

Childhood vaccination communication outcomes unpacked and organized in a taxonomy to facilitate core outcome establishment

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Abstract

Objectives: We present a comprehensive taxonomy of outcomes for childhood vaccination communication interventions. Adding to our earlier map of trial outcomes, we aimed to (1) identify relevant outcomes not measured in trials, (2) identify outcomes from stakeholder focus groups, and (3) organize outcomes into a taxonomy.

Study Design and Setting: We identified additional outcomes from nonvaccination health communication literature and through parent and health care professional focus groups. We organized outcomes into the taxonomy through iterative discussion and informed by organizational principles established by leaders in core outcome research.

Results: The taxonomy includes three overarching core areas, divided into eight domains and then into outcomes. Core area one is psychosocial impact, including the domains “knowledge or understanding,” “attitudes or beliefs,” and “decision-making.” Core area two is health impact, covering “vaccination status and behaviors” and “health status and well-being.” Core area three is community, social, or health system impact, containing “intervention design and implementation,” “community participation,” and “resource use.”

Conclusion: To our knowledge, this taxonomy is the first attempt to conceptualize the range of potential outcomes for vaccination communication. It can be used by researchers selecting outcomes for complex communication interventions. We will also present the taxonomy to stakeholders to establish core outcome domains. © 2017 The Authors. Published by Elsevier Inc. This is an open access article under the CC BY-NC-ND license (<http://creativecommons.org/licenses/by-nc-nd/4.0/>).

Keywords: Outcomes; Core outcome set; Childhood vaccination; Communication; Taxonomy; Immunization

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What is new?**Key findings**

- Taxonomy of outcomes identifies and organises all potentially relevant outcomes for childhood vaccination communication.
- Outcomes reflect a range of different social perspectives.
- Categorised into three core areas: psychosocial impact, health impact, and community, social or health systems impact.

What this adds to what was known?

- First known effort to identify the range of outcomes associated with vaccination communication interventions.
- Outcomes derived not only from existing trials and stakeholder consultation, but also through identifying and translating outcomes from the broader health communication area.
- This is a new methodological approach for identifying potential outcomes for core outcomes research, particularly in complex intervention areas.
- This taxonomy is a tool for researchers and evaluators to help improve understanding and appropriate selection of vaccination communication outcomes.

What is the implication and what should change now?

- This taxonomy forms the basis for a forthcoming international Delphi process to identify core outcome domains for vaccination communication interventions.
- Taxonomy development methods could be adopted by researchers interested in progressing the understanding of outcomes for complex or communication-related interventions.

1. Introduction*1.1. Vaccination communication interventions*

Communication about childhood vaccination is implemented around the world to generate and maintain demand for routine vaccination and to promote large-scale vaccination campaigns [1–4]. Interest in communication has grown with its emergence as a potentially effective strategy to address vaccine hesitancy [5–9]. The term “vaccination communication” includes many interventions with a number of aims or purposes: to inform or educate, remind or recall, enhance community ownership, teach skills,

provide support, facilitate decision-making, and enable communication [1,2]. Vaccination communication is dynamic, involves multiple actors, operates at an individual as well as a broad public health level, and is often delivered in complex packages with multiple components [10].

Evidence from high-quality studies and systematic reviews is necessary to inform implementation [11,12], but determining how to evaluate the effects of these diverse and often complex interventions is a significant challenge. Given the variety of vaccination communication strategies, it follows that there should be a similarly wide range of potential outcomes, from socially oriented outcomes related to communication and engagement to health status and health service outcomes, such as vaccination status or timely delivery [13]. But many of these relevant outcomes are not being adequately assessed. In an earlier study, we identified outcomes currently measured in trials of vaccination communication interventions, finding that too few concepts are measured in too many ways [14].

Most trials measure only vaccination-related end point outcomes like vaccination status or coverage, making it difficult to unpack how communication interventions work or why they fail. Much has been written about the importance of measuring intermediate or process outcomes to illuminate a complex intervention’s mechanism of action or the “black box” between implementation and end point impact [13,15–18]. Because current evidence for vaccination communication focuses on a few end points, without measuring process outcomes, it is often not clear why an intervention did or did not influence vaccination outcomes.

Our earlier assessment of trial outcomes also identified huge variability in the way the few common vaccination end point outcomes were defined and measured [14]. This makes it challenging or impossible to meaningfully compare individual study results or synthesize evidence in systematic reviews [19,20]. To better understand the impacts of vaccination communication interventions, we therefore need to measure similar outcomes consistently across studies, and these outcomes need to reflect the intervention’s theorized mechanism of action.

