Outcomes mapping study for childhood vaccination communication: too few concepts were measured in too many ways

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Abstract

Objectives: The objectives of this article are to (1) comprehensively catalog outcomes measured in trials of childhood vaccination communication interventions and (2) analyze patterns and trends in outcome selection. To achieve these objectives, we developed a Trial Outcomes Map for vaccination communication.

Study design: We searched the Cochrane Central Register of Controlled Trials for trials of childhood vaccination communication interventions, extracting verbatim all outcome information from included trials. Through thematic grouping, we categorized outcomes based on conceptual similarities, forming a Trial Outcomes Map.

Results: We identified 112 relevant trials containing 209 outcomes. Thematic analysis revealed three overarching Outcome Categories: consumer-, vaccination-, and health system-related outcomes. These categories contain 21 Outcome Types (eg, “knowledge,” “cost”), measured using 66 different Outcome Variables. Vaccination outcomes were measured most frequently and health system-related outcomes least frequently. Consumer outcomes are increasingly measured in more recent trials.

Conclusion: The number of measures used for the same outcomes complicates data synthesis and interpretation. Despite recent trends toward including consumer outcomes, intermediate outcome measurement is lacking, hampering understanding of how and why vaccination communication interventions do or do not work. This Map may improve outcome consistency in future trials and will contribute to a forthcoming core outcome set.

Keywords: Outcome; Core outcome set; Vaccination; Communication; Outcomes map; Outcome categorisation; Methodology

1. Background

Effective communication with parents and communities is critical to addressing vaccine hesitancy and improving global childhood vaccination uptake [1–4]. As the Global Polio Eradication Initiative states, “communications [sic] is the poor cousin of vaccine delivery, undeservedly receiving far less focus ... But communications is everybody’s business” [5].

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Communication intervention is defined as a purposeful, planned, and formalized strategy associated with a diverse range of aims, including to inform, educate, remind, support, or change behavior [6]. Communication for vaccination-related outcomes may target parents, health professionals, whole communities, or health organizations—or multiple different groups at once. Measuring the effects of this diversity of communication interventions therefore requires clarity and consistency in the outcomes used for such measurement. Additionally, as interest grows in strategies that involve and engage with communities [8], it is increasingly necessary to determine which outcomes are relevant and appropriate to different stakeholders (eg, parents, community leaders, vaccination program managers).

Communication about childhood vaccination is increasingly recognized as an area which can and should be evidence informed [7,9–11]. However, little research has focused on determining what outcomes should be measured in trials of vaccination communication interventions, and there are a number of challenges to developing the evidence base in this area. First, trials in this area often use different definitions for key outcomes, such as vaccination status or uptake, as well as different ways to measure them (eg, by vaccination cards and/or by mother’s report), making it difficult to interpret study findings or compare results across studies [12].

Second, interventions that aim to increase vaccine coverage may be complex and include several components, of which communication may only be one (eg, [13–15]). Measuring a single end-point outcome—such as vaccination status—can make it difficult to evaluate the effectiveness of the individual communication components, as compared to other parts of the intervention. These other components, such as monetary incentives or improved access to vaccine providers, may mask or boost the effects of the communication components. Without a clear understanding of which elements are effective and which are not, resources may be expended on multifaceted interventions in which only some components are effective [16].

Finally, intermediate outcomes—such as attitudes and beliefs or intention to vaccinate—should be measured in addition to typical end-point outcomes, such as change in vaccination rates. Intermediate outcomes help determine and test the pathways through which an intervention may work [16–18]. Understanding causal pathways is especially important when assessing the effects of complex interventions [19,20], but many trials and reviews of complex interventions measure only end-point outcomes [11]. For example, a recent Cochrane systematic review found a lack of meaningful intermediate outcome measurement in trials of face-to-face communication about childhood vaccination [9], and an overview of reviews found that intermediate outcomes were seldom assessed for communication around medicines use and vaccination [11].

