COGNITIEF

Designing and evaluating instructional materials

Instructional materials are a means for users to learn how to use a device. UL-Wiklund provides practical tips and tricks on designing and evaluating instructional materials that help users to learn how to use a device properly and that prevent users from experiencing any difficulties or committing any mistakes while interacting with a device and its instructional materials. While developing instructional materials it is important to take an iterative approach; moving back and forth between designing and evaluating the instructional materials. This approach will help to ensure that the instructional materials best meet users' needs and wishes.

Frauke Schuurkamp en Linda Giesselink

When people start using a new device they will first need to learn how to use the device. There are several ways for users to learn how to use a device. For example, they could use a trial-and-error method, receive training, or read instructional materials. This article focusses on the latter and specifically provides tips and tricks on how to design and evaluate instructional materials and includes references to applicable standards and guidance documents. UL-Wiklund gathered tips and tricks over the past decade by providing medical device manufacturers and pharmaceutical companies with HFE support and studying applicable standards and guidance documents. Notably, the tips and tricks focus on developing instructional materials for medical devices. However, most tips and tricks can be applied to designing and evaluating instructional materials for other type of products as well.

Designing instructional materials

When designing instructional materials for existing or newly developed devices, we use the following specific step-by-step plan:

1. determine the purpose of the instructional materials;
2. define requirements for the instructional materials;
3. define the content of the instructional materials;
4. format the instructional materials;
5. tailor the language of the information to the intended users
6. design graphics to clarify step-by-step instructions;

Determine the purpose

When designing instructional materials, you want to start off by determining the instructional materials' purpose; What do you want to achieve? What do you want readers to learn/do? Example purposes are: 'Having users use the product and instructional materials in a safe and satisfying manner' or 'Explaining users how to use the product in a safe and satisfying manner.'

Define requirements

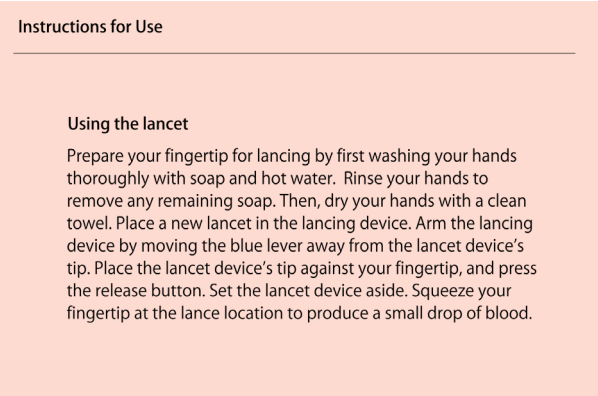
A next step would be to determine with which requirements the instructional materials should comply. The requirements for instructional materials are often determined by doing user research.

By doing user research, user characteristics (e.g., age, education, experience) and use environments (e.g., home, emergency room) are mapped. Furthermore, user research helps to identify the needs and wishes of intended users that also serve as an input to the design process.

Examples of user research are:

- *Observations*: Go to the actual use environment and observe how users behave in the environment, which steps they take, and how they interact with devices. Observing intended users in the intended use environment also enables you to investigate other factors (e.g., sounds, lighting, space, other people/devices) that might influence users' interaction with a device and instructional materials.

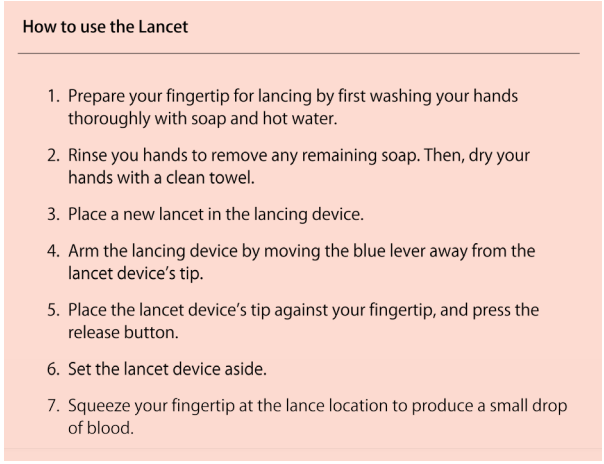
- *Interviews*: Invite intended users for an interview to learn more about their needs and wishes. The interviewer will ask the interviewee questions to understand what information users require and expect to find in instructional materials.


