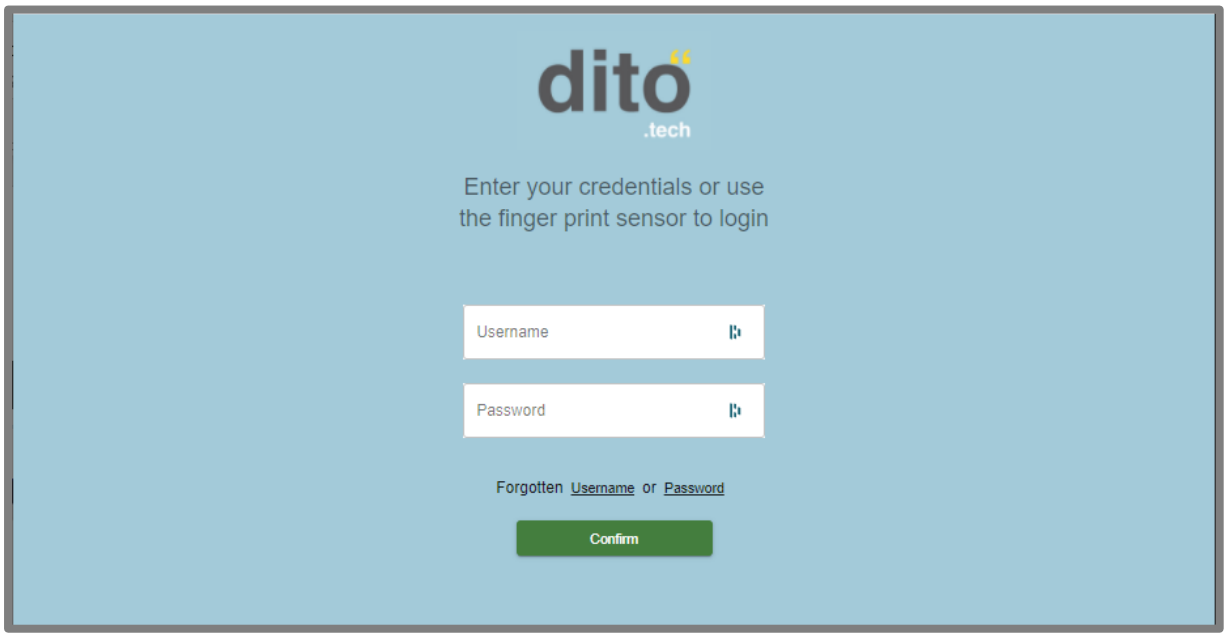
eREACT V2: Usability testing results



Project: Develop in the Open: Sustainable digital health-tech enabling transformed patient care

Version: 1.0

Date: 31st March 2021

Authors: Nikki Holliday MSc (corresponding author), Laura Wilde MSc, Dr. Kim Bul, Professor John Allen

Coventry University

dito .tech

Contents

Introduction

Many patients still experience sub-optimal care leading to adverse outcomes such as unplanned Intensive Care Unit admission, emergency surgery, cardiac arrest, and death. For example, in the UK an estimated 7% of in-hospital deaths may be preventable (NCEPOD, 2007). Collation of patient vital sign data aims to alert clinical staff to early signs of the deteriorating patient. This can facilitate prompt escalation of care to medical staff and, where appropriate, early escalation for critical care referral, for example, with patients at risk of sepsis, early recognition is important to reduce avoidable deaths (NICE, 2017). Traditionally, paper-based methods have been used to collect such data and are still used today, for example, use of the National Early Warning Score (known as NEWS2) in the United Kingdom (Royal College of Physicians, 2017). However, there are shortcomings with paper observations, such as the time it can take to complete paper forms, errors in calculations, omission of data, illegible handwriting (Aakre et al., 2017; Subbe et al., 2007; Wilson et al., 2013), storage and version control, and the difficulty of sharing data amongst clinical staff (Anton & Anton, 2016). Further to this, the sharing of paper-based data between healthcare professionals may constitute an information governance issue if misplaced. There is evidence emerging that when implemented correctly, the use of digital vital signs data, otherwise known as eObservations (eObs) may save clinicians' time, improve completeness of observations, reduce unplanned intensive care admissions and cardiac arrests (NICE, 2020; Pimentel et al., 2019; Wong et al., 2017). However, existing eObs solutions, whilst providing solutions to the problems inherent in paper charts, have shortcomings and thus barriers of their own. Many of these systems are proprietary, leading to vendor lock-in and expensive contracts (Ash et al., 2015), poor training and ongoing support for training (Ash et al., 2015; Nguyen et al., 2014) and lack of support for local configuration of systems (Cresswell et al., 2014; Krousel-Wood et al., 2018). Systems may also increase clinical workload (Cresswell et al., 2014; Nguyen et al., 2014; Perry et al., 2014; Tsoukalas et al., 2015), not always increase data quality over paper observations (Nguyen et al., 2014; Wilbanks et al., 2018), a lack of open standards can prohibit further learning and research (Kopanitsa, 2017; Legaz-García et al., 2016), no options to record narrative input or detail parent or clinician worry (Bansler et al., 2016; Jamieson et al., 2017; Kossman et al., 2013), lengthy log-in and log-out times (Adelman et al., 2017; Cresswell et al., 2014; Kossman et al., 2013), alert fatigue (Benthin et al., 2016; Finkel & Galvin, 2017; Manaktala & Claypool, 2017; Miller et al., 2015; Slovis et al., 2017), poor existing hardware infrastructure (Alsohime et al., 2019; Cresswell et al., 2014; Larsen et al., 2018; Nguyen et al., 2014), and poor or no interoperability with other systems (Dalal et al., 2016; Nguyen et al., 2014; Skyttberg et al., 2016). These barriers may lead to non-advocated workarounds for efficiency; however many of these workarounds may be dangerous, and may affect accuracy of auditing as systems do not reflect what actually happened in a particular setting (Adelman et al., 2017; Ash et al., 2015; Blijleven et al., 2017; Cresswell et al., 2014; Kossman et al., 2013; Lee et al., 2017; Slight et al., 2016).

It is argued that many of the barriers to effective use of EHRs described above can be tackled using Open Source Software (OSS), which due to the open nature of the source code, may support the development of innovative software solutions in healthcare adapted to the local healthcare context (Lundell et al., 2011) at a lower cost (Boehm, 2019). An open approach may also ensure quality of code, allaying fears some may have, arguably unfairly, of OSS being a 'wild west' (Kendall et al., 2016), due to the Open Source community being able to inspect, fix and improve the code, leading to fewer bugs and errors that would be less likely to come to light in the proprietary world (Lundell et al., 2011). There are, however, also some documented barriers to the widespread use of OSS in the setting of EHRs, for example, procurement teams do not always consider Open Source systems, often due to a

lack of understanding, and concern around liabilities, security and safety (Dixon et al., 2013; Finkel & Galvin, 2017; Ratwani et al., 2016). The InnovateUK funded the 'Develop in the Open (Dito)' project aimed to support the improvement of patient outcomes and reduce clinicians' workload by developing a new software prototype patient observation application using open standards and interoperability, collaboratively and iteratively with key stakeholders including doctors, nurses, patients, researchers, designers and OSS specialists. The prototype eObs application is called eREACT V2. This report describes the results of the usability testing aspect of the project, as part of the Clinical Development work-package. The study described in this report aimed to explore perceived usability and acceptability of the eREACT V2 eObs prototype application with a range of clinical staff via a think-aloud evaluation incorporating an online cognitive walk-through methodology (Beer et al., 1997; Lewis & Rieman, 1994), to ensure the prototype was optimised with regards end-user needs (Bradbury et al., 2019).

