A user-centered approach to developing a new tool measuring the behavioural and social drivers of vaccination

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ABSTRACT

Background: Children around the world remain under-vaccinated for many reasons. To develop effective vaccine delivery programmes and monitor intervention impact, vaccine programme implementers need to understand reasons for under-vaccination within their local context. The World Health Organization (WHO) Working Group on the Behavioural and Social Drivers of Vaccination (BeSD) is developing standardised tools for assessing childhood vaccine acceptance and uptake that can be used across regions and countries. The tools will include: (1) a validated survey; (2) qualitative interview guides; and (3) corresponding user guidance. We report a user-centred needs assessment of key end-users of the BeSD tools.
Methods: Twenty qualitative interviews (Apr-Aug 2019) with purposively sampled vaccine programme managers, partners and stakeholders from UNICEF and WHO country and regional offices. The interviews assessed current systems, practices and challenges in data utilisation and reflections on how the BeSD tools might be optimised. Framework analysis was used to code the interviews.
Results: Regarding current practices, participants described a variety of settings, data systems, and frequencies of vaccination attitude measurement. They reported that the majority of data used is quantitative, and there is appetite for increased use of qualitative data. Capacity for conducting studies on social/ behavioural drivers of vaccination was high in some jurisdictions and needed in others. Issues include barriers to collecting such data and variability in sources. Reflecting on the tools, participants described the need to explore the attitudes and practices of healthcare workers in addition to parents and caregivers. Participants were supportive of the proposed mixed-methods structure of the tools and training in their usage, and highlighted the need for balance between tool standardisation and flexibility to adapt locally.
Conclusions: A user-centred approach in developing the BeSD tools has given valuable direction to their design, bringing the use of behavioural and social data to the heart of programme planning.

1. Background

Children remain unvaccinated for many reasons globally, including logistics and supply issues, cultural norms and hesitancy [1–5]. A systematic review of hesitancy toward childhood vaccination found a number of contextual factors, as well as vaccine-specific issues and individual and social group influences. This review also identified that the majority of peer-reviewed studies on vaccine hesitancy were conducted in the European and Americas regions, describing a "dearth" of research available in other regions, where the majority of the world's people live [6]. An understanding of the local behavioural and psychosocial drivers of vaccine acceptance is necessary to inform programme implementation activities and assess impact of interventions. These can subsequently be linked to, or used in addition to, existing local and global mechanisms that enable reporting of programmatic

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immunisation data, such as vaccine coverage [7]. Numerous surveys have been developed for use across different countries to measure vaccine hesitancy and confidence [8]. However, there is currently no globally standardised set of measures available that include the full range of behavioural and social drivers of vaccination in addition to hesitancy that have been validated for use across a variety of low, middle and high income settings.

To address this gap, the World Health Organization (WHO) convened the Working Group on 'Measuring Behavioural and Social Drivers of Vaccination' (BeSD) in December 2018. Consisting of a multi-disciplinary and global group of experts, implementers, and programmatic partners (WHO, GAVI, UNICEF, Bill and Melinda Gates Foundation, US CDC), this group is developing comprehensive and modular tools with corresponding guidance for assessing vaccination demand and determinants of vaccination acceptance [5]. The proposed package will include three components: (1) a set of globally validated survey questions available in long and short form that provide national programmes and partners with quality measures of demand and acceptance that could be used in standalone assessments, or incorporated into existing data collection processes; (2) qualitative data collection tools suitable for deployment with parents, health workers and programme managers; and (3) user guidance to support the deployment of these tools in various settings worldwide.

This study reports the detailed needs assessments of the envisaged end-users of the BeSD multi-component tool. The evidence generated by this study is being used to inform the BeSD tool development process, aimed to ensure that the tools are readily available, easy to use in various resource settings, and well-matched to the ways in which country programme officers currently collect, analyse and use data.

2. Methods

2.1. Study design

This was a prospective, descriptive, multi-country study using qualitative methodology.

The study was reviewed and approved by the Human Research Ethics Committee of the University of Sydney (Approval number 2019/284).