Instructions for Use

Using the lancet

Prepare your fingertip for lancing by first washing your hands thoroughly with soap and hot water. Rinse your hands to remove any remaining soap. Then, dry your hands with a clean towel. Place a new lancet in the lancing device. Arm the lancing device by moving the blue lever away from the lancet device's tip. Place the lancet device's tip against your fingertip, and press the release button. Set the lancet device aside. Squeeze your fingertip at the lance location to produce a small drop of blood.

Figure 1. Determining important information and instructional steps. © 2017, Jonathan Kendler, UL-Wiklund.


How to use the Lancet

1. Prepare your fingertip for lancing by first washing your hands thoroughly with soap and hot water.
2. Rinse you hands to remove any remaining soap. Then, dry your hands with a clean towel.
3. Place a new lancet in the lancing device.
4. Arm the lancing device by moving the blue lever away from the lancet device's tip.
5. Place the lancet device's tip against your fingertip, and press the release button.
6. Set the lancet device aside.
7. Squeeze your fingertip at the lance location to produce a small drop of blood.

Figure 2. Including step-by-step instructional steps. © 2017, Jonathan Kendler, UL-Wiklund.

Notably, observations and interviews can be combined; users are first observed and then interviewed to understand their behavior better.

After identifying users' needs and wishes, you will translate these into requirements that are used as an input to the design process. Examples of requirements for instructional materials resulting from user research are:

- The instructional materials should provide instructions on how to set up a device, how to use the device, and how to break down, store, and clean the device.
- Each instructional step should be accompanied by a graphic.
- The font should be sans-serif, in accordance with HE75 – Section 21.4.6.2: Text style.

After identifying these requirements for the instructional materials, the design process will start. Notably, while designing instructional materials, it might be beneficial or even necessary to do additional user research to specify users' needs and wishes, and requirements of aspects that were not investigated before.

Define the content

By doing user research, you define requirements for the content that needs to be included in instructional materials. To further refine an instructional document's content you have to ask yourself the question: What information do people need for using a product in a safe and satisfying manner? This seems obvious, but we have seen many instructional materials in which the designer assumed that the reader already has some basic knowledge about the device, and therefore did not include all necessary information. For some users this might be okay, but other users, for example elderly or adolescent patients, this can result in harmful errors. For example, assuming that users know they should use a new needle for each injection and, therefore, not including an instruction to discard the needle after use, might result in users reusing the needle for multiple injections.

For many instructions you want to start off by providing an introduction to explain the purpose of the device and provide an overview of the device's components.
The main part of instructional materials is usually the section with instructional steps (i.e., step-by-step instructions) that users are expected to perform when using the device (see Figure 1). Examples of instructional steps are: 'Press the on/off button to switch on the device,' 'Use the arrow keys to increase or decrease the dose,' or 'Use soapy water to clean the control panel.'
Finally, instructional materials must contain safety information (i.e., danger, warning, and/or caution messages) to make readers aware of any risks associated with using the medical device and to provide them with warnings and cautions to reduce the likelihood of these risks happening. The risks associated with using the medical device are identified through use-related risk analysis. Refer to FDA's guidance document on Medical Device Patient Labeling, 2001[1] for guidelines for instructional materials for medical devices.

Format the instructional materials

Once you have identified the content of your instructional materials, you can start to structure the information to provide users with a clear overview of all information and instructional steps.

