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Clinical Trials Unit survey of translation and interpretation services: current practice, barriers and broader inclusion considerations

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Abstract

Background:

Language barriers can limit participation in clinical trials among ethnic minority populations, particularly for individuals with low first-language literacy, limited health literacy, or limited English proficiency. Although there is increasing recognition of the need to address these barriers, the provision of translation and interpreting services remains resource-intensive, requiring additional time, expertise, and financial investment. Previous methodological studies show there are key implementation issues of providing language provision in UK clinical trials with no clear processes. Evidence on their use and implementation is limited, and their contribution to improving access to research remains unclear. The INVITE study aims to explore how language barriers are currently addressed in UK clinical trials, to explore experiences and acceptability of current processes, and describe resource use and cost of these services. This paper presents findings from a survey of UK Clinical Trials Units (CTUs) examining current practices relating to the provision of translation and interpreting services.

Methods:

An online survey was conducted between July and December 2025 with all 52 UKCRC registered CTUs invited to explore current practices relating to translation and interpreting services in clinical trials. Survey responses were grouped under four key topics - implementation, monitoring and oversight, quality management and barriers to language services provision in clinical trials. Free text space allowed respondents to expand on their answers within the survey and to explain barriers to implementing translation and interpreting services in clinical trials. Quantitative data were analysed using descriptive statistics and free-text responses were analysed thematically.

Results:

There were 35 responses from 31 CTUs. Translation of trial documents was the most used strategy to address language barriers (97%, 34/35), while 66% (23/35) also considered interpreting services. Where translation and interpreting services were implemented, this tended to be on a trial-specific basis rather than routinely across all CTU trials (68%, 22/34 and 65%, 15/23, respectively). Most respondents reported that their CTU provided no training or guidance to site staff on the use of translated documents or interpreting services (91%, 32/35). Monitoring of service use was uncommon, with only 28% (8/29) and 4% (1/29) reporting oversight of translated documents and interpreting services, respectively. Most CTUs did not undertake quality checks of external providers of translation for study documents (62%, 21/34), citing responsibilities were with the sponsor and NHS site, and limited knowledge of how such checks should be conducted. Key barriers included uncertainties around operational aspect of translation and interpreting services, site-level constraints, and broader issues relating to inclusivity. Respondents recognised that translation and interpreting services can improve access to trials but

emphasised that addressing language barriers alone is insufficient to overcome wider cultural and trust-related barriers to participation.

Conclusion:

Translation and interpreting services are widely used by UK CTUs and are an important approach to supporting participation among people with limited English proficiency such as ethnic minority groups. However, opportunities remain to improve the planning, delivery, monitoring and quality assurance of these services, including improved guidance, sustainable funding, validated translated materials and outcome measures, clearer oversight processes, and a wider focus on language support across the entire trial life cycle.

Background

Despite increasing recognition of the importance of diversity in clinical trial populations, participants often remain unrepresentative of the populations for whom interventions are primarily intended. This under-representation arises from numerous complex, interconnected factors, including communication barriers, mistrust of research, and aspects of trial design and delivery that limit accessibility (1, 2). Language barriers are particularly significant for ethnic minority populations, especially those with low first-language literacy, limited health literacy, or limited English proficiency (3, 4). Historically, trials have not been designed with inclusivity as a central consideration; restrictive eligibility criteria, inaccessible study materials, and recruiter-led judgements about English proficiency may exclude individuals and disproportionately affect groups perceived as more difficult or resource-intensive to recruit (5–7).

Despite growing recognition of the need to address language barriers, the implementation of translation and interpreting services within clinical trials remains resource-intensive, requiring additional time, expertise, and financial investment (8). In the UK, trial staff report a lack of clear processes and standards for translation and interpretation (9) despite the availability of guidance (7, 10, 11). At the same time, UK funders, regulatory authorities, and Research Ethics Committees (RECs) increasingly expect participant-facing study materials to be available in languages appropriate to the populations being recruited, to support equitable access and valid informed consent (12, 13). Internationally, similar expectations are reflected in ethical and regulatory frameworks, including the International Council for Harmonisation Good Clinical Practice (ICH-GCP) guidelines and the Declaration of Helsinki, which emphasise that research information must be understandable to participants before consent can be obtained (14). In the United States, Food and Drug Administration (FDA) guidance states that informed consent information should be presented in language understandable to participants or their legally authorised representatives. Although this may be interpreted as plain language, for fully informed understanding, for someone who requires language support, the information would need to be presented in the appropriate language.

Effective translation requires more than linguistic conversion; materials should be clear, accessible and culturally appropriate, with quality assurance processes such as back-translation used to assess accuracy and equivalence (7, 10, 15). However, written translations alone may be insufficient, as literacy levels, cultural factors, and the absence of standardised written forms for some languages can affect understanding (16, 17). Professional interpreters are considered best practice in NHS settings and are preferred to support communication over family members or friends, who may lack the skills to accurately convey complex information or may consciously or unconsciously filter information (18).

There is limited evidence regarding the extent to which translation and interpreting services are used in UK clinical trials, how they are implemented in practice, and whether they successfully improve access to research for ethnic minority populations. Consequently, translation and interpreting have been repeatedly identified as priorities for methodological research (19–21). UK Clinical Trials Units (CTUs) are increasingly budgeting for these services, yet there is little evidence to inform decisions about when, how, and for whom such approaches should be implemented (9).

The research reported in this paper forms part of a broader National Institute for Health and Care Research (NIHR)-Research For Patient Benefit (RfPB) funded programme, *Evaluation of Translation and Interpreting Services Implemented by Clinical Trial Units (CTUs) to Increase Recruitment of Ethnic Minority Groups in Pragmatic Randomised Controlled Trials (the INVITE Study)* (22). This paper presents findings from a survey conducted with CTUs across the UK to explore current practices relating to the provision of translation and interpreting services in clinical trials. We aimed to understand how language barriers are currently being addressed and identify areas for future methodological development and guidance.

