








# BMJ Open Sample study protocol for adapting and translating the 5C scale to assess the psychological antecedents of vaccination

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## ABSTRACT

**Introduction** Published in 2018, the 5C scale is psychometrically validated to assess five psychological antecedents of vaccination (confidence, complacency, constraints, calculation and collective responsibility). The original version offers a validated English and German scale to assess these determinants with a short 5-item scale (1 item per antecedent) and a long 15-item scale (3 items per antecedent). This sample study protocol provides a step-by-step guidance for the process of adapting the 5C scale to another country, language or cultural context. Data obtained from the 5C scale can support developing, implementing and evaluating an intervention and monitoring of general vaccine acceptance and demand.

**Methods and analysis** Phase 1 comprises the adaptation of the 5C scale including the translation and back translation of the antecedents, an expert evaluation of the antecedents and the identification of new antecedents as well as a pretest. Phase 2 involves the validation of the translated and potentially expanded scale including the assessment of reliability, construct and concurrent validity of all items of the scale. Code for data analysis is provided.

**Ethics and dissemination** The University of Erfurt's institutional review board provided ethical clearance (EV-201900416.2). The authors suggest and encourage publicly sharing all data obtained from the translated 5C scale (eg, on publication). The materials and the code for data analysis to support the process described in this protocol are available in <https://osf.io/2agxe/>. Sharing data on vaccine acceptance and demand is in the public and the scientific interest and will facilitate gaining a global overview of its current state and development over time. The authors of the original 5C scale are currently working on an online platform to facilitate publishing the data and to visualise the psychological antecedents across different countries.

## INTRODUCTION

Since vaccine hesitancy has been identified as a global challenge,<sup>1</sup> scientists and professionals have made many attempts to develop metrics (typically understood as a questionnaire or scale, we will henceforth refer to this

## Strengths and limitations of this study

- Adaptation and validation of the existing 5C scale increase comparability across countries, contexts and languages.
- Validation of translated and adapted scales ensures that the scales measure the intended constructs.
- Openly available materials support the adaptation and validation process.
- The availability of validated scales allow countries to monitor and detect potential early warning signals of vaccine hesitancy and support evidence-based intervention design.
- The suggested process needs expertise from different fields and can be time-consuming.

as scales see box 1) to quantitatively assess why individuals avoid vaccination even though safe and effective vaccines are available (for an overview of the scales, see Betsch *et al*<sup>2</sup>). Betsch and colleagues have recently proposed measuring five psychological antecedents of vaccination that synthesise and extend prior models of vaccine hesitancy and confidence.<sup>3–5</sup> Antecedents are psychological reasons or determinants within a person (eg, a parent) that are related to whether or not a person vaccinates. The five antecedents are confidence, complacency, constraints, calculation and collective responsibility (detailed definitions below). The 5C scale assesses five psychological antecedents of vaccination and provides insights into the individual mental representations, attitudinal and behavioural tendencies that are a result of the environment and context the respondent lives in. For example, perceived constraints could be a function of a lack of access, inappropriate service delivery or, for minority groups, a reluctance to get registered.<sup>2</sup> In sum, the antecedents are related to how someone

## Box 1 Glossary

**Antecedent:** Reason or determinant that is related to vaccination behaviour (eg, confidence)

**Concurrent validity:** Indicates whether an antecedent predicts a vaccination behaviour or intention, as assessed simultaneously with the antecedent.

**Construct:** A theoretical, not directly observable, entity measured by several items; the antecedents of vaccination are also constructs.

**Construct validity:** Quality indicator that ensures that a scale measures what it aims to assess; usually assessed as correlations between constructs.

**Item:** Single question in a questionnaire; several items are used to measure one theoretical construct or antecedent.

**Reliability:** Quality indicator that indicates the scale's internal consistency, usually assessed as a Cronbach's alpha value.

**Scale:** Set of items (questions) to measure a construct (eg, antecedents of vaccination); synonyms are metrics, measure, tool, questionnaire.

**Subscale:** Subset of items; within a scale, there can be several subscales (eg, the 5C scale has five subscales, each measuring one antecedent).

**Validation construct:** To establish construct validity (Does a scale measure what it aims to measure?), validation constructs are correlated with the scale. Based on theories or prior findings there are hypotheses regarding the nature of the correlation (eg, if the confidence scales measure what it intends to measure, it should be positively correlated with the validation constructs attitudes, trust in health systems and the effectiveness of vaccines).

thinks and feels about vaccination and being vaccinated. They influence vaccination behaviour to varying degrees, depending on the specific vaccination and the setting where the scale is used.

The original version of the 5C scale offers a validated English and German scale to assess these antecedents with a short 5-item scale (1 item per antecedent; an item is a question in a questionnaire) and a long 15-item scale (3 items per antecedent; find all items in [table 1](#)). The items look at vaccination in general (as opposed to one specific vaccine, or childhood vaccines). Analyses showed that the general versus a specific wording of the 5C scale items work similarly well. When the 5C scale builds the basis of an intervention, for example, for a measles vaccine campaign, it is, however, recommended to change the wording of the items to make them vaccine-specific (eg, asking for people's confidence in the measles vaccine).<sup>2</sup>

Studies comparing the performance of several similar scales showed that, overall, the 5C scale outperformed other scales in the amount of explained variance of self-reported vaccination behaviour.<sup>2</sup> This may especially be the case because most of the existing scales assess only vaccine confidence, that is, the trust in the safety and effectiveness of vaccines and trust in healthcare providers or systems.<sup>2</sup> The 5C scale captures a broader range of antecedents such as constraints, while at the same time providing the possibility to assess them in a short and economic way. Therefore, the 5C scale is a valid, effective and economic tool to assess the psychological antecedents of vaccination.