Intermediate outcomes are also important because some vaccination communication interventions may lead to a better understanding among parents or caregivers of the need for vaccination, and more informed decision making, but they may still choose not to or may be unable to vaccinate (eg, because of barriers to access). Measuring the final—but not intermediate—outcomes would erroneously suggest that these communication interventions are not worth exploring. Additionally, consumer-related outcomes are not always intermediate outcomes. In some trials, they could be the end-point outcomes, as creating informed service users may itself be the goal of the intervention [21].

1.1. Core outcomes

The development and use of evidence-based core outcome sets (COs) is one way to bring consistency to outcome measurement and reporting in a given field or topic area. COs are agreed-on standardized groups of outcomes for particular health conditions or topics [22]. Although additional relevant outcomes may be measured, COs are intended to establish a minimum standard set of outcomes to be measured in all effectiveness trials on
a particular topic. COSs can help increase the relevancy of research evidence to decision makers, improve evidence synthesis across studies, or help reduce selective outcome reporting—a notable problem in trials [23–26].

At present, two leading research collaborations in COS research are The Outcome Measures in Rheumatology (OMERACT) and the Core Outcomes in Effectiveness Trials (COMET) (www.comet-initiative.org) initiatives. OMERACT has been engaged in developing COSs for rheumatology since 1992 [27]. COMET maintains a comprehensive database of projects and publications related to COS development and methodology across a range of topics [22,28]. OMERACT’s approach distinguishes between what to measure—which they term “domains”—and how to measure—“outcome measurements,” which covers the instruments used to assess each domain. Reflecting this distinction, an OMERACT “core outcome set” is actually a “core outcome measurement set.” COMET’s language is more general, with the word “outcome” referring to the concept to be measured and “instrument” referring to the way it is measured. In this article, we use the more general COMET language, as we describe the identification of the range of concepts measured as outcomes in trials of vaccination communication interventions. In later stages, as our conceptual work becomes more focused, we plan to develop what OMERACT terms “core areas” and “domains,” and we do not want to confuse the outputs of these two project stages.

Although interest in COSs is growing, the COMET database indicates that most COSs are related to clinical interventions; very few address interventions directed at consumers such as communication. We are therefore undertaking research on vaccination communication COS methodology and development as part of the “Communicate to Vaccinate (COMMVAC 2)” project (www.commvac.com), an international project addressing evidence-based communication about childhood vaccination in low- and middle-income countries. The ultimate output of this multistage project will be a preliminary COS for a vaccination communication intervention assessed as a priority by stakeholders.

There is no single methodology for developing a COS, although researchers from COMET and OMERACT have published some overarching guidance for the process [28,29]. Broadly speaking, both groups indicate that the process should include setting the scope of the COS, identifying existing outcomes through literature review, consulting with a range of stakeholders and engaging in a consensus process to identify what should be measured [22].

Much of the published literature on COSs focuses on this consensus process and the production of the final COS. There are fewer descriptions of the earlier stages of development, most notably the linking step between the literature review and the consultation and consensus processes. Communication for vaccination is still an emergent field of research: the COMMVAC interventions taxonomy was the first to comprehensively define the range of vaccination communication interventions [4]. To our knowledge, there has not yet been an effort to similarly illuminate the range of related outcomes that have been measured. Therefore, we have expanded this linking step between literature review and stakeholder consultation by developing a Trial Outcomes Map. The Map is a significantly enhanced literature review output, forming the basis for consultations with stakeholders in subsequent stages of this project. It is also the first step toward organizing this complex array of outcomes into core areas and domains—a process which has been described in a small number of articles predominantly focusing on clinical interventions for health conditions [29–32] but which has not yet been undertaken for outcomes of consumer-oriented preventive health interventions.

1.2. Objectives

The objectives of this article are to (1) comprehensively catalog which outcomes have been measured in trials of childhood vaccination communication interventions, in the form of a Map and (2) analyze patterns and trends in outcome selection across studies. In this article, we describe the methods for creating this Trial Outcomes Map, report the results, and reflect on a number of important trends in outcome reporting identified during this process.

2. Methods

In Fig. 1, we outline the steps of the COMMVAC COS development project. In this article, we will address the first three steps examining “What has been measured?”

