A taxonomy of impacts on clinical and translational research from community stakeholder engagement

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Abstract

Background: Community engagement is increasingly recognized as a valuable tool in clinical and translational research; however, the impact of engagement is not fully understood. No standard nomenclature yet exists to clearly define how research changes when community stakeholders are engaged across the research spectrum. This severely limits our ability to assess the value of community engagement in research. To address this gap, we developed a taxonomy for characterizing and classifying changes in research due to community engagement.

Methods: Using an iterative process, we (a) identified areas of potential impact associated with community engagement from author experience, (b) categorized these in taxonomic bins based on research stages, (c) conducted semi-structured interviews with researchers and community stakeholders, (d) validated the codebook in a sample dataset and (e) refined the taxonomy based on the validation. Community stakeholders were involved in every step of the process including as members of the primary study team.

Results: The final taxonomy catalogues changes into eleven domains corresponding to research phases. Each domain includes 2-4 dimensions depicting concepts within the domain’s scope and, within each dimension, 2-10 elements labelling activities through which community engagement could change research.

Conclusions: Community engagement has great potential to enhance clinical and translational research. This taxonomy provides a common vocabulary and framework for understanding the impact of community engagement and suggests metrics for assessing the value of community engagement in research.

KEYWORDS
community, community-engaged research, engagement, metrics, outcome measures, patient-centred, person-centred, stakeholder, taxonomy
1 | BACKGROUND

Patient and community stakeholders are being involved in re-shaping priorities for health research, setting the research agenda, establishing a presence on proposal review committees, and translating research results into easily understood findings for the public audience.1-3 Viewed retrospectively, community stakeholders’ contributions have added community needs to research priorities,4 produced culturally tailored and targeted recruitment strategies5 and patient-oriented study material,6 enhanced approaches to research design and implementation,7 and improved translation and dissemination of research findings. Community Engagement (CE) Studios,8 focus groups, community listening sessions,9 advisory/oversight councils,10 and grant review committees are examples of strategies employed to involve community stakeholders in clinical and translational research.11-13 Expanding the research process to include patients, caregivers, patient advocates or members of the general public involves bringing researchers together with those who are not primarily affiliated with academic research institutions. Community stakeholder engagement, then, is multi-disciplinary and complex, yet it lends a lived-experience perspective so that health research itself better reflects what is most important to the population it studies and serves.14

Lagging behind the growth of new stakeholder engagement approaches is the development of tools for evaluating, comparing and evolving those approaches, and there is an urgent need to develop these tools to demonstrate the impact of community stakeholder engagement in research.11,15,16 Interactions between researchers and community stakeholders are not consistently captured in a standard or ordered framework, nor is the value of community stakeholders’ activities to the research enterprise being measured.17-20

With valuation standards and metrics, the meaningful engagement of patients and other community stakeholders could be studied scientifically and adopted with more confidence in clinical research, which is still largely done to patients as participants rather than with them as stakeholders in a bidirectional interaction.21-23 It is imperative to capture community stakeholder input consistently and develop measures for the value of the community stakeholder contributions to research.

There are examples in the literature demonstrating the effectiveness of taxonomies for improving metrics and scientific reporting, suggesting a taxonomy would be an effective first step in establishing a standard vocabulary and developing value measures.24-28 Other stakeholder engagement efforts are illustrative of the benefits of improving vocabulary around this topic. These include the following: stakeholder engagement frameworks and guidance not focused on community stakeholders specifically,18,29,30 a scaleable approach to patient engagement for patient-centred outcomes research (PCOR),31 successful patient engagement for health-care experiences and outcomes,32,33 and community engagement measures focused on partnership strength.19,34 Specifically evaluating community stakeholders’ contributions to research, however, needs a framework specifically focused on characterizing and measuring community representative activities through the process of conceiving, conducting, analysing and reporting clinical and translational research.

Given the complexity of community stakeholder engagement in clinical research, a taxonomy would provide a common language and framework for community stakeholder engagement that will facilitate needed standards for reporting and measures for metrics development.35 Over time, reporting and evaluating stakeholder engagement systematically will accelerate advancements in and adoption of community stakeholder engagement across research broadly. We developed a Community Stakeholder Impacts on Research Taxonomy to address this need.