Original planned methodology – using the 'simulated living lab'

Prior to the COVID-19 outbreak, the eREACT V2 application was intended to be usability tested via a simulated living lab methodology. Living labs can be described as "a network that integrates both user-centred research and open innovation… in which companies team up with diverse types of partners and users to generate new products, services and technologies" (Leminen et al., 2012). Many universities now have access to medical simulation environments, traditionally used effectively for the teaching of health and care students (Beal et al., 2017), but can also, with little to no redesign be used as a "utilizer-driven living lab" (Leminen et al., 2012), allowing for new health technologies to be tested to support product and business development with no risk to patients. Controlled trials can be used to test the effectiveness of new technologies on patient outcomes, however are a costly and inappropriate way to identify usability issues, and there is risk of causing harm to patients via the use of untested software (Metelmann & Metelmann, 2016). Therefore, other methods are key to establishing the usability and likely acceptance of health technologies prior to embarking upon the traditional randomised control trial standard of evidence (Sieverink et al., 2017). Exploring usability in real-life ward settings also risks interrupting patient care (Dahl et al., 2010). The use of simulated living labs therefore ensures functionality and usability issues are identified and resolved in setting with high ecological validity prior to testing the clinical utility of the technology in a trial setting (Metelmann & Metelmann, 2016), and also allows for video recording of the simulation without compromising patient confidentially (Dahl et al., 2010; Jensen et al., 2012). The data collected can be rich and informative, despite the relatively intense timespan compared to traditional trials (Jensen et al., 2012). Higher ecological validity in a simulation setting also means that simulation results are more generalisable to the eventual trial or clinical context, due to the realism of the setting (Kushniruk et al., 2013).

Coventry University has a new state of the art Healthcare Simulation Area[1], which was designed with the key philosophy to function as a safe learning environment for students to practise their technical and non-technical skills in an environment that is as close to reality as possible. One of the key aspects in the design of the building was the ability to follow "the patient journey" from point of illness or injury through acute care to rehabilitation and recovery. The building therefore contains a mock ambulance (ambulance body), two four-bed wards, two high-dependency unit (HDU) rooms, midwifery area, and an operating theatre. The dimensions of bed spaces and the equipment (e.g., patient call systems,

[1] *https://www.coventry.ac.uk/study-at-coventry/faculties-and-schools/health-and-life-sciences/alison-gingell-building/patient-pathway-simulation/*

simulated medical gas system) are based on UK hospital standards. Patients are simulated using high-fidelity patient simulators (e.g., SimMan 3G, and MetiMan). Each bed space in the ward and HDU is equipped with one pan-tilt-zoom and one fixed-view camera, linked to a control room and the University's web-based capture system. This allows livestreaming of footage as well as recording to allow for data collection and later transcription, coding and data analysis. It is this environment in which the researchers planned to test to the eREACT V2 application. When developing a simulation to use within a living lab, it is important that it is designed with the following concepts in mind (Rehmann et al., 1995):

1. Equipment fidelity – does the simulation replicate the appearance and feel of the real system?

2. Environmental fidelity – are environmental factors of the real-life environment replicated, (e.g., visual and auditory cues)?

3. Psychological fidelity – does the simulation feel real to the participants? Are they able to suspend their disbelief that that are in a simulator living lab?

This project, therefore, planned to use the Coventry University Healthcare Simulation Area as a simulated living lab to test initial iterations of the eREACT V2 eObs application with clinical staff. Medical scenarios with high psychological fidelity were developed by clinical project partners to allow testing of the application across the patient journey, to test usability and acceptability of the application with a variety of end-users, as well as to ensure correct calculation of NEWS2 scores and subsequent prompts for clinical actions. Unfortunately, due to the COVD-19 pandemic situation from early 2020, it became no longer feasible to conduct face-to-face simulation testing.

COVID-19 Methodology – online 'think-aloud' usability testing

The usability testing aimed to explore perceived usability and acceptability of the eREACT V2 eObs application with a range of clinical staff via an online (therefore COVID secure) think-aloud evaluation incorporating a cognitive walk-through methodology (Beer et al., 1997; Lewis & Rieman, 1994), to ensure the prototype was optimised with regards to end-user needs (Bradbury et al., 2019). Participants were asked to 'think aloud' whilst completing tasks related to functionality, usability, intentions and problem-solving to identify problem areas within the prototype to inform recommendations for improvements to enhance the prototypes acceptability.

Ethical approval for the study was given by the Coventry University Ethics Committee (Reference: P113270) and local NHS Trust approval where appropriate. NHS Health Research Authority approval was not required as the study was not considered research as per NHS Health Research Authority Guidelines and did not take place in NHS Settings (NHS Health Research Authority, 2017). Informed consent was obtained from all participants who were assured of their rights of anonymity, confidentiality and their freedom to withdraw from the study up to the point of data analysis without giving a reason.

Prototype development

A front-end web application prototype of the eREACT V2 application was developed by OpusVL and UXCentric. The prototype was informed by previous research activities in the project including a scoping literature review and a co-creation workshop with nurses (results reported elsewhere, academic publications in preparation), as well as a series of expert meetings with clinical staff working as partners on the project. The medium-fidelity prototype stored only fictitious patient data and replicated the functionality of the intended end product

as much as possible, to allow participants to perform key patient observation tasks to assess the usability and acceptability of the application.

Participants and recruitment

Eleven healthcare practitioner participants from across the UK were recruited to the think-aloud usability testing using purposive sampling. This involved gatekeepers sending out email invitations to potential participants, and those who were interested in taking part were asked to contact the researchers. Eleven potential participants at Cheshire and Wirral Partnership Trust were identified by the gatekeeper as suitable to take part. All of these potential participants expressed an interest to contribute to the research, and ten of these actually participated in the study. The one participant who did not take part was unable to due to a problem sourcing a device for her. Four participants were recruited through Coventry University. Potential participants were then provided with a Participant Information Sheet and the given the opportunity to ask questions. Participants provided consent via a secure digital form, hosted via Qualtrics. The clinical staff who took part represented a range of roles who would be expected to interact with an eObs system and included Clinical Support Workers (n=2), Nurses (n=6), Doctors (n=2) and a Clinical Training Manager (n=1). Participants had a variety of experience with paper and digital Obs systems (see Table 1). A range of platforms were tested to assess usability. Participants were provided with the devices by the project, except in the case of the first three participants who pilot tested the methodology and application using laptops.

Participant	**Role overview**	**Obs experience**	**Tablet/computer device for testing**
1	Nurse	Paper only	PC laptop
2	Nurse	Paper and digital	PC laptop
3	Nurse	Paper only	PC laptop
4	Nurse	Paper only	iPad
5	Clinical Support Worker	Paper only	Samsung tablet
6	Consultant Nurse	Paper only	iPad mini
7	Clinical Support Worker	Paper only	Samsung tablet
8	Doctor	Mostly paper	Samsung tablet
9	Clinical Training Manager	Paper and digital	iPad
10	Nurse	Paper and digital	Samsung tablet
11	Doctor	Paper and digital	iPad

Table 1: Participant Characteristics

Procedure

Clinicians were invited to take part in an online think-aloud study, hosted via Microsoft Teams. Participants were given a link to the prototype eREACT V2 application and were asked to share their screen with the researcher whilst using the prototype. Participants were asked to think aloud whilst they completed key tasks inherent to the application including: finding and sorting patients, viewing and interpreting graphs and tables, entering patient observations and interpreting the NEWS2 scores, and running a sepsis screening. As the software has been designed for use with little to no training, the researcher asked participants to complete tasks with very little to no instruction (e.g., show me how you would search for the patient Joe William Doe). Further instructions were only provided to participants in the case where they could not complete a task. Following the think-aloud tasks, participants were also asked a series of semi-structured interview questions exploring

their views on the acceptability of eREACT V2, and its likely impact of clinician workload, patient safety, and suggestions regarding real-life implementation of the application. The online testing sessions were recorded via video (Microsoft Teams recording) and a separate audio recording via Dictaphone was made for the purposes of transcription. Each session lasted for approximately 1 hour. The audio recordings were deleted following transcription and the video recordings deleted following analysis.