This requires a conceptual understanding and identification of the full range of potentially relevant effects that may be outcomes of vaccination communication. It is also important to consider that different outcomes may be important to different stakeholders [21,22].

One way to address these evaluation issues is through the development of a core outcome set (COS). This is a set of outcomes or outcome categories (“domains”) that stakeholders agree should be considered in all evaluations of a particular topic or intervention [23,24]. COSs facilitate direct comparisons between studies and also reduce selective outcome reporting [25,26]. COSs have been developed for hundreds of specific conditions in disease and injury categories including cancer, rheumatology, orthopedics, and trauma [27,28], but there is little research into COSs for communication interventions and none to

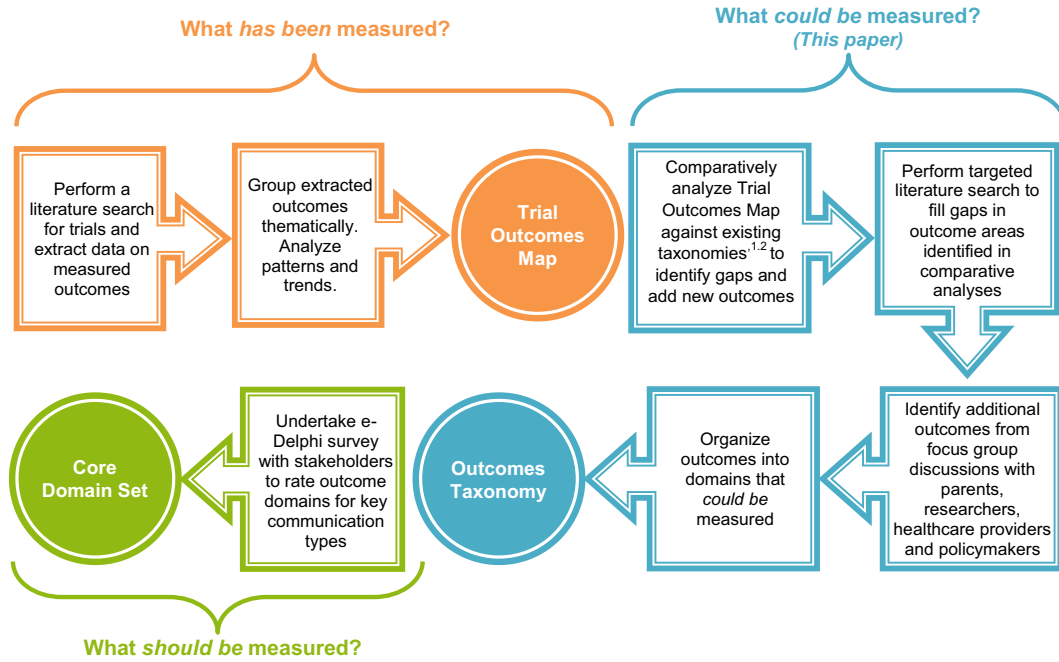


Fig. 1. Methods for developing the COMMVAC core domain set. ¹Cochrane Consumers and Communication group outcome taxonomy [29]. ²COMM-VAC interventions taxonomy [1,2]. COMMVAC, Communicate to Vaccinate.

our knowledge for vaccination communication. Therefore, the Communicate to Vaccinate (COMMVAC) project has undertaken a three-stage study into the outcomes of vaccination communication (Fig. 1). Our study plan is adapted from the methods established by the Outcome Measures in Rheumatology (OMERACT) collaboration in the OMERACT Filter 2.0 [30].

In stage 1, described above, we reviewed outcomes from trials (what has been measured) and categorized them in a Trial Outcomes Map to establish themes and patterns [14]. In stage 2, the subject of this paper, we added additional relevant outcomes to the Map and developed a thematically organized taxonomy of all potentially relevant outcomes for childhood vaccination communication interventions (what could be measured). In stage 3, we will invite vaccination communication stakeholders to participate in an online Delphi survey to establish a preliminary COS for different types of vaccination communication (what should be measured).

1.2. The outcome taxonomy: what could be measured?

A taxonomy is a useful tool to facilitate comparisons between diverse and complex concepts [31], such as outcomes. Indeed, OMERACT has developed a conceptual framework that is essentially a taxonomy for classifying potential outcomes in any area of health care—what could be measured—to facilitate stakeholder discussion and rating of outcomes for a COS [30]. However, the overarching categories or core areas of the OMERACT framework—death, life impact, resource use, and pathophysiological manifestations—do not

meaningfully categorize vaccination communication outcomes. A different taxonomy is needed.

