SUMMER 2020

Caduceus

Publication of the Medical Division of the American Translators Association

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The Stuck Inside Issue!

Contributors:

Editor's Note

By Maria Baker

Dear readers,

It's lovely to meet you again in this, our virtual space to learn and connect.

The latest exciting news is that the ATA conference, the academic event of the year, will be held in a fully virtual format this year (including a presentation by yours truly). I know we all long for personal contact, networking, and a reception with an open bar. However, this is an exciting opportunity to show the industry that we can overcome adversity and meet these new challenges with great success. We certainly hope to "see" our division members and friends there!

The Medical Division continues to work to bring you interesting content and to meet your needs through our social media, our mailing list, and of course, *Caduceus*.

For this issue, we are bringing you an article by Romina Marazzato Sparano on lay summaries of clinical trials, a field of opportunities for translators and medical writers alike. Romina goes into detail about what a lay summary is and what it should look like. This is great piece to get us started in this area!

Linda Pollack-Johnson, in turn, addresses a situation many of us have found ourselves in: the family member or friend that insists on being the interpreter. Her candid approach yields many insights and useful advice for medical interpreters.

I hope you enjoy this issue as much as we continue to enjoy putting it together for you. If you have ideas or articles you would like to see in *Caduceus*, email them to santi@achinelli.com and we'll work with you to get them published.

Have a safe and happy summer!

María

Maria Baker is a language instructor, medical interpreter, and translator. She obtained her B.A. in TESOL in Santa Fe, Argentina, and her M.A in Spanish and TESOL from West Virginia University. She is currently a freelance medical interpreter and translator, Outreach Coordinator for the IMIA, Vice President of the Interpreters and Translators Association of Alabama, and a volunteer in the ATA's Medical Division.

Letter from the Division Administrator

By Yasha Saebi

Dear Medical Division members,
Summer is here, and definitely a different summer than previous ones. As we are still dealing with COVID-19, other issues that need our serious attention have been raised. The 2020 summer is certainly not our typical summer. Meanwhile, the medical interpreters and translators are working at the frontlines of the pandemic battle alongside medical providers. I couldn't be prouder of my colleagues; they have a crucial role in the current pandemic battle. I hear many stories from medical interpreters that helped Coronavirus victims to say their good-byes to their loved ones. God bless all medical interpreters and translators that are offering their service at the high-risk field with the least protection.

Here is the latest from Medical Division Leadership Council:

- -The Medical Division distinguished speaker, Dr. Claudia I. Salazar with a topic in psychology field that is very popular among Medical translators and interpreters, was approved by the ATA conference organizer.
- -Soon you will receive a questionnaire via email designed by the MD LC team to explore your needs in your translating career and to discover ways that your division can help you.
- -Please join MD Facebook page or follow us on Twitter to take part in choosing the MD webinar topic (coming soon).
- -Currently, there are several open positions in MD LC. Please email us at divisionMD@atanet.org and tell us about your expertise. We can use your help. I encourage you to email us if you are familiar with layouts in the publishing industry or if you'd like to help us to monitor and maintain our social media accounts. Look out for our "call for volunteers" emails coming soon. You will find the division volunteering work very rewarding, as you will be beneficial to your colleagues.

In closing, I'd like to wish you all a very safe summer and once again thanks for being part of our division.

Yasha Saebi

Yasha Saebi is a linguist with a B.A. in Translation from Tehran, Iran. Her B.S. in Biology/Genetics and M.A. in Forensic Science/DNA are from George Mason University. She is certified by the Certification Commission for Healthcare Interpreters CCHI and Georgetown University. Currently, she is the head of ATA's Medical Division.

When a Friend Comes Along

By Linda Pollack-Johnson

I love my job as a freelance medical interpreter for Italian speaking patients. Though it is now established as a common practice to have a medical interpreter at a doctor's appointment for a patient who does not speak English fluently, I occasionally still get some surprised looks and some pushback during those initial moments in the waiting room. I used to get flustered when family members waved me off saying they preferred to interpret for "Mom" themselves. Now, I have developed strategies and phrases that I can use to defuse the tension in the room.