Data analysis

Audio data from the online testing were transcribed verbatim and analysed using Thematic Analysis (Green & Thorogood, 2018). A collaborative analysis approached was used, where three researchers (NH, LW and KB) read, re-read and coded data before organising into overarching themes (Flick, 2014). Video recordings were used to support analysis to ensure the researchers were interpreting data related to the correct screen and task. Following analysis of participants 1-3, the eREACT V2 software was updated for testing with the remaining participants. Initial codes and preliminary themes were developed collaboratively following independent analysis of the first three participants. Changes to the codes, themes and subthemes were discussed again following independent coding of the remaining think-aloud sessions. Results presented in this report reflect that of the updated software tested with participants 4-11. Detailed analysis of the think-aloud with participants 1-3 and recommendations to software developers have been reported elsewhere, and a summary of these recommendations can be found in Appendix 1.

Results

Usability – Task by task

Overall, participants found eREACT V2 very easy to use and navigate, describing it as clear and intuitive.

> *I have a bit of an affinity for those things that are instinctive …because… when it's not instinctive, I find it all awkward… like when things don't sit where you'd expect them to sit, like an icon… So for my expectations on things like that I like to work with, this app works well for that." (Participant 5)*

> *"It's laid out in a relatively intuitive way and the bits that I wouldn't necessarily know straight away they're very easy to learn, they're things that I'd only need to be shown once and then I'd know." (Participant 8)*

> *"I just think it's really clear" (Participant 9)*

Participants found the Patient List screen straightforward and clear, and liked the presentation of the first screen within the application.

> *"Yeah, so you've got the different patients, search name, NHS number, so the idea is that if you search in the search box so you can search for any patient with any NHS number. Yeah …that seems straightforward." (Participant 4)*

One participant noted how it was preferable to log-in and be presented with the patient list straight away – unlike other digital applications which may require a number of 'clicks' to access a patient list

"That's great. And a lot of software you're greeted by a sort of search for patients aren't you? You've got to do a few clicks to get into like your own patient lists so that'd be very handy if it just sort of automatically went straight into your sort of cohort." (Participant 8)

Task: Search for patient

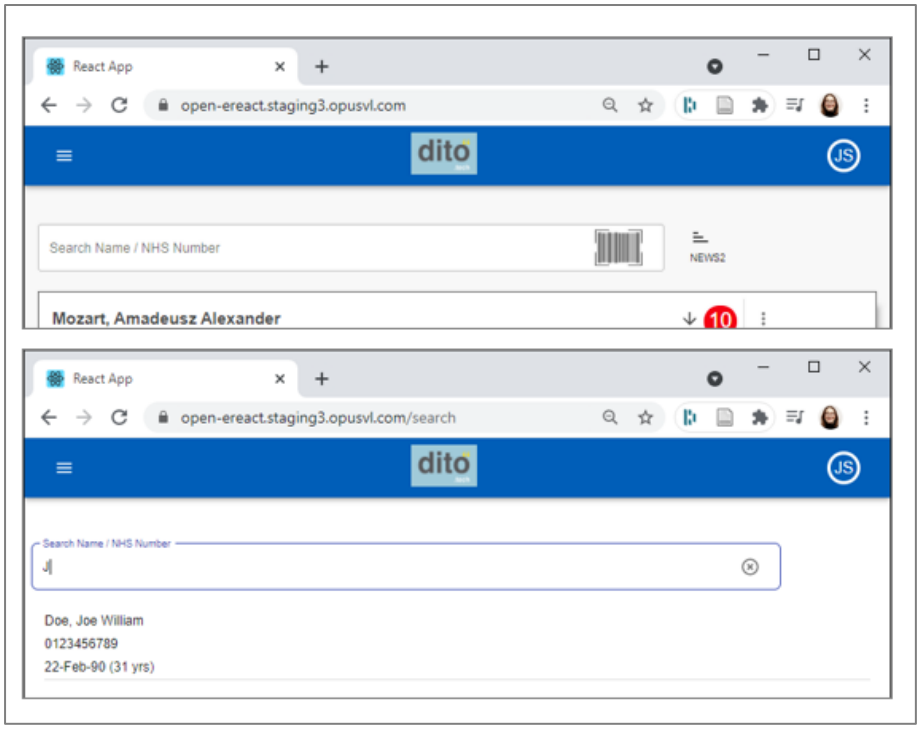


Figure 1: Task - Search for patient

Participants were asked to search for the patient 'Joe William Doe'. All participants quickly completed the task successfully, immediately navigating to the search bar to enter the patient's name. Participants liked that as they began to type the application offered suggestions of patients they might be searching for, which allowed them to select the required patient quicker than would be if they were required to type in the patient's full name.

"[It took] one second, straight away, the J made it come up… Very easy … as soon as you put the first letter in it came up." (Participant 7)

One participant noted that the keyboard on his tablet disappeared following the entering of each letter, which caused concern that this may increase the length of time required to search for a patient. This was not noted by other participants with either the same or different devices.

"Yeah I just put the J in and then… that's all I put in and then the keyboard disappeared. But if you're putting the surname in like that it would take quite a lot if the keyboard's disappearing after each letter… does that make sense, I didn't get a chance to put Joe in, I put J and the keyboard disappeared so I had to keep clicking on… it's okay on this test screen isn't it, but if you had a ward of …thirty patients, it may work, but if you had fourteen J's on there…?" (Participant 9)

Task: Navigate back to main patient list

After locating the Patient Summary screen for Joe William Doe, participants were asked to navigate back to the main patient list. Most participants intuitively pressed the back button within the web browser to navigate back (see red circles in Figure 2), expecting to navigate back to the list but this again took them back to the search bar. Although they were able to navigate back by pressing the back button twice, or by pressing the 'X' and then the back button, most expected to be able to navigate straight back by pressing the back or 'X' button once.

"Either press the X, where it says Patient Summary, just press back, one or the other… Okay to it brings me back to a clear screen saying 'Search'" (Participant 4)

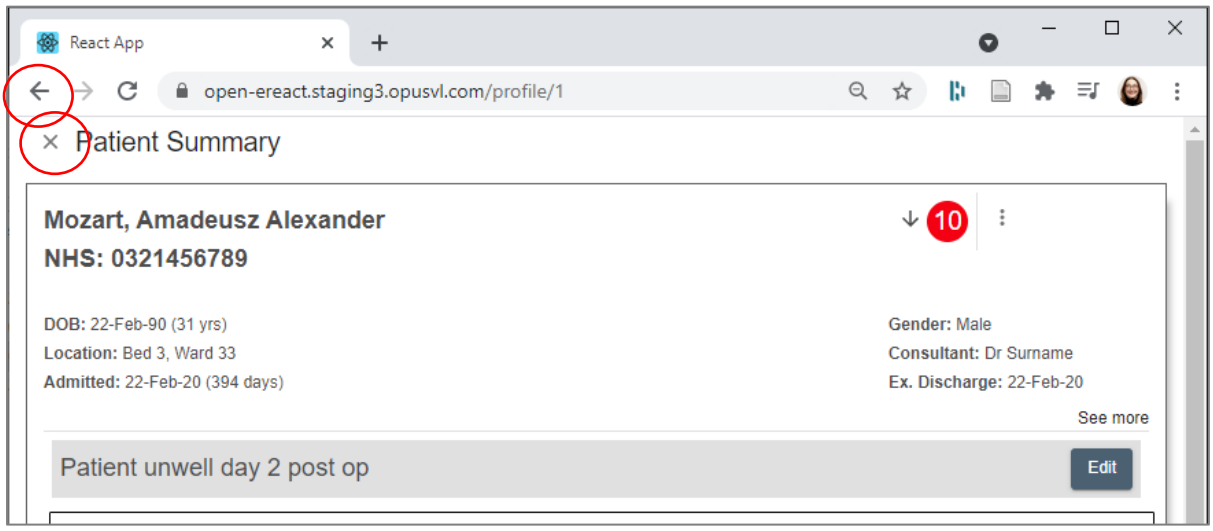


Figure 2: Navigating back to the Main Patient List from the Patient Overview screen

Task: Sort patients

Prior to being asked to sort patients, patients were asked what they thought the icon to the right of the search bar did (Patient Sort Button - Figure 3). All participants answered that they thought the button would allow them to begin a NEWS2 Patient Observation – none of the participants intuitively recognised that it was the button to indicate the sorting of patients.

