

Speaking your patients' language – Is it really worth it?

The impact of translation on multilingual patient education materials

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Abstract

This article discusses the role of translation and its impact on the success of patient education materials, particularly in the context of patient recruitment and retention for clinical trials. We examine how translation and localisation help foster trust, ensure safety, and increase efficiency, improving recruitment, retention, and regulatory compliance in trials which are becoming increasingly diverse. We also discuss inherent challenges and considerations and look into the future.

Introduction

Clear, accurate, and informative patient education materials are foundational to a well-run clinical trial. Ethically, patients need to fully understand what they are signing up for – the potential benefits, risks, and burdens. From a practical perspective, building trust with participants early on and throughout will also benefit the study as a whole. Good patient education materials improve comprehension and compliance and save time on duplicated explanations, questions, and answers, not to mention increasing the likelihood of enrolment.¹

So where does translation come into it? Well, in a global trial, language is a major consideration for communication with patients – arguably just as important as the drafting of the original materials, a phase generally given much more time, resources, and weight.



“Patients’ stories are the living testimonies of how well-translated materials transformed clinical trials into journeys of understanding, trust, and hope,” according to one patient recruitment manager.

Why so important? Try reading the first paragraph above again. If we can agree these statements are true for English-speaking participants, why would they be any less true for speakers of other languages? And how can you hope to produce clear material that helps to engage and build trust, without producing it in the participant’s native language? The results of one study evaluating this area seem categorical: 49.1% of adverse events affecting patients with limited English involved some physical harm (the corresponding figure for English speakers was

29.5%), with 52.4% of the former deemed to be the result of communication errors (compared to 35.9% for proficient English speakers).²

And this is before touching on the impact of better engagement on other tangible metrics like Return on Engagement (ROE).

“Recent return on engagement (ROE) research from Gallup reveals that brands who successfully engage their customers go on to see 63 percent lower customer attrition, 55 percent higher share of wallet, and 50 percent higher productivity,” according to Global Chief Executive Barbara Lopez Kunz, of the Drug Information Association (DIA). “Our experience and collected data point toward ROE benefits as being significant in healthcare product development as well.”³

The diversity of people taking part in clinical trials is a growing topic of discussion within the sector, particularly following examples such as that of Clopidogrel in the UK.⁴ Gone are the days (woefully recent though they are) when it was acceptable to run trials based on homogenous groups of men only.⁵ It is now generally accepted that, to effectively test the potential efficacy of a drug, participation should be reflective of real-world populations and especially include those most likely to use and/or benefit from the drug in practice. Different populations react differently to the same drug – both in terms of safety and efficacy – not to mention that equitable access is an important goal in and of itself. Although the numbers relating to diverse participation remain relatively uninspiring for now,⁶ new legislation on both sides of the pond is likely to positively impact these figures in the near term,^{7,8} meaning diversity is on the increase (hopefully rapidly). Diversity of participants begets diversity of

Communication is at the cornerstone of clinical trials.

language and communication. And language and communication barriers can have a significant impact on the recruitment process. By translating these materials, we facilitate broadening the scope of potential participants and foster a more inclusive environment.

“[Language barriers] translate into a possible decrease in trial recruiting and trial screening,” says medical oncologist Mohana Roy at Stanford University’s School of Medicine. “Communication is at the cornerstone of clinical trials.”

And so – for all the reasons above and others – a clear translation strategy, well-embedded into your larger processes (and not as an afterthought) becomes key to creating impactful patient education materials and, ultimately, running a successful clinical trial.

“Translation isn’t just about words; it’s about including bridges of understanding, opening doors to engagement, and welcoming diverse voices that strengthen the foundation of recruitment,” says Conversis CEO Craig Harrison.