First of all, I have found that if I err on the side of extreme kindness, "killing them with kindness" as it were, I can usually open their hearts enough to accept my words of reassurance. It seems that many family members are offended by the presence of an interpreter, as if it implies that they are not capable of helping (after all the years that they have been obliged to help in other settings). So, I usually start by showing empathy, acknowledging that they must have taken a day off from work and sympathetically bonding over any weather, traffic, or parking challenges we all experienced on the way to the appointment. I ask if this is the first time they have had an interpreter at an appointment, and if possible, I move on to the pre-session points about confidentiality, using the first person when speaking, interpreting everything that is said, et cetera.

If the patient is hard of hearing, I will move my body so that I am as close as possible to them, projecting my voice more, making eye contact and kneeling low (if necessary) so that I am showing the other family member(s) that I am capable of interacting directly and respectfully with their loved one.

If they ask me, "Who arranged for you to come?" I claim total ignorance (which is true) and simply respond with "Every patient has the right to have a certified medical interpreter at their appointment." I explain that I work for an interpretation agency, I show my badge, and I assure them that they do not have to pay anything for the service.

By this point, I'll usually have gained some acceptance and I point out to the family that they are (usually) welcome to be present and talk to the provider as I facilitate their role as a care advocate. They can focus on their questions and concerns rather than having the added responsibility of interpreting for "Mom".

If they continue to object and attempt to dismiss me, I politely clarify that the provider needs to weigh in on the decision. I offer to notify the provider (via the front desk staff) that the patient may decline my services. It has rarely happened that the provider agrees to dismiss me. Usually, there had been a "red flag" in some previous communication that sparked the request for an interpreter in the first place. Moreover, the provider does not want to risk allowing more communication gaps when there is an interpreter already on-site (who is getting paid anyway!).

I had a recent incident which is worth mentioning at this point. For reasons of confidentiality I will refer to the patient (P for patient) as "Patrizia" and her friend (F for friend) as "Franca". I arrived early to the clinic and was sitting in the waiting room when Patrizia and Franca arrived. I introduced myself to Patrizia and Franca immediately interrupted with hostility. She pushed back against all of my friendly attempts to establish some rapport. I'm sure you have heard the expression, "if looks could kill… I would be dead". That was the vibe I was getting from Franca. She insisted that she, and she alone, was the best person to interpret for Patrizia. Patrizia was quiet during this part of the conversation. An important observation, however, was that Patrizia did not chime in to back up Franca's statements.

The front desk staff witnessed the conversation and could probably sense the tension even though we were speaking Italian. I summarized the problem and asked that they alert the doctor. I was hoping that I could talk to the doctor before we got ushered to the examination room, but unfortunately, we were called to Room 2 to wait for the doctor together.

During that time, Franca questioned my qualifications, asking me if I had gone to medical school. Franca boasted that she had attended medical school. Evidently, she did not become a doctor because of some mishap at that point in her life. I expressed sympathy for that disappointment and started to briefly describe our certification process. She seemed receptive to hearing more about the training and I saw that if I could encourage her to become a medical interpreter, I may have found the chink in her armor. Franca started to ask me about the pay scale when the doctor walked in the room. Phew!

It was a freaky coincidence, but as it turns out I *knew* the doctor personally through my children. After explaining this to the patient, the doctor spent the first few minutes of the session asking for updates on my kids and giving me updates on his. I'm pretty

sure Franca was not pleased about this. Once the pleasantries were over, it never came up that I, as the interpreter, would be dismissed. We just launched into the session.

The doctor asked some medical history questions to Patrizia and I interpreted. Franca kept interrupting to add information in English. Franca voiced concerns about the need for general anesthesia during the procedure that was being considered. I rendered Franca's concerns into Italian so that Patrizia would know what was being said and at one point the doctor put up his hand toward Franca and indicated that he wanted to hear Patrizia's opinion and concerns about the procedure. I guess Franca felt she was put in her place at that point because she withdrew more from the conversation, allowing Patrizia to speak for herself and allowing me to do my job more smoothly. When we ended the session, I think everyone felt a bit better than when we walked in.

Several months later, I had another assignment with Patrizia for a different provider (a different medical issue). Patrizia was alone this time and to be honest I had completely forgotten about the interaction with her friend Franca. But during our initial time together in the waiting room, Patrizia vented with me about her friend. She said that Franca had been *way* too pushy with me, too invasive into Patrizia's medical care, and rather obnoxious toward the doctor about her own medical training. Patrizia said that after that experience, she has not let Franca accompany her for any subsequent medical visits. Patrizia apologized for the way that Franca had treated me. Patrizia was relieved to see that I was her interpreter again and looks forward to having me at future sessions.

