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Carly Daley PhD

Shauna Wagner BSN, RN

Ryan Ahmed MS

Romisa Rohani Ghahari PhD

Tammy Toscos PhD

See next page for additional authors

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Authors

Carly Daley PhD; Shauna Wagner BSN, RN; Ryan Ahmed MS; Romisa Rohani Ghahari PhD; Tammy Toscos PhD; and Michael Mirro MD, FACC, FHRS, FAHA

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Carly Daley PhD^a, Shauna Wagner BSN RN^a, Ryan Ahmed MS^a, Romisa Rohani Gharai PhD^a,
Tammy Toscos PhD^a, Michael Mirro MD, FACC, FHRS, FAHA^{a,b}

^aParkview Mirro Center for Research and Innovation, 10622 Parkview Plaza Drive, Fort Wayne
IN 46845

^bIndiana University Medical School, 340 West 10th Street, Indianapolis, IN 46202

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ABSTRACT

Background: Cardiac implantable electronic devices (CIEDs) are important life-saving and therapeutic devices for patients with heart failure with reduced ejection fraction (HFrEF). These devices capture a multitude of data, including factors that have potential to indicate worsening heart failure. Patients may be interested to monitor sensor data from their device as part of heart failure self-care, and are key stakeholders in designing visualizations and displays for interpretation of the data.

Objectives: The objective of this study was to explore the presentation of HF-related CIED sensor data in a small participatory design session with people who have HFrEF and CIEDs.

Methods: The 3-hour participatory design session took place at a mid-size, not-for-profit health system in the Midwestern United States. Participants were five adults who had HFrEF and cardiac synchronization therapy (CRT) devices. Activities included presentation and discussion of HF-sensor data across four levels of detail (“birds-eye view”, mini trend graph, detailed, and supporting information).

Results: Five themes emerged regarding information needs (3), benefits (1), and concerns (1) for displaying and monitoring CIED sensor data, as well as recommendations for displaying data at the various levels of detail.

Conclusions: The session revealed that there are information gaps to fill to transform raw CIED sensor data into displays that provide meaningful, contextual, and actionable information. Future work should be aimed toward closing these gaps in design sessions with patients and their health care providers to create displays that cultivate a shared understanding of CIED data.

Key Words: cardiac implantable electronic device, cardiac resynchronization therapy, heart failure with reduced ejection fraction, user-centered design, health monitoring

Abbreviations

CIED	Cardiac implantable electronic device
HFrEF	Heart failure with reduced ejection fraction
CRT	Cardiac resynchronization therapy
ICD	Implantable cardioverter-defibrillator
PM	Pacemaker
CRT-D	Cardiac resynchronization therapy - defibrillator
CRT-P	Cardiac resynchronization therapy - pacemaker

Introduction

Cardiovascular implantable electronic devices (CIEDs), namely implantable cardioverter defibrillators (ICDs) and pacemakers (PMs) that provide cardiac resynchronization therapy (CRT), are part of guideline directed medical therapy (GDMT) for heart failure with reduced ejection fraction (HFrEF).¹ These devices help protect patients who are at risk for sudden cardiac death by providing life-saving therapies, and cardiac resynchronization therapy can significantly improve symptoms of heart failure and ventricular function.²

There are factors which can indicate worsening heart failure leading up to hospitalization.^{3,4} CIEDs capture hundreds of data elements, including sensor data related to worsening heart failure. Device measurements show promise for indicating congestion and other predictors of heart failure decompensation, even before symptoms occur.^{5,6} Studies continue to leverage the remote monitoring technology to continuously measure diagnostics, namely patient activity (using accelerometry), heart rate variability, nocturnal heart rate, atrial and ventricular arrhythmias, and percent CRT pacing.⁵ However, a consistent, reliable indicator with high specificity and positive predictive value has yet to emerge from the research.^{5,7} Currently there are no clear guidelines for using CIED data to predict or manage worsening heart failure for patients with HFrEF.

