly under each long-term description. Finally, long-term outcomes are linked to down-stream health and societal benefits (and how these are measured) following the TSBM framework that includes clinical, community, economic, and policy benefits. Given RMTP is a training program embedded within a CTSA, it is important to note that some short-term and long-term outcomes, such as research conducted in collaboration with RMPT leaders, CTSA members and trainees may lead to immediate and direct health and societal impacts (e.g., new clinical and/or procedural guidelines for treating and studying infectious disease), as well as more long-term and down-stream TSBM impacts (e.g., the development of safe and cost-effective treatment options).

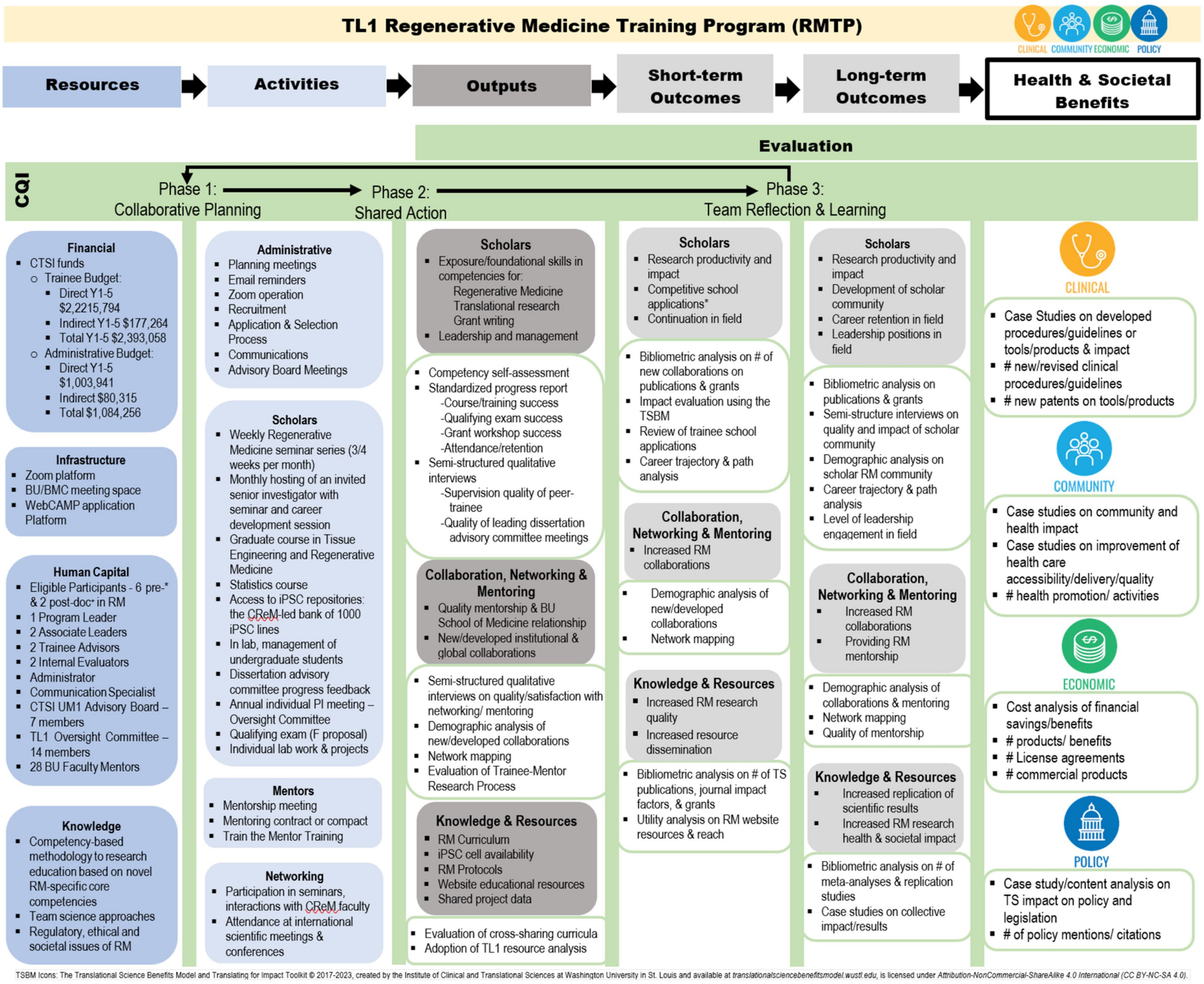

FIGURE 2
WE-CQI logic model example.

Collaborative planning

During the collaborative planning phase of our WE-CQI approach we examine current resources and activities that support the RMTP. This provides a foundation for understanding the current resource structure and activities being performed by the RMTP, which enables realistic planning for areas of improvement. The collaborative planning phase is placed in-between the resources and activities columns of the logic model given the high possibility of needing to allocate resources and/or adjust or re-envision activities to support planned WE-CQI efforts. It is important to note however, when collaboratively planning for quality improvement and impact evaluation, the entire logic model is reviewed given that CQI efforts may be identified throughout the logic model. For example, reviewing outputs, short-or long-term outcomes, and health and societal benefits, may uncover areas needing improvement which often requires changes/adjustments in resources and activities.

Shared action

The shared action phase of the WE-CQI framework is visually placed in-between the activities and outputs columns of the logic model to represent how RMTP activities are often partnerships across the CTSA and other teams, and how implemented WE-CQI initiatives during the collaborative planning phase become shared actions by RMTP and evaluation team members. In other words, quality improvement efforts developed in the collaborative planning phase become a shared responsibility among team members to implement the developed quality improvement plan (i.e., shared action).

Team reflection and learning

During the team reflection and learning phase of the WE-CQI framework, all members of the RMTP and CTSA evaluation team have an opportunity to reflect on quality improvement and evaluation data collected along with lived experiences of team members during the implementation of quality improvement efforts. This phase involves a comprehensive review of data collected from RMTP activity outputs, short-and long-term outcomes, and health and societal benefits, providing a holistic assessment of the program's progress and impact. During this reflection process, the team critically examines whether the CQI strategies developed in the collaborative planning phase effectively enhanced the RMTP objectives and overall impact. Integrating both quantitative and qualitative insights from team members' experiences fosters a comprehensive and meaningful reflection process. This approach enables the identification of successes, challenges, and areas for improvement. This iterative review not only strengthens the RMTP but also supports alignment with the

TABLE 2 Examples of RMTP CQI, evaluation, and TSBM impact activities.

Level	Example of CQI activities	Example of evaluation activities	Example of impact evaluation	
Trainee	• Competency assessment • Survey on mentorship quality • End-of-training satisfaction survey • Training implementation acceptability, adoption, feasibility, & fidelity	• Academic/research progress: trainee & mentor reporting on trainee academic/research progress, competencies, development of translational scientist characteristics & leadership skills • Bibliometric analysis during & after program; research productivity, influence, impact, co-author collaborations, & career pathway tracking	CLINICAL	• Development of clinical guidelines/ procedures • Case studies on implementation/ impact of clinical guidelines/ procedures
Mentor	• Mentorship behaviors & quality survey • Mentor support satisfaction survey • Mentor training implementation acceptability, adoption, feasibility, & fidelity	• Bibliometric analysis during program & mentorship: research & scholarly productivity, influence, impact, & network growth analysis	COMMUNITY	• Development of translational science & community/health education resources
Program	• Regular review of data, processes & outcomes for overall CQI: collaboratively plan (identify & operationalize strategies for improvement), shared action (implement strategies & collect data), & team reflection & learning (assess impact & decide to adopt, adapt & test for a second cycle, or abandon strategies)	• Fidelity & effectiveness of trainee & mentor recruitment: demographic analysis (trainees & mentors); assessment of recruitment activities/ challenges/modifications/selection • Dissemination & adoption of research/training resources: Tracking protocol downloads, iPSC vials shipped, stem cell & gene editing repositories, website visits, training curricula & resources • Pre-& post trainee assessment of translational science competencies, characteristics, & knowledge	ECONOMIC	• New license agreements/patents on developed intellectual property initiated by RMTP trainees/ mentors/program
			POLICY	• Influence on policy & legislation (measured using Overton policy analysis)

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TSMB by emphasizing impacts across clinical, community, economic, and policy domains. The reflection and learning phase concludes with the development of new strategies and priorities, which directly inform subsequent collaborative planning and CQI efforts, ensuring a cycle of continuous enhancement and alignment with translational science goals.

Case study methods

To illustrate our WE-CQI framework, case study methods on the RMTP were used to provide a practical application of the logic model. Case studies offer evidence about causal inference and program implementation and are widely recognized as an invaluable resource for understanding the dynamic influence of context on interventions, such as the RMTP training program. For example, case studies directly inform assessments of where, when, how and for whom the RMPT training program might be successfully implemented, by specifying the necessary conditions under which the program may have effects and to consolidate learning on how interdependencies and unpredictability can be managed to achieve and sustain desired effects (38). Data were collected from 2015 to 2023 using a mixed-methods approach that included semi-structured qualitative interviews with RMTP leaders, mentors, and trainees, document, bibliometric, and policy analysis, and quantitative surveys.

Semi-structured qualitative interview guides of open-ended questions were co-designed with the RMTP leaders and CTSA evaluators to assess quality and satisfaction with RMTP training and mentoring. Interview guides were reviewed yearly by RMTP leaders and CTSA evaluators and revised if needed based on participant feedback. Each RMTP participant trainee in each cohort were interviewed twice throughout their training program, a mid-point interview (typically at the end of Year 1) and a final exit interview at the end of their appointment. To protect trainee confidentiality and promote open and honest feedback, CTSA evaluators conducted interviews individually with trainees in a private meeting space and/or via Zoom. Interviews were transcribed by CTSA evaluators, and all personal identifying information of trainees were removed from the data. De-identified data was aggregated such that all participant responses were combined by interview question to ensure participant anonymity. Using constant comparative methods, qualitative data was thematically analyzed by two independent CTSA evaluators (39–42). Differences in emerged themes and codes were discussed until consensus was reached (interrater reliability of 90% or better). Qualitative data was used to help contextualize quantitative data (i.e., survey, bibliometric, policy and document analyses) and final summary reports were created to provide RMPT scholars, mentors, and leaders evidence-based feedback for guiding program enhancements.

Two separate quantitative surveys were co-designed by CTSA evaluators and RMTP leaders. A trainee survey (to be completed by the RMPT trainee) was used to assess the trainee's perceptions of quality and satisfaction with RMTP training and mentoring as well as their progress, challenges, and accomplishments. A separate mentor survey (to be completed by the trainee's mentor) was used to assess mentor perceptions of their trainee's progress, challenges, and accomplishments. Trainee and mentor survey results were matched by trainee-mentor pairs to examine possible discrepancies in trainee and mentor perceptions of the trainee's progress, challenges, and accomplishments. These surveys were distributed yearly to both the trainee and the trainee's mentor and sent through a secure standardized progress report application in WebCAMP (i.e., analytic tool created by Weill Cornell Medicine's Clinical and Translational Science Center in 2014). The WebCAMP software stores both administrative and evaluation data linked to RMTP training program implementation. It is centralized for use by our CTSA evaluator team who ensures data quality and reporting to the CTSA leaders and governance groups such as External Advisory Boards and internal oversight committees.

Document analysis included thematic reviews of internal standardized action plans (used to measure and assess trainee progress and individualized trainee programmatic changes over time); bibliometric analyses using a variety of external software analysis tools (e.g., Dimensions, BU Profiles, and iCite) to measure and assess research productivity, influence, and impact over time; and policy analyses conducted using external Overton policy analysis software (43). Publications that cite the RMTP program and all publications written by RMTP trainees were searched via the Overton tool, which shows any policy documents or policy mentions that utilize the specific publication. These policy documents are then aggregated and displayed in an overall report, highlighting policy sources by location (e.g., country), organization type, funder of cited research, publication date, and policy subject areas. For the purposes of the case study and application of the WE-CQI RMTP logic model, all data from document analysis, surveys, and interviews were aggregated by topic and theme (e.g., RMTP resources, activities, outputs, short-and long-term outcomes, and TSBM impacts). Specific examples of CQI efforts that emerged from the data were highlighted for more in-depth illustration of the WE-CQI framework.

Case study results

The sample includes RMTP Program Directors and CTSA members ($n = 2$), mentors ($n = 24$), and trainees ($n = 38$). Of the RMTP trainees, 66% self-identify as female and 21% self-identify being from a National Institutes of Health (NIH) defined under-represented racial and/or ethnic demographic group in medicine (44). 34 RMTP trainees have completed the two-year RMTP program, with 31 trainees remaining in regenerative medicine research and 3 trainees in healthcare consulting, medical writing, and health system clearance coordinating careers. Qualitative data from RMTP leaders revealed critical CQI processes that led to successful program implementation. This includes strategies that disentangle roles and responsibilities of CTSA team members and thoughtful approaches for how CQI and impact evaluation activities can be embedded in the logic model and throughout the program. For example, case study findings revealed a CQI process that RMTP leaders implemented to ensure timely reflection on program functioning and seek opportunities for program improvement from diverse perspectives: RMTP leaders implemented evaluation as a standing agenda item in their internal advisory committee meetings. This created dedicated time to review and reflect on program evaluation data (e.g., program activities, trainee/mentor feedback, barriers and challenges to trainee progress) and to discuss opportunities for program enhancement with members of the evaluation team and internal advisory committee.

Case study CQI & TSBM impact examples

The RMTP places a strong emphasis on cross-disciplinary collaboration and communication skills, centered in team science principles, such as inclusive leadership and fostering a climate for inclusion where diverse perspectives are actively shared and valued. Results from the CQI process, guided by these principles, have driven several programmatic changes that improved implementation and outcomes for RMTP trainees. Likewise, results from quantitative data and document and policy analysis demonstrate impact evaluation activities embedded within the logic model that connects how RMTP resources, activities, outputs, and outcomes led to positive health and societal impacts within the TSBM framework.

CQI building a sense of community

Trainee feedback from the Fall 2016 mid-program interviews ($n = 8$) revealed that trainees felt a lack of community with their peers. In response, the RMTP Program Director initiated two annual luncheons to facilitate peer interactions and build connections among trainees. By the 2018 exit interviews ($n = 4$), feedback indicated a strengthened sense of community as a result of this initiative. However, with the COVID-19 Pandemic in 2020, trainees again were impacted with their sense of community due to the need to self-isolate and not gathering in social or work settings. In the 2022 mid-point interviews ($n = 8$), majority of the interviewed trainees (75%) indicated the COVID-19 Pandemic influenced their training, including delays in lab training, feelings of isolation, loss of opportunities, and loss of mentorship time and opportunities. Recent interviews in 2023 ($n = 8$), indicated the majority of trainees (75%) believed the COVID-19 Pandemic was still having an impact due to the lack of availability of additional trainings from staffing shortages, limited resources due to supply chain issues, delays in graduation and project timelines, and lack of one-on-one mentorship during the pandemic. Nevertheless, trainees expressed a renewed sense of connection as they resumed attending seminars at the Boston University's Center for Regenerative Medicine (CReM), working collaboratively in shared laboratory spaces, and attending meetings with mentors.

To illustrate how CQI and impact evaluation examples from the case study align with the WE-CQI logic model—and to further demonstrate its application—we describe in more detail below how the *CQI Building a Sense of Community* example maps onto the WE-CQI logic model. In the Resources column of the WE-CQI logic model, financial (e.g., administrative support in coordinating additional trainings), infrastructure (e.g., integrating zoom as a platform for creating community and offering mentoring) and human capital (e.g., availability of mentors) resources were used to influence the types of activities supported in building a sense of community. In the Activities column of the WE-CQI logic model, administrative (e.g., coordinating annual luncheons for peer and mentor networking), scholar (e.g., training seminars), mentors (e.g., one-on-one mentorship meetings with trainees), and networking (e.g., CReM seminars) were particular activities related to building a sense of community for trainees. The Outputs column of the WE-CQI logic model displays outputs of RMPT activities as well as how outputs are being evaluated for CQI and impact [scholars (e.g., qualitative interviews on trainee satisfaction with mentorship), collaboration, networking and mentoring (e.g., examination of survey data on discrepancies between trainee-mentor perceptions on trainee research progress, barriers, and accomplishments), knowledge and resources (e.g., examination of trainee attendance and engagement with RMPT curriculum trainings and CReM networking seminars)]. This information helped uncover whether implemented CQI efforts, such as establishing annual luncheons with trainees, were effective in building a sense of community for trainees. Short-Term and Long-Term Outcomes are also represented in the WE-CQI logic model as well as CQI and evaluation methods for assessing these outcomes. This further helped evaluate the impact of implemented CQI efforts designed to build a stronger sense of community among trainees, e.g., short-term outcomes of increasing available mentorship through increased one-on-one mentor meetings and CReM networking seminars resulted in broader mentorship networks and long-term outcomes of increased training opportunities and collaborations on research publications. Research collaborations and mentored research publications are followed to examine the down-stream TSBM impacts, such as whether research contributes to the development of new clinical guidelines and methods for studying and treating infectious disease.

CQI enhancing performance evaluation and career development

Trainee feedback from the Fall 2016 mid-program interviews ($n = 8$) showed that trainees were satisfied with the quality and amount of informal feedback but wanted more formalized evaluation on their performance and progress. In response to this feedback, the RMTP Program Director started conducting annual performance reviews using a standardized evaluation form after each trainee's research presentation. Trainee feedback from the exit interviews in 2018 ($n = 4$) indicated the annual committee meeting did provide a formal review, and this meeting was useful for evaluating their performance and progress. Building on this enhancement, the program also incorporated individualized career development plans (IDPs) to support trainees in exploring potential career pathways. Trainees worked collaboratively with their mentors and an oversight committee to develop and refine their IDPs, aligning their training activities with their long-term career goals. This addition not only formalized performance evaluations, but also provided structured guidance to help trainees identify and pursue careers in areas such as academia, industry, healthcare consulting and medical writing. Using an inclusive leadership approach, RMTP mentors and oversight committee members encouraged diverse perspectives and demonstrated value for trainees' unique career interests. By the 2023 mid-point interviews ($n = 8$), seven of the eight trainees reported feeling confident in their growth toward becoming independent researchers and all eight trainees expressed progress toward feeling confident as they continued to work on activities such as submitting their first peer-reviewed publication or grant applications. All trainees expressed appreciation for the individualized career-focused support provided by the program.

CQI increasing diversity and inclusion

Applicant and awardee demographics from Fall 2015-Spring 2017 highlighted a lack of participation from underrepresented minorities, as defined by the NIH [i.e., people who identify being African American, Black, American Indian, Alaska Native, Native Hawaiian or other Pacific Islanders; Hispanic and/or Latino; women; having a disability; and/or those from disadvantaged backgrounds (e.g., first-generation college students, individuals from rural settings, or those with low socioeconomic status)] (44). In response, the RMTP Program Director enhanced recruitment strategies in Fall 2016. This plan included targeted outreach efforts to establish partnerships with minority-serving institutions and modifications to existing applications review criteria to prioritize a more holistic review. Additionally, the Emerging Scientific Scholars Program (ESSP) was introduced during the 2022 academic year to further enhance diversity at Boston University. The ESSP aimed to attract outstanding Ph.D. students from underrepresented groups by offering one-time financial scholarships. These scholarships were designed to support students transitioning to higher cost of living areas, such as Boston, and are tailored for United States citizens or permanent residents who are economically disadvantaged individuals, or first-generation college students. Scholarships are either included with the admission letter or communicated separately, with the primary objective of broadening the inclusivity of the incoming class. This financial support is part of an ongoing commitment to help students overcome economic barriers associated with relocating for advanced studies. Collectively, the changes implemented between 2015 and 2023 have contributed to notable increases in the representation of underrepresented groups in the program, as evidenced by demographic trends detailed in Table 3, as well as greater geographic diversity (data not shown).

TSBM clinical impact

Increasing the diversity of regenerative medicine research trainees aligns with our overall RMTP goals of increasing the overall regenerative medicine workforce (a broader TSBM clinical impact). Based on team science principles of inclusive leadership and creating a climate for inclusion, RMTP leaders partnered with our internal advisory board to collaboratively create the RMTP trainee recruitment plan following our WE-CQI process: collaborative planning, shared action, and team reflection and learning. This has allowed our RMTP program to successfully grow in all underrepresented demographic categories. By striving to increase the diversity of highly trained and competent researchers and practitioners in regenerative medicine, we aim to help enhance the larger regenerative medicine community. A more diverse workforce in this field has the potential to drive more innovative and novel research practices and theories. When there is a climate for inclusion, workforce diversity has shown to increase the generation of novel and groundbreaking ideas (45). When diverse members of a research community are treated in an inclusive manner, this creates a broader talent base and increases access to a wider range of knowledge, insights, and perspectives essential for innovation (45). This holds promise for enhancing health equity research topics and increasing participation of diverse and underrepresented participants

TABLE 3 RMTP demographic data for awarded trainees 2015–2023 ($n = 38$).

Self-identified demographic categories	2015–2018 ($n = 19$)	2020–2023 ($n = 19$)
Women	58% ($n = 11$)	74% ($n = 14$)
Hispanic/Latino ethnicity	5% ($n = 1$)	26% ($n = 5$)
Racial underrepresented minority	0% ($n = 0$)	11% ($n = 2$)

Racial Underrepresented Minority categories include American Indian/Native Alaskan; Native Hawaiian or Other Pacific Islander; Black or African American.

in clinical trials. In essence, the down-stream health and societal benefits of such engagement can lead to the development of medical treatments that better serve underrepresented communities, ultimately reducing health disparities and improving outcomes for all populations.

An example of our commitment to meaningful impact within the TSBM clinical domain is our focus on equipping trainees with the skills and resources necessary to become independent researchers through their RMTP training, mentoring, and access to resources. This approach has proven successful in that 91% ($n = 31$) of our trainees remain engaged in regenerative medicine research fields in academia and industry, while three trainees remain engaged in healthcare consulting, medical writing, and health system clearance coordinating careers. Our trainees are making significant contributions across a variety of areas, including biomedical technologies, drug development, biological factors and products, software technologies, investigative procedures, diagnostic procedures, and therapeutic procedures. Table 4 provides specific examples of industry research initiatives where our graduated trainees are driving innovation and are making an impact.

TSBM community and public health impact

One of our graduated trainee's current career position is within CME Outfitters, LLC, an independent accredited provider of multidisciplinary continuing medical education & accreditation services. This entails striving to increase health education resources with the goal of helping medical professionals improve the quality and delivery of health care services. Part of this entails helping current researchers and academics translate their scientific findings for a broader community audience, providing manuscript writing and editing services for biology and related research fields. In essence, their work aims to provide engaging evidence-based content that resonates with community and public health audiences. The down-stream health and societal benefits would be increased accessibility of science with a focus on marginalized communities.

TSBM economic impact

In the context of the Boston University CTSA, the RMTP program has demonstrated significant economic benefits, particularly in fostering financial mobility and driving innovation through diversity and industry collaborations. By increasing the representation of individuals from underrepresented groups in regenerative medicine research, the program not only addresses inequities in representation but also provides pathways for wealth generation and career advancement. This financial mobility is supported through initiatives such as the ESSP, which provides scholarships to economically disadvantaged students, helping them transition into high-cost areas like Boston to pursue their education and careers. These efforts enable individuals from underrepresented backgrounds to access high-demand fields in biomedical research and industry, creating long-term economic benefits for their families and communities.

TABLE 4 Examples of RMTP graduated trainee's employer and clinical topic area.

RMTP trainee employer	Clinical topic area
Plaia Technologies	Artificial intelligence consulting services
Sarepta	Development of precision genetic medicines
Pyxis Oncology, Inc. (PYXS)	Development of antibody therapeutics to cancer
Invicro	Quantitative biomarkers, advanced analytics and imaging solutions
Takeda	Pharmaceutical
Satellite Bio	Solid organ cells as medicine
United Therapeutics	Creating products for chronic illnesses
GENEWIZ	Sequencing, gene synthesis
Lumanity	Commercial strategies consulting
Sanofi	Development of breakthrough medicines and vaccines

Beyond its impact on individual trainees, the RMTP has contributed significantly to innovation and translational science through patents and industry partnerships. TL1 trainees and faculty have been instrumental in securing key patents, such as U.S. Patent No. 10,975,357 B2, titled *Methods and Compositions Related to Differentiated Lung Cells*, which was co-invented by a TL1 trainee, Anjali Jacob. Additional patents include U.S. Patent No. 10,386,368 B2, *Isolation of Human Lung Progenitors Derived from Pluripotent Stem Cells,* Patent No. 10,590,392 B2, *Generation of Airway Epithelial Organoids from Human Pluripotent Stem Cells,* Patent No. 10,449,221 B2, *Differentiation of Stem Cells into Thyroid Tissue*, PCT Application No. PCT/US21/18714, *Generation of Airway Basal Stem Cells from Human Pluripotent Stem Cells*, Trackone Application No. 18/792,994, *Airway Basal Cell Engraftment Methods*, and US Patent Application No. 63/698,841, *Materials and Methods for the Derivation Lung-Specific Mesenchymal Progenitor Cells from Pluripotent Stem Cells.* These patents underscore the RMTP's role in advancing regenerative medicine by addressing critical scientific and clinical challenges while creating intellectual property with significant commercial potential (see Table 5 for a description of impact of these patents).

These patents underscore the RMTP's role in advancing regenerative medicine and creating intellectual property with significant commercial potential. The program has also fostered strategic industry partnerships, notably the recently established collaboration in 2024 with GlakoSmithKline (GSK), a global biopharmaceutical leader. This partnership leverages the cutting-edge stem cell technology developed at CReM to advance the understanding and treatment of lung diseases, such as pulmonary fibrosis. Through this collaboration, GSK provides funding and expertise to scale up drug development efforts, translating basic research into potential therapies. Importantly, this collaboration also benefits RMTP trainees by offering them a unique opportunity to interact with industry professionals and gain insights into the biotech sector, where most graduate students ultimately pursue careers (thereby increasing economic mobility for members of the regenerative medicine workforce). Working alongside GSK during their training will afford trainees an opportunity to familiarize themselves with industry standards and processes, fostering career development and preparing them for future roles in the biotech and pharmaceutical industries. These interactions help trainees bridge the gap between academic research and industry application, enabling them to contribute effectively in both settings while conducting their dissertation research. This partnership not only

TABLE 5 Example RMTP patents and TSBM impacts.

Patent title	U.S. patent #	Description	TSBM impact
Methods and compositions related to differentiated lung cells	10,975,357 B2	This patent enables the generation of lung cells derived from pluripotent stem cells, which are invaluable for modeling diseases such as pulmonary fibrosis and for high-throughput drug screening. By providing a reliable platform to study lung diseases, this technology has attracted interest from pharmaceutical companies aiming to develop targeted therapies, such as GSK in their collaboration with the CReM.	CLINICAL ECONOMIC New procedure for studying lung diseases and high-throughput drug screening; enables safe and cost-effective treatment development
Isolation of human lung progenitors derived from pluripotent stem cells	10,386,368 B2	This innovation provides a method to isolate lung progenitor cells, a critical step for regenerative therapies. These cells have potential applications in developing treatments for chronic respiratory conditions and in advancing cell-based transplantation therapies, which represent a rapidly growing sector in biotech.	CLINICAL New procedure for isolating lung progenitor cells
Generation of airway epithelial organoids	10,590,392 B2	Organoid technologies derived from this patent enable researchers to recreate functional airway tissue in vitro, which is crucial for studying infectious diseases such as COVID-19 and for testing novel therapeutics. This has significant commercial applications in both the pharmaceutical industry and precision medicine.	CLINICAL ECONOMIC New procedure for studying infectious diseases; enables safe and cost-effective treatment development
Differentiation of stem cells into thyroid tissue	10,449,221 B2	This patent focuses on generating thyroid tissue from stem cells, which could lead to novel therapies for thyroid disorders, including hypothyroidism. The ability to produce thyroid tissue in vitro also has implications for personalized medicine and drug testing, which could lead to licensing opportunities in the biotech sector.	CLINICAL ECONOMIC New procedure for studying thyroid disorders; enables safe and cost-effective treatment development

TSBM icons: The Translational Science Benefits Model and Translating for Impact Toolkit© 2017–2023, created by the Institute of Clinical and Translational Sciences at Washington University in St. Louis and available at *translationalsciencebenefitsmodel.wustl.edu*, is licensed under *Attribution-NonCommercial-ShareAlike 4.0 International (CC BY-NC-SA 4.0).*

enhances the RMTP's translational impact but also demonstrates how academic-industry collaborations can drive economic and scientific progress.

These combined efforts highlight the RMTP's multifaceted down-stream economic contributions: fostering financial mobility and equity for underrepresented individuals, generating valuable intellectual property, and advancing translational science through industry partnerships. More specifically, together, these outcomes illustrate how the RMTP serves as a model for leveraging diversity and innovation to create widespread economic and societal benefits.

TSBM policy impacts

Utilizing the Overton Index policy impact analysis tool (43), we searched 39 publications' PMIDs/DOIs that were published by graduated RMTP trainees and included the citation for our Boston University CTSI TL1 grant (1TL1TR001410). Five publications (46–50) were cited in three policy documents (51–53) and two clinical guidelines (54, 55) by five policy sources across the United States, European Union, United Kingdom, and Canada. The three policy document publications cover the topics of replacing animal-based research models with human-relevant models in oncology and non-animal models in respiratory tract diseases. The two clinical guidelines cover the topics of clinical use of esophageal physiologic testing for diagnosing and managing esophageal disorders and venous thromboembolism prophylaxis in patients undergoing total hip or knee replacement surgeries. The down-stream health and societal benefits include setting formal quality assurance standards for various health study approaches and treatments.

Discussion

CTSA evaluation teams are challenged with implementing CQI processes that enhance the organization and infrastructure of CTSA programs, along with executing evaluation activities that assess health and societal impact of translational science. Limited theory and evidence-based approaches exist that help evaluation teams simultaneously accomplish both CQI and impact evaluation. Drawing on impact evaluation research from the TSBM (5), CQI (6–8, 16), and team science (9–12), we develop a theory-driven, team-based approach to CQI and impact evaluation. We extend the TSBM logic model framework to incorporate CQI and evaluation activities, providing a practical approach other CTSA evaluation teams can use to guide their efforts.

Our team science-based approach to CQI and evaluation involves creating a climate for inclusion wherein all program members feel like important members of the group and that their unique talents and perspectives are appreciated. This is accomplished through CTSA leaders (i.e., evaluation and program leaders) demonstrating inclusive leadership behaviors. Several published articles provide examples of how leaders and evaluators can foster inclusive leadership (25, 29, 56–58), and thereby inclusion and psychological safety. A brief review of this literature suggests leaders who recognize that every group member has unique needs and abilities, expresses appreciation for group members' unique talents and abilities, and values the contributions of others helps foster a climate for inclusion (25). In addition, when leaders proactively seek and value feedback from group members, regardless of group members' job positions or titles, this helps engender feelings of inclusion within the group (9, 27). This is particularly important when designing CTSA program CQI and evaluation activities as every program member needs to feel a shared sense of responsibility in the creation and implementation of improvement and evaluation efforts. One way this can be achieved is through inviting each program member to partner in the development of CQI and evaluation activities. In our theory-based CQI and evaluation approach we collaboratively create a logic model which provides a road map and guideline for how CQI and evaluation activities are embedded within program activities and ultimately how the program strives to make health and societal benefits. The success of the WE-CQI logic model and creating a shared sense of responsibility for the implementation of the activities in the logic model is largely dependent upon the creation of a climate for inclusion, otherwise this exercise fails to meaningfully engage CTSA members. When program members are not engaged in the CQI and evaluation process, implementation of these activities are weakened, resulting in low-quality program fidelity, data collection, and team reflection, learning, and improvement.

While previous research has demonstrated promising interventions for fostering inclusion (25, 29, 56–58) and psychological safety (59), more research is needed on how these approaches enhance outcomes for CQI and evaluation processes within complex multi-team systems. We strive to help address this gap in the literature using case study methods and illustrating how the WE-CQI team-science based approach can enhance quality improvement and evaluation activities. Through mixed-methods data collection, results highlighted how WE-CQI efforts helped strengthen several aspects of the RMTP (e.g., increasing diversity representation among trainees) and how RMTP activities ultimately made significant health and societal benefits using the TSBM framework. For example, several RMTP activities have led to the development of new tools and procedures for safely and effectively studying lung and thyroid diseases, which has enabled a more rapid and efficient process for creating novel treatments. This aligns with the mission of NCATS in the ability to effectively turn research into health solutions more quickly (60). As CTSA evaluation teams strive to help programs continuously improve through team science-based approaches to CQI, this can help increase the likelihood that program resources and activities get better at achieving meaningful TSBM impacts. Other CTSAs can apply our developed logic model and CQI and evaluation framework as a practical guide for how to enhance CTSA activities and the quality and impact of translational science. Having CTSA leaders and evaluators trained in inclusive leadership approaches and on the importance of fostering inclusive and psychologically safe team climates may be essential to successfully implementing a team-science based approach to CQI and evaluation activities.

Limitations

Future research is needed to test the generalizability of this approach to other CTSA programs. It is possible that variation exists in the fidelity of implementing the WE-CQI framework given the level of expertise and ability of CTSA evaluators in using a team science approach in the collaborative planning and reflection and learning phases of the model. For example, CTSA evaluators well-skilled in inclusive leadership and fostering a climate for inclusion may yield stronger results to successfully implementing the framework; however, while there is theoretical evidence and case study methods to support this hypothesis, more empirical research is needed. Current research on evidence-based inclusive leadership trainings and interventions is limited and need further development. Likewise, additional leadership approaches, such as authentic leadership and leader-member exchange (61, 62), could be examined as alternative avenues for implementing the WE-CQI framework.

Conclusion

CTSA evaluation teams face the dual challenge of implementing CQI processes designed to enhance the effectiveness of CTSA programs, while simultaneously evaluating the health and societal impacts of their initiatives. Building on research from CQI, impact evaluation and the TSBM framework, and team science, we have developed a theory-driven, team-based logic model that integrates CQI and evaluation processes. Using a case study of our CTSA supported programs (TL1 Regenerative Medicine Training Program), we demonstrate the practical application of this approach by providing a concrete example of how the WE-CQI framework can be utilized to support CQI and impact evaluation. Our findings offer other CTSA programs with a replicable and adaptable framework to guide their evaluation teams in striving for excellence in clinical and translational science. By adopting this approach, evaluation teams can better align their efforts with translational science goals, ensuring meaningful contributions to the greater public health.

Data availability statement

The datasets presented in this article are not readily available because participant confidentiality. Requests to access the datasets should be directed to Kim Brimhall brimhall@bu.edu.

Ethics statement

The studies involving humans were approved by Boston University Institutional Review Board. The studies were conducted in accordance with the local legislation and institutional requirements. The participants provided their written informed consent to participate in this study.

Author contributions

KB: Conceptualization, Data curation, Formal analysis, Investigation, Methodology, Writing – original draft, Writing – review & editing. KK: Conceptualization, Data curation, Formal analysis, Investigation, Methodology, Writing – original draft, Writing – review & editing. DK: Conceptualization, Data curation, Formal analysis, Writing – review & editing. MJ: Conceptualization, Data curation, Formal analysis, Writing – review & editing.

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Conflict of interest

The authors declare that the research was conducted in the absence of any commercial or financial relationships that could be construed as a potential conflict of interest.

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EDITED BY
Pamela Davidson,
University of California, Los Angeles,
United States

REVIEWED BY
Denise F. Lillvis,
University at Buffalo, United States
Jessica Sperling,
Duke University, United States

*CORRESPONDENCE
Kera Swanson
✉ knswanson@health.ucsd.edu

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An iterative approach to evaluating impact of CTSA projects using the translational science benefits model

Kera Swanson[1]*, Nicole A. Stadnick[1,2,3], Isaac Bouchard[1,4], Zeying Du[1], Lauren Brookman-Frazee[1,2,3], Gregory A. Aarons[1,2,3], Emily Treichler[1,2,5], Maryam Gholami[6] and Borsika A. Rabin[1,7]

[1]UC San Diego Altman Clinical and Translational Research Institute Dissemination and Implementation Science Center, University of California San Diego, La Jolla, CA, United States, [2]Department of Psychiatry, University of California San Diego, La Jolla, CA, United States, [3]Child and Adolescent Services Research Center, University of California San Diego, La Jolla, CA, United States, [4]Department of Psychology, California State University, Northridge, CA, United States, [5]Jennifer Moreno Department of Veterans Affairs Medical Center, San Diego, CA, United States, [6]UC San Diego Altman Clinical and Translational Research Institute, University of California San Diego, La Jolla, CA, United States, [7]Herbert Wertheim School of Public Health and Human Longevity Science, University of California San Diego, La Jolla, CA, United States

Introduction: Demonstrating the relevance and impact of translational research across diverse settings is crucial making the research-to-practice pipeline more efficient. The Translational Science Benefits Model (TSBM) is a framework used to report societal and health impacts of clinical and translational research.
Methods: A four-phase process was used to co-develop 12 TSBM Impact Profiles aimed at evaluating the impact of clinical and translational research and disseminating this information among diverse audiences. Content analysis was used to understand common and unique themes related to the TSBM domains and benefits across 12 projects.
Results: Across the 12 TSBM Impact Profiles, TSBM benefits covered all four TSBM domains (Clinical, Community, Economic, and Policy), with a notable focus on Clinical and Community-related benefits. TSBM Impact Profiles took an average of 9 h to complete, with each phase taking 1–3 h to complete. Common themes included Clinical Innovation and Care Integration, Advancing Health Equity and Accessibility, Community and Stakeholder Engagement, and Policy and Systems-Level Change. Three case exemplars that contextualize findings from the content analysis are presented.
Conclusion: This work validates and extends the processes originally developed by the creators of the TSBM and offers a process-oriented example of its successful application at an external institution & CTSA hub. Co-creating TSBM Impact Profiles and documenting their development ensured that information was synthesized for broad dissemination and accessibility. Results highlight an effective process for capturing a multitude of impacts and benefits across diverse research projects with future efforts aimed at expanding the application of this method.

KEYWORDS

clinical and translational science, dissemination, evaluation, translational science benefits model (TSBM), impact

Introduction

There is increased attention to making the research to practice pipeline more efficient. Prior work indicated that it takes about 17 years to turn research into practice and only about 14% of this research has been translated into real world practice (1). A more recent publication by Kahn and colleagues found similar delays in the translation of cancer prevention interventions (2). Clinical and Translational science aims to streamline this process, facilitating the uptake of research evidence in settings and communities accessed by those for whom the research is intended. It is essential to demonstrate the relevance and impact of translational research across diverse settings and contexts to successfully disseminate, implement, and sustain these evidence-based practices to positively impact communities and society as a whole (3–5). By doing so, individuals and groups within these contexts are able to gain deeper insights into the proximal and distal benefits derived from the research supporting these practices.

The Translational Science Benefits Model (TSBM) is a framework and associated tools designed to enhance the efficiency of translational science by assessing the broader clinical and community health impacts of research outcomes beyond traditional measures (4). The TSBM systematically contextualizes impact within four key domains: Clinical, Community, Economic, and Policy, identifying 30 specific health and societal benefits within these areas (4). This approach facilitates a comprehensive evaluation of clinical and translational research, enabling scientific discoveries to be translated in ways that are meaningful and relevant to audiences beyond the scientific community.

Since its inception, the TSBM has been used across a number of different research projects and public health areas to showcase potential and demonstrated benefits from these bodies of work (5–10). One notable example of this integration is the increased use of the TSBM across Clinical and Translational Science Awards (CTSA) Programs (5, 11–14) CTSA programs were established under the National Institutes of Health (NIH) National Center for Advancing Translational Science (NCATS) to support the advancement of clinical and translational science by transforming the academic research enterprise to better facilitate the translation of research discoveries into practical applications among patient and community healthcare settings (11, 15). The TSBM serves as a valuable tool to help CTSA programs evaluate the impact of clinical and translational research, support the dissemination and implementation of evidence-based interventions into practice, and guide decision-making by highlighting areas of impact (5).

While interest in the Translational Science Benefits Model (TSBM) continues to grow across the CTSA portfolio, the best approaches to effectively integrate the TSBM into clinical and translational research settings remain less well established. Identifying optimal strategies for incorporating the TSBM is essential to fully leverage its potential in capturing and communicating the real-world impacts of clinical and translational research. Further exploration and evaluation are needed to determine how the TSBM can be applied to different project stages, research goals, and community engagement practices across CTSA programs.

The University of California San Diego (UCSD) Altman Clinical and Translational Research Institute's (ACTRI) CTSA program aims to facilitate the translation of research conducted at UCSD through strategic management of the UCSD research enterprise, promoting workforce development and community engagement, generating clinical and translational science resources and pilot programs, and building innovative programs that expand the reach of clinical and translational science (National Institutes of Health, Grant UL1TR001442). In 2024, the ACTRI adopted the TSBM as a framework to evaluate the impact of UCSD's clinical and translational research efforts.

This paper describes how our team applied the TSBM to evaluate the impact of 12 diverse clinical and translational research projects and used an iterative approach to co-develop and disseminate TSBM Impact Profiles within our CTSA hub. To our knowledge, this is one of the first detailed accounts of applying the TSBM framework in this way at an institution distinct from its original developers. In doing so, we demonstrate the framework's feasibility and utility across institutional contexts. We also present findings from a content analysis conducted on the 12 profiles to identify cross-cutting themes and illustrate the process through three detailed case examples. By documenting this approach, we contribute to the growing literature on the TSBM by providing practical guidance for other institutions and reinforcing its potential as a structured tool for evaluating and disseminating translational research impact.

Methods

The ACTRI's CTSA program utilizes the TSBM in different ways in order to examine the health and societal impact of its research projects (16). One way this is accomplished is through the creation of TSBM Impact Profiles. The concept of the TSBM Impact Profiles was initially created by the TSBM developers as a product that could facilitate the dissemination and implementation of clinical and translational research information (17). These profiles highlight research projects and corresponding health and societal benefits. Profiles are published on the ACTRI's public-facing website and are shared among the non-academic and academic communities. It was determined by the ACTRI, that the TSBM Impact Profiles would be the ideal product for the dissemination of research information due to their ability to concisely summarize complex information and the fact that they can be easily shared with different audiences. The condensed nature of the profiles was optimal for creating individual webpages for each project and allowed creative flexibility to construct visually appealing and engaging outputs.