2.1. Literature search

We searched the Cochrane Central Register of Controlled Trials (CENTRAL) for trials of communication interventions related to childhood vaccination. For this search, we used a strategy developed for an earlier phase of the COMMVAC project in which we developed a taxonomy of vaccination communication interventions [4,7]. The search strategy incorporated communication terms derived from the Cochrane Consumers and Communication Review Group (CCCRG) scope [34] and vaccination terms based on a relevant Cochrane review [35] (Appendix A at www.jclinepi.com). There were no date limitations. We compared the search output with the output from the earlier phase to ensure that we captured all results.

The rationale for searching only CENTRAL was that we were specifically interested in outcomes measured in trials of vaccination-related communication interventions, and CENTRAL is the largest global database of trials. Our experience from undertaking two Cochrane systematic reviews on this
topic suggested that the considerable resources needed to screen other databases did not greatly increase the yield of relevant trials [9,10]. Furthermore, in future steps (outlined in Fig. 1) we will supplement our Trial Outcomes Map with outcomes raised by stakeholders and from other types of studies based on gaps identified through comparative analysis.

We included trials (randomized, quasi randomized, or cluster controlled) if they

1. evaluated a communication intervention [7].
2. focused primarily on a vaccination population of children up to 6 years of age.
3. addressed routine childhood vaccines only [36].
4. reported communication which was addressed to caregivers or community members and was related to childhood vaccination. Communication interventions directed to health professionals were not included unless they specifically impacted the encounter between the provider and parents. This focus reflects the scope of the COMMVAC project [4,7].
5. were written in English.

2.2. Extracting data on measured outcomes

For each outcome mentioned in an included trial, we extracted into a spreadsheet all information defining the outcome, such as type (eg, vaccination status), outcome variables (eg, up to date for all scheduled vaccines), age of the subjects (eg, up to age 2), and any other related details. We used the exact words of the trial authors. We did not extract data related to the timing and scale or tool used to measure the outcomes, as examination of how specific Outcome Variables were measured was not the subject of the research.

2.3. Thematic grouping

Two researchers (J.K. and S.H.) reviewed the extracted data. One author (J.K.) coded the individual outcomes according to what these measured, using the language of the trialists. These codes were discussed and confirmed with S.H. This first round of codes became the most specific level of the taxonomy. We retained a relatively large number of different groups, rather than aggregating the information and potentially losing important details.

We then repeated the inductive coding and grouping process to build to progressively broader Outcome Categories, informed by our experience and perspective on evaluating communication interventions [4,6]. We constantly compared the outcome information with the emerging codes until all outcomes were coded, establishing groups of thematically similar outcomes [37].

The process at each level was iterative and the final Map structure and organization was based on several rounds of discussion within the research team, which includes experts in vaccination and communication research with experience in taxonomy development [4,6,16].

The groupings in this Trial Outcomes Map enabled us to analyze patterns in the frequency of end point and intermediate outcome measurement across trials. Following the example of Sinha et al. [31], we also analyzed trends in outcome measurement over time, although this analysis was limited by sample size. To identify any clear or crude changes, we divided the trials into two groups by median...
year of publication (2000) and counted the number of times outcomes from each overarching Category were measured in these two groups.

3. Results

In the following sections, we report on steps 1 and 2 of the Trial Outcomes Map development process (Fig. 1), describe the Trial Outcomes Map produced, and identify key trends related to vaccination communication outcomes.

3.1. Included trials

We ran the search in November 2013 and found 889 trials. We compared these results with those returned in the earlier search (conducted in 2011 and screened by two researchers) and added nine additional trials that were not captured by the most recent search (most likely due to changes in indexing). This left us with 898 trials, from which we removed eight duplicates. One researcher (J.K.) screened these 890 results by title, abstract, and full text where necessary. A total of 112 trials met our inclusion criteria (see Fig. 2).

The included trials evaluated communication interventions that intended to inform or educate, remind or recall, teach skills, provide support, facilitate decision making, enable communication, or enhance community ownership related to childhood vaccination [4]. The complete reference list of included trials can be found in Appendix B at www.jclinepi.com.