Utilizing contextual information and patterns in the data at the individual level rather than the population level,⁸ may be a useful strategy as the different approaches to developing alerts, algorithms, and HF risk scores show inadequate sensitivity and specificity. It is important to leverage these data so that patients and clinicians have access to a visualization tool to help interpret the data, integrate contextual information, and make informed treatment decisions and timely adjustments to the device as well as daily self-care. Data visualization for patient symptoms have been shown to help report, monitor and understand symptoms and their relationships and trends with other data, as well as make decisions about treatment and facilitate communication.⁹

A recent trial explored sharing a dashboard with 10 participants with HFReEF and CRT-D devices over 6-11 months.¹⁰ The dashboard focused on percent LV pacing, included supplemental information, and was updated daily per the Biotronik Home Monitoring (automatic daily surveillance using a mobile wireless remote monitoring system; Biotronik SE & Co. KG, Berlin, Germany) transmissions. The dashboard was designed through focus groups and participatory design sessions before the trial.^{11,12} The study revealed that patients were interested in their data but wanted more information and tailoring to their needs.¹⁰ Participants in this trial were invited to enroll in a participatory design session following the trial.

The following report describes the methods and findings of the participatory design session. The objective of this participatory design session was to inform the design of a dashboard for self-monitoring, decision making, and follow-up treatment discussions with clinicians using feedback and input from patients on the presentation of HF-related CIED sensor data.

Methods

Design

This participatory design session involved presentation of educational materials, a dashboard prototype displaying HF-sensor data trends, and discussion about data trends. The session included prompts for participants, guiding questions and encouraged interaction among participants. The session also included poster boards and post-it notes to capture participants' feedback and ideas.

Setting and Participants

The session took place at a mid-size, not-for-profit health system in the Midwestern United States. Participants were recruited at the conclusion of a technology trial that provided remote monitoring data to patients with CRT devices in a patient-centered digital dashboard.¹⁰ The participants in this trial were adults (>18) with a history of HF_rEF and cardiac resynchronization therapy defibrillator (CRT-D) or cardiac resynchronization therapy pacemaker (CRT-P), who used Biotronik Home Monitoring. Those who agreed to be contacted for the session were recruited for the session. The study was approved by the hospital Institutional Review Board and participants were consented prior to participation. Participants were given a \$40 ClinCard® for their participation.

Procedure

Seven researchers assisted with the session: A lead moderator, (usability expert), a second moderator (research scientist), two facilitators who were clinicians (an electrophysiologist with over 30 years of experience and a cardiology nurse of over 15 years), and three researchers who observed, took notes, and helped with the post-it notes and poster

boards. The electrophysiologist provided additional education regarding the HF-related sensor data and answered specific questions from the group, and the cardiology nurse answered clinical questions from the group throughout the entire session.

The session began with introductions, ground rules for the discussion, and presentation of educational information about heart failure and CIED data. For the main activity, the lead moderator presented a screen with the trend graphs of HF-sensor data (See Figure 1). In addition to the 5-week LV Pacing trend tracked during the technology trial (Toscos et al 2020), the participants were presented with a mock visualization of HF-sensor data including the following: Nocturnal Heart Rate, Thoracic Impedance, Heart Rate Variability, Patient Activity and Bi-V Pacing. Following an explanation of the data, discussions centered around usefulness of the data, visualization, and presentation.

