

The Vaccine Trust Framework: mixed-method development of a tool for understanding and quantifying trust in health systems and vaccines

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Summary

Background Trust is a key component of vaccine demand, yet there is a lack of consensus on how to define trust alongside a lack of actionable, contextually grounded measurement tools validated in low-income and middle-income countries. This study aimed to develop and validate a contextually relevant trust framework and measurement tool, that can lever trust to drive resilient demand.

Methods An exploratory sequential mixed-methods study was conducted. Ethnographic research in Nigeria, Kenya, and Pakistan was undertaken to define trust in the context of childhood, human papillomavirus, and COVID-19 vaccines. The generated Vaccine Trust Framework was validated by fielding a nationally representative survey containing the constructed trust measurement tool to caregivers of adolescents in Kenya and Pakistan. Psychometric properties of the survey and associations between trust and vaccination behaviours were assessed using confirmatory factor analysis and logistic regression.

Findings The Vaccine Trust Framework, established through synthesis of ethnographic research, contains four interlinked domains—health system promise, health system delivery, vaccine promise, and vaccine delivery—and 15 measurable dimensions. Survey data were collected from 3670 participants in Kenya and 3734 in Pakistan. Trust was observed to influence vaccine behaviour and intentions, which was further supported by associations between quantitative trust scores and vaccination status across the studied vaccines. Regional trust variation was observed within Kenya and Pakistan, with patterns matching qualitative findings on the perceptions of local vaccine and health systems.

Interpretation The Vaccine Trust Framework provides a validated, contextually grounded tool for assessing trust in health systems and vaccines in low-income and middle-income countries. The Vaccine Trust Framework can be used as a prognostic tool, intervention design aid, or trust measurement tool within an intervention or monitoring study. Further research is in progress to assess its utility in designing and measuring the effect of trust-building interventions.

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Introduction

Although vaccines have dramatically reduced global morbidity and mortality, a substantial challenge remains to increase vaccination rates for new and existing vaccines.¹ This problem is particularly acute in underserved and marginalised populations. Historically, vaccine programmes have focused on supply to increase uptake, but it is increasingly recognised that achieving high and equitable vaccination coverage requires investment in interventions that stimulate demand.²

Vaccination decisions are embedded within broader social contexts and health-care experiences, and reflect complex decision-making environments. Getting demand right is critical as it can influence current and future health-seeking behaviours, and resilient demand can mitigate the negative effects of disruptions to vaccine-seeking behaviour such as fear, misinformation, and disinformation.³ Traditional demand-side approaches

focusing solely on providing accurate and accessible information to the public are insufficient.⁴ Stimulating resilient vaccine demand requires a fuller understanding of its components, including previous experience and interactions with the health system.

A critical understudied component of demand is trust. Higher trust leads to greater adoption of health behaviours across settings.⁵ Citizen trust shapes engagement with vaccine programmes and vaccine uptake.⁶ Conversely, damaged trust, uncertainty, and low trust undermine vaccination programme effectiveness. Trust is critical to achieve high coverage rates required for herd immunity, or for introducing relatively new and unknown vaccinations.⁷ The impact of trust extends beyond vaccination rates, with greater epidemic resilience being associated with higher trust in a study of 150 countries' COVID-19 responses.^{8,9} The trust–vaccination relationship is especially relevant in the

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For the French translation of the abstract see [Online](#) for appendix 3

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Research in context

Evidence before this study

Trust is recognised as crucial for health-seeking behaviour, yet its precise definition and measurement in health-care contexts remain elusive. Before the ethnographic research conducted in this study, we searched Web of Science from Jan 1, 2017, to Aug 31, 2021, and found 1999 articles using the search terms “trust” AND one of either “Nigeria”, “Kenya”, or “Pakistan”. Further filtering for “vaccine trust”, “COVID-19 vaccine trust”, “health misinformation”, and “social levers of trust” identified 150 texts that explored trust and health-seeking behaviour. These articles did not align on a common definition of trust and were not grounded in data from low-income and middle-income countries (LMICs). A subsequent PubMed search before the second round of ethnography was conducted on Oct 1, 2022 with refined keywords including “health care system trust/distrust”, “vaccine confidence”, “social trust”, and “institutional trust”, identifying 14 existing multi-dimensional frameworks for measuring health-related and vaccine-related trust. No frameworks linked health system trust with trust in specific vaccines. We also identified two systematic reviews that have highlighted the situational and imprecise nature of existing trust measures, alongside the paucity of validated vaccine-trust measures. Both indicate the need for trust measures developed in an LMIC context.

Added value of this study

We developed and validated the Vaccine Trust Framework through extensive ethnographic research (>400 engagements). The method for defining the framework is grounded in lived experiences and allows a rich understanding of trust in these contexts. Large-scale quantitative validation of the Vaccine Trust Framework survey instrument in Kenya and Pakistan illustrates how vaccine-specific trust data could be used by a variety of stakeholders to inform or measure the effect of interventions on trust.

Implications of all the available evidence

The Vaccine Trust Framework and measurement tool could be used to facilitate the development of resilient vaccine demand, which address a specific gap among existing trust measures by linking health system and vaccine trust in LMIC contexts. This approach complements rather than competes with tools focused on behavioural or psychological drivers. We expect the Vaccine Trust Framework and measurement tool to be utilised when diagnosing trust gaps, monitoring and evaluating programmes, and in the design of interventions sensitive to or aiming to build trust. This is especially relevant when a system-level understanding is required. Future studies should experiment with using the Vaccine Trust Framework and measurement tool for these purposes.

context of deteriorating trust in health-care systems—and the institutions charged with running them around the world.¹⁰ This deterioration, in turn, further threatens vaccine demand, requiring rapid assessment and scaling of counteractive interventions.