Methods

The survey questions were developed by members of the INVITE study team and comprised of the CTU's current Equality, Diversity and Inclusion (EDI) processes; the implementation of translated documents and interpreting services; the perceived effectiveness of these services; and the costing and management of the services. These questions were then refined externally by three members of the MRC -NIHR Trial Methodology Research Partnership (TMRP) Inclusivity subgroup. The survey was initially designed on Microsoft Word®, for ease of review, and then built using the JISC online surveys© tool (Supplementary Material 1). Three members of the MRC-NIHR TMRP Inclusivity subgroup tested the online survey's usability and technical functionality and refined it before it went live. The survey link with attached instructions was sent to the Directors of all UK Clinical Research Collaboration (UKCRC)-registered CTUs, the MRC-NIHR TMRP Trial Conduct groups and the UK Trial Mangers Network (UKTMN) during July–December 2025. The instructions requested staff who are involved in designing and delivering trials, and thus who are likely to have the most involvement in implementing translation and interpreting services, to complete the survey. A follow-up reminder email was sent two months after the initial invitation e-mails. The questions focused on the implementation of translation and interpreting services; the monitoring, oversight and quality management of these services; and the barriers to using translation and interpreting services in clinical trials. Respondents were asked their job title and to leave

their e-mail addresses if they wanted to receive a summary of the survey results and/or were happy to share their CTU's EDI strategy and/or wished to be entered into a prize-draw; otherwise, the responses were anonymous. Data collection and analysis was carried out by members of the INVITE study team. Raw data was downloaded to Microsoft Excel®. Quantitative data were analysed using simple descriptive statistics and summarised using percentages and frequency counts. Multiple responses from the same CTUs were combined and included in the overall analysis. Because completion of some individual survey items was optional, the number of respondents varied across questions. Percentages are therefore presented using the number of respondents to each item as the denominator. For multiple-response questions, percentages were calculated using the number of respondents to that question as the denominator. As participants could select more than one response option, percentages may exceed 100% when summed across categories. Free text responses to six questions that elicited substantial rich data were analysed thematically using Microsoft Word® and written up narratively. Initial findings from the survey were presented to the study's Patient and Public Involvement and Engagement (PPIE) contributors, who helped refine priorities for the subsequent work packages in the INVITE study (i.e., qualitative exploration of acceptability and costs/resource of translation and interpreting services in trials).

Results

31/52 (60%) of registered UKCRC CTUs responded to the survey with 35 respondents in total. 28 CTUs submitted one response, 2 submitted two responses, and 1 submitted three responses. The majority (71%, n = 25/35) of respondents reported they were trial managers, while the remaining (43%, n = 15/35) reported they were either a lead in operations or EDI, or a data management role within the unit. The responses indicated that some respondents had more than one role. Most respondents reported being based at a university-based CTU (85%, n = 30/35), followed by a National Health Service (NHS)-based CTU (9%, n = 3/35), with just two reporting other (6%, n = 2/35). The CTUs which contributed to the survey conducted clinical trials in a wide range of settings (Fig. 1). Survey responses were grouped under four key topics - implementation, monitoring and oversight, quality management and barriers to language services provision in clinical trials. Quantitative and qualitative data are presented together.

Implementation of translated documents and interpreting services

Translation

Translation of trial documents was the most considered EDI strategy 97%, (34/35) with two-thirds (66%, (23/35)) of respondents indicating that they also considered interpreting services (Fig. 2). Respondents could select multiple methods; therefore, percentages do not total 100%. Implementation of translated study documents and interpreting services were largely tailored to specific trials (68%, (22/34) and 65% (15/23) respectively) rather than applying to all clinical trials. Those who commented on why language

support was not implemented into all of the CTU's trials, stated it was trial or site dependent, they were small trials, there were delays in translating and gaining approvals from REC/HRA when a new language is required, and practical difficulties in terms of considering culturally appropriate translated documents within tight trial timelines and predicting language requirements before the trial starts:

Sometimes it's not practical without knowing which languages will be required, we often request funding for around 4 languages and monitor to see which are needed. (P31, Operations Lead, CTU26).

We keep hearing that translation is not the only consideration - translated materials need to be culturally appropriate too and we don't have the ability to do this or fit this into ever decreasing set-up timelines (P22, Trial Manager, CTU19).

Documents and materials reported as routinely translated in the CTU's trials included a wide range with the Patient Information Leaflet (PIL) (23/29, 79%), Consent Forms (21/29, 72%), and Easy Read Information leaflets (16/29, 55%) being the most translated (Fig. 3) of the 29 respondents who answered. Respondents could select multiple methods; therefore, percentages do not total 100%. The number of different languages provided of these documents varied; however, the typical range was 4–6 languages with respondents emphasising that the trial participant population drives the translation needs (i.e. it is trial-specific). CTUs reported that they were often asked by sites to provide translated documents in a language which was not pre-translated (17/29, 59%). Accommodating such site requests appeared to depend on whether there were sufficient funds to cover the translations and whether the translations were done through an external company, using local translation services or using multilingual NHS site staff:

Unfortunately had to explain that we don't have the funding to translate in additional languages (P29, Trial Manager, CTU24).

[We] accepted the request and re-profiled funds to cover the extra (P19, Trial Manager, CTU16).

Based on funding, this was done through either an external translation company or if funding was not available it was done by the coordinator who knew the language (P13, Trial Manager, CTU11).

When CTUs were deciding which languages to translate the trial materials into, they used a range of methods such as surveying sites to query language provision (72%, 21/29); checking most recent UK census data (52%, 15/29); using disease registries (24% 7/29); translating documents ad-hoc if requested by sites; and translating into Welsh as it is a legal requirement in Welsh sites/ CTUs. Respondents could select multiple methods; therefore percentages do not total 100%.

Interpretation

Of the 22 respondents who answered the question about interpretation, most said it was provided over the telephone or face-to-face (both 45%, 10/22) with 27% (6/22) indicating they 'don't know'. When asked

how they calculate the extra time at a routine consultation with an interpreter, 41% (9/22) ‘didn’t know’ and 23% (5/22) didn’t add any extra time. Interpretation by relatives, carers or friends was widely permitted 29% (10/35), with the majority reporting that this practice was trial-specific (43%, 15/35) and dependent on risk and PI’s discretion:

Studies are risk assessed for appropriateness to using the casual interpreter, researcher guides the interpreter to relay information verbatim and checks understanding along the way (P20, Trial Manager, CTU17).