Going beyond translation

Translation itself – while a step in the right direction – really only scratches the surface in terms of catering to specific audiences. To achieve meaningful impact, you will need to *localise* your materials, i.e., take into account participants’ geographic location, lived experience, cultural context, and other factors that will influence how they receive and process information. For example, think about the health literacy of your target populations: the US National Assessment of Adult Literacy (NAAL) has found that 53% of US adults have “intermediate” health literacy, with over 35% at basic or below-basic levels.¹⁰ What about general literacy? Based on a 2015 OECD survey, 1 in 6 UK adults have literacy skills below Level 1 – equivalent to an 11-year-old at most!¹¹ There is little point creating content – in the first instance *or* via translation – full of medical jargon and complex imagery, if a significant proportion of the people reading that material are left with a partial understanding at best! And it’s important to bear in mind that the chasm between literacy rates in the US and UK

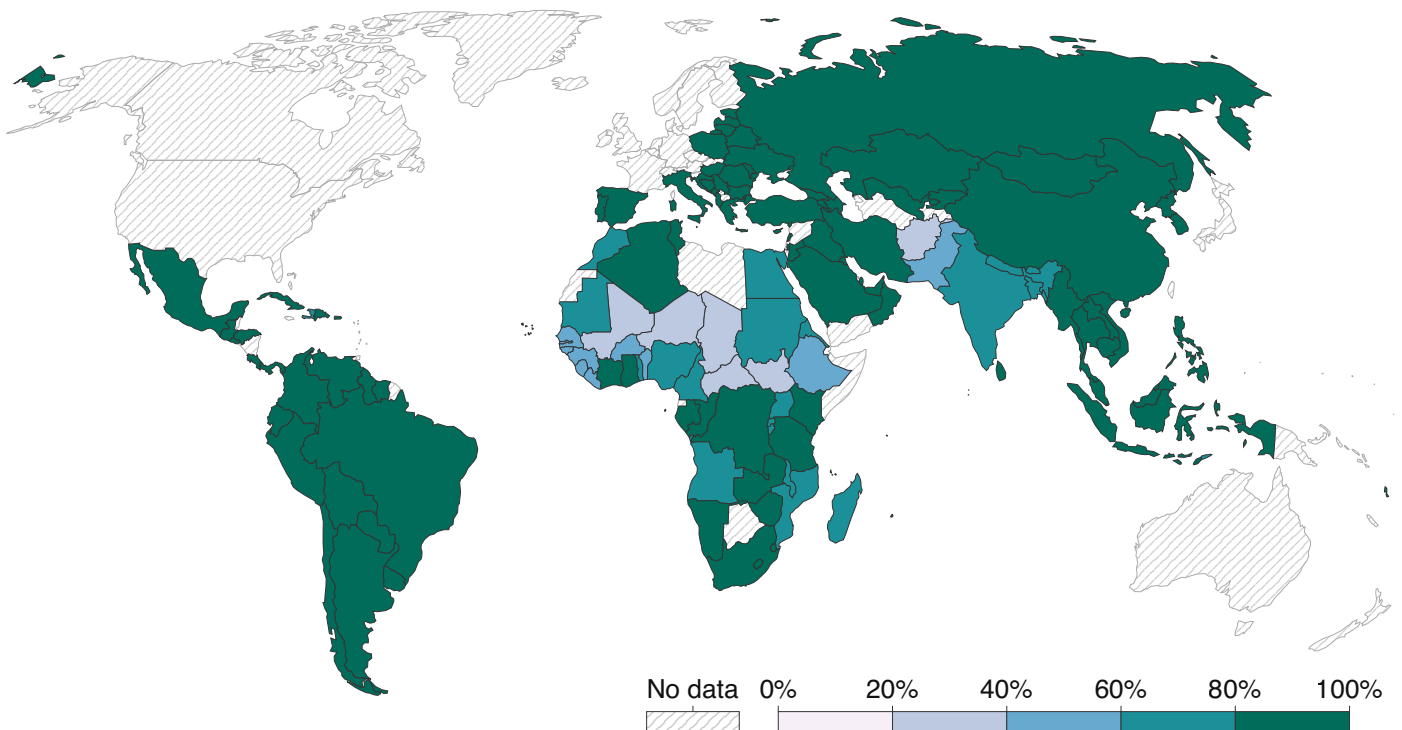


Figure 1. 2015 figures for global literacy rates among adults

The share of adults aged 15 and older who can both read and write

Data source: UNESCO Institute for Statistics via World Bank (2023) <https://uis.unesco.org/en/terms-and-conditions?wbdisable=true>

Note: UNESCO defines literacy as reading and writing brief daily life statements. However, criteria vary by country, and North American and Western European data uses more detailed assessment so isn't globally comparable.