1 Guidance on Medical Device Patient Labeling, FDA guidance published April 19, 2001

Depending on the amount of information, consider breaking down the instructional steps in sections, subsections, steps, and sub steps to provide readers with a clear overview of the expected actions without making it overwhelming. For example, include separate sections for setting up a device (i.e., preparation), using the device (i.e., usage), and breaking down, storing, and cleaning the device (i.e., storage and cleaning). Consequently, break down the sections into

separate step-by-step instructional steps in a way that each step provides readers with one clear action item (see Figure 2). Including these elements makes the information easier to read for users and helps them to navigate through the instructional document and find information they are looking for more easily. Refer to IEC 82079-1:2012[2] for more information about structure, content, and presentation of instructional materials.

Tailor the language

Your instructions should consist of language that is tailored to the user group of your device, taking into account your intended users' educational background and experience with the particular device. For many devices this means that the content should be written in a clear and simple way, and should not include any difficult to understand jargon.

In addition, you should create instructions that contain procedural steps that are written in active voice (i.e., starting with an action word) and are short and concise (see Figure 3). So instead of including 'Users are advised to consider disinfecting the vial before use' it is better to phrase it as 'Always disinfect the vial with an alcoholic swab before use.'

Design graphics

Include graphics for the majority of the instructional steps to convey the expected actions or add some more details that are hard to describe in words. By conducting usability tests, we see that users tend to skip large amounts of textual information and graphics enable them to understand the expected action in a short amount of time. Further, some users prefer to refer to text, others to graphics, so by including both you will serve most users.

Using graphics instead of photos enables emphasis of important features and subordination unimportant ones, enables you to include special elements (e.g., motion lines, arrowheads), illustrates features that might not be readily visible on the actual product, and enables making easy updates in case of product changes.

How to use the Lancet

Obtaining a blood sample

1. Wash your hands with soap and hot water.
2. Place new lancet in lancing device and arm device.
3. Lance your fingertip.
4. Squeeze fingertip to produce small blood droplet.

Figure 3. Writing instructions in a short, clear and concise way using active voice. © 2017, Jonathan Kendler, UL-Wiklund.

A helpful method for creating graphics is taking photos of actual people interacting with a device. Then, you can use the photos to trace the device and the user to have the most natural hand positions and interactions with the device (see Figure 4). Refer to ANSI/AAMI HE75:2009[3] and AAMI TIR49:2013[4] for more information on designing training and instructional materials for medical.

Evaluating instructional materials

After you have designed the instructional materials, your next step is to evaluate whether the instructional materials are clear, effective (i.e., inform users how to use a device in an appropriate way), and satisfying. The goal of the evaluation process is to identify strengths, shortcomings, and opportunities for improvement of the instructional materials. The best way is to do so in an iterative way:

1. Evaluate the instructional materials when they are in an early draft form;
2. Revise the instructional materials;
3. Re-evaluate the instructional materials in another evaluation round;
4. Iterate the steps above until there are no further ways to improve the instructional materials.

As long as you identify opportunities for improvement (e.g., misleading information that leads users to interact with the device in an unintended way) it is best practice to keep evaluating your instructional materials until all content is clear and effective, and all ways to further improve the instructional materials have been explored.

There are several methods you can use to evaluate instructional materials. Combining different evaluation methods is suggested, based on best practice. In the following, different methods will be explained including examples.

2 IEC 82079-1:2012. Preparation of instructions for use - Structuring, content and presentation - Part 1: General principles and detailed requirements.

3 ANSI/AAMI HE75:2009. Human factors engineering - Design of medical devices.

4 AAMI TIR49:2013. Technical Information Report - Design of training and instructional materials for medical devices used in non-clinical environments.