CTU respondents describe that in some trials, interpretation by family members and/or friends is actively encouraged and this detail is included in the study information leaflets that non-English-speaking participants are asked to bring family members or friends to assist with data collection, either alongside or instead of a professional interpreter. CTUs report that family members or friends are often used as professional interpreters are usually unavailable, especially in certain settings such as emergency medicine/ critical care. Using relatives and friends also helped to reduce costs and the challenges of organising an interpreter:

This [family/friend interpretation] was implemented to help lower costs and minimise difficulties that may arise with organising an interpreter to be present (P17, Trial Manager, CTU 14).

This is usually used if an NHS interpreter is not available at the time required (P24, EDI Lead, CTU21).

Monitoring and oversight of language provision at research sites

91% (32/35) of respondents indicated that CTUs did not provide any training or guidance to site staff on the use of translated documents or interpreting services in their trials. CTU respondents were asked whether they thought translated documents and interpreters were used by the majority of sites and from 29 respondents who answered this question, 45% (13/29) and 41% (12/29) responded either ‘Not sure’ or ‘No’ respectively. This may be due to CTUs not routinely monitoring their use in trials, with only 28% (8/29) and 4% (1/29) of respondents stating that they do monitor the use of translated documents and interpreters, respectively. A wide range of reasons were provided as to why they thought language support was not being provided at sites. These included sites not requesting them in the first place (if pre-translated material not provided up-front); when translated materials are provided, they are not being used due to funding and time limitations; site staff may be hesitant to approach people who require language support as it is deemed too challenging:

They may not see that particular patient population. Some sites may be reticent about including people who speak other languages as the visits would take longer (P23, Trial Manager, CTU20).

I'm not sure but I suspect many won't be approached due to their language barriers. Interpretation - I think sites may consider this too much of a challenge / too daunting to implement and may assume they are not allowed to (P19, Trial Manager, CTU 16).

Quality management of translation and interpreting services

There was variety in the quality and validation checks carried out by CTUs when translating trial materials (Fig. 4), with back-translation being the most common (59%, 17/29). Respondents could select multiple methods; therefore, percentages do not total 100%. When translation and interpretation are outsourced to external services or companies, the majority of CTUs use for-profit agencies (e.g. Language Line or Cintra) for translation of study documents (62%) and NHS in-house services for interpretation at the research sites (62%, 21/34). The choice of which external company to use depended on whether they were approved by the Sponsor, NHS Trust or University, whether they had ISO standards, and the CTU's previous experience of working with the company. When CTUs were asked whether they carried out checks on the external companies, 62% (21/34) said they didn't carry out checks. Reasons for this included services not being chosen by the CTU, with approved suppliers and any checks being centrally managed by the University or the NHS rather than CTUs, and uncertainty about the need for such checks or how to carry them out:

Use of services that are compliant with ISO standard and University approved we expect the services to be of high standard (P34, EDI Lead, CTU 30).

I'm not sure if any checks on the services are carried out (P08, Senior Research Manager, CTU06).

Barriers to using translation and interpreting services in clinical trials

CTU's were asked to describe what they thought were the biggest barriers to using translation and interpreting services in trial research. Thematic analysis revealed three key themes: uncertainties around operationalising efficient translation and interpretation services; site level barriers and challenges; and broader inclusivity issues, including proposed solutions and recommendations going forward (Table 1).

Table 1
Key barriers to implementing translation and interpreting services in UK clinical trials- survey response

Theme	Subtheme(s) and description/interpretation	Illustrative quotes (Participant ID)
Uncertainties around operationalising efficient translation and interpretation services	**Choosing which languages to translate into**: CTUs described that they were not always sure which languages to translate the trial documents into. They described the challenges in choosing the most appropriate languages for translation, given the large of number of languages to consider. They also noted that there was often a mismatch between the most spoken languages in an area versus the trial population. In some cases, ad-hoc translations can be possible and might work better than predicting in advance. The difficulty in choosing which languages was also linked to the costs and resources involved in the preparatory work and the lack of funding at the pre-grant stage to predict translation needs.	*'….it can be very difficult to determine which languages to translate into, the most commonly spoken languages in an area will not always be the population of the trial. In some instances ad-hoc translations may be possible, but it depends on patient flow into the study' (P01, Trial Manager, CTU01)* *'[there is a barrier with the] Difficulty knowing which languages will be required and cost and time associated with getting the documents translated '(P17, Trial Manager, CTU15)*
	Navigating costs, resources and timelines: Translation costs were described as being expensive with trial teams sometimes not budgeting for this because a) it was not perceived as a routine requirement for all trials; b) there was not enough funding available in smaller charity funded grants; or c) if the trial was recruiting a small number of participants. Additional barriers mentioned included the additional costs of translating study documents after an amendment, tight timelines during trial set-up and lack of resources, particularly when there are other trial-specific priorities.	*'Primarily cost, it can be expensive and not budgeted for until it was mandatory' (P12, Operations Lead, CTU10)* *'[there is a] lack of resource to give this [translation and interpreting services] the time and funding needed to apply this thoroughly' (P11, Trial Manager, CTU09)* *'Timelines are prohibitive. At the point we need material translated - we often don't know which trial sites will open and therefore activities like - translating into the five most common languages are not possible (and I would argue not inclusive)' (P22, Trial Manager, CTU19)*
	Ensuring quality and accuracy: There were significant concerns about the accuracy and quality of the translated study documents, as trial teams often lacked the expertise to verify them and felt that methods like back-translation did not guarantee accuracy. The complexity and nuance of medical language, combined with inconsistent quality and limited availability of skilled translators, further reduced confidence of CTUs in the translated materials. Additionally, one respondent commented that the wide range of languages across NHS	*'If using translating and back-translating there's still no guarantees that the translation will be accurate, as I can't check it!' (P01, Trial Manager, CTU01)* *'Medical translation is so nuanced and intricate, getting the same "feel" in a document is hard, and also hard for the trial team to check this was the case' (P12, Operations Lead, CTU10)*