2 | METHODS

2.1 | Definitions

In this work, the term “community stakeholder” includes patients, caregivers, patient advocates and members of the general public, but not payers, policy makers or health-care product producers. A “community representative” is a person whose primary affiliation is with a non-academic, non-research, community-based organization and/or who represents a defined community.36

2.2 | Overview

We (a) identified areas of potential impact and outcomes associated with community stakeholder participation in clinical and translational research based on author experience, (b) categorized these in taxonomic bins based on the research cycle, (c) conducted semi-structured interviews with researchers and community stakeholders to evaluate the resultant taxonomy, (d) validated the taxonomy in a sample dataset and (e) refined the taxonomy based on the validation. For qualitative analyses, all coding was completed using Dedoose software, an online suite for collaborative qualitative research analysis.

Our research team included leaders from two community organizations (Vaughan and Richmond) and faculty/staff from three institutions with expertise in community engagement, scale development, qualitative analysis and translational research. The experience of the team spanned facilitating CE Studios, conducting community outreach efforts, recruiting for programme participation, implementing public health interventions and evaluation, and advocating for social and economic justice. The study design, recruitment plans and semi-structured interview questions were approved by Vanderbilt University Medical Center’s IRB.

2.3 | Identification of potential community stakeholder impacts

To generate initial content for the taxonomy, we scanned the literature reporting research in which patient, community and provider
stakeholders have been involved. The content generation was

guided by our team’s expertise in engagement, the PCORI Patient

and Family Engagement Rubric,37,38 and a recent comprehensive re-

view of impact.39 Searches in PubMed and Google Scholar included

these keywords: Community-Engaged Research (CEnR), patient and

stakeholder engagement in research, participatory research, pa-

tient-centered outcomes research, impact of community/patient/

family/caregiver engagement in research, and evaluation of com-

munity/patient engagement in research.16,39–41

2.4 | Categorization of impacts into initial taxonomy

Two experienced faculty on our team independently reviewed the

identified publications and annotated the content related to changes

in research from stakeholder engagement activities. Codes were

generated using an inductive approach and subsequently grouped

based on thematic analysis. Through iterative rounds of review and
discussion, the full team (faculty/staff and community stakeholders)
developed an initial taxonomy with top-level domains, represent-
ing areas where research changes might occur (ie specific research
stage or overarching thematic area) and elements, defining the scope
of activity in each domain. The elements represent activities that
can be assessed or measured. We developed a codebook for quali-
tative analysis, making domains the parent codes and elements the
subcodes.

2.5 | Evaluation of initial taxonomy and external

content collection

We conducted 12 semi-structured interviews – six with academic

researchers and six with community stakeholders – to evaluate

the initial taxonomy and gather external content. One week prior to
the interview, interviewees were provided with the initial taxonomy
(Table 1A). Interviewees answered questions on taxonomy structure
(domain nomenclature, domain arrangement and element categori-
zations), utility and relevance (Table 1B). Interviewees were ques-
tioned about each domain and its elements and about their overall
impressions. Upon completion of the interview, both academic and

community participants were compensated $50 for their time. We

used a “think aloud” method to probe deeper into responses given
by the interviewees to provide a richer thought process with examp-
es.42 The semi-structured interviews were recorded, transcribed
verbatim and de-identified by two research team analysts who
also acted as coders. The two coders independently reviewed the
transcripts and coded participants’ responses to each domain and
element of the taxonomy as indicating “keep”, “remove”, “add”, or
“needs improvement” about that particular part of the taxonomy.
Discrepancies in codes were resolved through team adjudication.
Wording changes for clarity, element clustering into taxonomic di-

mensions, and element recategorizations were discussed among the

research team to improve and refine the taxonomy in accordance
with the interview results.