Getting that feedback from the patient was so validating of the work that we do that I wanted to share it with you, my fellow medical interpreters. By upholding the role of the interpreter, even to friends and family that mean well, we do our part to make sure that every patient, regardless of national origin, gets the healthcare they deserve. We do make a difference!

Linda Pollack-Johnson is a freelance translator and interpreter working out of her home in Philadelphia, Pennsylvania. She is a member of the American Translators Association, the Italian Language Division, the ATA Medical Division, the International Medical Interpreters Association, and the Delaware Valley Translators Association.

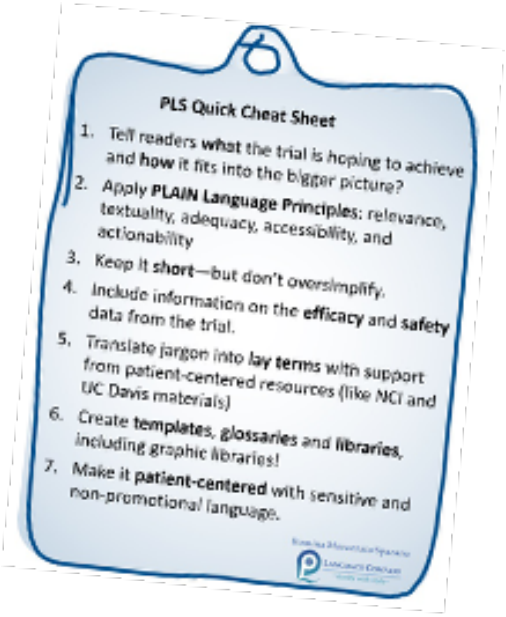
Plain Language Lay Summaries of Clinical Trials: A New Opportunity for Medical Translators

By Romina Marazzato Sparano, CT

A clinical trial is a scientific study designed to evaluate the efficacy and safety of interventions to prevent, detect, or treat, a disease. It is also called an interventional clinical study because interventions like drugs, treatments, or devices are tried on human volunteers.

The interest and need for relatable information about clinical trials is growing, particularly with the advent of the COVID-19 pandemic. To promote much needed transparency, and engagement, as shown in several polls, regulations now foster the creation of lay summaries.

The European Union passed, in 2014, the Clinical Trials Regulation EU CTR 536/2014 requiring the publication of lay summaries no later than 1 year after trial completion. The summaries must be available in the language of each country where the trial took place. Although full implementation of this regulation is awaiting the launching of a digital portal (now projected for 2021), many sponsors are already making lay summaries available.



In the US, no such regulation exists—yet. But, in 2017, the FDA issued a draft Guidance Document on the provision of lay summaries. While not binding, this document, together with the Plain Writing Act of 2010—requiring federal agencies to share information in a language the public can understand and use, has led US sponsors to voluntarily provide lay summaries.

What are Lay Summaries of Clinical Trials?

Lay summaries are descriptions of clinical trials in non-technical language to share the findings of the trial with study participants, families, caretakers, and the public. In easy-to-understand language, lay summaries explain why the research was done, what researchers found, and how it changes the way a condition is treated.

They are called *lay* rather than *plain* summaries, because plain language is needed for clarity in both technical and lay communication. Actually, when creating a lay summary, you might need to take a step-wise approach, by first streamlining the technical summary, and

Required Element	Lay-friendly Heading
1. Clinical trial identification (including title of the trial, protocol number, EU trial number, and other identifiers)	Study information
2. Name and contact details of the sponsor	Where can I learn more about this study?
3. General information about the clinical trial (including where and when the trial was conducted, the main objectives of the trial, and an explanation of the reasons for conducting the trial)	Why was the research needed? What were the main questions studied?
4. Population of subjects (number of subjects included in the trial in the Member State concerned, in the Union, and in third countries; age group and gender breakdown; inclusion and exclusion criteria)	Who participated in the study?
5. Investigational medicinal products used	What treatments did the participants take?
6. Description of adverse reactions and their frequency	What medical problems did the participants have?
7. Overall results of the clinical trial	What happened during the study? What were the results of the study?
8. Comments on the outcome of the clinical trial	How has this study helped patients and researchers?
9. Indication if follow-up clinical trials are foreseen	Within the "How has this study helped patients and researchers?" section
10. Indication where additional information could be found	Where can I learn more about this study?