The availability of validated scales of vaccine hesitancy/confidence and their regular use in a country allow monitoring the antecedents of vaccination and detecting potential early warning signals.<sup>6</sup> Repeated assessments could show declining confidence or increasing constraints, for example. This information will allow designing specific interventions that can address particular challenges.<sup>5</sup> Thus, identifying underlying causes and problems is linked to potential solutions. Moreover, assessments of the 5C scale in specific target groups (eg, the elderly) and comparisons of fully and undervaccinated subpopulations can identify the antecedents that contribute to vaccine uptake.<sup>7</sup> Campaigns or targeted interventions can aim at changing these particular antecedents, with the goal of an overall increase in vaccination. For example, using the 5C scale in a model region in Germany suggested that the elderly were undervaccinated due to their lack of confidence and high complacency.<sup>7</sup> A specifically designed intervention (with inputs from design, communication science, medicine and epidemiology) addressed these particular antecedents and increased the self-reported vaccine uptake in the subsequent year.<sup>8</sup> The 5C scale can also be a useful evaluation tool by (a) measuring the 5C antecedents before and after an intervention and (b) comparing the 5C scores of individuals who were either aware or unaware of the prior campaign.

### 5C antecedents of vaccination

In this section, we describe the 5C antecedents of vaccination and report the results and the quality indicators from previous validation studies, that is, information about the subscales' reliability (a subscale measures one antecedent with several items), as well as information about their construct and concurrent validity:

- ▶ *Reliability*, usually assessed by Cronbach's alpha, indicates the scale's internal consistency, that is, the mean item intercorrelation (provided in [table 1](#)).
- ▶ *Construct validity* refers to the fact that a scale measures what it aims to assess (eg, Does a scale measuring confidence indeed measure confidence in vaccines as it is defined?). This is assessed by correlating the antecedent with similar constructs. For example, the attitude toward vaccination is similar to but not the same as confidence in vaccines and should thus positively correlate with confidence. [Table 2](#) suggests constructs that can be used for validation. Previous studies have already assessed the antecedents' correlations with similar validation constructs.<sup>2</sup> These results are also provided in [table 2](#) to provide a benchmark.
- ▶ *Concurrent validity* indicates whether an antecedent predicts a vaccination behaviour or intention, as assessed simultaneously with the antecedent (eg, confidence is significantly related to whether a person has been vaccinated against the influenza<sup>2</sup>).

The first antecedent is *confidence*, defined as "trust in (i) the effectiveness and safety of vaccines, (ii) the system that delivers them, including the reliability and competence of the health services and health professionals, and (iii)

**Table 1** 5C definitions with original English and German items, to assess the psychological antecedents of vaccination<sup>2</sup>

Definitions of 5C	5C (US)—English version of 5C items	5C (DE)—German version of 5C items
<b>Confidence</b>	$\alpha=0.85$	
“trust in (i) the effectiveness and safety of vaccines, (ii) the system that delivers them, including the reliability and competence of the health services and health professionals, and (iii) the motivations of policy-makers who decide on the need of vaccines” <sup>3</sup> (p4162)	<p><b>I am completely confident that vaccines are safe.</b></p> <p>Vaccinations are effective.</p> <p>Regarding vaccines, I am confident that public authorities decide in the best interest of the community.</p>	<p><b>Ich habe vollstes Vertrauen in die Sicherheit von Impfungen.</b></p> <p>Impfungen sind effektiv.</p> <p>Was Impfen anbelangt, vertraue ich darauf, dass staatliche Behörden immer im besten Interesse für die Allgemeinheit entscheiden.</p>
<b>Complacency</b>	$\alpha=0.76$	
“perceived risks of vaccine-preventable diseases are low and vaccination is not deemed a necessary preventive action” <sup>3</sup> (p4162)	<p><b>Vaccination is unnecessary because vaccine-preventable diseases are not common anymore.</b></p> <p>My immune system is so strong; it also protects me against diseases.</p> <p>Vaccine-preventable diseases are not so severe that I should be vaccinated.</p>	<p><b>Impfungen sind überflüssig, da Krankheiten, gegen die man sich impfen lassen kann, kaum noch auftreten.</b></p> <p>Mein Immunsystem ist so stark, es schützt mich auch vor Erkrankungen.</p> <p>Krankheiten, gegen die man sich impfen lassen kann, sind nicht so schlimm, dass ich mich gegen sie impfen lassen müsste.</p>
<b>Constraints</b>	$\alpha=0.85$	
“physical availability, affordability and willingness-to-pay, geographical accessibility, ability to understand (language and health literacy) and appeal of immunization service affect uptake” <sup>3</sup> (p4163)	<p><b>Everyday stress prevents me from being vaccinated.</b></p> <p>For me, it is inconvenient to be vaccinated.</p> <p>Visiting the doctor makes me feel uncomfortable; this keeps me from being vaccinated.</p>	<p><b>Alltagsstress hält mich davon ab, mich impfen zu lassen.</b></p> <p>Es ist für mich aufwändig, eine Impfung zu erhalten.</p> <p>Mein Unwohlsein bei Arztbesuchen hält mich vom Impfen ab.</p>
<b>Calculation</b>	$\alpha=0.78$	
individuals’ engagement in extensive information searching; deliberate comparison of the risks of infections and vaccination from which to derive an informed decision <sup>2</sup>	<p><b>When I think about being vaccinated, I weigh its benefits and risks to make the best decision possible.</b></p> <p>For each and every vaccination, I closely consider whether it is useful for me.</p> <p>It is important for me to fully understand the topic of vaccination before I get vaccinated.</p>	<p><b>Wenn ich daran denke, mich impfen zu lassen, wäge ich Nutzen und Risiken ab, um die bestmögliche Entscheidung zu treffen.</b></p> <p>Ich überlege für jede Impfung sehr genau, ob sie sinnvoll für mich ist.</p> <p>Ein volles Verständnis über die Thematik der Impfung ist mir wichtig, bevor ich mich impfen lasse.</p>
<b>Collective responsibility</b>	$\alpha=0.71$	
“willingness to protect others by one’s own vaccination by means of herd immunity (flip side: willingness to have a free ride when a sufficient number of other people are vaccinated)” <sup>2</sup> (p7).	<p><b>When everyone else is vaccinated, I don’t have to be vaccinated, too. (R)</b></p> <p>I get vaccinated because I can also protect people with a weaker immune system.</p> <p>Vaccination is a collective action to prevent the spread of diseases.</p>	<p><b>Wenn alle geimpft sind, brauche ich mich nicht auch noch impfen zu lassen. (R)</b></p> <p>Ich lasse mich impfen, weil ich auch Menschen mit einem schwachen Immunsystem schützen kann.</p> <p>Impfen ist eine gemeinschaftliche Maßnahme, um die Verbreitung von Krankheiten zu verhindern.</p>