Table 1. Forecast of population changes in the US

The non-Hispanic White population is projected to shrink by nearly 19 million people by 2060

	2016		2030		2060		Change from 2016 to 2060	
	Number	%	Number	%	Number	%	Number	%
Total population (in thousands)	323,128	100.0	355,101	100.0	404,483	100.0	81,355	25.2
One race								
White	248,503	76.9	263,453	74.2	275,014	68.0	26,511	10.7
Non-Hispanic White	197,970	61.3	197,992	55.8	179,162	44.3	-18,808	-9.5
Black or African American	43,001	13.3	49,009	13.8	60,690	15.0	17,689	41.1
American Indian and Alaska Native	4,055	1.3	4,663	1.3	5,583	1.4	1,528	37.7
Asian	18,319	5.7	24,394	6.9	36,815	9.1	18,496	101.0
Native Hawaiian and Other Pacific Islander	771	0.2	913	0.3	1,125	0.3	354	45.9
Two or more races	8,480	2.6	12,669	3.6	25,255	6.2	16,775	197.8
Hispanic	57,470	17.8	74,807	21.1	111,216	27.5	53,746	93.5
Native-born population	279,283	100.0	301,318	100.0	335,150	100.0	55,867	20.0
One race								
White	222,942	79.8	232,638	77.2	236,955	70.7	14,013	6.3
Non-Hispanic White	189,896	68.0	188,169	62.5	165,964	49.5	-23,932	-12.6
Black or African American	38,345	13.7	43,013	14.3	51,195	15.3	12,850	33.5
American Indian and Alaska Native	3,465	1.2	4,036	1.3	4,975	1.5	1,510	43.6
Asian	6,377	2.3	9,373	3.1	17,289	5.2	10,912	171.1
Native Hawaiian and Other Pacific Islander	576	0.2	686	0.2	866	0.3	290	50.3
Two or more races	7,578	2.7	11,572	3.8	23,869	7.1	16,291	215.0
Hispanic	37,819	13.5	51,466	17.1	83,971	25.1	46,152	122.0
Foreign-born population	43,845	100.0	53,783	100.0	69,333	100.0	25,488	58.1
One race								
White	25,560	58.3	30,815	57.3	38,059	54.9	12,499	49.9
Non-Hispanic White	8,073	18.4	9,823	18.3	13,198	19.0	5,125	63.5
Black or African American	4,656	10.6	5,996	11.1	9,494	13.7	4,838	103.9
American Indian and Alaska Native	590	1.3	627	1.2	609	0.9	19	3.2
Asian	11,942	27.2	15,021	27.9	19,525	28.2	7,583	63.5
Native Hawaiian and Other Pacific Islander	195	0.4	227	0.4	259	0.4	64	32.8
Two or more races	902	2.1	1,097	2.0	1,386	2.0	484	53.7
Hispanic	19,652	44.8	23,341	43.4	27,242	39.3	7,594	38.6

Note: The official population estimates for the United States are shown for 2016; the projection uses the Vintage 2016, population estimate for July 1, 2016 as the base population for projecting from 2017 to 2060. Percentages will not add to 100 because Hispanics may be any race.

Source: U.S. Census Bureau. 2017 National Population Projections.

versus countries predominantly speaking other languages can be vast! These are by no means among the worst-case scenarios!¹²

Another thing to consider may be the historical context of clinical research within a community: for instance, the shameful example of the Tuskegee Syphilis Experiment.¹³ Such examples might go some way to explaining the continuing reluctance of certain communities to

participate in clinical trials at all! The importance of this kind of context is why we always recommend translation and localisation is completed by an expert from within the relevant community – for instance, content for the Mexican diaspora in the US should be translated by a Mexican Spanish native speaker living in the US. These experts can advise meaningfully on tone, cultural context and appropriateness,

localise accordingly and avoid specific pitfalls, to ensure content has maximum appeal and effect.

Beyond initial recruitment, quality translation can also be a major factor in retention, curbing dropout rates by keeping patients engaged and well-informed throughout the study. The generally accepted statistic is that 30% of patients recruited to a clinical trial drop out,¹⁴ with about 40% of those dropouts being avoidable. It also



costs nearly 3 times as much to replace a dropout as it does to recruit an individual in the first place.¹⁵ In one survey, 35% of dropouts cited difficulty in understanding as their primary reason for leaving a trial, while some of the main motivations for continuing participation were that expectations had been set clearly and importance explained.¹⁶ It seems obvious here that clear communication from the start and throughout is among the simplest and best ways to recruit and, crucially, *retain* participants (with everything that implies diversity, language, and translation).