Despite the opportunity of trust for increasing demand, existing measurement and monitoring tools rarely inform decision-making and remain confined to academic research.¹¹ In their systematic review, Ozawa and Sripad identified three major challenges for measuring trust in health-care systems and vaccine confidence.¹² These include development of tools in ad-hoc manners that are ungrounded in contextual understanding, lack of consensus on a trust definition across contexts, and under-representation of trust measures from low-income and middle-income settings. Larson and colleagues further showed that trust measurements in vaccine research often use single-item and unvalidated measures.¹³ As a highly actionable component of demand, methods to measure trust that overcome these limitations are urgently required.

This study presents the Vaccine Trust Framework and associated survey instrument, developed using a mixed-methods approach in Nigeria, Kenya, and Pakistan. These countries were selected for their diverse health systems, sociocultural diversity, existing disease burden, and vulnerability to vaccine-preventable diseases. We focused on three vaccines: routine childhood immunisations, human papillomavirus (HPV) vaccines,

and COVID-19 vaccines. The derived framework was converted into a survey instrument that quantified trust and its subcomponents in a modular and scalable way. The survey focused on caregivers of adolescents (aged 10–14 years) as an essential population owing to their decision-making power on their own and others' vaccinations, particularly in the context of childhood and HPV vaccinations.¹⁴ We further present initial associations between trust and vaccination based on the survey data. The Vaccine Trust Framework and measurement tool are intended to help individuals involved in design, implementation, and evaluation of interventions using trust as a lever for building resilient demand for vaccines.

Methods

Study design

An exploratory sequential mixed-methods study was used to explore and define trust.¹⁵ Ethnographic fieldwork in Kenya, Nigeria, and Pakistan was combined with cross-sectional household surveys in Kenya and Pakistan. Fieldwork themes were generated following a review of literature and expert interviews (appendix 4 p 163). Qualitative fieldwork, conducted over two rounds, aimed to construct a framework to describe and measure trust.

The first round was conducted during the COVID-19 vaccination campaign (September–October, 2021) in three to four locations in each of Kenya, Nigeria, and Pakistan. Included communities represented a range of

See Online for appendix 4

ethnic and religious groups, socioeconomic levels, health access, and rural versus urban living. The second round was conducted in three to four communities in both Kenya and Pakistan (January–February, 2023) and was focused on HPV vaccination. Each round of fieldwork collected data and observations on routine childhood vaccines at participants' homes or at vaccination facilities (including mobile vaccination units, vaccination sites, and larger hospitals). Up to five trained researchers with relevant professional backgrounds and language skills were recruited per country. Five qualitative methods were used to gather data: focus groups, extended observations, informant interviews (focusing on key profiles such as health-care workers), in-situ conversations, and immersions of ethnographers with participants over extended periods of time. All fieldwork was conducted according to pre-defined guidelines (2021 fieldwork: appendix 4 pp 21–50; 2023 fieldwork: appendix 4 pp 51–96). Interactions were documented in field notes (see template in appendix 4 pp 97–112), noting both the content and the context.

Framework development

Fieldwork data were analysed using a combination of theoretical and inductive thematic analysis.¹⁶ Data were screened, discussed, and synthesised by a group of ethnographers alongside experts in epidemiology and vaccination. The analytical team used Miro and FigJam software (web-based versions, 2023) to identify and group datapoints, iteratively identifying patterns during review. Patterns were combined into thematic categories, which were tested for qualitative validity against further field materials, literature, expert opinion, and synthesised member checking, where emerging findings and data were discussed with in-country researchers and community members. Robustness of qualitative analysis was ensured by using multiple data sources and analysts to cross-check findings (source and analyst triangulation). This approach led to the creation of the Vaccine Trust Framework.

Survey development, testing, and roll-out

The Vaccine Trust Framework guided survey development. Survey items were created to measure trust sub-dimensions that captured qualitative findings. Items created de-novo followed a strict do-no-harm principle. Where directly overlapping, validated items from the literature were incorporated to build on best practice and facilitate cross-study comparisons.^{17–19} The survey was supplemented with items capturing demographic information, family composition, vaccine behaviours, health-seeking behaviours, and HPV-related questions.

Cognitive testing in both Kenya and Pakistan assessed preliminary item comprehensibility and reliability. Following this, pilot testing aimed to identify alterations for translations, survey structure, filters, and the item response categories. The acceptability of the survey was

further reviewed by trust and gender experts (see appendix 4 p 163), alongside institutional review boards in Kenya and Pakistan. Feedback was collated and alterations were made to the preliminary survey.

The survey targeted a nationally representative sample of caregivers to adolescents aged 10–14 years in all provinces or administrative divisions in Kenya and Pakistan, using national population figures from the 2019 (Kenya) and 2017 (Pakistan) censuses. Surveys were rolled out between July 13 and Aug 27, 2023 (Kenya) and between Aug 7 and Sept 13, 2023 (Pakistan). Nigeria was excluded from the survey owing to logistical and budget constraints. Eligible caregivers were aged 18 years or older and willing and able to give informed consent. The caregiver definition was deliberately inclusive to accommodate diverse family structures: a caregiver was defined based on ethnographic observations as an adult who either makes financial, educational, or health-related decisions on behalf of children; engages in raising, rearing, or bringing up children; or is responsible for disciplining children. Interviewers were experienced with household surveys, face-to-face research, random walk sampling, household enumeration methods, and conducting research with underserved populations. Researchers attended project-specific training on the methods and context of the research and were supervised by a field supervisor. A stratified multi-stage clustered sampling design was used for Kenya and Pakistan (for detailed sampling plans see appendix 4 pp 113–118). Briefly, interviewers sent to randomly selected locations used a random walk method to randomly select households. Within a location at the lowest cluster level, eight to nine interviews at different households were conducted face-to-face by interviewers using tablets programmed with Ipsos's iField software. Interviews were conducted in multiple languages (ten languages in Kenya, nine languages in Pakistan) to ensure broad accessibility. Details on childhood vaccination were collected by asking if the specified child had received any childhood vaccines. In Kenya this was measles, hepatitis B, yellow fever, diphtheria–tetanus–pertussis (DTP), or tuberculosis vaccines. In Pakistan this was measles, hepatitis B, typhoid, DTP, or polio vaccines. Ipsos's iField software randomly selected one child from a roster of eligible children with a higher weighting (two-thirds) for female children, owing to the HPV focus.

