

Please note that this summary only contains information from the full scientific article:

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An opinion study of health care professionals about the Smartclic®/ClicWise® subcutaneous injection device



Autoinjector

<AW-toh-in-JEK-ter>

Subcutaneous

<SUB-kyoo-TAY-nee-us >

Biologics

<BY-oh-LAH-jix>

Chronic

<KRAH-nik>

Date of summary: March 2022

Study start date: September 2020

Study end date: October 2020

The full title of this article: High usability and applicability ratings for the new Smartclic®/ClicWise® injection device: Evidence from a health care professional opinion study

Key takeaways

- In this study, healthcare professionals reported that the Smartclic®/ClicWise® autoinjector device was easy to use.
- The Smartclic®/ClicWise® autoinjector could be an acceptable replacement to other injection devices for people with chronic diseases who inject their own medicines.

Additional information

More information can be found in the scientific article of this study, which you can access here:

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For more information on clinical studies in general, please visit:

<https://www.clinicaltrials.gov/ct2/about-studies/learn>

<https://www.cancerresearchuk.org/about-cancer/find-a-clinical-trial/what-clinical-trials-are>

The purpose of this plain language summary is to help you to understand the findings from recent research.

- This summary reports the results of a single study. The results of this study may differ from those of other studies. Health professionals should make their decisions on the most appropriate injection device together with a patient based on individual needs, not on the results of a single study.

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What did this study look at?

What are chronic diseases?

- A chronic disease is a long-lasting health problem that is not immediately life threatening and may not be cured.
 - In contrast, an acute disease is a health problem that occurs suddenly and requires short-term care.

How are chronic diseases treated?

- People with chronic diseases often inject medicines under the skin (or subcutaneously) using a syringe. People may also use other injection devices called autoinjectors.
- People with chronic diseases may have pain or limited mobility in their hands. As a result, they may struggle to inject themselves with their medication.
 - In previous studies, the researchers found that people usually preferred using autoinjectors instead of syringes because they were easier to use.

The Smartclic®/ClicWise® autoinjector

- The Smartclic®/ClicWise® device is a new type of reusable electronic autoinjector.
 - Disposable containers (cartridges) filled with medicine are loaded into the device for injection.
 - People inject the medicine subcutaneously through a needle that is hidden.
 - Many people who inject their own medicines dread their injections and have to mentally prepare themselves. As a result, people might delay or even skip taking their medicines.
 - Smartclic®/ClicWise® is designed to help with people's dread about injections so they can continue to take their medicine.
 - The Smartclic®/ClicWise® autoinjector is approved for use in Europe, Japan, and Australia at this time. It is also being considered for use in many other countries around the world.

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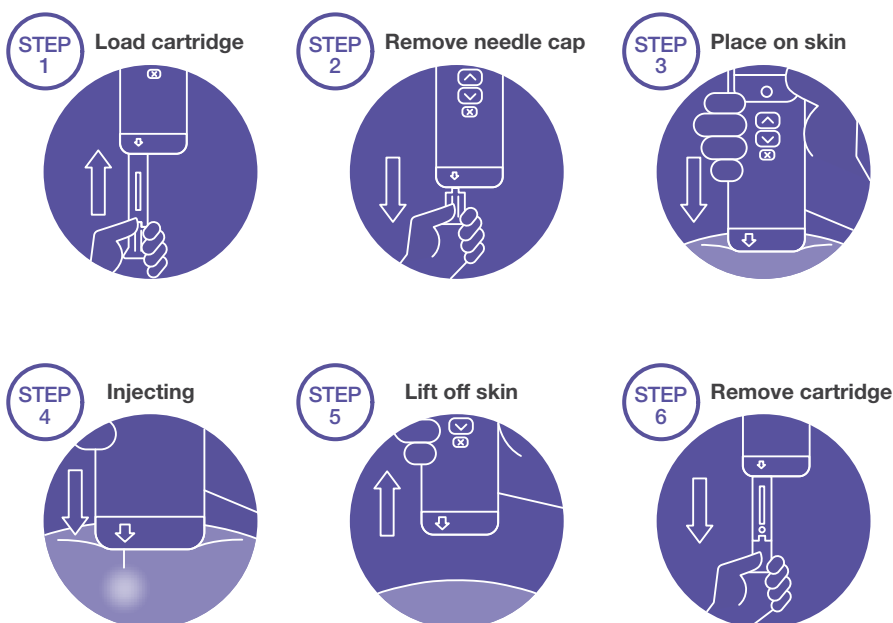
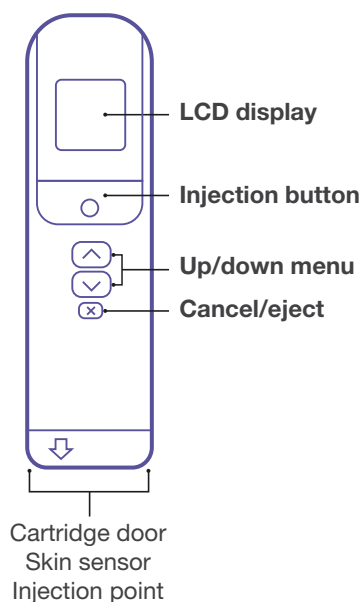
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How does the Smartclic®/ClicWise® device work?



