Research Protocol

Introduction

The objective of this evaluative research study is to explore, in an open-ended way, patient attitudes, perceptions and early usability surrounding smart labels, including two potential workflows (leveraging either a QR code or NFC tag) and a series of digitally-enabled (e.g., app) features.

This document outlines the intended structure, participant-prototype interactions, and discussion topics for these sessions. Sessions will be conducted in-person at Insight's Chicago office. Patient sessions will be conducted as one-on-one 60-minute interviews.

Key research questions to be answered:

- How valuable is smart label functionality to patients/ potential end users?

- How do the two workflows (leveraging either a QR code or NFC tag) compare from a user perspective?

- What additional functionality could a smart label and app enable?

- Would the use of smart labels require training and/ or supervision or could this technology be successfully leveraged without?

Research Sample

To meet the study objectives, we intend to interview 32 patients who have been diagnosed with Type 2 diabetes, with a mix of those who are injection naïve and injection experienced (administering GLP-1s, not using insulin pens). Participants will be recruited to meet the specific criteria as outlined in our Participant Screener.

Research Stimuli

We will have both technologies (i.e., QR code and NFC tag) functional, such that activating either via study smartphone opens a URL to a semi-functional Adobe XD prototype which represents the high-level flow and interaction.

Specific prototypes/ flows are outlined below:

- o **Workflow Q** presents the dose logging flow associated with the use of a QR code. Note with QR codes, dose data (i.e., dose and expiration date) must be manually entered or captured via photo of the label.

- o **Workflow N** presents the dose logging flow associated with the use of an NFC tag. Note with NFC, dose data (i.e., dose, expiration date and lot number) is automatically captured.

  - **Alerts:** NFC enables two additional functions: the ability to recognize redundant entries and tamper evidence; both will be shown following the NFC workflow

- o **Feature Menu** presents the additional features that could be enabled through an app, including reminders, Rx refills, symptom tracking, care team access, and a community forum.

In addition to the digital prototypes outlined above, we will have training devices with functional smart labels as well as a paper-based QRG which will include instructions for accessing the QR code or NFC tag.

Session Structure

Research sessions will be moderated by an Insight researcher and conducted in-person at Insight's observation facility. These 60-minute, one-on-one interviews will be documented with video and photos. Below is an outline of the session structure:

1. **INTRODUCTION & BACKGROUND (5 min)** – The moderator will welcome and thank the participant, then present the goals and activities of the session/study. They will then ask each participant to briefly discuss their experience and current care regimen for managing Type 2 diabetes. (This is largely to confirm recruit criteria.)

2. **CONCEPT INTRODUCTION (5 min)** – The moderator will then introduce the concept of smart labels to enable dose logging, followed by a brief set of questions to solicit participants' first impressions, perceived benefits, concerns, and challenges associated with the technology/ user experience.

3. **WORKFLOW EVALUATION & COMPARISON (35 min)** – The moderator will then share each of the prototypes/ workflows, asking participants to use each. Note that half the sample will be "trained" with the moderator walking through the QRG step-by-step, while the other half will not receive any type of instruction.

   Throughout use, participants will be encouraged to 'think aloud' highlighting any expectations, uncertainty and/ or

challenges. They will then reflect on the user experience associated with each, followed by a discussion asking them to compare and contrast the two flows to understand acceptability, preferences and tradeoffs.

4. **FEATURE MENU (10 min)** – Following the workflow comparison, a series of features will be introduced and assessed to understand perceived value and envisioned use.

5. **WRAP-UP (5 min)** – To conclude the session, participants will be given the opportunity to summarize their thoughts. At this time, we will also include any additional follow-up/ clarifying questions from those team members observing the session.

Discussion Guide

1. Introduction and Background (5 min)

Thank you for your time and participation in our research study. My name is _____, and I am a researcher from Insight Innovation Center. Insight is a design innovation consultancy - we help our clients develop new ideas and refine existing products. Today we will be discussing a concept that would enable people using an auto-injector to administer treatment to digitally log each dose.

We value your feedback and opinions. As we talk today, please be as open and honest as possible – there are no right or wrong answers. The research is not intended to evaluate you in any way or be promotional. Our goal is to better understand your opinions and preferences so we can develop a product that meets your needs.

The session today should last about 60 minutes. We'll start by getting to know you a little bit better – your background and experience with Type 2 diabetes. Then I'll share the concept with you overall, followed by a few different prototypes. I'll ask that you try out each, with the goal of understanding if and how you might envision using this, and any perceived benefits or concerns you may have.

Lastly, I want to call out that we'll be video recording today's session. This is for internal research purposes only, so this will not be shared publicly.