2.6 | Validation and refinement to final taxonomy

We piloted this revised taxonomy by asking researchers with

comprehensive backgrounds in qualitative research evaluation to

use the taxonomy on a sample dataset. The sample dataset was

transcripts of input on research from community stakeholders

in Community Engagement (CE) Studios (Joosten et al43) and from

researchers in Translational (T2) Studios (Byrne et al.43). CE

and T2 Studios are both project-specific consultative sessions in

which individuals with expertise provide input and feedback on

research. The two types of Studios are conducted similarly, but

CE Studios have community stakeholders as experts while T2

Studios have researcher experts. Comparing CE and T2 Studio

output affords a unique opportunity to study engagement’s im-

pact because a CE Studio is a discrete engagement method that

is replicable. We used verbatim transcripts from Studio session

recordings containing the input provided by community or fac-

ulty experts to investigators. Six coders not involved in devel-

oping the taxonomy were given the codebook, transcripts and

a one-hour orientation on the analysis design and objective.

Analysis of studio transcripts involved reading the text, creat-

ing text excerpts and labelling each excerpt with one or more

codes. Each coder received two transcripts, one from a CE

Studio and on from a T2 Studio. Coder Group A (n = 3) had two

transcripts with different topics (from a CE Studio on Improving

Healthcare Systems and from a T2 Studio on a Chest Pain Trial).-

Coder Group B (n = 3) had two transcripts on the same topic, one

each from a CE and T2 Studio both held on eConsent. (Table 2)
Afterwards, we interviewed each coder, asking: How did the tool
work for them? What challenges did they experience? How can the

taxonomy be improved? What were your overall likes and dislikes
in the utility of the system? The final taxonomy content and struc-
ture resulted from discussion in the research team. Elements
describing measurable activities were binned into subdomains,

or taxonomic dimensions, describing categories of research ac-

tivity in each stage.

3 | RESULTS

3.1 | Initial taxonomy content and structure

With iteration and evaluation by the research team, 41 conceptual

statements about research activities through which community

stakeholder engagement is likely to be impactful were binned ini-
tially into seven top-level taxonomic domains named for stages of

research (Table 1A). The conceptual statements were products of

research team members’ Community-Engaged Research (CEnR) ex-
perience as investigators, participants and community advocates for

research, and the scan of related literature on Community-Engaged

Research articles (results of PubMed query run today can be found
here). Example literature includes Khodyakov, et al44, Mullins, et
al42, and Brett, et al.45
### TABLE 1  Semi-structured interview materials

**(A) Initial taxonomy**

| Domain                  | Elements                                                                 |
|-------------------------|--------------------------------------------------------------------------|
| 1. Pre-research         | Idea/topic generation, Identify issues of greatest importance, Input on Relevance/Purpose, Identify stakeholders/potential partners |
| 2. Infrastructure       | Funding source decisions, Preparation of budget, Sharing of funds, Appropriate compensation for stakeholders (patients, consumers, community organizations), Time, Cost, Process/structure for shared decision making |
| 3. Research design      | Define population, Selection of patient-centred tools, Organize ideas and capture the way the research will be applied, Provide input on research methods, Grant writing/proposal development, Framing research questions, Selection of comparators & outcomes, Revise the research protocol, Input on cultural appropriateness |
| 4. Implementation of Research | Identify/hire research team members, Recruitment of research participants, Identify best approaches to recruitment and retention, Determine best approaches to data collection (in person vs online vs telephone; survey vs interview; self-report vs caregiver report), Assist with data collection |
| 5. Analysis of Research | Assist with data analysis (train to do qualitative analysis), Provide alternative interpretation of research results (especially those that are counterintuitive), Bring attention to factors (confounders) that may not have been measured or documented in literature, Interpret – assess plausibility of results, Review results and provide context for relevance to patients and stakeholders |
| 6. Dissemination of research findings | Provide culturally relevant and appropriate language, Co-authorship of manuscripts, Write for non-scientific publication, Advise on appropriate audiences and non-traditional venues for dissemination, Convene town hall meetings and other opportunities for dissemination, Create companion materials for dissemination – videos, newsletters, etc |