Vaccination communication differs from most COS topics in two key ways. First, there is no underlying disease to be treated; vaccines are intended for otherwise healthy individuals. Second, communication is another step removed from the disease/health model that shapes most current COS research. Vaccination is a health intervention that precedes potential disease; communication is an intervention in a social context that precedes potential vaccination. Therefore, we developed a new taxonomy for vaccination communication outcomes, using the basic OMERACT framework structure (core areas, domains, outcomes).

This taxonomy is an important stage in developing a COS. It is also a tool to help researchers plan vaccination communication evaluations in a more logical and holistic way and to help program managers unpack the impacts of vaccination communication interventions.

1.3. Aims and objectives

We aim to present a comprehensive taxonomy of outcomes for childhood vaccination communication interventions by:

- 1) Identifying outcomes from health communication literature (not vaccination-specific) applicable to evaluating vaccination communication
- 2) Identifying outcomes raised in stakeholder focus group discussions

| INTERVENTION PURPOSE |
|--|
| <p>Inform or Educate</p> <p>Interventions to enable people to understand the meaning and relevance of vaccination to their health and the health of their family or community. Interventions may be tailored to particular populations and can also serve to address misinformation.</p> |
| <p>Remind or Recall</p> <p>Interventions to remind consumers of required vaccinations and to recall those who are overdue.</p> |
| <p>Enhance Community Ownership</p> <p>Interventions to increase community participation and promote interaction between the community and health services. Interventions may build trust among consumers and generate awareness and understanding of vaccination. Interventions of this nature embrace community involvement in planning, program delivery, research, social mobilization, advocacy or governance.</p> |
| <p>Teach Skills</p> <p>Interventions focusing on the acquisition of skills related to accessing vaccination services and communicating about vaccination. Such interventions aim to teach parents early parenting skills such as how to find, access and utilize vaccination services. They also include interventions to train parents, communities and health care providers on how to communicate or provide vaccination-related education to others.</p> |
| <p>Provide Support</p> <p>Interventions, often tailored or personalized, to assist people in addressing specific challenges to vaccination that arise within their day-to-day lives (e.g. social issues such as disagreement within a family regarding vaccinating or emotional issues such as parental anxiety about vaccination).</p> <p>In contrast to interventions to inform or educate, interventions to provide support are more focused on addressing specific challenges faced by parents when making vaccination decisions.</p> |
| <p>Facilitate Decision-Making</p> <p>Interventions that extend beyond informing or educating by presenting all options related to vaccination decision-making in an unbiased and impartial manner. These interventions should explain the decision to be made, provide detailed, evidence-based information about the risks and benefits of vaccination and should help people consider their personal values and options related to the decision to vaccinate their child.</p> |
| <p>Enable Communication</p> <p>Interventions that explicitly and purposefully aim to bridge a communication gap/make communication possible with particular people or groups. This may include translation beyond routine practice in a particular setting, such as translation into local or minority languages, adaptation of materials for a low- or no-literacy population, translation into Braille, or the use of interpreters.</p> |

Fig. 2. Intervention purpose categories from the COMMVAC taxonomy of communication interventions for childhood vaccination. This figure is adapted from the COMMVAC interventions taxonomy [1,2]. COMMVAC, Communicate to Vaccinate.

- 3) Adding newly identified outcomes to the existing Trial Outcomes Map and restructuring it into a taxonomy organized by core areas, domains, and outcomes.

2. Methods

We combined several methods to develop the outcome taxonomy. To supplement the relatively limited outcomes measured in existing trials, organized previously into the Trial Outcomes Map [14], we added potentially relevant outcomes from wider health communication literature (identified in two ways, in sources 1 and 2) and from focus groups (source 3). First (source 1), we examined a taxonomy of outcomes measured in evaluations of health communication interventions related to

consumers' medicines use and shared decision-making—topics broader than vaccination communication but with conceptual similarities. The second source (source 2) was a targeted literature search for outcomes related to known vaccination communication interventions. Finally (source 3), we added outcomes raised in focus groups with stakeholders about their experiences with vaccination communication. We describe these processes in detail below.

2.1. Adding new outcomes

2.1.1. Source 1: Cochrane Consumers and Communication (CCC) group's taxonomy of health communication outcomes

Vaccination communication and broader health communication strategies share many of the same aims, such as

informing or educating, enabling communication, supporting and teaching skills [32] (see Fig. 2 for an overview the purposes of vaccination communication interventions) [1,2]. With so many similarities at the intervention level, it is reasonable to expect that vaccination communication and health communication also share common outcomes.