"If I tap that, it's going to give me a couple of options of whether I want NEWS, PEWS or something else?" (Participant 5)

Figure 3: Patient Sort Button

Participants suggested ways of making the sort button more obvious upon first glance, including changing the icon to have up and down arrows indicating the sort function, adding colour or a boundary line around the button, or adding the word 'Sort' to the icon.

"I think if it just says sort above that little icon, or sorting list, that would be a little bit more obvious of what it is." (Participant 4)

"I think it needs some kind of different colour or maybe a different symbol. I think the fact that it sits alongside the search bar, you've obviously got the barcode that's in the search bar, so my eyes… will look, my eyes are drawn to the barcode rather than the NEWS2 [symbol] to the side. But if you wanted my eyes to look differently at that, I think you would need to have a boundary around it or some colour." (Participant 6)

Most software, they normally have, well I'm thinking of things like Excel and things, they normally have up and down arrows don't they for sort functions, that's what I would have associated with it." (Participant 8)

"It could just have sort written next to it." (Participant 10)

"To me I would probably put a vertical down arrow… Just because, I think that's what you probably normally see on a website, for instance, when you're looking at say, search price high to low." (Participant 11)

Figure 4: Patient sort options

The participants asked what they thought of the range of patient sort options (see Figure 4). All participants agreed that the three options of by NEWS2 score, observation frequency and patient name were useful. Suggestions for additional sort options included by gender and ward/hospital area.

"It could be for if patients are in critical care or a higher dependency area, that might be the area as well where they're placed because that might give an indication of where they are you know rather than just the NHS as the search name, you might get to search for their dependency area because if they come in critically ill." (Participant 2)

"We have mixed sex wards here, but I don't know where there may be some areas… they'd want to do it by male or female, by gender, I guess. And maybe in different areas of the ward, you might want, you know, if you are on the female side, you might just want the female patients…" (Participant 6)

"The only other thing that might be helpful is for people who cover multiple locations, it might be if you could sort them by location, so you can have all of… Ward A, and then all of Ward B, because that's often how we work

isn't it? You do a ward round in one area and then another…" (Participant 8)

"The only other thing I'd say in terms of the search bar is there going to be an option to search by ward? … I think that would be, yeah that would be really useful because you could just say, I don't know, say I'm working on Ward 24, I'd just type Ward 24 in and it would bring up all the patients on Ward 24 because otherwise you're unlikely to have a list of patients like this and, you know, it would be useful to be able to set defaults for your own user ID. Yeah, so if I'm a nurse who only works on Ward 24, my default ward would come up with Ward 24." (Participant 11)

Preferred sort method tended to depend upon the participant's role in the hospital, with nurses and clinical support workers having a preference towards search by NEWS2 score or observations frequency, and doctors preferring to search by patient name or by ward, although they may use the sort list to prioritise patients when on call.

"For me as a support worker, it would probably be the observation frequency because we're on the actual ward, the shop floor as we call it, we're the ones doing most of the observations and the frequency, depending on what level of observations they're on." (Participant 7)

"I suppose it depends on the situation. I think if I was on call, I'd be more interested in sorting by the NEWS because you'd want to know who the ones to watch are and who might need your attention whilst if you were sort of working day to day, I think I'd rather sort probably by location so that it's sort of sequential with how you go around the ward… I think I would probably use patient name most often, that's how I tend to use most [software] now because I'm tending to go in and looking for one specific person and it's easier." (Participant 8)

Task: Finding more information on your patient

All participants found it intuitive and easy to move from the Patient Overview into the Patient Summary of a particular patient by clicking anywhere on the particular Patient's Card (see Figure 5). Overall participants liked the layout of the information finding it clear and were satisfied with the information presented on the page.

"Yeah, I think it's handy to have you know maybe just a, kind of a brief snapshot there to kind of just refresh your memory and then have maybe, yeah, some of the history and problems there." (Participant 1)

"Presenting complaint and problems, past medical and drug history …That's really good to be honest, yeah. Procedures and progress… Yeah." (Participant 4)

"I'll just click on his name. I've done that… it was very responsive, very quick, yeah." (Participant 6)

"Name… all of his personal details at the top, it tells me how long he's been in, where he is, that's always good, his consultants name, expected discharge, patient's unwell day 2 post-op, presenting problems, abdominal

pain, small bowel obstruction and escalation assessments. Yeah this, this is good isn't it?" (Participant 5)

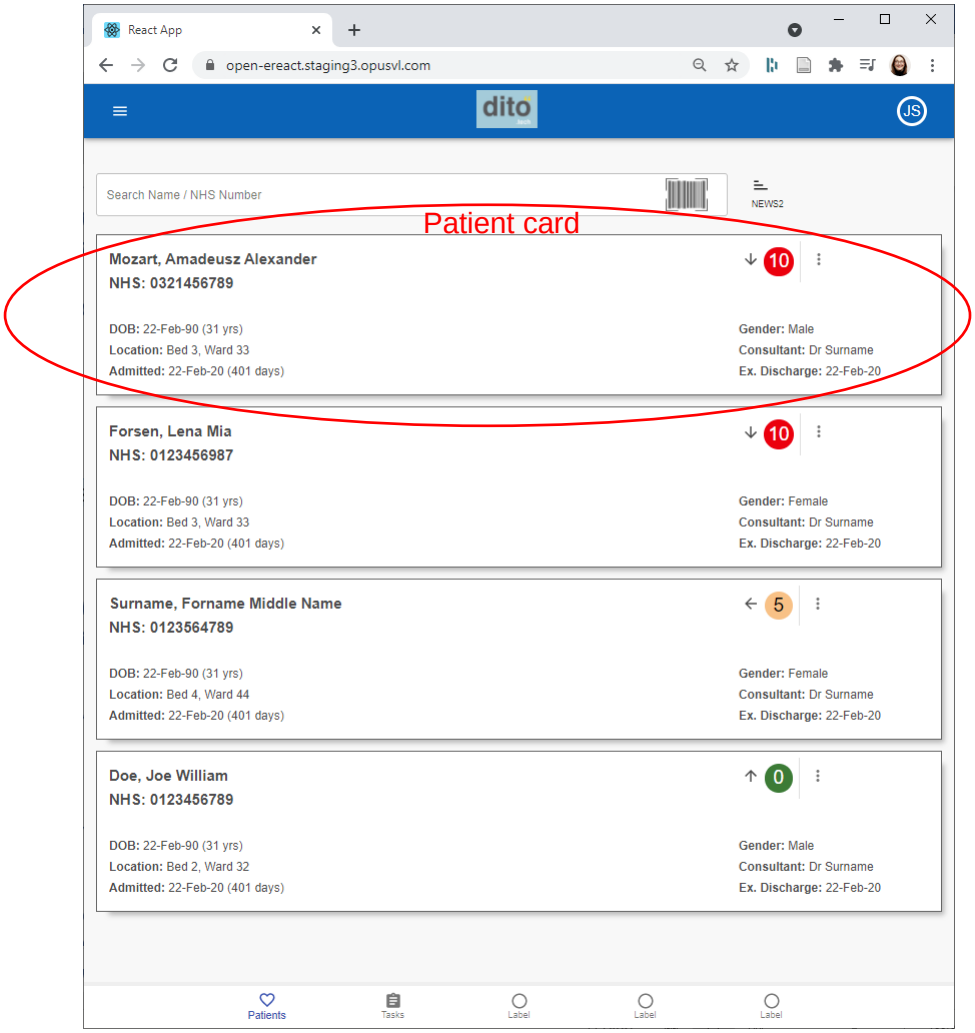


Figure 5: Patient Overview, showing the Patient Cards

When asked to access further information on 'Presenting Complaints and Problems', 'Independent Living & Escalation Assessments' and 'Vital Signs' information carousels, all participants who used a handheld device felt that the presence of the three dots (see Figure 6) suggested that the screen should be swiped, rather than the dots clicked, as per other device and software conventions.