Statistical analysis

Demographic characteristics of study participants were reported by country and stratified by respondent sex. Framework items were converted into a numerical scale (0–1) with inversely scored items reversed. Participant scores at each hierarchical level were calculated as the mean of the items forming that level (sub-dimensions [n=33], dimensions [n=15], quadrants [n=4], levels [n=2], total [n=1]; appendix 4 p 2). For levels above the dimensions, participants with missing data contributing

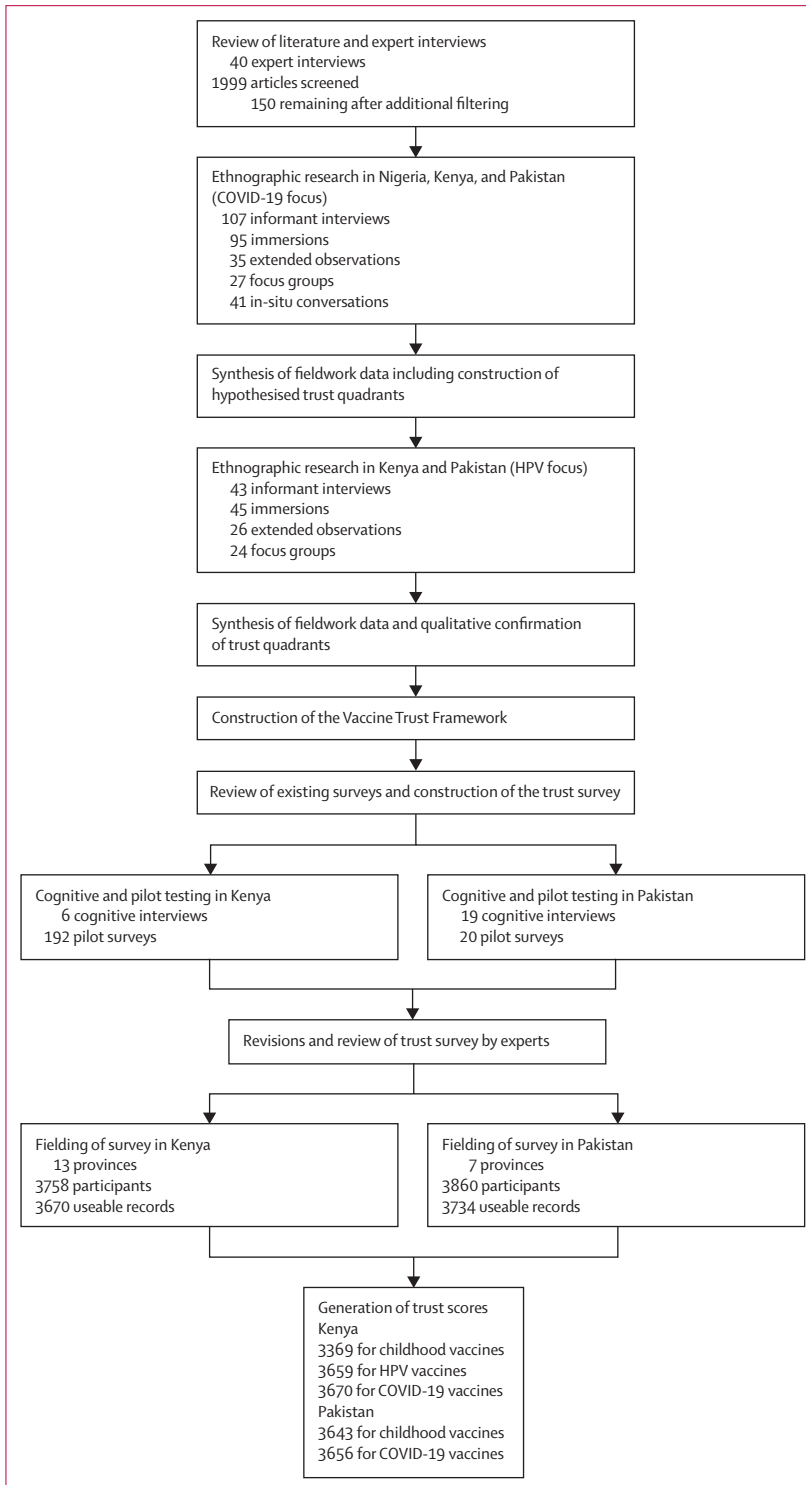


Figure 1: Study flow diagram for the Vaccine Trust Project

Flow diagram indicates the process from initial ethnography to analysis of survey data. Articles were identified from Web of Science from Jan 1, 2017, to Aug 31, 2021, with keywords of "trust" and one of either "Nigeria", "Kenya", or "Pakistan". Further health-seeking behaviour articles were identified by filtering for "vaccine trust", "COVID-19 vaccine trust", "health misinformation", and "social levers of trust". HPV=human papillomavirus.

to each quadrant were considered missing, and a quadrant score was not calculated. A full list of survey questions mapped onto each hierarchical level is provided in appendix 4 (pp 119–144). Radar plots visualised trust score patterns stratified by key geographical variables. Spearman rank correlation coefficients were calculated to understand the relationship between dimensions for each country and vaccine.

Vaccine delivery was assessed using an experiential approach, where participants are asked questions based on a lived vaccination experience. Consequently, two quadrant scores were generated, one with shared questions between vaccination groups and one with more questions for the vaccinated individuals. HPV data were not analysed in Pakistan as the HPV vaccine was yet to be rolled out. All analyses are presented separately for Kenya and Pakistan.