2.2. Theoretical framework

A user-centred approach to product or process development has been historically used in the software design sector, and more recently applied to health [9–11]. This approach focuses on the needs of key end-users of an envisioned product, and seeks to include them in the development process. In acknowledging the centrality of the end-user, this method ensures that their needs are met by the developed product, increasing the likelihood that those products will be implemented.

In keeping with the user-centred approach, BeSD first sought insight from the envisaged end-users of the tools. Individuals working within national ministries of health, as well as staff from UNICEF and WHO regional offices, were sought for input so the BeSD Working Group could better understand the challenges faced regarding the collection and use of data on the social drivers of vaccination acceptance, and how such a set of tools might be of benefit.

2.3. Participants and setting

The sampling approach sought to achieve a maximum variation among participant views and experiences, and thematic saturation in the overall findings. Following completion of an initial six pilot interviews, we interviewed twelve participants from across global regions and countries. We purposively sought participants responsible for immunisation activities in GAVI-eligible and middle-income countries, as well as input from individuals within other health organisations who held roles with a global focus.

Inclusion criteria, at a national level, included performing functions to encompass the diverse roles in relation to gathering and use of data to inform programme planning. Participants would be persons who routinely require data from their jurisdictions about why parents accept or refuse immunisation for their children, and who have working knowledge of the systems and practices used to deliver vaccines and collect vaccine acceptance data in their jurisdiction. A snowballing recruitment approach was taken, [12] whereby the investigators approached the regional WHO and UNICEF managers for an interview, and also asked them to identify potential in-country participants based on their regional and local operational knowledge. Following their own interview, regional participants then made contact with nominated potential participants to clarify their in-principle agreement to participate. If in-principle agreement was granted, the investigators directly contacted those individuals to confirm consent and arrange an interview.

2.4. Data collection

A semi-structured interview guide was developed based on the initial pilot interviews (see supplementary material). The interview began with general questions about the participant's role and responsibility, and what measures and systems they currently use regarding vaccine acceptance and demand. The proposed BeSD tools were subsequently described, and participants' input sought on the structure, implementation and support requirements, as well as how they envisaged the tools being used. Interviews lasted 30-45mins each, were conducted via telephone, zoom or in-person, in either English or French. Interviews were audio-recorded where possible, or handwritten notes were taken.

2.5. Analysis

All interviews were included in the analysis. Eleven were audio-recorded and transcribed verbatim, with the remaining nine recorded through interviewer's notes. Interview transcripts were translated into English for analysis. Framework analysis was used [13]. A coding framework was developed deductively and inductively based on the interview schedule and themes that emerged from the data as the study progressed. Themes emerging from the framework were summarised and illustrative quotes identified.

3. Results

The twenty interviews were conducted between April and August 2019, including six pilot (April-May) and 14 final (June-August).

3.1. Participant demographic information

Six participants held roles with regional-level responsibility, thirteen held roles with responsibility at a country-level within one of those regions, and one held a role in a health agency with global responsibility. Participants included Communication for Development (C4D) Specialists, National Ministry of Health Expanded Programme on Immunization (EPI) Managers, and other WHO and UNICEF staff from all five WHO regions.

For some participants, immunisation-related work comprised part of a broader set of responsibilities that incorporated areas as diverse as maternal and child health, nutrition, water safety, and adolescent health. Others had more immunisation-focused roles.

3.2. Thematic findings

We report on two high-level streams of inquiry: (1) the systems and practices currently in use for collecting vaccine-related data and the challenges faced; and, (2) reflections on the proposed BeSD tools (Table 1). In the sections that follow we present these streams, including subthemes, in some detail.

3.3. Current data systems, and practices

There was wide variation in the types of data used, the frequency of data collection, the systems in which these data are embedded, and how the data are used to inform immunisation programmes.

The data types used to inform immunisation programmes spanned social science, epidemiology and operational data, and were predominantly quantitative. Social science measures included knowledge attitudes and practice (KAP) surveys, "mini-surveys" and health care facility exit interviews, equity assessments, rapid social assessments, and social mapping. Also mentioned were data garnered using the Tailoring Immunisation Programmes (TIP) approach[14] and data for new vaccine introduction, which included qualitative data. Some participants acknowledged the need to incorporate more qualitative data in their decision-making:

"Mostly it's more quantitative data. And for my part, you know, if you want to bring some change in generation activity, you need some qualitative data…... for us this is important and what is missing is this qualitative data."