Theme	Subtheme(s) and description/interpretation	Illustrative quotes (Participant ID)
	populations makes it difficult to provide consistent, high-quality translations.	
Site-level barriers and challenges	At the site and Trust level, CTUs reported that they believed site staff may be reluctant to approach non-English-speaking participants and noted that some Trust policies explicitly exclude individuals who cannot understand English. CTUs also described that some site staff may have limited awareness, training, and support around inclusive research practices, contributing to patients not being approached despite being eligible. In addition, respondents highlighted capacity constraints within site teams and that site staff may have some uncertainty about how to access appropriate translation and interpretation services.	*'I do think there is reluctancy for site staff to approach potential participants that do not have English as their first language, but this is more anecdotal' (P15, Trial Manager, CTU13)* *'Individual Trust policies against inclusion of people who can't understand English (as reported by site staff in our survey)' (P10, EDI Lead, CTU08).* *'[We have an] example of a site that has taken immense efforts to look into this in detail at their site/hospital through site audits and feedback on language-based exclusion criteria in their study protocols and screening logs. Participants are excluded either because of exclusion criteria or where these are not problematic, site staff are likely not approaching such patients (as reflected in screening logs) due to lack of awareness/training, support, etc' (P18, Research Delivery Manager, CTU15)*
Broader inclusivity issues	**Outcome measures not translated**: Respondents questioned whether it is sufficient to translate PILs and consent forms for a patient who does not speak English as their first language, given the unavailability of translated versions of validated questionnaires and outcome measures that would be used subsequently.	*'One of the major barriers is the unavailability of the validated questionnaires. It's ok to have a patient who doesn't speak English as their first language consent using the translated PIS and consent form, but where there is no validated questionnaire in that language we have to use the English one and rely on family members to translate them' (P23, Trial Manager, CTU20).* *'The main barrier for most of our trials is the 1000s of potential languages and choosing the most appropriate ones for translation, as well as apps and other detailed outcomes/software that would need dedicated time and money to translate and may not be feasible in the overall grant budget-particularly smaller feasibility*

Theme	Subtheme(s) and description/interpretation	Illustrative quotes (Participant ID)
		studies and fellowships' (P30, Operations Lead, CTU26).
	Inclusion is more than just translation: Respondents from the CTUs also commented that inclusion is much more than translation of languages for non-English speakers, which by itself does not ensure diverse representation of participants in trials. They described a lack of evidence of the effectiveness of translation and interpretation in trials and that cultural understanding and addressing mistrust in communities stemming from historical misconduct is also crucial. CTUs reinforced the need for further support, information and awareness on language support implementation and noted the sense of disappointment felt when all the effort that goes into translation and interpretation does not lead to more inclusive trials.	*'Additionally increasing the diversity of trial participants is about so much more than translations. Even where translations have been provided, we often struggle to recruit participants who don't speak English. Anecdotally we are told this is down to a lack of cultural understanding, or even a lack of trust. There may be a wariness about clinical trials given prominent historical instances where research was done 'to' people rather than 'with and for' them. While translations may help get over language barriers, they do not go far in addressing cultural barriers' (P01, Trial Manager, CTU01).* *'Assumptions also that it is a gold standard for more inclusivity either deters or attracts people or creates a sense of (dis)appointment when it doesn't ultimately always lead to more inclusivity' (P21, EDI Lead, CTU18).*
	Recommendations and suggestions: CTUs recommended a more coordinated and flexible system for translation and interpretation, including an NIHR-funded centralised service alongside dedicated, easily accessible funding for ad hoc support. They emphasised that provision should be tailored to individual trials with proactive planning where needed, while still enabling rapid access to services when requirements emerge. Overall, participants highlighted the need for clearer system-level support to improve consistency and efficiency.	*'Inclusivity is a priority and can be addressed for specific studies and their target population. Routine translation is inefficient and does not address communication barriers. Rapid and easy access ad hoc translation or interpretation via an overarching EDI strategy with centralised/separate funding for CTUs' (P20, Trial Manager, CTU17).* *'It would be marvellous if NIHR set-up a dedicated translation/interpreter service for NIHR funded trials that applicants state that they want to make use of, should the funding application be successful' (P14, Trial Manager, CTU12)*

Discussion

This national survey of UKCRC-registered CTUs provides the first overview of current practices and processes relating to the implementation of translation and interpreting services in UK academic clinical trials. The findings indicate that translation of study documentation is the most commonly adopted strategy (97%, 24/25) to support EDI in UK clinical trial units, with provision of interpreters used to a slightly lesser extent (66%, 23/35). Most translated materials consisted of PILs, consent forms, and Easy Read documents, suggesting that language support is primarily concentrated at the recruitment and informed consent stages of the trial lifecycle. This suggests that less consideration may be given to the language support required for participants once they have been recruited into a trial.

While translation of recruitment materials is essential for enabling access to research, inclusion of people who require language support requires a broader approach that extends throughout the participant journey (23). Previous research has highlighted the importance of embedding language support across all stages of trial conduct rather than focusing solely on recruitment (24). Inadequate communication beyond enrolment may contribute to missed follow-up visits, incomplete data collection, participant withdrawal, and protocol deviations, ultimately affecting data quality and the generalisability of trial findings. These challenges were reflected in our findings, with CTUs frequently reporting difficulties in providing validated translated questionnaires and outcome measures. Consequently, some CTUs described relying on alternative approaches, including interpreters or family members to support questionnaire completion, while others reported that the inability to translate outcome measures acted as a deterrent to translating study documents more broadly. This finding suggests that barriers to language support in later stages of trials may undermine efforts to improve inclusivity at recruitment.

A notable finding was the considerable variation in how CTUs implement language support. Although some units reported applying translation and interpreting services across all trials, most indicated that provision was determined on a trial-by-trial basis (68%, (22/34) and 65% (15/23) respectively). Lack of dedicated funding and the challenges associated with proactively planning language support were commonly reported barriers. These findings align with previous work, including a US study in childhood cancer trials, which identified insufficient funding to support translation costs and a lack of in-person interpreters as barriers to the inclusion of participants who required language support (19, 25). Respondents frequently recommended greater system-level support, including developing clearer standards and resources to facilitate routine implementation of translation and interpreting services. Determining which languages should be prioritised for translation emerged as a particular challenge. Many respondents reported difficulties in deciding, at the trial design stage, which languages would most appropriately meet the needs of potential participants. Reliance on the most commonly spoken languages within a site's geographical catchment area may be insufficient, as local population-level language data (which usually consists of first or preferred language data) may not reflect the specific characteristics of the trial population or the prevalence of people who require language support within it. Consequently, this approach may leave smaller language communities under-served and potentially limit their opportunities to participate in research. However, CTUs must balance inclusivity with finite resources, particularly in trials recruiting from broad populations where the range of potentially required languages is substantial.