The Vaccine Trust Framework structure was validated using confirmatory factor analysis (CFA) on data from the survey. Models specified dimensions within their respective quadrants as factor levels, testing variable clustering and measurement quality. Robust maximum likelihood estimation, robust standard errors, and scaled test statistics addressed non-normality of dimensions. Missing data were handled using full information maximum likelihood estimation. CFA models were refined using modification indices, while maintaining theoretical justification. Dimension quadrant relationships were assessed with standardised factor loadings from models (excellent [>0.7], good [$0.6-0.7$], acceptable [$0.4-0.6$], or weak [<0.4]). Model fit was evaluated using standard indices: robust comparative fit index (CFI), Tucker–Lewis index, root mean square error of approximation, and standardised root mean square residual. Measurement invariance testing (metric vs configural and scalar vs metric) was performed across age, sex, urban or rural residence, and an income variable. In Kenya, income was categorised into above and below the World Bank poverty line (rural: KES 3947; urban: KES 7193). In Pakistan, household monthly income was collected across five categories, and was split into above and below PKR 30000 when used as a covariate in analysis.

The association of total trust and separate trust quadrants with the odds of childhood, HPV (Kenya only), and COVID-19 vaccination were assessed. Unadjusted and adjusted logistic regression models with a priori confounding variables were constructed. Models adjusted for respondent education, marital status, age, sex, and income. Childhood vaccine models additionally adjusted for adolescent age and sex. HPV models excluded male adolescents and adjusted for adolescent age. Trust scores were further associated with caregiver future HPV vaccination intent.

Analyses were performed in RStudio (version 2024.04.2). All datasets are available online. All data were anonymised during collection and analysis. Personal identifiers were

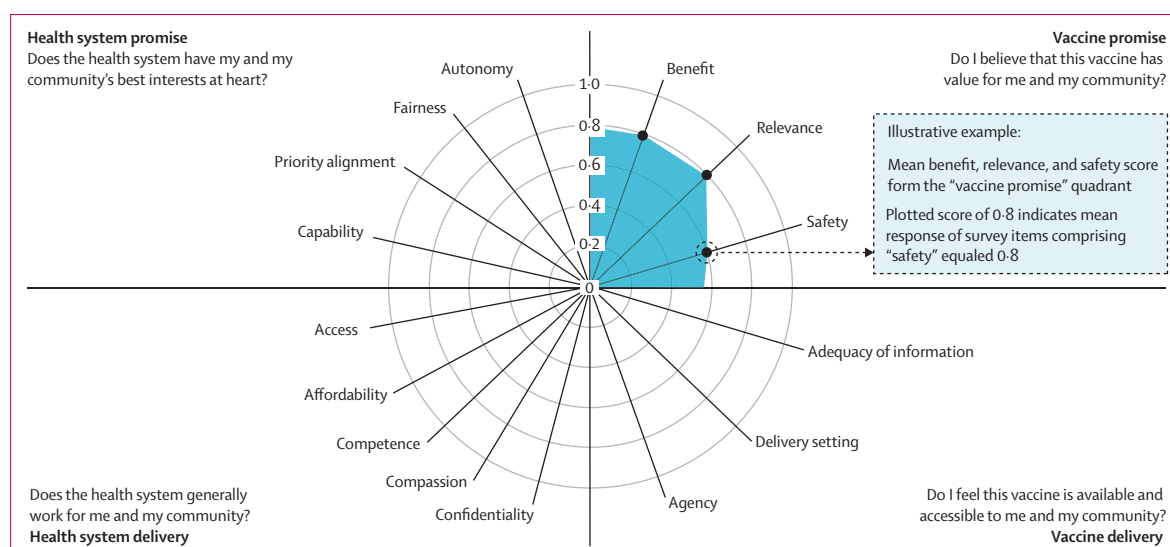


Figure 2: The Vaccine Trust Framework

Figure shows the 15 dimensions and four quadrants that were derived from the ethnographic study. Scores (0.0–1.0) are calculated as means of corresponding sub-dimensions and survey items. Quadrant scores are calculated from means of corresponding dimensions (eg, the score for the vaccine promise quadrant is calculated from the mean scores for benefit, relevance, and safety). Figure-presented scores are illustrative and do not reflect actual data collected in the survey.

removed, and data were stored securely with access restricted to authorised research team members. Public datasets contain only de-identified information to protect participant privacy. This study was approved by research ethics committees in Nigeria (NHREC/01/01/2007-25/09/2019), Kenya (Amref P1027/2021, P1434/2023), and Pakistan (Resdev/RADS and Advance Educational institute and Research Centre; IRB00010843, ERC/S20/P-020). All respondents gave written or recorded verbal informed consent (based on respondent literacy and comfort) during both the ethnographic and survey phases.

Role of the funding source

The funder of the study advised on the study design, but had no role in data collection, data analysis, data interpretation, or writing of the report.

Results

Over 400 ethnographic engagements were conducted in the two rounds of ethnographic research in September–October, 2021, and January–February, 2023. These included informant interviews (n=187), immersions (n=140), extended observations (n=61), focus groups (n=51), and in-situ conversations (n=41). Fieldwork included communities in Nigeria (Kano, Lagos, Kwara, Edo), Kenya (Kisumu, Nairobi, Kilifi, Isiolo), and Pakistan (Rawalpindi, Islamabad, Lahore, Karachi). Fieldwork data were combined with themes from 40 structured interviews with experts including organisations involved in vaccine roll-out (government stakeholders [n=10], non-governmental organisations and international non-governmental organisations [n=8], funders [n=12]) and demand creation (working group or research leadership [n=4], country level

logistics [n=6]). A study flow diagram is presented in figure 1.

Synthesis of collected ethnographic data indicated that two types of trust operate in the health-care space: trust in the promises inherent in the social contract surrounding health, and trust in the delivery of that contract. Each type of trust was observed to be linked with different types of health decisions, with promise-based trust closely linked to social motivations, while delivery-based trust was linked to practical health-seeking considerations. These two trust types operate at both health system and vaccine intervention levels, resulting in a model with four interlinked trust domains: the Vaccine Trust Framework (figure 2).