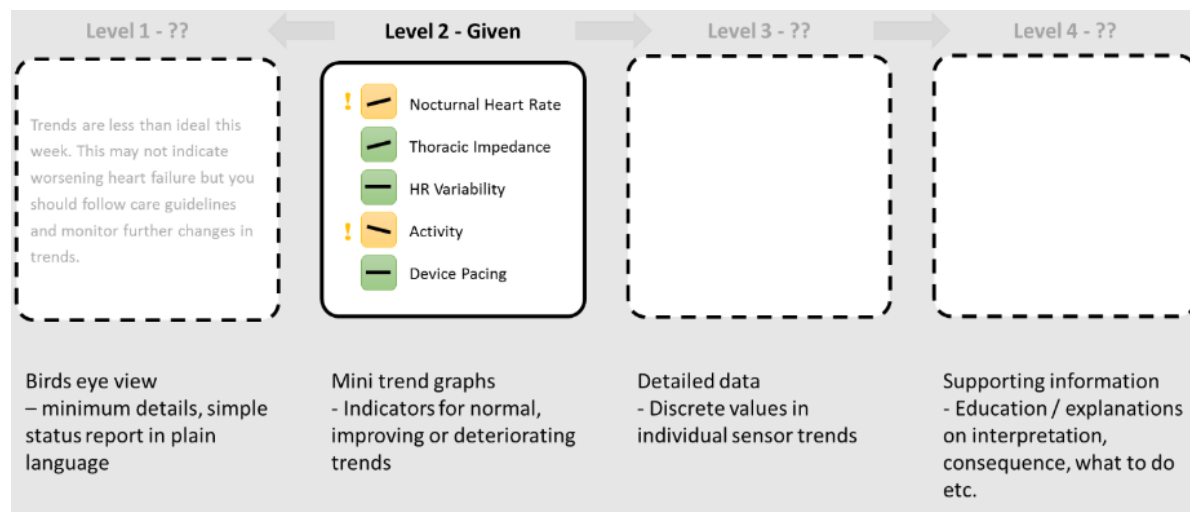


Figure 1. Presentation of the different possible levels of views of data and mini-trend graphs that were presented at the session

The screen included four “levels” of data; 1) ‘Birds-eye view’, 2) Mini trend graphs, 3) Detailed data, and 4) Supporting information. The discussion began with Level 2 (Mini trend graphs). The next part of the discussion was focused on what additional details they would want

to see alongside this view (Level 3) followed by what supporting information is needed (Level 4). Finally, participants were asked about a bird's eye view (Level 1) that they would like to see as a concise summary format. The entire session lasted approximately three hours.

Data collection and analysis

The participants were given materials (pens and post-it notes) and prompted to write down their ideas. The post-it notes were aggregated on poster boards at the front of the room (See Figure 2). The session was audio and video recorded and transcribed verbatim.

The transcript was analyzed to elicit themes related to monitoring CRT data, as well as to distill feedback to inform design considerations for the different views. Three team members (UX specialist, research scientist, and clinical research nurse project lead) reviewed the transcript individually and then met to discuss interpretations as a group. The interpretations were synthesized into broader themes that are presented in the results section. For the design considerations, two team members (UX specialist and research scientist) coded content related to requirements for displaying the data trends in a dashboard for the different levels of data presented during the session (1. Bird's Eye View (Essential Summary), 2. Mini Trend Graphs, 3. Detailed Data, 4. Supporting Information and 5. Other Notes, Suggestions and Points for Further Exploration). The design considerations reflect feedback mentioned during the session and do not consider recurrent themes or popular voting.

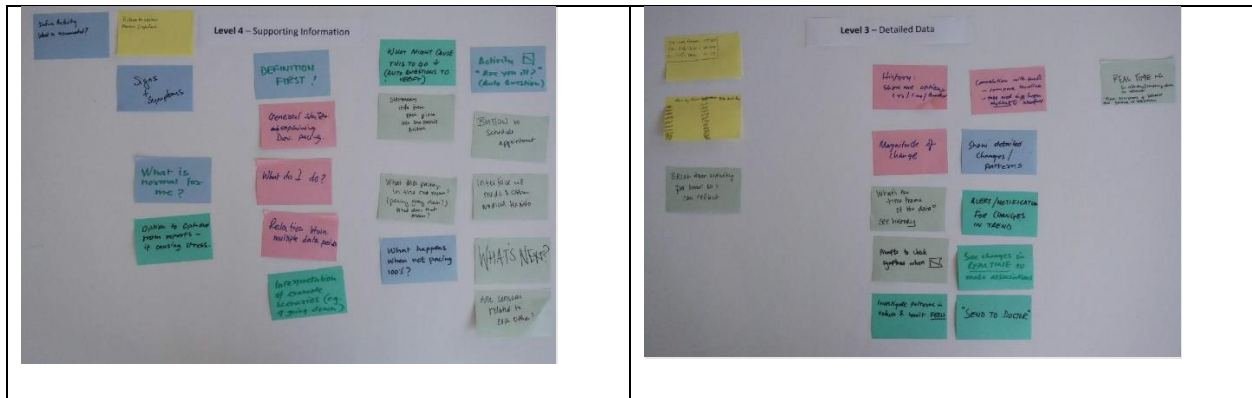


Figure 2. Photographs of the comments that were collected, including comments written by participants as well as observers recording what participants said.

Results

The session included five participants: 4 male, 1 female, all were white, ranging in age from 35-81, with CRT devices. Several themes emerged during the session related to participants responses as they explored CRT sensor data with clinician experts and discussed a hypothetical dashboard display.