The ACTRI TSBM Team was formed of individuals who were involved in the profile creation process. The team made up of seven individuals from the ACTRI Dissemination and Implementation Science Center (DISC) and the ACTRI Evaluation Unit, including five PhD-level and one Masters-level research faculty and staff and one graduate research intern, all with expertise in

Dissemination and Implementation Science (DIS), evaluation, and the TSBM.

The TSBM team began creating the TSBM Impact Profiles in April 2024. The process to create and disseminate the TSBM Impact Profiles spanned four phases: (1) Outreach; (2) Data & Information Gathering; (3) Creation & Refinement; and (4) Dissemination. See Figure 1 for an overview of the process.

In addition to describing the development process for the TSBM Impact Profiles, we also evaluated the content of the 12 finalized profiles. Specifically, we conducted a three-phase, Generative Artificial Intelligence (AI) (ChatGPT)-assisted content analysis to explore common themes, assess the distribution of benefits across TSBM domains, and examine differences by translational phase (18). Following the initial analysis, thematic and quantitative findings were synthesized to provide a more holistic understanding of the profiles' impacts across the TSBM domains. This evaluation aimed to illustrate the types of impacts captured through the TSBM framework and provide insight into how translational research projects manifest benefits across clinical, community, policy, and economic domains.

Outreach

The TSBM team identified and contacted investigators to gauge interest in co-developing an impact profile for one of their research projects. Investigators were UCSD faculty associated with the ACTRI and who were the principal investigators on a research study. A convenience sampling strategy was used to identify investigators based on their direct connection to the ACTRI's KL2 program or who were affiliated with the DISC. During the outreach process, the TSBM team provided information related to the TSBM, TSBM Impact Profiles, and intended use of the profiles so that the investigator could make an informed decision on if they would like a profile created.

Data & information gathering

An online survey was used to collect information about the research project from participating investigators (selection details described below). The survey was based on the TSBM Toolkit's Impact Profile Builder (17) and gathered information on the research project related to the challenge(s) it was addressing, the approach, intended impact, and relevant TSBM domains and benefits.

Once an investigator agreed to the creation of a TSBM Impact Profile, the survey was completed in one of two ways. The investigator (or one of their research staff) could complete the survey, or the TSBM team could complete the survey on behalf of the investigator by extracting information from various resources (e.g., research articles, protocols, websites etc.) that were provided by the investigator.

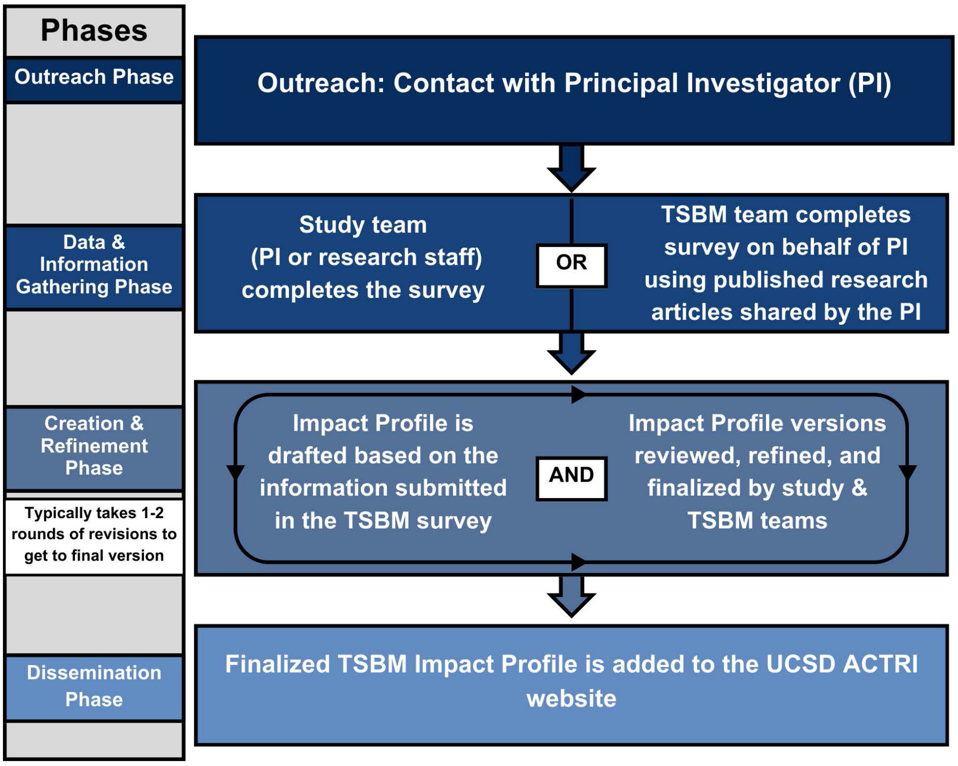

FIGURE 1
Translational science benefits model (TSBM) impact profile creation process.

The online survey included eleven sections: (1) information about the investigator & team members (e.g., name, email, job title, role on project); (2) funding information for the project; (3) project title; (4) the challenge the project was trying to address; (5) the approach to address the challenge; (6) 2–3 high-level research highlights; (7) selection of TSBM benefits; (8) additional information about the selected benefits (e.g., indicate whether that benefit was potential or demonstrated, and provide a brief description of their rationale for choosing that benefit)); (9) the impact summary; (10) option to upload additional resources (e.g., images, publications, websites etc.); (11) consent to publish the TSBM Impact Profile on the ACTRI website. See Supplementary File 12.1 for a copy of the survey.

The survey was piloted with four investigators who provided feedback on the format and language and was refined based on the investigators' feedback. Modifications were minor and included: (1) a detailed introduction section including information about the TSBM, the importance of identifying impact and benefits from research, and the intended use of the information to support clinical and translational research and foster meaningful community engagement; (2) removal of the brief impact statement at the beginning, as it was already covered in the detailed impact section; and (3) moving the impact section to after the selection of TSBM benefits to better contextualize them. These modifications led to an informative and user-friendly interface that enabled participants, who were generally unfamiliar with the TSBM, to successfully complete the survey with minimal assistance.

In order to keep the information collected through the survey brief, word limits (maximum 200 words) were placed on the free response options (e.g., the challenge, the approach, and the impact summary). The selection of benefits section was built with display logic and organized by TSBM domain. Each benefit option contained a definition of the benefit, as defined by the TSBM developers. Once submitted, the survey answers were combined into a single PDF and emailed to the TSBM team for review. They reviewed the selected benefits and determined if they were accurately selected based on the survey respondent's rationale and the TSBM developer's definitions. If there was overlap between benefits, a clear distinction would need to be made, and consensus reached among the TSBM team in order for the benefit to be included in the TSBM Impact Profile. Uncertainty was addressed through team discussion and in rare cases reaching out to the TSBM developers for additional clarity.

Creation and refinement

Based on the survey responses and agreed upon benefits, the TSBM team developed individual Impact Profiles. Using the TSBM developer's TSBM Impact Profile template from the Translating for Impact Toolkit as an example layout, the TSBM team populated each profile section with the relevant information and reviewed the content to ensure it was easily understood (17). This involved replacing overly technical language with terminology better suited for audiences with diverse backgrounds and education levels. ChatGPT was also used to help simplify language by inputting the technical language into the program and requesting that it produce an alternative text or supporting definition that could be read and understood at a 12th grade reading level (18). Multiple rounds of review and feedback occurred between the TSBM team and the investigator to ensure the information presented in the profiles were both accurate, comprehensive.

Dissemination

Finalized TSBM Impact Profiles were then transformed into profile web pages on the ACTRI website (19), featuring images of the project personnel, relevant resources (i.e., websites, publications, developed tools etc.) and a downloadable PDF version of the Impact Profile.

Evaluation of TSBM impact profiles

ChatGPT was used as a tool to facilitate initial content analysis of the Impact Profiles in order to understand common and unique themes related to the TSBM domains and benefits across projects (18, 20, 21). Prompts were co-designed by the TSBM team to optimize ChatGPT's ability to identify and collate information across TSBM Impact Profiles. Limited detail and structure in the initial prompts increased the likelihood of encountering inaccurate information (22) and response degradation in the outputs. A prompt framework (21) was adopted to guide the refinement of prompts aimed at reducing errors in outputs. Prompts were optimized by specifying the background of the task, teaching ChatGPT how to navigate the data input, ensuring the data input is consistent, and providing a detailed output template. The TSBM team purposefully did not provide guidance to ChatGPT on what themes to look for to reduce the allow for emergent patterns and reduce bias introduced by the TSBM team (21). Due to ChatGPT's conversational design, follow-up questions were used to prompt additional information and verify answers provided by ChatGPT. Once prompts were optimized, the TSBM team conducted the initial content analysis and reviewed the results for accuracy, using their in-depth knowledge of the completed TSBM Impact Profiles.

The initial content analysis was conducted in three phases, with validation checks occurring at each stage: Phase 1: Familiarization with TSBM Impact Profiles involved orienting ChatGPT to the TSBM framework and the 12 TSBM Impact Profiles. To begin, we prompted ChatGPT to summarize the TSBM, its four domains, and its 30 associated benefits using the development article by Luke et al. (4). We then uploaded a compiled PDF containing all 12 profiles and provided contextual information to help the model interpret the data structure (e.g., page numbers, section headings, and the intended purpose of the profiles). To assess the model's initial understanding, we asked ChatGPT to generate a summary of each profile, including the title, project description, identified domains, and whether the reported benefits were potential or demonstrated. We compared these outputs to the original profiles to evaluate accuracy. Where inaccuracies were identified, refinement prompts were used to correct errors and clarify domain classifications. For example, ChatGPT initially misclassified the benefit "Healthcare Delivery" under the Clinical domain rather than the Community domain, as it is currently listed in the model (4). These prompts enabled ChatGPT to revise its outputs and update its understanding accordingly. Once the summaries aligned with the original data and correct classifications, we were confident in the model's understanding of the content, which supported the decision to proceed to the content analysis phase. Prior to initiating each subsequent phase, we provided ChatGPT with the finalized results from the previous phase to ensure that accurate and validated information was used as the basis for further analysis. See Supplementary File 12.2 for ChatGPT Prompt Examples.

Phase 2: Initial Thematic Mapping with ChatGPT Assistance consisted of prompting ChatGPT to conduct a content analysis and provided instructions for it to follow. Instructions included: (1) Read each profile holistically, extracting high-level insights beyond just the TSBM domain classifications; (2) Identify and code for thematic elements; (3) For each project, note the themes present and include brief supporting evidence or examples; (4) Compare themes across profiles to identify: Themes that appear across multiple projects (common themes) and themes that are unique to a specific project or translational research phase; (5) Summarize: Common themes across profiles, themes that vary by translational phase; and provide examples from the profiles that support themes.

Following theme generation, the TSBM team conducted a manual review of ChatGPT's outputs by comparing the identified themes with the original profile content to ensure relevance, accuracy, and completeness. In cases where themes were overly broad, misaligned, or redundant, they were revised or consolidated through team discussion. For example, ChatGPT initially identified "Addressing Health Disparities" and "Healthcare Accessibility" as two separate themes, but we combined these under a broader theme of "Advancing Health Equity and Accessibility". Similarly, a theme labeled "Community Health" was reframed as "Community and Stakeholder Engagement" to better reflect the scope of activities described across projects. This human validation step ensured that the final set of themes reflected the depth and nuance of the profile content. The list of finalized themes was shared with ChatGPT prior to Phase 3 to ensure consistency in subsequent synthesis and triangulation.

Phase 3: Synthesis and Triangulation focused on consolidating thematic and quantitative findings. ChatGPT was prompted to generate a summary table that included both qualitative themes and quantitative metrics, such as the total number of benefits, domain representation, and classification of benefits as potential or demonstrated. We also requested it to provide supporting examples and direct quotes where available. We then cross-referenced these outputs with the original profiles to validate benefit categorization and ensure thematic accuracy. For example, when ChatGPT initially reported a total of 64 benefits, rather than the correct count of 62, we prompted it to provide the number of benefits identified for each individual profile. This led to the identification of duplicated benefits in its initial output, which were subsequently corrected. While this phase did not involve formal qualitative coding, it served as a critical triangulation step that integrated both qualitative and quantitative data to ensure consistency, accuracy, and completeness.

Results

Out of 20 investigators contacted, 12 agreed to co-create a TSBM Impact Profile for one of their research projects and eight did not respond to the outreach email, likely due to time constraints and competing demands (60% response rate). The investigators consisted of early to mid (Assistant or Associate-level) career researchers with backgrounds ranging from psychiatry and public health to nephrology and neurosciences. Four investigators were a part of the ACTRI's KL2 scholar program and eight were D&I researchers affiliated with the DISC. See Table 1 for additional information on the investigators and their research projects.

A total of 12 TSBM Impact Profiles were created using the described methods with six published on the ACTRI website and six soon to be published. Five profiles were based on investigator submitted surveys and seven surveys were based on information extracted and submitted by the TSBM team. The process used influenced the time and workflow required to complete each profile. Investigator-completed surveys allowed for greater investigator autonomy and the opportunity to draw from additional sources that may not have been readily available to the TSBM team. This process began with an initial introduction to the TSBM framework and profiles, typically requiring 1–1.5 h of communication over email or Zoom. Investigators then completed the survey independently, usually within 15–25 min. The TSBM team subsequently spent 2–3 h reviewing the submitted content, synthesizing the information into the profile template, and aligning it with the TSBM benefit domains. Follow-up communication and iterative revision cycles with the investigator added another 2 h on average. Finally, for publication on the ACTRI website the TSBM team would create a visual mock-up, send it to the investigator(s) for final review, and then build the webpage on the ACTRI's website, which required an additional 2–3 h.

In contrast, the TSBM team-led process involved the TSBM team completing the survey on behalf of the investigator based on project materials (e.g., publications, reports etc.). Initial communication, including introduction to the process and collection of relevant project documents, also required 1–1.5 h. Once materials were received, the TSBM team spent approximately 2–3 h extracting, synthesizing, and entering information into the survey instrument. This was followed by 1–2 h of follow up communication with the investigator to refine content and confirm accuracy. The final steps—creating the profile mock-up and webpage—were consistent with the

TABLE 1 Research projects and their initial characteristics included in the Altman Clinical and Translational Research Institute translational science benefits model impact profiles as of November 2024 ($n = 12$).

Project title	Principal investigator(s)	Type of research	Summary statement	Setting	Population
Access to Tailored Autism Integrated Care through Family Navigation (ATTAIN NAV)	Nicole A. Stadnick, PhD, MPH	T3 (Clinical Implementation)	ATTAIN NAV was co-designed with caregiver and healthcare partners and delivered by lay navigators to facilitate access to mental health and family support services for school-age children with autism (NIMH R34MH120190).	Pediatric Primary Care	School-age autistic children with co-occurring mental health needs.
Enhancing Collaborative Decision-Making Among Veterans of Color in VA Mental Health Care	Emily Treichler, PhD	T3 (Clinical Implementation)	This study used community-engaged mixed methods to identify the preferences, values, and current experiences related to treatment decision-making among these veterans. It also sought feedback to culturally tailor an empowerment-oriented group intervention called Collaborative Decision Skills Training, intended to boost collaborative decision-making in this group.	VA Psychosocial Rehabilitation and Recovery Center (PRRC) in Southern California	Veterans of color with serious mental illnesses in VA mental health care
Primary Prevention of Cardiovascular Disease in Patients with Elevated Lipoprotein	Harpreet Bhatia, MD, MAS, FACC	T2 (Clinical Research)	This project explores low-dose aspirin therapy as a potential method for preventing cardiovascular disease in individuals with elevated Lipoprotein(a) levels.	Multi-Ethnic Study of Atherosclerosis (MESA) Field Centers	Multi-Ethnic Study of Atherosclerosis (MESA) Field Centers
An Individualized Mental Health Intervention for Autism (AIM-HI Study)	Lauren Brookman-Frazee, PhD	T3 (Clinical Implementation)	AIM HI (An Individualized Mental Health Intervention for Autism) is a caregiver and child skill- building intervention and therapist training model for children 5 to 13 years old with autism receiving mental health services.	Publicly funded mental health services	Children with autism and caregivers
Strategies to Engage Underserved Communities in Southern California in COVID-19 Testing, Vaccinations and Trials (STOP COVID-19 Study)	Borsika Rabin, PhD, MPH, PharmD; Nicole A. Stadnick, PhD, MPH	T4 (Public Health)	The STOP COVID-19 CA UC San Diego-Global ARC project team, comprised of researchers from UC San Diego and members of the Global Action Research Center (Global ARC), aimed to identify strategies and create solutions to overcome barriers to COVID-19 testing, vaccination uptake, and participation in clinical trials, among Latino/a/x, African American, East African, Syrian, Afghan, Pacific Islanders, and South East Asian communities in San Diego County.	Federally qualified health center	Latino/a/x African American, East African, Syrian, Afghan, Pacific Islanders, and Southeast Asian communities in San Diego.
Implementation of state health insurance benefit mandates for cancer-related fertility preservation: following policy through a complex system	Irene Su, MD, MSCE; Sara McMenamin, PhD	T4 (Public Health)	This study aimed to document and understand the multi-level environment, relationships, and activities involved in using state benefit mandates to facilitate patient access to fertility preservation services.	Insurance regulators, insurers, and healthcare clinics	Young cancer patients
Community-based COVID-19 Testing Optimization for Women and Children in Underserved Areas (CO-CREATE & CO-CREATE-Ex)	Borsika Rabin, PhD, MPH, PharmD; Nicole A. Stadnick, PhD, MPH	T4 (Public Health)	CO-CREATE & CO-CREATE-Ex are linked projects aimed at providing equitable access to COVID-19 testing in medically underserved communities in central and south San Diego County through a partnership between UC San Diego, San Ysidro Health (SYH), and the Global Action Research Center (ARC).	Community health centers	Immigrant, refugee, and Black, Indigenous, People of Color (BIPOC) communities

(*Continued*)

TABLE 1 Continued

Project title	Principal investigator(s)	Type of research	Summary statement	Setting	Population
Novel Markers for Monitoring Kidney Transplants	Clarkson Crane, MD	T2 (Clinical Research)	This project aims to improve kidney transplant outcomes by developing personalized biomarkers that predict immune responses between recipients and donors.	Transplant Center within Healthcare system	Patients receiving kidney transplants
PRISM Contextual Survey Instrument (PCSI)	James Pittman, PhD	T3 (Clinical Implementation)	The PRISM Contextual Survey Instrument (PCSI) is a 29-item survey developed to assess contextual factors that influence the implementation and sustainability of interventions in healthcare settings, helping researchers and practitioners tailor strategies to improve implementation outcomes.	Veterans Affairs Military to VA (M2VA) transition programs	Veterans
Effects of Blood Pressure on Cognition in Parkinson's Disease	Katherine Longardner, MD	T2 (Clinical Research)	This study seeks to understand how low blood pressure when standing, known as orthostatic hypotension (OH), affects cognitive performance and hemodynamics (e.g., how blood flows through your blood vessels) in people with Parkinson's disease.	Hospital/Healthcare System	Patients with orthostatic hypotension (OH)
Translating Evidence-Based Interventions for Autism (TEAMS)	Aubyn Stahmer, PhD; Lauren Brookman-Frazee, PhD	T3 (Clinical Implementation)	Developed with mental health and education partners, the TEAMS study used leadership and provider training modules to enhance autism treatment fidelity and improve child outcomes in schools and mental health settings.	Schools and mental healthcare settings	Autistic children
Mailed Colorectal Cancer Screening (ACCSIS)	Elena Martinez, PhD, MPH; Samir Gupta MD, MSCS; Scott C. Roesch, PhD	T4 (Public Health)	ACCSIS is improving colorectal cancer screening, follow-up, and referral for care among populations that have low colorectal cancer screening rates. ACCSIS focuses on underserved groups, including racial and ethnic minority populations and people living in rural or difficult-to-reach areas.	Community health centers	Low-income and minority groups

investigator-led process and took 2–3 h. Across both pathways, the average total time to develop a TSBM Impact Profile was approximately 8.5 hours, with variation depending on the volume of available information, level of investigator engagement, consensus on selected benefits, and the number of content revisions required.

Based on the Translational Science Spectrum, a model that describes the process of moving research findings into clinical and community settings, the type of research varied among the TSBM Impact Profiles (14, 23). Three projects fell under T2 Research, which focuses on translating findings into patient applications by conducting controlled studies and developing evidence-based guidelines. Five projects focused on T3 Research, emphasizing translation to practice through dissemination and implementation, where research findings are applied in real-world clinical or community settings. Finally, four projects targeted T4 Research, which is concerned with community outcomes and policy impacts, aiming to influence population-level health improvements and policy reforms.

Content analysis

A content analysis of 12 Translational Science Benefits Model (TSBM) Impact Profiles revealed a consistent set of cross-cutting themes that characterize the translational impact of diverse health research initiatives. Despite variation in focus areas, study populations, and intervention types, the following common themes emerged: Clinical Innovation and Care Integration: The majority of the TSBM Impact Profiles introduced or adapted clinical procedures, interventions, or tools for real-world care settings. These innovations spanned therapeutic procedures, diagnostic approaches, and treatment delivery models. Several profiles also contributed to the development of clinical guidelines or diagnostic tools. Advancing Health Equity and Accessibility was a central theme across all profiles. Specifically, the commitment to reducing disparities in healthcare access, especially among historically underserved populations. Profiles focused on removing multilevel barriers through strategies such as community navigation, at-home diagnostic testing, and culturally tailored outreach. These approaches enhanced care delivery to often marginalized communities. Community and Stakeholder Engagement was another key theme identified. In particular, meaningful engagement of stakeholders—patients, community members, providers, and policy actors—was noted across these profiles. Many used co-design methodologies and Community Advisory Boards, ensuring that interventions were contextually grounded, culturally relevant, and co-produced with those most impacted. Evidence-Based Implementation and Workforce Training was observed across several profiles emphasizing efforts to bridge the research-to-practice gap through training and capacity building. Profiles highlighted initiatives focused on equipping providers with skills to implement evidence-based interventions (EBIs). Policy and Systems-Level Change appeared both directly and indirectly across profiles, particularly around health policy refinement or guideline development. These included informing clinical recommendations, enhancing implementation of state mandates, and supporting advocacy training among community leaders. Lastly, Multilevel Approach to Barriers and Solutions was demonstrated across all profiles showcasing a sophisticated understanding of the complex socio-economic system affecting health outcomes. These profiles addressed challenges at the individual (e.g., patient education), organizational (e.g., clinic workflows), and systemic (e.g., reimbursement policy) levels.

TSBM domains observed

All four TSBM domains were identified across the profiles, with the Community domain present in majority of profiles (Clinical: $n = 10$ profiles, 83.3%; Community: $n = 12$ profiles, 100%; Economic: $n = 8$ profiles, 66.7%; Policy: $n = 7$ profiles, 58.3%). A total of 62 TSBM benefits were identified across the 12 profiles, representing 19 individual benefits. On average, each profile included 5.17 benefits, with some benefits appearing in multiple profiles, as they were not mutually exclusive. The most frequently cited benefit within each domain was as follows: Therapeutic Procedures in the Clinical domain ($n = 6$ instances), Healthcare Accessibility in the Community domain ($n = 8$ instances), Cost Effectiveness in the Economic domain ($n = 5$ instances), and Policies in the Policy domain ($n = 7$ instances). Conversely, the least common benefits within each domain included Biomedical Technology in the Clinical domain ($n = 1$ instance), Healthcare Quality in the Community domain ($n = 1$ instance), Societal & Financial Cost of Illness in the Economic domain ($n = 3$ instances), and Standards in the Policy domain ($n = 1$ instance). Profiles included more potential ($n = 34$, $M = 2.83$) benefits compared to demonstrated benefits ($n = 28$, $M = 2.33$) (see Figure 2). See Table 2 for full list of benefits identified across profiles.

Three case exemplars are provided to further contextualize the content analysis findings. The first is the "Access to Tailored Autism Integrated Care through Family Navigation" (ATTAIN NAV) project, co-designed with caregiver and healthcare partners

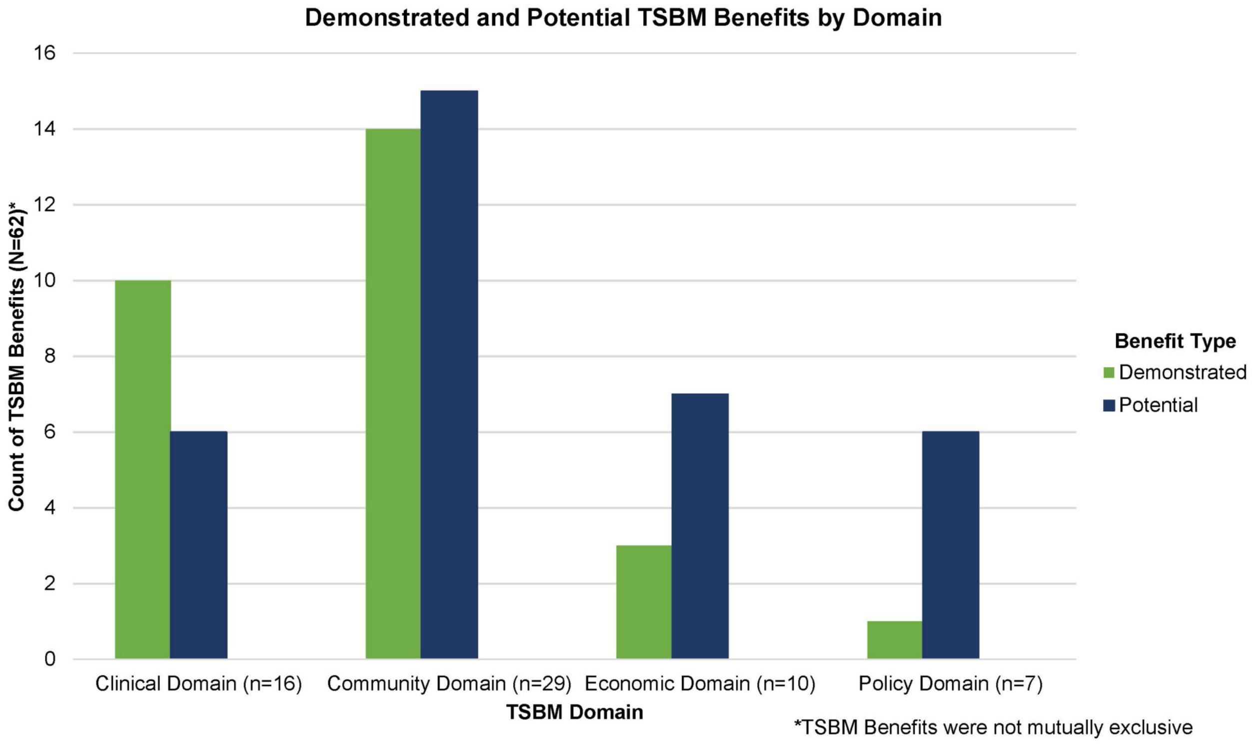

FIGURE 2
Demonstrated and potential translational science benefits across 12 sample projects by translational science benefits model (TSBM) domain.

TABLE 2 Identified potential (P) and demonstrated (D) translational science benefits across translational science benefits impact profiles.

Project title	Clinical domain	Community domain	Economic domain	Policy domain
Access to Tailored Autism Integrated Care through Family Navigation (ATTAIN NAV)	Therapeutic Procedures (D)	Health Education Resources (D), Healthcare Accessibility (D), Community Health Services (D)		Policies (P)
Enhancing Collaborative Decision-Making Among Veterans of Color in VA Mental Health Care	Therapeutic Procedures (D), Guidelines (D), Diagnostic Procedures (D)	Healthcare Accessibility (P), Healthcare Delivery (P), Public Health Practices (P)	Cost Effectiveness (D), Societal & Financial Cost of Illness (D)	Policies (P)
Primary Prevention of Cardiovascular Disease in Patients with Elevated Lipoprotein	Therapeutic Procedures (P), Guidelines (P), Drugs (P)	Disease Prevention & Reduction (P)	Cost Savings (P)	
An Individualized Mental Health Intervention for Autism (AIM-HI Study)	Therapeutic Procedures (D)	Health Education Resources (D), Healthcare Accessibility (D), Healthcare Delivery (D), Life Expectancy & Quality of Life (D), Public Health Practices (P)	Cost Effectiveness (P)	Standards (P)
Strategies to Engage Underserved Communities in Southern California in COVID-19 Testing, Vaccinations and Trials (STOP COVID-19 Study)	Investigative Procedures (D)	Healthcare Accessibility (P), Community Health Services (P), Public Health Practices (P)	Cost Effectiveness (D), Societal & Financial Cost of Illness (P)	Policies (P)
Implementation of state health insurance benefit mandates for cancer-related fertility preservation: following policy through a complex system		Healthcare Accessibility (P), Healthcare Delivery (P)		Policies (D)
Community-based COVID-19 Testing Optimization for Women and Children in Underserved Areas (CO-CREATE & CO-CREATE-Ex)		Community Health Services (D), Healthcare Accessibility (D)	Societal & Financial Cost of Illness (P)	Policies (P)
Novel Markers for Monitoring Kidney Transplants	Biomedical Technology (D), Diagnostic Procedures (P), Guidelines (P)	Healthcare Delivery (P)	Cost Savings (P)	Policies (P)
PRISM Contextual Survey Instrument (PCSI)	Guidelines (D)	Healthcare Quality (D), Healthcare Accessibility (P)		
Effects of Blood Pressure on Cognition in Parkinson's Disease	Diagnostic Procedures (P)	Disease Prevention & Reduction (P)		
Translating Evidence-Based Interventions for Autism (TEAMS)	Therapeutic Procedures (D)	Healthcare Delivery (P), Public Health Practices (P)	Cost Effectiveness (P)	
Mailed Colorectal Cancer Screening (ACCSIS)	Diagnostic Procedures (D)	Health Education Resources (D), Healthcare Accessibility (D), Healthcare Delivery (D), Disease Prevention & Reduction (D)	Cost Savings (P)	

and delivered by lay navigators to facilitate access to mental health and family support services for school-age children with autism; The second is the "Strategies to Engage Underserved Communities in Southern California in COVID-19 Testing, Vaccinations and Trials" (STOP COVID-19) project aimed to identify strategies and create solutions to overcome barriers to COVID-19 testing, vaccination uptake, and participation in clinical trials, among Latino/a/x, African American, East African, Syrian, Afghan, Pacific Islanders, and South East Asian communities in San Diego County. The third is the "Enhancing Collaborative Decision-Making Among Veterans of Color in VA Mental Health Care" project aimed to enhance collaborative decision-making among Veterans of color with Serious Mental Illness (SMI) in VA mental health care.

Additionally, we examined the observed TSBM benefit domains by translational research phase. The T3 (clinical implementation) phase demonstrated the greatest number of total benefits ($n = 29$), with 59% reported as demonstrated and 41% as potential. This phase showed the highest representation in the community domain ($n = 15$), including benefits such as healthcare accessibility, health education resources, healthcare delivery, and public health practices. The clinical domain was also prominent in T3 ($n = 7$), reflecting the translation of evidence-based interventions into routine practice. In contrast, the T4 (public health) phase accounted for 20 total benefits, with a slightly higher proportion of demonstrated (55%) compared to potential (45%) benefits. Like T3, the T4 phase also showed its strongest representation in the community domain ($n = 11$), reflecting a continued emphasis on community-level outcomes and interventions across later-stage translational efforts. T2 (clinical research) studies showed the fewest total benefits ($n = 13$), with only 8% demonstrated and 92% potential. These projects were primarily concentrated in the clinical domain ($n = 7$), consistent with early-phase research focused on diagnostic and therapeutic innovation. Benefits in the community ($n = 3$), economic ($n = 2$), and policy ($n = 1$) domains were limited and predominantly classified as potential (see Figure 3).

Case examples

ATTAIN NAV

Observed Themes:

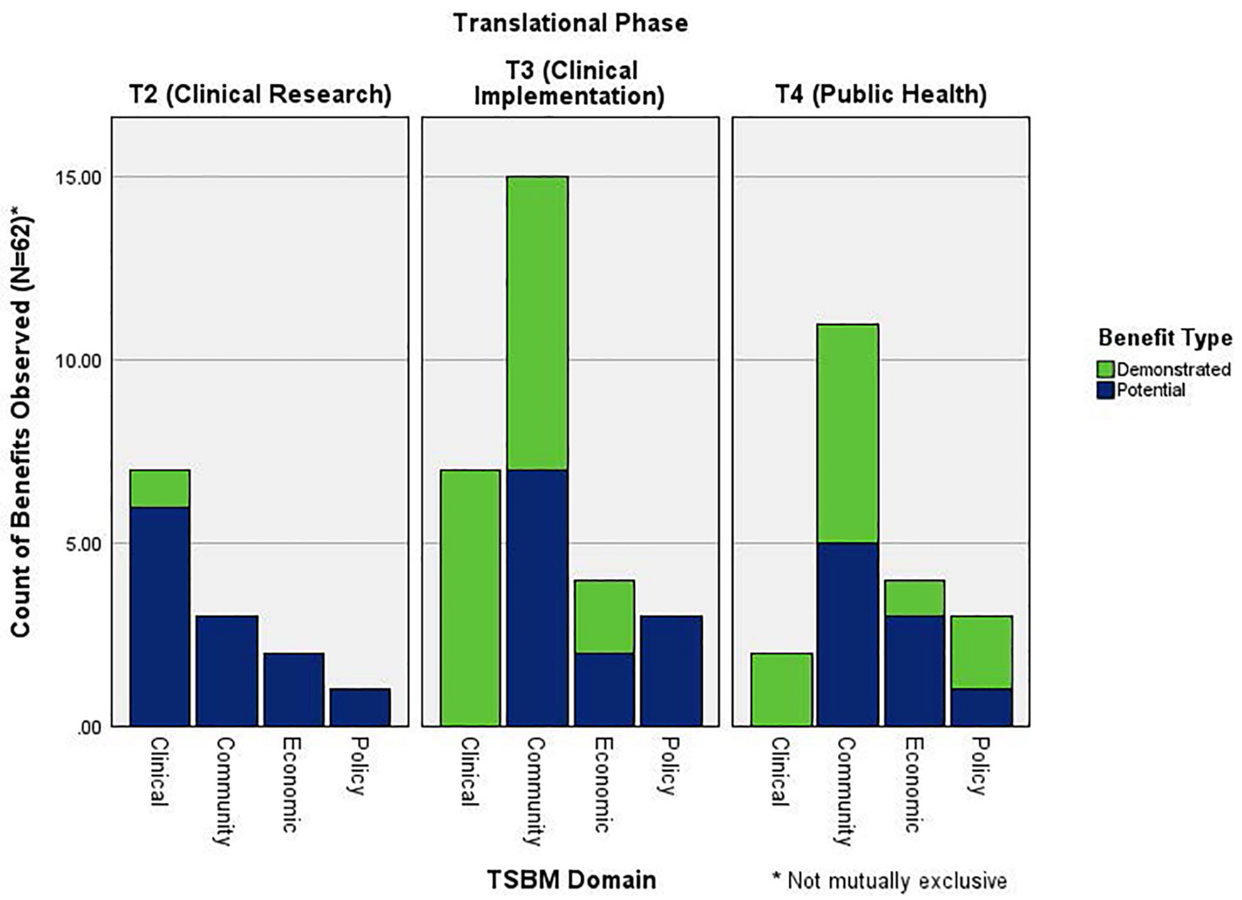

FIGURE 3
Count of TSBM benefits by translational phase and domain.

- Clinical Innovation and Care Integration
- Advancing Health Equity and Accessibility
- Community and Stakeholder Engagement
- Policy and Systems-Level Change

Identified Benefits:

- Clinical: Therapeutic Procedures (Demonstrated)
- Community: Health Education Resources (Demonstrated); Healthcare Accessibility (Demonstrated)
- Policy: Policies (Potential)

The ATTAIN NAV project had a significant impact on improving mental health service access for autistic children and their families through a family navigation intervention implemented in pediatric primary care (24). The project facilitated greater engagement with necessary health and community services, with 90% of families accessing at least one needed service. This clinical benefit was reflected in high levels of family satisfaction and successful connections to vital services. ATTAIN NAV empowered caregivers with the advocacy skills and knowledge necessary to navigate complex health systems more effectively. This not only facilitated access to mental health and allied health services but also enhanced families' ability to engage with care providers, helping them overcome structural barriers that often limit access to specialized care. By demonstrating the positive impact of family navigators in improving access to care, ATTAIN NAV could influence policy decisions on the role of navigation models to accelerate mental health care access and engagement. This could lead to more inclusive healthcare systems that are better equipped to serve more families. See Supplementary File 12.3 for ATTAIN NAV TSBM Impact Profile.

STOP COVID-19

Observed Themes:

- Advancing Health Equity and Accessibility
- Community and Stakeholder Engagement
- Policy and Systems-Level Change
- Economic and Societal Impact

Identified Benefits:

- Clinical: Investigative Procedures (Demonstrated)
- Community: Healthcare Accessibility (Demonstrated); & Public Health Practices (Demonstrated)
- Policy: Policies (Potential)

- Economic: Cost-Effectiveness (Potential) & Societal & Financial Cost of Illness (Potential)

The San Diego STOP COVID-19 CA UC San Diego-Global ARC team made significant strides in increasing awareness and understanding of factors that contribute to health disparities, focusing on improving COVID-19 testing and vaccination access for diverse groups, including Latino/a/x, African American, East African, and Asian communities (25). Their research led to better ways of reaching and helping these groups, using the findings to direct resources effectively. The team created a Theory of Change, a guide that helps others expand their services to similarly underserved populations, using methods like ethnographic documentation to understand and engage communities better. This work is crucial for providers to understand the challenges and needs of different communities, building trust and paving the way for more equitable healthcare.

The STOP COVID-19 project findings, including information gained through the Theory of Change process, have the potential to inform best practices for public health that directly relate to COVID-19 prevention, as well as other disease prevention. These actions have the potential to improve healthcare accessibility for historically underserved groups by fostering trust and increasing engagement in preventive healthcare. Additionally, the findings from STOP COVID-19 underscore the cost-effectiveness of community-based interventions and highlight the broader societal and financial cost of illness avoided through early and accessible testing services. The project's evidence-based approach has the potential to inform future health policies aimed at reducing healthcare disparities by identifying systemic barriers and tailoring solutions to meet the specific needs of immigrant and refugee communities. See Supplementary File 12.4 for STOP COVID-19 TSBM Impact Profile.

Enhancing collaborative decision-making among veterans of color in VA mental health care

Observed Themes:

- Clinical Innovation and Care Integration
- Community and Stakeholder Engagement
- Policy and Systems-Level Change
- Multilevel Barriers and Solutions

Identified Benefits:

- Clinical: Therapeutic Procedures (Demonstrated), Guidelines (Demonstrated), & Investigative Procedures (Demonstrated)
- Community: Healthcare Accessibility (Potential), Healthcare Delivery (Potential), & Public Health Practices (Potential)
- Policy: Policies (Potential)

The Enhancing Collaborative Decision-Making Among Veterans of Color in VA Mental Health Care project highlighted the impact of collaborative decision-making and associated patient empowerment approaches for improving mental health care for Veterans of color with serious mental illness (26). The project assessed multilevel factors including collaborative decision-making associated with satisfactory care experiences in VA mental health care. The team used community engaged strategies to work closely with Veteran partners as well as gathering mixed methods data to inform cultural tailoring of an intervention that supports Veteran-clinician collaboration. Feedback from these partners and participants also informed a new set of clinical guidelines that may improve VA mental health care accessibility and quality for Veterans of color.

The findings from this project have the potential to inform future public health practices by better incorporating the collaborative decision-making approach into mental health treatment among Veterans. By improving therapeutic procedures and public health practices that focus on Veteran engagement, the project demonstrated that involving Veterans in their care decisions can lead to more effective, tailored services. These insights have the potential to shape future healthcare policies by advocating for collaborative decision-making as a standard practice in VA mental health services. Such policy shifts would ensure that mental healthcare is more responsive and tailored to the diverse needs of Veterans, leading to greater care utilization and improved outcomes. See Supplementary File 12.5 for the Enhancing Collaborative Decision-Making Among Veterans of Color in VA Mental Health Care TSBM Impact Profile.

Discussion

This work validates and extends the processes originally developed by the creators of the TSBM, offering a process-oriented example of its successful application at an external institution and CTSA hub. The findings highlight the TSBM's feasibility, utility, and value for broader dissemination and institutional use. By documenting the development of the TSBM Impact Profiles and presenting detailed case examples, this project offers a practical approach for operationalizing the TSBM framework to assess the health and societal impacts of clinical and translational research. These results demonstrate a replicable process for identifying and communicating a wide range of benefits across diverse research contexts. The use of concise, standardized profiles provides an accessible and engaging product for dissemination to multiple audiences. Moreover, the collaborative co-creation process with investigators ensured that complex research findings were accurately synthesized and translated into a format that is both scientifically rigorous and broadly understandable. While the TSBM Impact Profiles themselves are not new, this application demonstrates how they can be used by external institutions to support structured, co-created, and scalable dissemination of research findings. Prominent themes such as advancing health equity and access to care, supporting community-engaged research, and informing policy or systems change reflect the multidimensional nature of translational research impacts. Notably, these themes often spanned multiple TSBM domains, illustrating the interconnectedness of clinical, community, economic, and policy-level outcomes.

The consistent identification of TSBM benefits across the four domains (Clinical, Community, Economic, and Policy) underscores the model's strength in contextualizing the impacts of clinical and translational research to enhance population-wide well-being. The majority of benefits were identified within the Clinical and Community domains, suggesting that the research being conducted is applied, community-focused, and aimed at creating sustainable and equitable improvements to healthcare systems. The identification of Policy and Economic benefits, though less frequent, signals that some translational science research projects are poised to make substantial, long-term contributions by informing policy and improving economic sustainability in healthcare. This suggests that the impact of these projects may extend beyond immediate clinical or community health improvements, ultimately contributing to broader systemic change and long-term cost savings.

The distribution of benefits across translational research phases illustrates how impacts can shift as projects move from early-stage clinical research (T2) to implementation (T3) and public health application (T4). T2 studies primarily generated clinical benefits, such as diagnostic innovations and therapeutic procedures, which were largely identified as potential rather than demonstrated-highlighting the discovery-oriented nature of this phase. In contrast, T3 projects had the highest number of total benefits, with a greater proportion of demonstrated outcomes, particularly in the clinical and community domains. Reflecting a focus of T3 studies on applying and adapting evidence-based interventions in real-world service settings, where measurable impacts on access, delivery, and provider behavior are more readily observed. Similar to T3, community benefits were also predominant across T4 projects, underscoring an emphasis on improving public health through community-based strategies such as increasing access, enhancing delivery systems, and promoting public engagement. While policy and economic benefits were present, they occurred less frequently, suggesting a potential opportunity for future research to further explore and strengthen impacts within these domains.