**(B) Semi-structured interview question**

| Researcher (n = 6) | Stakeholder (n = 6) |
|-------------------|---------------------|
| (1) What is your first impression of the taxonomy? What makes sense to you? Are the domains/elements rational? | X | X |
| (2) How would you improve the taxonomy? | X | X |
| (3) Are there domains/elements you would eliminate? Why? | X | X |
| (4) Would you add any domains/elements? What would you add? | X | X |
| (5) Which domains/elements are you most familiar with? | X | X |
| (6) Do you feel you can contribute to any of the domains/elements? If so, which ones and how? | X |
| (7) Which domains/elements are most beneficial to you when seeking stakeholder input? | X |
| (8) How likely are you to provide feedback in these domains/elements? | X |
| (9) Are there domains/elements that are particularly important to you? | X | X |

### 3.2 | External review results

Semi-structured interview results from the coding of researcher and community stakeholder interview transcripts were suggestions of what in the initial taxonomy to keep, remove, add or improve. From these data and subsequent research team discussion, Translation,
Quality Improvement, and Engagement domains were added and domain descriptions drafted. The amended intermediate taxonomy had 10 domains and 64 elements (not shown).

### 3.3 Pilot and validation results

Table 3 shows the numbers of codes for each taxonomic domain and the frequency difference by Studio type. Results from the qualitative analysis and the subsequent coder interviews were discussed by the research team. Based on this analysis, two domains, Communication and Post-Research, were added.

### 3.4 Final taxonomy

The final taxonomy of Community Stakeholder Impacts on Research has eleven domains (codes) describing stages of clinical and translational research, 36 dimensions naming research activity concepts into which subcodes were binned, and 71 elements (subcodes) describing specific community stakeholder activities that can be assessed or measured (Table 4). Links observed while piloting the Community Stakeholder Impacts on Research Taxonomy support a cyclical and iterative model of the research process with opportunities for stakeholders to engage at all phases of research and inform next steps (Figure 1). The taxonomy systematically characterizes and categorizes community stakeholder activities that can impact the research process and also suggests possibilities for standard measures to assess that impact (Table 4 and Figure 1). Examples of possible measures are listed in the rightmost column of the taxonomy (Table 4).

### 3.5 Pre-research and Infrastructure Domains

These research phases frame the overall study and the potential outcomes. Categorized in these domains are elements of the research
The impact from involving community stakeholders can show in a study's augmented relevance and reach. Community stakeholders can increase the patient or community centredness of the research topic, questions and hypotheses, increasing the project's relevance to the target population and possibly increasing enrollment and retention (see quote). The Governance and Policy-making dimensions have elements reflecting how community stakeholder feedback on compensation and time/ cost burden on research participants, power balance and team roles can affect a study.

"If you want more minorities in your research, you need to change the way you tell us about your studies. Find a way to get our input, not on your terms, but ours. Put something in place for me to tell you what I want to study."

3.6 | Study design and Implementation Domains

Many of the elements in these practical domains involve research logistics and operational decisions about how, where and when the research will occur. Stakeholders can provide ideas for relevant comparator groups and patient- or community-centred study barriers or outcomes that may influence data collection strategies, target population decisions (see quote), recruitment materials and strategies, retention and completion methods, and best communication practices for the team.

"What do you mean by healthy? Why are you only interested in healthy people? What about including people like me who have conditions like diabetes or hypertension? We need to learn how to be healthy too. And don't you want to see how exercise can benefit people with these conditions?"

3.7 | Analysis and Dissemination Domains

In these phases of research, the cultural relevance and appropriate language brought to interpretation and presentation affects uptake of the health message and the diversity of the research participation pool (see quote). Research and community stakeholder interview participants both described these activities benefiting greatly from patient and community stakeholders. Challenges with cross-cultural communication that occur during these phases can be incredibly costly to research over the long term (eg the damage to research's reputation and cost to participant diversity of the poorly handled Havanusapi tribe analyses in the United States) and can be overcome through appropriate training between investigators and stakeholders and though peer-to-peer communication of results.