From a more prosaic perspective – though no less important in terms of overall success, as some will know to their detriment – translation can facilitate

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compliance with the international regulations that apply to patient education materials. Take, for instance, the COVID-19 vaccine trials. For just one of the many COVID-19 trials Conversis worked on, we translated English into six South African languages and four Philippines dialects! The sheer scale of the pandemic necessitated wide-ranging expertise in international regulation. Deadlines for various national and transnational bodies had to be met; there was certainly no time to spare for rejected submissions! Translation serves as the compass guiding patient education materials through the complex terrain of international regulations, ensuring that compliance paves the way to safer and more inclusive clinical trials.

Where the challenges lie

So far, the positive impact of translation on multilingual patient education materials seems obvious. But the translation of medical content is not without its challenges. Here follow just a handful of the very many, varied challenges we have encountered over the last 20 years.

- Handling highly specific terminology is tricky on many levels. Some especially tricky instances include: where the terminology just does not exist in a given language, as a certain condition has never been discussed in that community before (happens more often than you might think); or translating said terminology for a layperson or patient, and having to bear in mind both technical accuracy and basic understandability.
- Guaranteeing accuracy – This is difficult to do wherever humans are involved, and even more essential *because* humans are involved! We have quality management systems, independently audited processes, key



keep abreast of local changes, new regulations, and shifting demands for specific language pairs within specialities. It will mean making sure we have the people we need, with the experience, expertise, and context to hit the ground running as soon as we feel the next shift coming.

The greatest tool available to the life sciences sector as we move into this changing future will be collaboration! We're hearing it again and again from clients and at conferences. The sector as a whole needs to collaborate more and better. We need to streamline the systems of approval and work more smoothly cross-functionally. This is as true of language and translation as it is of any clinical trial function. Collaborative efforts between medical professionals, healthcare providers, language experts and patient advocates are crucial to the success of us all and to our

performance indicators, a dedicated QA function, and work with experts only.

- Adhering to varying in-country regulations – This is particularly tricky when translating for the 27 countries of the EU. We handle this in a variety of ways, including the creation of country-specific source texts – for example, removing all mention of reimbursement for South Africa or any language which may be seen to actively encourage people to take part in a clinical trial in Turkey.
- Tight timelines – We all know how it goes. Source content is tweaked, refined, updated, and amended right up to – and beyond – the timeline in which in-country recruitment is due to start. Then translation is commissioned, when already late, and the recruitment window grows smaller and smaller until said country is abandoned as no longer viable. We work with our clients to incorporate translation into all their workflows, so it becomes a part of the process, rather than an add-on. This means timelines are anticipated up-front, and those mad dashes at the end are – more often than not – avoided.
- File and submission conventions – The format requirements of ethics committees and various authorities can be tedious and labour-intensive. Think footer formats, file

naming requirements, and bookmarking. We have created custom tools to automate these manual processes – saving billable time and avoiding the human error that can be caused by rote work of this type.

Clearly, challenges exist. But we've seen above the far greater value of the end goal, and that none of these obstacles are insurmountable – with experience and the will to innovate. If it were easy, everyone would be doing it. If it were of less value, far fewer of us would bother!

Future outlook

We've illustrated some of the difficulties we have faced and found solutions for in the past. But what about the challenges of the future? What is the outlook going forward for medical translation in patient education?

AI and machine translation will almost certainly improve and become a more viable option for facilitating medical translation. And Conversis, and others like us, will continue to develop tools to solve recurring problems. But most important will be the shifting demographics of patient populations, influenced by globalisation, decentralised trials, changes to regulation, and gradual population change.¹⁷ For us, this will mostly mean an increasing need to

collective role in crafting multilingual patient education materials.

One thing that is not likely to change anytime soon is the importance of producing targeted, multilingual patient education materials that work. As we've seen, these materials, when done well, can improve recruitment and retention rates, boost comprehension, keep people safe, and lead to greater engagement throughout the clinical trial lifecycle. There are many challenges to getting it right; challenges which are likely to grow more complex and varied as we move into a future of constant change. And so, we must strive for perpetual improvement and expansion of our offerings and solutions in the space; we must continue innovating and embracing these challenges head-on. The benefits so heavily outweigh the difficulties, there is no question – certainly in our minds – as to whether that effort is worthwhile.

Disclosures and conflicts of interest

The authors declare no conflicts of interest.

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