"I don't know what the three dots are, that would say to me that you can like slide across but nothing's happening… Oh you press it, sorry." (Participant 4)

On this device [Samsung tablet] when you see three dots, it normally means swipe right and it will give you a different page." (Participant 5)

"Like the little circles at the bottom but again, most of this is if you're using it for the first time, you don't necessarily know, but it's quite fiddly to move from one page to the next. I think if you could swipe across it, that's what most people are used to now is seeing those dots and you swipe across to see the next dots." (Participant 11)

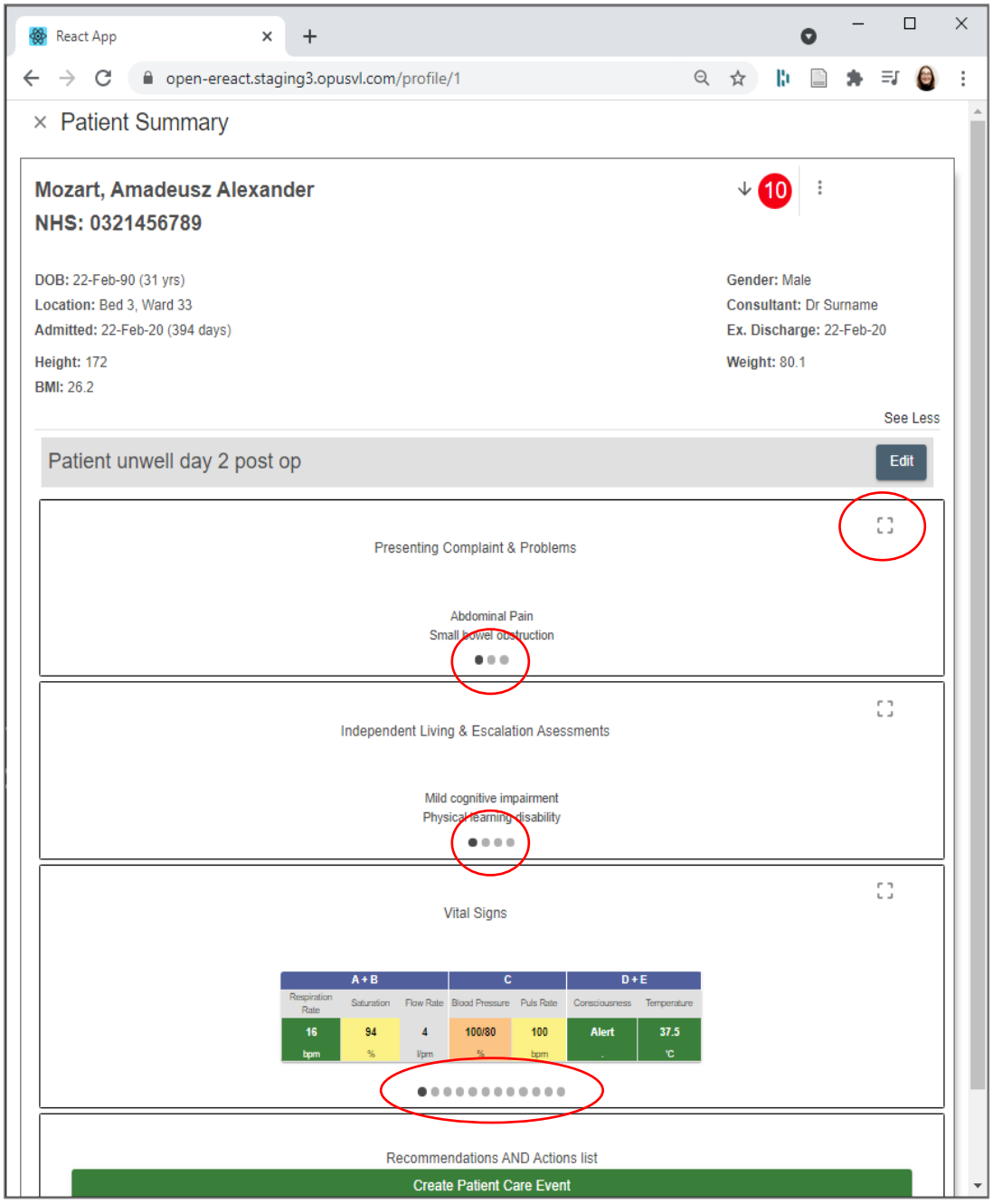


Figure 6: Patient summary information carousel – dots and expand button

Some participants identified the expand icon to see further details for each information carousel (Figure 6), however for some this button was not immediately obvious. Some participants expected to press the information card itself (similar to pressing the patient card in the previous screen) to expand upon the information.

> *"I'll probably press the top right [to see more information], it looks like a camera button." (Participant 5)*

> *Well I would press it [information carousel card], but I'm pressing it and nothing is happening. So maybe… I wouldn't have known that you have to press a little square at the top right hand corner, but trial and error got me to find it, so I pressed in the middle of the box because I would have*

thought to press in the middle like any normal app… My natural instinct is to press the centre of the box" (Participant 6)

Regarding the option to 'See More' or 'See Less' of the Patient Summary (Figure 7), participants liked the additional information, although some felt that it did not warrant the inclusion of the See More/See Less button and could have been presented as standard.

"And if I touch See More it gives me a little bit, oh it's got, oh right, good, height and BMI – that's good as well." (Participant 9)

"Well, all I'm losing really is weight and BMI, so it may as well just remain on the screen really… an unnecessary loss, unnecessary hide if you like." (Participant 5)

"See More… but all it's giving me is height, weight and BMI. I would have expected to see more than that. I think if I'm expecting to see more, I'm probably expecting much more of a clinical summary or something… Certainly I wouldn't have just expected it to be height, weight and BMI." (Participant 6)

One participant also felt that the See More button could have stood out more:

"It's clear now that obviously it would've expanded that list that's already there with some more information. I think maybe, I that was like in a different colour, like a red… just to kind of bring it out a bit, that might be a bit more obvious." (Participant 4)