These patterns showcase the TSBM's ability to capture phase-specific impacts and demonstrate how different types of benefits accumulate and become more visible at later stages of translation. The presence of numerous potential benefits indicates that many projects are still in development phases, collecting the necessary evidence or fine-tuning processes to achieve broader or more definitive outcomes. In contrast, demonstrated benefits signify the tangible, real-world impacts that the research projects have already achieved. This balance between potential and demonstrated benefits, suggests the importance of fostering these projects through each stage, transitioning potential benefits into demonstrated ones, to maximize their full impact.

The case exemplars highlighted the broader cross-cutting themes identified across the TSBM Impact Profiles. Advancing health equity and accessibility was central to all three case examples, with each project targeting historically underserved populations—autistic children, immigrants and refugees, and Veterans of color—using tailored, contextually grounded and community-engaged strategies. Community and stakeholder engagement were foundational, evident in co-designed interventions such as ATTAIN NAV's caregiver-partnered model, STOP COVID-19's use of a Community Advisory Board, and the Veteran-engaged design of the collaborative decision-making intervention. The projects also reflected evidence-based implementation and workforce training, especially in the integration of navigators, community educators, and culturally informed communication strategies. Additionally, each project addressed policy and systems-level change, either through identifying areas for future policy development or informing guidelines and models of care delivery. These case exemplars illustrate the multilevel, multidomain nature of translational science, capturing how community-based, clinically effective, and system-focused approaches can yield broad translational science benefits in real-world contexts.

Overall, these findings demonstrate the utility of the TSBM as a valuable tool for evaluating the impact of clinical and translational research, identifying knowledge gaps, offering a structured approach for disseminating research benefits and outcomes, and enhancing communication with stakeholders, the academic community, and the general public. This dissemination method increases the visibility and understanding of research contributions by clearly linking scientific advancements to their practical applications across clinical, community, economic, and policy settings. By showcasing tangible outcomes, this application of the TSBM serves as a dissemination framework that not only validates the importance of research investments but also fosters collaboration and support for ongoing and future initiatives.

Limitations

The use of the TSBM to evaluate the impact of clinical and translational research, as well as the dissemination of these impacts through the TSBM Impact Profiles, shows promise as a means to improve the translation of research for various audiences. However, there are limitations to this work that we aim to address in the future. First, the primary aim of this study was to apply and evaluate the TSBM process within an institution external to the TSBM developer's institution. For this reason, the analysis was limited to profiles created within the UCSD ACTRI CTSA hub. Future work should explore cross-institutional applications of the TSBM to assess generalizability, refine dissemination strategies, and build comparative knowledge across institutions.

Second, TSBM Impact Profiles are designed to provide concise summaries, which—while accessible—may not capture all contextual details, methodological nuance, or longer-term outcomes of the projects. Moreover, the current evaluation reflects a cross-sectional snapshot of impacts. We recognize the possible value in tracking TSBM indicators longitudinally to observe how potential benefits evolve into demonstrated ones over time and aim to evaluate this with future efforts.

Third, the type of research plays a critical role in how easily information can be translated in a way that is relevant and meaningful to the public. Research situated at the earlier stages of the translational science continuum (T0, Basic Research, and

T1, Preclinical) is inherently more difficult to translate into clinical or community settings, as it is further from real-world application. Our goal is to apply TSBM across all T-phases as we see opportunities to discuss translational potential throughout the continuum.

Fourth, it is crucial to consider contextual and cultural differences across target populations, particularly regarding language. For example, use of "disease" and "symptom" terminology may be inconsistent with current community preferences (e.g., in the case of autism where person-first language is prioritized). We encourage users of TSBM to adapt language to be accessible and respectful to their community audiences. In our work to date, we addressed this issue by relying on the research team's expertise in best language to describe their priority communities and topics.

Fifth, many investigators had limited knowledge of the TSBM prior to completing the survey to describe their project. As a result, the individuals completing the survey may not have been as fully informed about the TSBM, potentially impacting the quality and depth of the evaluations provided prior to review by the TSBM team. To address this concern, we worked closely with each research team and provided explanation of the TSBM impacts and examples. To enhance consistency across project, we are planning to develop trainings and continue providing technical assistance for projects.

Sixth, the use of generative AI tools such as ChatGPT introduced additional limitations. Although ChatGPT was used to support both content analysis and language simplification, all outputs underwent human review and refinement. This included not only the profile summaries but also the thematic outputs, which were critically assessed and modified by the TSBM team to ensure accuracy and completeness. Similarly, while ChatGPT was used to assist in refining plain language sections of the Impact Profiles, the resulting text sometimes lacked nuance or introduced phrasing that required revision to remain faithful to the original meaning.

Nonetheless, we acknowledge that reliance on AI-generated suggestions introduces potential bias, and that further research is needed to define best practices for integrating generative AI into qualitative methods. These limitations reflect the current constraints in AI's ability to fully grasp complex, context-specific research content. Future work should continue to explore how best to incorporate AI into qualitative research and science communication, including rigorous validation procedures, prompt design refinement, and attention to bias or overgeneralization in AI-generated language.

Finally, there were limited methods to assess the usefulness of the TSBM Impact Profiles. While website metrics are available to track how often the profiles are visited or downloaded, we have not yet been able to gather data on how community members and stakeholders perceive the usefulness of these profiles. This represents a gap in understanding their true impact and value and will be the focus of our future work.

Future directions

This project has identified several areas for growth and expansion. First, we plan to collaborate with the UCSD ACTRI Community Advisory Board to gather feedback on the TSBM Impact Profiles. This input will help refine language, format, and content for improved relevance and accessibility across diverse audiences. Second, training and education for investigators will be central to supporting TSBM adoption. Leveraging resources from the original developers, we aim to integrate the TSBM into the research lifecycle—starting at project planning—and increase awareness of translational impact frameworks. Third, we plan to apply the TSBM to research-adjacent efforts, such as workforce development, community partnership initiatives, and training programs. These applications may help further expand the model's utility beyond traditional research outcomes. Fourth, by identifying both potential and demonstrated benefits, this work lays the foundation for future longitudinal evaluation, where projects can be re-assessed over time to track evolving impact. Finally, we will develop and implement a systematic dissemination strategy, leveraging tools such as the Dissemination Planner from the Translating for Impact Toolkit and incorporating SMART (Specific, Measurable, Achievable, Relevant, Time-Bound) goals. This strategy will aim to maximize reach, engagement, and meaningful use of TSBM Impact Profiles. Together, these efforts will strengthen the TSBM's role as a dynamic tool for evaluating, communicating, and advancing the real-world impact of translational research.

Data availability statement

The original contributions presented in the study are included in the article/Supplementary Material, further inquiries can be directed to the corresponding authors.

Ethics statement

Written informed consent was obtained from the individual(s) for the publication of any potentially identifiable images or data included in this article.

Author contributions

KS: Conceptualization, Data curation, Formal analysis, Investigation, Methodology, Project administration, Validation, Visualization, Writing – original draft, Writing – review & editing. NS: Conceptualization, Supervision, Writing – review & editing. IB: Visualization, Writing – review & editing. ZD: Visualization, Writing – review & editing. LB-F: Supervision, Writing – review & editing. GA: Supervision, Writing – review & editing. ET: Writing – review & editing. MG: Writing – review & editing, Investigation. BR: Conceptualization, Methodology, Supervision, Writing – review & editing.

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Conflict of interest

The authors declare that the research was conducted in the absence of any commercial or financial relationships that could be construed as a potential conflict of interest.

Generative AI statement

The author(s) declare that Generative AI was used in the creation of this manuscript. Generative AI was used as a tool to facilitate the content analysis of the Translational Science Benefits Model Impact Profiles and validation checks occurred across multiple phases of the analyses.

Publisher's note

Supplementary material

The Supplementary Material for this article can be found online at: https://www.frontiersin.org/articles/10.3389/frhs.2025.1535693/full#supplementary-material

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Leveraging the translational science benefits model to enhance planning and evaluation of impact in CTSA hub-supported research

Andrea Molzhon[1], Pamela M. Dillon[1] and Deborah DiazGranados[1,2]*

[1]C. Kenneth and Dianne Wright Center for Clinical and Translational Research, Office of the Vice President for Research and Innovation, Virginia Commonwealth University, Richmond, VA, United States, [2]Department of Psychiatry, Virginia Commonwealth University, Richmond, VA, United States

EDITED BY
Joe Hunt,
Purdue University Indianapolis, United States

REVIEWED BY
Carolynn Thomas Jones,
The Ohio State University, United States
Anna La Manna,
Washington University in St. Louis,
United States

*CORRESPONDENCE
Deborah DiazGranados
✉ diazgranados@vcu.edu

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Introduction: Increasingly, the public, policymakers, and funders expect clinical research to show tangible effects on public health. However, assessing research impact is challenging. Most researchers are not trained to consider the broad-ranging impacts of their work. The TSBM is a conceptual framework that includes four domains of impact: clinical, community, economic, and policy. We assess the utility and acceptability of using a survey based on the TSBM as a means to help researchers identify their potential research impacts.

Methods: CTSA program-supported investigators self-reported the potential benefits of their research projects in an electronic survey based on the TSBM. Responses were reviewed and scored by program evaluators. Survey acceptability was measured by response and completion rates; utility was measured by comparing benefits identified in the survey but not described in the researcher's grant application; and quality was measured by the degree of congruence between investigators' responses and evaluators' determinations regarding the potential benefits of the research.

Results: Of the investigators invited to participate, 67% completed the survey. Half of the investigators identified at least one benefit from their research not described in their research proposals. The rate of agreement across all responses between the investigators and the evaluators was 60%.

Discussion: Our study showed that a survey based on the framework of the TSBM was an acceptable and useful tool to help investigators identify research impact. However, our work also suggested that there are opportunities to educate investigators especially about the long-term, broad-reaching effects of their work. Ultimately, this work may help researchers conceptualize and realize the public health impact of their research.

KEYWORDS

research impact, evaluation, translational science, CTSA, impact evaluation models, translational science benefits model

Introduction

In the past decade, there has been an increasing call to evaluate the impact of research and to equip researchers with the skills necessary to enhance the reach and influence of their work (1, 2). As competition for research funding grows, it is essential to demonstrate that research contributes meaningfully to society and the broader world. However, assessing research impact is inherently complex—both in defining what constitutes impact and in tracking its wide-ranging effects. Most discussions of research impact focus on its benefits (3), yet capturing these effects requires establishing clear links between research outputs and tangible outcomes. While research may not be the sole driver of a given impact, it must be shown to be a necessary component of change (2, 4).

Impact evaluation involves identifying both intermediate and downstream effects of research, often requiring multiple forms of evidence (2, 5). The assessment of impact considers both its significance, the magnitude of the effect and its reach, and the size and composition of the populations affected. One approach to evaluating research impact is through indicator-based methods, which use measurable outputs to assess the extent to which research has contributed to observed outcomes. If research outcomes align with anticipated effects, this can strengthen claims of causality or impact. In this paper, we apply an indicator-based approach based on a published framework, the Translational Science Benefits Model (TSBM; 6), to evaluate investigators' conceptualizations of the impact of the research produced by a Clinical and Translational Science Award (CTSA) program. We report on the utility of applying the selected framework to helping investigators anticipate and define various potential benefits of their research and to assess investigators' abilities to interpret the expected results of their research.

Clinical and translational science (CTS) aims to bridge the gap between research and practice, transforming scientific discoveries into improved clinical practice, policies, and health outcomes (6). While the short-term, academic impacts of research can be quantified through publications, citations, and subsequent research funding, measuring the broader, downstream effects of research on human health remains challenging (7–9). Unlike academic outcomes, research impact, which encompasses patient, community, and societal benefits resulting from research, is harder to link directly to a single project or even a researcher's body of work. The reasons for this are many-fold and include the complexity of factors impacting health, the temporal distance between research and clinical implementation, and the rapidly changing clinical, regulatory, and policy environment (2). Despite these challenges, an assessment of research impact is critical to fully understand the value of research to public health.

Researchers often lack training in capturing the broader, long-term impacts of their research, yet funding agencies increasingly require grant applications to articulate potential research impacts (10). This highlights the need for tools and frameworks that enable researchers to better understand and measure the full spectrum of their work's impact, such as how research informs or influences clinical care guidelines, health policies, and community health initiatives. The TSBM (11) offers a conceptual framework for this purpose. The TSBM is a multifaceted approach to defining the benefits that could result from CTS research. As illustrated in Figure 1, the model includes four broad domains of impact/benefit with indicators of specific impacts/benefits for each domain. This provides a clear

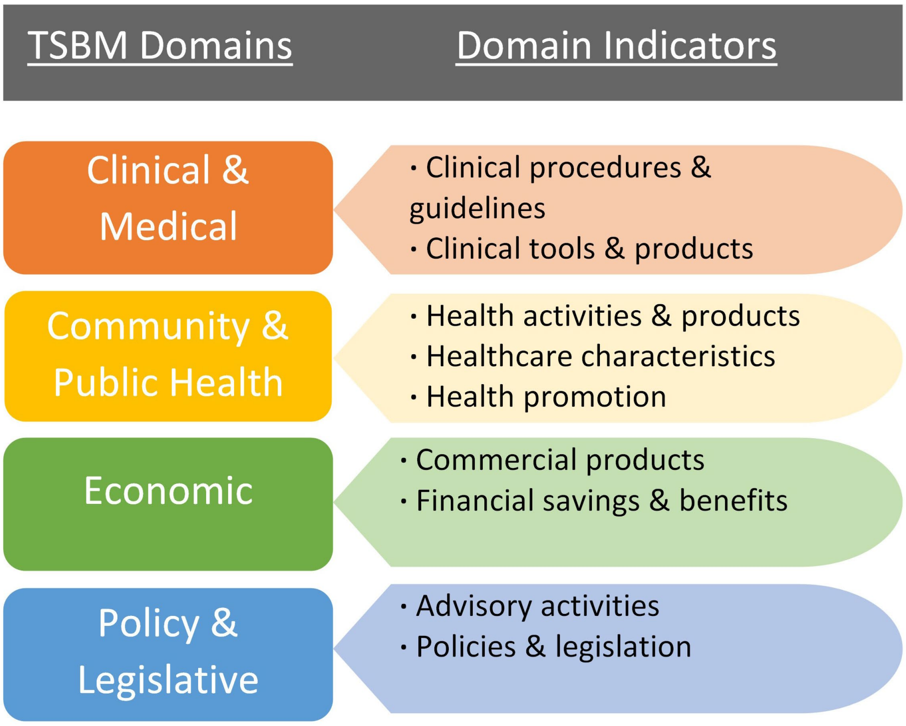

FIGURE 1
The domains and components of the TSBM (11).

framework for researchers to plan for, assess, and track ways their research may be used to benefit a broad range of stakeholders, such as practitioners, community organizations, and policy makers. Evidence suggests that the model may be useful particularly for researchers who are in the early stages of the research process (12). Though, while there is clear evidence that the model can be used effectively as a framework for the presentation of case studies (12–14), evidence that the model can be used as a tool to improve researchers' competencies in impact measurement is limited (12). Despite the potential added value of assessing impact beyond academic publications and grants, the TSBM is a relatively new evaluative framework in CTS, so it is uncommon for researchers to receive targeted guidance or training to use the model for research planning and evaluation.

The project is being conducted under a CTSA, a seven-year program grant awarded by the National Institutes of Health's (NIH) National Center for Advancing Translational Sciences (NCATS) to support and advance CTS. This paper describes the initial phase of an ongoing project to improve our evaluation of the public health impact of the work of our CTSA program. The broad goal of this paper is to examine and describe our CTSA program-supported researchers' ability to conceptualize the potential impacts of their CTS research. The specific objective of this phase of our impact evaluation project is to evaluate the utility and acceptability of collecting self-reported research impact data using a survey based on the TSBM framework. We surveyed CTSA-supported investigators who were beginning their research projects, as well as those who had recently completed their CTSA-supported projects. The findings will be used to help our CTSA program develop new resources and training opportunities for researchers to improve how they consider, plan for, and track a broad array of near- and long-term benefits resulting from their research, ultimately optimizing the public health impact of their work. The findings also will form a basis for the development of a robust framework to evaluate the research impact of our CTSA-funded program.

Methods

Design and participants

We conducted a cross-sectional descriptive study in which investigators supported by our CTSA hub who were awarded pilot funding or training grants (e.g., K scholars or Supplement Scholar Awards) were recruited to participate in an electronic survey based on the TSBM. We began collecting survey data in May 2024.

Measures

We utilized a survey that was informed by the TSBM framework. The survey was based on an instrument developed at Case Western University and adapted to align with our specific evaluation needs (15). Surveys were electronically completed using Research Electronic Data Capture (REDCap; 16), a secure, web-based survey platform. The survey was designed to be an investigator's self-assessment of their project's potential impacts across the domains of the TSBM. First, items were included to capture information on the respondent's project (i.e., project dates, title, aims, etc.); this data provided context about the project for the evaluators. Second, respondents were directed to, "Use this checklist to identify the anticipated/potential CLINICAL (including TOOLS & PRODUCTS), COMMUNITY, ECONOMIC, and/or POLICY benefits of your work," and the checklist included nine yes/no items that aligned with each indicator of the four domains of the TSBM, as depicted in Figure 1: (1) Clinical and Medical (one indicator/checkbox), (2) Clinical and Medical Tools and Products (one indicator/checkbox), (3) Community and Public Health (three indicators/checkboxes, combined to form one score), (4) Policy and Legislation (two indicators/checkboxes, combined to form one score), and (5) Economic (two indicators/checkboxes, combined to form one score). We separated the domain of *clinical and medical benefits* into two parts to increase the accuracy and specificity of the data we collected (i.e., *clinical and medical*, and *clinical and medical tools and products*). For each potential benefit endorsed with a *yes* response, an open-text field appeared and respondents were asked to provide a description of those potential benefits.

Data collection procedure

Surveys were electronically sent to our CTSA program-supported investigators (e.g., K12 Scholars, Diversity Supplement Scholars, and TS Pilot Awardees) via email followed by up to five reminders to investigators who did not initially respond.

Survey analysis

We analyzed survey responses to identify and summarize indicators of survey acceptability, utility/value, and response quality. Evaluating acceptability, utility, and response quality was essential because the survey serves as a primary measure of impact within our evaluation plan and provides key information that will be used to inform training for investigators on research impact. Survey acceptability and utility/value were scored by the first author (AM). For response quality, we used a score-rescore method in which two evaluators scored investigator responses (AM and PD) in 100% of completed surveys. When scores differed between evaluators, scores were discussed until a consensus was reached.

Survey acceptability

Survey acceptability was defined as the willingness of investigators to take part in the TSBM survey. Understanding how willing investigators were to participate in the survey allowed us to assess its feasibility as a data collection tool. We calculated acceptability as response rates (percent of those who responded to the survey compared to those who were invited to participate) and completion rates (the percent of submitted complete surveys).

Survey utility/value

Survey utility was defined as the value or usefulness of the survey in helping respondents identify potential benefits of their research that they previously had not identified in their research applications. To measure this, we compared responses on the *potential benefits* survey items with the language included in the respondents' research award applications. Each yes/no item that was endorsed with a *yes* response and was previously described in the grant application or their abstract received a score of *0*, as this indicated that the TSBM survey did not serve as a mechanism for investigators to conceptualize and describe the potential benefits of their research beyond what the investigator previously had articulated. Each benefit domain that was endorsed in the survey but not articulated in the corresponding award application received a score of *1*. As there were nine yes/no *potential benefits* indicators, survey utility scores ranged from 0 (low utility) to 9 (high utility).

Survey response quality

Response quality was defined as the perceived accuracy of investigator-endorsed or -unendorsed benefits across each TSBM domain. To measure response quality, we compared responses on each of the five *potential benefits* sections of the survey (i.e., Clinical and Medical, Clinical and Medical Tools and Products, Community and Public Health, Policy and Legislation, and Economic) with the language in the corresponding research award applications. If the evaluators identified a potential benefit of the investigator's research that was not endorsed by the investigator in a given section, the score for that section would be 0. If the evaluators agreed with the investigator's response, the score for that section would be 1. Response quality scores for each survey were calculated by counting the number of times the evaluators' determinations matched the investigators' responses across all survey sections. As there were five sections, *response quality* scores ranged from 0 (poor quality) to 5 (excellent quality).

Results

Participants

Seven investigators whose research projects were in the beginning stages (78% response rate) and three investigators whose projects had recently concluded completed a survey (50% response rate). See Table 1 for a summary of the groups of principal investigators (PIs) supported by our CTSA program who received and completed the survey.

Survey acceptability

Of the 15 invited to participate, 11 responded (73.3%, response rate) and 10 (66.7%) completed the survey. This indicates that most investigators were willing and able to dedicate time to the survey.

Survey utility/value

In 5 (50%) of completed surveys, there was at least 1 instance in which investigators identified a potential or demonstrated benefit of their research that they had not described in their grant application. This occurred at least once for every type of benefit domain represented in the TSBM. For example, one survey respondent expanded on what was included in their award application in the *clinical and medical* benefits domain, mentioning not only the potential benefits to *therapeutic procedures* (previously mentioned in award application), but also described potential benefits to *investigative procedures* that had not been described previously in their award application. Of the 5 survey respondents who endorsed at least one new potential benefit of their research, utility scores ranged from 1 to 4 (maximum score of 9) with an average score of 2.2. This indicates that, in 50% of survey respondents, the survey helped them to identify an average of 2 benefits that they previously had not articulated in their funding applications.

TABLE 1 Survey distribution and completion counts by survey type and investigator group.

Investigator group	Distributed (*n*)	Completed (*n*)
2024–2025 and 2023–2024 pilot awardees	7	5
2025–2027 and 2022–2024 K12 scholars	6	3
2024–2025 diversity supplement scholars	2	2

Survey response quality

Across all completed surveys, investigators endorsed *clinical and medical* benefits most frequently (endorsed in 100% of completed surveys) and endorsed *policy and legislative* benefits the least frequently (endorsed in 20% of completed surveys); see Table 2. In 100% of the surveys, evaluators disagreed with at least one determination that the investigators made. The overall rate of agreement between the evaluators and the investigators across all responses was 60%. The evaluators determined that the investigators missed a potential benefit of their study that was identified by the evaluators in 30% of responses. In 6% of responses, the evaluators determined that benefit(s) endorsed by the investigators were incongruent with what one would expect from the described research project. In 4% of responses, the evaluators agreed with investigator endorsements but did not agree with the justification that the investigator provided. The *community and public health* benefits domain comprised the highest percentage of missed endorsements or incongruent responses from investigators (40%), followed by *economic* benefits (30%), and the *clinical and medical* benefits domain comprised the fewest number of missed endorsements or incongruent responses (5%). Of the items in the *community and public health* benefits domain that were flagged by evaluators, 75% were due to benefits identified by the evaluators but not the investigator (missed endorsements). Missed endorsements accounted for 100% of evaluator-flagged responses in the *economic* benefits domain.

Discussion

Research impact is increasingly recognized as a critical component of scholarly work, shaping funding decisions, policy developments, and societal advancements. As research funders and governments worldwide demand evidence of public benefits from research investments, impact assessment has become essential for demonstrating the value of academic work (2). Evaluating research impact is important for ensuring accountability, optimizing resource allocation, improving research translation into practice, and fostering interdisciplinary collaboration. However, measuring research impact remains complex due to its subjective nature, diverse beneficiaries, and the challenges of attribution. Current methodologies for impact

TABLE 2 Investigators' endorsements of benefits across TSBM domains.

	Benefit domain				
	Clinical and medical	Tools and products	Community and public health	Economic	Policy and legislative
Count of investigator endorsements					
Potential benefits (respondents = 10)	10 (100%)	5 (50%)	4 (40%)	3 (30%)	2 (20%)
Incongruent investigator endorsements					
Count (% of investigator endorsements)	1 (1%)	0	1 (25%)	0	1 (50%)
Missed endorsements by investigators					
Count (% of surveys)	0	2 (20%)	6 (60%)	6 (60%)	1 (10%)

evaluation vary widely, from experimental and statistical methods to qualitative, systems-based, and indicator-driven approaches, each offering different insights into the significance and reach of research contributions. Despite the growing emphasis on impact evaluation, many existing frameworks struggle to capture the full spectrum of research benefits, particularly in fields where impacts are indirect, long-term, or difficult to quantify. Moreover, there is limited evidence on how to effectively train investigators to consider, plan for, and track a broad array of near- and long-term benefits resulting from their research. Addressing this gap is essential for optimizing the public health impact of research by equipping investigators with the tools to systematically integrate impact considerations into their work.

In this study, we used a survey based on the TSBM framework to capture self-reported descriptions of potential impacts. Responses were analyzed to identify and describe our CTSA program-supported researchers' abilities to conceptualize the potential impacts of their CTS research across the four domains of the TSBM. This study is the first to our knowledge to assess investigator understanding of research impact using the TSBM framework. We found that completing the TSBM survey enabled investigators to identify more potential benefits of their research than they initially had articulated in their research applications. This speaks to the potential advantages of providing investigators with a guide to help them conceptualize and define the potential impacts of their work. Encouraging investigators to consider a more expanded view of the potential benefits of their research could influence their dissemination practices, perhaps helping to close the gap between translating research into practice. Our results add to the current literature on impact evaluation by contributing to the understanding of investigators' perceptions of impact and providing insights into how to effectively frame the evaluation of research impact to capture both near- and long-term benefits.

Limitations

The sampling technique used in this study limited the results in several ways. As our sample was small in size and non-randomized, selection bias may affect the wider generalizability of the findings and implications. Our sample consisted of CTS researchers supported by a university-based CTSA program who voluntarily completed the survey, so the findings may not generalize to all types of researchers or investigators in varied settings and under varied conditions. However, this was an exploratory, quality improvement study meant to inform the development of new resources and initiatives specifically for the CTS researchers at our CTSA program hub, so the findings were not intended to generalize to the wider population. Moreover, due to our small sample size, we were unable to examine possible moderating effects of individual-level variables such as award type, career stage, research experience, professional position, or other demographic-level variables. Future efforts to examine investigators' conceptualizations of research impact within the context of the domains of the TSBM could include investigators from multiple CTSA programs to generate a larger, more representative sample that would allow for the examination of potential moderating factors.

The survey measure, itself, and the procedure used to score the survey also contributed to the study's limitations. The survey primarily is meant to be used as a tool for self-reflection and self-report rather than for evaluation, therefore, scoring was subjective. Consensus-scoring served to minimize the subjectivity of the scores that were assigned. As the survey requested project information from the respondent and the two scorers were well-acquainted with the pilot projects of each survey respondent by virtue of their roles in the CTSA program (e.g., CTS pilot program director and evaluator) blinding was not possible. However, the background knowledge that the two scorers had in relation to each investigator's project meant that scoring decisions were informed by a clear understanding of the research, and the two-scorer consensus process mitigated potential biases in scoring.

Future directions

We already have begun the next phase of this research, which involves conducting investigator interviews. These interviews will gather feedback on investigators' impressions of the TSBM-based survey, their current methods of tracking their research impact, and their ideas for how our CTSA hub can better support impact evaluation using the TSBM as a guiding framework. The broad goal of this research is to improve impact evaluation in our CTSA program. The specific goals of the second phase are to refine the survey to improve its clarity and utility and to develop new resources and/or training opportunities to assist investigators in understanding, measuring, and describing their research impact. Ultimately, this effort seeks to help investigators conceptualize and realize the multifaceted impacts of their research on public health.

Conclusion

Researchers face challenges in identifying, tracking, and articulating the broader significance of their work. This study provides an initial understanding of how to better inform and support investigators in this process. By capturing investigators' perceptions of research impact, our findings lay the groundwork for developing targeted resources and training opportunities.

Data availability statement

The datasets presented in this article are not readily available because the Virginia Commonwealth University Institutional Review Board (IRB) designated this project as "not human subjects research" due to it being a quality improvement project. Requests to access the datasets should be directed to diazgranados@vcu.edu.

Author contributions

AM: Writing – review & editing, Formal analysis, Methodology, Project administration, Writing – original draft, Data curation, Investigation, Visualization, Conceptualization, Validation. PD: Writing – review & editing, Formal analysis, Data curation, Validation, Conceptualization. DD: Writing – review & editing, Supervision, Conceptualization, Validation, Investigation, Methodology, Funding acquisition, Resources, Project administration, Writing – original draft.

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Conflict of interest

The authors declare that the research was conducted in the absence of any commercial or financial relationships that could be construed as a potential conflict of interest.

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The authors declare that no Gen AI was used in the creation of this manuscript.

Publisher's note

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EDITED BY
Nicolai Savaskan,
Public Health Service Berlin Neukölln,
Germany

REVIEWED BY
Ohbet Cheon,
Clarkson University, United States
Keyonna King,
University of Nebraska Medical Center,
United States

*CORRESPONDENCE
Pamela L. Davidson
✉ pdavidson@mednet.ucla.edu

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Clinical and translational science award hub portfolio analysis and interorganizational collaborations with Los Angeles County to improve population health and health care delivery (ID 1565096)

Pamela L. Davidson[1,2]*, Terry T. Nakazono[1], Andrea Min[1], Jim Morrison[1] and Omira Quail[3]

[1]CTSI-Evaluation, Clinical and Translational Science Institute (CTSI), University of California, Los Angeles, Los Angeles, CA, United States, [2]Department of Health Policy and Management, Fielding School of Public Health, University of California, Los Angeles, Los Angeles, CA, United States, [3]Bachelor of Science Program, Biology with Minors in Epidemiology and Biostatistics, University of Western Ontario, London, ON, Canada

Demonstrating impact in the Clinical and Translational Science Award (CTSA) Program is crucial to continue governmental, taxpayer, institutional, and donor support and investment. We present an innovative portfolio analysis to summarize the Scientific Achievement Translational Science Impact at the hub level. Additionally, a unique feature of the UCLA CTSA hub includes the many interorganizational collaborations with Los Angeles County (LAC). This is the first study to examine the Translational Science Benefits Model (TSBM) impact on projects with CTSA hub-county interorganizational collaborations. A Framework for Evaluating Scientific Achievement Translational Science Impact (SATSI) was used to guide the analyses, with impact indicators derived from the TSBM: (i) clinical and medical, (ii) community and public health, (iii) economic, and (iv) policy and legislation. Two major data sources were used for the evaluation: (i) The CTSI's Longitudinal Scientific Achievement and Impact survey (LSAS-I), and (ii) longitudinal interviews with principal investigators who reported high-impact projects in hub-county collaborations. We reported baseline data from 2 years of LSAS-I data showing n = 507 new CTSA-assisted grants and the associated demonstrated and potential impact using the hub portfolio analysis. Eighteen (n = 18) of these grants involved a hub-county interorganizational collaboration. Among these, we identified the highest impact projects and developed impact stories and vignettes describing improvements in health care delivery and population health. Our research offers a model for other CTSA hubs to summarize impact using the hub portfolio analysis, and to partner with local public health departments and governmental agencies to address health concerns in low-income and at-risk populations. This research directly addresses the mission of the UCLA hub, "to produce and implement innovations that impact the greatest health needs of Los Angeles and the nation."

KEYWORDS

translational science, CTSA program, knowledge translation, interorganizational collaborations, hub-county collaborations, TSBM, translational science impact

1 Introduction

The NIH National Center for Advancing Translational Science (NCATS) funds the Clinical and Translational Science Award (CTSA) Program, supporting over 60 hubs across the nation. This study examines the overall knowledge translation (as an intermediate impact measure) of the University of California Los Angeles (UCLA) Clinical and Translational Science Institute (CTSI) using the TSBM: Translational Science Benefits Model (1). In the 2021 CTSA Evaluators Survey, 68% of hubs reported using the TSBM for evaluation impact measurement; by 2024 the percentages had increased to 75.5% of hubs responding to the survey (Hunt, 2025, unpublished)[1]. This Frontiers in Public Health Research Content aims to assess the state-of-the-science in TSBM research and development in the CTSA Program. The TSBM is used to collect demonstrated and potential impact in four domains: (i) clinical and medical, (ii) community and public health, (iii) economic, and (iv) policy and legislative benefits. Demonstrating impact is crucial to expand and sustain stakeholder investment. This paper presents a novel approach for reporting CTSA hub profile analysis to graphically illustrate to funding agencies and institutional donors the Scientific Achievement Translational Science Impact (SATSI).

Additionally, this innovative study examines TSBM impact in hub-county interorganizational collaborations; no other studies were found in the peer-reviewed literature that looked at impact in a systematic way using quantitative analysis. Spanning four Los Angeles-based partner institutions (Cedars-Sinai, Charles R. Drew University, Harbor-UCLA/The Lundquist Institute for Biomedical Innovation, and UCLA), the CTSI is involved in interorganizational collaborations with Los Angeles County (LAC) health departments, as well as other county governmental agencies. Figure 1 shows the hub institutional partners along with a sample of the vast opportunities for interorganizational collaborations with LAC. Our research offers a model for other CTSA hubs to partner with local health departments to improve health and healthcare.

2 Materials and methods

Methods for this study include: (1) assessing the national context of CTSA hub-county interorganizational collaborations; and (2) CTSI evaluation framework to guide quantitative and qualitative data collection and analysis to examine TSBM knowledge translation impact both overall in the hub portfolio and in hub-LAC interorganizational collaborations.

2.1 National context of hub-county interorganizational collaborations

Limited research exists on the extent to which CTSA hubs collaborate with their local city, county, and/or state governmental organizations and no studies were found that examined quantitative data on the impact of these collaborations. Among the available studies which were descriptive, one study concluded that strong public health partnerships improve research dissemination, policy development, and community health outcomes (2), while other studies emphasized the importance of collaboration for advancing public health initiatives, application to rural health initiatives, and the importance of trust in collaborator relationships (3–5). None of the studies collected or analyzed quantitative data on impact.

The justification for conducting this internet research was to provide a context for the hub-county collaborative activity at our CTSA and others across the nation. Since no systematic data were available on the extent of interorganizational collaborations among the CTSA

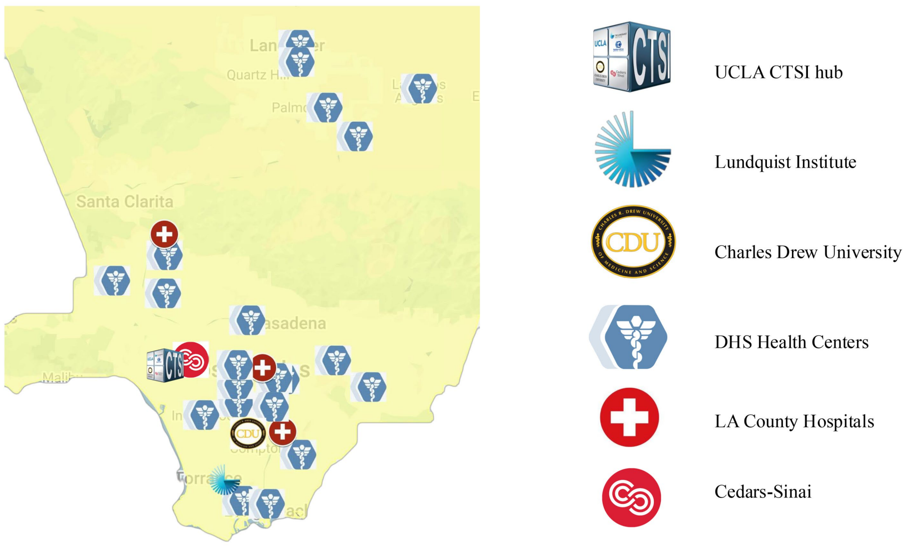

FIGURE 1
CTSI partner institutions and Los Angeles County health centers and hospitals.

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[1] Hunt J. Personal Communication Indiana Clinical and Translational Science Institute (CTSI) (2025) (unpublished).

hubs and county health departments, we wanted to understand how our hub compares with other hubs across the nation. We conducted internet research using publicly available website information to count the number of collaborations with county agencies associated with each of the hubs. Content analysis was used to rank CTSA hubs on the level of collaborations with county governmental institutions using a methodology created by Tafuto et al. (2).

To quantify the extent of CTSA hub interorganizational collaborations, we applied a ranking-based content analysis methodology (2), which was originally designed to evaluate and compare CTSA hub websites on the content alignment with NCATS goals and initiatives. The findings from this study were determined using a structured ranking system like Tafuto et al. (2). This system quantifies website content and assigns numerical scores based on defined criteria. In Tafuto's research, each CTSA hub was evaluated for the presence of relevant content, the variety of content formats, and the navigational ease of accessing this information. These three metrics were merged into a composite score for each hub, allowing for standardized comparisons across all 58 hubs.

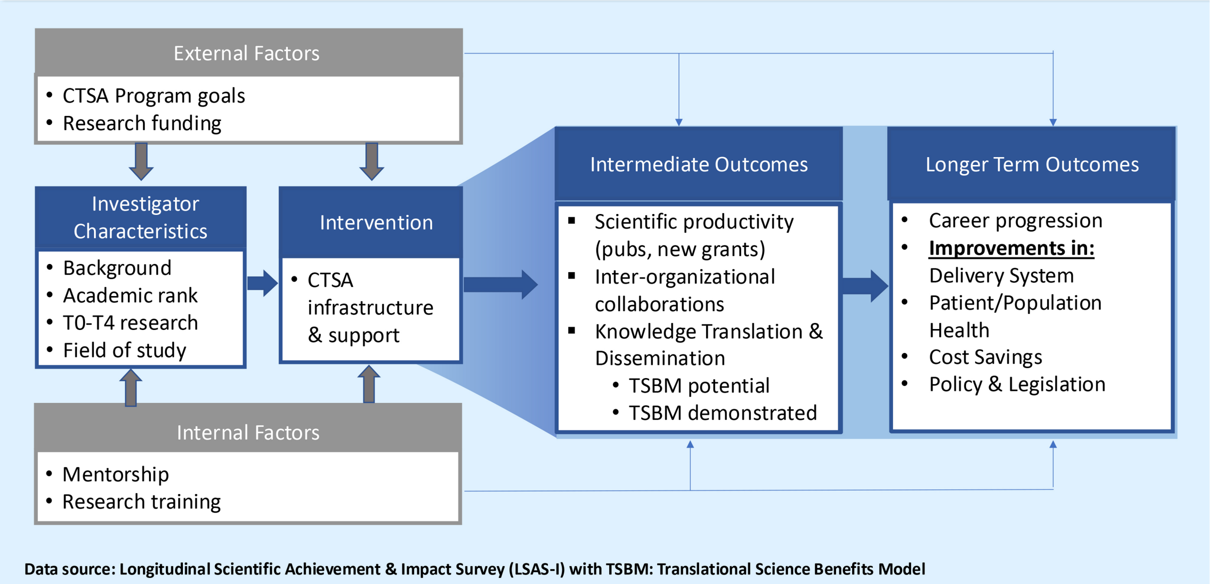
In our study, we adapted this ranking framework to systematically categorize and score CTSA hubs on their level of collaboration with county and governmental organizations, using publicly available web data. This approach was essential for the study given the absence of centralized data sources on hub-county partnerships. This approach provided a consistent and replicable method for gauging engagement trends among hubs. The validity of this ranking system has been demonstrated through its prior application to all 58 CTSA hubs in Tafuto's study, and its structured scoring ensured objective differentiation between varying levels of interorganizational engagement based on information posted on CTSA hub websites.

For our analysis, we constructed an ordinal 4-point scale—ranging from no evidence of collaboration (0) to three or more collaborations (3+)—inspired by Tafuto's scoring thresholds for content representation showing the intensity of hub-county collaborations. Specifically coded as: (0) No internet evidence suggesting hub-county collaborations, (1) hub had limited (only one) collaboration with county organizations, (2) hub had a moderate level (two) collaborations, and (3) CTSA website showed three or more hub-county collaborations.

Internet publicly available website data search was the most appropriate method since no other data source on hub-county collaborations was found. Sixty-one ($n = 61$) hubs were identified on the NIH CTSA hub directory (6). Each CTSA hub website and/or related content were examined through queries and evaluated for content related to hub-county interorganizational collaborations. Hubs were categorized using a ranking system showing the presence and accessibility of information related to collaborations with county organizations. This allowed us to compare our hub's activities relative to national peers as well as draw data-driven conclusions about the frequency and intensity of hub-county collaborations across 61 hubs. Hence, this analysis, building on the Tafuto et al. (2) methodology, provides an approach to constructing contextual variables to assess and compare national context, in the absence of a systematic data source (7–10).

2.2 Evaluation framework to guide quantitative and qualitative analysis of TSBM impact

CTSI-Evaluation continuously engages in hub-level evaluation, using the CTSI Framework to evaluate Scientific Achievement Translational Science Impact (SATSI). The Figure 2 framework shows how the CTSA infrastructure and support lead to intermediate and long-term outcomes. Intermediate outcomes are investigator-centric, focusing on scientific achievement (publications and grants), and research centric focusing on interorganizational collaborations, "potential" and "demonstrated" impact of new grant awards, and



Data source: Longitudinal Scientific Achievement & Impact Survey (LSAS-I) with TSBM: Translational Science Benefits Model

FIGURE 2
CTSI framework for evaluating Scientific Achievement Translational Science Impact (SATSI).

dissemination and implementation. Longer-term outcomes include career progression of investigators and improvements in the delivery system, patient and population health, costs, and policy and legislation. The new knowledge generated by the Framework is used to make recommendations for continuously improving the hub infrastructure and operations to innovate and accelerate clinical translational science (Figure 2).

Major data sources used for the evaluation include: (1) quantitative LSAS-I: longitudinal scientific achievement and impact survey, (2) evaluation master database (EMD), and (3) longitudinal qualitative interviews conducted with principal investigators (PIs) who reported high-impact hub-county collaborations supported by the CTSI. The LSAS-I sampling frame of investigators who received CTSI support was formed when the institution was first launched in 2011–2012 with $n = 261$ investigators, now reaching over $n = 2{,}400$ in 2024. The EMD is a longitudinal data repository which contains information on all CTSI support and services provided to each investigator (e.g., consulting hours, NIH grant writing workshops, pilot awards, bioinformatics data provisioning, Clinical Translational Research centers, CTRC).