We therefore looked to an existing taxonomy of outcomes for health communication: the CCC group's outcome taxonomy [29]. CCC manages the production of Cochrane systematic reviews of interventions affecting consumer health care participation. CCC developed this outcome taxonomy for authors of reviews of health communication and participation interventions, by analyzing trials and systematic reviews and consulting relevant experts [13].

We compared outcomes in the CCC taxonomy with those in our Trial Outcomes Map to identify gaps in our Map; that is, communication-related outcomes from the CCC taxonomy that could potentially measure the effects of vaccination communication. Three researchers (J.K., S.H., and R.R.) discussed each outcome uniquely found in the CCC taxonomy and added to the Map those we agreed were relevant for capturing the effects of vaccination communication.

2.1.2. Source 2: *COMMVAC* interventions taxonomy and targeted literature search

From earlier analysis of the Map, we knew that vaccination communication trials were not measuring all outcomes related to the broad scope of vaccination communication intervention purposes. In this step, we extrapolated additional potential outcomes—particularly intermediate or process outcomes—from the full range of known vaccination communication interventions cataloged by the *COMMVAC* interventions taxonomy [1,2].

We hypothesized that the communication purposes in the interventions taxonomy (Fig. 2) each indicated an area in which vaccination communication should have an effect and therefore where potential outcomes should exist. For instance, interventions to inform or educate would be expected to change knowledge or understanding levels, and interventions to enhance community ownership might affect levels of community participation in vaccination-related activities.

We compared the outcomes implied by intervention purposes with those in the Map to identify gaps where there were few or no reported outcomes. Gaps suggested that existing vaccination trials had either not evaluated a particular intervention type or had not reported outcomes reflecting all identifiable aspects of the communication.

We found that trials often failed to measure outcomes related to enhancing community ownership or facilitating decision-making. To add specific outcomes to fill these gaps, we conducted targeted literature searches in nonvaccination contexts for evaluations of interventions such as community-focused communication and patient decision aids. We searched Google Scholar and reference lists of

relevant papers, extracting applicable outcomes. Examples of these topics and key references are outlined in Table 1.

2.1.3. Source 3: *focus groups*

Our final source of outcomes was from focus group discussions, to be described in detail in a future publication. We used a combination of convenience sampling and stratified purposive sampling to recruit parents and health care professionals (researchers, health care providers, government/NGO representatives) (Table 2) [45]. Evidence for the optimum number of focus groups is inconclusive [46]. We used our limited resources to organize at least one session with each stakeholder group, acknowledging that participants' views may not be fully comprehensive for each group.

The discussion topic was how participants experienced and perceived vaccination communication within their stakeholder roles and what qualities they felt made communication “good/effective” or “bad/ineffective.” Discussion guides differed slightly for parents and professionals because most parents were not immediately familiar with the concept of outcomes. Sessions were audio recorded and transcribed. One researcher (J.K.) analyzed the transcripts using a modified framework analysis approach [47], described briefly below.

First, we thematically analyzed all parent and all professional transcripts and inductively identified two “data themes” lists, based on their experiences and perspectives. We translated these data themes into “outcome themes,” which more closely related to measurable outcomes. For example, one data theme from parents, “trust is essential,” translated into the outcome theme “trustworthiness of communicator/provider.” Professionals also explicitly discussed several outcomes, such as “intention to vaccinate” or “decisional conflict,” which were directly added to the outcome themes list. Using framework analysis, we then charted and interpreted outcome themes by applying a draft outcome taxonomy, facilitating incorporation of new outcomes raised by the focus groups.

2.2. *Organizing the outcomes into the taxonomy*

Through iterative discussion and informed by our research team's considerable experience with taxonomy development [1,2,32,48,49] and the organizational principles of OMERACT's conceptual framework [30], we organized the outcomes into domains and overarching core areas.

3. Results

In Fig. 3, we present an overview of our taxonomy based on the OMERACT conceptual framework [30].

3.1. *Core areas, domains, and outcomes*

According to Boers et al., core areas are intended to “encompass the complete content of what is measurable in

Table 1. Targeted literature search topics and reference examples

| Intervention category | Topics searched |
|-----------------------------|--|
| Enhance community ownership | <ul style="list-style-type: none"> • Community-directed interventions (CDIs) [33] • Community-based participatory research [34,35] • Community coalitions [36,37] • Capacity building [38] • Social capital [37,39] |
| Facilitate decision-making | <ul style="list-style-type: none"> • Patient decision aids • Shared decision-making • The International Patient Decision Aids Standards (IPDAS) Collaboration [40–44] |

a trial” [30] and a COS should include at least one outcome from each core area. We have defined three core areas for vaccination communication, but as the potential purposes of these interventions are highly variable, at this stage, we do not suggest that a COS should include outcomes from each core area. The three core areas in our taxonomy are psychosocial impact; health impact; and community, social, or health system impact. These encompass the key values of communication, reflecting principles of democratic participation and consumer empowerment in which “consumers are seen as equal partners and citizens” who “participate individually or collectively in health decisions” [50].