"I think that's where you get that openness and the willingness to really want to participate ... "Well, how can I help further what you're doing? I believe in it so much, because you took the time to come and just let me ask you questions, just let me pick your brain." ... just to have that opportunity, I think, is very, very important with the dissemination. Like I said, that end right there is really the beginning of whatever you want to do, because then you have it open to you."

3.8 | Post-research Domain

This domain, identified during the taxonomy evaluation, centres on how research results become actions for improved health or clinical care. It was identified in an interview with a researcher during which the investigator described questions from research participants about what happens after completion of a study (see quote). The elements in the post-research domain are activities around defining the next steps for the field, such as, What is the next question? What type of follow-up needs to happen now that the initial research questions were addressed? What is the overall impact on the community and what other social constructs that influence an individual's health are impacted by these results?

"The only thing I can think of potentially, and it could be included in this, is just kind of post-research dissemination, the follow-up piece. ... It's the biggest complaint I have received in my experience, is yeah, we participate in studies all the time and nothing happens on the back end..."

3.9 | Ethics and Engagement Domains

The research team placed Ethics and Engagement as universal/overarching domains relevant to all phases of research and developed elements that described corresponding activities. At one point in discussion, the Engagement domain was divided into two subcodes reflecting the difference between community stakeholder engagement as part of the research team or research oversight board and engagement when implementing and disseminating the research findings. In the first scenario, the stakeholder role can be seen as a community advocate within research. In the second scenario, the stakeholder's role reflects advocacy in the community on behalf of research. When considering the cyclic nature of the domains and the overarching nature of the Engagement domain, however, it made sense to collapse those two subdomains back into one Engagement domain, as they simply reflect engagement activities during different research stages.

3.10 | Process improvement Domain

In addition to providing new elements for the Ethics domain, the community interviewees identified Process Improvement as a domain in which they felt they had contributed guidance and oversight (see quote).
| Research stages | Activity clusters | Conceptual statements about community stakeholder activities | Examples of metrics suggested by the taxonomy elements |
|-----------------|------------------|----------------------------------------------------------|------------------------------------------------------|
| **Taxonomy domains** | **Parent codes** | **Taxonomy elements** (Subcodes) | (CS = Community Stakeholder) |
| **Research stages** | **Research question** | **Conceptual statements about community stakeholder activities** | **Examples of metrics suggested by the taxonomy elements** |
| **1. Pre-research** | **Research question** | 1. Generate ideas | • # ideas generated by community stakeholders |
| **Stage in which the overall study and hypothesized outcomes are considered and developed.** | **Significance/Rationale** | 2. Identify issues of greatest importance to community stakeholders | • CS-rated Importance |
| | **Proposal development** | 3. Provide input on topic and project relevance and purpose | • PCoR rating of research abstract or other product |
| | | 4. Identify community partners | • Recruitment and retention rate/ improvement |
| | | 5. Contribute to choices made in specific aims | • # and diversity of CS on team |
| | | 6. Contribute to grant writing | |
| | | 7. Provide lived-experience perspective to research question framing | |
| **2. Infrastructure** | **Governance** | 1. Add extra breadth to possible funding source lists | • # of CS-identified grant opportunities |
| **Stage in which the logistics of the project, distribution of funds, research team members and roles, and other planning decisions are made** | **Team roles** | 2. Aid in budget preparation | • # of CS participants in grant writing process through focus groups, community engagement studies, town halls, meetings |
| | **Balance of power** | 3. Consult on appropriate compensation for community research contributors (patients, consumers, community organizations), including issues around time as research team members, time for participation, and cost for travel and lost work hours. | • Per hour rate of CS compensation compared to other stakeholders |
| | **Compensation model** | 4. Contribute to designing a shared decision-making process | • # of hours of meetings attended by CS |
| | | 5. Contribute to appropriate scopes of work | • Diversity in NIH study types with CS representation – biomedical, community engagement, cancer, etc |
| | | 6. Contribute to decisions on participant payment system (eg what does insurance cover in a clinical study) | • Percent of funding that is distributed to CS or community organizations |
| | | | • Number of educational backgrounds represented on study team |
| | | | • $ spent to support CS participation such as virtual meeting platforms, transportation costs, reimbursements |
| | | | • Presence or absence of a separate reimbursement structure for non-academic participants |
| **3. Study design** | **Study population** | 1. Provide lived experience to the process of defining the population | • Demographic diversity of participants in research study |
| **Stage of research in which how the study will be conducted, who will be included in the cohort to be studied.** | **Person-centred methods** | 2. Provide relevant input on cultural appropriateness in the population of interest | • Demographic diversity in research participation overall and over time |
| | **Person-centred protocols** | 3. Identify potential stigmas for condition studied | • Presence or absence of systematic review for cultural appropriateness either through focus group analysis or review by health communication expert |
| | | 4. Provide input on the research setting and how that will impact the participants | • Frequency of research occurring in non-academic settings such as churches, schools, etc |
| | | 5. Consult on generalizability to other groups or communities | • Presence or absence of opportunity for CS to give feedback on study applicability to multiple study sites |
| | | 6. Participate in selection of patient-centred tools, including technology used during participation and data capture, literacy and numeracy levels of participant materials, clinical workflow, and impact of protocol logistics on participant experience | • Range of formats for communication to participants such as phone, email, text, etc |
| | | 7. Organize ideas and capture the way the research will be applied. | • Measured PCoR score |
| | | 8. Add to possible comparators and outcomes | • Number of modifications to research protocol made by CS |
| | | 9. Familiarize researchers with the participants’ need for clarity | • Measured participant confidence in research protocol on a Likert scale |
| | | 10. Assess community comfort level with study plans | (Continues) |
### TABLE 4 (Continued)