Given these practical and resource challenges, neural machine translation (NMT) tools, such as Google Translate, are increasingly used in healthcare and research because they are accessible, cost-effective, and easy to implement (26). While these AI-based technologies may help reduce language barriers for ethnic minority populations, concerns remain regarding their accuracy and the limited regulatory oversight of their use in healthcare and clinical research settings (26). These issues raise important ethical, methodological, and patient safety considerations, particularly when translated materials are used to support informed participation in clinical trials. The complexities translating trial documents should not be underestimated (8) and further highlights the need for pragmatic, evidence-informed approaches to language support planning, alongside sustainable funding mechanisms that enable equitable access to research participation. One project currently underway, for example, is assessing the accuracy and patient acceptability of AI translated patient information study documents (27).

Nevertheless, the survey findings indicate that a wholly proactive approach may not be feasible in all settings. Many CTUs described implementing language support reactively, responding to requests from recruiting sites after trial opening and adapting provision according to needs identified during recruitment. This may reflect the practical challenges of predicting translation and interpreting requirements at the trial design stage, particularly for studies recruiting heterogeneous populations. Consequently, a hybrid model may offer the most realistic and sustainable approach, combining advance planning and centralised support with flexible funding arrangements that enable timely responses to unanticipated language needs that arise during trial conduct. Similar recommendations have been reported previously (23).

The survey also highlighted the complexity of implementing language support within a multi-stakeholder environment involving CTUs, sponsors, host institutions, and NHS recruiting sites. Most CTUs reported either being unaware of whether sites were using translated documents and interpreters or indicated that such use was not routinely monitored. CTUs reported that they are planning to start collecting resource data, however this lack of oversight may reflect the limited mechanisms available to CTUs for evaluating how language support is implemented at site level. Similarly, only a minority of CTUs reported conducting quality assurance checks on external translation providers, with responsibility for these processes often delegated to sponsors or host universities. These findings suggest that responsibility for implementing and monitoring language support may not always be clearly defined across the different organisations involved in trial delivery. The extent and consistency of these checks remain unclear and warrants further investigation, which is planned within the next phase of the INVITE study. Another related finding was the almost complete absence of training provided by CTUs to recruiting sites on the use of translated documents and interpreters. Whether this reflects a gap in training provision or uncertainty regarding responsibility for such training remains unclear. Given that CTUs themselves reported limited guidance, standardised processes as well as lack of funding and resources available to deliver effective language support services, they may not currently be best positioned to lead training initiatives.

The quality of interpretation services represents a further area of concern. Challenges relating to interpreter quality, training, and availability have previously been reported in NHS healthcare settings and elsewhere and may similarly affect the conduct of clinical research (23, 25). In the present survey, respondents indicated that family members or friends were sometimes used to facilitate communication during recruitment discussions despite guidance recommending otherwise (7). While such approaches may offer pragmatic solutions when professional interpreters are unavailable, they raise important questions regarding accuracy, confidentiality, and the validity of informed consent (7). This highlights a tension between recommended practice and what may be feasible in practice, particularly where access to professional interpreting services is limited by availability, cost or time. Further research is needed to evaluate the quality and impact of different interpretation approaches within clinical trials, including both professional and informal sources of support, and to identify models that are acceptable, effective, and sustainable.

Several respondents also identified site-level barriers to implementing language support. These included limited requests for translated materials, concerns regarding the additional time and resources required, and perceptions that recruiting participants requiring language support presents additional complexity. This aligns with recent studies demonstrating that English language proficiency remains a common eligibility criterion, with recruiters assessing eligibility through both explicit and implicit language-related gatekeeping practices (6, 21). As language ability is frequently assessed without the use of formal or standardised measures, recruiters are left to apply their own judgement when determining whether an individual has sufficient proficiency to participate. These findings also suggest that organisational and behavioural barriers may influence the extent to which available language support resources are utilised and making language support available may not, on its own, be sufficient to improve inclusion if research staff lack the time, confidence or support to use these resources in practice. These issues will be explored further in the qualitative and resource/ cost components of the INVITE study, which aims to understand the experiences and perspectives of NHS research staff involved in trial delivery and the resources required to implement language support in clinical trials.

Finally, and encouragingly, respondents emphasised that translation and interpreting services are only one component of a broader accessibility agenda. Improving language access alone is unlikely to eliminate the underrepresentation of diverse populations in clinical trials, though it is necessary for the inclusion of people who require language support. Respondents suggested that barriers may occur earlier in the recruitment pathway, with some under-served groups potentially not being approached about research opportunities at all. Addressing these challenges is likely to require greater investment in inclusive patient, public, and community engagement, as reported previously (28), alongside training and support for research staff to engage effectively with diverse populations. Importantly, these engagement activities must themselves be accessible and inclusive (29). The ongoing INVITE study will provide further insight by collecting screening log data across multiple host trials, enabling examination of whether individuals from ethnic minority groups and those requiring language support are being approached for participation and where barriers arise within the recruitment pathway.

This study has several strengths. It included responses from a broad range of UKCRC-registered CTUs and provides the first national assessment of how translation and interpreting services are implemented within UK clinical trials. The survey primarily captured the perspectives of trial management staff, reflecting the survey's focus on those directly involved in coordinating language support processes. Although perspectives from other CTU roles may have provided additional insights, trial managers are well placed to describe the practical and operational challenges associated with implementing language support.

Several limitations should also be acknowledged. Not all UKCRC-registered CTUs participated in the survey; however, the response rate is comparable to similar surveys conducted across CTUs (25, 30, 31). It is also possible that individuals with experience of implementing language support provision in clinical trials were more likely to complete the survey, while the perspectives of those with limited or no experience, or those who perceive translation services to be less necessary, may be underrepresented. Consequently, the survey may not have captured the full range of barriers, experiences, and viewpoints relating to the implementation of translation and interpreting services. Consequently, while the findings may not represent all UK CTUs or all the UK clinical trials community, they provide valuable initial evidence regarding current practices and perceived barriers to the implementation of translation and interpreting services. These findings form an important foundation for subsequent phases of the INVITE study, which will explore these barriers in greater depth through qualitative research with key stakeholders.