In each core area are two or three domains. These are broken down into outcomes, which are conceptually grouped for clarity. Outcomes are the effects of exposure to a vaccination communication intervention [30]. The taxonomy does not extend to the level of outcome measurement instruments, and instruments may not yet exist for every identified outcome. Depending on the context and the specific intervention, outcomes in the taxonomy may be assessed in individual parents or community members (consumers), health care providers, or at a community or health systems level. We did not specify the level at which each outcome might be measured because vaccination communication is dynamic and involves a range of actors.

Below, we describe the taxonomy’s main features and content. The complete taxonomy is available in Appendix at www.jclinepi.com.

3.1.1. Core area 1: psychosocial impact

The definition and use of the word “psychosocial” about health is variable, depending on the discipline or context in

which it is used. This term, as a core area, encapsulates concepts underpinning the relation between individuals’ psychological characteristics and the social factors manifested in interpersonal relationships [51]. The three-component domains are “knowledge or understanding,” “attitudes or beliefs,” and “decision-making” (Table 3). Each of these domains is experienced by an individual but can influence or be influenced by the individual’s social interactions, whether these are interactions between consumers and health care providers, or between family members or peers.

“Knowledge or understanding” includes outcomes dealing primarily with the different ways that knowledge can be expressed or demonstrated. In the full taxonomy, there is a list of vaccination communication-specific topics for which knowledge or understanding might be assessed (Appendix at www.jclinepi.com). Focus group parents raised outcomes about how and where to find relevant information or how to judge the quality of information or sources.

The “attitudes or beliefs” domain is particularly relevant for identifying or predicting vaccine hesitancy or the degree of uncertainty that people feel about vaccinations [7,52–54]. Several of the outcomes in this category were discussed at length by focus group participants. For example, parents and providers in particular discussed issues of trust, whereas researchers discussed potential outcomes to measure vaccine acceptance.

The “decision-making” domain has been extensively studied in the context of patient decision aids and shared decision-making [40,42,43]. Many of the outcomes in this category were added through the targeted literature search (Table 1). To retain the important distinction between the process of making the choice and the choice itself, which is highlighted by decision aids researchers [42,43], we included headings to group the outcomes in this domain.

3.1.2. Core area 2: health impact

Communication affects people’s health and health behaviors, and this is reflected in the two domains in the core area of health impact, “vaccination status and behaviors” and “health status and well-being” (Table 4). Most vaccination communication interventions are implemented to improve some aspect of vaccination status or behavior, and most trials measure outcomes in this domain, although in different ways. Appendix at www.jclinepi.com

Table 2. Focus group overview

| Stakeholder group | | Number of focus groups | Setting/s in which the participants were based | Total number of participants |
|--|--|------------------------|--|------------------------------|
| Parents | Parents | 3 | Melbourne, Australia | 12 |
| Professionals | Health care providers | 1 | Melbourne and Sydney, Australia | 4 |
| | Researchers | 1 | Sydney, Australia | 3 |
| Government, multinational or non-governmental organization (NGO) representatives | Government, multinational | 2 | Melbourne, Australia | 5 |
| | or non-governmental organization (NGO) representatives | | Cameroon, Mozambique, Nigeria; Switzerland (multinational organizations) | 7 |