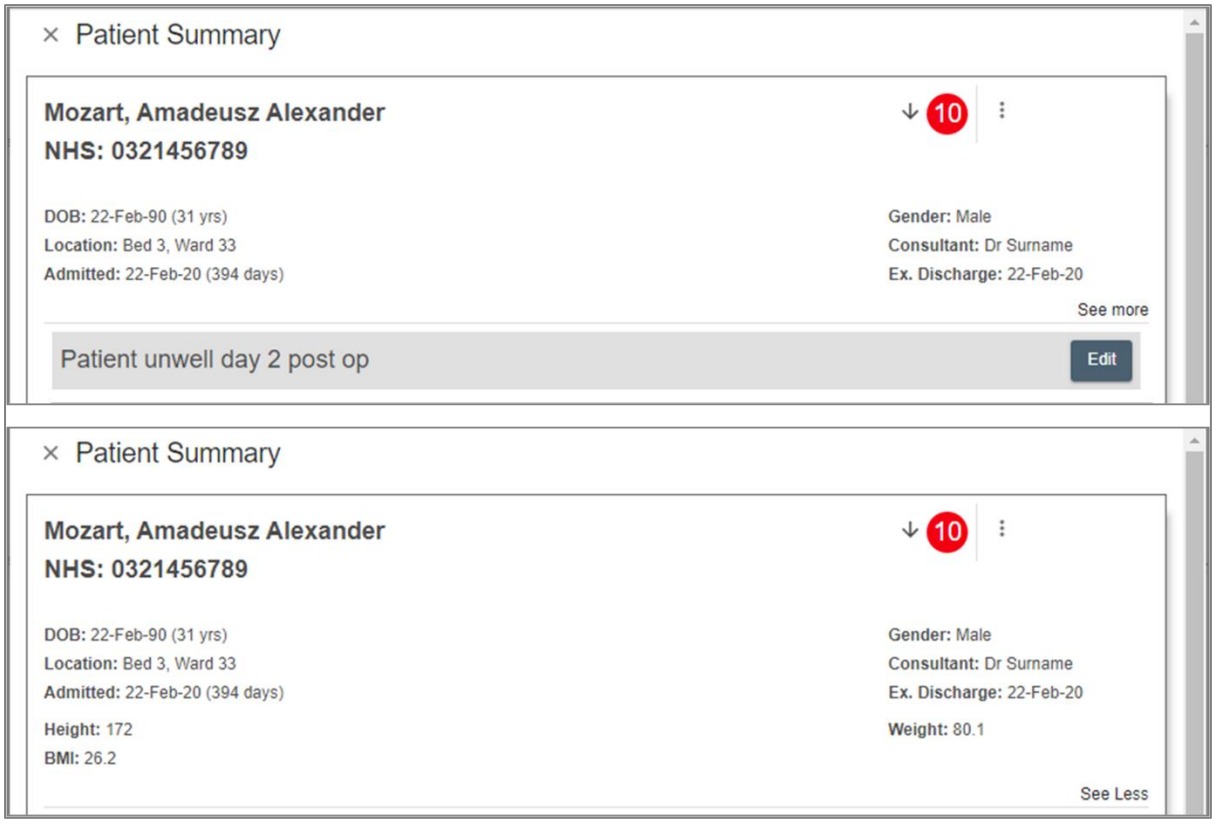


Figure 7: See More vs See Less

Finally, participants were easily able to navigate back from the expanded patient information back to the patient summary via the back arrow (Figure 8)

"So I'd just go back, yeah." (Participant 4)

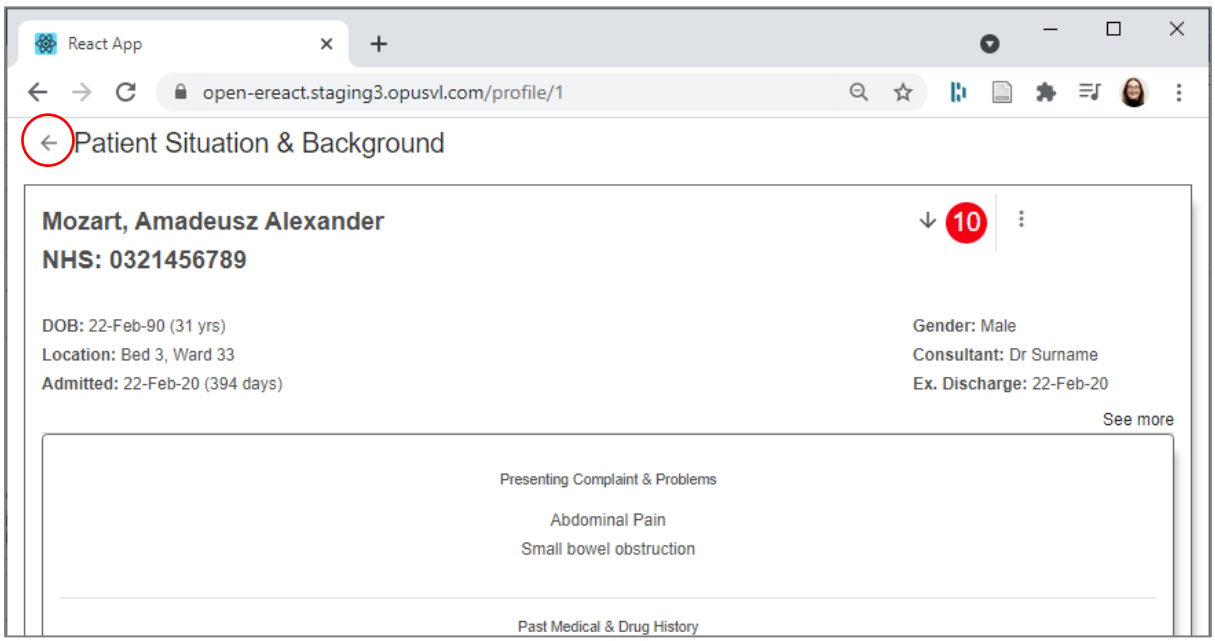


Figure 8: Navigating back from the expanded patient information

Task: Begin entering patient observations – Create Patient Care Event (Monitoring)

Participants were asked how they would begin to enter new patient observations once in the patient summary screen. This could be achieved via two methods, the three dots icon to the right of the current NEWS2 score, or via the Create Patient Care Event button (Figure 9).