Instruction for the 5C scale: “Please evaluate how much you disagree or agree with the following statements.” (1=strongly disagree, 2=moderately disagree, 3=slightly disagree, 4=neutral (or: neither disagree nor agree), 5=slightly agree, 6=moderately agree, 7=strongly agree). Scoring: mean score across items per antecedent. Each item with (R) is reverse-coded. The items used for the short scale are in bold font. Cronbach’s  $\alpha$  refers to the English version (as published in Betsch *et al*<sup>2</sup>). The German translation of the collective responsibility scale has not yet been tested in a German sample.

5C, scale to assess five psychological antecedents of vaccination.

the motivations of policy-makers who decide on the need of vaccines”<sup>3</sup> (p2). Studies have revealed that individuals who lack confidence have negative attitudes toward vaccination (table 2); lower confidence is also related to more misinformation, the belief in conspiracies, doubts about the benefits of medicine and mistrust in the healthcare system.<sup>2</sup>

*Complacency* “exists where perceived risks of vaccine-preventable diseases are low and vaccination is not deemed a necessary preventive action”<sup>3</sup> (p2). In correlational analyses (table 2), higher complacency is related to the perceived lower risk of a disease and when vaccination is not perceived a social norm. Higher complacency is related to a greater interest in immediate outcomes

**Table 2** Suggested validation constructs for phase 2

Antecedents	Suggested validation constructs for the respective antecedents	Previous correlations between the mean 'C' (three items) and validation constructs <sup>2</sup>
Confidence	<i>Attitude toward vaccination</i> is defined as the degree to which the performance of the behaviour is positively or negatively valued (eg, "Vaccination is necessary.") <sup>19</sup> .	0.78
	<i>Vaccination knowledge</i> is defined as a set of items that reflects common misconceptions about vaccinations in general, including 'questions about the immunisation process related to vaccination, the impact of vaccination and the consequences of vaccination' (eg, "The efficacy of vaccines has been proven.") <sup>20</sup> .	0.47
	<i>Trust in the healthcare provider</i> is defined as how patients perceive healthcare providers in terms of their competence, honesty, maintaining confidentiality and fidelity/agency (eg, "My healthcare provider is usually considerate of my needs and puts them first.") <sup>21</sup> .	0.46
	<i>Trust in healthcare institutions</i> (eg, "Healthcare institutions provide the highest quality of medical care.") <sup>21</sup> .	0.32
Complacency	<i>Perceived risk of a disease</i> , one item (eg, "Suppose that you do not have measles—vaccination and that you are not yet suffering from measles. How high do you estimate the likelihood of contracting measles in your lifetime?")	-0.28
	<i>Invulnerability</i> is defined as a felt sense of invulnerability to injury, harm and danger (eg, "I'm unlikely to be hurt if I do a dangerous thing.") <sup>22</sup> .	0.47
Constraints	<i>Perceived behavioural control</i> is defined as individual control beliefs regarding the performance of a behaviour, such as the perceived ease or difficulty of being vaccinated (eg, "It is mostly up to me whether I get vaccinated.") <sup>17</sup> .	Not yet determined, expected: negative correlation
	<i>Perceived access to healthcare</i> is defined as the individually perceived likelihood of accessing the necessary healthcare ("Please report the likelihood of accessing healthcare if you should need it over the next 12 months.") <sup>23</sup> .	-0.17
Calculation	<i>Preference for deliberation</i> is defined as a reflective, cognition-based mode (beliefs, evaluations and reasons) (eg, "I prefer making detailed plans rather than leaving things to chance.") <sup>24 25</sup> .	0.30
	<i>Conscientiousness</i> is defined as an individual's inclination to be organised, productive and responsible (eg, "I am someone who is reliable and can always be counted on.") <sup>26</sup> .	Not yet determined; expected: positive correlation
Collective responsibility	<i>Communal orientation</i> is defined as the desire or feeling obligated to benefit another person in need (eg, "I often go out of my way to help another person.") or it refers to expectations of reciprocity <sup>27</sup> .	0.35*
	<i>Empathy</i> is defined as an individual's emotional reaction (eg, compassion) to another's emotion (eg, sadness) <sup>28</sup> (eg, "I have a strong urge to help when I see someone who is upset.")	0.37*

Validation constructs are expected to be meaningfully correlated with the respective 5C construct. The items for the suggested validation constructs are provided (in English) in <https://osf.io/2agxe/>

\*Denotes the correlation with the one-item version.