Conclusion

Translation and interpreting services are widely used by UK CTUs and represent an important strategy for improving EDI in clinical research. This survey highlights both the commitment of CTUs to supporting participants with limited English proficiency and the opportunities to strengthen how language support is planned, delivered, and monitored across trials. Key areas for development include sustainable funding, improved infrastructure, greater availability of validated translated materials and outcome measures, more consistent quality assurance of external translation services and oversight, and a wider focus on language support across the entire trial life cycle.

Respondents recognised that promoting equitable participation extends beyond the provision of translated documents and interpreters alone. Meaningful inclusion requires culturally appropriate communication, community engagement, and sustained efforts to build trust with underserved populations throughout the research pathway. With continued investment in guidance, standardised processes, and evidence-based approaches to language support, there is a significant opportunity to enhance the accessibility and inclusivity of clinical trials for people with diverse language needs.

Abbreviations

AE

Adverse event
AI
Artificial Intelligence
CEHR
Centre for Ethnic Health Research
CTIMP
Clinical trial of investigational medicinal products
CTU
Clinical Trials Unit
HRA
Health Research Authority
MT
Machine Translation
NHS
National Health Service
NIHR
National Institute for Health and Care Research
PIL
Patient Information Leaflet
PRO
Patient-reported outcomes
REC
Research Ethics Committee
SWAT
Study Within a Trial
SoECAT
Schedule of Events Cost Attribution Tool

Declarations

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Authors' contributions

KR conceived the idea for the study and led the study team. KR, SD, AL, SP and KB designed the study and obtained funding. KR designed, conducted and analysed the CTU survey with support from the study

team. SP analysed the qualitative data from the free text responses in the survey. KR wrote the first draft of the manuscript. All authors have provided intellectual input, reviewed subsequent manuscript drafts and approved the final version of the manuscript prior to submission.

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Availability of data and materials

The data generated or analysed during the current study are included in this published article (and its supplementary information files). Additional information is available from the corresponding author on reasonable request.

Ethics approval and consent to participate

Information regarding the purpose of the survey was included at the start of the online survey and in the corresponding e-mail invitation. Participant consent was assumed by completion and submission of the survey. Ethics approval was granted by the Faculty of Health Sciences Research Ethics Committee (FREC), University of Bristol.

Consent for publication

Not applicable. The manuscript does not contain data from any individual person

Competing interests

The authors all declare that they have no competing interests.

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Figures

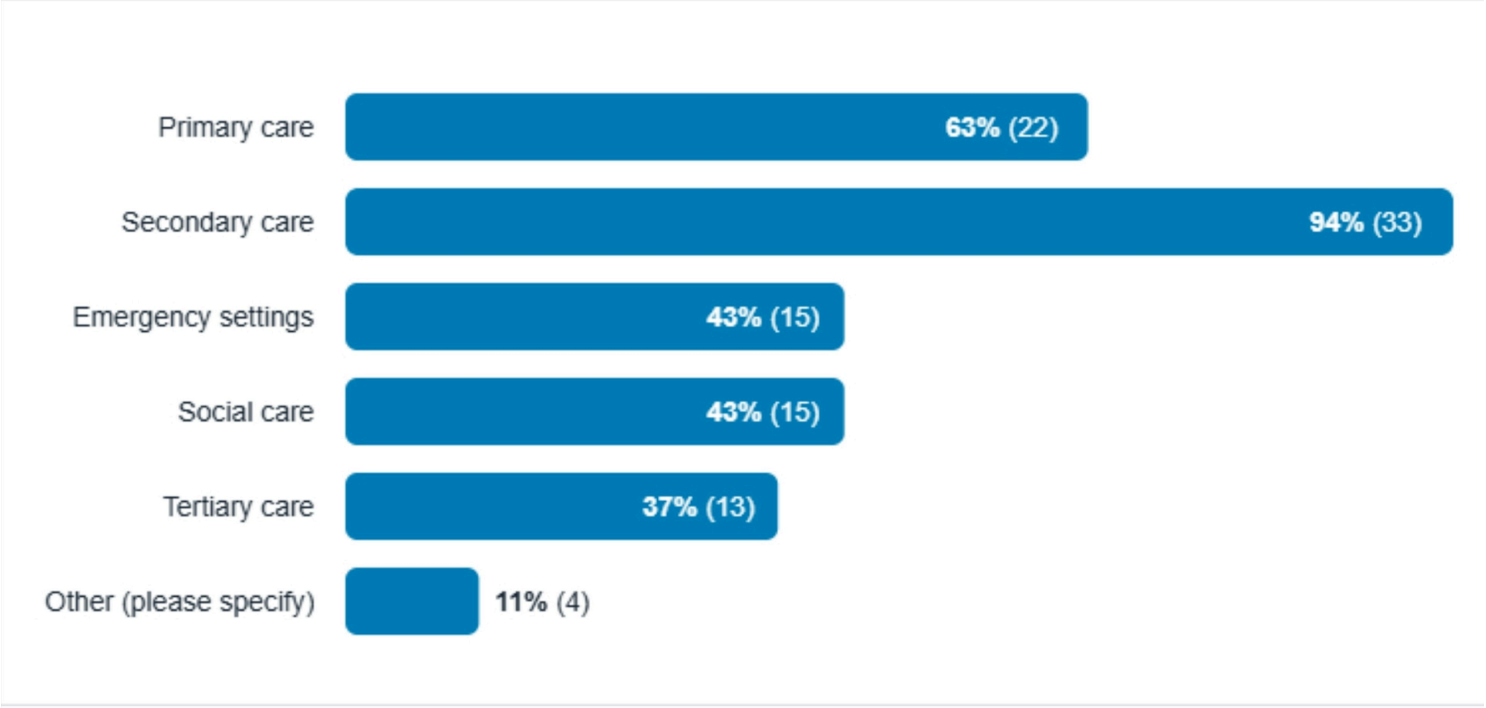


Figure 1

Clinical trials settings described by respondents in the survey. Other settings included learning disabilities services, intensive care, community settings (e.g schools, Non-Governmental Organisations (NGOs)), online delivery settings, mobile vans, national data through digi-trials, self -enrolment, existing cohorts.