Qualitative examples that led to the 15 measurable dimensions of the Vaccine Trust Framework, alongside their definitions, are shown in appendix 4 (pp 5–8). Each dimension uniquely impacted trust involved in vaccine decision making, although vaccine promise was observed to be front-of-mind and of increased priority in the moment of vaccine access. Low perception within any dimension or quadrant impacted vaccine trust, and these perceptions were changeable. Research participants described how vaccination experiences had impacted the dimensions. For example, one participant, describing how the COVID-19 vaccine roll-out impacted her perceptions of autonomy, benefit, and relevance dimensions, said:

"There were a lot of threats from the government during COVID-19 vaccination and yet in our village we never saw or heard anyone who had contracted COVID. I think it was all fake... I now think adult vaccines have no practical utility."

Nurse, Lahore, Pakistan (2023)

	Kenya		Pakistan	
	Women (n=2946)	Men (n=724)	Women (n=2482)	Men (n=1252)
Caregiver characteristics				
Respondent age, years	36.0 (31.0–41.0)	39.0 (32.0–46.5)	36.0 (32.0–40.0)	42.0 (35.0–47.0)
Marital status				
Divorced or widowed	385/2928 (13.1%)	64/723 (8.9%)	90/2481 (3.6%)	10 (0.8%)
Married	1908/2828 (65.2%)	591/723 (81.7%)	2365/2481 (95.3%)	1178 (94.1%)
Single	635/2928 (21.7%)	68 (9.4%)	26/2481 (1.0%)	64 (5.1%)
Education level*				
Lower education	701 (23.8%)	129 (17.8%)	798 (32.2%)	213 (17.0%)
Medium education	1094 (37.1%)	192 (26.5%)	784 (31.6%)	468 (37.4%)
Higher education	1151 (39.1%)	403 (55.7%)	900 (36.3%)	571 (45.6%)
Lives in urban setting	2046 (69.5%)	499 (68.9%)	1317 (53.1%)	597 (47.7%)
Does any paid work	2178 (73.9%)	608 (84.0%)	226 (9.1%)	1084 (86.6%)
Economic status				
Above poverty line in Kenya†	1924/2769 (69.5%)	573/688 (83.3%)	..	..
Monthly income in Pakistan				
<PKR 10 000	..	..	35/1947 (1.8%)	36/1171 (3.1%)
PKR 10 000–15 000	..	..	157/1947 (8.1%)	82/1171 (7.0%)
PKR 15 001–30 000	..	..	808/1947 (41.5%)	373/1171 (31.9%)
PKR 30 001–50 000	..	..	639/1947 (32.8%)	361/1171 (30.8%)
>PKR 50 000	..	..	308/1947 (15.8%)	319/1171 (27.2%)
Defined self as head of household	1346 (45.7%)	639 (88.3%)	292 (11.8%)	1120 (89.5%)
Self-reported awareness of HPV	1734 (58.9%)	367 (50.7%)	163 (6.6%)	77 (6.2%)
Awareness of HPV or cervical cancer vaccine	2321 (78.8%)	471 (65.1%)	107 (4.3%)	74 (5.9%)
Vaccinated against COVID-19	1871 (63.5%)	421 (58.1%)	2061/2477 (83.2%)	1061/1245 (85.2%)
Child characteristics				
Age of child, years	12.0 (10.0–13.0)	12.0 (10.0–13.0)	12.0 (10.0–13.0)	12.0 (10.0–13.0)
Child female sex	1724 (58.5%)	344 (47.5%)	1567 (63.1%)	555 (44.3%)
Child received any childhood vaccine‡	2900/2934 (98.8%)	695/718 (96.8%)	2271/2477 (91.7%)	1134/1245 (91.1%)
Child received HPV vaccine§	1151/1672 (68.8%)	150/331 (45.3%)	..	..
Data are n (%), n/N (%), or median (IQR). HPV=human papillomavirus. *Education level defined as no or incomplete primary education (lower), complete primary or incomplete secondary education (medium), or complete secondary or higher education (higher). †Poverty line as defined by the World Bank (rural: KES 3947; urban: KES 7193). ‡Defined as self-reported having received any childhood vaccine. §Data only collected for adolescent females (Kenya, n=2086 caregivers).				
Table: Demographic and vaccination characteristics of recruited participants split by caregiver sex for Kenya and Pakistan				

In total, 65 items were included in the survey to facilitate quantification of the Trust Framework. Cognitive interviews (Kenya, n=6; Pakistan, n=19) and pilot surveys (Kenya, n=192; Pakistan, n=20) confirmed the usability and cultural relevance of items. Changes made following these exercises are detailed in appendix 4 (pp 9–11). For example, difficulty communicating scale questions, especially in Swahili, led to scale items being dropped from a 5-point to a 3-point scale. Trust Framework questions took less than 30 min to complete. The final survey instrument including additional non-framework questions are provided in appendix 4 (pp 119–144).

Demographic and vaccination characteristics of the study populations are reported by country and sex in the table. Survey fielding resulted in a total of 3670 (80.3% women) and 3734 (66.5% women) participants with useable records from Kenya and Pakistan,

respectively. Sampling targets and representativeness are shown in appendix 4 (pp 12–13).

Caregivers reporting on female adolescents accounted for 2068 (56.3%) of 3670 caregivers in Kenya and 2122 (56.8%) of 3734 caregivers in Pakistan. The proportion of children receiving at least one dose of a vaccine was 3595 (98.4%) of 3670 in Kenya and 3405 (91.5%) of 3734 in Pakistan. COVID-19 vaccination rates among caregivers were lower in Kenya (2292 [62.5%] of 3670) compared with Pakistan (3122 [83.6%] of 3734).

