SENSILE MEDICAL

BUILDING BRIDGES FROM DRUGS TO PATIENTS: USABILITY & HUMAN FACTORS

Sensile Medical has been conducting usability engineering for a number of years in its projects in order to consider these factors and develop appropriate solutions. Here, Nicolas Sandoz, Head of Product Management, describes Sensile Medical's approach to ensuring it takes usability and human factors into account during the development of its devices, in particular for subcutaneous delivery.

> "The shift from hospital or clinic setting delivery to home self-administration using a wearable injector needs careful consideration regarding patient safety, as well as reflection on the ease of use, comfort and, more generally, the usability of the injector unit."

With the advance in biotechnology over the last two decades, therapies using biologic drugs are becoming increasingly frequent. Very often, those biologics are large and complex molecules and cannot be administered orally. Indeed, their size and polar surface prevent them from diffusing through the epithelial layer of the intestine and stomach and they may also be damaged during their journey through the gastro-intestinal tract.

Consequently, these large molecules necessitate a different administration route and frequently parenteral delivery is appropriate. However, such administration is a more complicated and technical process than just swallowing a few pills or a few millilitres of a drug, and can result in higher therapy costs and more burden for the patients. For instance, intravenous (IV) administration requires the placement of an IV line by a nurse, and patient surveillance during delivery in case of complications.

Subcutaneous (SC) delivery provides the possibility of self-administration, for example at the patient's home, thus helping to lower therapy costs. As a result a growing number of drugs are now being reformulated for SC delivery using a wearable injector for home use. Various scenarios, where IV delivery in a hospital setting could be substituted or supplemented by SC delivery at home have been discussed in a previous issue of ONdrugDelivery.[1] They are still valid today so will not be re-visited here.

Some drug manufacturers also want to use automated delivery devices to simplify the act of administering the medication, thus diminishing the burden on patients, and giving them more flexibility.

The shift from hospital or clinic delivery to home self-administration using a wearable injector needs careful consideration regarding patient safety, as well as reflection on the ease of use, comfort and, more generally, the usability of the injector unit.

BENEFITS AND RISKS

A shift from delivery conducted in a hospital or clinic environment, where trained professionals administer the therapy,

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to self-delivery by the patient at his or her home brings a number of benefits to the patient but also a few risks.

The first obvious benefit is that self-delivery does not necessitate the presence of a healthcare professional (HCP) once the patient is trained to self-administer the drug. Furthermore, home therapy provides the patient with an environment that is personal, familiar and comfortable – clear advantages on top of the cost decrease.

Depending on the therapy, home administration gives more flexibility and freedom to the patient who may even be able to carry out other activities or work while the drug is being delivered by the device. This not only saves time but also allows the patient to be productive during the therapy, and can be beneficial to several parties, the patient, the employer and payers.

Self-administration reduces the need for regular trips by the patient to a healthcare centre and the stress related to transportation and traffic. This also brings advantages in terms of comfort, time and cost savings.

The resulting benefit is that the therapy has less impact on the daily routine of the patient, thus helping the patient to remain active and mobile, and continuing a regular social life. All these factors may contribute to better patient compliance and improve therapeutic outcome.

"Even though the benefits speak in favour of self-administration at home, the related risks are real. This is where usability engineering can play a central role to understand potential problems and develop mitigation measures."

On the risks side, a wrong manipulation of the drug or delivery device, or a misunderstanding of a setting, can lead to administration of the wrong dose, potentially resulting in an adverse effect. Absence of personnel with medical training in case of anaphylactic reaction or simple forgetfulness leading to missing or skipping one or more deliveries are also increased risks.

Such eventualities must be avoided and necessitate a thorough understanding of the therapy, its possible side effects, the environment it's being used in as well as patients' limitations, for example limitations caused by their condition.

Even though the benefits speak in favour of self-administration at home, the related risks are real. This is where usability engineering can play a central role to understand potential problems and develop mitigation measures. Issues related to device use, understanding patients and their interaction with the drug and delivery system are tested during usability studies. The results are subsequently integrated into the product design.