5C, scale to assess five psychological antecedents of vaccination.

(than future ones) and to more risk-seeking behaviour. Individuals with high complacency indicate higher feelings of invulnerability than those with low complacency.<sup>2</sup>

*Constraints* are structural or psychological barriers (eg, lack of or limited (perceived) access, lack of self-control) to the conversion of vaccination intentions into actual behaviour. The correlations (table 2) show that higher scores on the constraints variable are negatively related to

perceived behavioural control, self-efficacy and perceived access to healthcare. Perceived higher constraints are also positively related to the feelings of being under time pressure and being overwhelmed with daily challenges.<sup>2</sup>

*Calculation* refers to individuals' engagement in extensive information searching and indicates a deliberate comparison of the risks of infections and vaccination from which to derive an informed decision. As shown



in the correlational analyses (table 2), individuals who score high in calculation are risk averse, perceive higher risks related to vaccination and have a more deliberative cognitive style of decision-making. However, calculation is not associated with a better ability to understand or use numbers (numeracy).<sup>2</sup>

*Collective responsibility* is defined as “the willingness to protect others by one’s own vaccination by means of herd immunity. The flipside is the willingness to have a free ride when a sufficient number of other people are vaccinated”<sup>2</sup> (p7). In the validation studies, high collective responsibility was positively correlated with collectivism, communal orientation and empathy (table 2).<sup>2</sup>

## OBJECTIVES

To make the benefits of the tool available to a broader range of countries, this sample study protocol aims to provide a step-by-step support for translating, adapting and validating the 5C scale in another country, language or cultural context. Thus, when the scale is intended to be used in a setting other than Germany or the USA, where previous validation studies have been conducted, it is strongly advisable to first, *translate* the items into the local language. Second, it should be critically evaluated whether all relevant antecedents are covered by the scale or whether it needs *adaptation*. Other cultural settings may make it necessary to include other antecedents, such as compatibility with religious beliefs, the existence of other traditional ways of healing, the role of particular social influence (eg, strong influence by husbands on the vaccination decision) or other factors. Third, it will be necessary to conduct a new *validation*, that is, to correlate the 5C antecedents with the validation constructs. This method will ensure that the translated items will measure the antecedents as defined.

Following the same study protocol allows better comparability of the data obtained from the scale when used in different countries, contexts and languages—even if slight changes in the wording of the items are necessary or when new context-specific antecedents are added to the scale. The remainder will provide detailed methodological and statistical support for this process.

## METHODS AND ANALYSIS

This protocol suggests a study with two phases. Figure 1 provides an overview of the phases and steps, and table 3 provides a checklist for the process and gives an overview of the materials needed in each step. Phase 1 translates the existing items and assesses whether adaptation is needed, that is, whether it needs to be extended. Phase 2 adds a protocol for the validation of the translated version and of newly added antecedents including the description of the study design and an estimation of how many participants will be needed.

We share materials mentioned in table 3 (eg, translation tables, data legend, syntax for data analysis) to support the

process described in this protocol via the Open Science Framework (OSF; see <https://osf.io/2agxe/>), a ‘free and open-source project management repository that supports researchers across their entire project life cycle’ (cited from the website<sup>9</sup>). We encourage other scientists to ‘fork’ the OSF component and make their data and materials available to other scientists in the new fork. Forking means creating ‘a copy of an existing project and its components. The fork always points back to the original project, forming a network of citations’ (from the website<sup>10</sup>). In this way, an international open network of vaccine acceptance and demand research can emerge, making global monitoring possible. The authors of the original 5C scale are currently working on an online platform to share the data and visualise the psychological antecedents across different countries.

### Phase 1: translation and adaptation

The objective of phase 1 is to assess whether the first translation of the 5C items covers the definitions of the antecedents. Moreover, it aims to assess which antecedents need to be added beyond the 5C and to generate a set of items for the potential new antecedent(s).