Survey item completion was high (missing <5% for all items across both countries). Aggregated trust scores (dimension, quadrant, level, and total) are presented by country and sex (figure 3; appendix 4 p 14). Radar plots of overall and province-specific levels by dimensions for Kenya and Pakistan are shown in figure 3. Variation in trust dimensions across geographies in both Kenya and Pakistan was observed, matching observations from the

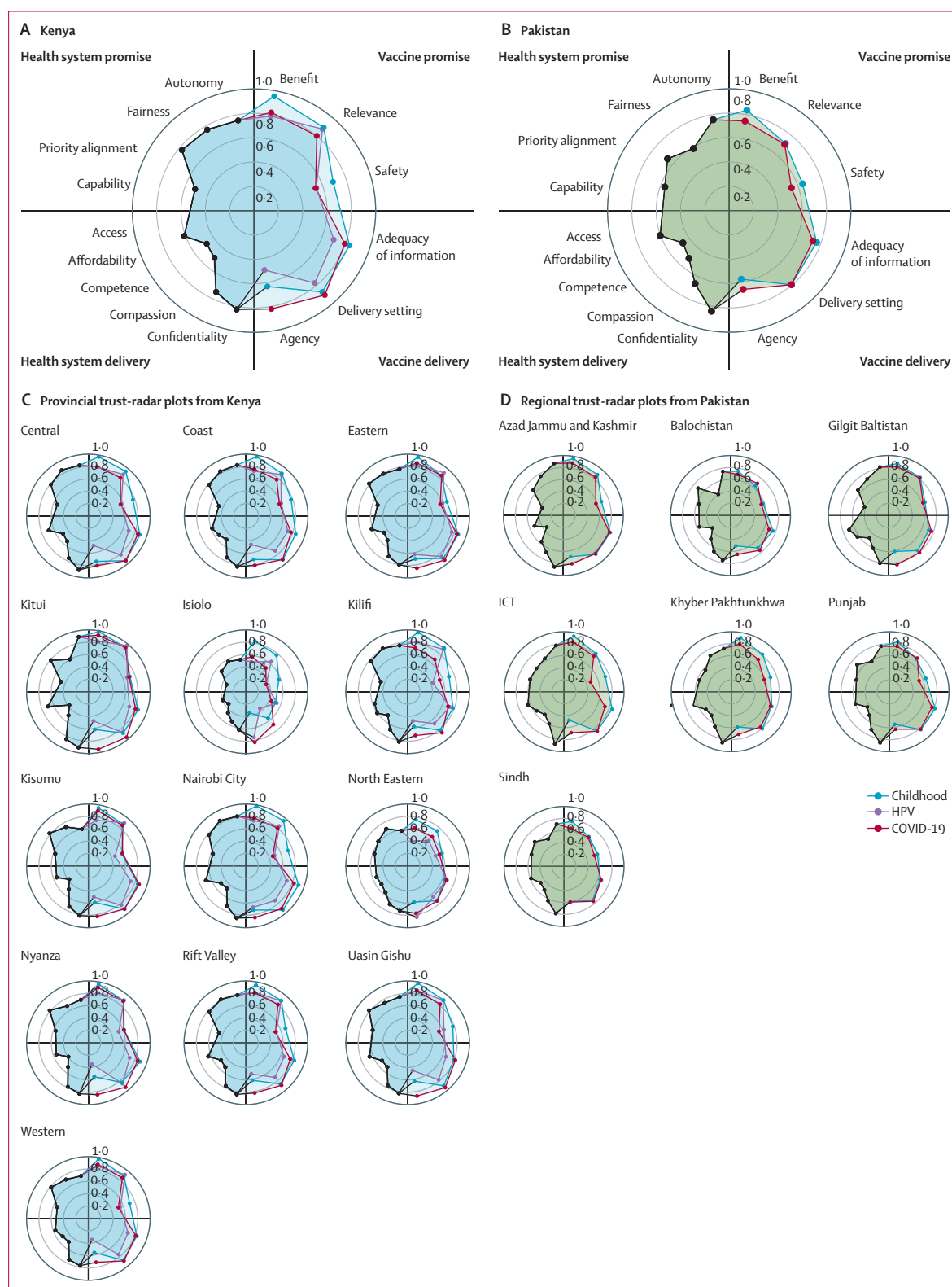


Figure 3: Radar plots illustrating vaccine trust scores across childhood, HPV (Kenya only), and COVID-19 vaccines across geographies in Kenya and Pakistan
 Derived scores for each dimension as defined in the framework are plotted. (A) Radar plots of the Vaccine Trust Framework in Kenya. (B) Radar plot of the Vaccine Trust Framework in Pakistan. (C) Radar plots across the provinces of Kenya included in this study. (D) Radar plots across regions in Pakistan included in this study. Dimensions on sub-plots in panels C and D follow same order as panels A and B. HPV=human papillomavirus. ICT=Islamabad Capital Territory.

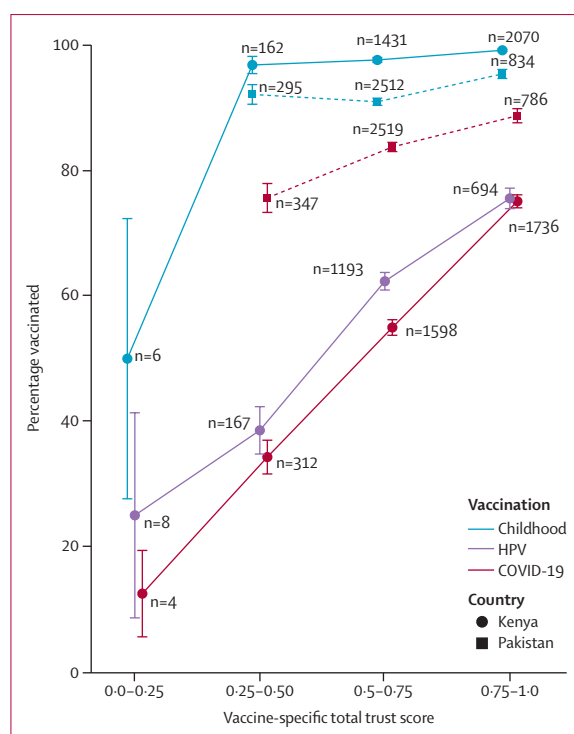


Figure 4: The relationship between total trust score and percentage of group vaccinated across vaccines

Data are presented across all three vaccines for Kenya and childhood and COVID-19 vaccines for Pakistan. Vaccination refers to any caregiver-reported childhood, HPV, or COVID-19 vaccine. Childhood and HPV refer to vaccination of the caregiver's child. Error bars indicate standard deviation. Total trust scores are binned into four categories. For HPV, only female children are included in the population analysed. HPV=human papillomavirus.

qualitative data. For example, trust dimensions within the health system level were lower in Isiolo, reflecting observed feelings of distance and neglect from health authorities.