| Research stages | Activity clusters | Conceptual statements about community stakeholder activities | Examples of metrics suggested by the taxonomy elements |
|------------------|-------------------|-----------------------------------------------------------|------------------------------------------------------|
| **4. Implementation**<br>Stage of research in which a research team details how the planned project is accomplished and carries out those operations | Operations Framing Community-researcher team formation Data collection | 1. Identify possible research team members, especially among patients, caregivers, and other community stakeholders 2. Assist with data collection 3. Assist with participant recruitment 4. Contribute to community needs assessment for effective and ethical consent. | • Opportunity for CS involved in hiring process for research team members  • Presence or absence of non-academics involved in data collection  • Diversity in CS responsibilities  • CS-initiated suggestions for recruitment/retention that are implemented; recruitment goal achievement  • Presence or absence of changes to recruitment protocol after CS feedback on stigma  • PCoR score as related to study recruitment plan  • Number of participants recruited by CS  • Change in recruitment rate after CS input implemented  • Presence or absence of changes to data collection protocol after CS feedback |
| **5. Analysis**<br>Stage of research during which data are analysed and interpreted | Data management Data analysis Interpretation | 1. Assist with data analysis (training may be needed) 2. Provide alternative interpretation of research results (especially those that are counterintuitive) 3. Bring attention to factors (confounders) that may not have been measured or documented in literature 4. Interpret and assess plausibility of results 5. Review results and provide context for relevance to patients and their communities | • Presence of training opportunities for qualitative/quantitative analysis  • CS participating in analysis  • Presence of CS authors on manuscript  • Presence or absence of presentations to CS to discuss analysis prior to publication |
| **6. Dissemination of research findings**<br>Stage of research in which final results or intermediary outcomes or works-in-progress communicated orally or in writing, along with edifying impact information and requests for feedback, when appropriate. This stage can be ongoing through the project implementation | Audience & Methods Health/Scientific literacy Culturally adapting messaging | 1. Participate in co-authorship of manuscripts 2. Write experience non-scientific publication 3. Advise on appropriate audiences and non-traditional venues for dissemination 4. Convene town hall meetings and other opportunities for dissemination 5. Identify appropriate community organizations who would benefit from the research 6. Provide input on audience for appropriate message delivery 7. Provide advice on cultural relevance and appropriate language 8. Participate in co-creation companion materials for dissemination (videos, newsletters, brochures, PowerPoint presentations, handouts, etc) 9. Conduct social media outreach 10. Organize ideas and capture the way the research will be applied | • Presence of CS coauthors  • # of non-scientific publications on results  • # CS authors in non-scientific publications  • # of presentations led by CS in non-traditional venues;  • # of town hall meetings  • # participants in presentations at non-traditional venues and at town halls  • Presence of meetings with CS to discuss results  • Presence or absence of review by CS for intended audience; for cultural appropriateness  • Number of non-traditional media outlets identified for dissemination  • # of companion materials produced and reach of their distribution  • # of social media shares by non-scientific organizations or individuals  • # of non-scientific articles which cite the original publications |
| **7. Post-research**<br>Stage of research concerning translation of research findings for the purposes of improving health | Translation Health policy Research policy | 1. Assess actionability of recommended actions, if any, from research results 2. Suggest ways to meaningfully follow up with participants 3. Discern overall impact of the research on the community (implications for health policy) 4. Assist in formulating next steps, convening appropriate audiences for post-research action 5. Helping to formulate follow-up research questions 6. Provide support for research in their communities (implications for research relevance and policy) | • Subsequent grant funding received  • Number of participants successfully contacted after study completion  • Ratio of investment in study expenses to that into results dissemination effort  • Dollars invested into research follow-up initiatives  • Number of policy proposals following study completion  • Number of meetings held with other stakeholder, such as businesses, new research groups, policymakers, constituents, after publication  • Advocacy activity for related research in the community |
“I think a lot of times it is broken and we just don't know how to fix it because it is huge. So, someone needs to step back and go, okay, we can do this better.” ... "... and I can't quote it, but I came out of it feeling this is really good. You know, if they can implement what we just talked about ..." "I think it really will reduce patient stress and reduce all of the risks the patients have. It doesn't make sense to be stressed out while you're in the hospital, which happens a lot. I went to the emergency room one time, and I was worse off when I left than when I went because it was stressful. So, it seems like you are cleaning up all that. And to be asked how to do that was really a good thing ... just the fact that someone was looking to change it and fix it.”

