Human Factors for a Closed-Loop Insulin Delivery System: A Review of Remote Methods for Assessing the Usability of the Tidepool Loop Mobile Application

Jierui Fang, Kelly Watson, Matt Lumpkin, Brooke Matthews.

TIDEPOOL

Introduction

Remote usability testing in software development has prompted increased interest in its application to mobile medical device human factors, accelerated by Covid-19. Remote testing widens recruitment to provide a better representation of the intended use population and more realistic assessment in participants' everyday use environments. The objective was to assess remote methods utilized in Tidepool's human factors studies of Tidepool Loop, an iOS application for automated insulin dosing.

Methods

112 test sessions included participants of mixed age, gender, caregiving responsibility, device experience and geographic location assessed in simulated use scenarios. During formative studies, participants were tested on a webview of the digital prototyping software (Figma) and associated software allowing analytics tracking (Maze). During the validation study, participants who lacked devices required were shipped a preloaded and configured study device. Participants who had necessary iOS equipment, downloaded Participate (by the usability testing platform, Lookback) from the App Store. Dual-camera setup allowed moderating in Lookback from the iPhone with Zoom teleconferencing platform serving as a secondary camera on the computer.

References: McLaughlin, Anne Collins et al. "Evaluating Medical Devices Remotely: Current Methods and Potential Innovations." Human factors vol. 62,7 (2020): 1041-1060. doi:10.1177/0018720820953644
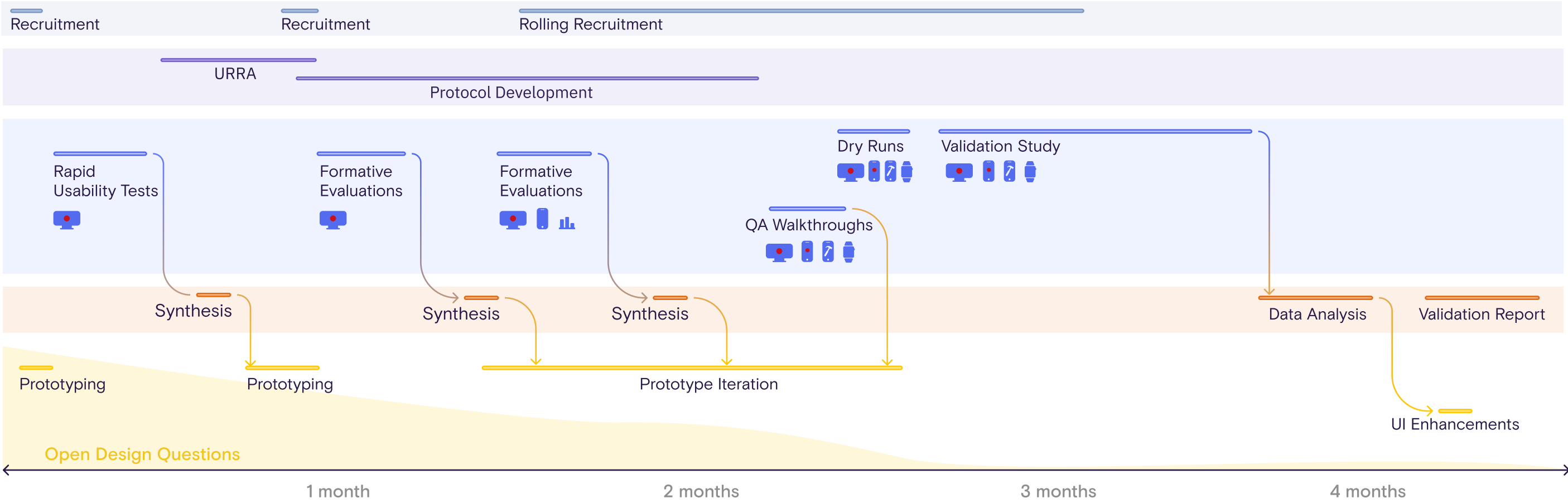
Figure 1. Parallel workstreams and different testing configurations led to progressively higher fidelity evaluations in the run up to the validation study.
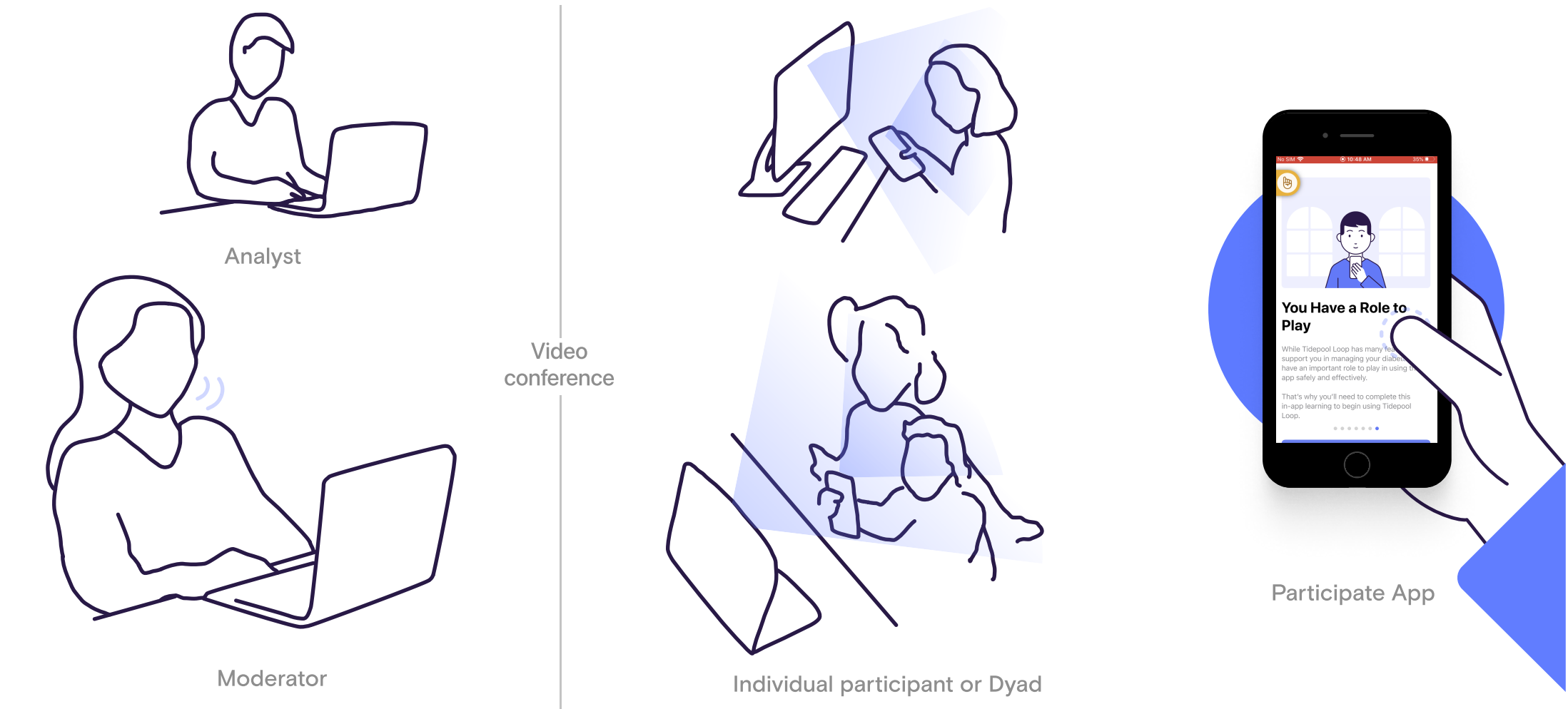

Figure 2. The validation study configuration setup on Tidepool's end (left) and the participant's end (right). Dual camera view from the iPhone front-facing camera and video conferencing web camera, as well as tap interaction recording, allowed for realistic and detailed study conduct.

Conclusion

The software and study protocol enabled recording of participants from multiple perspectives in intended use environments, recording tap gestures, tagging saved video, and unobtrusive, live communication between moderators and data analysts.

The formative and validation studies leveraged a combination of Figma, Lookback, Zoom, TestFlight, and mobile device management software to assess the usability of Tidepool Loop, a product in development submitted to the FDA in December 2020. Tidepool was able to interact with geographically diverse participants in their intended use environment while realistically simulating use on native mobile devices. The benefits of decentralized, remote human factors research suggest further exploration of this framework is appropriate.