Over the years, LSAS-I has been continuously reviewed and updated to keep pace with CTSA Program priorities and innovations. In the Supplementary material for this study, the TSBM checklist provides a description of each of the 30 indicators. Before incorporating TSBM, we collected open-ended qualitative data on impact that was challenging to code and analyze. LSAS-I now generates systematic data on investigator characteristics, types of research (e.g., NCATS priority areas, T0-T4 bench-to-bedside-to population health translational research), interorganizational collaborations, publications, the number and type of new grants and industry support attributable to CTSI, and the reported TSBM knowledge translation impact of the new grants (Figure 2 SATSI).

Collection of both quantitative and qualitative data were used to assess TSBM knowledge translation impact. The 4 domains of the TSBM include 30 quantifiable indicators of knowledge translation impact and the option of indicating either a demonstrated and/or potential benefit per indicator. However, qualitative interviewing was required to understand the impacts on improving health and healthcare in a manner more in-depth than what the TSBM indicators can provide alone. Indicators give us frequencies across a wide range of projects and an opportunity to systematically identify specific types of impact (e.g., computer software development/AI), while the longitudinal interviews give us a rich in-depth understanding summarized in the three impact stories which are presented in the results section.

To understand hub-level impact, we analyzed TSBM demonstrated and potential knowledge translation using a novel hub portfolio analysis. All new grants attributed to CTSI support were reported by investigators in the LSAS-I: 2021 and 2022, with 2021 being the first year for collecting the TSBM impact data at the UCLA hub. The hub portfolio analysis reports results by the 4 TSBM domains, subdomains, and the 30 indicators (Figure 3).

Subsequently, we focused on the subset of hub-county interorganizational collaborations using a systematic 5-point plan drawing upon both quantitative and qualitative data analyses. Inclusion criteria determined by our hub evaluation office counts interorganizational collaborations which: (i) were supported by the CTSI, and (ii) yielded a new grant from that support and included an LAC collaboration. While Table 1 presents the national context for hub-county interorganizational collaborations (n=61 hubs), Table 2 (see "Results" section) presents the 18 new grants and the associated interorganizational collaborations reported in the LSAS-I with some minor augmentation reported in PI interviews.

The systematic process involved: (i) selecting all the PIs and new grants supported by the CTSI that included an LAC interorganizational collaboration, (ii) summarizing characteristics of the investigators and their research projects; (iii) counting the total number of demonstrated impacts for each research project, (iv) interviewing PIs with the highest number of demonstrated impacts, and finally, (v) using the results to create an Impact Library for research training to build capacity for accelerating translational science.

3 Results

3.1 National context: CTSA hub-county interorganizational collaborations

Table 1 summarizes findings from the CTSA Program ($n = 61$ hubs) internet search, showing almost 50% (47.5%) of hubs had three or more research collaborations with county agencies, 38% had two collaborations, 11.5% had one collaboration, and only 1 hub reported no collaborations on their website in 2024. By utilizing the ranking methodology documented in the methods section, we ensured that our findings were grounded in a systematic, transparent, and reproducible evaluation process, which lent credibility to establish that the UCLA CTSI hub was among the leading institutions in interorganizational collaborations with county governmental agencies.

3.2 Hub portfolio analysis showing demonstrated and potential impact

This study combines 2 years of LSAS-I data (2021, 2022). In the 2-year reporting period, 507 new grants were reported by CTSI investigators. Of these 390 new grants (77% of the 507) reported demonstrated and/or potential impact.

Figure 3A shows the graphic hub portfolio of new grants reporting demonstrated and potential impact by the 4 TSBM domains: (1) clinical and medical, (2) community and public health, (3) economic, and (4) policy and legislative. Underlying the 4 domains are the 30 indicators. In the Supplementary material for this study, the TSBM checklist provides a description of each of the 30 indicators. For each new grant, investigators reported whether each indicator had a potential or demonstrated impact. A grant can have multiple TSBM domains and indicators, in other words the categories are not mutually exclusive.

Figure 3A shows the overall TSBM Impact by the 4 Domains. By far, clinical and medical benefits were the most often reported with 325 demonstrated and 998 potential impacts. These data were collected early in the research incubation period, so it is not surprising that almost 1,000 impacts were "potential" over the grant implementation period. In addition to clinical and medical, the other domains are presented in descending order of knowledge translation impact: community and public health (164 demonstrated, 483 potential), policy and legislative (43 demonstrated, 119 potential), and economic (37 demonstrated, 110 potential).

Figure 3B shows the 2 sub-domains (Procedures and Guidelines, Tools and Products) and the 9 indicators categorized as clinical and medical in the TSBM. Under Procedures and Guidelines, investigative procedures (78 demonstrated, 147 potential) and therapeutic procedures (43 demonstrated, 158 potential) were reported most frequently by the investigators. Under Tools and Products, biomedical technology (39 demonstrated, 113 potential) and biological factors and products (39 demonstrated, 124 potential) were reported most frequently by the investigators. Similarly Figure 3C (Community and Public Health), Figure 3D (Economic) and Figure 3E (Policy and Legislative) report the demonstrated and potential impact for each domain, subdomain, and underlying indicators. A similar pattern emerges throughout the Figure 3 graphics with smaller numbers of demonstrated and greater numbers of potential impact reported. Again, this is due to the reporting of TSBM impact early in the incubation period.

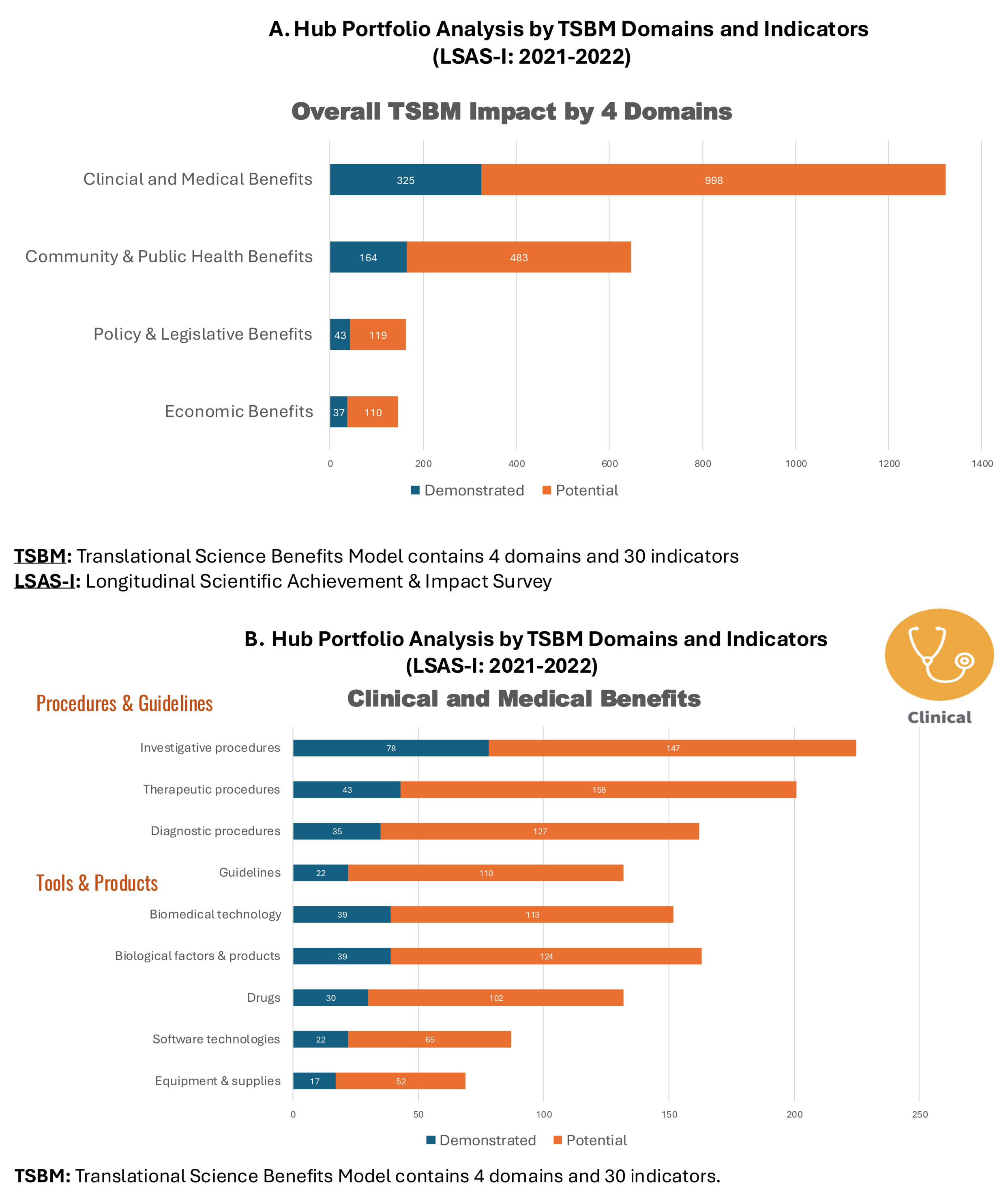
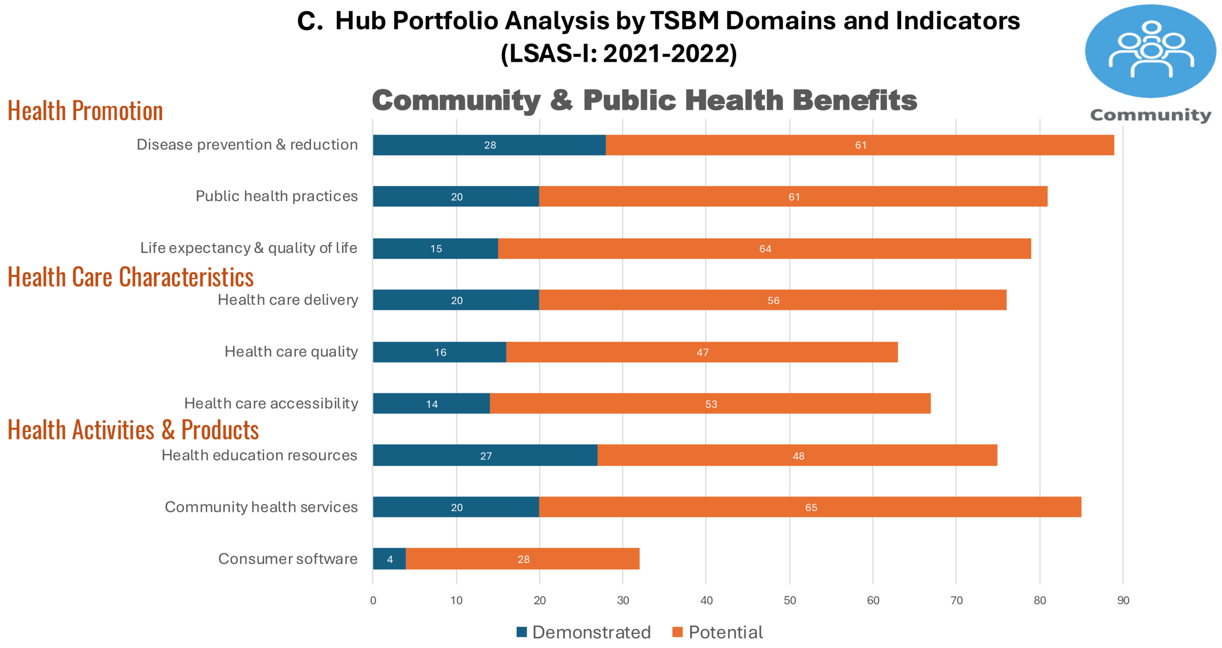
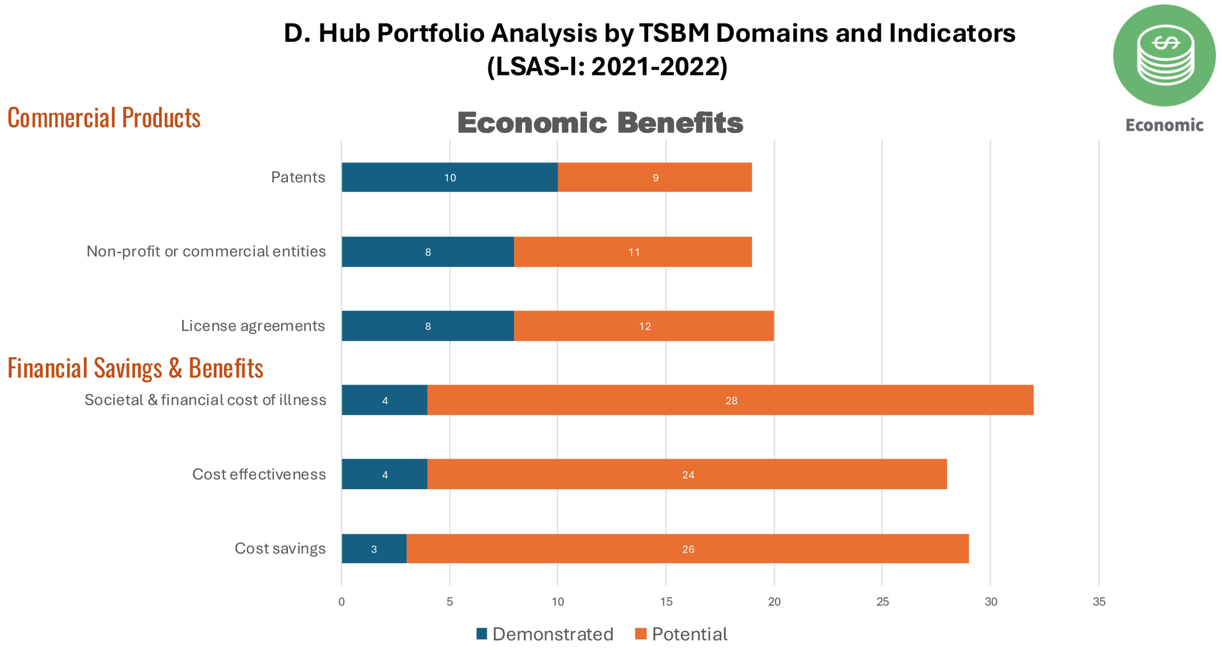


FIGURE 3 (Continued)



TSBM: Translational Science Benefits Model contains 4 domains and 30 indicators.

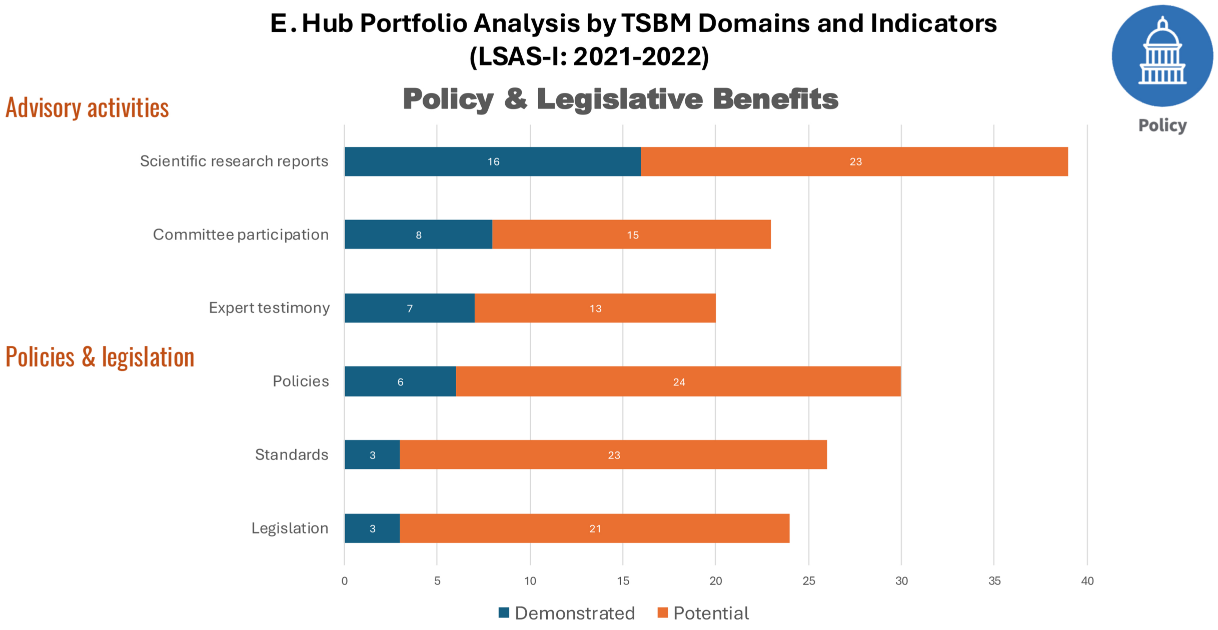


TSBM: Translational Science Benefits Model contains 4 domains and 30 indicators.

FIGURE 3 (Continued)

3.3 Hub-LAC interorganizational collaborations and impact stories

In the methods section, we described the systematic process for identifying high impact hub-LAC collaborations. We started by selecting all the new grants and associated investigators who were supported by the CTSI that also included an LAC collaboration in the 2-year period (2021–2022). Eighteen new research projects with 21 hub-county collaborations met our criteria for inclusion in the study. Table 2 summarizes the type of county collaboration with the highest percentages reported for county safety net hospitals (38%), LAC unified school district (19%), and smaller percentages of other county health departments, and varying mix of other.



TSBM: Translational Science Benefits Model contains 4 domains and 30 indicators.

FIGURE 3
(A–E) Hub portfolio analysis by TSBM domains and indicators (LSAS-I: 2021–2022).

TABLE 1 National context: CTSA hub-county interorganizational collaborations (2024 internet search).

Number of hub-county research collaborations	0	1	2	3 or more	Total
Frequency	1 (1.6%)	7 (11.5%)	23 (37.7%)	29 (47.5%)	61 (100%)

In terms of characteristics of projects and PIs (data not shown), 67% ($n = 12$) were based at UCLA and 17% ($n = 3$) were based at The Lundquist Research Institute. Regarding academic rank, 50% of the PIs were senior, 28% assistant, and 22% associate-level investigators. Not surprisingly, more than 50% of the PIs reported their T0-T4 research areas as T3 (delivery system) and T4 (patient and population health).

Among the 18 hub-county collaborations, 3 PIs and projects were selected for more intensive longitudinal interviews to document the impact stories. These 3 impact stories were selected based on the highest number of demonstrated impacts reported by the PIs within the TSBM's four domains and 30 indicators within the domains.

The first collaborative project was conducted by Dr. Naser Ahmadi, a physician with specialties in psychiatry and biobehavioral sciences. He reported the highest demonstrated impact in the TSBM Clinical and Medical domain. The collaboration was formed between the CTSI hub and Olive View Medical Center, a Los Angeles County safety net hospital serving a low socioeconomic population with high percentages of Medi-Cal insurance (California's State Medicaid Program). His research has led to new software technology and Artificial Intelligence (AI) which allows more universal screening for high-risk individuals in emergency room care. Dr. Ahmadi created a screening tool to identify risk factors, protective factors, and outcome measures of adolescent suicide. A new app using AI physiology markers (audiovisual measures) was created to identify high-risk individuals, possible treatment plans, and prediction of how they would respond to each treatment plan. The impact on health and healthcare is a rapid intervention (within 2 days), that can be implemented in any community emergency room, to quickly identify and prevent suicide in high-risk adolescents.

The second collaborative project was conducted by Dr. Elizabeth Barnert, a pediatrician who has emerged as a national expert in identifying the needs and pathways for reentry of incarcerated youth. She reported the highest demonstrated impact in the TSBM Legislative and Policy domain. Based at the CTSI hub, Dr. Barnert formed collaborations with LA County Departments of Mental Health, Health Services, Probation, and the Sheriff's Department. Her legislative interest is to improve the healthcare delivery system by increasing access and continuity of care and successful reentry. This was achieved by creating partnerships between community providers and the juvenile legal system so that youth in conflict with the law and/or survivors of child sex trafficking can have better medical and mental health services. In the longer-term Dr. Barnert's research emphasizes the creation of developmental pathways associated with better physical and mental health as they grow into adulthood.

The third collaborative project was spearheaded by Dr. Catherine Sarkisian, a geriatrician and NIH-funded research scientist. Dr. Sarkisian's "K24 Midcareer Investigator Award in Patient-Oriented

TABLE 2 CTSI hub-Los Angeles County (LAC) interorganizational collaborations (*n* = 18 projects with 21 interorganizational collaborations).

Grants/projects (*n* = 18)	Safety net hospitals[1]	LAUSD[2]	LAC DHS[3]	LAC DPH[4]	LAC DMH[5]	Other[6]	Total
Dementia diagnoses in a safety-net population			1				1
Mitigating toxic stress response in patients with ACE-related health conditions (obesity management in a community clinic setting)			1				1
A mixed methods evaluation of assisted outpatient treatment in LAC					1		1
Midcareer award in patient-oriented community-academic partnered aging research (K24)						1	1
The impact of youth incarceration on health in adulthood						2	2
Healthy tomorrow's partnership for children program						1	1
Impact of covid-19 testing and mitigation on return-to-school in the second largest US school district		1		1			2
Leveraging school environments to shape social networks and improve adolescent health: a randomized trial of a social network intervention		1					1
LCIRN: life course intervention research network, scholar's pilot program (qualitative interviews)		1					1
RAD-X underserved populations safe return to school diagnostic testing		1					1
Cedars Sinai Bairey-Merz lab collaborating with the LAC Department of Public Health	1						1
Effectiveness and implementation of the care ecosystem during COVID-19	1		1				2
Trauma focused traumatic stress evaluation/management for adolescents with posttraumatic stress	1						1
UCLA undiagnosed diseases network clinical site	1						1
Overcoming sleep apnea with mild vibration	1						1
UCLA clinical site undiagnosed disease network: admin supplement 1	1						1
UCLA clinical site undiagnosed disease network: admin supplement 2	1						1
UCLA-UCI center for eliminating cardio-metabolic disparities in multi-ethnic populations	1						1
Total collaboration types (*n* = 21)	8	4	3	1	1	4	21

[1]LA County Safety Net Hospitals (i.e., Olive View-UCLA Medical Center). [2]LAUSD, LA Unified School District. [3]LAC DHS, Los Angeles County Department of Health Services. [4]LAC DPH, Los Angeles County Department of Public Health. [5]LAC DMH, Los Angeles County Department of Mental Health. [6]Other (i.e., Parks and Recreation, LA City Department of Aging, Department of Probation, Sheriff's Department).

Aging Research," evolved into the UCLA Healthcare Value Analytics and Solutions (UVAS), a new consultation service and a portfolio of novel research projects. Dr. Sarkisian reported the highest impact in the TSBM Economic indicators by implementing effective interventions to reduce costs and improve health care practice. As illustrated, Figure 4 shows demonstrated economic benefit of this research on three TSBM indicators: (i) cost effectiveness, (ii) cost savings, and (iii) society and financial cost of illness. UVAS illuminates the substantial economic benefits of various quality improvement initiatives. Utilizing plan-do-study-act cycles, a quality improvement nurse reviewed medical records and educated staff with data on overuse of preoperative medical visits, chest x-rays, laboratory tests, and electrocardiograms. The intervention was found to have projected savings of $67,000 over 3 years for LAC-DHS facilities.

4 Discussion

The study reports baseline TSBM knowledge transfer data for the initial 2 years of our TSBM data collection (LSAS-I: 2021–2022) at the UCLA hub. In addition to looking at overall TSBM impact, we took a deeper dive into hub-county interorganizational collaborations to learn more about their effects on health care delivery systems and patient and population health improvement. This study examines TSBM impact in hub-county collaborations; no other studies were found in the peer-reviewed literature that looked at impact in a systematic way.

The TSBM baseline data were collected early in the incubation period. Of the 507 new grants, 77% of investigators reported TSBM impact. Nevertheless, TSBM knowledge translation impact is still a relatively new and unknown concept at our hub. Greater effort will be required to hardwire and widely implement TSBM into research training and career development to accelerate translational science innovations and successful knowledge transfer, ultimately leading to improvements in health and healthcare. Additionally, some hubs, e.g., Washington University St. Louis CTSA, are using TSBM as a foundation for dissemination and implementation (D&I) planning and execution (11). We expect this trend to increase in the CTSA Program as TSBM continues to be tested as a foundation for these efforts.

Across the national CTSA program, almost 50% of hubs were found to report three or more interorganizational collaborations with county health agencies. Prior to this research we had no systematic knowledge about the national landscape for hub-county collaborations or the impact of these collaborations. Further we did not understand how our hub ranked in this national context. The data from the 61 hub website searches clearly underestimates the number of interorganizational collaborations. In fact, in the 2021–2022 reporting period, our hub had 18 hub-county collaborations and most of these were ongoing. These collaborations are not reported on our website but rather captured in our LSAS-I annual surveys. Additionally, Figure 1 shows the substantial opportunities for hub-county health innovation and intervention projects and the potential for multisite clinical and translational science research collaborations with Los Angeles County.

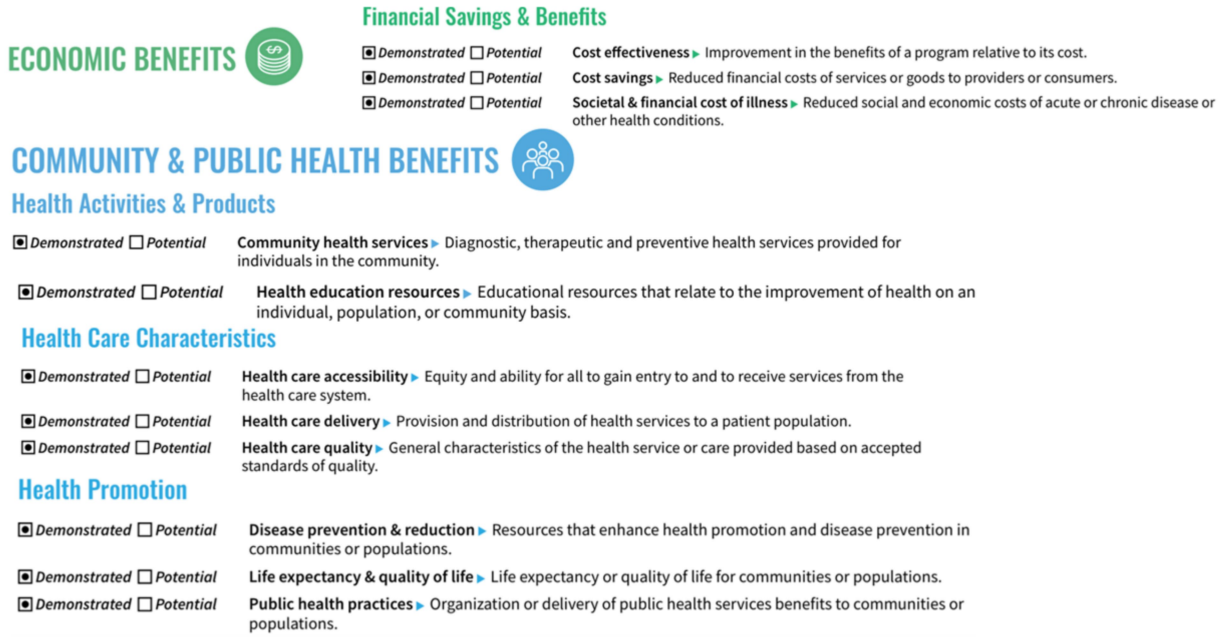
We also note that 50% of the PIs of the UCLA hub collaborations were senior investigators, and the majority of PIs (> 50%) indicated their translational research was conducted in the T3-T4 translation space (clinical implementation and public health). The increasing number and type of interorganizational collaborations suggest an emerging trend for hubs across the nation to more seriously pursue research and development (R&D) to improve county delivery systems and patient and population health, particularly among uninsured or underinsured patients who utilize the county safety net system.

4.1 Generalizability of study methods and findings

Generalizability is concerned with the wider applicability of the findings across geographic locations, settings, populations, disease conditions, public health and health promotion interventions. Measuring impact is increasingly critical for any research enterprise—large, small, or even a smaller portfolio of sponsored research projects. Impact measures are a pivotal tool to demonstrate that continued investment is worthwhile and serves as a constructive indicator of ROI.

The results of our study are generalizable in at least two ways: (i) hub portfolio analysis to examine Scientific Achievement Translational Science Impact (SATSI), and (ii) hub-county interorganizational collaborations to improve health and healthcare. This study is innovative in that it applies a standardized methodology, TSBM checklist as a data collection mechanism in our annual LSAS-I survey, to produce comparable data across research settings and projects, a key aspect of generalizability. In terms of best practices in translational science impact measurement, the TSBM alone does not fully capture all essential dimensions. It is equally important to consider the research organization in terms of structures, operations, and innovations whether large-scale, small-scale, or a portfolio of sponsored research projects—that influence outcomes and impact. Hence, our evaluation designs must also measure structural and process innovations and opportunities for continuous quality improvement.

Additionally, we need to test research training activities to increase awareness of the growing importance of impact and measurement using the TSBM model that can also be used as a foundation for building dissemination and implementation (D&I) strategies (11–14). Finally, our study provides a valuable framework for assessing interorganizational collaborations within the national CTSA program. The methods of this study and findings are applicable to the 60 + hubs and across other research infrastructures.



ECONOMIC BENEFITS

Financial Savings & Benefits

☑ Demonstrated ☐ Potential **Cost effectiveness** ▸ Improvement in the benefits of a program relative to its cost.

☑ Demonstrated ☐ Potential **Cost savings** ▸ Reduced financial costs of services or goods to providers or consumers.

☑ Demonstrated ☐ Potential **Societal & financial cost of illness** ▸ Reduced social and economic costs of acute or chronic disease or other health conditions.

COMMUNITY & PUBLIC HEALTH BENEFITS

Health Activities & Products

☑ Demonstrated ☐ Potential **Community health services** ▸ Diagnostic, therapeutic and preventive health services provided for individuals in the community.

☑ Demonstrated ☐ Potential **Health education resources** ▸ Educational resources that relate to the improvement of health on an individual, population, or community basis.

Health Care Characteristics

☑ Demonstrated ☐ Potential **Health care accessibility** ▸ Equity and ability for all to gain entry to and to receive services from the health care system.

☑ Demonstrated ☐ Potential **Health care delivery** ▸ Provision and distribution of health services to a patient population.

☑ Demonstrated ☐ Potential **Health care quality** ▸ General characteristics of the health service or care provided based on accepted standards of quality.

Health Promotion

☑ Demonstrated ☐ Potential **Disease prevention & reduction** ▸ Resources that enhance health promotion and disease prevention in communities or populations.

☑ Demonstrated ☐ Potential **Life expectancy & quality of life** ▸ Life expectancy or quality of life for communities or populations.

☑ Demonstrated ☐ Potential **Public health practices** ▸ Organization or delivery of public health services benefits to communities or populations.

FIGURE 4
TSBM economic and community and public health impact.

Beyond the UCLA hub, our findings have broader implications for improving national reporting. NCATS leadership may consider embedding the 30 TSBM indicators into the hub annual reports (RPPR) to systematically track knowledge translation impact. These data reports could be aggregated to: (i) assess strengths and gaps in translational science outcomes nationwide, and (ii) build a database of contextual variables to examine factors influencing knowledge translation impact, such as the number and type of interorganizational collaborations (e.g., multi-CTSA partnerships, hub-county health initiatives, and hub partner institutions).

4.2 Future studies opportunities and challenges

Moreover, our findings suggest limited TSBM activity within the economic, and policy and legislative domains. Future research and development might focus on these gaps and test interventions and approaches to increase the impact of translational science in these domains. Addressing these gaps would not only strengthen the CTSA Program but also advance real-world impact of research by improving how scientific discoveries are translated into medical practice, the delivery system, community-based interventions, and public health policies.

While we relied on an internet search to quantify county collaborations, future research could be strengthened by conducting a systematic survey to gather direct responses from each CTSA hub. For example, in addition to constructing contextual variables, targeted items could be added to an existing CTSA Program Evaluators Survey to enhance our understanding of the national context of the CTSA Program, such as the role of interorganizational collaborations in influencing patient access, research outcomes, and broader systemic impact.

Finally, although hub portfolio analysis offers promising methodology, our findings do not represent the complete demonstrated impact of the hub. Results show SATSI reported over only 2-years (2021–2022). Currently, we collect TSBM data from investigators early in the incubation period. Thus, baseline data reported here underestimates the true knowledge translation impact of our hub.

Data availability statement

The raw data supporting the conclusions of this article will be made available by the authors, without undue reservation.

Author contributions

PD: Conceptualization, Formal analysis, Funding acquisition, Investigation, Methodology, Project administration, Supervision, Validation, Writing – original draft, Writing – review & editing. TN: Formal analysis, Methodology, Validation, Writing – review & editing. AM: Data curation, Formal analysis, Investigation, Methodology, Validation, Writing – original draft, Writing – review & editing, Visualization. JM: Data curation, Formal analysis, Validation, Writing – review & editing. OQ: Conceptualization, Data curation, Formal analysis, Investigation, Methodology, Validation, Writing – original draft, Writing – review & editing, Visualization.

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Conflict of interest

The authors declare that the research was conducted in the absence of any commercial or financial relationships that could be construed as a potential conflict of interest.

Generative AI statement

The author(s) declare that no Gen AI was used in the creation of this manuscript.

Publisher's note

Supplementary material

The Supplementary material for this article can be found online at: https://www.frontiersin.org/articles/10.3389/fpubh.2025.1565096/full#supplementary-material

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EDITED BY
Douglas Luke,
Washington University in St. Louis,
United States

REVIEWED BY
Nasser Sharareh,
The University of Utah, United States
Todd Combs,
Washington University in St. Louis,
United States
Jessica Sperling,
Duke University, United States

*CORRESPONDENCE
Lixin Zhang
✉ lxz849@case.edu
Clara M. Pelfrey
✉ clara.pelfrey@case.edu

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Demonstrating public health impacts of translational science at the clinical and translational science collaborative (CTSC) of northern Ohio: a mixed-methods approach using the translational science benefits model

Lixin Zhang[1]*, Umut A. Gurkan[2], Kelli Qua[3], Shannon Swiatkowski[1], Sheree Hemphill[1] and Clara M. Pelfrey[1]*

[1]Clinical and Translational Science Collaborative of Northern Ohio, Case Western Reserve University School of Medicine, Cleveland, OH, United States, [2]Department of Mechanical and Aerospace Engineering, Case School of Engineering, Case Western Reserve University, Cleveland, OH, United States, [3]Center for Medical Education, Case Western Reserve University School of Medicine, Cleveland, OH, United States

The Clinical and Translational Science Award (CTSA) program, funded by the National Center for Advancing Translational Sciences (NCATS), aims to accelerate the translation of research into public health impacts. However, measuring the societal impact of translational research poses challenges due to extended timelines for implementation. This study uses the Translational Science Benefits Model (TSBM) to evaluate the societal impact of CTSA-supported research at the Clinical and Translational Science Collaborative (CTSC) of Northern Ohio at Case Western Reserve University (CWRU). Using the TSBM, we asked how investigators have used the CTSC to demonstrate translational science impacts in public health practice both domestically and internationally. Using a mixed methods approach, this study analyzed TSBM-based survey data from CTSC-supported KL2 Scholars and Pilot Program awardees, along with key publications and interviews, to document societal benefits across four TSBM domains: Clinical & Medical, Community & Public Health, Economic, and Policy & Legislative. Findings demonstrate that CTSC-supported research improved public health by enhancing healthcare access, improving health outcomes, informing policy, and generating economic benefits. These impacts span local, national, and global contexts. By applying a mixed methods approach, we demonstrate the value of using the TSBM not just as an evaluative framework, but as a strategic tool for capturing the real-world significance of translational science. This approach strengthens the ability of CTSA hubs to highlight the broader public value of their work, reinforcing the CTSA program's mission to transform scientific discoveries into lasting health and societal benefits.

KEYWORDS

translational science, translational science benefits model (TSBM), public health, policy, impact evaluation, translational science case studies, mixed method research

1 Introduction

The Clinical and Translational Science Award (CTSA) program, funded by the National Center for Advancing Translational Sciences (NCATS), aims to accelerate turning scientific discoveries into actionable solutions that improve human health. The CTSA is committed to improving health outcomes, increasing access to quality healthcare, and fostering advancements that benefit all populations. However, effectively demonstrating these societal impacts remains challenging. Translational research often requires long-term implementation and validation to produce measurable health benefits, making it difficult to immediately quantify the public health gains from CTSA-supported research. This difficulty is particularly significant in assessing health impact, where translating findings into improved health outcomes require sustained efforts that are difficult to measure over short periods.

To address the need for more robust evaluation of translational science's real-world impacts, the Translational Science Benefits Model (TSBM) was developed as a structured framework to document the societal benefits derived from translational research efforts. TSBM identifies and categorizes translational impacts across four domains: Clinical & Medical, Community & Public Health, Economic, and Policy & Legislative (1). The TSBM enables researchers to capture specific, tangible examples of societal benefits, enhancing transparency and accountability in reporting the impacts of research. This approach is valuable for evaluating CTSA programs, where documenting health improvements across these domains can yield comprehensive insights. Despite its potential, empirical evidence on the TSBM's applicability within real-world CTSA environments remains limited, especially regarding its effectiveness in public health impacts.

The CTSC of Northern Ohio plays a vital role in advancing translational research that addresses health challenges that affect people of all backgrounds. Through its KL2 Scholars and Pilot Grant programs, the CTSC supports early-career researchers and innovative projects aimed at improving health and healthcare access. The KL2 program provides tailored training and mentorship, while the Pilot Program funds high-impact studies targeting critical health issues in all communities. Together, these programs foster collaboration and drive health outcomes through translational science.

However, capturing the real-world impact of such research requires more than simply categorizing outputs. Traditional methods, such as surveys or administrative metrics, often lack the nuance needed to fully explain how research leads to meaningful societal change. Surveys alone can produce limited or outdated insights and often miss the context-specific pathways through which translational work achieves impact. Moreover, quantitative data may obscure critical mechanisms—such as stakeholder engagement or community partnerships—that are essential to translational success but difficult to measure with standardized tools.

To overcome these limitations, this paper first leverages the TSBM to assess the societal impact of translational research supported by the CTSC. We focused on projects led by CTSC-supported KL2 Scholars and Pilot Program awardees, investigating how these initiatives have advanced public health outcomes both locally and globally. We employed a mixed-methods approach, supplementing TSBM with semi-structured interviews to capture deeper insights into how these projects addressed public health challenges. This approach allows us to demonstrate the TSBM's utility while highlighting the public health impacts of research supported by the CTSC.

2 Materials and methods

This study utilized a mixed-methods approach to evaluate the translational benefits of research supported by the CTSC. Figure 1 presents a flowchart outlining the process of the TSBM survey and semi-structured interviews with selected KL2 Scholars and Pilot Program awardees. By integrating survey data with interview results, the study provides a multidimensional evaluation of how CTSC-supported research drives advancements in public health.

2.1 Study participants

Participants were selected through a multi-step process designed to identify researchers whose work embodies the translational goals of the CTSC. This process, detailed below, ensured the broad participation of researchers with demonstrable contributions to advancing public health.

The first phase involved administering surveys to two groups: former KL2 Scholars ($n = 72$) and Pilot Program awardees ($n = 469$) from 2008 to 2022. These groups were selected for their varied research projects and potential for translational impact. By including these distinct groups, the analysis captured a broad spectrum of research areas, reflecting the CTSC's commitment to bridging scientific discovery and societal benefit.

To complement the survey data, a purposive sampling strategy was employed to identify survey responses that showed significant contributions to public health advancements. The selection process adhered to stringent criteria, ensuring the reliability, relevance, and impact of the chosen examples:

- **Substantive Detail and Documentation**: Respondents who selected "Demonstrated" for a TSBM indicator were required to provide supporting evidence (e.g., publications, URLs, or CVs). Only responses with sufficient detail and credible documentation were included. Two research team members independently verified outcomes to ensure reliability.
- **Varied Beneficiaries**: Selected examples highlighted benefits for populations experiencing health challenges unique to their situation (e.g., pregnant women, intimate partner violence survivors, Medicaid recipients), international populations (e.g., those in low resource countries with genetic disorders or parasitic infections), rural populations, and professions at high-risk of developing cancer.
- **Contextual Breadth**: Selected research represented societal benefits achieved at local, national, and international levels, ensuring a comprehensive view of translational impact.
- **Scalability**: Projects demonstrated the potential for replication and implementation across numerous healthcare settings, considering economic and logistical feasibility.
- **Multidisciplinary Engagement**: The research demonstrated collaboration among healthcare providers, local organizations, policymakers, and academic researchers, highlighting the importance of interdisciplinary approaches.

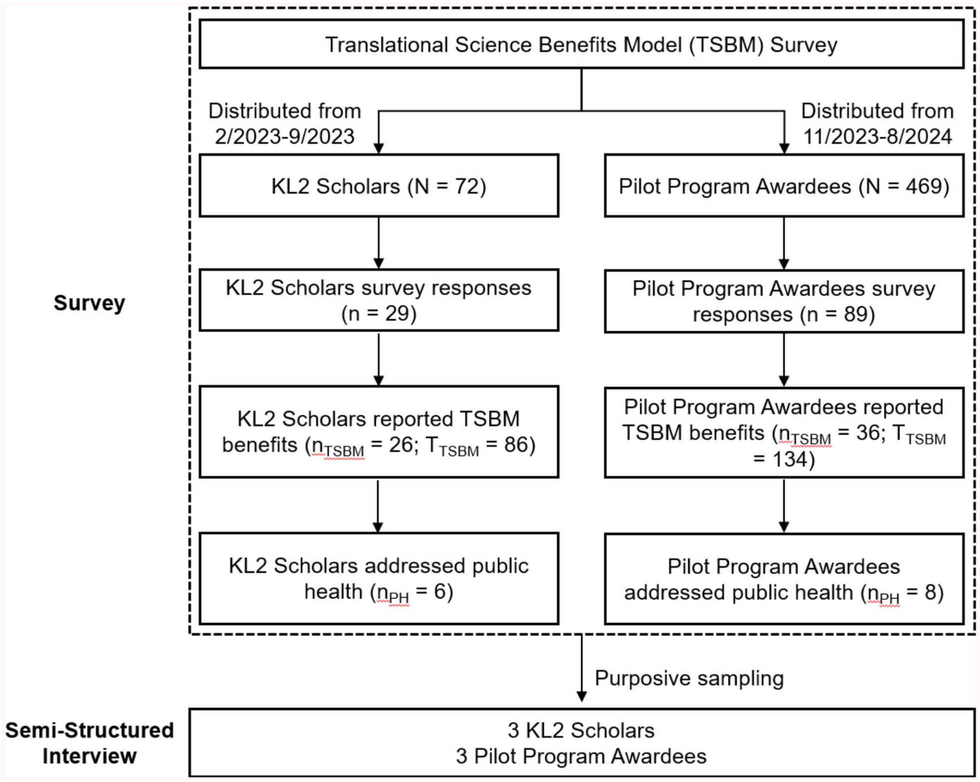

FIGURE 1
Flowchart of translational science benefits model (TSBM) survey and semi-structured interviews. N: Total number of participants invited to complete the survey. n: Total number of survey respondents. $n_{TSBM:}$ Number of survey respondents who reported at least one TSBM benefit. T_{TSBM}: Total number of TSBM benefits reported by the group. $n_{PH:}$ Number of survey respondents addressing public health.