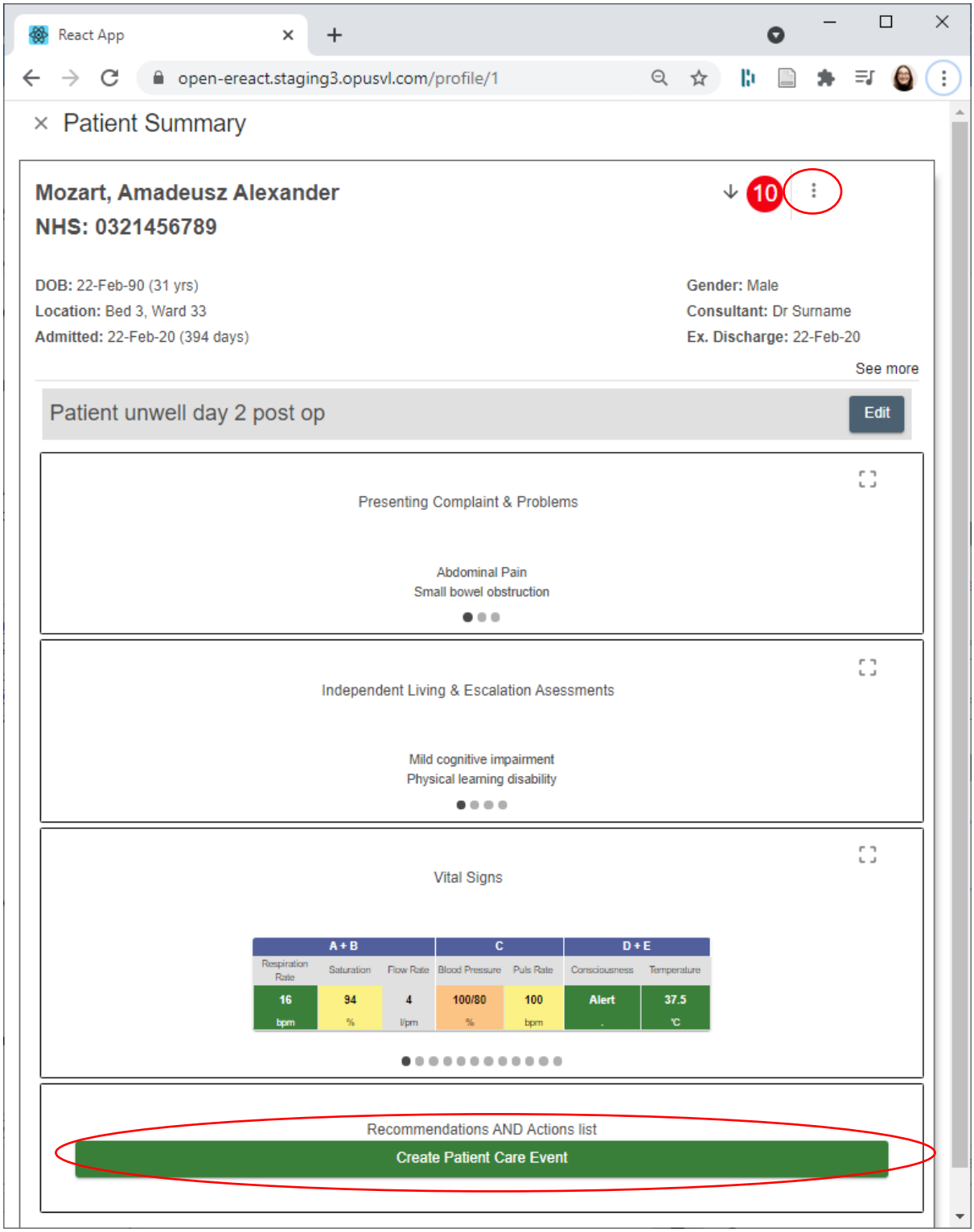


Figure 9: Methods to begin entering patient observations

Nearly half of the participants identified the correct method straight away, either via Create Patient Care Events or the three dots next to the NEWS2 score:

> *"Create patient event there, so Create Patient Event. So new care event for Mozart." (Participant 2)*

"Erm, back down, Create Patient Care Event, is it the box there?" (Participant 3)

"I would imagine you press 'Create Patient Care Event'" (Participant 7)

"Now d'you know, the three dots at the top, I just pressed, I got the same box with Monitoring on it… You can press the three dots or you can go to the bottom. That's good actually you've got two ways in, I think lots of people would press the three dots." (Participant 9)

There were a few participants who incorrectly thought that the 'Edit' button may also allow one to begin entering patient observations (see Figure 10).

"So I think it would probably either be the 'Edit' one or maybe 'Create Patient Care Event'" (Participant 8)

Figure 10: Participants incorrectly assumed that the Edit button may allow one to enter patient observations

One participant felt that the language 'Create Patient Care Event' may be confusing due to variations in wording used in different software products and different settings.

"I struggle a lot with the different software with the language that they use, where they talk about care events and spells and episodes and things like that and I often don't know what those things are. Sometimes they're talking about, say an actual …well this is an event, you've met the patient, you've assessed them, so that's what we're talking about. Sometimes they are talking about an actual sort of file on the system so you need to create a new episode or something. So whenever I see anything like 'Create Patient Care Event;' I'm always a bit wary of am I creating a new file or am I just adding a note in." (Participant 8)

For the rest of the participants, it was not immediately obvious how they would begin entering patient observations, and they had to be prompted by the researcher. When asked if they could suggest alternatives to make such a step more intuitive no clear solutions were presented by the participants, who argued that due to the different colouring was probably an adequate button already, and with some learning you would remember the function of the button.

"I think I probably would've gone to vital signs to be honest." (Participant 1)

"It's a green tab bar, so it's adequate enough you know." (Participant 5)

"Generally speaking, with those things it's not a problem really, as soon as I've used the things for, you know a couple of minutes, and I know where the bits I need to use are." (Participant 8)

"I don't know, I think the colour is different… it's green… I think that's okay." (Participant 10)

Task: Enter patient observations

Overall, all the participants found it easy to enter patient observations within the Patient Observations tabs (Figure 11), although one participant stated that he would prefer to see all the observations on one screen, similar to the layout of the NEWS2 score summary screen presented to the user once observations are complete. One participant noted that he liked the ABCDE structure of the observation entry tabs.

"Yeah, so they're pretty easy" (Participant 4)

"…It says A plus B C D and E which I'm assuming is referencing an ABCDE assessment which is interesting, I've not seen anything else actually, you know, it's something we write and document but I've not seen any software that follows the same thing… It's a way we intuitively think.. we're trained to, and it's a good structure to have, so having a software that follows that logic is helpful." (Participant 8)

"I mean arguably, that page, to me, would be better as a first page. If I was to fill out the obs, I would probably prefer it to be like that anyway and then I could just change the respiratory rates." (Participant 11)

Participants liked the wheel method of entering data, citing the improvement to data quality and accuracy (discussed further in 'Data Quality' below), however, participants had a poorer user experience of the blood pressure wheel, which scrolled slower than the other data entry wheels, although one participant recognised that a slower wheel was preferable to a very quick wheel.

"You know with a scroll wheel you make less errors, you know, less mistypes, because you can only hit the numbers that are relevant." (Participant 5)

"Oh, okay. So you click on respiration rate and you have to keep tapping to go up or down." (Participant 2)

"That's quite a long time, especially if you're trying to input data quite quickly." (Participant 3)

"Yeah I would say it's a bit slow to be honest… Usually on a list like that you can just sort of like do one scroll and it will go quite fast, whereas this is quite slow, and I'm thinking if you're working on a busy ward and you're in a bit of a rush or whatever then it might be a bit annoying… The pulse rate [wheel] is quicker." (Participant 4)

"The blood pressure thing is alright, it doesn't roll very well on this in terms of trying to select down onto the…roll down to the diastolic, it seems a little bit clunky when you're scrolling down… Yeah, which only sounds like a minor thing but it would probably annoy nurses if they're having do it on loads and loads of patients." (Participant 11)

Participants who tested the application using a PC had some issues with the wheel bouncing when trying to enter data. Although the application was designed for use with tablets, some participants (discussed in more detail in 'Implementation' below) argued that some clinicians may wish to use the application on a PC rather than a handheld device, although this would be more likely to be a doctor reviewing patients rather than entering observations.

> *"With the – shame you haven't got one of those – Do y'know like, when I use my keyboard, I know that actually it's quite simple when you realise I can use the arrows, the up and down arrows. But then, again, it's just no, can you see what's happening when I'm trying to go up?" (Participant 3)*

One participant stated they would have a personal preference for typing in the data, and another expressed their surprise at the use of wheels over typing in data, but did not have a preference either way.

> *"Just because I always find I tend to overshoot it one way or the other so I just prefer to type it." (Participant 2)*

> *"I thought I was going to [type] 21 but this scroll wheel's perfectly fine… Because we're only dealing in two digits. I mean it really is splitting hairs here, it would just be quicker to type 21, you know, scroll wheels are normally reserved for great fields of numbers… it doesn't matter, it's quick enough to do it, it only cost me, what, half a second?" (Participant 5)*

Some participants did not immediately notice that to complete the observations to enable the 'Finish Observations' button that they had to work through tabs C and D&E:

> *"It's not letting me enter it [Finish Observation], I wonder why that is then?" (Participant 8)*

> *"Possibly, yeah, I suppose once you know it's fine, it's when you've done it once it's fine, it's pretty obvious but at first, my instinct would be to click on finish observation and then it would move you onto C and then finish observation for that and move you onto that... So you could have another button at the bottom, saying finish observation or continue with the rest of obs or something like that." (Participant 11)*

There was concern by some that being forced to enter a full set of observations could be a barrier in some care events, for example where a patient refused to have particular observations taken, and there should be an option to record such an event with a reason for missing data.