Quadrant and dimension trust score correlations for childhood, HPV (Kenya only), and COVID-19 vaccines are shown in appendix 4 (pp 3–4). Broadly, all dimensions were positively associated in Kenya, except for fairness and affordability, which had a weak negative correlation. Correlations were more heterogeneous in Pakistan, but all quadrants remained positively correlated.

The framework's factor structure performed better in Kenya than Pakistan. Modification indices supported permission of error term covariance between access and affordability (Kenya and Pakistan), fairness and capability (Kenya), and fairness and priority alignment (Pakistan; appendix 4 pp 15–16). Fit indices for initial and modified models are shown in appendix 4 (p 17). Factor loadings of dimensions onto quadrants are shown in appendix 4 (p 18). In Kenya, four dimensions showed excellent loadings, three good, five acceptable, and three weak. In Pakistan, five dimensions showed excellent loadings, two good, four acceptable, and four weak. Fairness, affordability, and access were the worst-performing

dimensions across Kenya and Pakistan. Metric versus configural measurement invariance (similar construct conceptualisation across groups) was largely maintained except for a borderline result for childhood vaccines and sex in Pakistan ($\Delta CFI -0.013$; appendix 4 p 19). In Pakistan, scalar measurement variances (required to enable group comparisons) were observed for both COVID-19 and childhood vaccines by caregiver sex, income category, and urban versus rural living (ranging from -0.021 to -0.037).

A 10-point change in vaccine-specific total trust score was associated with increased odds of having previously been vaccinated for all vaccines (childhood vaccines in Kenya: odds ratio [OR] 1.61, 95% CI 1.36–1.91, $p<0.0001$; childhood vaccines in Pakistan: OR 1.23, 1.10–1.37, $p=0.0002$; HPV vaccines in Kenya: OR 1.51, 1.38–1.64, $p<0.001$; COVID-19 vaccines in Kenya: OR 1.55, 1.47–1.64, $p<0.0001$; COVID-19 vaccines in Pakistan: OR 1.28, 1.18–1.38, $p<0.0001$). All quadrants were associated with increased odds of previous vaccination across all vaccines except for health system promise and vaccine delivery for childhood vaccines (appendix 4 p 20). The relationship between trust scores and having previously been vaccinated by country and vaccine type is shown in figure 4. In Kenya, vaccine promise was associated with odds of responding positively to future HPV vaccination (OR 1.74, 1.37–2.29, $p<0.0001$). Post-roll-out improvements to the survey and revised framework-only items are presented in appendix 4 (pp 145–162).

Discussion

We present the development and initial findings of the Vaccine Trust Framework and associated trust measurement survey, grounded in ethnographic research, and tailored for decision makers in low-income and middle-income countries (LMICs). Research led to the definition of vaccine trust as a combination of the perceived promise and delivery of both the specific vaccine and the broader health-care system. These trust quadrants are multi-dimensional, contextualised, and shaped by experience and social influence, and can change over time. Correlations between trust scores, vaccination history, and future vaccination intent establish this framework for understanding and measuring trust as a key component of vaccine demand.

Geographical differences in trust dimensions within Kenya and Pakistan demonstrate the tool's sensitivity to population-specific variation. This likely reflects the quality of local vaccine and health-care services. For example, comparatively low trust in the health-care system across all dimensions in Isiolo, Kenya, was corroborated by local ethnographic findings. Isiolo-based research participants reported a feeling of distance and neglect from health authorities. In this context, interventions targeting vaccine promise without addressing underlying local health system-based trust issues could be ineffective, marginal, or potentially damaging, as is observed for other

interventions that ignore a broader context.^{4,20} Different trust gaps hinder vaccine uptake in different ways. Low trust in the promise can drive apathy and lack of trust in delivery can drive avoidance of care-seeking.²¹ Lack of trust in both can create a vacuum, which might then be filled with concerns and rumours.

To be an actionable lever for vaccine demand, tools that measure trust need to be linked to health behaviours. The associations described between trust measures and having been vaccinated across vaccines is evidence of this link. Quadrant-level models highlighted the central importance of vaccine promise for vaccine uptake, aligning with findings from a large quantitative analysis in 149 countries showing a strong positive association between vaccine uptake and confidence in vaccine effectiveness, safety, and medical advice.²²

The Vaccine Trust Framework and associated measurement tool have a range of practical uses and users. Health workers can use the framework to develop communication strategies that address the trust concerns in the community they service. At the decision-maker level, trust data could be used to develop tailored policies and strategies sympathetic to geographical or demographic trust heterogeneity. Targeting trust deficits rather than using general demand-building approaches could better target the root causes of vaccine hesitancy. The breadth of the Vaccine Trust Framework's dimensions allows for targeted trust-building experimentation. Linking the Vaccine Trust Framework and survey data to intervention-designing tools such as the Behavioural Change Wheel could connect best-practice interventions to trust outcomes.²³ We encourage the use of the framework and its modularity as a monitoring tool or study endpoint to better define the modifiable elements of trust and vaccine uptake. Additionally, as a long-term experiential relationship, serial trust measurements and long-term interventions would be highly informative of the framework's performance.