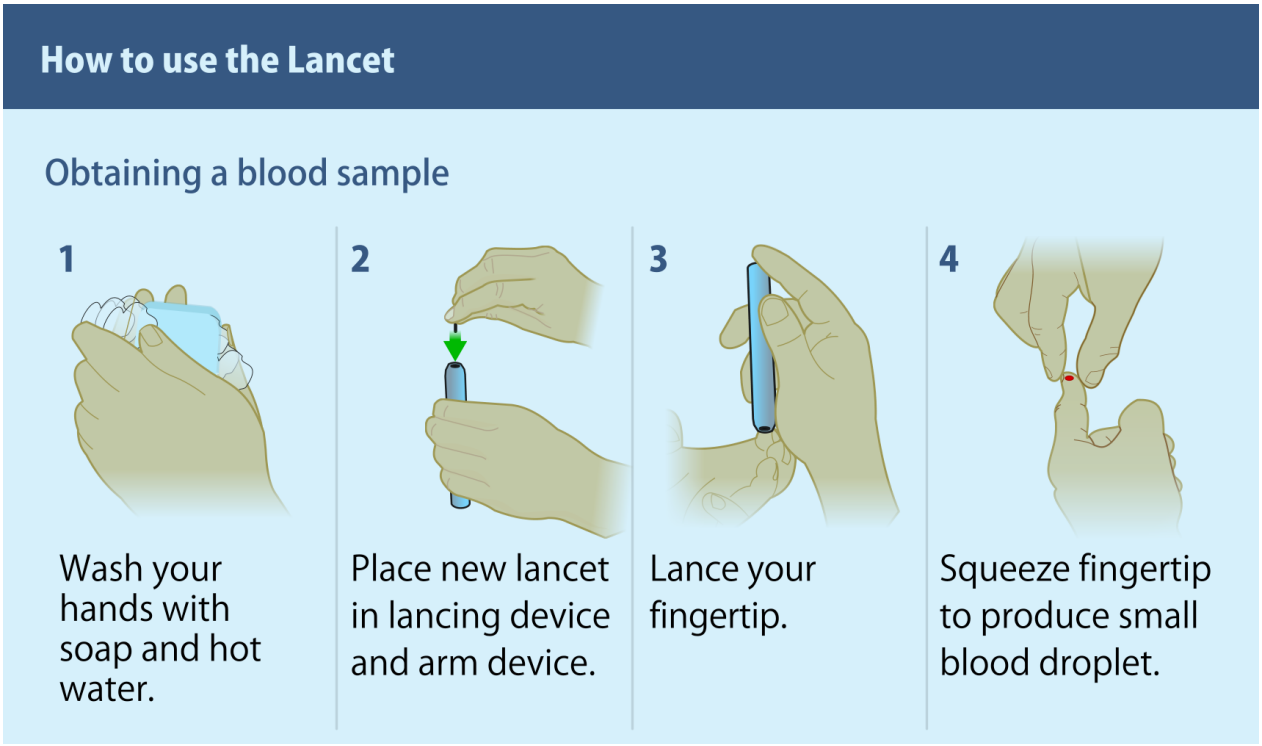


Figure 4. Graphics and textual instructions. © 2017, Jonathan Kendler, UL-Wiklund.

Expert review

Perform a design critique and identify the document's strengths and opportunities. This activity does not involve any actual users, but is a quick way of identifying opportunities to improve your instructions.

Example: One or more Human Factors Specialists review the instructions for a device that can detect Influenza A+B. They determine that one of the document's strengths is the use of headers and sub-headers for sections so users can quickly identify which section is of interest to them. On the contrary, they also identify that not all instructional steps are numbered and are not written in active voice. As such, users might skip steps when referring to the document because they think the text is passive information rather than calling for action.

Interviews

Interview intended users to retrieve inputs and insights about what users want and need. Users are the ones who will ultimately use your instructional materials, so involving them from an early point on will lead to clearer and more effective instructions. Notably, this method is also a very valuable way of identifying users' needs and wishes before starting the design process.

Example: A researcher interviews intended users to gather their impressions on instructional materials for a patient monitor that is in development (see Figure 5). The researcher shows the interviewees several early stage concepts of the instructions to see which format and structure users prefer most. Examples of questions that the researcher might ask the interviewees is 'What are your thoughts about the amount of information?' 'What are your impressions of the instructions' lay out?' or 'Is there any information missing from these instructions?' The results from the interviews will be used to develop the instructions further.