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- Researchers are also developing a mobile app for the Smartclic®/ClicWise® device. This optional app would allow people to track the dates and times they inject their medicine, record changes in their symptoms, and allow people to choose to export their information that they may want to share with their doctor.



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What was the aim of this study?

- In this study, researchers organized a study of health care professionals (HCPs for short). Researchers wanted to find out what HCPs thought of the Smartclic®/ClicWise® autoinjector and mobile app.
 - An HCP is a member of the medical, nursing, pharmacy, or dental professions.
- All of the HCPs individually tested the device by performing up to 20 injections into injection pads using cartridges filled with water.
 - An injection pad is a block of artificial (made by humans) skin and muscle that is used for injection training practice.
- This would help HCPs understand what it is like to give injections to people with chronic diseases using Smartclic®/ClicWise®.
- The HCPs answered questions by responding to researchers in interviews and filling out paper questionnaires. The study was split into 3 parts:
 1. A questionnaire on the HCPs' experience in treating patients with chronic diseases.
 2. A questionnaire on the Smartclic®/ClicWise® device.
 3. An interview in which the researcher asked questions about the mobile app.
- This summary describes how usable HCPs found the Smartclic®/ClicWise® device and how useful the planned app would be.

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Who took part in this study?

HCPs took part in this study:



In Germany



Between



.....▶



22 women



20 nurses



4 physician/medical assistants



1 care assistant for the elderly (older people)



All HCPs had experience giving injections
• **5** had experience injecting biologics

HCP medical specialities:*



8 intensive care



5 surgery



4 cardiology



3 emergency department



3 orthopedics (treatment of bones, muscles, joints, tendons)



3 neurology (treatment of the brain and spine)



3 anesthesia (putting people to sleep or numbing areas of the body for surgery)



2 psychiatry (treatment of mental health)



9 other specialities

*The HCPs could choose more than one speciality

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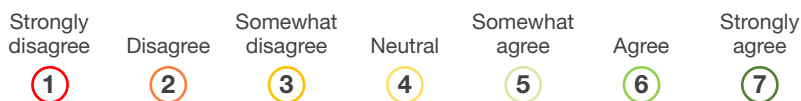
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What were the results of the study?

- The HCPs responded to study questions on the Smartclic®/ClicWise® device by selecting how much they agreed with a question on a scale of 1 to 7.



Questionnaire about how easy HCPs found Smartclic®/ClicWise® to use



On average, HCPs strongly agreed **7**:



- Smartclic®/ClicWise® is easy to use
- Smartclic®/ClicWise® is easy to learn how to use



- Smartclic®/ClicWise® is:
 - Easy to prepare and inject
 - Easy to handle and control



On average, HCPs agreed **6**:



- Smartclic®/ClicWise® feels reliable, durable, and good quality



- Visual and audio feedback are effective during injection
- Audio feedback is easy to hear and helpful



- Smartclic®/ClicWise® is easy to grip



- It is easy to inspect medication in the cartridge
- It is easy to remove the needle cap
- Digital display is clear, easy to read, and helpful