3.2. The outcomes

Of the 112 trials, 87 measured fewer than three outcomes; 21 trials measured three to five outcomes; and four trials measured more than five outcomes. In total, we extracted information on 209 separate outcomes, cataloging what has been measured to develop the Trial Outcomes Map. We present the Map from the largest to smallest level

![Fig. 2. Classification of articles retrieved.](image-url)
of conceptual specificity for clarity, but as explained in the Section 2, it was developed in the reverse direction.

The three levels of the Map from the broadest to smallest are Outcome Categories (of which there are three), Outcome Types (21), and Outcome Variables (66) (see Table 1) [38–40].

The three overarching Outcome Categories are as follows:

- Consumer-related outcomes (ie, outcomes relevant to the thoughts, feelings, experiences, and decision making of parents or community members dealing with childhood vaccination),
- Vaccination-related outcomes (ie, outcomes assessing changes in vaccination status or behavior), and
- Health system-related outcomes (ie, outcomes relevant to systems-level issues).

Outcome Types are the concepts being measured. These are organized alphabetically, rather than by frequency of measurement or other criteria, so as not to suggest a hierarchy of importance.

Outcome Variables refer to the ways in which different trials define and measure outcomes. They are not the instruments or scales used to collect data, which would be more specific still. For example, the Outcome Type “appointment attendance” was assessed with nine separate Variables, including the following: number of appointments attended; kept appointment rate; and canceled; or no-show appointments.

Some Outcome Types contain similar Variables, but with nuanced differences. For example, “receipt of vaccine” includes measures of whether any kind of vaccination was received by children, although “vaccination status” refers to the extent to which the child received the vaccinations that they should have (eg, by a particular time).

3.3. Outcome patterns and trends

Grouping the Map into Outcome Categories, Types, and Variables helped us identify patterns and trends in outcome selection and measurement. Fig. 3 shows the number of different Variables for each Outcome Type, listed in order of most to fewest Variables.

3.3.1. Variation across outcomes used to assess vaccination

As might be reasonably expected, the most commonly measured Outcome Types were end-point vaccination outcomes. Of the 112 trials identified, 89 (80%) measured at least one vaccination-related outcome. We identified six vaccination-related Outcome Types: “appointment attendance,” “on time vaccination,” “probability of reaching one year without each immunisation,” “receipt of vaccine,” “time to vaccination,” and “vaccination status.” These Outcome Types evaluate different aspects of vaccination that may be impacted by a communication intervention.

At the level of Outcome Variables (ie, the level at which they are measured), we found a substantial degree of variation. The six Outcome Types are represented by 28 different Outcome Variables. This is most concerning in the Types “receipt of vaccine” (measured using nine Variables) and “vaccination status” (five Variables). The fact that trialists do not appear to be drawing on standard measures for these end points may create a range of problems, not least of which is difficulty comparing the effects of interventions.

3.3.2. Consumer- and health system-related outcomes

Consumer-related and health system-related outcomes are also important when evaluating the effectiveness of vaccination communication interventions, but this Map again shows the lack of consensus around which Outcome Types and Variables are and should be assessed in trials.

Consumer-related outcomes were measured by 31 trials, or 28% of the total mapped trials. “Knowledge” and “attitudes or beliefs” were the two most commonly measured consumer-related Outcome Types, assessed by 16 and 5 trials respectively. “Intervention evaluation,” which addresses consumers’ views, impressions, and assessments of the communication intervention itself, was measured by five trials. As with vaccination-related Outcome Types such as “receipt of vaccine,” key consumer-related outcomes such as “knowledge” were measured by a large number of different Outcome Variables (nine). The variation in the consumer-related outcomes assessed by trials is evidenced by the fact that 31 trials measured 14 different Outcome Types using 33 different Outcome Variables.

Health system-related outcomes included “missed opportunities for vaccination” and “cost or cost-effectiveness of the intervention.” These outcomes were measured by 20% of the trials (22 trials).