– Participant 7, Regional responsibility

Epidemiology and operational data included coverage monitoring, cold chain inventory (as a way of determining infrastructure needs), vaccine preventable disease (VPD) surveillance, and registry data of child health visits for vaccination.

The frequency of data collection varied widely from relatively regular, centralized data collection to "nothing, really". This is reportedly a function of variable resource availability and prioritisation across settings.

Participants reported different ways of using the data. Some mentioned using it to inform multi-year plans for single vaccine programmes (e.g. polio), others use it to inform full portfolio planning. This was contingent on the type of data they were able to access. Despite having some data available, sometimes little action can be taken owing to the cost of an action plan balanced against small gains in terms of numbers of extra children vaccinated as a result:

"Even though we do the user satisfaction, often times, not a lot has been done about it. Especially if it is about opening hours or access…. you may end up getting just a few more children."

– Participant 17, Country responsibility

Some health ministries intend to move toward a dashboard-type reporting system, but currently there are no tools to feed data into such a tool, and the people that need them do not have time to develop one.

"[T]he health department, they have [a] kind of a dashboard….if we have such information, it will be easier to adapt and customise it rather than do it from scratch, because there's a lot to do at country level. So we rarely ever get the time to do this kind of thinking."

– Participant 14, Country responsibility

3.4. Current challenges faced

Participants discussed a range of difficulties in collecting and using data. These fell broadly into sub-themes of data collection and quality challenges; technical capacity; and barriers to advocacy and change.

3.4.1. Data collection and quality challenges

Sometimes barriers were due to security issues in some regions that prevent physical access to data collection, other times it was because the priorities of other stakeholders were influencing what kinds of data were collected. The majority of issues mentioned were around data quality, triangulation and interpretation. Inaccurate denominator data was consistently mentioned. Participant 11 (country responsibility) spoke of denominator issues impacting funding, planning and delivery: *"[I]t's very hard to come up with the denominator. And birth registrations. Children are not registered…...the parents do not go to receive the birth certificate until child is seven, before he goes to the school. "*

Further to this, participants spoke of challenges triangulating the different sources of data they have, making it very difficult to interpret and act upon. Participant 12 (Country responsibility) said that vaccine coverage data and vaccine preventable disease outbreak data "*does not correlate at all*". Similarly, some spoke of different data sources not correlating:

"Smaller INGOs, NGOs they do, they collect [social data], but…. when you go into the field you do your own bottleneck analysis. You find out that somehow their data doesn't match with the actual situation on the ground"

- Participant 14, Country responsibility

3.4.2. Technical capacity

Participants either reported that there is not adequate capacity, or that they are making efforts to increase it – so that data are better linked to making changes to vaccination programmes.

"[W]e need to build capacity in evidence-based planning."

– Participant 2, Regional responsibility

Others reported having good capacity for data analysis and planning / implementation, reporting that they offered support to other agencies in their jurisdiction.

"[Other stakeholder organizations] seek our guidance whenever they have to use social and behaviour change communications or social mobilisation within their initiative."

- Participant 14, Country responsibility

High turnover of EPI staff was reported to make continuity in data collection and analysis difficult, and participants felt some kind of standardisation would be useful in dealing with this.

"[I]t would really help to have things standardised and also help them monitor because there is a high turnover in EPI managers … EPI managers need more training. So, maybe when you have these standardised surveys you can actually have a baseline and you can pick up where you left or maybe when a new person comes in, they know where things were left at kind of in a surveillance, monitoring trend way."

– Participant 9, Regional responsibility

Where capacity was limited, participants reported the use of external consultants; however, it was stressed that consultants

Table 1
Main thematic findings.