Table 1.

then adapting it for people without prior knowledge about the subject. You can read more about this topic here.

All of this opens great new opportunities for medical writers and translators!

Lay summaries are becoming part of a larger drive for patient-centered communication with patient information sheets, informed consent forms, etc. now written using plain lay language.

Lay summaries typically include 10 key elements listed in Annex V of the EU regulation (see table 1)

Although guidance about the writing of lay summaries is not robust yet, the European Expert Group Recommendation Document and the latest version of the Multi-Regional Clinical Trials (MRCT) Center Return of Results Toolkit in the US address a variety of issues to consider when creating a plain language lay summary.

What do lay summary writers and translators need to know?

Lay summary writers and translators need to have solid writing skills and a sound understanding of the science underpinning the trials to explain and distill information, including some statistical knowledge to interpret data and create visualizations. Also, lay summaries writers and translators need experience, affinity, and training in communicating with non-scientists. And, in the age of social media, this also includes the ability to present information creatively yet factually, and in different platforms.

In addition, as part of the communication team who creates the various deliverables related to clinical trials—spanning from peer-reviewed articles and Clinical Study Reports (CSRs) to lay summary and press releases (PRs)—lay summary writers and translators need to become comfortable communicating with the team. By the way, you can find an ever expanding list of clinical trial acronyms here.

Writers and translators must adhere to the 5 principles of plain language:

1.Relevance: Select only pertinent information for the non-technical audience. This requires great ability to reduce complexity and understand what information will be useful to patients and caregivers. This will most often require you to answer why the research was needed, how it fits into the bigger picture, what interventions the participants received to what effect, and what the side effects were.

2.Textuality: Draft text concisely, applying grammar, cohesion, and coherence. This is at the core of any clear writing, whether for lay or technical audiences. The challenge for lay summaries is to maintain the coherence in the information flow and connections between ideas while avoiding details that would overwhelm the lay reader.

3.Adequacy: Adapt style, terminology, and design. For lay adaption, it is often useful to develop templates, glossaries, and concept and graphic libraries within a therapeutic area. As we will see, the same lay translation of a technical term may not survive across therapeutic areas. In adapting terminology, it is useful to consult patient-facing publications from reputable sources like the National Cancer Institute and the UC Davis Institutional Review Board Administration.

4.Accessibility: Develop and implement structure and design that strengthens the communication. For this, writers must be able to create or help create visuals that convey a clear message to lay audiences. It is often essential to be able to distill complex statistical information into a succinct visualization and to develop easily trackable yet visual layouts. Also, especially for uploaded information, it is important to follow Web Content Accessibility Guidelines for people with disabilities, which help with voluntary compliance with Section 508 of the Rehabilitation Act of 1973 (which technically only applies to federal agencies.)

5.Actionability: The usability of a lay summary is a key aspect that informs the planning of the lay communication and also requires testing through feedback from different stakeholders. Informally, you can request feedback from a non-medical colleague and you can use readability formulas if you prep your text properly and ensure coherence, create, maintain and apply glossaries and style guides. Lay summaries also go through a formal review process, that includes an independent lay

review panel, patient review (or user testing), and the sponsor review.

Of course, these skills require practice and collaboration.

What are the biggest challenges in a lay language summary?

The biggest challenge is to strike a **balance** between being accurate and complete, on one side, and brief and non-technical, on the other. Technical language is full of terms that have been carefully crafted to reflect granular layers of meaning to an expert, and there is no real shorthand way to explain them; often only an extended explanation will begin to express the nuances hiding in a technical term.

Terminologist Sue Ellen Wright states (in a personal communication) that "[i]n addition, if the difficult term is never referenced, in today's knowledge-based environment, people who do want to inform themselves of more detail can't find valuable resources because they have been locked out of the key words that might be their link to valuable information." *

Let's look at results of a trial reported in a journal article:

"*In the primary end-point analysis, the adjusted annual rate of change in FVC was -52.4 ml per year in the nintedanib group and -93.3 ml per year in the placebo group (difference, 41.0 ml per year; 95% confidence interval [CI], 2.9 to 79.0; P=0.04).*"

You can see from this data, illustrated in Figure 1, that the decline in forced vital capacity between nintedanib and placebo patients is 41 mL, which amounts to 44% of the biggest decline of 93 mL.