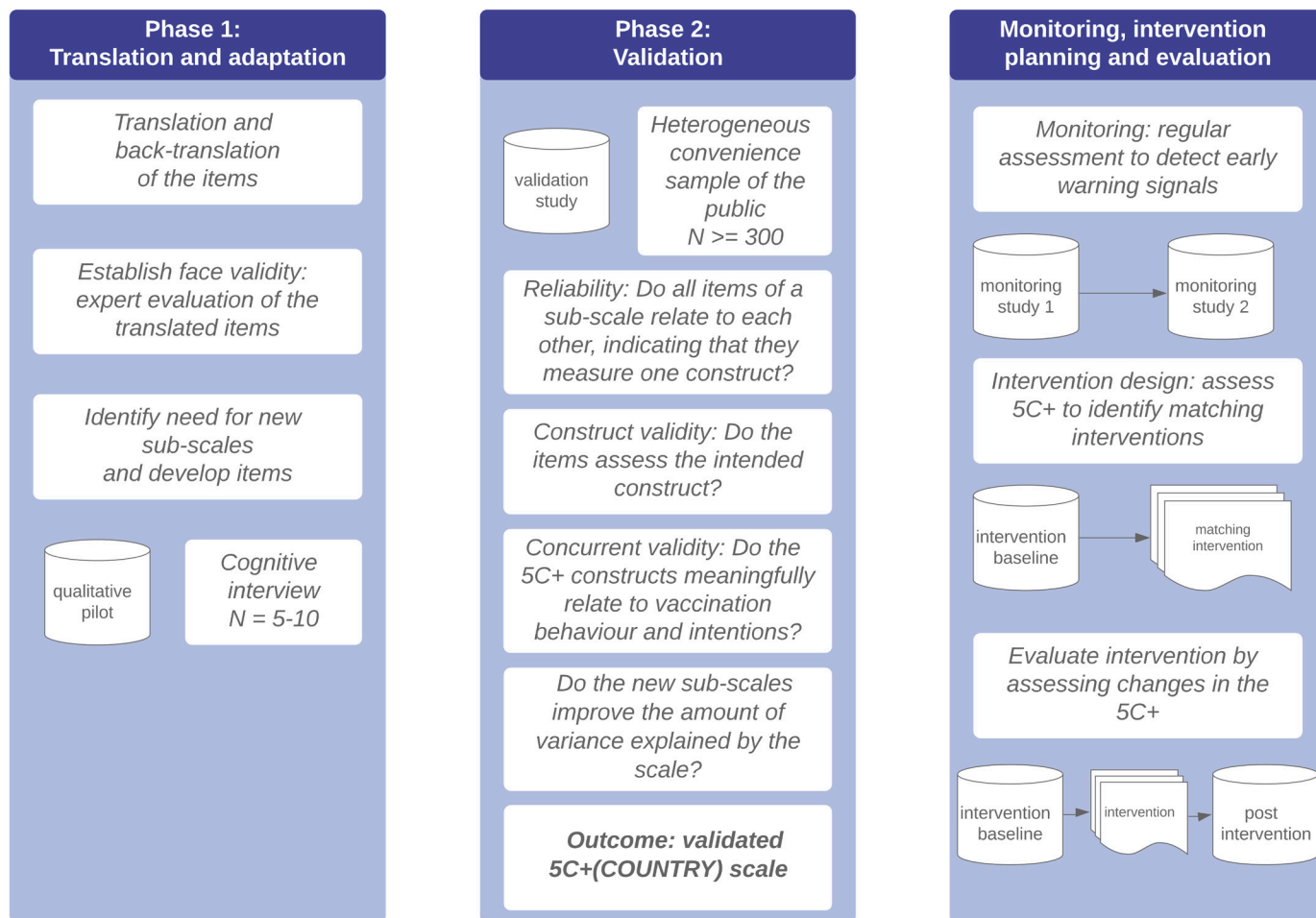
#### Translation of the existing items

In the beginning of the process, it is necessary to translate the original items into the target language. It is recommended that the translation be made by at least two independent translators: Person A translates 5C from English/German into the new language, Person B back-translates the items into English/German. The research team should then compare the original items with the back-translated items and identify where items or words seem to differ. Person A and B should then develop an agreed-on version based on the comments, the original items and the translated items. In some cases, it can be useful to consult a linguist.

#### Expert evaluation

Next, it should be critically examined whether the agreed-on translation covers the concepts as defined. Thus, experts should rigorously evaluate the existing translated items vis-à-vis the definitions of the antecedents (eg, as provided in table 1). The experts may be stakeholders, such as policy-makers, other researchers (from social and behavioural sciences and epidemiology), EPI (Expanded Programme on Immunisation) managers, clinic managers, funders, healthcare providers, parent or patient organisations. We suggest that researchers who undertake the translation and the adaptation hold either a stakeholder workshop or conduct focus group discussions to gain these experts’ feedback on the translated 5C items, inviting discussions on where the antecedents and associated items should be extended to comprehensively capture vaccine acceptance, demand and behaviour.

In general, we advise that the original 5C items should not be changed substantially with respect to the wording of the items as this limits comparability of the results at



**Figure 1** From 5C to 5C+(COUNTRY). In naming the resulting scale, we suggest adding the country in parentheses, in which the validation took place (eg, 5C (DE) or 5C (US)) and a '+' sign when an antecedent is added. 5C, scale to assess five psychological antecedents of vaccination; 5C+(COUNTRY), extended scale to assess more than five psychological antecedents of vaccination, translated in the language of a certain country (given in parentheses).

later stages. If needed, the set of items can be extended by adding new items that cover additional facets of an antecedent. For example, in case of a preconception that a service delivery may pose a problem, the stakeholders may wish to add an item to assess the antecedent 'constraints' that pertains more explicitly to this aspect (eg, 'The way in which vaccines are offered keeps me from being vaccinated').

#### Identifying new antecedents

Based on the stakeholder workshop or the focus group discussions, the antecedents of the existing 5C scale may be extended. For each of the newly identified antecedent, the researchers and the stakeholders should agree on a clear definition. This is important to build the foundation for the item generation, as well as to select the validation constructs. It is important to note that vaccination is a very complex topic and there is a plethora of possible reasons why people vaccinate or do not vaccinate. No scale will ever be able to capture every single reason—and lots of reasons may be summarised under one conceptual umbrella (eg, positive attitudes toward vaccination and trust in the system under the umbrella of confidence).

The challenge with this process is to find distinct antecedents (umbrellas, to stay with this metaphor) that add unique information and to group items that capture different behaviours or reasons under the same umbrella.