Do you have any questions or concerns before we get started?

[Start recording.]

Okay… to start, I would like to learn a little bit more about you.

PARTICIPANT BACKGROUND

- Age
- Occupation
- Household makeup

TREATMENT REGIMEN

- When were you diagnosed with Type 2 diabetes?
- What is your current diabetes medication regimen/ routine?

  [For injection experienced only]

- What specific medication do you inject? How often?
- How long have you been administering diabetes treatment via injection?
- Do you log your injections in any way? Why or why not?

- If so, how? Why? What purpose does the log serve?

2. Concept Introduction (5 min)

Thank you for sharing that information. Now I'd like to share a bit more about the concept overall.

This concept leverages a "smart label" on a single-use autoinjector. When used with a smartphone, the label facilitates digitally logging that dose.

- Do you have any questions regarding the purpose of the label before we begin?

- To what extent do you think this might be helpful/ valuable to you? Why or why not?

- Do you have any concerns?

3. Workflow Evaluation & Comparison (35 min)

Okay, let's imagine you are starting a new medication to treat Type 2 diabetes called Tranzium (note this is the name just for the purposes of this study). Tranzium is administered via an autoinjector (i.e., self-injection device) and utilizes a smart label.

In front of you is a phone that we're going to ask you to interact with (as if it was your own). I'll also be providing a series of empty, needleless autoinjectors with smart labels so you can get a feel for the process of use.

We have two primary workflows to walk through - for each, I'm going to ask that you go ahead and use the phone to interact with the label, then follow the prompts on the phone. As you do so, please think aloud – we'd love to know what's unexpected, confusing, challenging, etc.

Please note that because these are prototypes still in development, they are not fully functional. For example, only some buttons are active and there's no text entry; data will populate with a pre-selected name, dose, etc.; so we ask that you use your imagination a bit!

The workflows will be accessible on a phone provided by Insight. The screen will be shared via Teams such that the moderator (and anyone observing the sessions remotely) will be able to see what the participant sees on the phone.

*The two workflows, **Workflow Q** and **Workflow N** will be presented to participants in alternating order so as to minimize any potential for order bias.*

Moderator will provide participant with corresponding training device/ label and QRG. The moderator will walk through the QRG and provide guidance throughout for "trained" participants only.

Do you have any questions before we get started?

Okay, whenever you're ready go ahead!

Moderator will first have participants go through the entire flow self-directed. For those untrained, we will classify participants in three groups: success (able to successfully navigate through entirety of process with little to no guidance), near miss (struggled to navigate through the process and required moderator guidance) and failure (unable to go through the process and required moderator intervention). Specific steps and challenges associated with near misses and failures will be noted. After participants have completed the process of logging their dose, they will be asked the following:

- What did you think of that process overall?
- Was anything confusing or challenging?
- Did anything stand out as particularly positive or negative?
- Based on your experience thus far, when would you envision "activating" the label? Why?

Moderator will then ask participants to go through the flow again, this time pausing interaction at each interval outlined below in order to assess utility and comprehension of each interaction/ screen state.

Activating the Label
- What did you think of the process of activating the label?
- Was anything confusing or challenging?

Home Screen (First workflow only)
- What are your initial thoughts on this screen? Can you explain to me what you are seeing?
- To what extent do you think this timer would be helpful? Why?
    - Do you think you would use it? Why or why not?
- What do you think you would do next? Why?

Injection Guidance (First workflow only)

[Moderator will prompt participants to swipe right if they haven't otherwise done so.]

- What do you think of this content? Why?
- To what extent do you think this guidance would be helpful? Why?
    - Do you think you would use it? Why or why not? In what scenarios?
- Is there anything you would want/ expect to see within the digital instructions to make them more useful? *(Probe on animations, web links, videos, etc.)*
    - If these aspects were available, to what extent would this influence use?

Logging the Dose

- [For Workflow Q only] How would you envision entering the dose data? *(Probe on manual text entry versus photo.)* Why?
- What do you think of the process of logging the dose data?
- Was anything confusing or challenging?
- [First workflow only] To what extent do you think the notes option would be helpful? Why?
    - Do you think you would use the notes option at all? Why or why not? In what scenarios?
    - What types of information would you want to include? *(Provide examples, as-needed including wet injection, pain level, medication remaining, etc.)*
    - Specifically, to what extent is noting the injection site location helpful? Why?

Injection History (First workflow only)

- What do you think of this content? Why?
- To what extent do you think this information would be helpful? Why?
    - Do you think you would reference it? Why or why not? In what scenarios?
- Is there any additional information you would want included here?