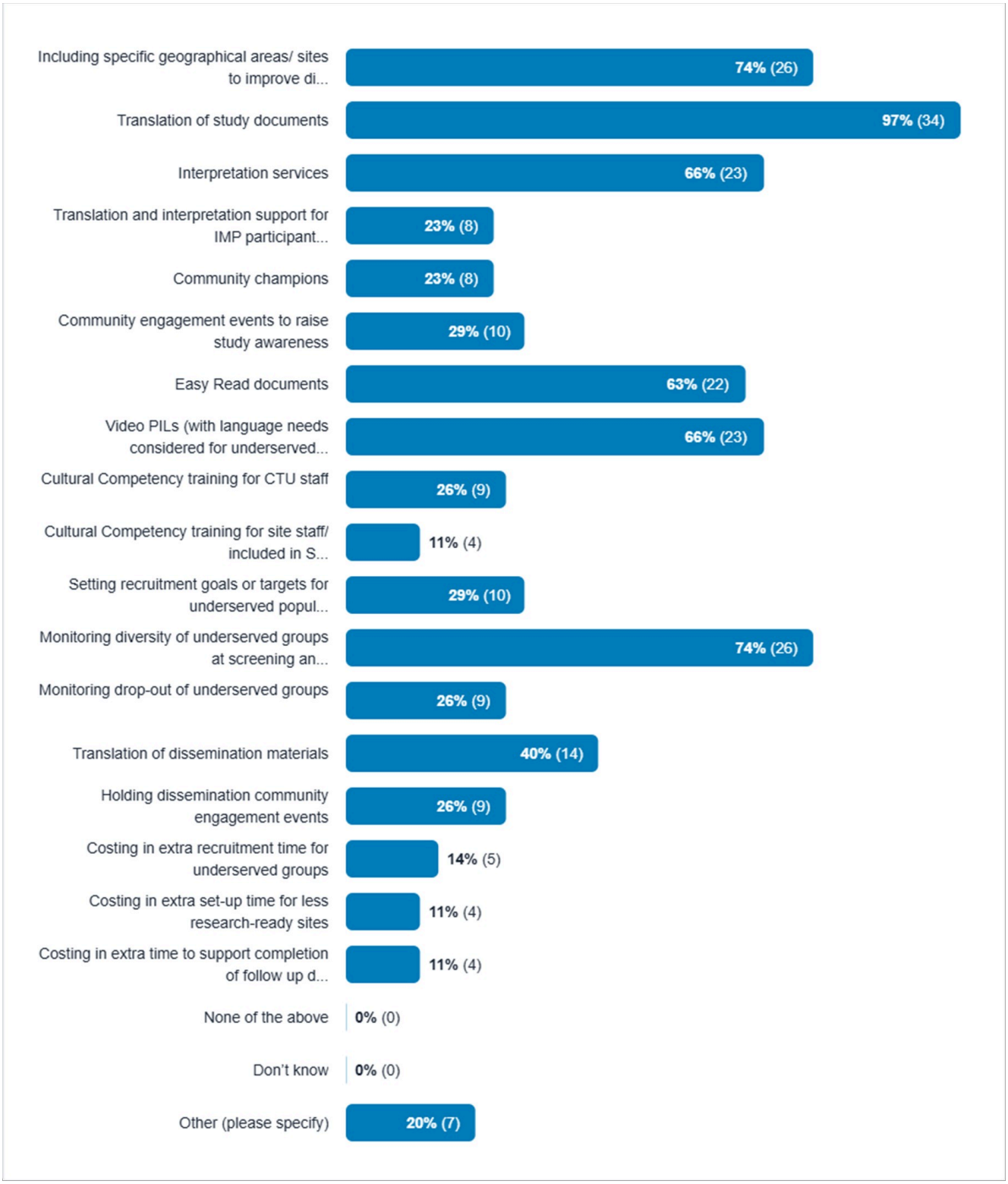


Figure 2

EDI strategies considered by CTUs. Respondents could select 'all that apply'; therefore percentages do not total 100%. Other responses included opening sites globally, holding EDI recruitment training for sites, reimbursing travel costs, promoting awareness of disabilities that limit trial participation.