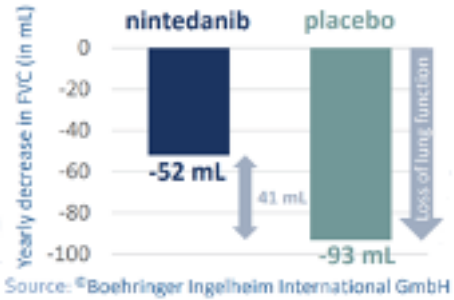


Figure 1.

Now, the same information reported in a press release:

"Results show that nintedanib slows the loss of pulmonary function in patients with SSc-ILD compared to placebo. Patients taking nintedanib showed 44% reduction in the rate of decline of their lung function, measured in FTC assessed over 52 weeks."

**SSc-ILD: Systemic sclerosis associated interstitial lung disease, FVC: Forced Vital Capacity*

And, finally, the information reported in the plain language lay summary:

"On average, after 1 year of treatment, nintedanib slowed down loss of 44%"

So, be choosy on the details you include so that important information doesn't get lost in minutiae for the lay reader.

Another example I like from Kasim McLain, Michelle Reed, and Jennifer Pilgrim (at the American Medical Writers Association) addresses the process of adapting terminology. The writers originally "translated" *subcutaneous* as "under the skin" but later had to revise the rendition to accommodate the term *intradermal* as follows:

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Original Technical to Lay Translation

Technical Term	Original Lay Term
Intravenous (IV)	given through a needle into a vein
Intramuscular (IM)	injection (or shot) into the muscle
Subcutaneous (SC)	injection under the skin

Updated Technical to Lay Translation

Technical Term	New Lay Term
Intravenous (IV)	given through a needle into a vein
Intramuscular (IM)	injection (or shot) into the muscle
Subcutaneous (SC)	injection into the fat under the skin
Intradermal (ID)	injection just under the skin

A second challenge is the use of **sensitive language**. Researchers, imbued in their work, use the most direct way to reference information. But, in lay summaries, nuance becomes important, particularly when referencing life and death outcomes. Remember that you are ultimately writing for survivors of a condition and their families, friends, and caregivers, or those of non-survivors. So, you may, for instance, report survival rather than deaths.

A third challenge is that lay summaries are to be **non-promotional** in nature. They should make no claims of superiority or efficacy. While it may seem easy to avoid promotional language or a commercial design in a marketing sense,

☒ 25% of patients died before the end of the trial.
↳ ☑ 25% of patients passed away before the end of the trial.
↳ ☑ 75% of patients lived beyond the trial.

writers and translators need to be cautious about subtleties. For example, you should list and explain adverse reactions rather than make comparative statement with placebos or other interventions.

☒ This study proved that using Drug X to prevent <condition> is effective.
↳ ☑ This study found that people with <condition> who got <Drug X> had <primary endpoint*>.

☒ <Drug X> is better tolerated than <Drug Y>.
↳ ☑ In this study, fewer people who got <Drug X> had <list of specific adverse events> than people who got Drug Y.

**an outcome that represents direct clinical benefit, such as survival, decreased pain, or the absence of disease.*

Lastly, lay summaries, as any translation project, require **education of stakeholders**. At the sponsor review stage, for instance, reviewers may forget that the summary is for non-specialists and suggest deletion of adverse events descriptions, because they know them inside out. Or, reviewers may focus only on their area of concern, with feedback from doctors even contradicting feedback from lawyers in the team. For translations, many sponsors rely on back translation to assess the validity of the lay summary, so education here is particularly important.

Overall, lay summaries provide an opportunity for translators to be involved in creating greater awareness and transparency in a process that aims to make the world a healthier place with the development of safer, more effective drugs, treatments, and devices.

Romina Marazzato Sparano, CT is a translator, editor, and educator with 20 years of experience working with technical, medical, and creative materials for a variety of organizations, including Fortune 500 companies.

Got any cool leads for cool article ideas? Send them to our Copy Editor, Santiago Achinelli at santi@achinelli.com