Interview Question Areas	Main Thematic Findings
CURRENT SYSTEMS, DATA AND CHALLENGES – Current data uses and practices – Most pressing questions to answer that will help with programme prioritisation	Current systems: – Wide variation in types of data and systems between jurisdictions – Wide variation in frequency of data collection – Wide variation in how data used for programme planning. – Mainly quantitative data used, little qualitativeCurrent challenges: – Data collection and quality 　o Inaccurate denominator data 　o Difficult to triangulate different sources 　o Security issues limiting data collection ability – Technical capacity 　o varied between jurisdictions 　o high staff turnover can impact skill retention within jurisdictions 　o Use external consultants if no internal capacity. This presents challenge of balancing technical expertise with local cultural knowledge (hard to find both) – Barriers to advocacy for change 　o Cultural / political sensitivities can present challenges 　o Sometimes limited capacity for using data to affect change – Areas currently in focus and areas that need to be 　o Health care provider perspectives also important 　o Specific reasons for vaccine refusal 　o Comparable data to enable view of global trends
THOUGHTS ON THE PROPOSED TOOLS: – Foreseeable barriers to using the tools – Foreseeable uses of the tools and the data they generate – Capacity to conduct qualitative research – Implementation of the tools	– Resources needed 　o Funding 　o Capacity – Required attributes of the tools 　o Cover practical and community factors as well as individual attitudes 　o Balance between flexibility and standardisation 　o easy to use – User guidance 　o clear, easy to follow 　o Address sampling, analysis and guidance on how to apply to local cultural settings – Rollout and implementation 　o Include proof of concept example 　o Provide facility for continual updater based on learnings from field use 　o Provide periodic "refresher" updates on the tools

with technical expertise alone were insufficient, and that consultants need a high degree of familiarity with the local setting and culture, which can be hard to find.

> "[P]eople from outside they know how to do the research, they know to conduct research to have the best quality. But they need to understand the local context, and to understand the context, you need some people living in the country."

– Participant 8, Regional responsibility

The general low quality of the research output of external consultants was also a consideration:

> "Normally we outsource this kind of research, because of capacity issues, but it is not easy to find consultants who can deliver quality."

– Participant 2, Regional responsibility

Finding the balance between the need for high quality expertise and local knowledge was a common problem. Some reported training local researchers to deploy surveys in a culturally acceptable way (e.g., utilising interviewers of a certain religion or gender), some trained local researchers fluent in local dialects to deploy a survey written in a national language and translated "on the fly" into the local dialects as needed. Others reported bringing in external researchers and pairing them with local social mobilisers:

> "Their social mobilisers went with us, asked the right questions."

– Participant 14, Country responsibility

3.4.3. Barriers to advocacy for change

Once data are available, difficulties can arise in use for planning and implementation. Cultural and political sensitivities were reported to hinder how the data are reported and used, lest a less-than-favourable result be seen to reflect badly on the programme, although some participants felt this was becoming less of an issue. To protect against this there was mention of the possibility of selective or skewed reporting; however others pointed out that denominator data is often problematic, and inconsistencies can be attributed to data source inconsistencies, rather than intentional manipulation. Others reported the issue to be more structural, whereby reports alone were not sufficient, with face to face forums being the preferred way to leverage data to advocate for change:

> "They discuss their issues. And that is, for us, the golden moment when we can…. advocate for the implementation or prioritisation of the certain [things] – because if you go through the hundreds of recommendations of all these reports, you will be lost."

– Participant 11, Country responsibility

Limited capacity in the ability to use data for planning was also mentioned, with examples of countries that do multiple KAP studies, but have no capacity to use it, and limited capacity at a regional level to provide technical assistance with this. This issue appeared to be secondary to broader political pressure, as "[a] lot of political processes and systems overshadow technical assistance and recommendations" (Participant 2, Regional responsibility).

3.5. Areas of current focus and where it's required

There were a variety of areas of current focus, including: behavioural determinants of vaccine acceptance, service delivery and systems, health care worker perspectives and focus on specific sub-populations within the participant's jurisdiction. Some reported focus on evaluation of interventions and others on routine uptake data. How these things were measured varied widely.

When asked what they would like the BeSD tools to focus on, participants expressed a need for understanding of a range of things including healthcare worker perspectives, the practical and social or cultural factors affecting vaccine uptake, wanting to understand the specific reasons for vaccine refusal, and the need for data that is standardized enough to enable comparison between jurisdictions.