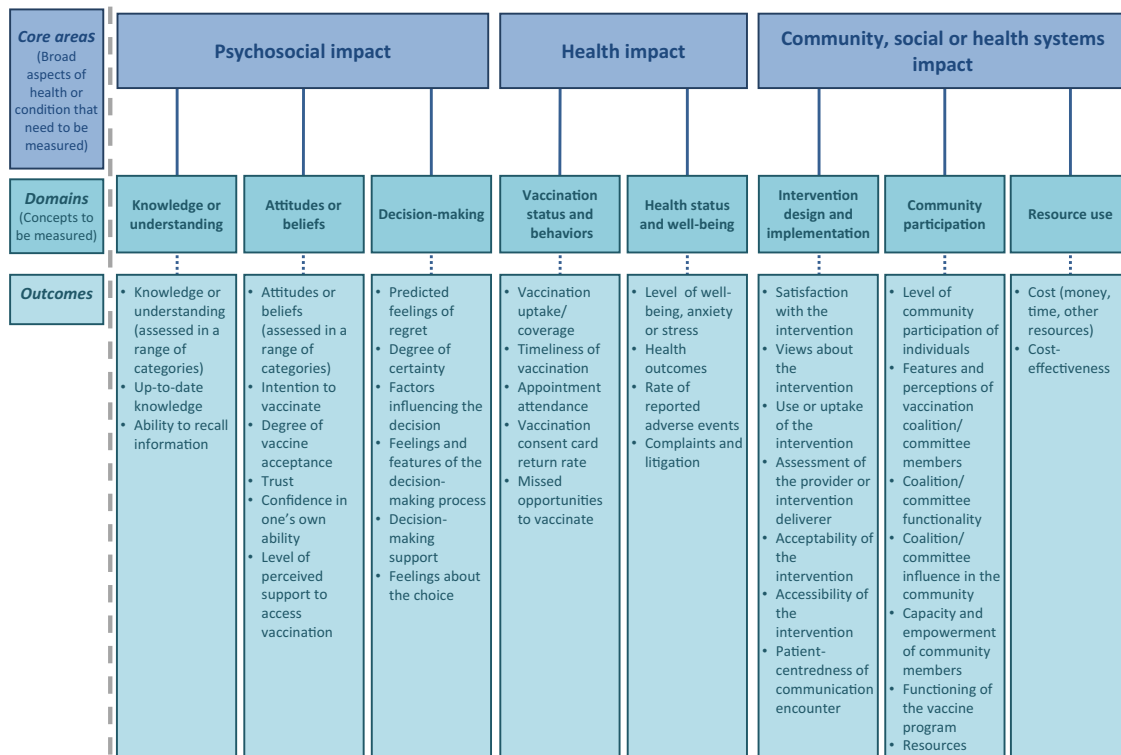


Fig. 3. Overview of COMMVAC outcome taxonomy for childhood vaccination communication. COMMVAC, Communicate to Vaccinate.

comprehensively lists outcomes in this area. Government and NGO focus group participants added the outcome of vaccination consent card return rate.

Communication may also directly impact on people’s physical or psychological health and well-being. Morbidity or mortality associated with vaccines or vaccine-preventable diseases are not direct consequences of communication but may be measured as longer-term indicators of the success or failure of a vaccination communication effort. Additionally, communication may either reduce or increase psychological outcomes such as feelings of anxiety or stress. For health services, there may be complaints or litigation associated with vaccination communication interventions or with the vaccination itself. Some outcomes in this domain were added from the CCC taxonomy (source 1).

3.1.3. Core area 3: community, social, or health system impact

This core area, encompassing three domains, deals with the broader impacts of vaccination communication interventions, including how communication affects communities and health systems and also how interventions can shape the design and implementation of future interventions (Table 5).

The outcomes in the first domain, “intervention design and implementation,” were discussed at length by all stakeholders’ focus groups. Many of these are considered process outcomes or measures of intervention fidelity. These are rarely included as primary outcomes in trials, but the focus

groups indicated their importance as factors affecting whether a communication intervention achieves its end point goal.

The “community participation” domain includes a range of outcomes assessing the effects of interventions to enhance community ownership of vaccination. Several of the outcomes are relevant to monitor and process evaluation of vaccination-related community coalitions or committees, such as Nigerian Ward Development Committees. These organizations are responsible for engaging the community in social mobilization and other aspects of vaccine program delivery [55]. International focus group participants discussed community-level monitoring and evaluation at length, and many outcomes in this domain were added through the targeted literature search (Table 1).

The final domain is “resource use.” Information on the necessary resources and costs (including time and personnel) and cost-effectiveness of communication interventions is crucial to implementation decision makers [56,57].

4. Discussion

Communication for childhood vaccination is a globally evolving field, and a comprehensive understanding of outcomes and their role in evaluation in this area is critical for future evidence production. There remains much to be learned about how vaccination communication works, and this requires a broader conceptual awareness of potentially relevant outcomes than currently exists.