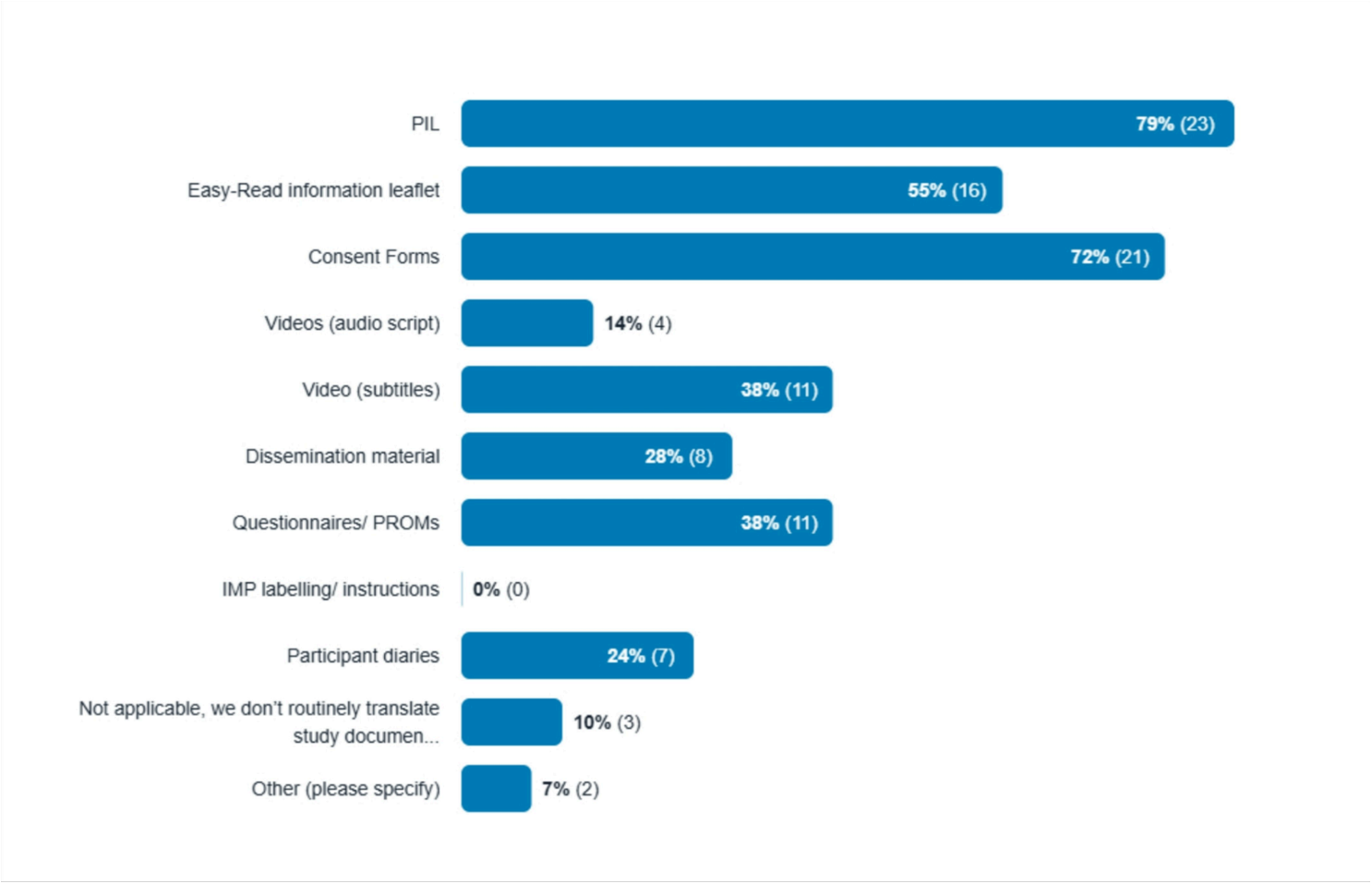


Figure 3

Documents and materials routinely translated by CTUs from 29 respondents who answered this question. Respondents could select all options that applied. Other responses included documents and materials are not routinely translated and are trial-specific, depending on population need, funder requirements, international collaboration or specific inclusivity goals.

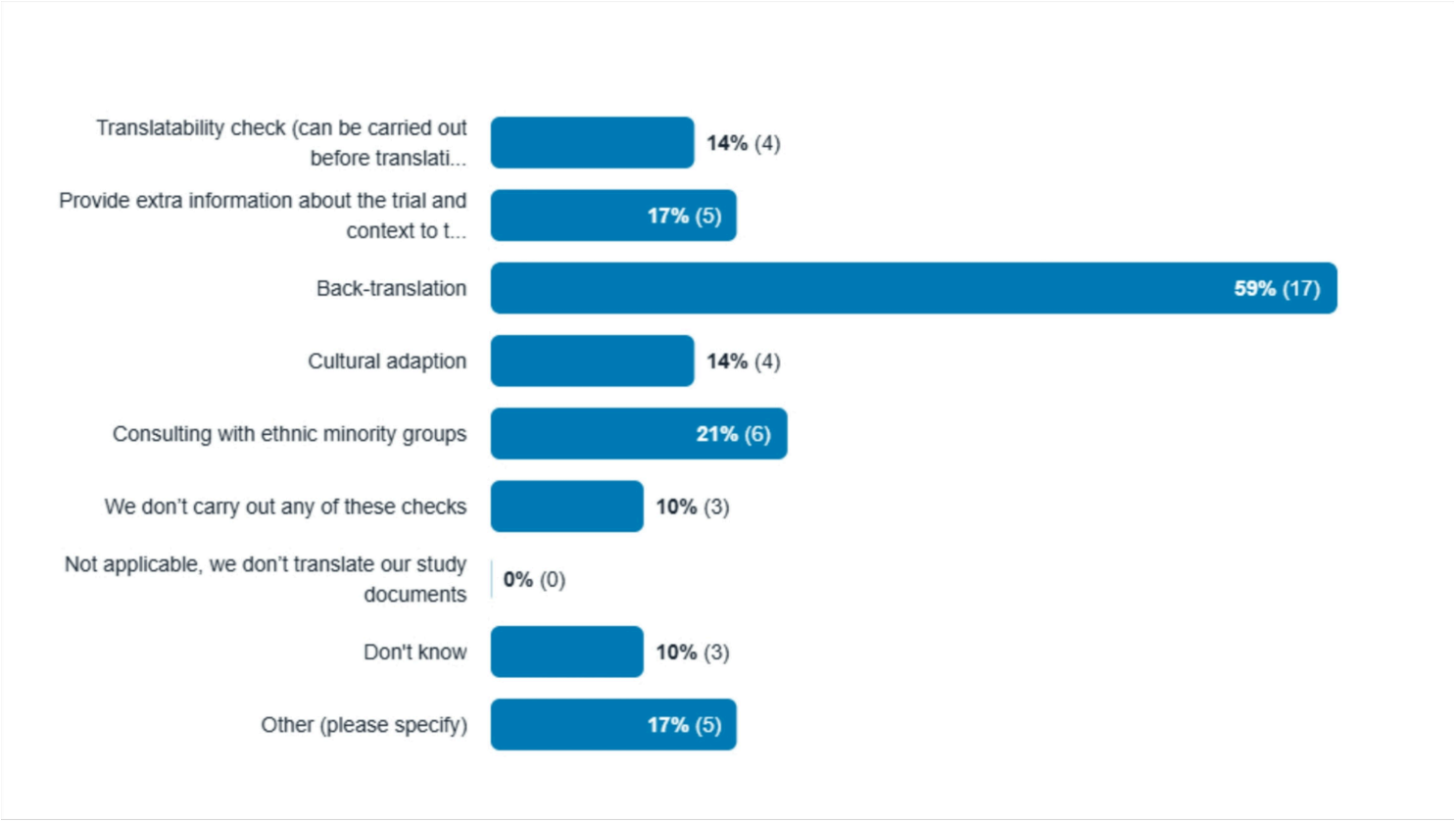


Figure 4

Validation checks carried out by CTUs when translating trial materials from 29 respondents who answered this question. Respondents could select all options that applied. Other responses included: translation companies providing 'Certificates of Translation'; only use ICO certified translators who perform back-translation as standard.

Supplementary Files

This is a list of supplementary files associated with this preprint. Click to download.

- AdditionalFile1copyINVITEsurvey.pdf