3.5.1. Healthcare worker perspectives

A strongly recurring theme was the need to understand the perspectives of those delivering healthcare. Many spoke of their feeling that healthcare workers perhaps lacked knowledge, or capability to be able to deal with vaccine hesitancy among their patients or clients, and a number mentioned worrying that the healthcare workers themselves may be vaccine hesitant:

"[Healthcare workers] have their own beliefs, religious beliefs, they see the myths, and sometimes they might even be implicitly sharing their beliefs with parents."

– Participant 12, Country responsibility

3.5.2. Practical factors

The need to understand non-attitudinal factors, such as logistic and practical factors, that impact vaccine uptake was expressed by some participants. Some spoke of already undertaking investigations in this area; for example Participant 11 (Country responsibility) spoke of having identified that the use of multi-dose vials was hindering vaccination in some areas as clinic staff would only open a vial if at least 15 children had presented for vaccination that day. If fewer presented, the families were turned away. Others suggested it was an issue that needs further exploration:

"We just think that it's a behavioural issue that they're not doing it. We don't look at it from the other perspective that it might be because they don't have the funds to travel the distance."

- Participant 14, Country responsibility

3.5.3. Cultural and social factors

The ability to understand the nuanced needs and attitudes or beliefs among specific sub-populations in different jurisdictions was described by a number of participants. Sub-populations included certain cultural or religious groups, itinerant workers and migrant groups.

"It's very challenging for the system to understand who are these migrants …. Where they are consuming these vaccines – and usually it's the young people going for the labour migration"

- Participant 11, Country responsibility

It was also articulated that this information could then be used to tailor interventions for these groups.

3.5.4. Specific reasons for vaccination refusal

Wanting to understand the specific reasons for vaccine refusal was also common, however the nuanced situations differed. Participant 12 (Country responsibility) for example, wanted to understand parents' apparent change in attitude and why they accepted vaccines at birth and later appeared to refuse them. That same participant also mentioned that while they had data on this from the public health sector, a percentage of the population use private health and they had no data for this. Participant 18 (Country responsibility) spoke of doubting routine survey data that covered reasons for refusal, and the need to dig deeper to clarify:

"[O]ne needs to dig deeper… mothers they say, that my child was sick, my child was not available. It's very hard to accept that that for one whole year the child was not available"

– Participant 18, Country responsibility

On the other hand, a general assumption about vaccine hesitancy and refusal was mentioned, which needs to be challenged:

"[M]ost of the time [we] *hypothetically think that safety issues as the one reason* [for vaccine refusal]. *But we really don't know*

–Participant 8, Regional responsibility

3.5.5. Comparable data

Some participants also indicated desirable practical traits for data. For example, Participant 3 (Regional responsibility) spoke of wanting to understand global trends, and how they affect vaccine acceptance. Similarly, Participant 5 (Global responsibility) and Participant 19 (Country responsibility) wanted to see a standardised measure that could be used to compare and discuss progress, while Participant 4 (Regional responsibility) spoke of the need to be able to measure trends longitudinally to track progress.

3.6. Reflections on proposed BeSD tools

Participants reflections on the BeSD tools fell into the sub-themes of the resources that would be required and the attributes the tools would need to facilitate their adoption, the requirement for clear user guidance, and attention to how the tools are rolled out.

3.6.1. Funding

The most commonly required resources mentioned were "*time and money, that's for sure*" (Participant 16, Country responsibility). Some mentioned that they would hope that some external funding would be provided in rolling the BeSD survey out, as many jurisdictions would not have the funds independently. For example, Participant 20 (Country responsibility) said, 'We would hope to get money from WHO to do this work. We are not a poor country but we are not a rich country". Participant 11 (Country responsibility) suggested, *"you should think about keeping this tool sustainable with or without funding"*.

3.6.2. Capacity

Capacity was also commonly required resource, both for analysis of the data, but also data collection. Related to this was a common need for training; many participants discussed the need for training local data collectors as crucial to the successful use of the BeSD tools. Similarly, training in data analysis was also raised as a requirement, especially at a local level, as well as training in how to use the findings identified by the tools to advocate for change.