3.3.3. Trends over time

The analysis indicates a number of trends in outcome measurement over time. We divided the trials into two groups by median year of publication (2000) and compared across these groups the number of times outcomes from each of the three broad Outcome Categories were measured. Fifty-four trials measuring 92 outcomes were published before 2000, and 58 trials measuring 117 outcomes were published since 2000. The most notable trend is the increase in consumer-related outcome measurement. Of the outcomes measured by the pre-2000 trials, 15% were consumer related (14 separate outcomes). This increased to 34% of all outcomes measured after 2000 (40 outcomes) (see Fig. 4). Although more consumer-related outcomes were measured in recent years, this increase is not distributed evenly across all trials: of the 40 consumer-related outcomes measured since 2000, 23 were measured in only four trials [41–44]. The frequency of vaccination-related outcome measurement has remained broadly stable over time (68 vaccination-
Table 1. COMMVAC Childhood Vaccination Communication Trial Outcomes Map

<table>
<thead>
<tr>
<th>Outcome Categories</th>
<th>Outcome Types (N)</th>
<th>Outcome Variables</th>
</tr>
</thead>
<tbody>
<tr>
<td>Consumer-related outcomes</td>
<td>Anxiety (2)</td>
<td>• About vaccine-preventable diseases</td>
</tr>
<tr>
<td>Attitudes and beliefs (8)</td>
<td>• As a result of the intervention</td>
<td></td>
</tr>
<tr>
<td>Decision making (2)</td>
<td>• About vaccination</td>
<td></td>
</tr>
<tr>
<td>Evaluation of the communication intervention (5)</td>
<td>• About specific vaccine(s)</td>
<td></td>
</tr>
<tr>
<td>Information retention over time (1)</td>
<td>• About the intervention</td>
<td></td>
</tr>
<tr>
<td>Intention to vaccinate (4)</td>
<td>• Decision anxiety</td>
<td></td>
</tr>
<tr>
<td>Knowledge (16)</td>
<td>• Decision satisfaction</td>
<td></td>
</tr>
<tr>
<td>Patient-centeredness of care (2)</td>
<td>• Decisional conflict</td>
<td></td>
</tr>
<tr>
<td>Perceived behavioral control (1)</td>
<td>• Acceptance of intervention</td>
<td></td>
</tr>
<tr>
<td>Perceived outcome efficacy (1)</td>
<td>• Readability and comprehension</td>
<td></td>
</tr>
<tr>
<td>Reason for undervaccination (1)</td>
<td>• Opinion on effectiveness</td>
<td></td>
</tr>
<tr>
<td>Risk perception (2)</td>
<td>• Information material preference</td>
<td></td>
</tr>
<tr>
<td>Subjective norm (1)</td>
<td>• Information timing preference</td>
<td></td>
</tr>
<tr>
<td>Use of the communication intervention (1)</td>
<td>• Response to information</td>
<td></td>
</tr>
<tr>
<td>Vaccination-related outcomes</td>
<td>Appointment attendance (18)</td>
<td>• Long-term memories of or actions resulting from intervention</td>
</tr>
<tr>
<td>On-time vaccination (9)</td>
<td>• Intended choice</td>
<td></td>
</tr>
<tr>
<td>Receipt of vaccine (46)</td>
<td>• Likelihood of immunizing on time</td>
<td></td>
</tr>
<tr>
<td>• Change in knowledge about vaccination and other child health issues</td>
<td></td>
<td></td>
</tr>
<tr>
<td>• About particular disease(s) and related vaccines</td>
<td></td>
<td></td>
</tr>
<tr>
<td>• About schedule</td>
<td>• About side effects of immunization</td>
<td></td>
</tr>
<tr>
<td>• About general child health issues including vaccination</td>
<td></td>
<td></td>
</tr>
<tr>
<td>• About contraindications to vaccination</td>
<td></td>
<td></td>
</tr>
<tr>
<td>• About risks and benefits of immunization</td>
<td></td>
<td></td>
</tr>
<tr>
<td>• About local vaccine services</td>
<td>• Physician knowledge about vaccination</td>
<td></td>
</tr>
<tr>
<td>• Satisfaction and experiences with seeking care</td>
<td></td>
<td></td>
</tr>
<tr>
<td>• Perceived ease or difficulty of keeping a vaccination appointment</td>
<td></td>
<td></td>
</tr>
<tr>
<td>• Perceived benefits and costs of performing the recommended health behavior</td>
<td></td>
<td></td>
</tr>
<tr>
<td>• Missed opportunity or missed visit</td>
<td></td>
<td></td>
</tr>
<tr>
<td>• Self-reported perception risk of immunization and of disease</td>
<td></td>
<td></td>
</tr>
<tr>
<td>• Self-reported assessment of whether significant others think a person should or should not engage in a behavior</td>
<td></td>
<td></td>
</tr>
<tr>
<td>• Number of hits to Web site and calls to helpline</td>
<td></td>
<td></td>
</tr>
<tr>
<td>• Number of appointments attended</td>
<td>• Rate of participation in screening services</td>
<td></td>
</tr>
<tr>
<td>• Number of appointments scheduled</td>
<td>• Number of vaccines per study group</td>
<td></td>
</tr>
<tr>
<td>• Timeliness of well-child visits</td>
<td>• Number of vaccines brought up to date</td>
<td></td>
</tr>
<tr>
<td>• Attendance at at least one visit</td>
<td>• Number of children brought up to date</td>
<td></td>
</tr>
<tr>
<td>• Attendance at four or more visits in 1 year</td>
<td></td>
<td></td>
</tr>
<tr>
<td>• Number of children attending health center once in particular time frame</td>
<td></td>
<td></td>
</tr>
<tr>
<td>• Kept appointment rate</td>
<td>• Proportion of eligible children who received vaccine</td>
<td></td>
</tr>
<tr>
<td>• Canceled or no-show appointments</td>
<td>• Compliance with health care maintenance procedures (including vaccination)</td>
<td></td>
</tr>
<tr>
<td>• Rate of participation in screening services</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