    [As necessary, prompt participant to open card to see specific dose data.]
    - What do you think of this information specifically?
    - Do you think you would reference it? Why or why not? In what scenarios?

       ○   Is anything missing?

Overall

- What do you think of this workflow overall?

- Is there anything you particularly like or dislike? Why?

- Is anything confusing or challenging?

- Is there anything you would change or add to make this concept better? What impact would this have?

- [For current injectors only] What impact would logging each dose with this concept have on your injection process overall?

- Would you be willing to use this to log your doses? Why or why not?

Alerts (Workflow N only)

Let's imagine you have been taking this medication for a while now and you activate the label as usual. *(Moderator to provide AI with label linked to 'Standard NFC error' URL.)*

- What is this screen telling you?

- What would you do next?

- What do you think of this functionality?

- To what extent do you think this information would be helpful? Why? In what scenarios?

Now let's imagine some more time has passed and you intend to use this device. (Moderator to provide AI with label linked to 'Tamper evidence 2nd scan' URL.)

- What is this screen telling you?

- What would you do next?

- What do you think of this functionality? What do you think of the tamper evident seal itself?

- To what extent do you think this digital alert would be helpful? Why? In what scenarios?

- To what extent do you think this might influence the timing of when you'd log the dose? What are your thoughts on that?

Workflow Comparison

- How do the two workflows compare? Which do you prefer overall? Why?

- What stands out as the benefits and/ or tradeoffs of each?

- o [If not mentioned] How does the method of activating the label compare (capture QR code v. tap NFC tag)? Which method do you prefer? Why? To what extent is this important to you?

- o [If not mentioned] How does the method of entering the dose data compare (manual entry/ photo v. autofill)? Which method do you prefer? Why? To what extent is this important to you?

- o [If not mentioned] Only Workflow N can enable tracking of redundant entries (preventing one from using/ logging the same autoinjector twice). To what extent is this valuable/ important to you? Why?

- o [If not mentioned] Only Workflow N can enable the use of the tamper evident seal (preventing one from using/ logging an autoinjector that may have been tampered with). To what extent is this valuable/ important to you? Why?

- Do you have any concerns with either workflow?

- Is either workflow considered unacceptable?

4. Feature Menu (10 min)

Now I'd like to show you a few additional features and get your thoughts on them.

Moderator will prompt participant to click on menu in upper left corner of screen, which reveals list of features. Participant will be encouraged to explore those of interest to them; as such the order in which features are discussed will be participant-directed.

Reminders

Here you can set a reminder for your injection, such that you'll receive a notification on your phone reminding you to take your medicine on the day/ time its required.

- What do you think of this?

- To what extent do you think this feature would be helpful? Why?

  - o Do you think you would use it? Why or why not? In what scenarios?

RX Refill

Here you can see when you are due for your next refill. It might link with your pharmacy such that you can see how many refills remain and confirms orders.

- What do you think of this?

- To what extent do you think this feature would be helpful? Why?

- o Do you think you would use it? Why or why not? In what scenarios?
- What if it only communicated when you are due for your next refill, but didn't link with your pharmacy. Would this still prove valuable to you? Why or why not?

Symptom Tracker

The symptom tracker allows you to track how you are feeling each day. It might have a scale of 1-5 and/ or a means to flag particular days with specific notes.

- What do you think of this?
- To what extent do you think this feature would be helpful? Why?
  - o Do you think you would use it? Why or why not? In what scenarios?
  - o What, if any, notes would you imagine including? Why?

My Care Team

This feature allows you to share your symptom tracking and injection history (i.e., logged doses) with doctors and family members.

- What do you think of this?
- To what extent do you think this feature would be helpful? Why?
  - o Do you think you would use it? Why or why not? In what scenarios?

Community

This feature allows you to connect with others who might share similar experiences surrounding your treatment/ condition.

- What do you think of this?
- To what extent do you think this feature would be helpful? Why?
  - o Do you think you would use it? Why or why not? In what scenarios?

Overall

- What do you think of the features overall?
- Which, if any, stand out as helpful/ positive? Why?
- Would the inclusion of any of these features make the system more compelling to use?

5. Wrap-Up (5 min)

Now that you've had a chance to see and use the app, I'd like to ask again some of the questions surrounding how, if at all, you

would envision using it and understand the extent to which any of your initial opinions or expectations may have changed.

- In summary, what do you think of this concept overall?
- What do you see as potential benefits of using the concept?
- What do you see as potential challenges?
- Would you feel confident using this? *(Probe on both workflows)* Why/Why not?
- Is there anything else you'd like to share with us today?