The amount of antecedents and items should be balanced with respect to costs and efforts for scale validation. When adding a new antecedent, we recommend to generate items that reflect a great variety of possible facets of the respective antecedent. A minimum of 6 to 10 items should then be formulated for each new antecedent to undergo pretesting and validation (phase 2). We recommend following the principles of good item generation (for overviews, see, eg, table 1 in Simms<sup>11</sup> or table 1 in Tsand *et al*<sup>12</sup>). The goal is to develop a new subscale that covers the antecedent well; therefore, at least three valid and reliable items should be selected in the validation process (phase 2) to match the three-item-per-antecedent structure of the original scale.<sup>2</sup>

#### Pretest

Small-scale qualitative pretesting of the resulting items should be conducted to ensure their comprehensibility before conducting phase 2. This applies both when new

**Table 3** Checklist for translating, adapting and validating the 5C scale and overview of supporting materials

Phase 1. Translation and adaptation	Documents in OSF to support the process
Translation and back-translation of all items.	Translation tables
Identify whether the items capture the definitions of their respective antecedents (discussions, face validity).	Slides for a workshop
Draft additional items for the existing 5C scale if necessary.	
Identify new antecedents and draft new items.	Draft topic guide for a focus group discussion; slides for a workshop
Qualitative pretest: cognitive interviews with n=5–10 people to clarify whether the questions are easy to understand.	Instructions for the cognitive interviews
Phase 2. Validation of the translated 5C scale (5C+(COUNTRY))*	
Validation study involving n=300+ participants, a heterogeneous convenience sample. Use the suggested validation constructs, and, if new antecedents were added, add items to validate that new antecedent. Aims:	Items of the validation constructs, translation table
<ul style="list-style-type: none"> <li>▶ Assess the <i>reliability</i> of the 5C+ antecedents. Do all items belonging to one antecedent relate to each other, indicating that they indeed measure the same antecedent?</li> <li>▶ Assess <i>construct validity</i>. Do the items assess the intended antecedent by showing expected correlation patterns with other constructs?</li> <li>▶ Assess <i>concurrent validity</i>. Do the 5C+ antecedents meaningfully relate to vaccination behaviour and intentions?</li> <li>▶ Does adding the new antecedents improve <i>the amount of variance explained</i> by the scale?</li> </ul>	
Data analysis, selection of items and finalising the scale.	Data legend Syntax for data analysis
Phase 3. Data collection for monitoring or interventions (beyond this study protocol)	
For monitoring, use the general version of the validated scale in a representative sample (eg, “I am completely confident that vaccines are safe.”)	–
For interventions, use the vaccine-specific version of the validated scale in a predetermined target group (eg, for a campaign on influenza vaccination targeting the elderly, assess confidence in a 60+-year-old sample with specific phrasing, such as “I am completely confident that the influenza vaccine is safe.”).	–

We share materials, a data legend and the syntax for data analysis to support the process described in this protocol via the OSF, a ‘free and open-source project management repository that supports researchers across their entire project life cycle’ (cited from the website<sup>9</sup>). Visit <https://osf.io/2agxe/> to access the mentioned documents that support the process.

\*In naming the resulting scale, we suggest adding the country in which it was validated in parentheses (eg, 5C (DE) or 5C (US)) and a ‘+’ sign when an antecedent is added (eg, the data from Nigeria suggest adding compatibility with religious beliefs, so the resulting version would be ‘5C+(NG)’).

5C, scale to assess five psychological antecedents of vaccination; 5C+(COUNTRY), extended scale to assess more than five psychological antecedents of vaccination, translated in the language of a certain country (given in parentheses); OSF, Open Science Framework.

items were added as well as when existing items were translated. This pretesting involves distributing the questionnaire to a small sample comprising 5–10 participants of the target group and conducting brief cognitive interviews with them to obtain their feedback on the questionnaire (for sample instructions, visit <https://osf.io/2agxe/>). As a result of these cognitive interviews, the items may be adjusted to be easy to understand, unambiguous and without jargon.<sup>11 13</sup> The resulting items should then be subjected to the procedure described in phase 2.

### Phase 2: validation of the translated 5C scale

Phase 2 aims at validating the translated 5C scale and the potentially added new items and antecedents. The objective of this phase is to assess the reliability, as well as the construct and the concurrent validity of each 5C antecedent. The outcome of phase 2 will be a translated, adapted and validated scale. In naming the resulting scale, we suggest adding the country in which it was validated in parentheses (eg, 5C (DE) or 5C (US)) and a ‘+’ sign when an antecedent is added (eg, the data from Nigeria

suggest adding compatibility with religious beliefs, so the resulting version would be ‘5C+ (NG)’.

### Participants

Validation entails conducting a survey involving a heterogeneous convenience sample with a broad range of demographic characteristics and assumed vaccination behaviours.<sup>13</sup> Note that it is unnecessary to use a representative sample for validation since the study focuses on the correlations between 5C antecedents and validation constructs, not on the distribution of the 5C antecedents in a population. However, it is not advisable to use a convenience sample from a student population because of its homogeneity in education. Instead, it is sufficient to use a convenience sample from the general population.

### Sample size

The recommendations about the sample sizes for validation studies vary widely.<sup>12</sup> Given that the assessment of validity is based on the inspection of correlation patterns, we suggest using a sample comprising at least 300 participants, which will allow detecting small correlations ( $r=0.2$ ) with at least 95% power.<sup>14</sup>

### Measures

The participants will provide their demographic data, answer the items of the translated (and potentially extended) 5C scale, the validation constructs (to assess construct validity), as well as additional outcome measures, such as the intention to vaccinate and the vaccination behaviour (to assess concurrent validity).