This approach identified six high-impact researchers based locally in Cleveland whose work exemplified translational success in addressing critical health challenges. These researchers were invited to participate in semi-structured interviews to explore the pathways through which their research advanced public health outcomes.

2.2 Survey instrument

The survey instrument for this study was developed using the TSBM, a framework for evaluating the societal benefits of translational research (1). This model systematically captures many different outcomes, including policy influence, public health advancements, and other health outcomes. It served as the foundation for constructing a robust quantitative dataset to evaluate the impact of CTSC-supported research.

The survey was designed using the REDCap Electronic Data Capture platform (2) and incorporated the TSBM indicators (1). In the survey after each indicator, respondents were asked whether the indicated benefit was "Demonstrated" or "Potential." If "Demonstrated" was selected, branching logic opened a text box where respondents were required to "Briefly describe demonstrated [benefits] using lay language. Please provide evidence or URL link, if available (e.g., published materials)." Examples of documented evidence may include, but are not limited to, published policy documents, press releases, newspaper articles, white papers, collaborating or corroborating research studies that have been published, regulatory approval, governmental bills and laws, formal records documenting grants or milestones, or review articles (e.g., meta-analyses and scientific reviews). The survey was administered to two distinct groups: KL2 Scholar trainees and Pilot Program awardees. For the KL2 Scholar trainees, the survey was conducted between February and September 2023, while the survey for Pilot Program awardees took place between November 2023 and August 2024. The extended administration period for the Pilot Program was necessary due to the nature of the program, with several investigators having received up to five different pilot grants between 2008 to 2022. To avoid survey fatigue, surveys were distributed in non-overlapping periods, preventing any single investigator from receiving multiple surveys at the same time. Both survey instruments can be found in Appendix A.

2.3 Semi-structured interview protocol

To complement the quantitative analysis, semi-structured interviews were conducted with researchers whose work demonstrated measurable contributions to public health. All participants were consented under CWRU IRB STUDY20241228 to use their names, survey responses and interview material in constructing case examples. The interviews aimed to uncover the processes and mechanisms through which their research influenced societal outcomes, with a focus on public health impacts and the CTSC's role in supporting these impacts. This qualitative approach emphasized actionable insights and a deeper understanding of researchers' experiences. The interview protocol is provided in Appendix B. Additionally, research databases such as Overton (3) and Dimensions (4) were used to supplement the qualitative data by tracking the influence of CTSC-supported research on policy and legislation, highlighting the broader implications of translational efforts for public health. Overton Index is the world's largest policy and gray literature database (3). Dimensions. AI, part of Digital Science, is a comprehensive database and platform focused on research and innovation. Dimensions was used to link research data, including publications, patents, media coverage and policy documents (4).

3 Results

3.1 Survey results

Survey responses were collected, analyzed, and categorized into the four major TSBM domains: Clinical & Medical, Community & Public Health, Economic, and Policy & Legislative. KL2 Scholars had a response rate of 29 out of 72 (40%). Among the respondents, 26 out of 29 (90%) reported a total of 86 demonstrated benefits across the four TSBM domains. Pilot Program Awardees had a response rate of 89 out of 469 (18%). Of the 89 respondents, 36 (40%) reported a total of 134 demonstrated benefits across the four TSBM domains.

Figure 2 highlights the translational outcomes achieved by CTSC-supported KL2 Scholars and Pilot Program Awardees, with demonstrated benefits across clinical, public health, economic, and policy domains.

- **Clinical & Medical Contributions**: CTSC-supported research has led to 64 demonstrated benefits in diagnostic, therapeutic, and investigative procedures, directly enhancing clinical practices and patient care. Additionally, researchers developed 10 biological products, 13 biomedical technologies, and 10 software tools.
- **Community & Public Health**: These researchers have made meaningful strides in public health, with 8 contributions to local health services, 7 health education resources, and 15 improvements in healthcare access, delivery, and quality. Research efforts addressing disease prevention, quality of life and public health practices resulted in 11 reported benefits.
- **Economic Benefits**: Economic outcomes from CTSC-supported research include 12 patents, 11 license agreements, and the establishment of 3 commercial or non-profit entities.

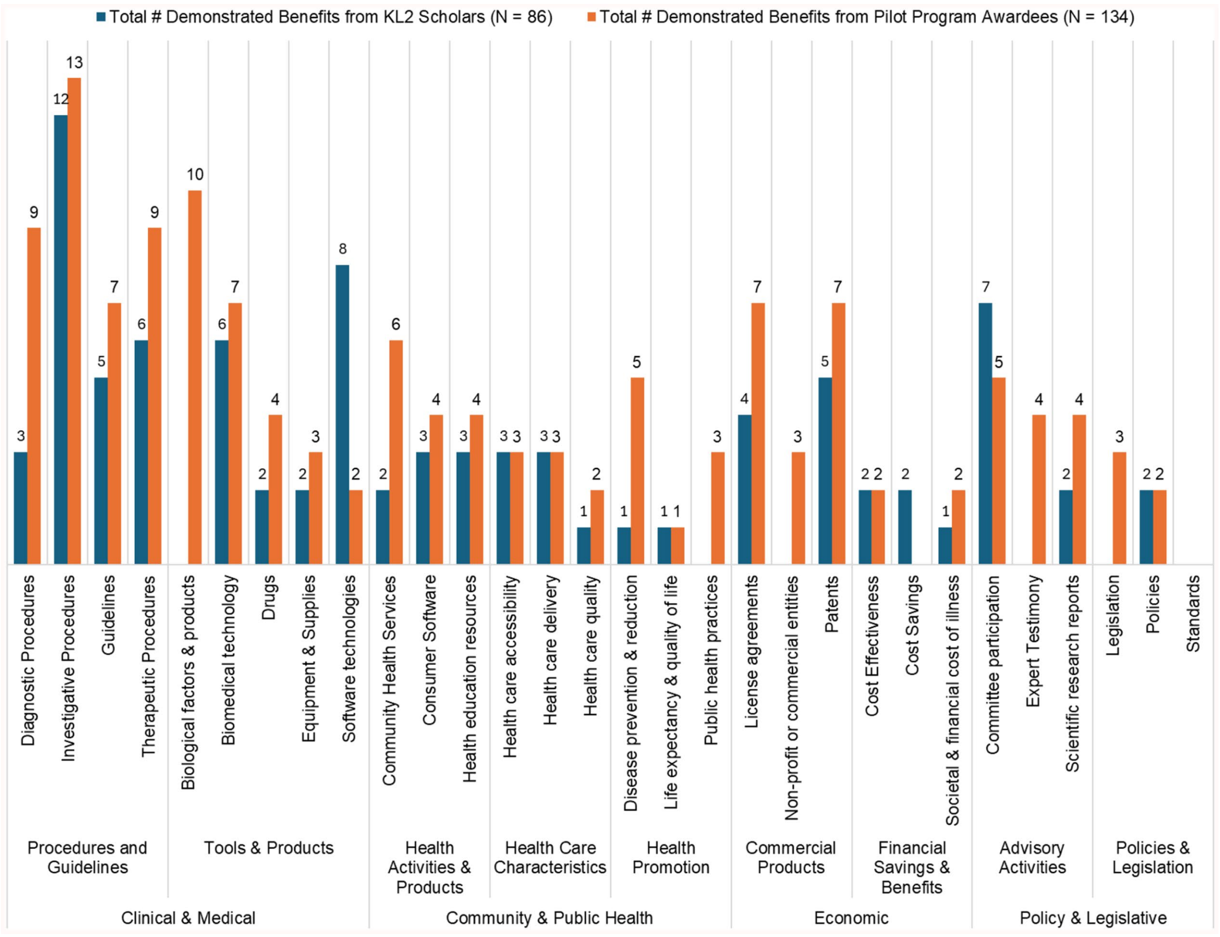

FIGURE 2
Demonstrated TSBM benefits from CTSC-supported 26 KL2 scholars and 36 pilot program awardees.

Additionally, contributions to cost savings and cost-effectiveness highlight the financial value of translational research.

- **Policy and Legislative Influence**: CTSC researchers reported policy contributions, with 22 advisory activities, including committee participation and expert testimony, and 7 outcomes influencing policy and legislation.

3.2 TSBM case study results

The six cases highlighted below were constructed from both survey data and interviews and demonstrate the potential of translational science to address obstacles to health and improve public health outcomes. These researchers, supported by the CTSC, underscore the critical role of dedicated resources, interdisciplinary approaches, and community-centered solutions in achieving meaningful impact. The findings offer valuable insights into the mechanisms of success, the challenges faced, and the future directions needed to expand the reach and efficacy of translational science initiatives.

3.2.1 Case study 1. *The essence of primary care*, Shari Bolen, MD, MPH

3.2.1.1 Utilization of the CTSC

Bolen's research has been significantly influenced by her extensive engagement with CTSC resources. As a KL2 scholar, Bolen benefited from protected time to deepen her expertise in mixed-methods research, essential for the nuanced exploration of healthcare interventions. The CTSC's support facilitated her participation in meetings, which, as she described, "*brought all of the scholars together and supported a transdisciplinary model.*" These collaborative experiences laid a solid foundation for her work on complex healthcare challenges.

After completing the KL2 program, Bolen continued to leverage CTSC resources, such as the REDCap data management tool, to allow efficient management of large datasets. The CTSC informatics module played a critical role in helping Bolen design and implement innovative health information dashboards. These tools have been pivotal to her work, especially in monitoring and improving health outcomes across affected communities.

3.2.1.2 Societal benefits in TSBM categories

Bolen's research demonstrates substantial societal benefits across multiple TSBM domains:

Clinical & Medical Benefits: The innovative use of the positive deviance approach in primary care has revolutionized hypertension management, addressing one of the most prevalent and challenging chronic conditions (5, 6). This approach identifies high-performing clinics or communities—outliers that have achieved exceptional success in blood pressure control—analyzes their strategies and adapts these best practices to drive improvements across other primary care settings.

Community & Public Health Benefits: Bolen's development of comprehensive health education resources supports ongoing education of healthcare providers and local health workers (personal communication, November 2024). Bolen's initiative has been disseminated widely, enhancing the overall quality of healthcare delivery and facilitating widespread adoption of best practices in patient care.

Policy & Legislative Benefits: Bolen has influenced health policy and legislative outcomes at both state and national levels, championing universal reforms to expand healthcare access and improve outcomes for all populations. Through strategic advisory roles, innovative research, and collaboration with key stakeholders, she has addressed immediate policy challenges while laying the groundwork for long-term change in chronic disease management.

In her advisory roles, Bolen has provided strategic leadership on national committees that shape health policy. As a member of the National Clinical Care Commission (NCCC), she contributed to a landmark congressional report that identified critical gaps in federal diabetes policies and offered actionable solutions to improve care delivery for millions (7, 8). Her participation in the CDC National Hypertension Roundtable further underscores her role as a national leader, where she developed strategies to enhance hypertension prevention and treatment, directly addressing public health (personal communication, November 2024).

Bolen's ability to translate research into policy has been pivotal in driving widespread change. Her publications in Diabetes Care have informed federal diabetes policies (7, 8), while her Medicaid-focused research (9, 10) have led to significant reforms in healthcare delivery. These efforts positioned her as a trusted resource for bridging the gap between research and regulation.

Bolen's policy achievements are particularly notable in chronic disease management. She has driven Medicaid reforms that expanded coverage for research-informed interventions such as the Diabetes Prevention Program and Diabetes Self-Management Education, ensuring patients have access to preventive care. She also advanced efforts to increase access to diabetes technology, such as continuous glucose monitors, and improving care for countless patients. These accomplishments, supported by her research funded by the Ohio Department of Medicaid, demonstrate the tangible benefits of her policy leadership (personal communication, November 2024).

Beyond diabetes, Bolen's work in hypertension policy has shaped state and federal initiatives to incorporate best practices into routine primary care. Her strategies have been instrumental in advancing blood pressure control across all populations, further reinforcing her impact on chronic disease prevention and management (11).

Policy Citations: Table 1 provides a global overview of policy documents from 17 different countries that cite Bolen's research, highlighting the interplay between research, guidance, and practice in shaping healthcare policy. The findings reveal a significant concentration of healthcare policy contributions in publications (60%) and clinical guidance (27%), underscoring their importance in advancing global health practices and recommendations.

3.2.1.3 Populations affected, geographical impact and research expansion

Populations Affected: Bolen's research focuses on improving healthcare access and outcomes for Medicaid-covered individuals in Ohio, particularly those facing significant economic challenges and chronic conditions like diabetes and hypertension. Her work directly impacts healthcare outcomes by targeting roadblocks that prevent timely and effective care for all populations. By tailoring interventions for both rural and urban communities, Bolen ensures that all

TABLE 1 Policy citations of Bolen's research, by country*.

Source country	Policy document type					Grand total
	Clinical guidance	Legal documents	Publication	Scholarly article	Working paper	
Australia			4			4
Canada	1		1	1		3
Colombia			1			1
France	1					1
Germany	1					1
IGO			7		2	9
Ireland			1			1
Kosovo			1			1
Malaysia			2			2
Netherlands			1			1
Nigeria			1			1
Norway	1					1
Peru			2			2
Portugal				1		1
Spain			2	3		5
Sweden	1	1	2			4
Switzerland			1			1
UK	4		1			5
USA	7		9			16
Grand Total	16	1	36	5	2	60

*Retrieved from https://www.overton.io/ on December 1, 2024.

populations across Ohio benefit from improved healthcare access and chronic disease management support.

Geographic Focus and Impact: Bolen's research primarily targets northeastern Ohio and Cuyahoga County, regions with disproportionately high rates of hypertension and cardiovascular diseases. Collaborating with local health organizations and policymakers, she identifies communities with the greatest need and implements data-driven, community-based solutions. Programs such as Cardi-OH (12) bridge the gap between healthcare providers, Medicaid enrollees, and community resources. Additionally, programs such as Better Health Partnership deliver research-informed healthcare improvements, addressing system challenges and reaching thousands of individuals across Ohio, including urban and rural communities in Cleveland (13).

Focus on High-Risk Populations: Bolen's work particularly focuses on addressing the needs of high-risk populations who experience higher rates of chronic diseases like hypertension and diabetes and disproportionately worse health outcomes (14). By leveraging community engagement and data-driven approaches, Bolen ensures that healthcare strategies are relevant and responsive to the specific needs of these populations in both rural and urban areas. Her collaborations with the Northeast Ohio Medical University (NEOMED) to establish the Medicaid Technical Assistance and Policy Program funded Northeast Ohio Quality Improvement (QI) hub further amplify her impact by enhancing quality improvement efforts and community outreach (personal communication November 2024).

3.2.1.4 Advancements in public health

Bolen's research has significantly contributed to developing targeted interventions within primary care practices to improve health outcomes. A key highlight is the use of the positive deviance approach to improve blood pressure control among high-risk populations. This work focused on low-performing practices that served economically challenged populations. By implementing varying intensities of research-informed care strategies, the project significantly reduced variance in blood pressure control between different insured groups, such as Medicaid, Medicare, and commercial insurance (6). Recognized as a leading implementation study, this research garnered national attention (personal communication, November 2024).

3.2.1.5 Expanding the research impact

Bolen's research is evolving to meet the health needs of Ohio's population. Central to this vision is the ongoing development of community engagement and workforce training initiatives, which enhance the capability of primary care settings to manage a broader spectrum of health issues. A key component of this effort is the integration of social determinants of health into everyday clinical practice—a step that promises to make healthcare more available.

To support these objectives, Bolen's research team is actively seeking additional funding, particularly through Medicaid initiatives and grants from the Agency for Healthcare Research and Quality (AHRQ), to strengthen their infrastructure for community engagement and workforce development in behavioral health areas. These efforts aim to create a sustainable model that not only improves health outcomes but also prepares the healthcare system to respond to emerging health needs.

The next steps for Bolen's research involve a dual focus: continuing to address the existing gaps in health outcomes through targeted interventions and broadening their scope to incorporate more comprehensive approaches to public health challenges. Key priorities include fostering stronger partnerships and aligning with state health improvement plans to ensure interventions are well-supported and strategically focused on Ohio's most pressing health issues.

3.2.2 Case study 2. *Development of a patient hand cleaning system for older adults in healthcare settings to support self-management*, Shanina C. Knighton, PhD, RN, CIC

3.2.2.1 Utilization of the CTSC

Knighton leveraged CTSC resources to advance her research on patient hand hygiene solutions. As a KL2 Scholar, she utilized mentorship, funding, and infrastructure to dedicate 80% of her time to research focused on innovative tools addressing patient behavior and hygiene challenges in healthcare settings. The program provided her with invaluable mentorship from experts such as Drs. Mary Dolansky, Colin Drummond, and Curtis Donskey, enriching her understanding and approach to developing patient-centered interventions.

In 2020, Knighton secured a CTSC Annual Pilot grant alongside Colin Drummond to develop a "Patient Hand Cleaning and System." This grant enabled feasibility studies for optimizing original technologies, supporting incremental progress in design, testing, and refinement of components—including a specialized bracket for bedrails and careful materials selection. This foundational work led to the NIH-funded Clean Hands Accessible and Manageable for Patients (CHAMPs) R01 study in 2023. The CHAMPs study focuses on infection prevention through a smart dispenser designed to support hand hygiene and reduce hand contamination among older adults (15). CTSC resources also facilitated access to clinical sites like MetroHealth and the Cleveland VA, enabling Knighton to conduct a randomized controlled trial aimed at reducing hand contamination. The incremental support from the CTSC was pivotal in advancing her innovative work from initial feasibility studies to a federally funded clinical trial.

3.2.2.2 Societal benefits in TSBM categories

Knighton's research demonstrated broad societal benefits within the following TSBM categories:

Clinical and Medical Benefits: Knighton's work addressed gaps in patient hand hygiene practices, particularly among older adults, by focusing on identifying and mitigating challenges to infection prevention. Her clinical trials tested the effectiveness of her interventions in reducing pathogens such as MRSA, MSSA, and Enterococci on patient hands. Her contributions include the development of innovative biomedical technology, such as a patented smart dispenser that attaches to patient bedrails, providing verbal reminders to support hand hygiene, especially for patients with limited mobility (16). Additionally, she pioneered a tracking system to differentiate prompted versus unprompted hand-cleaning behaviors, offering critical insights for improving patient engagement strategies (17). Expanding her focus, Knighton and her collaborators published a paper calling for the development of wearable sensors for COVID-19 (18). This work is also cited in a wearable device patent for reducing exposure to pathogens (19). Her work is cited in international clinical guidelines for infection control (20), further underscoring her impact on global infection control practices.

Community and Public Health: During the COVID-19 pandemic, Knighton expanded her research focus to address hygiene poverty in lower-income, multigenerational households. She created and disseminated over 300,000 copies of 12 sets of COVID-19 infographics nationwide, promoting actionable infection prevention education (personal communication, December 2024). These infographics offered plain language practical strategies to reduce germ exposure and transmission, particularly in public settings and multigenerational households, where hygiene imbalances are more prevalent (Figure 3). Alongside her educational efforts, her interventions, such as the smart dispenser and other educational resources, effectively reduced pathogen contamination in both healthcare and community environments. These efforts not only mitigated infection risks but also equipped communities with tools to strengthen public health practices.

Policy and Legislative: Knighton contributed to the drafting of Ohio's House Bill 628 (21), calling for mandatory patient hand hygiene education in healthcare settings. The data presented in Table 2 highlights the distribution of policy document types across three countries: Germany, Ireland, and the United States.

3.2.2.3 Populations affected, geographical impact and research expansion

Populations Affected: Knighton's research primarily targeted older adults in acute and long-term care settings, a group at increased risk for infections due to widespread challenges and reduced access to hygiene resources. During the COVID-19 pandemic, her efforts expanded to address lower-income, multigenerational households who faced additional challenges such as hygiene poverty, economic pressures, limited access to infection prevention tools, and inadequate health education. Many participants reported challenges such as the inability to afford basic cleaning supplies or lack of time to maintain hygiene due to economic pressures (22). These populations included communities living in Cleveland's low-resource areas, such as Buckeye-Shaker, Woodland, and Kinsman, where worse health outcomes are often found.

Geographic Impact: The geographic impact of Knighton's work extends beyond Cleveland. Her educational materials and COVID-19 infographics, created in collaboration with SeeYourWords.com, were disseminated nationwide, reaching urban and rural populations, including those in Florida and Pennsylvania. Partnerships with national nurses' organizations extended her reach to rural communities with limited hygiene resources, addressing critical gaps in infection prevention education (personal communication, December 2024).

Research Expansion to Additional Populations: Knighton is broadening her focus to include individuals with mobility limitations, pediatric populations, and outpatient care settings. Her work includes refining smart dispenser technology and developing tailored educational materials to meet the specific needs of these groups. Knighton continues to prioritize rural and low-income communities by leveraging public health partnerships to scale her interventions, reflecting her commitment to sustainable, long-term improvements in infection prevention.

3.2.2.4 Advancements in public health

Knighton's research tackles the root causes of infection prevention by addressing how opportunity, motivation, and capability influence hygiene behaviors at the household level. As she stated,

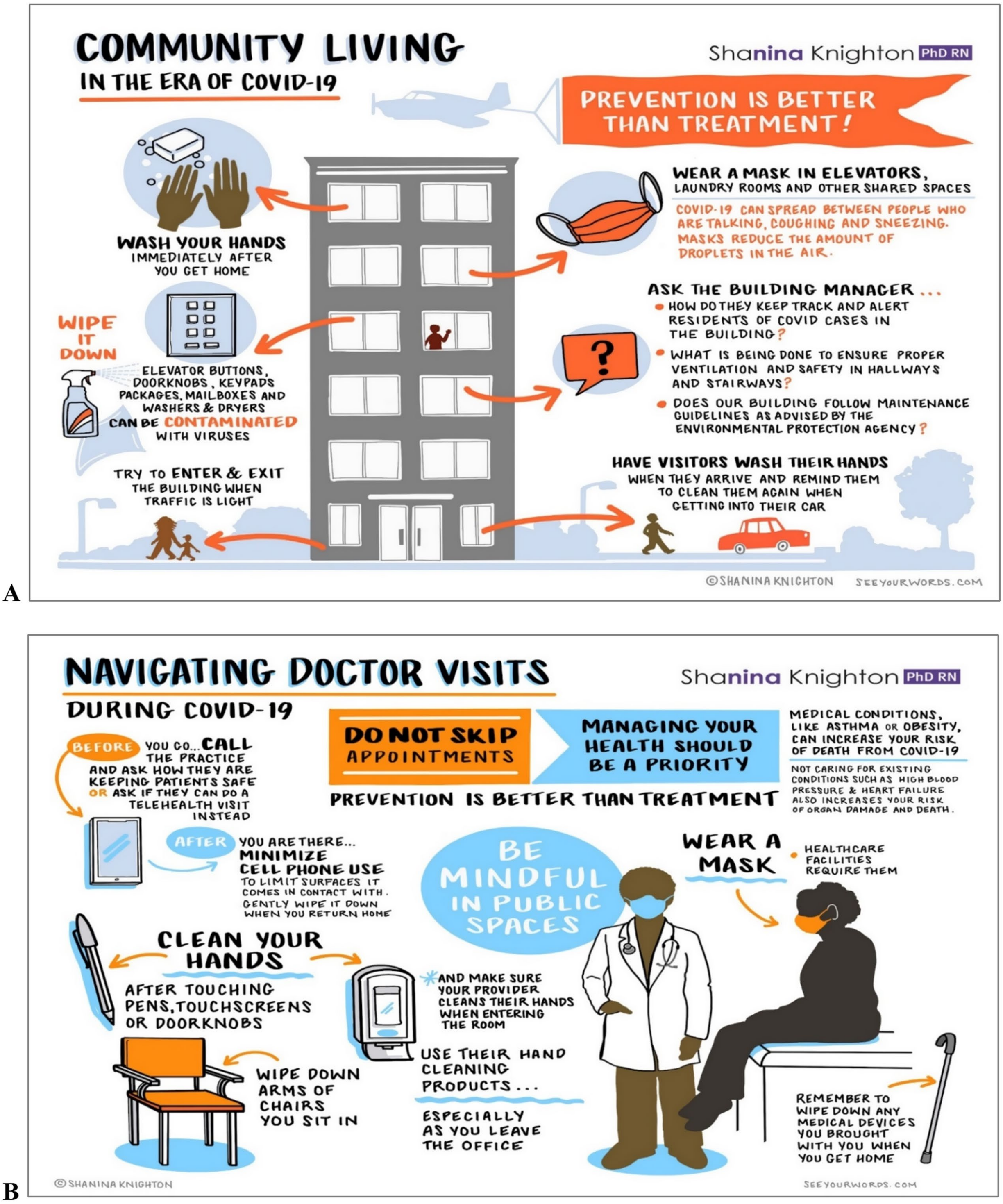

FIGURE 3
Community living in the era of COVID-19 **(A)** and navigating doctor visits in the era of COVID-19 **(B)**.

> *"Hygiene poverty significantly impacts [high-risk] populations, and my research integrates this understanding into both technology and education to drive [system-wide] change. By addressing these factors, I aim to empower families and communities to adopt sustainable infection prevention practices...."*

Her work has made substantial contributions in improving public health outcomes by overcoming obstacles to infection prevention. Knighton developed understandable educational materials that empower populations to adopt sustainable hygiene practices. These efforts have improved access to critical hygiene tools, enabling communities to engage effectively in infection prevention measures.

TABLE 2 Policy citations of Knighton's research, by country*.

Source country	Policy document type					Grand total
	Clinical guidance	Legal documents	Publication	Scholarly article	Working paper	
Germany	1					1
Ireland			1			1
USA			1			1
Grand Total	1		2			3

*Retrieved from https://www.overton.io/ on December 1, 2024.

A key element of Knighton's work is her smart dispenser technology, designed to address mobility challenges and support hand hygiene. This practical solution has been effective among older adults in clinical and home settings. Highlighting its focus on usability and behavior change, Knighton observed:

> "*Patients are able and willing to practice hand hygiene if they are reminded and if their hand hygiene products are conspicuously placed and easy to use. I learned from one of my studies that most patients perceive health care worker hand hygiene to be more important than their own, and that the hand hygiene products in the hospital are intended for health care workers, not for patients*" (23).

During the COVID-19 pandemic, Knighton's commitment to improved health outcomes became even more apparent. She tackled dual challenges of health literacy and misinformation, noting:

> "*In addition to the challenge of health literacy, people, during COVID-19, [we]re challenged with both misinformation and a lack of [available] visual information regarding practical infection prevention steps they can take to manage their care and quality of life.… I felt compelled to do something for communities. I wanted to walk with people in their day-to-day lives so that I could ease their stress levels by providing them with practical tools*" (23).

In response, Knighton led the creation and dissemination of carefully designed infographics targeting multigenerational households and low-resource communities. This large-scale educational effort provided actionable infection prevention strategies, bridging critical knowledge gaps and promoting behavior change.

Knighton's work extends beyond research and education to policy reform. Her support for universal solutions, such as Ohio House Bill 628 (21), underscores her commitment to ensuring everyone has access to hygiene education and resources. By translating research into actionable policy, she has worked to improve access to hygiene materials, further advancing public health outcomes.

By focusing on high-risk populations and tailoring her interventions to their unique needs, Knighton's work has led to measurable improvements in public health at both individual and community levels. Her approach—combining technology innovation, education, and policy promotion—serves as a model for how to improve health outcomes for all people.

3.2.2.5 Expanding the research impact

Knighton's next steps focus on scaling her smart dispenser technology across healthcare settings, community health centers, and lower-income households while developing community centered educational materials to address hygiene differences. She plans to collaborate with public health organizations to drive widespread changes targeting hygiene poverty and will expand her research to include individuals with mobility limitations, children, and rural populations. By addressing the root causes of hygiene imbalances and tailoring solutions to many different needs, Knighton aims to create sustainable improvements in infection prevention, improve health outcomes, and advance public health on a broader scale.

3.2.3 Case study 3. *Do antenatal maternal infections [affect] childhood vaccination?* Indu Malhotra, PhD

3.2.3.1 Utilization of the CTSC

Malhotra secured three pivotal pilot grants through the CTSC, each addressing critical aspects of maternal and child health in low-resource environments. The 2010 Core Utilization Pilot (CUP), titled "*Do antenatal maternal infections [affect] childhood vaccination?*," investigated how maternal infections during pregnancy influence infant immune responses to vaccines. This project used biostatistical and epidemiological tools to assess complex immunological interactions. The 2012 CUP focused on the "*Effect of maternal infections on B-cell responses to vaccines mediated by infant T-cell responses to malarial antigens*." This project employed Luminex technology to develop high-throughput diagnostics for antibodies against multiple antigens, providing a cost-effective approach to evaluating vaccine responses. In 2017, the focus shifted to the "Effect of antenatal maternal infections and anemia on childhood anemia," examining how maternal anemia and parasitic infections impact infant health through specimen-sparing diagnostic assays.

CTSC resources enabled the development and implementation of innovative diagnostic techniques, such as the bead assay, which required minimal blood samples. This advancement was crucial in reducing the ethical and logistical challenges associated with studying nutritionally deficient and high-risk groups. Moreover, the CTSC facilitated collaborations between Malhotra's team and Kenyan health authorities, leading to the establishment of diagnostic laboratories and training programs for local researchers and health workers. These collaborations were instrumental in enhancing healthcare infrastructure in the region, ensuring the sustainability of the project's impact (24, 25).

3.2.3.2 Societal benefits in TSBM categories

Malhotra's research yielded multifaceted societal benefits:

Clinical & Medical Benefits: The research introduced novel diagnostic and therapeutic interventions tailored to resource-limited settings. The team developed a multiplex flow immunoassay capable of detecting antibodies against parasitic infections such as lymphatic filariasis and schistosomiasis using minimal blood samples. This high-throughput assay significantly improved diagnostic accuracy while minimizing the invasiveness of testing procedures. Similarly, Luminex assays were developed to test for the presence of antibodies to malaria and childhood vaccines. Therapeutic protocols were equally innovative, incorporating prophylaxis for malaria, intestinal helminths, and other parasitic diseases. These interventions markedly improved maternal health, reducing risks of adverse pregnancy outcomes and creating a healthier start for newborns (25, 26).

Community & Public Health Benefits: The research also delivered significant public health benefits. Conducted in rural areas of Kwale District, the study addressed the needs of populations with limited access to healthcare. Community health workers were trained to educate mothers on the importance of antenatal care, proper sanitation, and regular vaccinations for their children. This grassroots outreach model effectively increased compliance with vaccination schedules, which now exceeds 90% among the study population, reducing the prevalence of malaria. Mothers who could not visit healthcare facilities were reached through home visits, ensuring comprehensive community participation (24, 27).

Policy & Legislative Benefits: The research produced actionable insights that informed national health policies in Kenya. Findings highlighted the economic and societal costs of untreated maternal parasitic infections, leading to the integration of preventive therapies into routine healthcare guidelines. Recommendations on optimal timing for antenatal treatments and the need for post-infancy booster vaccinations shaped vaccination strategies and helminth control programs. The research also emphasized the importance of maternal health as a determinant of child health outcomes, influencing public health policies at the local and national levels (24).

Policy Citations: Table 3 highlights the geographic distribution of policy citations referencing Malhotra's research. Her work is cited in five policy documents across multiple countries and organizations, reflecting its global impact on policy and clinical guidance. Notably, two citations appear in United States. clinical guidance documents, underscoring its practical relevance to clinical decision-making. The remaining three citations originate from the European Union, France, and intergovernmental organizations, further demonstrating the broad applicability of Malhotra's contributions.

TABLE 3 Policy citations of Malhotra's research, by country*.

Source country	Policy document type		Grand total
	Clinical guidance	Publication	
EU		1	1
France		1	1
IGO		1	1
USA	2		2
Grand Total	2	3	5

*Retrieved from https://www.overton.io/ on December 1, 2024.

3.2.3.3 Populations affected, geographical impact and research expansion

Populations and Geographic Focus: Malhotra's research targeted economically challenged populations in Kenya's Kwale District, specifically pregnant women and their infants, who face heightened risks from parasitic infections such as malaria and schistosomiasis. These infections often result in severe health challenges, including malnutrition and anemia, which disproportionately affect maternal and child health outcomes in low-resource settings. Kwale, a rural region along Kenya's south coast, exemplifies the intersection of poverty and endemic disease, with challenges like inadequate access to healthcare, potable water, and sanitation creating an environment where vector-borne and parasitic diseases thrive (24). By focusing on this region, the study aimed to develop locally relevant and scalable interventions to improve health outcomes for mothers and infants. The findings underscored the critical need to address underlying factors such as sanitation, healthcare access, and nutrition to mitigate the impacts of parasitic diseases, providing an integrated approach to improving maternal and child health in low-resource environments.

Focus on High-Risk Populations: The populations studied were socially and economically challenged. The communities faced extreme poverty, with household incomes often below $25 per month. Educational attainment was low, with high illiteracy rates among adults, particularly women. These conditions limited the ability of individuals to access and understand healthcare services. Moreover, the prevalence of parasitic infections in these populations was alarmingly high, affecting 60–70% of pregnant women, with many suffering from co-infections. Malnutrition, anemia, and stunted growth exacerbated their already precarious condition. The patriarchal social structure in these communities added another layer of complexity, as decisions regarding healthcare were often made by male heads of households, requiring additional efforts to engage and educate families. Combined with social stigmas surrounding conditions like HIV, these factors deterred many women from seeking antenatal care, highlighting the critical need for community-based interventions (personal communication, November 2024).

Research Expansion to Additional Populations: Building on its success in Kwale, the research model has been adapted to other endemic regions, including Kenya's South Coast (personal communication, November 2024). These expansions address similar challenges, such as parasitic infections, anemia, and malnutrition, with a growing focus on children's health. The team continues to work in partnership with local governments and international organizations to develop scalable, context-specific interventions aimed at promoting sustainable improvements in health outcomes across regions affected by parasitic diseases.

3.2.3.4 Advancements in public health

Improving access to care was the guiding principle of Malhotra's research, which introduced low-cost, efficient diagnostic innovations such as the specimen-sparing bead assay for susceptible communities. These innovations mitigated obstacles to disease detection and treatment, particularly among populations where invasive procedures were either clinically impractical or met with cultural resistance.

A major strength of this initiative was its emphasis on capacity building. Training programs for local health workers, laboratory scientists, and researchers enhanced the delivery of healthcare services while establishing a foundation for long-term public health improvements. By empowering communities with the skills to address future health challenges, the project reduced reliance on external support and fostered sustainability (28).

The research also emphasized a community-centered model that combined education and preventive care. Local health workers engaged mothers in promoting practices like malaria prophylaxis and vaccination. This approach not only reduced infection prevalence but also equipped healthcare providers with the skills to independently manage and monitor parasitic infections (personal communication, November 2024). The success of this model highlights the transformative impact of community engagement in achieving sustainable health outcomes.

3.2.3.5 Expanding the research impact

The research team is pursuing new directions to expand the impact of their work. Current efforts include studies on anemia and malnutrition among children, building on previous findings of stunting and growth deficiencies in the population. By examining the complex links between maternal health, infections, and childhood nutrition, and collaborating with local initiatives, the team integrates health improvement with environmental sustainability to address broader determinants of health. Proven interventions, such as maternal treatments and mass vaccination campaigns, are being scaled to other regions with similar needs. Through partnerships with local and international stakeholders, the team strives to translate research into actionable policies and programs that improve health outcomes.

3.2.4 Case study 4. *Traumatic brain injury among the survivors of intimate partner violence (IPV),* Gunnur Karakurt, LMFT, PhD

3.2.4.1 Utilization of the CTSC

Karakurt engaged with the CTSC through the KL2 Training Program, which played a pivotal role in supporting her career development. In addition to structured training, Karakurt leveraged a broad array of CTSC resources, including expert reviews to assess health outcomes in research instruments, editorial support to enhance the clarity of research documents, and guidance in the technological development of diagnostic tools. Furthermore, participation in CTSC-sponsored networking events facilitated valuable community support and fostered interdisciplinary collaborations.

3.2.4.2 Societal benefits in TSBM categories

Karakurt's research demonstrated societal benefits across several TSBM categories:

Clinical and Medical Benefits: Subtype Identification of IPV (29) and IPVDetect (30) are web-based applications that leverage clinical data and AI technology to improve the identification, understanding, and management of intimate partner violence (IPV), thereby supporting both individuals and professionals in addressing this critical social issue effectively.

The IPV Subtyping Tool is a questionnaire-based application that categorizes relationships into specific subtypes of IPV based on the responses provided. It utilizes statistical models developed from integrated datasets, which include clinical data and community observations from both healthy and unhealthy relationships. The tool identifies six subtypes of relationships, ranging from emotionally abusive to physically and sexually abusive scenarios. This categorization helps individuals in troubled relationships understand the severity and nature of their situation (31). For individuals, it delivers a scientific assessment of relationship health, helping them recognize the severity of their situation. Therapists benefit from precise subtype identification, enabling more targeted therapeutic approaches. The tool also connects users to appropriate resources, such as information about shelters or counseling, based on their results (personal communication, November, 2024).

Designed during the pandemic to address rising IPV cases, IPVDetect uses AI-driven text analysis to identify abusive patterns in user-generated content. It screens user-generated content (e.g., personal anecdotes) for indicators of IPV. By analyzing the language used, the tool highlights phrases and sentences that suggest different forms of abuse—physical, emotional, or sexual (32). It provides individuals with immediate feedback on abusive dynamics, fostering self-awareness. For clinicians, it offers a rapid assessment mechanism to determine the type of abuse and severity, enabling more focused and informed clinical interventions. Additionally, it has potential applications in legal and educational contexts, enhancing understanding of IPV nuances in courtrooms and training environments.

Community and Public Health Benefits: The research enhanced community health services by developing diagnostic tools for IPV survivors. Notably, potential collaborations with healthcare systems such as Epic EHR may integrate these tools into broader health IT infrastructures, facilitating risk assessments and information delivery for IPV survivors.

Policy and Legislative Benefits: Karakurt's research has had tangible impacts on policy, notably in the Philippines where it influenced the legal treatment of emotional abuse (33). Furthermore, the research was presented in a United States. Congressional hearing, highlighting its relevance and applicability in shaping public policy and legal frameworks (34, 35).

Policy Citations: Table 4 highlights the global influence of Karakurt's research, cited in 28 policy documents across 9 countries and IGOs, demonstrating its critical role in research-informed policymaking. The distribution of citations across countries and document types underscores the relevance of Karakurt's research. Its integration into clinical guidance, legal frameworks, academic publications, and working papers highlights its interdisciplinary nature and its ability to inform complex, cross-sectoral challenges.

3.2.4.3 Populations affected, geographical impact and research expansion

Populations: Karakurt's research on IPV responds to the critical gaps in resilience-informed care for affected populations facing persistent access challenges. The study examined survivors receiving services at a Rape Crisis Center located in an urban area of the Midwestern United States, with participants representing high-risk groups (36). These populations intersecting challenges such as social and economic hardship, cultural stigma, and inadequate access to tailored support. By integrating a range of perspectives across educational and economic backgrounds, the study highlights the critical need for user-friendly interventions (personal communication, November 2024; 36).

Focus on High-Risk Populations: Karakurt's research centers on populations experiencing compounded challenges, with a

TABLE 4 Policy citations of Karakurt's research, by country*.

Source country	Policy document type					Grand total
	Clinical guidance	Legal documents	Publication	Scholarly article	Working paper	
Australia			3			3
Canada			1	1		2
Colombia			1			1
Finland			1			1
IGO			5		2	7
Norway	1					1
Peru			2			2
Philippines			1			1
Sweden	1	1	2			4
USA			6			6
Grand Total	2	1	22	1	2	28

*Retrieved from https://www.overton.io/ on December 1, 2024.

particular focus on the multifaceted impact of IPV. Children exposed to violence are at an elevated risk for developmental delays and long-term psychological health challenges stemming from Adverse Childhood Experiences (ACEs). IPV-related injuries frequently result in traumatic brain injury (TBI), with 60 to 92% of female survivors reporting facial, head, or neck strangulation injuries (37, 38). These findings underscore IPV as a pressing public health concern with enduring, cross-generational consequences. Karakurt's work further highlights the unique challenges faced by high-risk groups and calls for community-centered approaches that are responsive to the needs and lived experiences of all communities (personal communication, November 2024).

Expansion to Additional Populations: Karakurt is expanding her research to include IPV prevention, with a focus on public education around emotional abuse, healthy relationships, and available support systems. For example, she contributes as an advisor to the UN Women Implementation Guidance (39). By empowering individuals with knowledge about the early warning signs and preventive strategies, Karakurt aims to curb IPV before it escalates, which aligns with foundational public health strategies of disease prevention and health promotion.

3.2.4.4 Advancements in public health

Improving health outcomes is at the core of Karakurt's work, reflecting her commitment to developing practical, data-driven solutions for all populations. Acknowledging the structural challenges that limit access to care for under-resourced individuals, she has deliberately designed her research methodologies and intervention tools to be both easy to use and cost-free. This intentional approach ensures that no individual is denied help due to social and economic constraints. As Karakurt notes, "*Intimate partner violence is considered a public health problem, and there is an urgent need for scalable … interventions*." Her emphasis on ease of use not only addresses the immediate needs of survivors but also contributes to broader system improvements. By expanding access to care, increasing public awareness, and equipping individuals with actionable resources, Karakurt's work contributes meaningfully to reducing both the incidence and societal burden of intimate partner violence.