More explanation about the CRT data would be helpful

Overall, participants discussed that the data require more explanation for them to be able to understand, and they had different suggestions for how to provide explanation. Suggestions included a cheat sheet to explain what thoracic impedance is, maybe a picture, and a list of signs and symptoms, or an acronym to help remember these things. One participant asked if there could be a course for patients, early after implant, to help with learning about the data. Specific questions about the data themselves included straightforward questions, such as “what is *activity* referring to? Activity of the device?” (P3) and more complex questions, such as the following question related to thoracic impedance “how does the device know what is causing whatever (thoracic impedance)?” (P5).

An understanding of the relationships between CRT data and other health data would be useful

Participants expressed that it would be helpful to know what can impact the thoracic impedance level that is indirectly related, such as bronchitis, or the connection between nocturnal heart rate and sleep apnea. Given the complexity of the data, P1 suggested having a summary that packages all the data elements into an overview of what is going on, and what is next (what to expect or what to do about it). Additionally, P1 suggested having all the different combinations of data and what they could mean.

In light of the complexity of the data, having dependable interpretations and knowing what to do based on the data would be helpful

Although some participants wanted to have explanations for what to do when there is an “abnormal” result, participants also expressed awareness of the complexity of data and that context is important. For some participants, it would be ideal to have instructions or explanations for what the data (or certain combinations of data) mean. One participant asked if “there is a general statement out there that describes device pacing and the implications of it going up and down” (P2). Upon hearing an explanation that there are different factors that impact the pacing, P2 stated : “you really couldn’t have what I said, a general statement, because everybody’s going to be different... it’s an indication of me, but it’s not everybody here. It could mean a little bit something different for everybody else.” (P2). Another participant asked about nocturnal heart rate and had questions about what a normal nocturnal heart rate would be.

In addition to desiring consistent explanations of what the data mean, the findings suggest that patients want to use their interpretations of the data to inform them of what to do next. For

example, one participant expressed that they would like to see the impact of their actions: I can look at (the data) and say, okay, every time I do this activity, this is what happens... If I don't do the activity, is it going to happen and it doesn't... at my next doctor appointment I can tell him" (P5). Another participant envisioned "being able to track could be positive reinforcement or helping see what I can do better" (P3).

Personal engagement with the data is an important part of monitoring for one's health

Participants expressed awareness that they are the most connected with their bodies, and therefore can monitor the data and make assessments in a way that no one else can. As such, it would be helpful to monitor data in a way that includes contextual factors, such correlating stress to changes in heart rate. Further, a few people talked about being able to check their data and correlate it with what is happening at the time. Or, having an easier way to correlate and track data, such as heart rate and activity, with life events when reviewing the data. A couple people expressed that continuous, or real-time, data monitoring would be helpful. As one participant stated, being able to relate to one's own CRT data for health-related decision making is important, because "nobody cares more about me than me" (P2). Access to the data can serve as a communication tool where the patient is at the center of care and can provide context to providers and point out changes in the data so that clinicians can make appropriate adjustments, rather than only monitoring in the clinic for "red flags."

Monitoring CRT data has the potential to be misleading and create worry or anxiety

Participants raised concerns from their experience in the technology trial about how the data were misleading or were not changing or providing any useful information. For example, one participant shared that during the time period, their pacing value remained at 100%, and the

participant wondered “how hard the device is working compared to how well their heart was running” (P3). The participant was discouraged to find out that their EF value did not improve during this time, even though the pacing was always 100%. A couple other participants did not feel that the data was informative, so they stopped looking at their data. One person stated that they would prefer having a notification sent once per week, or if anything changed. Conversely, another person explained that if they receive information and don’t know what it means, they could become worried and end up unnecessarily going to the ER (P1).

Discussion

The findings from the session suggest that people who have cardiac implantable electronic devices and are interested in monitoring their data require more information and context to be able to understand their data, as well as support with monitoring their data so they can learn what it means for them, personally. Health data tracking has advantages and disadvantages, as demonstrated by the experiences of people who monitor their health data using wearable devices. For example, self-monitoring devices such as smartwatches may help with tracking atrial fibrillation, however doing so can increase anxiety, as fear and uncertainty can lead to hyper-vigilant behavior.¹³ Further, self-monitoring can improve timeliness for follow up for medical conditions, however there is a risk of misinterpretation of data that could lead to inappropriate action.¹⁴