### 5C

The instruction for the 5C scale are as follows: “Please evaluate how much you disagree or agree with the following statements.” (1=*strongly disagree*, 2=*moderately disagree*, 3=*slightly disagree*, 4=*neutral* (or: *neither disagree nor agree*), 5=*slightly agree*, 6=*moderately agree*, 7=*strongly agree*). It is advisable to keep these answer options in future studies. However, in telephone surveys or face-to-face settings, using a 5-point (1=*strongly disagree*, 2=*somewhat disagree*, 3=*neutral* (or: *neither disagree nor agree*), 4=*somewhat agree*, 5=*strongly agree*) or a 3-point scale could be advisable (1=*no*, 2=*undecided*, 3=*yes*) to reduce complexity and errors. Current research in Ghana has revealed that in some settings using Likert-type answering formats (eg, 1 = *I totally agree*, 7 = *I totally disagree*) may be a challenge for the participants.<sup>15</sup> Changing to other formats (eg, 1=*no*, 2=*undecided*, 3=*yes*) seems advisable to reduce error variance. For the scoring, calculate a mean score across items per antecedent. Each item with (R) in [table 1](#) is reverse-coded. If desired, a *don't know* answer option can be provided additionally to the answer options. In that case, note that these should not be used alternatively to the undecided option but need to be analysed separately, and they can serve as an indicator of whether there was a challenge with the question (high percentages of *don't know* answers could indicate that the issue is not relevant or the wording of the question is not suitable).

### Construct validity

Appropriate validation constructs should be selected. As stated, [table 2](#) provides an overview of recommended measures, their respective definitions and one sample item (for a full list of the items, visit <https://osf.io/2agxe/>). The validation constructs have been justified and used in the development of the scale.<sup>2</sup> All items need to be translated into the language in which a study will be conducted. This is crucial because stating the items in a different language (eg, English in a German-speaking sample) will lead to error variance due to a lack of understanding. We also recommend applying the translation/back-translation process described in phase 1 to ensure that the meaning of each item will be captured appropriately. Researchers should also check whether there are available validated scales in the local language that assess the same validation constructs. If this is the case, the scales validated in the specific language should be preferred. The English version of a potential questionnaire to facilitate translation is provided in the <http://osf.io/2agxe/> repository.

### Concurrent validity

This part of the analysis provides the first insight into what the newly translated scale can predict. [Table 4](#) provides an overview of potential measures with their respective sources to assess concurrent validity. It comprises previous vaccination behaviour (as this has been shown to be a powerful predictor of future behaviour<sup>16</sup>), future vaccination intentions (as intentions predict behaviour<sup>17</sup>), and the timeliness and the completeness of the vaccination status (as these are objective criteria for following the recommended schedule). We suggest assessing previous vaccination behaviour for several recommended vaccinations, which will allow both separate and combined analyses. Additionally, the future intention to vaccinate should be assessed as it provides an estimate of the scale's predictive validity. Timeliness and completeness are more objective measures; note, however, that they will require more resources and may raise data protection issues (eg, entering data from the vaccination card, linking a patient to a doctor's registry). No work has correlated all possible measures, so the correlation between the constructs is not known yet. Future work should strive for assessing all recommended measures to explore correlations between them.

### Procedure

The questionnaire comprising all items described in the Measures section can be administered online, as a telephone survey (computer-assisted telephone interview (CATI)) or as a face-to-face survey (paper-pencil or computer-assisted personal interview). Informed consent forms must and demographic information should be collected first, then the participants will fill in the 5C+ items, followed by the validation constructs and the constructs for the concurrent validity. In each scale, the items should be presented in a randomised order (online



**Table 4** Constructs suitable for the assessment of concurrent validity

Construct	For adult/adolescence vaccines	For childhood vaccines
Intention to vaccinate (can ask for a specific vaccine X)	“Imagine that your next vaccination/X is due at your next routine visit to your general practitioner (GP). How would you decide?” (from 1= <i>definitely not be vaccinated</i> to 7= <i>definitely be vaccinated</i> ). <sup>2</sup>	“Imagine that your oldest child’s next vaccination/X is due at his/her next routine visit to the GP. How would you decide?” (from 1= <i>definitely not have my child vaccinated</i> to 7= <i>definitely have my child vaccinated</i> ). <sup>2</sup> “I would like to take my preschool child for X” (from -3= <i>strongly disagree</i> to 3= <i>strongly agree</i> ). “How likely is it that you will take your preschool child for X?” (from -3= <i>very unlikely</i> to 3= <i>very likely</i> ); average of both variables. <sup>29</sup> “How likely I am to get my child any future recommended vaccines ( <i>not at all likely/ very likely</i> ).” “If I had another child now, I would get him/her ( <i>no recommended vaccines/all recommended vaccines</i> ).”; average of both variables. <sup>30</sup>
Previous vaccination behaviour Sum of all vaccines or single vaccines <sup>2 31 32</sup>	“Have you received at least one dose of the following vaccines?” (coded as 1= <i>yes</i> , 0= <i>no</i> , missing value= <i>don’t know</i> ).	“Has your oldest child received at least one dose of the following vaccines?” (coded as 1= <i>yes</i> , 0= <i>no</i> and missing value= <i>don’t know</i> ).
Completeness of vaccination status <sup>2 31–33</sup>	Number of doses received relative to the total number of recommended doses. A copy of the vaccination card or the provider-recorded data can be retrieved to obtain objective data.	
Timeliness of vaccination <sup>34–36</sup>		Age in days (and reported as whole months) when a child being administered each vaccine dose is calculated by subtracting his/her date of birth from the vaccination date. This age in days is compared with the recommended age ranges based on the official vaccination card.