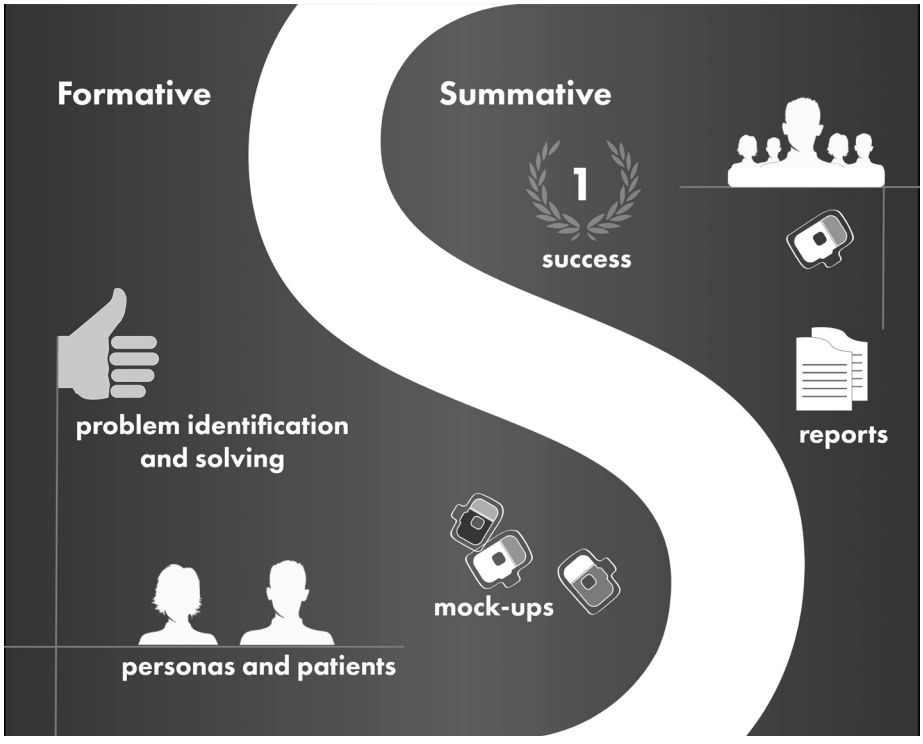

Figure 1: The purpose of using both formative and summative testing.

USABILITY ENGINEERING

Sensile Medical utilises human factors and usability studies and integrates them into their development projects as part of a usability engineering process.

Originally developed to study and optimise military equipment during the Second World War, human factors is often nowadays wrongly thought to be mainly a discipline for interactions between human and computer only. It actually applies to the development of any product interacting with human beings. For medical devices, usability engineering has evolved with US FDA Guidance[2] and the IEC 62366 standard.[3] The latter takes the patient condition and resulting limitations into consideration in order to improve the usability of the device, to make sure its user-interface is understandable and to contribute to safety.

In addition to risk mitigation, usability engineering also provides the opportunity to create and optimise the design. The look and feel of a device should address patient concerns and fears (e.g. needle phobia) and provide the best possible user experience.

The usability process at Sensile Medical consists of an iterative approach integrated into the various phases of the development project. It begins with formative studies where the preferences of patients are tested followed by further studies where various aspects of the device design are evaluated and refined. The formative studies series ends with a confirmation study testing the whole product as well as the set-up foreseen for validation. Finally, a summative study demonstrates the safe use of the design and acceptance by its users and formally provides its validation (see Figures 1 & 2).

FORMATIVE STUDIES

Preference Studies

Preference studies are formative studies usually carried out at the beginning of a development project to determine which concept is the most suitable for patients

among a choice of several alternatives. At Sensile Medical, we start with elaborating use scenarios and performing a use error analysis to identify wants and needs as well as potential risks arising from the operation of the device.

Using semi-functional mock-ups presented to a sample of patients and HCPs for them to simulate the injection process, their behaviours are observed and their opinions evaluated through a number of targeted and specific questions. These studies can address the complete unit or only a part of its functionalities. Very often elements like preparation of the unit before therapy, or interface and position of the auxiliary equipment, or type of user interface are tested during such studies.

The advantages of this formative step are: a reduction of the multiple solution possibilities at an early stage of a development; gathering information by observing the patient handling the mock-ups; and confirming whether patients' conditions may affect their use of the device. A difficulty arising at this stage is often the wide behavioural spectrum of patients and subsequent development of the corresponding mitigation measures in the next design iteration.

Concept and Design Refinement

Concept refinements also involve formative studies used to refine the product concept further. The use error analysis is further detailed based on the chosen concept and the foreseen use scenarios. This becomes part of the instrument risk analysis and enables risk-mitigation solutions to be tested with patients and HCPs. Aspects like user interface concept, warning messages and alarm signals as well as instructions for use (IFU) and training are evaluated.

Concept refinement is often an iterative process happening during the feasibility and design input phases. It may continue beyond the concept stage into the prototype stage of the design output phase to refine and finalise the product design. Depending on the stage of the development, these studies make use of semi-functional mock-ups or semi- or fully-functional prototypes.