3.6.3. Required attributes of the tools

When asked about what they felt the tools should include, responses covered what topics the tools should cover, flexibility for adaptation, and user-friendliness.

Many participants specified the need to measure access and practical issues, in addition to attitudes and beliefs affecting vaccine acceptance. The importance of awareness of the different ways that vaccine decisions are made in various cultures, and that individual-centered questions might not be useful in all settings was highlighted:

"[V]ery often where we come from our western [perspective] . . . we tend to think that it's an individual that makes decisions, whereas in most developing countries . . .very often decisions are also taken at a family level or even at a community level."

– Participant 19, Country responsibility

The need for a striking a balance between flexibility and standardization was emphasized. Almost all participants discussed the need to modify or adjust the tools for local settings. This included having standard high quality translations available, but also the flexibility to adjust for local languages and contexts:

"It will have to be adapted in local languages. And that's where the problem comes in, because sometimes a tool might be excellent in English, but when it's adapted it depends on the local teams on how they adapt it."

– Participant 14, Country responsibility

Another dimension of flexibility required was in how the tools are used. One mentioned that being able to use the tools routinely and also for rapid assessment if the need arises would be beneficial; another suggested using the tools longitudinally in an evaluative capacity following a campaign. The flexibility in deploying the tools at national, provincial or district levels was also thought to be useful. Some participants imagined the BeSD tools could be used at a very granular level such as at a given clinic to "diagnose" under-vaccination.

3.6.4. Other considerations

Two participants mentioned the need for data quality *"checks and balances"*, especially to ensure information isn't lost during translation exercises. Most spoke of the need for a website or online capacity with the facility for users to feed back to suggest improvements to the BeSD tools.

3.6.5. User guidance

Almost all participants mentioned the need for a good user guidance to accompany the tools. Many spoke of the need for such guidance to be user-friendly, suggesting that the user-friendliness of the entire package will hinge on the user guidance. Participant 2 (Regional responsibility) said, *"if there are simple tools and concrete guidance on sampling, data collection, analysis, if there is simple clear guidance on that, then a lot of countries could do this"*. Similarly, Participant 8 (Regional responsibility) felt if the guidance was too long or hard, they wouldn't be used regularly in the long term.

Suggestions included that *"a clear and step by step guide would be best. . . for example, have you considered something like a decision tree almost. . ."* (Participant 4, Regional responsibility) that included flow charts, diagrams and tables, that aren't too lengthy.

Some participants specified that the guidance document needs to address more than just the tools. Participant 3 (Regional responsibility) said, *"Make sure the guidance goes beyond just the questions or scales, you need the guidance on sampling and analysis . . . to make*

it easy for countries to implement. . .", while Participant 14 (Country responsibility) cautioned of the need for guidance on how to train local data collectors in how to ask question appropriately *"because without that, you would just be giving them a weapon and it can turn the others away. . . [they could ask the questions the wrong way]. . .. Or in an unethical way. They might not be aware of the kind of body language they need to use, the kind of tone"*.

The inclusion of an "FAQs" section that is updated with continued use in the field was also suggested, as was guidance on how to deal with unanswered or refused questions.

3.6.6. Proof of concept and implementation of the tools

Participants suggested that attention should be paid to how the tools are rolled out, as this will impact on their continued use. Participants felt that some kind of 'proof of concept' would be needed to ensure maximum uptake of the proposed tools globally. Many mentioned the need to pilot the tools successfully and then present the process and outcomes as a case study of something that can be successfully implemented. A few also mentioned the need for local government buy-in to maximize acceptance of the tools. This would possibly require presentation of the proof of concept case study presented by a of team of accomplished experts from respected institutions to encourage confidence in the use of the tools locally. Further to the identification of the need for training to be included in the package, some participants felt this training should form part of the roll-out strategy for the tools. Other suggestions to encourage successful roll-out was to use existing WHO and other networks to disseminate them, and that an official "kickoff" followed by regional support during deployment would be beneficial. A follow-up to these activities, perhaps a year after deployment with "refresher" and "update" sessions was also thought to be useful.