3.2.4.5 Expanding the research impact

Karakurt plans to continue exploring IPV through funding for advanced statistical tool development and national health data integration, aiming to address prevention and early intervention more effectively. The research goals include enhancing the access and functionality of existing tools and extending their reach to impact a broader demographic nationally and internationally.

3.2.5 Case study 5. *Non-endoscopic screening for Barrett's esophagus*, Amitabh Chak, MD

3.2.5.1 Utilization of the CTSC

Chak utilized the CTSC resources across multiple projects related to Barrett's Esophagus (BE). In October 2016, he received the Core Utilization Pilot grant to use the FDA Guidance Core, facilitating crucial early development of non-endoscopic screening technologies. Chak further accessed the CTSC in January 2023 to support a multicenter randomized controlled trial, SURVENT, which compares surveillance versus endoscopic therapy for BE with low-grade dysplasia. In October 2024, Chak used the University Hospitals REDCap to support a project aimed at detecting BE in patients without symptoms of gastroesophageal reflux disease (GERD), broadening the applicability of his work.

3.2.5.2 Societal benefits in TSBM categories

Chak's research has shown profound societal benefits across several TSBM categories:

Clinical and Medical Benefits: The EsoCheck device and EsoGuard lab test have revolutionized the diagnosis of esophageal conditions, offering a non-invasive, highly accurate alternative to traditional endoscopy. Recognized in guidelines by the American College of Gastroenterology (ACG) and American Gastroenterological Association (AGA), and awarded Breakthrough Device Designation by the FDA, these technologies are endorsed as transformative tools in gastroenterology (40).

EsoGuard, a laboratory-developed test, analyzes 2 methylated DNA biomarkers with remarkable precision. In a pivotal NIH-sponsored clinical trial involving 86 patients, the test demonstrated over 90% sensitivity and specificity for detecting BE (41). A follow-up study confirmed these results in 322 patients (42). Beyond BE, EsoGuard detects a range of esophageal conditions, including dysplastic BE and esophageal adenocarcinoma, making it a versatile tool for early detection and prevention.

EsoCheck is the only minimally invasive, nonendoscopic method for detecting BE that is approved for use in the US. Its non-invasive approach reduces the need for endoscopy, aligning with modern, patient-centered diagnostic practices.

Community and Public Health: The deployment of these innovations in rural areas and through mobile health units addresses healthcare access, particularly in rural areas such as Wayne County, Ohio, and in health fairs across Florida.

Economic Benefits: The commercialization of these technologies through Lucid Diagnostics, co-founded by Chak and colleagues, has translated research into practical applications, leading to patented innovations and the creation of economic value through new healthcare products and services (43).

Policy Citations: As displayed in Table 5, Chak's research has influenced 60 policy citations across 11 countries, including 50 that were cited in clinical guidance documents. The predominance of clinical guidance citations (83%) highlights the research's practical impact in shaping healthcare standards.

3.2.5.3 Populations affected, geographical impact and research expansion

High-Risk Groups and Screening Needs: EsoGuard and EsoCheck are used to screen patients with GERD, non-dysplastic and dysplastic BE, and early-stage adenocarcinoma of the esophagus or gastroesophageal junction. BE, the only known precursor to esophageal adenocarcinoma (EAC), is most common in individuals with chronic GERD, yet the low annual progression rate to cancer requires cost-effective and scalable monitoring solutions (44).

TABLE 5 Policy citations to Chak's research, by country*.

Source country	Policy document type		Grand total
	Clinical guidance	Publication	
Australia		2	2
Canada	1		1
EU		1	1
Finland	1		1
Germany	12	1	13
Italy	1		1
Netherlands		1	1
Spain		1	1
Turkey		1	1
UK	12		12
USA	23	3	26
Grand Total	50	10	60

*Retrieved from https://www.overton.io/ on December 1, 2024.

Geographic Impact: Chak's research addresses improved health outcomes for all people by deploying EsoGuard and EsoCheck in geographically isolated regions. Screening programs in rural Ohio counties and mobile health fairs in Florida bridge gaps in healthcare access, providing life-saving diagnostics to populations lacking proximity to specialized care (43). Mobile health initiatives further extend the reach of these technologies, ensuring that economically challenged communities benefit from early detection services.

Registry-Based Research: Registries such as the Prospective REView of Esophageal Precancer DetectioN in AT-Risk Patients (PREVENT) Registry and the CLinical Utility of EsoGuard (CLUE) study collect real-world data on the performance of these technologies (45, 46). Additionally, the PREVENT-FF Registry focuses on high-risk firefighter populations (47). These registries provide essential insights into the use of EsoGuard and EsoCheck in high-risk groups, enabling the optimization of screening protocols and expanding their utility (43).

Focus on High-Risk Populations: A key element of Chak's work is its emphasis on high-risk groups, including rural populations and high-risk occupations. Initiatives in Wayne County, Ohio, and Florida provide essential screening services to individuals who may lack healthcare access (48, 49). Firefighters, who face a 62% higher risk of esophageal cancer due to occupational carcinogen exposure, are a priority group in this research (47). Targeted screening programs not only offer early detection but also address the unique healthcare needs of those serving their communities, demonstrating the importance of tailored healthcare solutions (50).

Expanding Research to Broader Populations: Chak's research continues to broaden, extending to former NFL players and other populations via #CheckYourFoodTube events, which raise awareness and improve access to life-saving diagnostics (51).

3.2.5.4 Advancements in public health

The research on BE has improved public health by introducing innovative, non-invasive screening methods. These advancements make detection more convenient, less intimidating, and more practical for high-risk populations.

The introduction of EsoCheck (EC) with EsoGuard (EG) has transformed BE screening practices. This approach reduces the discomfort, risk, and logistical challenges associated with traditional endoscopy, thereby increasing patient willingness to undergo screening (40, 41).

The portability and ease of use of the EC/EG device have enabled its deployment in mobile health units staffed by nurse practitioners. These units serve rural communities, where access to specialized care is often limited. By bringing screening directly to these populations, this research bridges critical gaps in healthcare access, fosters early detection and intervention, and improves health outcomes.

3.2.5.5 Expanding the research impact

To address the rising burden of esophageal cancer, Chak proposes a comprehensive strategy to expand access and enhance early detection. Central to this effort is advocating for health insurance coverage of EC/EG screening tests. Insurance support is crucial for improving affordability and access, especially for high-risk populations. Removing cost-related obstacles is essential to expanding access to life-saving diagnostic technologies.

Expanding screening access is another critical objective. By collaborating with health centers nationwide, Chak aims to establish a robust network of advanced screening programs. This expansion will prioritize high-risk groups, including firefighters, middle-aged individuals with GERD, former NFL players, people over 50, individuals with elevated body weight, and smokers. Targeting these populations enables efficient resource use and improved outcomes.

An urgent challenge is the "silent risk" of EAC—cases where patients develop cancer without presenting GERD symptoms. These asymptomatic cases often go undetected until the disease is advanced, reducing the chances of successful treatment. To address this gap, Chak has submitted grant proposals to support research and interventions targeting high-risk individuals who lack GERD symptoms, aiming to improve early detection in these cases.

Additionally, advancing biomarker research is pivotal to refining screening strategies. By developing and validating biomarkers that identify individuals at the highest risk of EAC, screening can be tailored to those most likely to benefit. This precision approach will enhance the impact of early detection efforts.

3.2.6 Case study 6. *Hemoglobin electrophoresis Biochip for newborns*, Umut a. Gurkan, PhD

3.2.6.1 Utilization of the CTSC

Gurkan and his team at CWRU leveraged the CTSC's funding, infrastructure, and logistical support to advance groundbreaking research from concept to innovation. The CTSC provided critical pilot funding for key projects, including the foundational 2014 *"Hemoglobin Electrophoresis Biochip for Newborns"* project, which established scalable diagnostic technologies, and subsequent studies such as the 2020 *"Microfluidic Blood Cell Adhesion Test for Anti-Adhesive Therapies"* and the 2021 *"Microfluidic Blood–Brain-Barrier for Modeling Permeability during Health and Disease States."* Further support came through a CTSC Research consultation, aiding the development of the SMART (Sickle, Malaria, Anemia Rapid Test) device, and the facilitation of the 2020 Doris Duke Clinical Foundation Data Sharing Project, contributing to a national sickle cell disease database. Beyond funding, the CTSC streamlined operational processes like IRB approvals, funded personnel, and fostered interdisciplinary collaboration, enabling Gurkan's team to overcome early-stage research challenges and propel these projects toward impactful outcomes.

3.2.6.2 Societal benefits in TSBM categories

Gurkan's research has demonstrated societal impact across multiple TSBM categories:

Clinical and Medical Benefits: The Gazelle platform transforms diagnostics with portable, affordable point-of-care testing for conditions like sickle cell disease, thalassemia, anemia, COVID-19, and hemoglobin disorders. By bridging diagnostic gaps in economically challenged regions, Gazelle enables global access to accurate testing (52–59).

- Clinical microfluidic assays, developed through a 2020 Pilot Award, are now used as biomarker endpoints in pharmaceutical clinical trials and distributed by BioChip Labs Inc. (60).
- The ClotChip device, developed with Dr. Pedram Mohseni's team, assesses whole-blood coagulation and addresses critical needs in areas such as congenital disorders, anticoagulant therapies, and preoperative evaluations (61). Awarded FDA Breakthrough Device Designation in March 2020, ClotChip is undergoing clinical trials to further expand its impact (62).

Community and Public Health Benefits: Gurkan's research targeted global populations, including groups in India and rural communities in Sub-Saharan Africa. By integrating diagnostic tools into local healthcare workflows, such as vaccination programs and primary care visits, the team advanced healthcare delivery.

Economic Benefits: The HemeChip, an earlier version of the Gazelle platform, was licensed to Hemex Health in 2016, leading to its global commercialization. Deployed in over 42 countries, the device strengthens local healthcare systems and creates sustainable diagnostic infrastructure (63). With 49 US patents and/or patent applications related to diagnostic technologies, including the Gazelle, clinical microfluidic assays, and ClotChip devices, Gurkan has built a strong intellectual property foundation that ensures scalability and global impact.

Policy and Legislative Benefits: Persistent promotion led to adding hemoglobin electrophoresis to WHO guidelines for universal sickle cell disease screening, a major step in addressing global health. Regulatory approvals of the Gazelle platform in India, Europe, and Africa underscore the technology's adaptability (64).

3.2.6.3 Populations affected, geographical impact and research expansion

This research has transformed healthcare for groups affected by hemoglobin disorders, anemia, and other infectious diseases worldwide (personal communication, December 2024).

Populations Affected: The research has targeted many groups facing critical health challenges:

- **Sickle Cell Disease (SCD) Patients**: In malaria-endemic regions like Sub-Saharan Africa and India, SCD is often underdiagnosed or misdiagnosed, exacerbating health outcomes.
- **Thalassemia Patients**: Widespread in the Middle East, Europe, Southeast Asia, Turkey, and India, thalassemia impacts rural and general populations.
- **Anemia Patients**: Anemia affects individuals with nutritional deficiencies, parasitic infections, or complications from SCD and thalassemia. Women and children are disproportionately affected due to malnutrition and limited healthcare.
- **Children and Newborns**: In regions without newborn screening programs, many infants born with SCD remain undiagnosed, leading to high mortality rates.
- **Undiagnosed Patients**: Many individuals with genetic hemoglobin variants remain undiagnosed due to a lack of affordable diagnostic technologies.

Geographic Scope: The Gazelle diagnostic platform has been deployed in over 42 countries, addressing diagnostic gaps worldwide (65).

- **Sub-Saharan Africa**: A significant focus of the research is on countries like Nigeria, Ghana, where rural and tribal populations face the dual burden of malaria and sickle cell disease due to limited access to healthcare.
- **India**: Tribal populations and rural communities with high prevalence of sickle cell disease and thalassemia are key targets.

India supports national programs for hemoglobinopathies using tools developed through this research.

- **Middle East and Turkey**: Thalassemia affects both rural populations and the general population, demonstrating the disease's widespread impact in these regions.
- **Southeast Asia and South America**: Populations in these regions benefit from scalable diagnostic tools that address hemoglobin disorders, anemia, and other health challenges.
- **Developed Countries**: In the United States, Canada, and Europe, the research supports public health programs for diagnostic gaps among hemoglobin variants.

Focus on High-Risk Populations: The research targeted populations that are disproportionately affected due to social, economic, and other obstacles (personal communication, December 2024):

- **Tribal Populations**: Limited access to mainstream healthcare among tribal communities in Africa and India contributes to elevated rates of diseases such as sickle cell disease and thalassemia.
- **Rural Communities**: Residents of remote areas lack access to healthcare infrastructure, leading to higher rates of undiagnosed conditions.
- **Women and Children**: Women bear the burden of anemia due to nutritional deficiencies and reproductive health issues, while children in low-resource settings often face delays in diagnosis and treatment of blood disorders.
- **Economic and Geographic Obstacles**: Populations in sub-Saharan Africa and India frequently encounter obstacles such as the high cost of diagnostics and the absence of systematic screening programs.
- **Contextual and Structural Limitations**: In some regions, local practices or logistical challenges (e.g., short hospital stays after birth) hinder early screening efforts. In rural Africa, integrating screening into vaccination programs was necessary to reach broader populations.
- **Middle Eastern and European Contexts**: In regions like Turkey, refugees and displaced individuals face disproportionate burdens of thalassemia and other conditions due to sometimes limited healthcare access.

3.2.6.4 Advancements in public health

Gurkan's vision is encapsulated in his statement:

> *"I wish that everyone living with sickle cell disease had access to the same quality of care, diagnostic technologies, and curative treatments anywhere in the world. We're working on making these diagnostic technologies more affordable and more available to everyone. We don't want dust, temperature, dirt, cost, or complexity to be a [obstacle] for using technology to fight disease"* (66).

This vision underpins his pioneering efforts to improve public health globally. Gurkan's research addresses widespread healthcare challenges through transformative approaches:

- **Available Diagnostics**: By developing cost-effective, portable diagnostic devices like the Gazelle platform, he has made screening and diagnosis feasible even in resource-constrained environments. These devices overcome obstacles such as cost, environmental challenges, and complexity, making them usable in remote regions.
- **Prioritizing High-Risk Populations**: Rural and native communities, particularly in Africa and India, are at the center of his intervention efforts. This prioritization ensures that populations with the highest disease burden and least access to care directly benefit from these innovations.
- **Culturally Adapted Solutions**: Diagnostic tools are tailored to local contexts. For instance, in regions where newborn hospital stays are brief, diagnostics were integrated into routine vaccination programs, enhancing access without disrupting existing healthcare workflows.

Furthermore, Gurkan's work has significantly improved public health outcomes through targeted interventions:

- **Integration with Public Health Programs**: In Ghana, diagnostics were incorporated into newborn and vaccination-based screening programs, enabling early detection and treatment of sickle cell disease. In India, his research supported national programs addressing both sickle cell disease and thalassemia.
- **Improved Diagnostic Accuracy**: In malaria-endemic regions, where sickle cell disease is often misdiagnosed as malaria or another infectious disease, Gurkan's technologies have transformed diagnostic accuracy. This ensures appropriate treatments are administered, reducing morbidity and mortality rates.
- **Strengthening Health Systems**: By addressing diagnostic gaps in low- and middle-income countries, his research has bolstered public health infrastructures, supporting the sustainable delivery of care to all populations.
- **Recognition by WHO**: In 2019, the WHO listed hemoglobin electrophoresis as an essential *in vitro* diagnostic test for SCD and sickle cell trait in low- and middle-income countries (64).

3.2.6.5 Expanding the research impact

Gurkan's research continues to evolve with a clear focus on tackling urgent healthcare challenges and amplifying the global impact of diagnostic technologies. Key initiatives driving this progress include:

- **Regulatory Approvals**: Securing FDA approval for diagnostic devices is a critical milestone, ensuring compliance with stringent regulatory standards and clinical requirements. This will enable widespread adoption in the US healthcare market, enhance international credibility, and unlock global market opportunities.
- **Development of Non-Invasive Diagnostics**: The team prioritizes the development of non-invasive methods to (a) eliminate the need for blood samples, addressing logistical and cultural obstacles associated with invasive testing; (b) increase access for rural and low-resource populations; (c) enhance patient experience, particularly for children and those apprehensive about traditional testing.
- **Expanded Diagnostic Capabilities**: The platform is evolving into a versatile tool to combat multiple health challenges:

  o **Blood Disorders**: Sustained advancements in sickle cell disease and thalassemia diagnostics remain central.

  - o **Nutritional Deficiencies**: The addition of ferritin testing enables comprehensive anemia diagnostics, addressing critical nutritional issues.
  - o **Chronic Diseases**: Expanding capabilities to include diabetes testing (55) demonstrates the platform's commitment to addressing the growing burden of chronic diseases.
  - o **Oral Cancer Screening**: Introducing biomarker-based diagnostics for oral cancer (67), particularly targeting high-risk populations in regions like India where tobacco-related cancers are widespread.

- **Data Integration and Advanced Analytics**: Advanced analytics drive future breakthroughs:

  - o Contributions to national disease databases, such as sickle cell anemia, enhance research and care.
  - o AI and data mining uncover insights, improving diagnostic algorithms and public health strategies (57, 68–70).
  - o Refinements in diagnostic accuracy and efficiency strengthen the platform's impact.

- **Customization for Local Contexts**: To ensure effective adoption across multiple healthcare systems, the team tailors diagnostics to regional needs:

  - o Adapting workflows to align with local practices and resources.
  - o Engaging healthcare workers and patients to develop user-friendly, appropriate solutions (71, 72).

4 Discussion

4.1 Addressing methodological challenges in translational research

Although the TSBM provides a robust framework for capturing the societal benefits of translational research, the use of single-method study designs, such as surveys, can quantify the TSBM benefits but with limitations to fully explain the value of translational research. This study addresses critical methodological challenges in evaluating the outcomes of translational research. Traditional survey methods often fall short in capturing the multifaceted and dynamic nature of translational research. Issues such as outdated data, participant survey fatigue, and the undervaluation of surveys pose significant obstacles to collecting actionable and comprehensive insights. These limitations underscore the necessity of adopting complementary methodologies that can capture the breadth and depth of translational research impacts.

To overcome these challenges, this study employs a mixed-methods approach that integrates various tools designed to enhance the evaluation of translational research outcomes. First, supporting documentation—such as CVs, publications, and other tangible outputs—was incorporated to validate and enrich the survey data. These materials offer concrete evidence of scholarly productivity and societal benefit, providing a more complete picture of how research translates into real-world impact. By grounding the analysis in verified outputs, this approach enhances both the robustness and credibility of the evaluation.

In addition, qualitative interviews provide in-depth narratives that offer critical insights into the lived experiences of researchers and the pathways through which their work advances public health. These interviews move beyond surface-level outcomes to reveal the nuanced, context-dependent processes that drive successful translational efforts. They help illuminate how discoveries move from academic settings into policy, practice, and community benefit.

An innovative component of this study is the use of research databases including Overton (3) and Dimensions (4) to identify and analyze global policy impacts of translational research. By generating policy citation data, these tools provide a comprehensive lens to evaluate the societal relevance and international reach of translational science. They complement qualitative and survey data by documenting the influence of research on policy and legislative decisions, underscoring the broader implications of translational efforts on public health.

Together, these integrated methods demonstrate the value of a mixed-methods approach in evaluating the translational impact of research supported by the CTSC. The combination of survey data, publications, qualitative interviews, and policy citations enables a nuanced understanding of how research contributes to tangible societal benefits. This methodological framework not only addresses critical gaps in traditional evaluation practices but also offers a replicable model for future translational impact evaluations. Importantly, by leveraging multiple methods and data sources, the study advances a comprehensive and adaptable evaluation paradigm that aligns with the complex and dynamic nature of translational science.

4.2 Advancing public health through translational science: insights from six case studies

4.2.1 Advancing health outcomes through targeted interventions

A consistent theme across all six case studies is the focus on addressing healthcare challenges through tailored, innovative interventions for low-resource and high-risk populations. For example, Bolen's work in Ohio targeted Medicaid-covered individuals disproportionately affected by chronic conditions such as hypertension and diabetes. By employing a positive deviance model in primary care, her interventions significantly improved hypertension control and overall health outcomes across multiple affected groups. Similarly, Malhotra's maternal health research offer valuable evidence for optimizing immunization schedules and maternal health interventions. The development of minimally invasive, cost-effective diagnostic technologies, like multiplex bead assays, has broad applicability for high-risk US communities where healthcare access and early disease detection remain challenges. Additionally, her community-engaged, capacity-building model also underscores the effectiveness of grassroots health education and decentralized care, offering scalable strategies to improve maternal-child health outcomes among economically challenged populations.

4.2.2 Transformative innovations in technology and public health

Innovation was the cornerstone of these projects, propelling breakthroughs in diagnosis, treatment, and prevention. Chak's non-invasive screening tools, EsoCheck and EsoGuard, have transformed healthcare delivery for BE and esophageal cancer. By offering accurate, affordable, and convenient alternatives to traditional endoscopy, these technologies have expanded screening access to high-risk populations, including those in rural areas. Similarly, Gurkan's Gazelle diagnostic platform has redefined point-of-care testing for conditions like sickle cell disease, thalassemia, and anemia. Compact and affordable, the platform delivers rapid, reliable diagnostics in resource-limited settings, reducing dependency on centralized laboratories and facilitating early treatment interventions.

4.2.3 Policy and systems-level impact

These projects demonstrated the far-reaching impact of translational science, driving systemwide changes in policies and healthcare systems while addressing complex health challenges. Bolen's research played a pivotal role in shaping Medicaid reforms, expanding access to preventive care for diabetes and hypertension, and removing obstacles to diabetes technology. Her contributions exemplify how research can directly influence state and national policies, creating better healthcare systems for all people. Similarly, Malhotra's maternal health project integrated research findings into Kenyan health strategies by collaborating with local authorities, resulting in sustainable improvements to vaccination schedules and parasitic disease control programs.

The global policy citations of these researchers' findings further highlights their broad influence. Their work informed many policy documents, including clinical guidelines, legal frameworks, and scholarly analyses. This variety underscores the adaptability and relevance of their research across different policymaking contexts.

Collectively, these efforts illustrate the transformative power of aligning research priorities with public health needs. By bridging disciplines and fostering collaboration, these projects created scalable, research-informed interventions with long-term, global impact. The success of these researchers underscores the critical role of translational science in shaping policies that improve health outcomes, demonstrating how robust science and interdisciplinary approaches can drive sustainable change.

4.2.4 Implications for translational science and public health

Collectively, these case studies highlight four core principles that underpin effective translational science and its public health impact:

- **Prioritize Effective Innovations**: Translational efforts must directly address challenges faced by high-risk populations. Malhotra's maternal health initiative used tailored diagnostics and education to tackle parasitic infections and anemia, creating lasting improvements in maternal and infant health. These approaches help close care gaps while fostering trust and engagement within economically challenged communities.
- **Ensure Scalability and Sustainability**: The success of translational science hinges on its ability to produce models that are both scalable and sustainable. The case studies highlight how interventions can be effectively adapted for multiple contexts while maintaining their core impact. Gurkan's Gazelle diagnostic platform, originally designed for sickle cell disease, now addresses multiple conditions and is deployed in over 42 countries, demonstrating its scalability. Sustainability complements scalability by embedding community ownership and capacity-building into intervention frameworks. Malhotra's project trained local healthcare providers, ensuring the longevity of diagnostics and educational initiatives. Such approaches guarantee that innovations outlive their research phases, delivering long-term benefits.
- **Align with Policy to Maximize Impact**: A critical takeaway from these case studies is the necessity of aligning research objectives with public policy to maximize impact. Bolen's work informed Medicaid reforms, expanding access to preventive care and life-saving technologies, while Knighton's hygiene education initiatives shaped state-level COVID-19 policies. When research influences legislation, localized interventions evolve into universal, transformative change.
- **Foster Collaborative Approaches**: The case studies highlight the critical role of interdisciplinary collaboration and community engagement in creating impactful and sustainable health solutions. Translational science thrives with broad collaboration from many areas of expertise—researchers, practitioners, policymakers, and community stakeholders—converges to address complex health challenges. Malhotra's maternal health initiative exemplifies this by partnering with local health authorities and community leaders to ensure relevant and widely accepted interventions. Engaging communities as co-creators not only builds trust but also fosters ownership, ensuring solutions are tailored to local needs and sustainable over time. This collaborative model drives lasting impact and empowers communities to embrace and sustain meaningful change.

4.3 Challenges and facilitators in CTSC-supported research

The six case studies presented here reveal a shared landscape of opportunities and obstacles faced by investigators engaged in translational, community-based, and technology-driven research initiatives supported by the CTSC. Despite the wide-ranging focus areas—including infection prevention, IPV, global diagnostics, and early-stage medical technologies—these projects shared common struggles that reflect broader universal challenges within the translational research ecosystem. At the same time, they demonstrate how strategic organizational support, coupled with community-rooted approaches, can convert local challenges into scalable innovations.

4.3.1 Persistent challenges in translational and community-engaged research

Resource constraints emerged as a foundational obstacle across nearly every initiative. Investigators frequently cited insufficient, short-term funding as a limiting factor, especially in efforts requiring longitudinal engagement with communities or extended periods to demonstrate health outcomes. Bolen and Malhotra, for instance, described how the episodic nature of grant funding clashed with the sustained effort needed to build trust, infrastructure, and evidence in high-risk populations. Similarly, Knighton's public health intervention struggled to scale due to the high upfront costs of technology deployment and limited avenues for sustained financial support.

Administrative and regulatory requirements posed significant obstacles, especially for projects situated at the intersection of clinical innovation and public health. Complex processes—such as coordinating across multiple IRBs, obtaining FDA approvals, and managing subcontracts—often caused delays and placed additional strain on already limited resources. Karakurt and Chak's experiences underscore the sustained time and effort required to conduct ethically sensitive or high-risk research. These challenges disproportionately impact early-career researchers and community-based organizations, which often lack the administrative infrastructure needed to manage such complexity.

In parallel, investigators encountered deep-seated obstacles to access and engagement. Mistrust of research institutions—whether due to historical abuses, cultural beliefs, or lack of representation—was a recurrent theme, particularly in projects working with specific subgroups or rural populations. Malhotra's work with traditional birth attendants and community leaders and Karakurt's engagement with IPV survivors reveal the fragility of researcher-community relationships when not rooted in humility and sustained presence. Moreover, logistical issues such as transportation, electricity, and internet access in global or rural settings amplified these engagement challenges, threatening both recruitment and retention.

Researchers working in emotionally demanding fields such as IPV often encountered less visible, yet deeply impactful, challenges—including secondary traumatic stress and emotional exhaustion. These burdens, which extend beyond measurable scientific outputs, underscore the need to embed emotional resilience as a foundational element of the research environment.

4.3.2 Key facilitators of research success

Several key facilitators emerged that enabled investigators not only to overcome these challenges but to generate meaningful, lasting impact.

First, the CTSC itself functioned as a backbone of support, offering more than just funding. Across cases, the CTSC provided essential mentorship, infrastructure, pilot grants, and access to cross-disciplinary expertise. For many investigators, particularly those in the early stages of their careers, this ecosystem of support was catalytic—transforming isolated efforts into well-resourced, collaborative programs with the credibility to secure additional investment. Programs such as the KL2 training grant equipped researchers with the technical, ethical, and collaborative skills required to navigate complex research environments.

Equally critical was the commitment to community engagement and capacity building. The most effective projects invested in the long game: building trust, co-designing interventions, and empowering community members as co-investigators rather than passive participants. Malhotra's use of community health workers and Bolen's participatory research workshops not only enhanced research rigor and relevance but also laid the groundwork for sustainable change. These partnerships shifted power toward the community, increasing project legitimacy and fostering mutual accountability.

Strategic, cross-sector collaborations further amplified reach and resilience. Partnerships with health systems, philanthropic foundations, local leaders, and global organizations provided crucial credibility and operational support. For example, Knighton's alignment with foundations enabled deeper community penetration during the pandemic, while international diagnostic projects leveraged global partnerships to overcome regulatory and cultural challenges across healthcare systems.

Another powerful enabler was the emphasis on adaptive, user-centered design. Investigators who embedded iterative feedback loops—whether from community members, healthcare providers, or policymakers—were able to refine tools and interventions to better fit real-world needs. This responsiveness not only improved adoption and engagement but also allowed for scalable, context-sensitive solutions.

Finally, small-scale pilot funding and seed grants played an outsized role in transforming early ideas into fundable, high-impact initiatives. These initial investments provided more than capital—they served as proof-of-concept platforms where investigators could test feasibility, generate preliminary data, and build stakeholder trust. The strategic deployment of pilot projects allowed for risk mitigation while creating momentum for larger-scale implementation and dissemination.

4.3.3 Implications for CTSAs and translational science

These findings suggest that the most transformative translational research occurs not in isolation, but at the intersection of organizational infrastructure, community wisdom, and adaptive innovation. The CTSC's role in these success stories was not merely transactional—it was transformational. By providing flexible support mechanisms, convening stakeholders, and fostering a culture of mentorship and collaboration, the CTSC created the conditions for innovation to take root in often challenging environments.

Yet, the work also illuminates persistent challenges in the translational research ecosystem. From inflexible funding timelines to burdensome administrative processes and limited emotional support for investigators, these difficulties must be addressed if translational science is to fulfill its promise of improving health for all.

These case studies offer not only insight but a blueprint—a roadmap for how organizational support, when aligned with local leadership and responsive innovation, can overcome universal challenges and catalyze meaningful change. They remind us that translational science, at its best, is not merely about moving discoveries from bench to bedside, but about bridging worlds: connecting knowledge to need, innovation to impartiality, and research into real life it seeks to serve.

Data availability statement

The datasets presented in this article are not readily available because it is private evaluation data from the Clinical and Translational Science Collaborative of Northern Ohio. Requests to access the datasets should be directed to clara.pelfrey@case.edu.

Ethics statement

Written informed consent was obtained from the individual(s) for the publication of any potentially identifiable images or data included in this article.

Author contributions

LZ: Conceptualization, Data curation, Formal analysis, Investigation, Methodology, Project administration, Writing – original draft, Writing – review & editing, Validation, Visualization. UG: Investigation, Data curation, Writing – review & editing. KQ: Investigation, Data curation, Writing – review & editing. SS: Data curation, Investigation, Resources, Writing – review & editing. SH: Data curation, Resources, Writing – review & editing. CP: Conceptualization, Data curation, Formal analysis, Investigation, Methodology, Project administration, Supervision, Writing – original draft, Writing – review & editing.

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Conflict of interest

The authors declare that the research was conducted in the absence of any commercial or financial relationships that could be construed as a potential conflict of interest.

Generative AI statement

The author(s) declare that no Gen AI was used in the creation of this manuscript.

Publisher's note

Supplementary material

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EDITED BY
Pamela Davidson,
University of California, Los Angeles,
United States

REVIEWED BY
Keith A. Herzog,
Northwestern University, United States

*CORRESPONDENCE
Jessica Sperling
✉ jessica.sperling@duke.edu

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Taking the Translational Science Benefits Model from concept to operationalization: opportunities and challenges in defining impact using the Translational Science Benefits Model

Jessica Sperling[1,2]*, Eman Ghanem[1], Stella Quenstedt[1] and Tarun Saxena[1]

[1]Clinical and Translational Science Institute, Duke University School of Medicine, Durham, NC, United States, [2]Social Science Research Institute, Duke University, Durham, NC, United States

The Translational Science Benefits Model (TSBM) was developed to conceptualize and communicate the benefits and impact of translational research. While the TSBM was developed as a conceptual model rather than an operational process, it can be integrated into operational processes to provide evidence and clearly explain the impact of translational research and translational science. This paper discusses the use of the TSBM not only as a conceptual framework but also as a program-integrated operational mechanism. First, it discusses three TSBM-informed programmatic processes for addressing intended and achieved impact: case studies, Pilots program reporting, and an organizational database. Then, it outlines the key factors emerging from these processes that should be considered before employing TSBM as an integrated structure for collecting information on translational research outcomes. In particular, this paper discusses key *who* questions with a focus on who codes or reports TSBM data, including accounting for the coder or reporter's understanding of the TSBM, while balancing feasibility with validity. Key *how* questions including a specific focus on how potential TSBM outcomes are defined and determined. Key *when* questions address potential limitations or adaptation needs in TSBM-based measurement based on specific areas of focus, particularly workforce development and translational science-specific outcomes. Ultimately, this paper provides key lessons to consider when using the TSBM as a data collection tool and also explores opportunities to expand the utility of the TSBM as a data collection tool to understand, demonstrate, and augment the impact of translational research and science.

KEYWORDS

translational science, translational research, evaluation, scientific impact, research operations, Translational Science Benefits Model (TSBM)

1 Introduction

The benefits of translational research (TR), which focuses on moving scientific discoveries from the laboratory settings to clinical applications for improved health outcomes, can be challenging to measure, as a TR enterprise intentionally spans across multiple domains. To address this and better communicate the positive effects and impacts of TR, various models and frameworks have been proposed. One frequently used model is the Translational Science

Benefits Model (TSBM) (1, 2), which was developed to provide an organizing framework for conceptualizing and communicating the impact of TR.[1] The TSBM, in its origin, focuses on 30 measurable benefits across four domains that span the following content areas: clinical benefits, community benefits, economic benefits, and policy benefits. Clinical benefits include factors such as biomedical technology and diagnostic procedures. Community benefits encompass improvements in healthcare delivery quality. Economic benefits include patents and licenses, as well as cost savings. Policy benefits include legislative or standards changes and the provision of expert testimony.

The TSBM has been a core impact framework used to address the outcomes of TR. Clinical and Translational Science Award (CTSA) Hubs, which are supported by the National Institute for Health's (NIH) National Center for Advancing Translational Sciences (NCATS), are designed to support and advance translational research. They have used the TSBM as a central mechanism for conceptualizing, assessing, and communicating the impact of their work; it has served as a basis for research impact assessment and has provided a framing for public communication of impact across numerous Hubs (3–5). Beyond the CTSA utilization, TSBM utility has informed similar efforts in multiple other research entities and studies; for instance, the Centers for Diabetes Translation Research (CDTR) adapted the TSBM to develop its Research Impact Framework, and the QUARTET USA trial, a randomized study on hypertension treatment, utilized the TSBM to assess its impact across clinical and community domains (6, 7). The original TSBM publication by Luke et al. (1), has shown a clear scholarly impact with an upward trajectory in its citations over time. Citations more than doubled in recent years—from 15 in 2018–2019 and rising sharply to 36 in 2024–early 2025—indicating growing recognition and increasing integration of the TSBM framework into the broader TR or translational science (TS) discourse.

The originally-published TSBM set the expectation that future use could employ it as an assessment framework, but it was not designed as a specific data collection process or organizational operational structure. However, over time, TSBM has been increasingly used to more directly assess impact. It has supported evaluation of training programs, helping junior investigators articulate broader benefits of their work, and been used to map implementation project outcomes to specific TSBM domains (8, 9). In addition, many institutions have created TSBM-based case studies (5, 10), often as *ad hoc* efforts focused on select projects, but newer guidance and tools for developing impact profiles more efficiently could support broader organizational adoption (11). The embedding of the TSBM into research training and institutional evaluation systems demonstrates its practical utility, beyond theoretical application, as a base for advancing and measuring the impact of TR.

The transition from a conceptual framework to an operationalized system that is concretely used across programmatic activities introduces new questions and considerations about the model. In this article, we identify three active processes within the Duke Clinical and Translational Science Institute (CTSI), which has advanced translational research and translational science via NCATS CTSA support and other funding sources, that employ the TSBM as a mechanism for collecting and organizing data on benefits. We then outline key considerations emerging from these cases that are relevant to using the TSBM as a structure for data collection on outcomes, and which provide opportunities to consider modifications or enhancements to the model itself. We focus on four considerations: who is collecting data, how potential outcomes are conceptualized and applied in measurement, potential limitations of TSBM use for programs (as compared to research projects), and potential limitations of TSBM use for examining TS (as compared to TR) impact. This publication offers key insights for using the TSBM as a data collection tool and highlights opportunities to expand its utility to understand, demonstrate, and augment the impact of TR and TS.

2 Application of the Translational Science Benefits Model

Below, briefly in text and with additional information in Figure 1, we identify and describe three distinct opportunities to utilize the TSBM including in concrete operational efforts (hereafter described as "use cases"). These use cases were selected because they represent primary mechanisms the Duke CTSI has integrated TSBM into organizational processes; because they each differ in their purpose and the ways the TSBM was operationalized, thereby representing variation in forms of TSBM application; and because each use case raised specific considerations and questions regarding TSBM operationalization, providing a diverse basis for subsequent (Section 3) discussion of these points. These represent application at the level of cases (projects, specific initiatives), program, and an institutional enterprise.

2.1 Translational research/TSBM case study

A case study, or an in-depth examination of a specific subject (project), is a relatively common mechanism for applying the TSBM (5). As of early 2025, the authors' research institution has published 7 case studies focused on a range of studies and programs that were supported by the CTSI by a variety of mechanisms (12). In a case study, the TSBM was operationalized using its domains to identify and prioritize specific indicators of translational impact that might not have been traditionally emphasized in research dissemination. For example, in a case study addressing research focused on maternal morbidity (13), the TSBM prompted a focus on the potential for guidelines that may result from the research, which would not have been captured using standard clinical metrics alone.

2.2 Pilot funding awards

The pilot awards program funds and supports a variety of projects that generate translational discoveries relevant to human health or disease. The CTSI has integrated the TSBM into all funded Pilots projects to track benefits over time, from applications to regular awardee updates. At the application stage, TSBM indicators were not specifically

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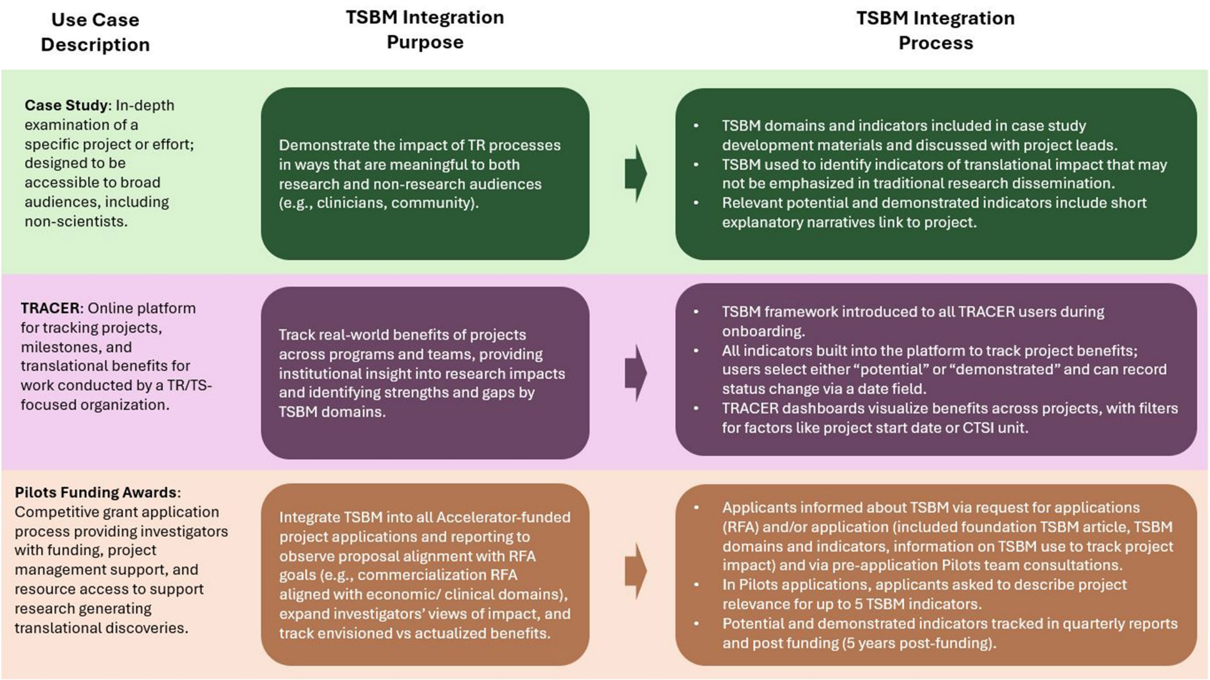
[1] The TSBM has been described as addressing translational research (TR) impacts and/or translational science (TS) impacts. Over time, TR and TS have come to be defined more distinctly (21). We discuss the TSBM in this section as most directly addressing TR impacts; this is further addressed later in this paper.



Use Case Description	TSBM Integration Purpose	TSBM Integration Process
Case Study: In-depth examination of a specific project or effort; designed to be accessible to broad audiences, including non-scientists.	Demonstrate the impact of TR processes in ways that are meaningful to both research and non-research audiences (e.g., clinicians, community).	• TSBM domains and indicators included in case study development materials and discussed with project leads. • TSBM used to identify indicators of translational impact that may not be emphasized in traditional research dissemination. • Relevant potential and demonstrated indicators include short explanatory narratives link to project.
TRACER: Online platform for tracking projects, milestones, and translational benefits for work conducted by a TR/TS-focused organization.	Track real-world benefits of projects across programs and teams, providing institutional insight into research impacts and identifying strengths and gaps by TSBM domains.	• TSBM framework introduced to all TRACER users during onboarding. • All indicators built into the platform to track project benefits; users select either "potential" or "demonstrated" and can record status change via a date field. • TRACER dashboards visualize benefits across projects, with filters for factors like project start date or CTSI unit.
Pilots Funding Awards: Competitive grant application process providing investigators with funding, project management support, and resource access to support research generating translational discoveries.	Integrate TSBM into all Accelerator-funded project applications and reporting to observe proposal alignment with RFA goals (e.g., commercialization RFA aligned with economic/ clinical domains), expand investigators' views of impact, and track envisioned vs actualized benefits.	• Applicants informed about TSBM via request for applications (RFA) and/or application (included foundation TSBM article, TSBM domains and indicators, information on TSBM use to track project impact) and via pre-application Pilots team consultations. • In Pilots applications, applicants asked to describe project relevance for up to 5 TSBM indicators. • Potential and demonstrated indicators tracked in quarterly reports and post funding (5 years post-funding).