- Smartclic®/ClicWise® is easy to use without any help



- They would recommend Smartclic®/ClicWise® to patients



- Smartclic®/ClicWise® is comfortable to hold and does not slip
- Smartclic®/ClicWise® is an appropriate weight



- They would recommend Smartclic®/ClicWise® to colleagues



On average, HCPs somewhat agreed **5**:



- Smartclic®/ClicWise® is easy to use with one hand
- Smartclic®/ClicWise® is an appropriate size



- Smartclic®/ClicWise® can be used with significant hand pain to inject yourself



- Smartclic®/ClicWise® can be injected by people who lack grip strength



- Injection procedures were not time consuming

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Questionnaire about the features of Smartclic®/ClicWise® and its effectiveness



On average, HCPs strongly agreed **7**:



- Smartclic®/ClicWise® is reusable



- Smartclic®/ClicWise® confirms that cartridge medication has not expired



- Smartclic®/ClicWise® has a skin sensor to help inject yourself



- Smartclic®/ClicWise® protects against needle stick injury



On average, HCPs agreed **6**:



- It is easy to choose injection speed



- The needle is hidden during injection and disposal



- Smartclic®/ClicWise® displays an alert if used within 2 days of last injection



- Smartclic®/ClicWise® bluetooth connects to mobile phone



On average, HCPs somewhat agreed **5**:



- Choosing injection speed may reduce worry about injections

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How long would people need to be trained to use Smartclic®/ClicWise®?



HCPs thought people could learn how to use the device in



5 mins



HCPs thought people could learn how to use the device in



10 mins



HCPs thought people could learn how to use the device in



20 mins



HCP thought people could learn how to use the device in



30 mins

- 21 HCPs provided comments on the Smartclic®/ClicWise® device features.
 - 11 said the device was easy to understand, safe, and easy to use.
 - 10 said the device was large or heavy.



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Questionnaire about how useful the HCPs thought the Smartcllic®/ClicWise® mobile app would be to users



On average, HCPs said they strongly agreed **(7)**:



- Injection reminders will help people take their medicine regularly



On average, HCPs said they agreed **(6)**:



- Injection tracking on the app will be useful



- Injection site recording on the app will be helpful for users



- The app will help people track their pain symptoms



- The app will be easy to understand and easy to use



- The app will help patients to improve how they manage their condition



- Information recorded on the app would help in either virtual or face-to-face consultations



- They would recommend the app to colleagues and patients



- The app will help people keep a record of their fatigue (how energetic or tired they feel)



- Tracking joint stiffness when they wake up will be useful

- 11 HCPs provided open-ended comments to researchers about the Smartcllic®/ClicWise® mobile app.
 - 5 said that older patients may not use smart phones.
 - 4 said the app would be useful.
 - 2 said the app should be simple to use to help people keep taking their medication.

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What were the main conclusions reported by the researchers?

- The HCPs who took part in this study and used the Smartclic®/ClicWise® autoinjector gave positive feedback.
 - On average, HCPs gave a score of 6 out of 7 (agreed) for ease of use, features of the device, and how well it worked.
- HCPs also gave positive feedback for the Smartclic®/ClicWise® mobile app.
 - On average, HCPs gave a score of 6 out of 7 (agreed) for how useful the app was.
- On average, HCPs somewhat agreed (scoring 5 out of 7) that the device was an appropriate size, and agreed (scoring 6 out of 7) that the device was an appropriate weight and comfortable to hold, based on their experience.
 - However, 10 HCPs commented that the device was large or heavy. These comments might reflect how HCPs thought the device could be improved.
- It is important to keep in mind that a small number of HCPs took part in the study. This means that their opinions may not be shared by all HCPs.
- HCPs could not be certain how people with chronic diseases would view the device.
 - More studies are needed to research whether patients find the Smartclic®/ClicWise® injection device useful and a good alternative to how they normally inject their medicine.

Are there any plans for further studies?

- The Smartclic®/ClicWise® injection device is being evaluated in a separate study by patients with rheumatic diseases.

Who sponsored this study?

Pfizer Inc.

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Phone (United States): +1 212-733-2323

Pfizer thanks all of the people who took part in this study.

Acknowledgements

Writing support for this summary was provided by Jake Evans, PhD, Envision Pharma Group, Inc. and was funded by Pfizer.

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