It is important to use a user-centered design (UCD) process to ensure that data are presented in a way that do not create confusion for patients.^{10,15} In the domain of CIEDs, patients have expressed interest in receiving more detailed information from remote monitoring of their device.¹⁶ Conversely, some people would rather have less information unless something needs

attention.¹⁷ Interpretation of CIED data requires taking multiple factors into consideration, making it difficult to simply share the data from remote monitoring without multiple layers of context. Further, the complexity of CIED data may require a level of comfortability with the uncertainty, which is perhaps more accessible for some people than others.¹⁸

Engaging with health data can be an important part of self-care. For example, among 872 patients who provided data on a survey about their use of an OpenNotes portal, 83% thought that being able to read their notes improved their self-care and it did not increase their anxiety.¹⁹ Research with the OpenNotes initiative supports the idea that access to notes facilitates understanding and helps build a stronger relationship between patients and clinicians.²⁰ Thus, for those who are interested in monitoring their device data, an increase in digital transparency may help people engage with their data, build understanding, and over time, strengthen their ability to make meaning of the data. The themes that emerged from the focus group reinforces the need to strengthen communication between patients and clinicians about the device data, so they can cultivate a shared understanding of what the data mean by including clinicians' medical expertise and patient experiential knowledge.

The findings from the session also contributed to a set of design considerations for presentation of the CIED sensor data for heart failure. The following list outlines the design considerations for the four levels of data that participants worked with in this session. A consideration across all four levels of data that requires further exploration is when to use technical terminology, and when to use simplified terms.

Design considerations for the four levels of data:

Level 1: Birds Eye View (Essential Summary)

- Briefly state what is going on and what is next.
- Include an action button for scheduling an appointment.

Level 2: Mini Trend Graphs (Starting point/provided)

- Include the definition of each data point (for example, click on the mini-trend graphic to pop up explanation)
- Clarify the meaning associated with the direction of trends; for example, a downward trend in nocturnal heart rate is desired, whereas for other measures, an upward trend is desired.

Level 3: Detailed Data

- Offer flexible timeline options for the historic view Historic view should offer flexible timeline options for 5 years / 1 year / 1 month such as stock market reports
- Include possible answers or ways to investigate what may have caused a change. For example, prompt “have you been ill?”
- Provide the “normal” range of values in a way that is personalized
- Provide what action to take when there is a change in the data
- Indicate the severity of the change in data
- Indicate if there is any connection or correlation between the changing sensors when multiple sensors change.
- Outline an action plan
- Compare actions (changes in meds, exercise etc.) with sensor trends, over time.
- Offer ability to relate data with experiences within the same timeframe, e.g., unusual feeling, in the middle of an activity, with option to share with doctor.
- Provide the option for a snapshot of a timeframe with note to share with doctor or on MyChart especially when symptomatic.
- Allow the ability to opt out from specific data or entire dashboard.
- Send a notification only when data or trend is abnormal.

Level 4: Supporting Information

- Explain what causes the device to not pace at 100%, and what it means when the device is pacing less than 100% in terms of how the heart is working
- Provide information about other conditions / comorbidities that can influence the values, e.g., sleep apnea influencing nocturnal heart rate, kidney failure impacting thoracic impedance.
- Include pictures / visuals to go with definitions and explanations.
- List expected signs and symptoms for changes in values / trend.

Conclusion

Some people who have CIEDs, including the five participants in this participatory design session, have a desire to receive more information about their device data and be able to perform some degree of monitoring of their device data as part of their health-related decision making. As the session revealed, there is much work to be done with patients who have CIEDs and clinician experts who are trained to understand what the data mean in order to create data visualizations that are meaningful to both patients and clinicians. This participatory design session highlighted key areas where further investigation is needed to support effective and accurate interpretation of the data. Future work should include engaging clinicians and patients in design research aimed toward cultivating a shared understanding of CIED data as it relates to self-care and health-related decision making.

References

1. Maddox TM, Januzzi Jr JL, Allen LA, et al. 2021 update to the 2017 ACC expert consensus decision pathway for optimization of heart failure treatment: answers to 10 pivotal issues about heart failure with reduced ejection fraction: a report of the American College of Cardiology Solution Set Oversight Committee. *Journal of the American College of Cardiology*. 2021 Feb 16;77(6):772-810.
2. Aranda JM, Woo GW, Schofield RS, et al. Management of heart failure after cardiac resynchronization therapy: integrating advanced heart failure treatment with optimal device function. *Journal of the American College of Cardiology*. 2005 Dec 20;46(12):2193-8.
3. Bennett SJ, Huster GA, Baker SL and Milgrom LB. Characterization of the precipitants of hospitalization for heart failure decompensation. *American Journal of Critical Care*. 1998;7:168.