FIGURE 1
TSBM use cases overview.

assessed as part of competitive proposal review; they were included to prompt investigator thinking about real-world impact from the project start and to provide a foundation for future tracking. Quarterly progress reports and annual follow-up reports incorporated the TSBM to track and update progress made towards benefits and any changes during the course of the project and for 5 years after the funding cycle.

2.3 Integration into organizational project and program tracking platforms

The TSBM has been integrated into an online relational data platform, the Translational Research Accomplishment Cataloguer (TRACER), which is used across the full Duke CTSI enterprise (14). It was developed at Duke and is utilized by Duke CTSI program staff and leadership; it houses information about all programs supported by the CTSI, and includes mechanisms for documenting and tracking milestones and benefits of projects supported by a CTSI. The TSBM was built into the data platform as specific fields available for projects in the database, providing an added mechanism of tracking real-world impact. The platform contains fields where teams can indicate which specific TSBM indicators are achieved or can potentially be achieved by each project (see Supplement for visual). This allows teams to trace the benefits for each individual project, and it permits a high-level view of real-world impact across an entire portfolio of projects.

3 Four considerations in operationalization of TSBM

The application of the TSBM across these specific use cases described above—TSBM case studies focused on individual projects, the pilot grants program, and the enterprise-level TRACER program to assess knowledge translation impact in the hub—helped to reveal key critical considerations across these operationalizations. Below, we highlight four considerations with implications for integrating the TSBM into program processes; these address questions about "who" (who determines benefits), "how" (how one determines potential benefits), and "when/how" (when and how the TSBM works to different applications).

3.1 Consideration # 1: Who determines relevant benefits?

While TSBM benefits include specific definitions, the individuals determining which benefits apply varies. For case studies, a bidirectional process between research teams and program staff and the Duke CTSI's Evaluation, Improvement, and Impact team (EII) was used to determine relevant benefits. While research teams and program staff are not required to have any knowledge of the TSBM, members of EII have in-depth knowledge and experience with it. In this process, application of the TSBM is reviewed and/or discussed multiple times by both EII and research teams, to ensure agreement and proper application of the indicators. For TRACER, users are primarily program staff and researchers housed within Duke CTSI who have prior knowledge on the TSBM through use of the model in their own work and are provided TSBM materials to review prior to being onboarded to the TRACER platform. In addition, TSBM definitions and resources are built directly into TRACER where users would enter a project's TSBM indicators. TRACER processes then rely on teams' and their leadership's assessments to determine relevant TSBM indicators for their projects. The EII team is available for additional guidance as requested but, based on the volume of projects as well as individual teams' contextual knowledge, does not vet or inform each individual benefits selection. For pilot awards, relevant benefits are determined by the primary investigators applying for the award. These investigators are provided access to TSBM materials during their application, including Luke and colleagues' foundational TSBM manuscript (1), the TSBM website, examples of case studies, TSBM definitions in the application form, and a pre-application discussion with the Pilots team during broader consultations; these are provided to create a TSBM foundation.

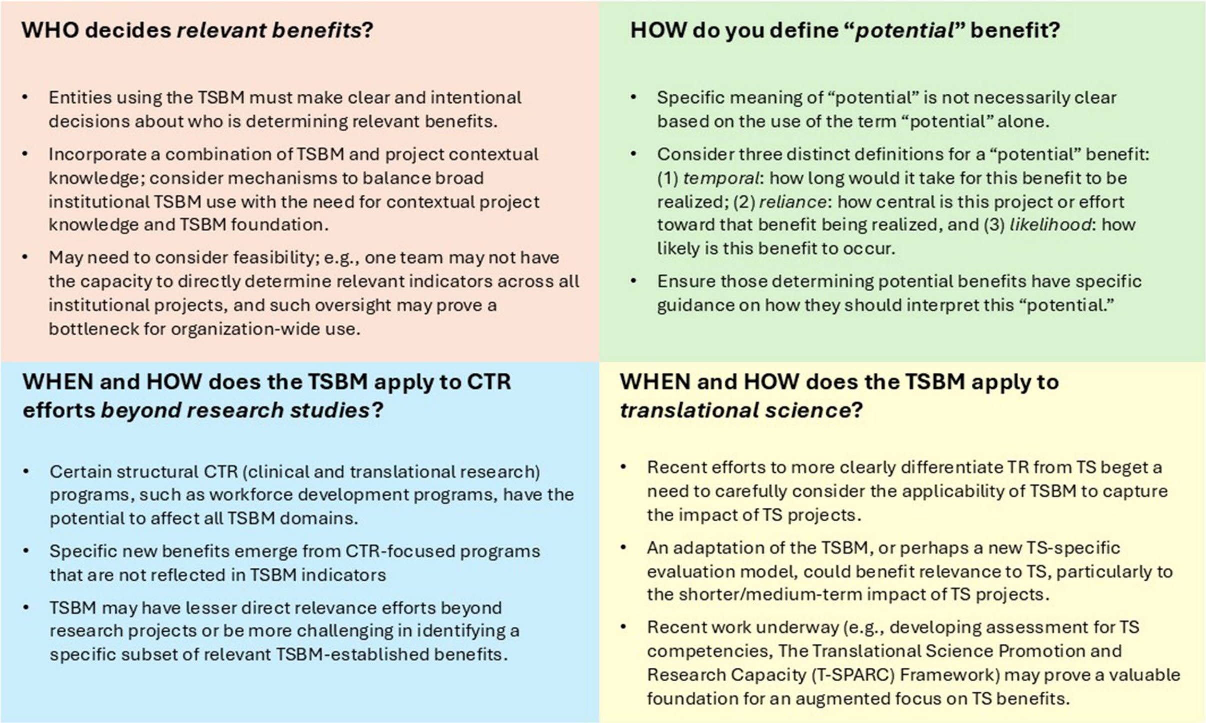
3.2 Consideration # 2: definitions of "potential" benefit

The concept of a *potential* benefit was a key feature of the TSBM in its early application in case studies. The process of translation can take many years to achieve the specific TSBM benefits. To address this, TSBM case studies often included a mechanism to document both demonstrated (benefits that had been achieved) and potential (benefits that had not yet been achieved but could be achieved by the project) indicators. While this is a key value of the TSBM, it also raised important questions about how *potential* can be defined in the operationalization process.

In the case study application, potential was determined by the evaluation team and considered the anticipated timeframe for benefit realization, how central this project or effort is toward that benefit being realized, and the overall likelihood of a benefit occurring. In the TRACER database, the indication of a potential benefit was determined by the organizational team member who entered the project into the platform, with *ad hoc* review by CTSI leadership. In these cases, potential was defined by likelihood, as benefits that were expected with moderate to high confidence. In this context, potential was similarly defined by the perceived likelihood of a benefit occurring, where moderate to high confidence reflected a reasoned belief, based on organizational team members' prior knowledge of and experience with similar projects, that the benefit was likely to emerge. In the pilot awards, a potential benefit and the definition of potential were determined by researchers. They were instructed to select expected benefits in their proposals, which were not explicitly defined but described as expected benefits aligned with the likelihood definition. See Figure 2 for a summary of ways to define "potential," based on these applications.

3.3 Consideration # 3: application to research projects vs. capacity-development programs

TSBM use for case studies raised questions about its applicability to programs beyond research studies for which it was originally developed. Two specific case studies addressed clinical translational research workforce development programs rather than research projects. One case study focused on the development and implementation of North Carolina Central University's Clinical Research Sciences program, which offers a certificate, minor, and bachelor's degree (15, 16). Designed to build a highly trained workforce in clinical research and to increase access to entry into this workforce for all populations, the program aligned with many TSBM community-domain indicators, such as development of a *health education resource* and potential for improved *healthcare accessibility* through increased workforce representation. The



WHO decides *relevant benefits*?

- Entities using the TSBM must make clear and intentional decisions about who is determining relevant benefits.
- Incorporate a combination of TSBM and project contextual knowledge; consider mechanisms to balance broad institutional TSBM use with the need for contextual project knowledge and TSBM foundation.
- May need to consider feasibility; e.g., one team may not have the capacity to directly determine relevant indicators across all institutional projects, and such oversight may prove a bottleneck for organization-wide use.

HOW do you define "*potential*" benefit?

- Specific meaning of "potential" is not necessarily clear based on the use of the term "potential" alone.
- Consider three distinct definitions for a "potential" benefit: (1) *temporal*: how long would it take for this benefit to be realized; (2) *reliance*: how central is this project or effort toward that benefit being realized, and (3) *likelihood*: how likely is this benefit to occur.
- Ensure those determining potential benefits have specific guidance on how they should interpret this "potential."

WHEN and HOW does the TSBM apply to CTR efforts *beyond research studies*?

- Certain structural CTR (clinical and translational research) programs, such as workforce development programs, have the potential to affect all TSBM domains.
- Specific new benefits emerge from CTR-focused programs that are not reflected in TSBM indicators
- TSBM may have lesser direct relevance efforts beyond research projects or be more challenging in identifying a specific subset of relevant TSBM-established benefits.

WHEN and HOW does the TSBM apply to *translational science*?

- Recent efforts to more clearly differentiate TR from TS beget a need to carefully consider the applicability of TSBM to capture the impact of TS projects.
- An adaptation of the TSBM, or perhaps a new TS-specific evaluation model, could benefit relevance to TS, particularly to the shorter/medium-term impact of TS projects.
- Recent work underway (e.g., developing assessment for TS competencies, The Translational Science Promotion and Research Capacity (T-SPARC) Framework) may prove a valuable foundation for an augmented focus on TS benefits.

FIGURE 2
Lessons for application of TSBM in operational use.

team also proposed a new indicator under economic benefits: career access, given North Carolina's rapidly growing clinical research industry. Overall, by advancing the number and breadth of individuals in a potential workforce and their competencies, the program could impact all TSBM domains. Another case study addressed YOJO (Your Journey), an online platform designed to facilitate persistence and sustainability in educational and professional development programs (17). Recognizing that pathway programs often operate in silos, YOJO was developed to connect them, simplify applications, track participants, and promote persistence among participants (18). When considering benefits, the team expanded beyond current TSBM benefits to add an additional potential benefit of workforce development, based on scholarship indicating that engaging individuals from all populations can strengthen the biomedical workforce (19–21). Like the Clinical Research Sciences program, YOJO has the potential to impact nearly all indicators via development of the clinical translational research workforce.

These case studies highlighted a challenge in applying the TSBM to capacity-building programs like education and training. Designed to build foundation for translational research, these programs often yield systemic, long-term impacts. Individual-level outcomes, such as skill development, knowledge gain, networking, and attitudinal change, are difficult to map to specific TSBM domains as one might with traditional research. In both case studies, the broad potential for impact across all TSBM domains revealed a limitation of the framework: it does not fully accommodate initiatives whose impact is foundational or systemic to enabling future translational activity. Additionally, the absence of categories such as "career access" and "workforce development" represents a meaningful gap when evaluating efforts to expand the translational science workforce. These insights point to the need to refine the TSBM to better capture the contributions of educational and workforce development programs to TR or TS ecosystem.

3.4 Consideration # 4: application to translational science

The TSBM was primarily designed to capture the outcomes of TR projects by focusing on benefits such as the development of new treatments, diagnostic tools, interventions, or community health change. In recent years, the National Center for Advancing Translational Sciences (NCATS) has implemented a strategic shift in its funding priorities, emphasizing TS as a priority, in addition to traditional TR, across CTSA hubs (22). As such, the NCATS required a shift to TS-focused Pilots projects and away from prior TR-focused projects. When considering how to advise applicants on TSBM benefits for their TS projects, the Pilots and EII teams questioned the fit. TR focuses on turning lab or clinical observations into health-improving interventions, often with focus on specific disease or patient population; TS focuses on scientific and operational principles underlying translational processes, with focus on addressing cross-cutting challenges across diseases or interventions to make translation more efficient across many diseases. The TSBM does not necessarily reflect the direct benefits of TS-specific projects and research. For instance, while some of TS developments may be captured within a TSBM benefit (e.g., new investigative procedures), other potential benefits such as improvements toward facilitating boundary-crossing collaborations or addressing persistent regulatory challenges, would not be as easily reflected in TSBM indicators.

4 Implications

This work provides evidence for methods to integrate the TSBM into operational processes within entities supporting TR. The TSBM can be applied in commonly used case studies, but it can also be used in other ways. For instance, it can be used in funding award processes to preemptively consider potential outcomes, to utilize the TSBM as a basis for regular reporting during the grant period, and to continue ongoing toward longer-term tracking of research outcomes. This provides a way to integrate the TSBM across all stages of a funded project and across a research portfolio. Additionally, it can serve as a part of organizational and program-level tracking in an entity that seeks to advance TR, helping to systematically evaluate impact across an organization and inform strategic decision-making. While the TSBM is valuable as a conceptual framework, its utility is further enhanced when applied in concrete, operational contexts.

The operational use of the TSBM, while valuable, also highlights certain challenges or considerations for the use of the TSBM. Although these may be viewed as limitations, they also present opportunities for refinement and further development of the framework. In our experience, key challenges include definitional inconsistencies and lack of specificity (e.g., as relevant to the "who" and "how" considerations), which can lead to measurement difficulties; this speaks to potential issues in data quality and validity and to the importance of data standards and operational guidelines to aid in transforming TSBM from theory to practice. With this basis, our applications of the TSBM highlight the need for clearer definitions, such as specifying what constitutes a *potential* benefit, and suggest the addition of new indicators within the framework, such as incorporating economic benefits related to workforce development programs. Additionally, the TSBM may not be fully suited for certain areas of the TR enterprise, such as training and workforce development programs, nor for assessing more direct TS outcomes. This limitation is especially relevant to TS/TR entities that are placing greater emphasis on advancing TS, as is the case for CTSAs based on emphasis in the most recent CTSA Funding Opportunity Announcement (22); while the TSBM remains relevant to ongoing TR efforts and even some TS components, it does not necessarily capture the full range of TS impacts. These limitations suggest the need for additional or complementary frameworks to more fully assess TS impact. For example, the NCATS TS principles (23) or the Translational Science Promotion and Research Capacity (T-SPARC) framework (24), which includes proximal and distal indicators of TS impact in a logic model format, can provide useful foundations for refining and expanding future TS impact frameworks. Figure 2 utilizes the four considerations to provide lessons in the application of the TSBM in operational use.

Such advancements of a framework or model based on application across new contexts is consistent with framework and model development more broadly; in other fields, applying conceptual models and frameworks in applied uses has been essential for refining their applicability and enhancing their impact in healthcare and medical research. For instance, within implementation science, the RE-AIM framework has developed and refined over time based on its use across public health, clinical, and community-based settings (25). Similarly, the Consolidated Framework for Implementation Research use identified the need for more explicit considerations of sustainability within the framework (26, 27). These adaptations have improved the framework's ability to guide the design and evaluation of implementation strategies in various healthcare contexts. Similarly, very recently, the TSBM has begun to be adjusted or augmented. For instance, recent work expands the TSBM to formally include additional indicators, and additional research offers modifications for an implementation science application (9, 28, 29). Additional work has developed the model by integrating key tenets from engagement science (30), demonstrating processes for adapting the TSBM by directly linking it to other aligned conceptual work. Shifts to the TSBM, informed by our work, can guide additional future enhancements and modification opportunities.

Beyond development of the model itself, the work presented in this paper builds upon other emerging developments informing operational use of the TSBM. For example, recent efforts to develop and provide initial validation of an instrument assessing TSBM benefits have introduced greater specificity and clarity to key indicators, which could enhance consistency in implementation across different systems (31). This, combined with added specificity in defining what comprises a *potential* impact, could help to create greater validity and reliability to TSBM measurement and enhance potential for system-wide applications. Additional work on the TSBM, including studies featured in this special issue, represents important steps toward refining its applications, identifying limitations, and expanding its scope and utility. We recommend future work that continues to apply the TSBM in practical and operational contexts, both to maximize its impact in real-world settings and to identify ways in which the model can be continually improved and refined.

Data availability statement

The original contributions presented in the study are included in the article/Supplementary material. Further inquiries can be directed to the corresponding author.

Author contributions

JS: Writing – review & editing, Methodology, Writing – original draft, Conceptualization. EG: Writing – review & editing, Conceptualization, Writing – original draft. SQ: Writing – review & editing, Methodology, Writing – original draft, Conceptualization. TS: Writing – review & editing.

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Conflict of interest

The authors declare that the research was conducted in the absence of any commercial or financial relationships that could be construed as a potential conflict of interest.

Generative AI statement

The authors declare that Gen AI was used in the creation of this manuscript. Generative AI (ChatGPT) was used to generate suggestions for rephrasing portions of the manuscript during the editing process for clarity in writing. All content was determined, reviewed, and finalized by the authors.

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Supplementary material

The Supplementary material for this article can be found online at: https://www.frontiersin.org/articles/10.3389/fpubh.2025.1612590/full#supplementary-material

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Topic analysis on publications and patents toward fully automated translational science benefits model impact extraction

Tejaswini Manjunath, Eline Appelmans*, Sinem Balta, Dominick DiMercurio, Claudia Avalos and Karen Stark

Digital Infuzion LLC, Rockville, MD, United States

Background: The Clinical and Translational Science Award (CTSA) program, funded by the National Center for Advancing Translational Sciences (NCATS), has supported over 65 hubs, generating 118,490 publications from 2006 to 2021. Measuring the impact of these outputs remains challenging, as traditional bibliometric methods fail to capture patents, policy contributions, and clinical implementation. The Translational Science Benefits Model (TSBM) provides a structured framework for assessing clinical, community, economic, and policy benefits, but its manual application is resource-intensive. Advances in Natural Language Processing (NLP) and Artificial Intelligence (AI) offer a scalable solution for automating benefit extraction from large research datasets.

Objective: This study presents an NLP-driven pipeline that automates the extraction of TSBM benefits from research outputs using Latent Dirichlet Allocation (LDA) topic modeling to enable efficient, scalable, and reproducible impact analysis. The application of NLP allows the discovery of topics and benefits to emerge from the very large corpus of CTSA documents without requiring directed searches or preconceived benefits for data mining.

Methods: We applied LDA topic modeling to publications, patents, and grants and mapped the topics to TSBM benefits using subject matter expert (SME) validation. Impact visualizations, including heatmaps and t-SNE plots, highlighted benefit distributions across the corpus and CTSA hubs.

Results: Spanning CTSA hub grants awarded from 2006 to 2023, our analysis corpus comprised 1,296 projects, 127,958 publications and 352 patents. Applying our NLP-driven pipeline to deduplicated data, we found that clinical and community benefits were the most frequently extracted benefits from publications and projects, reflecting the patient-centered and community-driven nature of CTSA research. Economic and policy benefits were less frequently identified, prompting the inclusion of patent data to better capture commercialization impacts. The Publications LDA Model proved the most effective for benefit extraction for publications and projects. All patents were automatically tagged as economic benefits, given their intrinsic focus on commercialization and in accordance with TSBM guidelines.

Conclusion: Automated NLP-driven benefit extraction enabled a data-driven approach to applying the TSBM at the scale of the entire CTSA program outputs.

KEYWORDS

Translational Science Benefits Model (TSBM), Natural Language Processing (NLP), Latent Dirichlet Allocation (LDA), Clinical and Translational Science Award (CTSA), impact analysis, Artificial Intelligence (AI), Large Language Model (LLM), topic analysis

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EDITED BY
Pamela Davidson,
University of California, Los Angeles,
United States

REVIEWED BY
Ameni Kacem,
Seafrigo, France
Barbara Tafuto,
Rutgers University, Newark, United States
Kayla Jamie Kuhfeldt,
Boston University, United States

*CORRESPONDENCE
Eline Appelmans
✉ elinea@digitalinfuzion.com

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1 Introduction

Translational science plays a critical role in bridging the gap between scientific discoveries and real-world health outcomes. The National Center for Accelerating Translational Science (NCATS) Clinical and Translational Science Award (CTSA) program has funded more than 65 hubs at leading medical institutions nationwide (National Center for Advancing Translational Sciences, 2024). Between 2006 to 2021 CTSA hubs produced 118,490 publications with 13% of CTSA-supported articles were referenced in policy documents, demonstrating a pivotal role in translating basic research into clinical applications (Llewellyn et al., 2023).

However, measuring the CTSA program's real-world impact remains a challenge. The program's evolving and growing scope and the variety of outputs (from publications, to patents, policy and clinical guidelines) make it difficult to select and deploy methods that are both comprehensive and practical. Traditional bibliometrics reliably quantify publications and citations but systematically miss non-publication contributions, such as policy briefs and clinical implementation guides (Llewellyn et al., 2023), and they offer little insight into the downstream benefits that inform strategic decision-making. Although recent bibliometric innovations have begun to trace connections between research and policy outcomes (Llewellyn et al., 2023), these methods still rely on labor-intensive workflows. As a result, there is a critical need for automated, reproducible approaches that can capture the full spectrum of translational benefits and deliver actionable insights at program scale across all output types.

Historically, some other methods have been applied. The Common Metrics Initiative was originally developed to assess the efficiency of clinical research processes and was used by the CTSAs program to leverage change based on objective results (Daudelin et al., 2020). However, implementing the Common Metrics across the CTSA Program proved to be effort-intensive (Welch et al., 2021). In 2022, the CTSA hubs were tasked with continuing quality improvement programs to make individualized decisions that improve their processes.

In response to the need for a more specific understanding of the impacts of the CTSA research, the Institute for Clinical and Translational Sciences Tracking and Evaluation Team at Washington University in St. Louis developed the Translational Science Benefits Model (TSBM) in 2018 (Luke et al., 2018). The TSBM moves beyond traditional bibliometrics as a sole measure of scientific productivity by offering a framework for assessing the real-world impact of translational research across four domains: clinical, community, economic, and policy benefits.

While the TSBM framework offers a structured approach to capturing the diverse benefits of translational science, even creating a single case study using the model is a labor intensive process with one published case studying taking up to 9 hours to complete, which aligned with our experience also (Swanson et al., 2025). Applying TSBM to the vast corpus of all CTSA program outputs would require infeasibly high levels of subject matter expertise to perform case studies. This manually intensive process limits the scalability of the model for application to the CTSA program as a whole. Given that the CTSA publications contain valuable evidence of benefits, a more efficient solution is needed to highlight directly the many benefits that have been derived from the research funding.

Advances in Natural Language Processing (NLP) and Artificial Intelligence (AI) methods provide capabilities for extracting desired content from such large-scale document corpora. Toolkits such as the Python Natural Language Toolkit (Loper and Bird, 2002) have become commonplace and Large Language Models (LLMs) such as GPT4.0 (OpenAI et al., 2024) provide advanced text understanding and generation.

In addition to saving effort, a key motivation for a data-driven pipeline is that NLP enables benefits and topics to arise from the documents themselves and can extract benefits that may not be evident without such a bottom-up approach. Topic Analysis, such as Latent Dirichlet Allocation (LDA) (Blei et al., 2003), provides a broadly accepted method for analyzing a large data corpus. Without such an NLP system in place, demonstration of value relies largely on "top-down" methods for searching, querying, or targeted data mining that typically require specific pre-conceived ideas around potential benefits.

The Impact Analysis Team of the Coordination, Communication and Operations Support (CCOS) Center for the CTSA program has therefore developed an NLP-based software pipeline to apply the TSBM to the CTSA documents. This pipeline enables rapid identification of potential TSBM benefits across thousands of documents, significantly reducing the manual effort required for such analysis. LDA is applied to pre-processed publication, patent, and grant data to uncover emerging themes and patterns across these datasets. The identified topics are then mapped to TSBM benefits, allowing us to systematically link research outputs to potential impacts. This data-driven approach allows for the emergence of previously unrecognized benefits directly from the text of the program outputs, helps reveal the underlying structure of the data, and enhances our understanding of how different research efforts contribute to translational science benefits.

2 Materials and methods

2.1 Overview

This paper presents an innovative approach leveraging NLP and AI to automate the extraction of TSBM benefits from unstructured text in publicly available research outputs. By applying advanced topic modeling techniques, we systematically enrich publications, patents, and other research outputs with TSBM benefit categories.

The foundation of this NLP-driven approach is LDA, a generative probabilistic model that identifies latent topics within a collection of text documents by analyzing word distributions and co-localization patterns, where certain words tend to co-occur in similar contexts.

An overview of the NLP pipeline methods is given in Figure 1. In Step 1, CTSA specific data (National Center for Advancing Translational Sciences, 2024) is pre-processed and prepared for input to the LDA algorithm. In Step 2, The LDA is tuned to optimize its performance on the specific corpus of data. After LDA has created topics from the data, it assigns each document its probability of discussing each specific topic. Next, we use GPT4.0, an LLM, to assign short descriptive titles to each topic. Since this

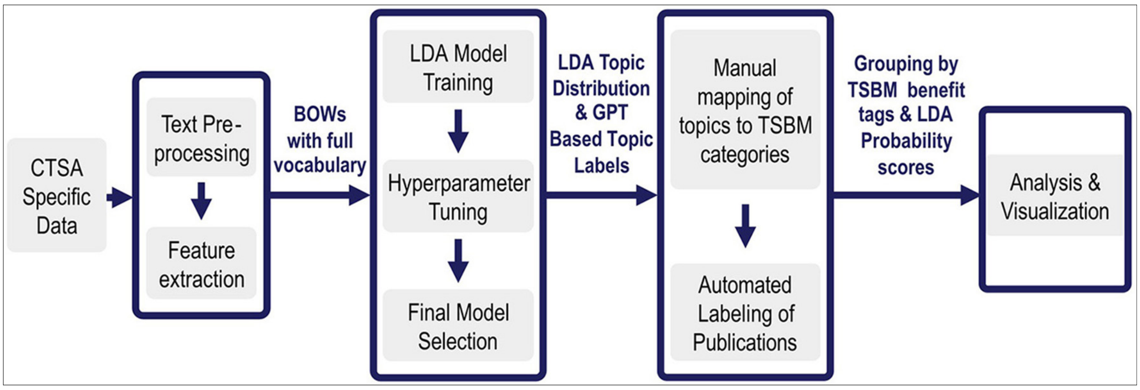

FIGURE 1
Overview of benefits extraction pipeline. Step 1: The pipeline ingests tens of thousands of CTSA specific documents and pre-processes them into a Bag of Words. Step 2: LDA then extracts a few hundred topics that are most prevalent in them. Step 3: Each topic is then assigned a label by GPT4.0 and given benefits tags by an SME. The appropriate benefits and goal tags are then automatically assigned to each appropriate document based on its prominent topics. Step 4: This enriched set of documents enables further automated analysis and visualizations. For the first time, the tagged datasets enable comprehensive impact analysis and interactive visualizations across over 100,000 documents, providing NCATS with a first-ever large-scale analysis of CTSA research benefits.

occurs on a manageable set of no more than a few hundred topics rather than tens of thousands of documents, it is feasible to validate the labels using a subject matter expert (SME). The LLM is thus used as an enhancement for understanding the topics, rather than as a foundational tool for generating them.

During expert validation in Step 3, each topic is manually assigned TSBM benefit tags based on the most important words in each topic, as described in detail in Step 3 below. Once this is completed for each topic, the automation then takes each document, looks at the probability scores assigned by LDA for each of its topics, and tags each document in turn with all the appropriate TSBM benefit tags based on the tags assigned to each of its high probability topics. This means that once a topic is tagged with TSBM benefits, all documents having a high probability for that topic inherit the same benefit tags. For example, if Topic 5 is linked to a community benefit, then all documents with a high probability score for Topic 5 receive the community benefit tag, ensuring consistent and scalable classification.

Finally, in Step 4, we conduct multiple types of benefits analysis and produce visualizations based on the topic-enriched and tagged data sets. The details for each of these major steps are presented next, followed by a discussion of the data sources and the flow of data through the pipeline.

2.2 Detailed methods

2.2.1 Step 1 text pre-processing

The first step required to apply LDA is text pre-processing. Its primary objective is to standardize the text representation while minimizing irrelevant or noisy information and we used well-established NLP pre-processing techniques to prepare the data for analysis, primarily using the Python NLTK (Loper and Bird, 2002):

- Convert all text to lowercase to avoid duplication of terms due to differential capitalization
- Remove special characters while retaining hyphenation that enhances meaning
- Tokenization to break text into words
- Part-of-speech tagging so that the same root word is counted separately for verb or noun forms
- Lemmatization (using WordNet) so that all forms of the same root word are counted together
- Remove standard stop words (such as “the” and “a”) that convey little meaning
- Removal of custom stop words including common acronyms, organizational names, and other irrelevant terms empirically derived from the CTSA corpus
- Convert numerical values (except dates) to words so all forms are commonly identified

LDA requires a standard Bag of Words (BoW) (Qader et al., 2019) representation that contains the features (words) to be used as input. We used CountVectorizer from SciKit-learn with the following parameters to create the BoW:

- max_df = 1.0: Includes all words regardless of their frequency.
- min_df = 2: Excludes terms that appear in fewer than two documents.
- n-gram_range = (1, 3): Captures unigrams, bigrams, and trigrams.

We chose CountVectorizer over TfidfVectorizer based on established best practices for LDA pre-processing. LDA is a generative probabilistic model that assumes documents are generated from mixtures of topics, where topics are distributions over words. The model works with raw word counts (document-term frequency) rather than normalized weights, as it needs the actual frequency information to estimate the multinomial distributions that underlie the topic-word and document-topic relationships.

TfidfVectorizer applies term frequency-inverse document frequency weighting, which downweights common words across the corpus. However, this pre-processing can interfere with LDA's ability to identify topics, as some frequently occurring words may actually be important topic indicators when considered in their proper distributional context. Additionally, LDA's internal processes already account for word frequency patterns through its Dirichlet priors and sampling procedures.

This choice aligns with standard LDA implementations and recommendations in the literature (Blei et al., 2003). Scikit-learn was selected for its robust, well-documented implementation and seamless integration with our pre-processing pipeline

These pre-processing steps were applied separately to each of the datasets used, and the BoW for each dataset was given as input to the next step.

2.2.2 Step 2 LDA modeling

LDA modeling is a two-part process (Blei et al., 2003; Rehurek and Sojka, 2010). In the first part of LDA, topics are generated by comparing word co-occurrence across the full corpus to identify latent topics present in the corpus and then create a topic model. This helps create an initial set of topics. In the second part of LDA, a document is compared to a previously created topic model, and the document is assigned a probability (score), representing the extent to which it is associated with each topic in the model. These probability scores help determine which topics are most relevant to a given document.

2.2.2.1 Model generation

A critical aspect of LDA modeling is the careful selection of hyperparameters to balance thematic granularity, interpretability, and computational efficiency. In Binkley et al. (2014) underscore the necessity of informed and context-dependent parameter selection in LDA applications rather than universally applicable LDA parameter values. Following this principle of corpus-specific parameter selection, we empirically tested threshold values from 0.1 to 0.5 on both datasets. For the smaller patent corpus (350 documents), empirical testing revealed that higher thresholds were necessary to reduce noise and spurious topic assignments that were more prevalent in the smaller dataset. A threshold of 0.3 provided the optimal balance between meaningful topic assignments and document coverage. For the larger publication corpus (∼130,000 documents), a threshold of 0.2 maintained broad coverage while preserving semantic relevance, as the larger sample size provided more robust topic-document associations.

We implemented LDA using the Gensim library (Rehurek and Sojka, 2010), a widely used framework for topic modeling in Python, and systematically tuned the following key parameters:

- Number of Topics: Determines the granularity of topics. We optimized this parameter iteratively, balancing meaningful groupings with interpretability.
- Alpha (document-topic distribution) and Eta (word-topic distribution): Control the sparsity of topic distributions. These parameters fine-tune how specific documents align with individual topics and how words are distributed across topics.
- Passes, Update Every, and Iterations: Impact model stability and convergence by controlling the number of revisions in topic assignments.
- Chunk size and Learning Method: Influence the efficiency and scalability of the model, particularly for large datasets.
- Random Seed: Set to ensure reproducibility.

To evaluate the effectiveness of our topic modeling approach and fine-tune the hyperparameters, we considered a combination of quantitative and qualitative evaluation metrics: We measured the semantic consistency of the topics using the coherence metric, u_mass, which evaluates the co-occurrence patterns of word pairs within topics. Supplementary Figure 5 shows the coherence score for different topic numbers in the publication data. While high coherence scores are often considered a sign of topic quality, we found that they do not always correlate with effective topics. In some cases, models with slightly lower coherence scores produced more distinct topics, which proved more useful for grouping related documents. The highest coherence scores for publication data using fixed hyperparameters were observed for topic numbers 250 and 300. Based on SME reviews of the topics, topic number 300 was determined to be the best fit for the publication data. Consequently, hyperparameters were initially selected based on coherence scores, and further fine-tuning was performed with input from SME. Reviews were conducted to ensure the topics were both semantically coherent and sufficiently distinctive for analytic clustering tasks, as well as the accurate representation of the underlying themes within the corpus.

We separately tuned the hyperparameters for each of the models that were created from the discrete document types: publications, projects, and patents. Supplementary Figure 6 shows an example of the final hyperparameter tuning for Project Dataset. The final hyperparameters used for each dataset are summarized in Table 1.

The output of LDA for each model includes a list of topics and the word-topic distribution matrix, which shows the probability of each word contributing to specific topics. This helps identify the most relevant terms for each topic and aids in the interpretation of the discovered topics. For interpretability, the top 10 most frequent words for each topic were extracted from the LDA model, providing key terms that define each topic. This is a widespread practice to make topics more interpretable (Blei et al., 2003). Additionally, we leveraged PyLDAVis outputs to identify the top relevant words for each topic (Sievert and Shirley, 2014), since the LDA model itself provides only the most frequent words.

2.2.2.2 Application of models to datasets

Note that once a topic model is generated by the LDA algorithm from a corpus of documents, it can then be applied to the same corpus from which it was generated and the LDA model will assign a probability that each document discusses each specific topic in the model (Blei et al., 2003; Blei and Lafferty, 2009). A generated topic model, however, is not limited in application to solely the documents from which it was created. Any corpus of documents can be pre-processed and a model generated from a distinct set of documents may be applied to it. A document may be compared to any LDA model and be assigned a score for the topics the model contains.

The output of the application of an LDA model to a dataset is the document-topic distribution matrix. This provides the probability of each document being associated with each specific

TABLE 1 Final hyperparameter configuration for the topic model from datasets publications, patents, and grants/projects.

Model data source	Number of topics	Passes	Update every*	Iterations	Learning method	Chunk size	Alpha	Eta	Random state
Publications	300	5	5	100	Online	10,000	0.5	0.0001	0
Patents	150	5	5	50	Online	20	0.1	0.0001	0
Grants/projects	100	1	1	50	Online	20	0.5	0.0001	0

*Update_every is the LDA hyperparameter that controls how often the model updates its parameters during training.

topic in the model. This allows us to understand how strongly a document relates to different topics, which is key for interpreting the thematic relevance of individual documents.

In the current work, we applied two topic models to the Grants/Projects dataset. We first applied the topic model generated from the Grants/Projects dataset itself to all the Grants/Projects documents. Next, we applied the LDA model, which was generated from the larger corpus of publications to the Grants/Projects dataset. We found that many of the documents contained latent topics that were explored in greater detail in the publications, which were more appropriate for analyzing benefits (see Section Results).

We also applied two models to the Publications data set, both the one generated on the Publications data (see Section Results below) and the one generated on the Grants/Projects data.

We applied only the Patents LDA Model to the patent data due to the prevalence of patent legal jargon in these documents and present the results below.

2.2.2.3 Generation of short labels for each topic

Since listing large numbers of topic words in visualizations for subsequent data analysis can be counterproductive, having short meaningful labels for each topic facilitates labeling the topics in analytics and graphics. The top 30 most relevant words and top 30 most frequent words per topic were input into GPT-4.0, which generated a topic label. Guidelines for the prompts used in this process are given in Supplemental Table 1. An SME then validated and refined these labels before applying benefit tags. The ChatGPT prompt objective was to extract labels based on relevant and frequent words from the datasets with relevant words weighted higher. Each short label was then included in the spreadsheet alongside the relevant and frequent words for SME review described in **Step 3**.

2.2.3 Step 3 tagging of topics and documents

2.2.3.1 Human in the loop tagging of topics

Manual tagging of each topic with its appropriate benefits category by a SME is feasible since it occurs at the level of a few hundred or fewer topics, and not directly for each of thousands of documents. Using a spreadsheet that included the 30 most relevant words for the LDA topic, the 30 most frequent words for the LDA topic, the short labels generated by GPT-4.0, and the descriptions of TSBM benefits categories and subcategories from the latest revision of the TSBM (Luke et al., 2018), GPT-4.0 assigned initial TSBM tags and a SME reviewed each topic in the spreadsheet. A 1 (TRUE) tag was assigned to all relevant benefits categories in a designated column when the topic matched a benefit description. The SME also documented supporting terms from the relevant word list in another column and categorized the topic within the TSBM framework in a separate column to facilitate a secondary review of the assignments. A secondary review was conducted by spot-checking. This followed the same process as that described for the manual tagging but was performed by a second SME to ensure that the benefits assignments agreed.

2.2.3.2 Manual review of short topic labels

During the Manual Tagging of Topics, the SME also validated the short labels and made corrections or refinements as needed.

2.2.3.3 Automated tagging of documents

After completion of the manual reviewing and tagging, an automated process applied the TSBM benefit tags for a topic to all documents with a topic score of 0.2 or higher for that specific topic for Projects/Grants and Publications. A score of 0.3 was used for Patents accounting for the small number of patents present. By manually tagging just a few hundred topics and automatically transferring the tags to documents having those topics, a large corpus can be effectively tagged with expected TSBM model benefits assigned to each appropriate document.

2.2.4 Step 4 analysis and visualizations of pipeline outputs

Analysis and visualizations are of primary importance in understanding the topic models, their application to the data and to evaluating the results of the automated tagging system. Using the word-topic distribution matrix output by the first part of LDA that shows the probability of each word contributing to specific topics helps identify the most relevant terms for each topic and aids in the interpretation of the discovered themes. We also leverage the topic distribution matrix output by the second part of LDA that gives the probabilities that each document has a topic. To explore and visualize these outputs, we utilized heatmaps, Principal Component Analysis (PCA) (Jolliffe, 2002), t-Distributed Stochastic Neighbor Embedding (t-SNE) (Van der Maaten and Hinton, 2008), and clustering techniques. Each of these methods provided complementary insights into the underlying structure of the data.

2.2.4.1 Heatmap generation

We converted the topic distribution matrix from the LDA into a DataFrame to analyze the topic probabilities across individual documents. This DataFrame was further enriched by integrating metadata, such as PMID, year, and organization names. Including such metadata enables contextual analysis and allows us to observe how topics are distributed across distinct groups.

A heatmap was generated to visualize the distribution of topics across organizations or hubs. Min-max scaling was used to normalize the topic probabilities within the range of [−1, 1], making it easier to compare topics across documents. Hierarchical clustering (Ward's method, Euclidean distance) was applied to reorder columns in the heatmap to reveal patterns of similarity between documents or topics. This approach is well-suited for identifying hierarchical relationships between topics (Müllner, 2011).

2.2.4.2 Visualizing topic clusters

Clustering was performed to visualize the LDA output. Although LDA is a soft clustering method, it can be difficult to interpret its results in high-dimensional data like publications and project corpora without further analysis. When applying the model to a dataset, the topic probability distribution table will give a score for every topic to every document, and therefore selecting a cutoff score for considering that the topic is significantly present in the document is a key, tunable feature.

We explored multiple methods for clustering documents based on their topics including PCA on LDA Topic Distribution, PCA on TF-IDF, K-means clustering, Naïve LDA (Sun, 2014), and LDA-Max. We selected LDA-Max, further supplemented with T-SNE, based on empirical exploration and spot-checking of clusters to ensure meaningful and cohesive groupings of documents, which was evaluated by comparing them to document titles and abstracts.

Under results, we show these LDA topic models applied to different datasets. The top 5 topics in projects/grants, patents, and publications were identified using the LDA-MAX approach, where each document was assigned to its most probable topic based on the highest topic probability score after the cutoff. This process is not needed to count the benefits but is useful for visualizing how the overall corpus is organized and what topics are part of its primary focus.

Notably, some topics encompass multiple subtopics and there may be nearly duplicated topics produced by the LDA. This requires tuning to balance increasing the number of topics to reduce compound topics while minimizing the redundancy of too many very closely related topics. We tested topic models with 25, 50, 75, 100, 150, 200, 250, 300, and 350 topics on publications. The 300-topic model provided a good balance, yielding distinct topics with minimal repetition yet does have subtopics in some of the topics.

2.2.4.3 Inclusion of MeSH terms

The National Library of Medicine has developed an extensive system for assigning Medical Subject Headings (MeSH) terms to publications. This system is built upon a vast corpus of scientific literature, leveraging human curation and algorithmic methods to standardize topic categorization. MeSH terms serve as controlled vocabulary descriptors that categorize biomedical and health-related research, making them a valuable tool for contextualizing the impact of translational science. To enhance topic modeling outputs and explore whether additional insights could be gained, particularly in domain areas with fewer TSBM tags, we incorporated MeSH terms into select clustering visualizations when using publications as the dataset.

This supplementation was directed primarily to enhance subsequent analysis and exploration of the research outputs and specifically aimed to:

- Refine topic clusters by incorporating additional structured metadata
- Identify underrepresented areas in the TSBM framework by detecting Research Topics heavily represented in MeSH but with sparse TSBM tagging

MeSH terms were integrated into the clustering process in the following ways:

- Co-occurrence Analysis: We cross-referenced MeSH terms assigned to publications in our dataset with the topics generated by LDA. This quantified the overlap between NLP-identified themes and MeSH-annotated research categories.
- Topic Enrichment: After running LDA topic modeling, we mapped MeSH terms to the top words in each generated topic. The presence of MeSH terms in the generated topics validated topic coherence and identified areas where TSBM benefit tags were sparse but significant biomedical themes emerged.
- Identifying Additional TSBM Benefits: After running the LDA topic model, we mapped certain MeSH terms to the TSBM Benefits. The presence of these MeSH terms was used for comparison to assign TSBM Benefit tags. Comparisons between TSBM-tagged and MeSH-tagged research outputs could reveal areas where one method or the other identifies unique benefits and serve to reveal the overlap between the approaches.

2.3 Data sources and pipeline data flows

This study utilizes three key datasets: Projects/Grants, publications, and patents, all integral components of the CTSA program (Figure 2). These datasets were selected for their relevance in identifying and tagging societal benefits in research, aligned with the CTSA program's mission to accelerate the translation of research into clinical practice. The titles and abstracts from each dataset were chosen due to their ability to succinctly summarize the core themes, goals, and findings of the research while enabling computational feasibility compared to the processing of entire documents.