The measurement details are provided in their respective references.

survey or CATI); alternatively, several versions with different orders of the items should be created before printing (paper-and-pencil version for a face-to-face survey).

#### Data analysis

A syntax, along with the data legend provided at <https://osf.io/2agxe/>, can assist researchers in conducting the following steps. Note that when using the provided syntax, the variable names should match the names in the data legend.

#### Reliability

For each 5C antecedent and validation construct, Cronbach’s alpha should be calculated to assess the scale’s internal consistency (ie, the extent to which a set of items measures the same construct). Before calculating Cronbach’s alpha, reverse-coded items need to be recoded (cf. the syntax at <https://osf.io/2agxe/>). The Cronbach’s alpha value should be above 0.70<sup>13</sup> for each 5C antecedent. Assuming that  $\alpha \geq 0.70$ , the mean values are calculated per antecedent. Sensitivity analysis is conducted by using the ‘if item deleted’ procedure; for each 5C antecedent, Cronbach’s alpha is assessed as it would occur without each of the items. This indicates which item could be eliminated if the Cronbach’s alpha

value is too low. Moreover, it should be ensured that the item-total correlation is sufficient. This process should also be applied when there are additional items to adapt the scale to the cultural or the epidemiological context (eg, ‘The way in which vaccines are offered keeps me from being vaccinated’ as a potential additional item for constraints). The items that lead to the highest internal consistency should be selected even if it means dropping original items from the scale or resulting in a version that has more or less than three items. We suggest, however, to strive for three items per antecedent. When high reliability is assured, the next step should assess whether the translated (and potentially changed) antecedents still possesses construct validity.

#### Construct validity

To assess construct validity, Pearson’s correlations are calculated between the 5C antecedents (eg, confidence) and their respective validation constructs (eg, attitude, knowledge, trust in healthcare providers). The set of correlations indicated in [table 2](#) is obtained from the development process<sup>2</sup> and serves as a benchmark. The validation study’s results should be similar to the original correlations. If one or several of the correlations turn out to be substantially lower (eg, 0.10 instead of 0.30), this



can indicate that either the 5C antecedents or the validation constructs lack reliability. In either case, double check whether all constructs have sufficient reliability and consider eliminating items that decrease the reliability by performing the previously described 'if item deleted' procedure. Moreover, it is possible that the translation process has changed parts of the meaning of the constructs. In this case, double-check the translations of the specific constructs. It could also be that in a specific country, not all antecedents are correlated with their respective validation constructs (eg, confidence is related to a positive attitude toward vaccination but not to trust in authorities). The interpretation of the pattern of the results should consider these aspects.

#### Validation of new 5C antecedents (5C+)

When the 5C scale has been extended (5C+), the same procedure, as described for reliability and construct validity, should be applied to the new antecedent(s). For example, regarding compatibility with religious beliefs, a research team might have selected religiosity as a validation construct, for example measured by the Centrality of Religion Scale.<sup>18</sup> A potential hypothesis could be that there would be a positive correlation between compatibility with religious beliefs and centrality of religion, as someone who is less religious may not care whether vaccination is compatible with his/her religious beliefs.

#### Concurrent validity

The next step assesses whether the 5C antecedents predict the intention to vaccinate, as well as previous vaccination behaviour(s) or any of the other constructs suggested in table 4. For each dependent variable, a stepwise regression analysis is conducted (eg, logistic regressions predicting having versus not having been administered a specific vaccine by using the 5C+ antecedents, or linear regressions predicting the sum of the administered vaccines). The demographics are added as predictors in the first step, and all original 5C antecedents are included in the second step. If the scale has been extended (5C+), the new antecedent(s) is (are) added in the third step. Increases in  $R^2$  (coefficient of determination indicating the percentage of explained variance) should be compared in each step. It should be explored whether the extended version (5C+) consistently (ie, across several dependent variables) explains significantly more variance than the original 5C scale does. If so, the extension should be used in further work. Otherwise, the original version is sufficient and should be used for economic reasons.

#### Selecting items for a short scale

To develop a short scale, one item should be selected to represent each antecedent. To determine which item is best suited, the mean of the three items assessing one antecedent, as well as each of these three items, is correlated with the validation constructs. The item that correlates most similarly with the validation construct

compared with the three-item mean should be selected (expected direction, to a similar extent).<sup>2</sup>

#### Patient and public involvement

Members of the target group can be involved in phase 1 in the expert evaluation phase (eg, in focus groups with parents to explore potential further antecedents) and as participants providing feedback in the pretest phase. In phase 2, there is no further public and patient involvement other than recruiting participants from the public to assess their psychological antecedents of vaccination.

#### ETHICS AND DISSEMINATION

The University of Erfurt's institutional review board provided ethical clearance (EV-201900416.2). All participants who will take part in the study will provide their written informed consent to use and share their data for scientific purposes without disclosure of their identity. Analyses and data storing use anonymised data and cannot identify individual participants.

The authors suggest and encourage publicly sharing all data obtained from the translated 5C scale used (eg, on publication). Sharing data on vaccine acceptance and demand is in the public and the scientific interest and will facilitate gaining a global overview of its current state and development over time. The authors of the original 5C scale are currently working on an online platform to visualise the psychological antecedents across different countries.

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