(Continued)

4. Discussion

This Trial Outcomes Map comprehensively catalogs the outcomes that have been measured in trials of childhood vaccination communication interventions, categorizing them into three overarching Outcome Categories: vaccination-related, consumer-related, and health system-related outcomes. Analysis of the patterns shows that most trials focus on vaccination-related outcomes, but that there is wide variation in how these key outcomes are measured. Potentially important consumer-related and health system-related outcomes are not widely measured, although a basic analysis of trends over time does suggest some increased awareness of consumer-related outcomes.

4.1. Too much variation in the way in which key vaccination outcomes are measured?

The trial literature defined key Outcome Types using many different Outcome Variables, meaning there is
considerable inconsistency at the level of actual measurement. The most significant concern from the perspective of building an evidence base is that this kind of variation makes it difficult or impossible to compare key outcomes, for example, vaccination status, or to combine them in a useful synthesis.

It is unclear if the proliferation of vaccination-related Outcome Types and Variables represents a reasonable response and adaptation to the varying contexts of different trials or if it indicates a problem—for example, trialists legitimately diverging from past research because of its limitations or trials conceived in isolation from previous research [45,46]. Some variation may be inevitable due to practical limitations in the way that data are defined, recorded, or made available to researchers [12]. For example, immunization registries or records are not equally available or may not contain the same information in all settings.

However, trialists often have a choice of which outcomes to measure, and their selections should be—but are not always—based on the available evidence. For instance, research evidence indicates that age-appropriate immunization Outcome Variables that address the timeliness of vaccination (e.g., receipt of a specific vaccine within the recommended time frame for that vaccine’s delivery) are more accurate and precise than measures of up-to-date vaccination at a particular time point, such as 24 months of age [47–50]. Stakeholder consensus in the form of a COS could help reduce unnecessary outcome variation, help decide which outcomes are more important for trials of communication interventions as compared to other types of vaccination interventions, and ensure that recommended outcomes are based on appropriate evidence.

In the next steps of the COS research process, we will build on the Outcomes Map by consulting with parents, health providers, researchers, and policy makers to identify additional outcomes and determine which outcomes are most relevant and important to these stakeholders. Additional future research could investigate which outcome measurement tools are used at the Variable level and whether these are logical adaptations of existing tools or wasteful development of new tools.

4.2. The narrow scope of outcomes assessed in trials of childhood vaccination communication interventions—what’s missing?