2.3.1 Publication data set

The data for publications were sourced using ExPORTER [National Institutes of Health (NIH), 2023], a publicly available resource that provides bulk administrative data from NIH RePORTER. CTSA-specific hub projects (National Center for Advancing Translational Sciences, 2024) were identified using Notice of Funding Opportunity Numbers (NOFOs) as filters, and publication IDs (PMIDs) linked to these projects were extracted through ExPORTER's link tables. Using these PMIDs,

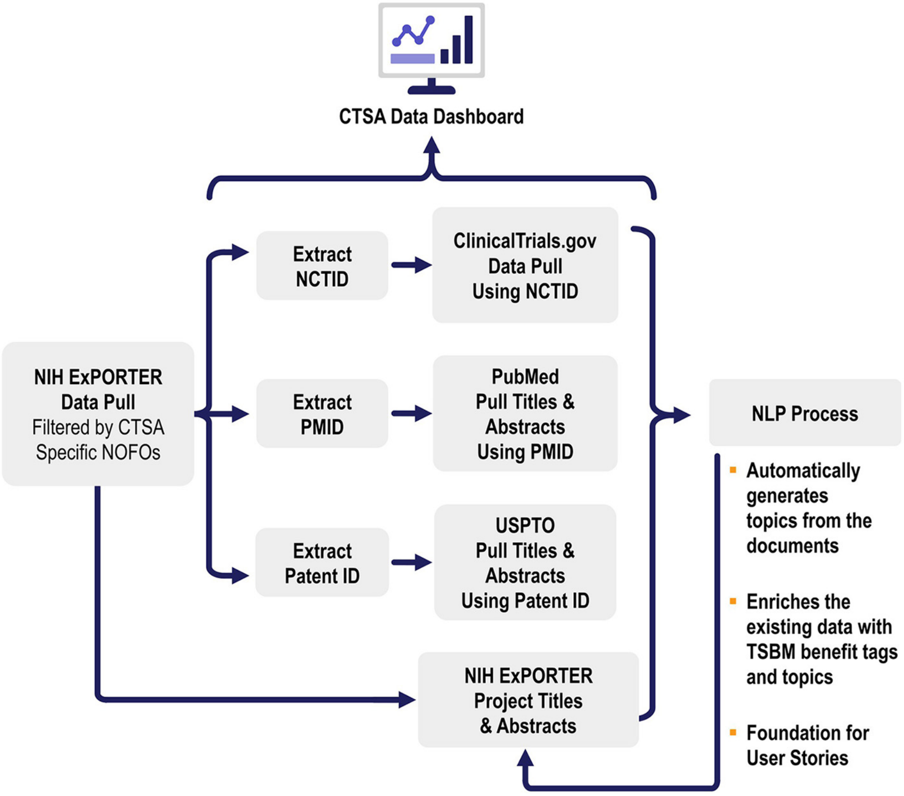

FIGURE 2
Data sources and data workflows. This figure illustrates the data workflows for automated translational science benefits model impact extraction. The process begins with data pulled from NIH ExPORTER filtered by CTSA-specific NOFOs, followed by the extraction of NCTIDs, PMIDs, and Patent IDs. These identifiers are used to pull data from ClinicalTrials.gov, PubMed, and USPTO, respectively. The extracted titles and abstracts are then processed using NLP and the results are used to enrich the pulled data.

we obtained CTSA-specific publications, enabling the extraction of associated publication records. Since ExPORTER lacked the detailed textual data required for the topic analysis, we enriched the dataset using the PubMed API. This process added abstracts, MeSH terms, keywords, and other essential metadata, ensuring a more comprehensive resource. Quality control measures included removing duplicates and filtering publications based on organization names and activity codes.

Initially, publications were identified based on Notice of Funding Opportunity (NOFO) filters. After extracting metadata for publications and filtering by hub, activity code, and project-aligned publication years, we deduplicated records with identical titles and abstracts. The final dataset only included the deduplicated results.

2.3.2 Patent data set

Patent data was sourced from ExPORTER by linking the NOFO-filtered project IDs to related patents. Metadata, including abstracts, titles, and filing dates, were retrieved through the PatentsView API. In alignment with the TSBM model, patents are considered a direct economic impact, as they represent tangible innovations that have the potential to lead to commercialization, contributing directly to societal and economic benefits.

Initially, patents were identified through project links. After filtering based on CTSA hub organization names and activity codes, and deduplicating records, only the patents that remained were included in the final dataset.

2.3.3 Project/grants data set

The Project Data Set consisted of grant data that was sourced from ExPORTER and filtered by NOFOs. Key fields such as abstracts, titles, health relevance, and associated terms were included in the data set.

Grant abstracts were first identified, then filtered by hub-specific activity codes and organization names, and finally deduplicated to yield the final set of projects.

2.3.4 Information from ClinicalTrials.gov

Although not directly included in the benefits extraction pipeline, CTSA-funded clinical trials information was extracted as meta-data.

3 Results

This section presents the outcomes of our NLP-driven benefit extraction pipeline, demonstrating how LDA topic modeling and automated tagging facilitate the identification of TSBM benefits

(1) Projects (2) Patents (3) Publications

FIGURE 3
BoW Results. The visualizations presented in this figure illustrate the thematic focus of CTSA research across three distinct datasets: Projects/Grants, Patents, and Publications. Each word cloud highlights the most frequently occurring terms within the respective dataset, providing a visual summary of the key research themes and priorities.

across CTSA-funded research outputs spanning CTSA hub grants awarded from 2006 to 2023. The corpus comprised 127,958 publications and 352 patents linked to 1,296 grants. We first conducted a BoW analysis, which provides an initial thematic overview of CTSA research by highlighting frequent terms in Projects/Grants, patents, and publications. We then examine the application of LDA topic models on the datasets. We summarize the distribution of extracted benefits, detailing which categories, clinical, community, economic, and policy, were most prevalent and where the gaps remain. We compare the results of this topic-based analysis to the use of benefits identified with MeSH-based classifications to assess the strengths and limitations of each method. Next, we present topic trends using heatmaps to visualize how Research Topics align across the CTSA program and its hubs. Finally, we present the LDA topic modeling results, illustrating how different datasets group into distinct research themes and how these topics map to TSBM benefit categories.

3.1 BoW results

The BoW analysis provides an initial thematic overview of the CTSA-funded datasets by identifying the most frequently occurring terms in different datasets. Figure 3 illustrates word clouds generated for projects/grants, patents, and publications. We find that the word frequencies accurately reflect the different purposes of these types of documents.

In the Projects/Grants dataset, the word cloud highlights key terms such as “community,” “training,” “development,” “career,” and “support,” reflecting a strong emphasis on workforce development, mentorship, and community engagement within translational science initiatives that reflects the purpose of the grants funded by CTSA. The Patents dataset is characterized by terms like “treat,” “device,” “cell,” and “treatment,” underscoring a focus on medical innovations, therapeutic interventions, and biotechnology advancements appropriate to a corpus of documents referencing novel inventions created with CTSA funding. The Publications dataset prominently features words such as “cell,” “patient,” “disease,” “cancer,” “association,” and “risk,” indicating a strong concentration on disease research, clinical applications, and patient outcomes as would be expected for scientific publications of research results in translational science. Collectively, these results illustrate the distinct yet complementary research priorities across CTSA-funded projects, patents, and publications.

3.2 LDA results

LDA topic modeling was applied to CTSA-funded projects, publications, and patents to identify thematic structures and research focus areas represented as topics. Three distinct LDA models were generated, each optimized for its respective input dataset and tested for applicability on both its own and other relevant datasets. Here we present in detail the resulting LDA models including their top topics and topic distributions.

We generated three LDA topic models from these datasets:

- Projects/Grants LDA Model, generated from the titles and abstracts of NCATS funded grant applications aligned well with NCATS and CTSA strategic goals but proved less useful for TSBM benefit identification due to their high-level nature. As might be expected for a grant application, many of these abstracts focused on the core mission of the CTSA and the topics identified in these documents reflect that.
- Publications LDA Model, generated from titles and abstracts of CTSA-linked publications, produced detailed, domain-specific topics, many of which aligned directly with TSBM categories and subcategories. The greater scientific detail present in journal abstracts combined with far larger numbers of publications than project abstracts, enabled the Publications model to have a rich set of research-related topics.
- Patents LDA Model, generated from title and abstracts of CTSA-linked patents, captured the distinct vocabulary and purpose of patents compared to scientific publications. Unsurprisingly, given the highly specific nature of patents and their legal requirements, this model was more focused on specific invention description language, pragmatic utility than the model derived from publications

In Figure 4, we show these LDA topic models applied to different datasets

We applied the Projects/Grant Model to Projects/Grant Data (see Figure 4A). We found that this revealed the projects (grant abstracts) aligned well with NCATS and CTSA strategic goals but were not as useful for TSBM benefits (see Figure 4A). The

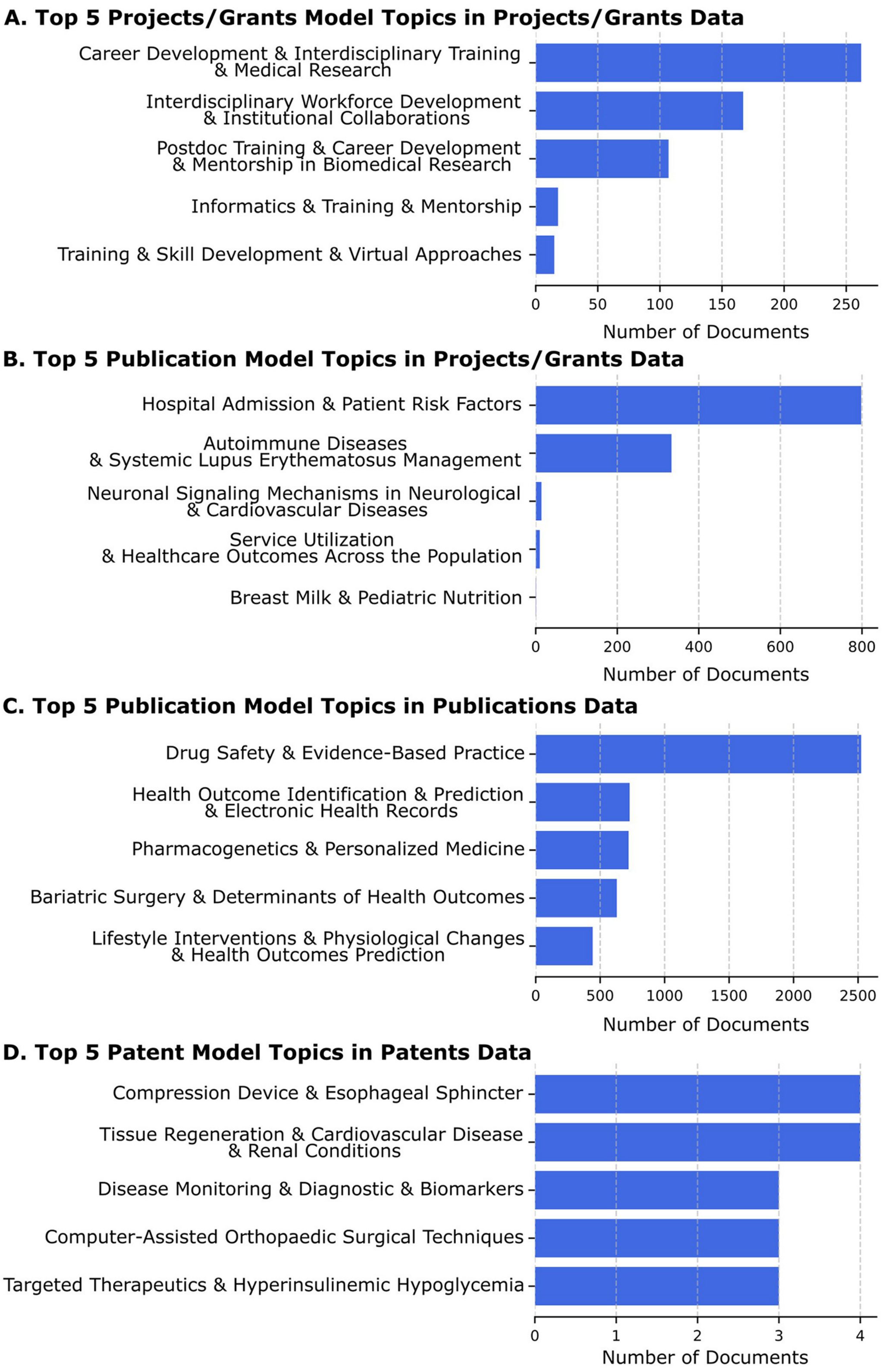

FIGURE 4
The top 5 topics for each model application to a dataset are shown, along with a bar graph of the number of documents assigned to that topic with a high probability by the LDA model on that corpus. The labels shown are the short ones derived from GPT4.0. **(A)** The top 5 patent model topics found in projects/grants are based on the highest LDA probability scores. The leading topic, "Career Development and Interdisciplinary Training and Medical Research" has over 250 grant abstracts assigned. **(B)** The top 5 publication model topics seen in projects/grants are based on the highest LDA probability scores. The leading topic, "Hospital Admission and Patient Risk Factors" has over 800 projects associated with it based on LDA probability

(Continued)

FIGURE 4 (Continued)
scores. It is an example of a compound topic that still includes two related topics, both of which would be expected to be well-represented in translational science grant applications. **(C)** The top 5 publication model topics assigned to publications based on the highest LDA probability scores. The leading topic, "Drug Safety and Evidence-Based Practice" has about 2,500 publications associated (out of the more than 100,000 in the corpus) with it based on LDA probability scores. It appears to be an appropriate topic that would be expected to be found in many translational science research publications. **(D)** The top 5 patent model topics assigned to patents based on the highest LDA probability scores. The leading topic is found in just 4 of the 352 patents, not surprising given that a patent by its nature is expected to describe a unique invention.

leading topic, "Career Development & Interdisciplinary Training & Medical Research" has over 250 project/grant documents assigned to it based on the probability scores, highlighting its prominence, it also appears to be a compound topic, with each subtopic likely to be well-represented in a translational science grant application. We also applied the Projects/Grant Model to the Publications data but also found this did not facilitate the identification of TSBM benefits (data not shown).

To achieve improved alignment with TSBM, we examined the Projects/Grants data set using the model we generated using the Publications data (see Figure 4B). This process was able to identify many TSBM benefit related topics. The leading topic, "Hospital Admission & Patient Risk Factors" has just under 800 grant abstracts associated with it based on LDA probability scores. This topic seems appropriate for an analysis of applications to conduct clinical research in accordance with the NIH Opportunity descriptions, and it would be expected that most Project/Grant titles and abstracts would include this topic.

We next applied the Publications Model to the publications data itself, and this produced a wealth of highly relevant topics, showing the publications data to be a rich source of potential TSBM benefits (see Figure 4C). The leading topic, "Drug Safety & Evidence-Based Practice" has about 2,500 publications (out of the 100,000+ publications) associated with it based on LDA probability scores. This topic is also expected to be well-represented in a corpus of publications resulting from translational science research.

Finally, we applied the Patents Model to the patents data. Since the language used in patent applications is very specific for patent legal requirements and uses common jargon, this model was the only one that we tested on the patent data (see Figure 4D). The leading topic, "Compression Device & Esophageal Sphincter" has 4 associated patents. The entire corpus of patents is 352 documents, and a patent is expected to be unique, so a much lower number of patents sharing similar topics is also expected by the documents. The method can still serve to identify small groups with related topics that may highlight advancements in translational science within a highly focused medical area.

3.3 Automated extraction of the TSBM benefits and summary counts

Following the generation of the topics, their association with benefits tags, and the assignment of tags to each document based on its topics, counts were made of each of the types of benefits identified. The results indicate that clinical and community benefits were most effectively identified using the Publication Model applied to Projects/Grants and Publications data. We note that while grant applications discuss benefits, these are potential benefits since the project/grant abstract is proposing a research approach rather than reporting on research accomplishments, while publication data reflects research that has been conducted with benefits partially or completely realized.

TABLE 2 **Summary of total number of documents tagged with TSBM potential benefits.**

Benefit category	Projects/grants*	Patents	Publications
Clinical	1,158	87	6,380
Community	546	0	5,874
Economic	14	352**	638
Policy	517	2	419

*Refers to the Publication Model applied to Projects/Grants data. Note that the tagged documents do not represent direct TSBM benefits, as they originate from grant applications via NIH ExPORTER and instead reflect research aspirations rather than realized outcomes.

While economic benefits were less prominent in Projects/Grants and Publications data, all 352 Patents were tagged with Economic Benefit, as Patents are inherently classified as such under the TSBM framework. In addition, clinical benefits were identified in 87 Patents shown in Table 2.

3.4 MeSH term comparison

We selected a subset of MeSH terms that were related to TSBM to examine how their use compares to the NLP pipeline. Figure 5 shows that many of the benefits captured by the LDA-extracted topics are not captured by the MeSH terms. This may be due to the structured nature of MeSH classifications, which are based on a broad range of scientific publications, whereas NLP-driven insights are more directly tied to the actual outputs of the CTSA program. Although many publications may contain MeSH terms that could suggest potential benefits, their relevance has not been systematically verified. Specifically, it remains unclear whether the presence of a single MeSH term provides sufficient evidence that a publication contains a benefit that aligns with the TSBM. Verifying this is beyond the scope of the current project.

3.5 Overview of topic to CTSA hub organization relationships

The heatmaps in Figure 6 visualize the distribution of topics across CTSA hubs, providing insights into research focus areas and the concentration of specific themes within organizations.

FIGURE 5
A Venn diagram of the publications found to contain TSBM-related MeSH terms compared to the automated TSBM benefits tags on Publication data. The majority of the publications found to have TSBM specific benefits identified with the automated process are not identified using MeSH terms. Further investigation is required to see if the publications containing a TSBM-related MeSH term in fact describe a benefit that fits the TSBM.

The y-axis shows three selected examples of topics, while the x-axis corresponds to 10 example hub organizations (anonymized), demonstrating the possibility for a comparative analysis of the prevalence of topics across institutions. A full set of topics vs. CTSA hubs is shown in Supplementary Figures 1–4.

Bright rows indicate ubiquitous topics that are widely represented across multiple hubs, while bright segments within an otherwise rather dim row highlight institution-specific focus areas. Conversely, dark rows signify topics with less emphasis across all hubs, reflecting areas of limited engagement. These patterns offer a data-driven perspective on institutional research strengths and thematic priorities within the CTSA program. Shared topics likely indicate potential or existing research collaborations.

Compared to the projects and publications topics that include many widely shared among hubs, the patents show more unique focus areas as would be expected for the development of a unique, patentable invention.

3.6 t-SNE projections of LDA topics across CTSA datasets

An alternative to looking at heatmaps to identify shared topics, is to look at how each data item (project, publication, or patent) clusters with other data items based on topic similarities. t-SNE projections were used to visualize thematic relationships within each dataset and across LDA models. Each point in the figures represents a document, colored by its most prominent topic, with large clusters therefore visualizing the most predominant topics in each corpus.

3.6.1 Project/grant dataset analyzed with the projects/grants LDA topics model

The t-SNE projection of LDA Projects/Grants Topics on CTSA Projects/Grants data shown in Figure 7 visually captures the program's thematic landscape. Using LDA with 100 topics, we identified key research areas, with each point in the t-SNE plot representing a project grant, color-coded by its most prominent topic. The clustering reveals groupings of similar Projects based on their most dominant topic, highlighting areas of concentrated research efforts. Notably, grants related to "Informatics & Training & Mentorship" (brown) and "Career Development & Community Education" (blue) form distinct, dense clusters, suggesting strong thematic coherence indicative of close similarity among these grants with respect to this topic. In contrast, topics such as "Interdisciplinary Workforce Development and Institutional" (orange) appear more dispersed, potentially reflecting that while a large group of grants discuss this topic, they do so with different emphasis. These patterns illustrate the diverse yet interconnected nature of CTSA-funded research.

FIGURE 6
Heatmaps of LDA topic distributions across CTSA Hubs. **(A)** Project/Grants model topics in Projects/Grants data, **(B)** Publication model topics in Projects/Grants data, **(C)** Publication model topics in Publications data, **(D)** Patent model topics in Patents data, showing topic frequency for three example topics across 10 example organizations named anonymously. Blue indicates low topic prevalence in a hub, while yellow represents high prevalence. Full figures displaying the complete dataset can be found in Supplementary Figures 1–4.

3.6.2 Project/grant dataset analyzed with the publication LDA topics model

The t-SNE projection of LDA Publication Topics on CTSA Project/Grants shown in Figure 8 offers a detailed view of the program's research outputs, highlighting key areas of focus in contrast to the broader project topics. Using LDA with 300 topics, this visualization maps each project as a point, color-coded by its dominant Research Topic.

The clustering reveals distinct topic groupings, showcasing concentrated research efforts. The two most dominant topics across multiple projects are "Hospital Admission & Patient Risk Factors" and "Autoimmune Diseases & Systemic Lupus Erythematosus Management." These topics, initially identified in publications, also appear prominently in the project data, indicating their widespread relevance and significance in CTSA-funded research. Each grant likely references additional specialized topics but, in this figure, we are only highlighting the single most predominant topic for each grant.

This analysis highlights that while these topics are present in the grant data, their significance becomes evident only through the publication-based model. They did not reach a level of significance in the Grants/Projects model. The use of the publication model offers a more nuanced perspective on CTSA-funded research, revealing both well-established areas and emerging fields that may not be as prominent in project grants. The model uncovers the interconnections between themes, demonstrating the program's role in supporting both ongoing research and innovative, specialized studies.

FIGURE 7
t-SNE Projection of LDA Topics of Projects/Grants Dataset Analyzed with the Projects/Grants Topic Model. Each point in the figure represents a project grant that is color-coded by its most prominent topic. Clusters reveal closely related projects, and the key gives the list of the top 10 topics found within the Project/Grants model when applied to the Projects/Grants dataset.

3.6.3 Publication dataset analyzed with the publication LDA topics model

The t-SNE projection of LDA Publication Topics on CTSA Publications as shown in Figure 9 offers a snapshot of the program's vast research output, covering over 130,000 publications. Using LDA with 300 topics, this visualization provides a detailed mapping of research themes, with each point representing a publication color-coded by its dominant topic.

Due to the large number of publications covering a wide range of topics, the data forms many clusters of closely associated publications. Several topics are dominant, with "Drug Safety & Evidence-Based Practice" being the most widely observed, clearly aligning with the goals of translational science. Other highly prevalent topics include "Health Outcome Identification & Prediction & Electronic Health Records" and "Pharmacogenetics & Personalized Medicine," which emphasize advancements in predictive healthcare and personalized treatments. Beyond these larger clusters, even the smaller ones reveal additional specialized topics, further demonstrating the breadth of research in the CTSA Program. While some relevant topics are not shown here due to highlighting only the most dominant topic in each publication and only the top 10 topics for the model, the additional topics still contribute to the overall impact of the research landscape.

3.6.4 Patent dataset analyzed with the patent LDA topics model

The t-SNE projection of LDA Patent Topics on CTSA Patents as seen in Figure 10 shows a focused landscape of technological innovation and medical advancements. The figure shows a distribution of patents where no single topic stands out as dominant, which is consistent with the observation in Figure 4, where the leading topic appeared in only four documents. This aligns with the inherently specialized nature of patents indicating a diverse range of innovative efforts across multiple domains, reflecting the program's broad support for pioneering technologies in healthcare. The topics shown in the figure tend to be more unique and specific, further underscoring the focused and specialized nature of patent-related research within CTSA-funded projects. In summary, this pattern reflects the targeted and niche

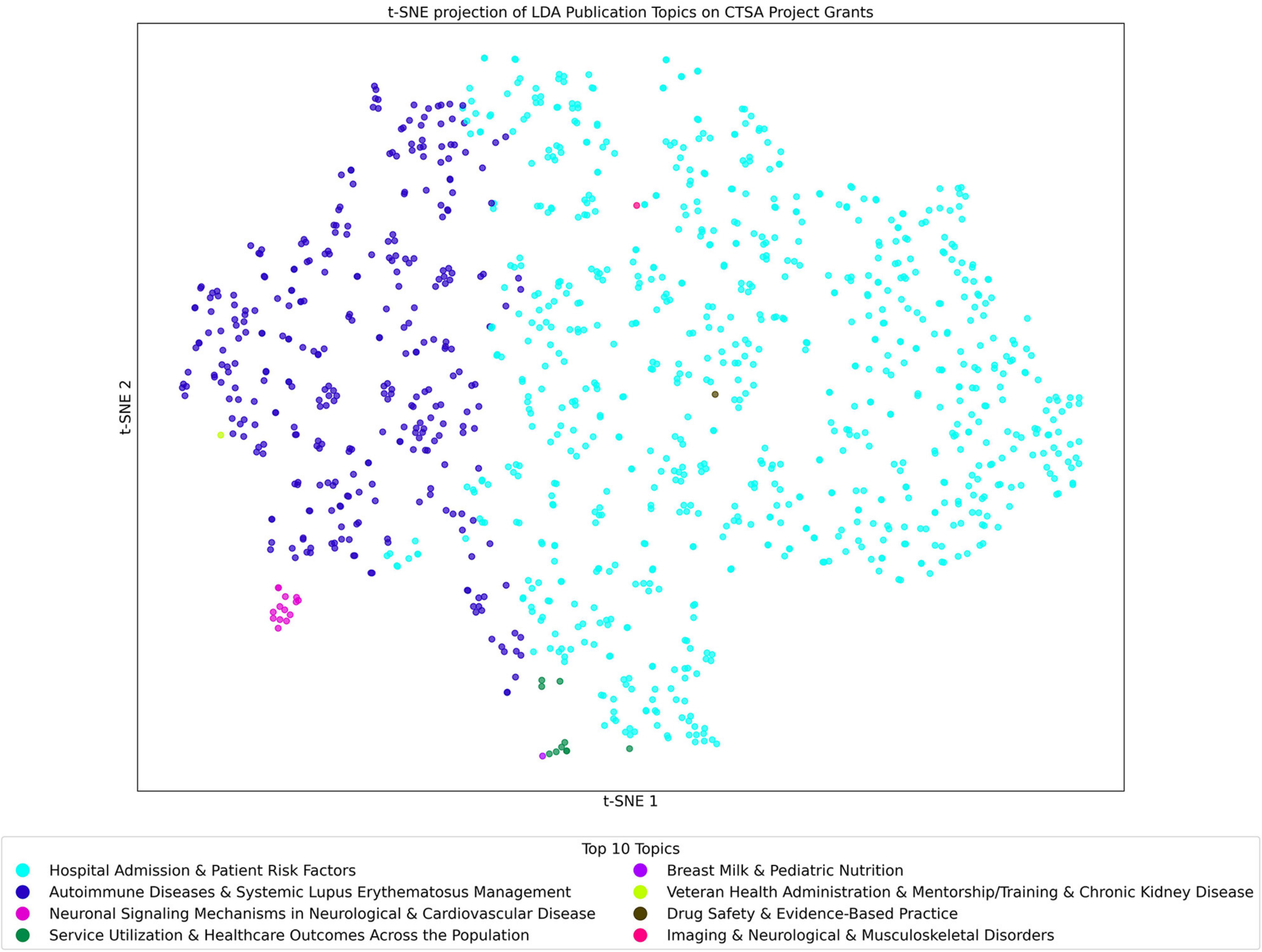

FIGURE 8
t-SNE Projection of LDA Topics of Project/Grant Dataset Analyzed with the Publication Topic Model. Each point in the figure represents a project grant that is color-coded by its most prominent topic. Clusters reveal closely related projects, and the key gives the list of the top 10 topics found within the Publication model when applied to the Projects/Grants dataset.

nature of the topics present in patents while confirming that, as expected for unique inventions, only a few examples of shared topics exist.

4 Discussion

By automating the application of the TSBM to CTSA-funded research outputs, this NLP-driven approach enhances both the efficiency and scalability of translational research impact analysis. Swanson et al. reported that completing a single case study required ~9 h, which aligns with our own manual case study experience. Extrapolating this effort across the full corpus of CTSA-funded outputs would require thousands of hours of SME time (Swanson et al., 2025). By applying LDA topic modeling to publications, patents, and project grants, we identified their innate topics and mapped them to the TSBM framework reducing SME time to reviewing the hundreds of topics instead of the hundreds of thousands of documents. This approach augments bibliometrics, extracts a considerable amount of additional benefit information that is complementary and larger in scope and quantity to that found with MeSH terms, and enhances our understanding of how translational research contributes to public health, clinical advancements, policy changes, and economic benefits. To our knowledge, it is the first attempt to apply the TSBM at the scale of an entire program with over a hundred thousand research outputs.

The option to leverage LDA over trained methods such as SVM analysis was essential due to the lack of available training data for such machine learning tools. While a number of case studies using the TSBM have been published, their numbers are too small to support an accurately trained learning machine across all the variations of the TSBM benefits categories and the differing types of subcategories that can lead one of the four major benefits types. A methodology such as LDA that allows the topics to emerge from the corpus of documents, and the utilization of human expertise to match those topics to the TSBM benefits categories enabled a feasible approach to automation.

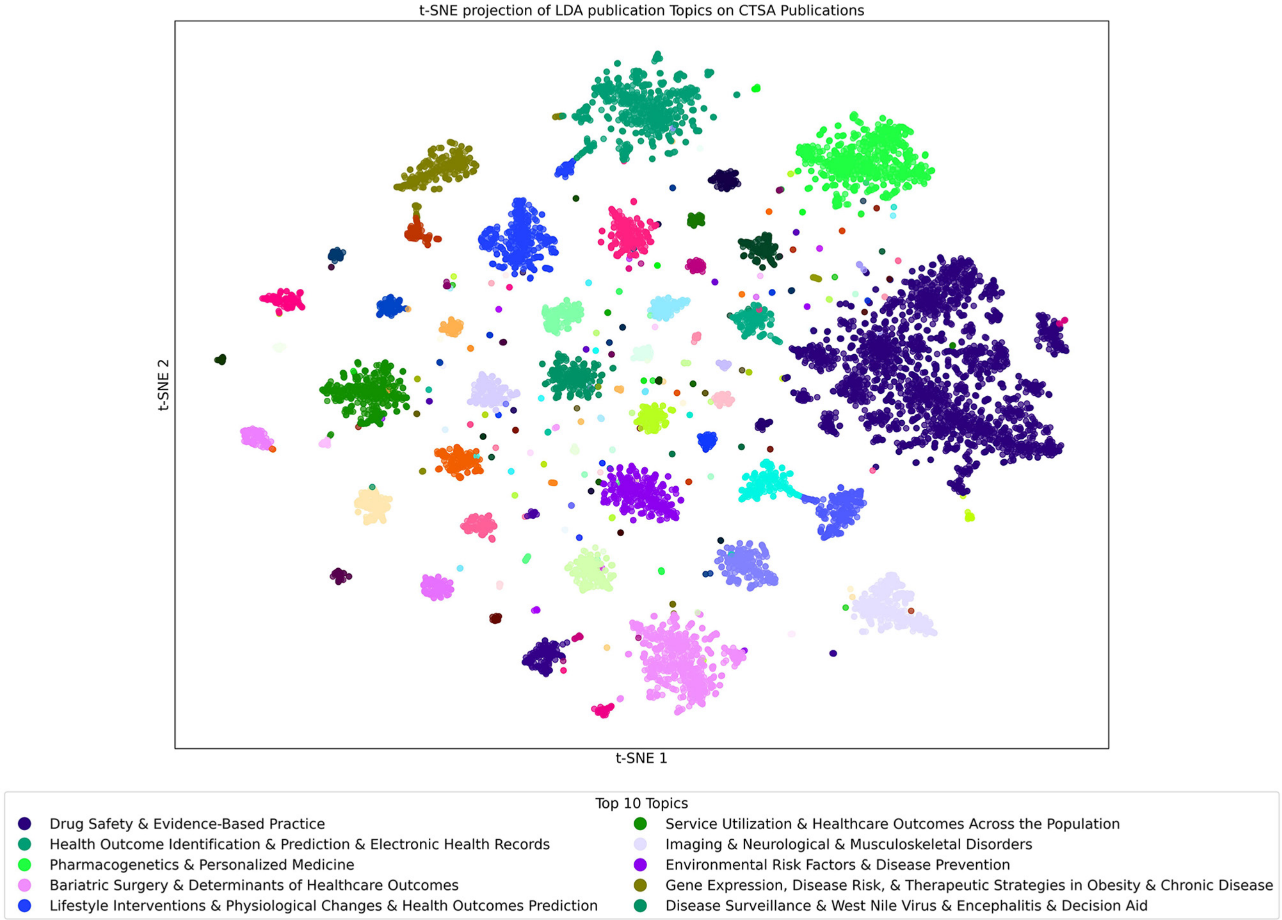

FIGURE 9
t-SNE Projection of LDA Topics Built on Publication Dataset Analyzed with the Publication LDA topic model. Each point in the figure represents a publication that is color-coded by its most prominent topic. Clusters reveal closely related publications, and the key gives the list of the top 10 topics found within the Publication model when applied to the Publications dataset.

This bottom-up, data-driven approach enables the data itself to reveal trends and impacts, that can be applied to the CTSA program outputs as a whole and does not require directed queries or require preconceptions for guiding data mining. This greatly enhances the ability of the method to find new and emerging trends and benefits for the CTSA program overall.

Our findings indicate that clinical and community benefits were well-represented in publications and projects, reflecting the CTSA program's strong emphasis on patient-centered and community-driven research. In contrast, economic and policy benefits were extracted less frequently, leading to the inclusion of patents to supplement the information on economic benefits. In the future, we are exploring additional sources of policy-related documents to improve coverage of this area. The ability to systematically map LDA-derived topics to the TSBM framework provides a novel approach for measuring and visualizing the impact of translational science at scale.

Our approach integrates subject matter expertise into assigning benefit tags to the extracted topics while the initial topic modeling is automated. The expert can then focus on a manageable set of topics, which renders the review process feasible and efficient. The integration of subject matter expertise ensures that the assigned benefits accurately reflect the nuances of each topic, enhancing the reliability of the automated analysis. Subsequent tagging of large volumes of documents with the tags for each of its topics further enables automation of one of the most insurmountable steps for manual application.

This NLP approach is statistically reproducible and minimizes the risk of errors associated with more opaque methods, such as those involving LLMs prone to generating hallucinations (Vaswani et al., 2017) and ensures that the output accurately reflects the content of the documents themselves. We do introduce an LLM for generating short labels for topics, while the main extraction of the topics from the documents rests exclusively on the LDA.

While NLP-driven benefit extraction is well-suited for identifying program benefits and trends, caution is advisable for its use of comparative evaluation methodology. Since topics emerge by being present across multiple documents, more unique contributions and novel improvements in translational science methods can be overlooked or shown as less prominent topics

FIGURE 10
t-SNE Projection of LDA Topics from the Patents Topic Model used on the Patents Dataset. Each point in the figure represents a Patent that is color-coded by its most prominent topic. Clusters reveal closely related patents. The key shows the top 10 topics from the model that are found in the Patent documents.

and these gaps are disproportionately important in evaluating the outputs of individual grants. It also implies that the counts of TSBM benefits on the documents as a whole likely miss some potentially important but less common types of benefits.

4.1 Choice of models for each dataset

To achieve improved alignment with TSBM, we examined the Projects/Grants data set using the model we generated using the Publications data (see Figure 4B). This process was able to identify many TSBM benefit related topics, likely because the benefits topics were latent in the grant abstracts but had less emphasis in the text than the overall CTSA program goals and therefore did not surface as major topics in the model. However, when these latent topics were developed in detail in scientific publications, those topics could be found in the grant abstracts. We do note that while this is a useful exercise to identify what benefits are discussed in the grant abstracts, they are anticipated but not realized benefits since they occur at the time of funding application, not because of finalized research.

4.2 Leveraging MeSH terms

To complement the TSBM benefit extraction, we incorporated MeSH terms from PubMed. Results indicate that MeSH terms identified some benefits not captured by NLP, while our automated system extracted many benefits not identified by MeSH. This complementary nature is likely due to the MeSH system being trained on a broad scientific corpus that includes full-text publications, whereas our LDA-based system is tailored specifically to CTSA-funded documents using only titles and abstracts.

For maximizing benefit extraction, leveraging both approaches together can be important: incorporating MeSH terms for structured biomedical categorization while utilizing NLP-driven topic modeling to uncover translational science themes unique to CTSA-funded research.

4.3 LDA topic scores and considerations for benefit tagging

Current TSBM benefit tagging applies labels to topics and links them to documents. LDA assigns probability scores to indicate the strength of affiliation between topics and documents, and these scores vary based on dataset size. Careful interpretation of these scores is necessary to ensure that TSBM benefit tags are applied to the topics most likely to be present in a document. Using a relatively low LDA topic score can cast a wide net to capture all potential benefits but may raise the risk of false positive results, while the use of a more stringent score ensures that benefit tags are not given to documents that are only peripherally related to the topic that corresponds to a benefit and reduces the possibility of false positive results. For the study's purposes, we used a relatively stringent topic score, potentially erring on the side of missing some benefits due to false negative errors. Moreover, the inclusion of the human-in-the-loop for the assignment of benefits tags to topics, should largely eliminate these types of errors for that key step and its subsequent application of the each of the documents with a significant score for the topic.

For some uses, such as identifying groups of documents that might contribute information about a trend or research focus, it may be desirable to set a less stringent score in order to cast a wider net and not miss potentially related documents. Further analysis could then be done by subcluster analysis to generate user stories or compelling research narratives. This flexibility in the pipeline enables its use to both broadly identify benefits as well as to explore refined research groupings and it can distinguish broad thematic trends from specific, demonstrated program outcomes. The ability of NLP-driven tools to measure and communicate translational research outcomes and trends at scale is currently not well-addressed by any other methods.

4.4 Future directions

This study focused on directly linkable and publicly available data, such as grant applications, patents, and publications, which are explicitly connected to CTSA-ing. While this approach enables structured and systematic benefit extraction, it does not yet capture broader downstream impacts, such as policy adoption, clinical implementation, or long-term public health outcomes. We also acknowledge that there may be some omissions in the completeness of data identified primarily through NIH Reporter. However, the pipeline, despite these limitations, has enabled the first feasible examination of the TSBM applied to the CTSA program overall its lifespan and all of its hubs and represents a significant advancement over being strictly limited to the manual application of the TSBM model.

Future efforts expand beyond direct research outputs to incorporate downstream translational impacts by integrating additional data sources, including Policy citations from private commercial databases such as Overton to assess how CTSA-funded research informs policy and regulatory frameworks. Use of the pipeline for a new set of documents, such as those potentially obtained from the Overton database, is a straightforward application of the pipeline from data pre-processing through benefits tagging.

Clinical practice guidelines to evaluate how research findings translate into clinical decision-making and healthcare interventions. Further exploration of other datasets and methodologies will be required to enhance our understanding of how CTSA-funded research translates into real-world applications over time.

5 Conclusion

This study demonstrates the feasibility of NLP-driven automation in systematically identifying and classifying translational science benefits at scale for over 100,000 documents representing research outputs. Moreover, it allows the benefit topics to emerge from the corpus of documents without directed searching or preconceived notions of benefits that may be present. By applying LDA topic modeling, TSBM tagging, and complementary validation techniques, we successfully extracted thousands of translational benefits from CTSA-funded research outputs. By continuing to refine and expand NLP-based methodologies, we aim to enhance the ability to measure, analyze, and communicate the true impact of translational research, providing actionable insights for funders, researchers, and policymakers within the CTSA network.

Data availability statement

Publicly available datasets were analyzed in this study. This data can be found through the following links: https://reporter.nih.gov/exporter, https://pubmed.ncbi.nlm.nih.gov/download/, https://data.uspto.gov/home; https://clinicaltrials.gov/data-api/api.

Author contributions

TM: Methodology, Investigation, Data curation, Formal analysis, Software, Visualization, Validation, Writing – original draft, Writing – review & editing. EA: Project administration, Supervision, Validation, Investigation, Methodology, Writing – original draft, Writing – review & editing. SB: Validation, Methodology, Writing – original draft, Software. DD: Data curation, Visualization, Methodology, Software, Writing – review & editing. CA: Project administration, Methodology, Validation, Writing – original draft. KS: Conceptualization, Methodology, Investigation, Supervision, Validation, Writing – original draft, Writing – review & editing.

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Conflict of interest

All authors are current or former employees of Digital Infuzion, LLC.

Generative AI statement

The author(s) declare that Gen AI was used in the creation of this manuscript. Generative AI was used in the research methodology for the creation of descriptive topic labels. Generative AI was also used in copy editing.

Publisher's note

Supplementary material

The Supplementary Material for this article can be found online at: https://www.frontiersin.org/articles/10.3389/frma.2025.1596687/full#supplementary-material

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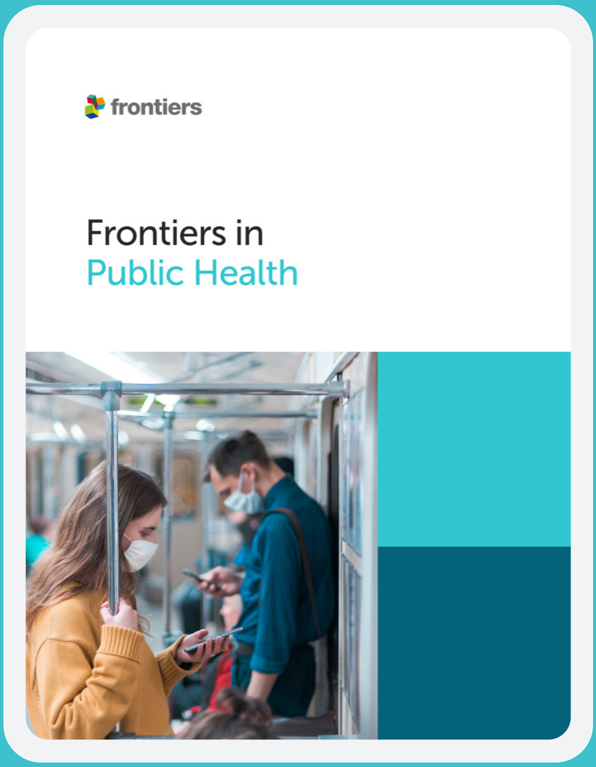
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