4. Discussion

While there have been multiple knowledge, attitude and practice surveys developed over the years to examine childhood vaccination, few are widely and routinely used for planning and programming. This is partly because they have not been tailored to user needs across different settings or are not compatible with existing processes. This qualitative study illuminated the challenges faced by immunisation programme managers, partners and stakeholders in obtaining and utilising good quality data on the behavioural and social drivers of vaccination, providing key evidence to inform the design of the BeSD suite of tools. It also serves as an illustrative example of how a user-centred approach can help develop tools to address global health issues.

We found wide variation in the systems used globally for collection of data on immunisation drivers, as well as variation in the technical capacity of countries/systems to undertake such work. Where internal expertise was not available external consultants are often employed, noting that when using such consultants, local cultural knowledge is just as important as technical skill. Most of the countries and regions routinely use quantitative KAP data, with comparably fewer reporting also using qualitative data. Participants further reported a variety of challenges faced in gathering and using social and behavioural data on childhood immunisation, some of which are possible to address in the design of the proposed BeSD tools, whilst others, such as political and cultural challenges, are wider and hence fall outside the scope of any 'tool' as such to address.

Our findings support the utility of the BeSD planned approach: the proposed incorporation of both qualitative and quantitative tools was well-received by all participants. There were several

other requirements identified by the participants that were also key to the development of the BeSD tools. The tools will need to offer a balance between flexibility and standardisation: they must be standardised enough to provide a mechanism for global reporting and comparison of data, while flexible enough to be locally adaptable. This finding was incorporated into the development of the tools by translating the survey and interview guides into all six UN languages (Arabic, basic Chinese, French, Russian, and Spanish in addition to English), and the tools are scheduled to undergo psychometric validation in a variety of global low- middle- and high-income settings in 2021 to ensure applicability across a variety of settings. Other findings, such as the requirement for gathering the perspectives of healthcare workers (the tools are primarily intended for parents and caregivers of children under 5 years old) were addressed by incorporating qualitative interview guides in the package for healthcare workers as well as community advocates and other immunisation stakeholders.

Also identified was the need for easy data analysis and reporting and a clear user guidance that covers setting-specific modification of the tools, sampling, data collection, analysis and use. These findings highlight the integral importance of the user guidance document, which will provide instruction on how to modify and validate the survey for use in different settings, how to sample and how to analyse the data. Suggestions will also be included on how to make the findings actionable regarding programme planning. Some of the more difficult challenges mentioned by participants can also be covered to some extent, such as including content to help counter certain political sensitivities and encouraging cross-partner ownership of the data and findings.

This study has some limitations. While effort was made to purposively sample a wide variety of prospective end-users from a range of settings, there may be immunisation programme managers, partners or stakeholders in jurisdictions we did not interview who have insights unique to their setting that were not captured. However, small and focussed sample sizes are a characteristic feature user-centred approaches [15], and our acknowledgement of this has been incorporated into the development process. As we progress with pilot testing of the tools, we are continuing to gather information from in-country colleagues not originally interviewed to add to our understanding of the needs of the end-users.

Our novel application of a user-centred approach enabled key end-user insights to be a central part of the development of the BeSD tools, increasing their viability for widespread adoption by immunisation programme managers and partners in the future. These findings represent the first of several planned iterative steps to be taken by the BeSD Working Group in incorporating end-user perspectives into the development of their quantitative and qualitative tools and guides. The tools are currently in the early stages of field testing across several countries and languages. Learnings from the experiences of field testing in countries are systematically reviewed and evaluated to inform iterative modifications to the tools and the suggested processes for their implementation.

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Author Conflicts of Interest and funding

Declaration of Competing Interest

The authors declare the following financial interests/personal relationships which may be considered as potential competing interests: [NS is the director of the London Safety and Training Solutions Ltd, which offers training in patient safety, implementation solutions and human factors to healthcare organisations and the pharmaceutical industry, including Sanofi-MSD and Merck. NS also holds an unrestricted educational research grant by Sanofi Pasteur for the project 'Social and psychological determinants of vaccination uptake – Linking attitudinal and behavioural data to policy analysis and implementation', 2021-24. Gillian SteelFisher's husband is a minority owner of a firm that does consulting work for Eli Lilly. The other authors have no conflicts of interest to declare.].

Appendix A. Supplementary material

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