This Map outlines what has been measured in trials to date, but how can we address the gaps—outcomes that should be measured but are currently measured infrequently or not at all? Vaccination communication typically comprises complex interventions and the causal pathways between delivery of the communication intervention itself and changes in end points such as vaccination behavior are not well understood. To enhance our understanding of the mechanisms by which vaccination communication interventions function, researchers need to measure appropriate intermediate outcomes as well as end points.

The trend in the more recently published trials toward measuring consumer-related outcomes is promising and may reflect an increased focus on trying to understand intervention processes [17,51,52] or overall trends in public health toward adoption of interventions that aim to improve consumer experiences, engagement, and participation in health [6,53–56]. However, qualitative literature and trials from other related fields indicate that the outcomes derived from trials and included in this Map are not yet sufficient or complete. For instance, a number of important decision making outcomes such as value clarity and self-efficacy, which are highly relevant to the aim of improving informed choice about vaccination, were not measured in any vaccination communication trials and therefore do not appear in the Map [57,58].

The Map also shows that health system-related outcomes are measured relatively infrequently in communication intervention trials. This may be due in part to the scope of the included trials, which reflect the scope of the
COMMVAC project in their focus on communication interventions directed to or directly impacting parents or communities [4]. However, some key health system-related outcomes such as cost or cost-effectiveness are relevant for any intervention trial, including those oriented toward consumers. The importance of evidence on costs to decision makers has been highlighted by key organizations such as The Cochrane Collaboration and the US Agency for Healthcare Research and Quality [59,60].

To identify additional potential outcomes, in the next steps of this project, we will conduct focus groups with consumers and other stakeholders and compare the Map with other sources of relevant outcomes, such as the related communication outcomes taxonomy of the CCCRG [33]. COMMVAC researchers are also conducting a qualitative evidence synthesis focusing on parents’ and carers’ views and experiences of routine early childhood vaccination communication. This synthesis may help clarify which outcomes are most relevant and important to parents and carers and also the pathways between intervention delivery and important end points.

4.3. Strengths and limitations

This Map is the first comprehensive methodological scoping of outcomes associated with interventions for vaccine-related communication. It encompasses outcomes related to consumers’ views and experiences, vaccination status and behavior, and health systems. Our methodological approach adapts and extends the relatively limited descriptions of the processes for outcomes mapping in clinical areas [29–32] and sheds light on the complexities associated with measuring the effects of vaccination communication interventions. This Map also furthers the field of COS development research by making explicit the methodological link between literature review and stakeholder consultation.

Because we conducted our search only in CENTRAL, which indexes primarily randomized controlled trials (RCTs), we may have missed some relevant studies that used other research designs such as non-RCTs, controlled before and after, interrupted time series, or qualitative studies. Different study designs may have included a different range of outcomes. However, for this Map, we were primarily interested in the outcomes reported in RCTs because these provide the most reliable evidence on the effectiveness of health interventions and are the basis of systematic reviews of intervention effectiveness. Therefore, limitations or inconsistencies in outcome reporting at the RCT level have repercussions for policy makers, guideline and guidance developers, health providers, and other decision makers who use systematic review evidence.

The future comparative analysis steps of the process will cover other study designs and literature including material not published in English.

5. Conclusion

With the growth in the evaluation and systematic review of health interventions [61], there has been new interest in the development of COSs, simultaneously influenced by the interest in specifying outcomes of most importance to different stakeholders [28]. Most COS-related studies focus on clinical conditions [22]. There are a small number of projects, most also in the early stages of development, addressing interventions directed at consumers or health systems (e.g., interventions for informed consent [62]), but this project is among the first to develop a COS for a consumer-oriented preventive health intervention such as vaccination communication.

Communication around childhood vaccination is a developing area with many innovative and often complex interventions that are not yet rigorously evaluated or their mechanisms of effect well understood [4]. We have created this Trial Outcomes Map to bring clarity and organization to an area that is complex, and to highlight patterns and potential problems that were previously unexplored. The Map is a base platform that illustrates the current state of outcome measurement in trials; from this platform, we can explore additional potential outcomes through stakeholder consultations and comparative analyses.

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Supplementary data

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