Usability test

Let intended users perform tasks with the device that is in development while using the instructional materials, and retrieve input about how these intended users use the instructional materials. You can decide to leave it to the users to use the instructional materials or not (to identify whether they can locate the instructional materials or think it is necessary to use the instructional materials) or instruct users to follow the instructional materials step-by-step. In addition, a usability test is a good way to collect users' subjective feedback about aspects they did and did not like about the instructional materials. In the end, the instructions should not only be clear and effective, but also satisfying to use. Refer to FDA's guidance document 'Applying Human Factors and Usability Engineering to Medical Devices', 2016[5] and IEC62366-1:2015 standard 'Application of usability engineering to medical devices'[6] for guidelines and requirements on

5 Applying Human Factors and Usability Engineering to Medical Devices, FDA guidance published February 3, 2016.

6 IEC 62366-1:2015. Medical devices - Part 1: Application of usability engineering to medical devices.

Figure 5. An interview to gather users' impressions on early stage concepts. © 2017, Jonathan Kendler, UL-Wiklund.

conducting usability tests of medical devices and their instructional materials. Example: Nurses have to perform a task in which they need to adjust the dose of dopamine in an infusion pump (see Figure 6, page 20).

The infusion pump has a Quick Reference Guide that explains the high level steps of device use. However, during the usability test it is observed that most nurses use a trial-and-error approach rather than referring to the instruction materials when using the infusion pump. Some people who did read the instructions misinterpreted the Quick Reference Guide's text, leading to situations that can be very harmful for the patient. The test moderator will follow up with participants to identify the causes for them misinterpreting the text. These causes and possible recommendations will then be used to improve the Quick Reference Guide during a following design iteration.

About UL-Wiklund

Frauke Schuurkamp and Linda Giesselink are Human Factors Specialists at UL-Wiklund (Utrecht, the Netherlands). A group of more than 50 Human Factors Specialists and User-Experience Designers at UL-Wiklund support medical device manufacturers and pharmaceutical companies with their product development process from a Human Factors Engineering (HFE) perspective. Activities for supporting their clients consist of (but are not limited to) conducting usability tests, use-related risk analyses, and expert reviews. They also provide clients with regulatory advice to ensure medical device manufacturers and pharmaceutical companies comply with the regulatory standards and guidance documents. Moreover, they design medical devices' user interfaces and training and instructional materials for a wide range of medical devices and pharmaceutical products.

Figure 6. A usability test to evaluate how intended users interact with the device. © 2017, Jonathan Kendler, UL-Wiklund.

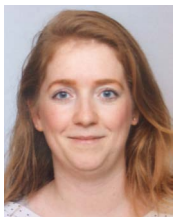
Epilogue

While developing instructional materials, it is important to take an iterative approach:

- Research the users and use environments to define the requirements for the instructional materials.
- Design the instructional materials by defining the content, formatting the instructions, tailoring language to the users, and including graphics to clarify the step-by-step instructions.
- Evaluate the design to identify strenghts and opportunities for improvement.
- Redesign the instructional materials to address the findings from the evaluation.
- Move back and forth between designing and evaluating the instructional materials until all content is clear and effective, and all ways to further improve the instructional materials have been explored.

This approach will help to ensure that the instructional materials best meet users' needs and wishes, help them to learn how to use the device properly, and do not result in users making any mistakes or experiencing difficulties while interacting with the device and its instructions.

About the author:



F. Schuurkamp, MS
Managing Human Factors Specialist
UL-Wiklund
UL International (Netherlands) BV,
Utrecht
frauke.schuurkamp@ul.com
www.wiklundrd.com

L.H. Giesselink, MS
Senior Human Factors Specialist
UL-Wiklund
UL International (Netherlands) BV,
Utrecht