The Vaccine Trust Framework complements existing approaches that assess vaccine demand, such as the Behavioural and Social Drivers of vaccination (BeSD), which aims to understand broader reasons for low vaccine uptake, and is widely used to inform implementation efforts.¹⁸ The combination of the Vaccine Trust Framework and BeSD components could paint a more complete picture of vaccine behaviour drivers, which can be used to improve the design and selection of tailored interventions. Similarly, considering broader trust in the health-care promise and delivery, alongside experiential options which builds trust measurement on the basis of lived experiences, complements the Vaccine Confidence Index, which focuses on perceptions of vaccination importance, safety, effectiveness, and religious compatibility.²⁴ Moucheraud and colleagues have also highlighted a strong link between system-level trust and vaccine perception.²⁵ The Vaccine Trust Framework is distinct from the 5C model (a measure of

vaccine acceptance) as the Vaccine Trust Framework contextualises trust within the specific health systems and social contexts.²⁶ This allows for the targeting of systemic barriers reducing resilient vaccine demand that are particularly relevant in an LMIC setting.

Strengths of this study include the ethnographic underpinning of the framework, encompassing extensive fieldwork across three diverse countries. Quantitative validation through survey data from over 7000 participants, linking trust to health behaviours, supports the explanatory power of the framework and effectiveness of the mixed-methods approach. Measurement of trust in the health system, beyond just health-care professionals, is a key strength, reflecting the complexity of health systems.

Limitations include sampling biases (higher vaccination rates, higher socioeconomic status, and older age of participants) and reliance on self-reported data, which can be subject to recall and social desirability bias. The consequence of the sampling bias is hard to define as there is an absence of data specific to caregivers in both Kenya and Pakistan. The exclusion of adolescent perspectives due to sensitivities around asking questions on HPV vaccination in settings where there are strong cultural attitudes to sex before marriage overlooked adolescent agency surrounding HPV vaccination. Fieldworkers observed teenage girls not getting vaccinated despite parental consent, potentially introducing type II error, and consequent underestimation of differences between vaccination groups.

The 3-point response scale introduced substantial floor and ceiling effects, did not allow participants to fully express themselves, and limits comparisons with other tools.¹⁸ CFA results indicated that certain dimensions could be better captured, to load stronger onto each quadrant. Mild deviations in scalar invariance (eg, between sexes in Pakistan) means that comparisons between these groups should be interpreted with caution but might, for example, represent the local societal role of women which leads to different responses to questions, including social desirability bias and different reference points. The fairness–priority alignment and access–affordability relationships suggest that these dimensions are similar in the respondent's mind. This makes sense as financial and physical barriers to health care are often experienced together in LMICs. Although suggestive of statistical redundancy, these dimensions were clearly distinct in fieldwork. Therefore, local tailoring of these questions might be required to fully capture their complexity.

Ongoing work addresses these limitations by developing vaccine delivery questions not tied to a specific vaccine that can be more widely answered, expanding response scales, modifying items of poorly loading dimensions, and exploring longitudinal designs. Furthermore, shorter forms of the survey are being piloted and will be updated on the Vaccine Trust Project

For the Vaccine Trust Project see
<https://www.thevaccinetrustproject.com>

website. Revised tools aim to make the Vaccine Trust Framework and associated quantitative measure more accessible to all users.

In conclusion, the Vaccine Trust Framework is a practical tool, grounded in qualitative work conducted in LMIC contexts, that directly addresses research gaps in the literature.^{12,13,27} The multi-dimensional understanding of trust captures the environmental and social context that leads to vaccination decisions and moves away from individual blaming narratives.²⁸ We hypothesise that interventions designed with this understanding of trust can generate resilient demand for vaccines, building long-term relationships between the health-care system and communities that keep vaccination rates high. As global capacity for vaccine development, manufacture, and delivery expands, the challenge of generating resilient vaccine demand becomes increasingly critical for both new and existing pandemic threats. Trust-increasing interventions could also combat waning trust in existing vaccines, driven by intentionally polarising debate.²⁹ We encourage practitioners and policy makers to incorporate this multi-dimensional understanding of trust into their vaccination programmes, recognising trust as a fundamental component of resilient vaccine demand.

Contributors

DHB was involved in conceptualisation of the analysis phase, data curation, investigation, formal analysis, methodology, visualisation, and writing the original draft, reviewing, and editing. LC and WA were involved in conceptualisation of ethnographic phases, data curation, investigation, designing methodology, project administration, provision of resources, and reviewing and editing the manuscript. EL was involved in investigation, methodology, data curation, and review of the manuscript. SOM, JO, NSR, and SFA were involved in investigation, supervision, project administration, provision of resources, and writing (review and editing). SOM and NSR were additionally involved in data curation. MH and CV were involved in funding acquisition, supervision, project administration, and in reviewing the manuscript. TJ was involved in funding acquisition and conceptualisation. All authors read and approved the final version of the manuscript. All authors had full access to all the data in the study and had final responsibility for the decision to submit for publication. DHB, LC, WA, and EL directly accessed and verified the underlying data reported in the manuscript.

Equitable partnership declaration

The authors of this paper have submitted an equitable partnership declaration (appendix 5). This statement allows researchers to describe how their work engages with researchers, communities, and environments in the countries of study. This statement is part of *The Lancet Global Health's* broader goal to decolonise global health.

Declaration of interests

DHB, LC, WA, EL, MH, and CV are employees of ReD Associates who received the grants from the Gates Foundation on which this work was funded. TJ was a program officer at the Gates Foundation for the grant that funded this work.

Data sharing

All the individual participant data collected during the study (including data dictionaries), after de-identification, will be available immediately following publication, with no end date, to anyone who wishes to access the data, for any purpose, at www.thevaccinetrustproject.com. Further enquiries and queries can be made at thevaccinetrustproject@redassociates.com.

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of the Foundation, a Creative Commons Attribution 4.0 Generic License has already been assigned to the Author Accepted Manuscript version that might arise from this submission. The ReD Trust Group consists of many members who contributed to this work. Further, we would like to acknowledge the work of several organisations who participated in elements of the research. Ipsos ran the practical elements of the survey. Research And Development Solutions (RADS) provided operational support for the conduct of the first round of ethnographic research in Pakistan. During the preparation of this work the authors used Claude.ai to look for inconsistencies in the manuscript file. After using this tool, the authors reviewed and edited the content as needed and take full responsibility for the content of the publication.

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See Online for appendix 5

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