Table 3. Psychosocial impact core area—domains and examples of outcomes

| Core areas | Domains | Outcomes | |
|---------------------|----------------------------|---|---|
| Psychosocial impact | Knowledge or understanding | <ul style="list-style-type: none"> • Knowledge or understanding <ul style="list-style-type: none"> - Related to vaccines, schedule, diseases, risks, accessing services, finding and judging information, child health, vaccination guidelines, or communication | <ul style="list-style-type: none"> • Up-to-date knowledge (currency of knowledge) • Ability to recall information (retention) |
| | Attitudes or beliefs | <ul style="list-style-type: none"> • Attitudes or beliefs <ul style="list-style-type: none"> - Related to vaccines, reactions, delivery or pain, safety, diseases, or health system • Intention to vaccinate • Degree of vaccine acceptance • Level of perceived support to access vaccination | <ul style="list-style-type: none"> • Trust <ul style="list-style-type: none"> - In communication deliverer, provider, communication content, or health system • Confidence in one's own ability (self-efficacy) <ul style="list-style-type: none"> - To vaccinate on time, find and understand information, make decisions, or deliver vaccines or information |
| | Decision-making | Considering the options <ul style="list-style-type: none"> • Predicted feelings of regret (anticipated regret) • Degree of certainty (decisional conflict) and clarity of values • Factors influencing the decision <ul style="list-style-type: none"> - Perceived risks of vaccine or disease, perceived ability to vaccinate, views of others (social norms) | Making the choice <ul style="list-style-type: none"> • Feelings and features of the decision-making process <ul style="list-style-type: none"> - Satisfaction with process, perceived control, perception of shared decision-making, informed consent • Decision-making support <ul style="list-style-type: none"> - Perceived support, satisfaction with support • Feelings about the choice <ul style="list-style-type: none"> - Value congruence, decision satisfaction, confidence in decision, decision anxiety, regret |

This taxonomy is a methodological advancement for core outcome research, an important stage in the process of developing a core domain set for vaccination communication, and a tool to help improve understanding and assessment of vaccination communication's many potential impacts.

4.1. Methodological advances

Using a taxonomy to categorize outcomes is not unique, but our approach to identifying potential outcomes in this field is innovative. We knew that any COS built from outcomes that were not comprehensive would only reinforce existing limitations in vaccination communication research. Therefore, while we began with established COS methods such as a review of trial literature and stakeholder consultation [24,58–60], we also expanded and adapted standard COS methodology by identifying and translating potential

outcomes from the wider field of related health communication literature.

This may be a useful strategy for researchers studying interventions rarely assessed in trials or where existing trials measure limited outcomes. One approach is to identify interventions in related areas that share key features with the study intervention, assessing the outcomes measured in trials of those related interventions. For example, we looked at outcomes for communication interventions applied to topics other than vaccination. Another approach is to consider the study intervention in terms of its intended purpose, developing a sort of hypothetical logic model, to identify the full range of potential impacts [13,32]. We used our existing taxonomy of vaccination communication interventions, organized by purpose, to identify areas where we expected outcomes. We then conducted a targeted search for studies that had evaluated that type of outcome.

Table 4. Health impact core area—domains and examples of outcomes

| Core areas | Domains | Outcomes | |
|---------------|----------------------------------|--|---|
| Health impact | Vaccination status and behaviors | <ul style="list-style-type: none"> • Vaccination uptake/coverage • Timeliness of vaccination | <ul style="list-style-type: none"> • Appointment attendance • Vaccination consent card return rate • Missed opportunities to vaccinate |
| | Health status and well-being | <ul style="list-style-type: none"> • Level of well-being, anxiety, or stress <ul style="list-style-type: none"> - Related to receiving or delivering communication intervention, vaccination, diseases • Health outcomes (morbidity or mortality) <ul style="list-style-type: none"> - Related to vaccination or disease | <ul style="list-style-type: none"> • Rate of reported adverse events <ul style="list-style-type: none"> - Related to intervention or vaccination • Complaints and litigation <ul style="list-style-type: none"> - Related to intervention |

Table 5. Community, social, or health system impact core area—domains and examples of outcomes

| Core areas | Domains | Outcomes | |
|--|--|--|--|
| Community, social, or health system impact | Intervention design and implementation | <ul style="list-style-type: none"> • Satisfaction with the communication intervention • Views about communication intervention <ul style="list-style-type: none"> - Perceived accuracy, quality, effectiveness, or influence of intervention on decision • Use or uptake of communication intervention • Patient centeredness of the communication encounter | <ul style="list-style-type: none"> • Assessment of the provider/deliverer <ul style="list-style-type: none"> - Confidence in abilities, perceived competence or knowledge, adherence to planned intervention • Acceptability of the intervention <ul style="list-style-type: none"> - Cultural appropriateness, acceptability of time required to receive/deliver communication • Accessibility or clarity of the intervention |
| | Community participation | <ul style="list-style-type: none"> • Level of community participation of individuals <ul style="list-style-type: none"> - In vaccination events, intervention design, program delivery, research, policymaking, coalitions, or programs • Features and perceptions of vaccination coalition or committee members <ul style="list-style-type: none"> - Membership numbers or diversity, perceptions of coalition influence, satisfaction or confidence in coalition functioning, perceptions of leadership or of being a member • Vaccination coalition or committee functionality <ul style="list-style-type: none"> - Communication between staff/members/community, meeting frequency, adherence to goals, community perceptions of functionality | <ul style="list-style-type: none"> • Vaccination coalition or committee influence in the community <ul style="list-style-type: none"> - Percentage of community who know their committee members • Capacity and empowerment of community members <ul style="list-style-type: none"> - Perceived ability of the community to organize or influence decisions, perceived knowledge facilitated by program, perceived ability to participate, social inclusion • Functioning of the vaccine program <ul style="list-style-type: none"> - New programs, services, and practices facilitated, policy changes influenced, involvement of local leaders • Resources <ul style="list-style-type: none"> - Mobilized or required to scale up/down |
| | Resource use | <ul style="list-style-type: none"> • Cost (money, time, other resources) related to intervention or vaccination | <ul style="list-style-type: none"> • Cost-effectiveness of intervention development, delivery, or design |