4. Ouwerkerk W, Voors AA, and Zwinderman AH. Factors influencing the predictive power of models for predicting mortality and/or heart failure hospitalization in patients with heart failure. *Journal of the American College of Cardiology: Heart Failure*. 2014;2:429-436.
5. Hawkins NM, Virani SA, Sperrin M, et al. Predicting heart failure decompensation using cardiac implantable electronic devices: a review of practices and challenges. *European Journal of Heart Failure*. 2016;18:977-986.
6. Braunschweig F. Therapeutic and diagnostic role of electrical devices in acute heart failure. *Heart Failure Reviews*. 2007;12:157-166.
7. Blair TL. Device diagnostics and early identification of acute decompensated heart failure: a systematic review. *Journal of Cardiovascular Nursing*. 2014;29:68-81.
8. Maier SK, Paule, S. Jung, W, et al. Evaluation of thoracic impedance trends for implant-based remote monitoring in heart failure patients-Results from the (J-) HomeCARE-II Study. *Journal of Electrocardiology*. 2019;53:100-108.
9. Lor M, Koleck TA , and Bakken S. Information visualizations of symptom information for patients and providers: a systematic review. *Journal of the American Medical Informatics Association*. 2018;26:162-171.
10. Toscos T, Daley C, Wagner S, et al. Patient responses to daily cardiac resynchronization therapy device data: A pilot trial assessing a novel patient-centered digital dashboard in everyday life. *Cardiovascular Digital Health Journal*. 2020 Sep 1;1(2):97-106.
11. Ghahari RR, Holden RJ, Flanagan ME, et al. Using cardiac implantable electronic device data to facilitate health decision making: a design study. *International Journal of Industrial Ergonomics*. 2018 Mar 1;64:143-54.

12. Ahmed R, Toscos T, Ghahari RR, et al. Visualization of cardiac implantable electronic device data for older adults using participatory design. *Applied Clinical Informatics*. 2019 Aug;10(04):707-18.
13. Rosman L, Gehi A, and Lampert R. When smartwatches contribute to health anxiety in patients with atrial fibrillation. *Cardiovascular Digital Health Journal*. 2020 Jul;1(1):9.
14. Sobrinho A, da Silva LD, Perkusich A, et al. Design and evaluation of a mobile application to assist the self-monitoring of the chronic kidney disease in developing countries. *BMC Medical Informatics and Decision Making*. 2018 Dec;18(1):1-4.
15. Cornet VP, Toscos T, Bolchini D, et al. Untold stories in user-centered design of mobile health: Practical challenges and strategies learned from the design and evaluation of an app for older adults with heart failure. *Journal of Medical Internet Research: mHealth and uHealth*. 2020 Jul 21;8(7):e17703.
16. Petersen HH, Larsen MC, Nielsen OW, et al. Patient satisfaction and suggestions for improvement of remote ICD monitoring. *Journal of Interventional Cardiac Electrophysiology*. 2012 Sep;34(3):317-24.
17. Skov MB, Johansen PG, Skov CS, and Lauberg A. No news is good news: remote monitoring of implantable cardioverter-defibrillator patients. In *Proceedings of the 33rd annual ACM Conference on Human Factors in Computing Systems 2015* Apr 18 (pp. 827-836).
18. Daley C, Cornet V, Patekar G, et al. Uncertainty management among older adults with heart failure: responses to receiving implanted device data using a fictitious scenario interview method. In *Proceedings of the International Symposium on Human Factors and Ergonomics*

in Health Care 2019 Sep (Vol. 8, No. 1, pp. 127-130). Sage CA: Los Angeles, CA: SAGE Publications.

19. Mishra VK, Hoyt RE, Wolver SE, et al. Qualitative and quantitative analysis of patients' perceptions of the patient portal experience with OpenNotes. *Applied Clinical Informatics*. 2019 Jan;10(01):010-8.
20. Bell SK, Mejilla R, Anselmo M, et al. When doctors share visit notes with patients: a study of patient and doctor perceptions of documentation errors, safety opportunities and the patient–doctor relationship. *BMJ Quality & Safety*. 2017 Apr 1;26(4):262-70.