3.11 | Communication Domain

Communication, a stakeholder impact domain that crosses all phases of research, was identified during the taxonomy pilot. Communication was particularly pronounced through these dimensions: Research Question, Significance/Rationale, Proposal Development, Governance (especially in the shared decision-making activity), Person-Centred Methods and Protocols, Interpretation, Culturally Adapting Messaging, Translation, and Policy.

4 | DISCUSSION

The Community Stakeholder Impact on Research Taxonomy contains standardized global categories and naming structures that could be used as a defining and classifying tool, plus categorized community stakeholder activities in research that can be assessed or measured. Over time, these impact measures will build a body of comparative effectiveness knowledge crucial to both PCOR and CEnR science. The taxonomy could thereby standardize reporting and evaluation of engagement activities in research projects. Some specific examples of how the taxonomy can be used include: reporting community stakeholder engagement methods, setting criteria for patient-centred research, and guiding those researchers seeking stakeholder input who may be unfamiliar with the possibilities for community stakeholder engagement activity. Equally, community stakeholders themselves could use the taxonomy to determine where in the process they could be most valuable in providing project-specific input to researchers. Both scenarios add to the pragmatism of patient-centred research. The taxonomy fills a critical gap in our ability to build an evidence base for the value of community stakeholder engagement.

Prior reports support community stakeholder engagement as an approach to increase the translation, dissemination and uptake of research findings. Additional evidence supports the value of community stakeholders in prioritizing research and empowering patients to be more engaged. Although community
stakeholder engagement in research has been more widely embraced in recent years, literature demonstrating its value and impact is limited and is often derived from descriptive, retrospective data. Prospective studies of engagement have been case reports or qualitative analysis of engagement across multiple studies with differing types of engagement strategies and no comparison or control.\textsuperscript{47,49,50}

Lacking in the literature to date are metrics and tools needed for studying community stakeholder engagement rigorously. The elements of this taxonomy, the categorized community stakeholder activities in research that can be assessed or measured, suggest possible measures that we have added to the taxonomy table to engender discussion and follow-on research (Table 4, rightmost column). One recently developed tool to measure an outcome of engagement is the validated Person-Centeredness of Research Scale (PCoR Scale).\textsuperscript{51} The PCoR Scale can be used to quantify person-centredness in research products, and we have indicated in the taxonomy table where this scale could be effectively used to assess the impact of community stakeholder engagement.