The studies performed at this stage represent a first confirmation of product acceptability and help to adjust its design and functionalities. They also provide valuable insights for potential improvements and help identify features that may not be very useful.

Formative vs. summative tests
What's the difference?

Formative Studies	Summative Studies
Purpose: to guide the whole design process	**Purpose: to formalize the outcome of the formative process**
• From the beginning of and during the development • Shaping the design iteratively • Testing/improving with sketches, mock-ups, prototypes or similar • Problem identification and solving • Gain valuable insights – to reach user goals	• At the end of development phase • Formal documentation of the usability of a product, its user interface and inst-ruction for use • Testing with series product • Using metrics (task durations, success rates, satisfaction scores) • Generate data to support marketing claims about usability
Output: • ***Qualitative as well as (semi-)quantitati-ve results with respect to usability of the future product*** • ***Participant comments and questions (attitudes, sources of confusion, rea-sons for actions...)*** • ***Photographs/Videos*** • ***Usability problems and suggested solutions***	***Output:*** • ***Statistical measures of usability (success rate, average time to complete a task, number of assists...)*** • ***Formal validation reports***

Figure 2: The differences between formative and summative tests.

Confirmation of Design

Towards the end of the design output phase we test the full product as planned as part of a pre-validation step. This helps confirm that the system works as foreseen and can be used by patients and HCPs as planned before transferring the design into commercial series production. This step also enables testing the validation set-up for the summative studies. At this stage, the product and its IFU are tested along with packaging, training materials and training procedures.

During patient interviews, it is useful to test error states to make sure the users can resolve potential problems with the information that would be available to them in real use conditions.

This step is comparable with the final rehearsal before the premiere of a show. It is the last confirmation that everything runs smoothly. The size of the patient and HCP sample need not to be as large as for the validation but big enough to be representative.

SUMMATIVE STUDIES

Summative studies are carried out to validate the usability of the device. They confirm that the training materials and procedures are effective, and that the IFU is understandable. The usability of the device is tested under normal use conditions. Tests of error state and troubleshooting procedures make sure that the interpretation of warnings or error signals are correct and that the patients can resolve problems on their own.

LEARNINGS

The use of techniques and tools like personas, patient journey and use cases have been found very helpful at various stages of development. Elaborated during the requirement elicitation phase, they help to illustrate and understand the role, environment of use and condition, as well as limitations of users of the product. They are particularly helpful in usability engineering to determine the focus and content of the handling studies, as well as to elaborate a choice of design alternatives for the product.

Collaborating with companies specialised in human factors studies has proven very useful. Sensile Medical partners with them not only for the logistics aspects such as providing appropriate location and facilities for the studies but also for them to

manage patient recruitment, and conduct the testing and interviews. These firms also develop interview protocols based on the goals and content that Sensile Medical provides.

Another important factor that such partnerships bring is a neutral position with respect to design alternatives during the interviews, thus preventing an influence on the results by the interviewer. Indeed, an interview by someone involved in the device design could involuntarily bias the outcome of the study.

Interview facilities are usually equipped with filming capabilities. Videos of the tests are recorded with user consent. This provides useful material that can be examined to re-confirm the observations and understand the context in which they happened.

CONCLUSION

The advance of biotechnology has led to an increase of large biologic molecules requiring parenteral administration for various indications. SC delivery through self-administration by patients using advanced drug delivery systems is an opportunity to improve therapies and decrease costs, as well as provide patients with more flexibility and comfort.

However, self-administration may bring a number of challenges with it regarding the safe and effective use of these devices. Most of these challenges can be addressed with a usability engineering approach. Sensile Medical recognised the importance of this discipline long ago, and has integrated it into its development projects with positive results.

In addition to the benefits this discipline can bring to patient safety, satisfaction and compliance with the therapy, the iterative nature of Sensile Medical's approach of usability engineering provides an early indication of product acceptance on the market.

ABOUT SENSILE MEDICAL

Sensile Medical is a leading company in the area of advanced micro pump technology developing a broad range of customer-specific delivery and dosing solutions. Sensile Medical is a full-service provider of pump-based drug delivery solutions, with in-house specialists for engineering, electromechanics, software development and more. Our partners include well-known pharmaceutical companies and research organisations.

REFERENCES

1 *Muntendam P, Mayer G, Krinelke L, "Large-volume injector enables anytime anywhere delivery of parenteral drugs". ONdrugDelivery, Issue 51 (July 2014), pp16-20.*

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3 *IEC, "Medical devices – Part 1: Application of usability engineering to medical devices". IEC 62366-1:2015 and "Part 2: Guidance on the application of usability engineering to medical devices". IEC TR 62366-2:2016.*

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