4.2. The importance of intermediate outcomes

There are many studies of vaccination communication interventions, but limitations in study design and inconsistent or incomplete outcome measurement have made it difficult for systematic reviews to reach conclusions about effectiveness [8,19,20,61,62]. Communication is a complex, often multifaceted intervention, and its effects cannot be unpacked with trials measuring outcomes dominated by “hard” end points [63]. This pattern is also reflected in other areas where complex interventions predominate, such as medicines use [64,65].

This creates difficulties for a range of reasons. First, if a complex intervention “fails,” we cannot tell whether this is due to deficits in implementation or the underlying theoretical approach. Similarly, even if the complex intervention is “successful,” we cannot tell how it could be improved, which pathways are being influenced to effect change, or whether all parts of the intervention are necessary to achieve that outcome [18,66]. This last point is particularly relevant for vaccination communication, where communication strategies are often combined in packages [6], frequently in resource-constrained settings. Finally, as focus group discussions highlighted, process outcomes are often important to stakeholders: communication delivery can impact whether parents follow recommendations, and policymakers may use intervention uptake as a proxy for

difficult-to-assess outcomes like satisfaction with the intervention.

These issues also have substantial implications for research wastage [67]. Ultimately, research that focuses on end point outcomes and outcomes that are not important to stakeholders is far less informative than it could be. In an area like vaccination communication, which has the potential for community-wide (and in some cases global) impacts, this is a serious issue. Moving into the future, we need to focus on the right outcomes to ensure that evaluations produce meaningful evidence that advances the field and contributes to improved interventions.

4.3. Next steps: toward developing a COS

We will use this taxonomy in the next stage of developing a set of core domains for three types of vaccination communication interventions. In an online Delphi survey, we will present the domains of the taxonomy, with examples of key outcomes for illustration, to international stakeholders including parents, health care providers, researchers, and government or NGO representatives. They will rate the importance of the outcome domains in the context of three key types of vaccination communication. We will also gather feedback on the utility of the taxonomy itself as a tool to facilitate COS development.

4.4. Strengths and limitations

The outcomes in the taxonomy reflect a range of social perspectives and consider outcomes at different levels (e.g., consumers, communities, health providers). However, some specific outcomes may be missing. We were only able to hold seven focus groups, predominantly in Australia, and although the literature sources we reviewed were international, all were published in English. Outcomes may also change as the field develops and as the taxonomy is exposed to broader communities of stakeholders. Nevertheless, we believe that the overarching organizational structure of the taxonomy is comprehensive and adaptable enough to incorporate these refinements.

This taxonomy could be used by trialists or program evaluators as they select the outcomes to report for a vaccination communication evaluation or by intervention designers and theorists hypothesizing and testing communication strategies for behavior change. The taxonomy development methods and format are also relevant for COS researchers in other fields, particularly those interested in complex or communication-related interventions.

The taxonomy does not include measurement methods or instruments, which means that some included outcomes may be more difficult to operationalize in an evaluation than others and some specific outcomes could be combined in one measurement tool. By using the taxonomy to prioritize key outcome domains in the forthcoming Delphi consultation, however, we hope to bring methodological research attention to those outcomes which are considered important but for which no validated instrument yet exists.

5. Conclusions

This taxonomy is a novel exploration of the potential outcomes associated with vaccination communication, bringing to light a range of concepts that are otherwise rarely considered but which might help to unpack how these complex communication interventions are—or are not—working. It can be used by researchers or other evaluators who are making choices about which outcomes to assess and will be an integral feature of a forthcoming effort to establish core outcome domains for vaccination communication interventions.

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Supplementary Data

Supplementary data related to this article can be found at <http://dx.doi.org/10.1016/j.jclinepi.2017.02.007>.

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