Other community engagement logic models and frameworks guide engagement processes and allow reporting of numbers of community stakeholders and/or the strategies used mapped to different engagement goals or principles.\textsuperscript{19,31,37} Like these frames, our taxonomy contains concepts around infrastructure to support engagement (cf. Team Roles and Balance of Power dimensions), the value of education (cf. the Analysis domain and Health/Scientific Literacy and Translation dimensions), dissemination, expansion of research teams to include community stakeholders (cf. the Infrastructure domain), and diversity in both participants and participation activities (cf. the Study Design and Implementation domains). The Community Stakeholder Impact on Research Taxonomy, however, was developed from the idea of quantifying outcomes of engagement, starting with a comprehensive taxonomy vetted by community engagement academic researchers and community stakeholders. In the validation results, the difference in priorities and even feedback styles of the community stakeholder and the academic faculty Studio experts are reflected in the distinctively different code frequencies observed in analysis. The method we used is reproducible, allowing for building in new concepts as community stakeholders engagement increases and is evaluated through the taxonomy. Further, we learned from our interviews that community stakeholders often want to follow up about study results, support the research through advocacy in their community, continue to be involved through informing follow-up research questions, and participate in the research itself. That the conceptual elements used to build the taxonomy came from researchers and community stakeholders supports our view that collaborative stakeholder involvement, rather than consultative involvement only, favours full and continued engagement. The potential of the Community Stakeholder Impacts on Research Taxonomy to guide community engagement reporting standards and metrics development supports its adoption and use and indicates its implications for engagement science.

4.1 | Limitations

The listing of measurable elements can and will grow as we were not able to capture every existing encounter between researchers and stakeholders. This taxonomy was pilot tested on transcripts from real-world studies; however, this does not capture all contexts in which stakeholders are engaged. This limitation is reflected in the high number of free codes found during the validation (Table 3). Since the method we used is reproducible and the taxonomy flexible, new concepts can be built in as different engagement contexts are evaluated using the taxonomy.

The taxonomy development process revealed cross-over concepts. Some conceptual elements uncovered in our study belong in more than one dimension and even more than one domain. We believe, however, that this mirrors the research process itself, which is iterative and not always linear. The cross-over elements also reflect the complexity of investigator–community stakeholder interactions. Many research activities repeat, iterate and occur in multiple process domains. For example, stakeholders can share input on creating materials (such as recruitment materials), survey design and summary of results, activities which can occur in the Research Design, Implementation, and/or Dissemination domains. This multiplex hierarchical structure is common in medical terminology and similar to that seen in medical subject headings (MeSH). The taxonomy’s illustration of, and standard structure for, areas of value from stakeholder input is its primary contribution.

5 | CONCLUSIONS

Community engagement has great potential to enhance clinical and translational research. The Community Stakeholder Impact on Research Taxonomy provides a common vocabulary and framework for understanding the impact of community engagement and suggests metrics for assessing the value of community engagement in clinical and translational research. The taxonomy organizes the complexity of engagement into a framework that can be used to consistently report engagement activities and measure their impact. Measuring stakeholder impact as engagement strategies are envisioned and tried will drive increased stakeholder involvement and channel it towards the most effective strategies, a needed advance for this field. We anticipate types of engagement will grow as engagement science grows. We see value in the taxonomy’s flexibility, and in the reproducibility of the method used to devise it, to capture that growth in a structured way.

5.1 | Ethics approval and consent to participate

The reported approach and interview questions were approved by Vanderbilt University’s IRB (#140955). The study was deemed exempt, and the consent procedures were approved. For the randomization to CE or T2 Studios part of the study, investigators were administered a survey and survey completion served as implied
Data sharing is not applicable to this article as no new data were created or analysed in this study.

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