> *"…A lot the time you can't get a full set of obs. If it's a patient… in psychiatry, there's all sorts of reasons why you might not… like you might have someone with autism who doesn't tolerate the blood pressure cuff, or you might have someone in seclusion or restraint and you can check a pulse but you're not going to get a full set of obs, so I guess it's a shame to not be able to record anything when you've only got a partial set of obs really isn't it? …You could even maybe have a couple of options. So in the same way that… a lot of drug charts have a numbering system where one means patient refused, two means not indicated, or not available, maybe you could just have a couple of options for the nurses to select because that forms part of the evidence… if there ever is any problem and anything happens then it's documented then isn't it?" (Participant 8)*

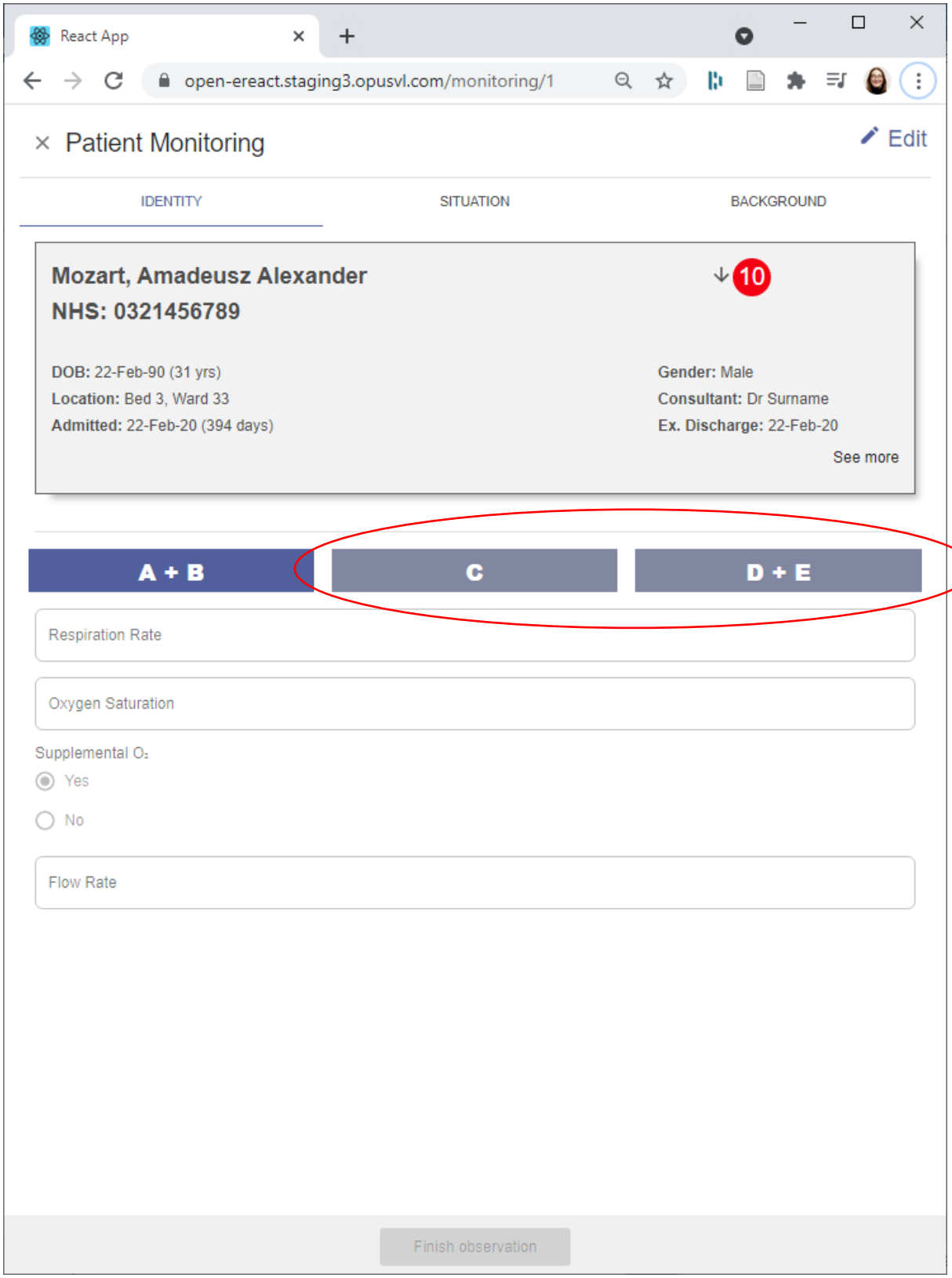


Figure 11: Patient observation ABCDE tabs

One participant had an issue where the background of the application would move whilst he was trying to scroll the wheels, however this issue was not present in the other online testing sessions and could only be recreated by researchers on an iPhone device, not any tablet or laptop devices.

"I'm finding this wheel [Oxygen Saturation]… if I go up it's quite easy, if you come [down] …it's pulling my whole screen. So the background, the actual background …that's moving with it." (Participant 9)

Following entering the patient observations and pressing 'Finish Observation' (which participants then felt was intuitive once they realised – or had been informed by the researcher – that all tabs needed to be completed before progressing to the next tab), the NEWS2 score is calculated and presented via the Patient Monitoring Summary (Figure 12). Participants liked the clear summary, the automatic calculation of the NEWS2 score, and the option to edit individual scores in the case of a mis-entered observation.

"So I like the fact that it's clear and visual and is telling me where there are areas of concern., but also of high risk." (Participant 6)

"…It's giving a NEWS2 score of 10 which is high risk, that's all really clear. You're not sort of having to add up and do it, like on the ward, you'd be doing all this in pen and adding it all up and checking against a key." (Participant 7)

"That's good, I like the breakdown actually, so it's broken down into A, B, C, D, E." (Participant 9)

"No I think that's good, yeah because you can easily add something in accidentally, you know, put some weird blood pressure or some weird temperature in so it's quite good, just to give you that final little set-up… Yeah with a final sort of, you confirm and it gives you another summary page saying this is what you've put in, are you sure?" (Participant 11)

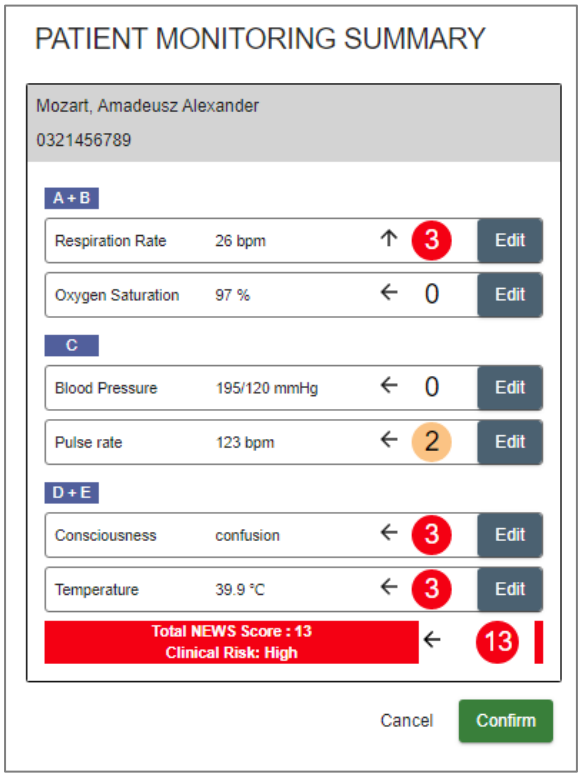


Figure 12: Patient monitoring summary

Task: Sepsis screening

Participants were asked to conduct a Sepsis Screening (Figure 13) for their patient. Overall, participants found the sepsis screening easy and intuitive to complete. The presence of the Sepsis Screening option presented at the end of the Patient Summary would be a prompt to run the Sepsis Screening after each round of patient observations.

> *"It's easy to navigate around that …. That's really good that tool, it's quick, it's easy." (Participant 4)*

> *"So I think that with it being there [presented after the Patient Summary] you know, it's not like an option is it, it's there, and they've got to do it." (Participant 10)*

One participant felt that the text colour within the Sepsis Screening tool may be too light for some people to read easily.

> *"Funnily enough, the text is quite small, I don't think it's necessarily that the text is small but it's quite light in colour, so for me, it feeds into the background. So the word 'suspicion' is quite clear because it's in bold and black, but the rest… the questions themselves are not very distinct… I think I would prefer them to be a bit darker." (Participant 6)*

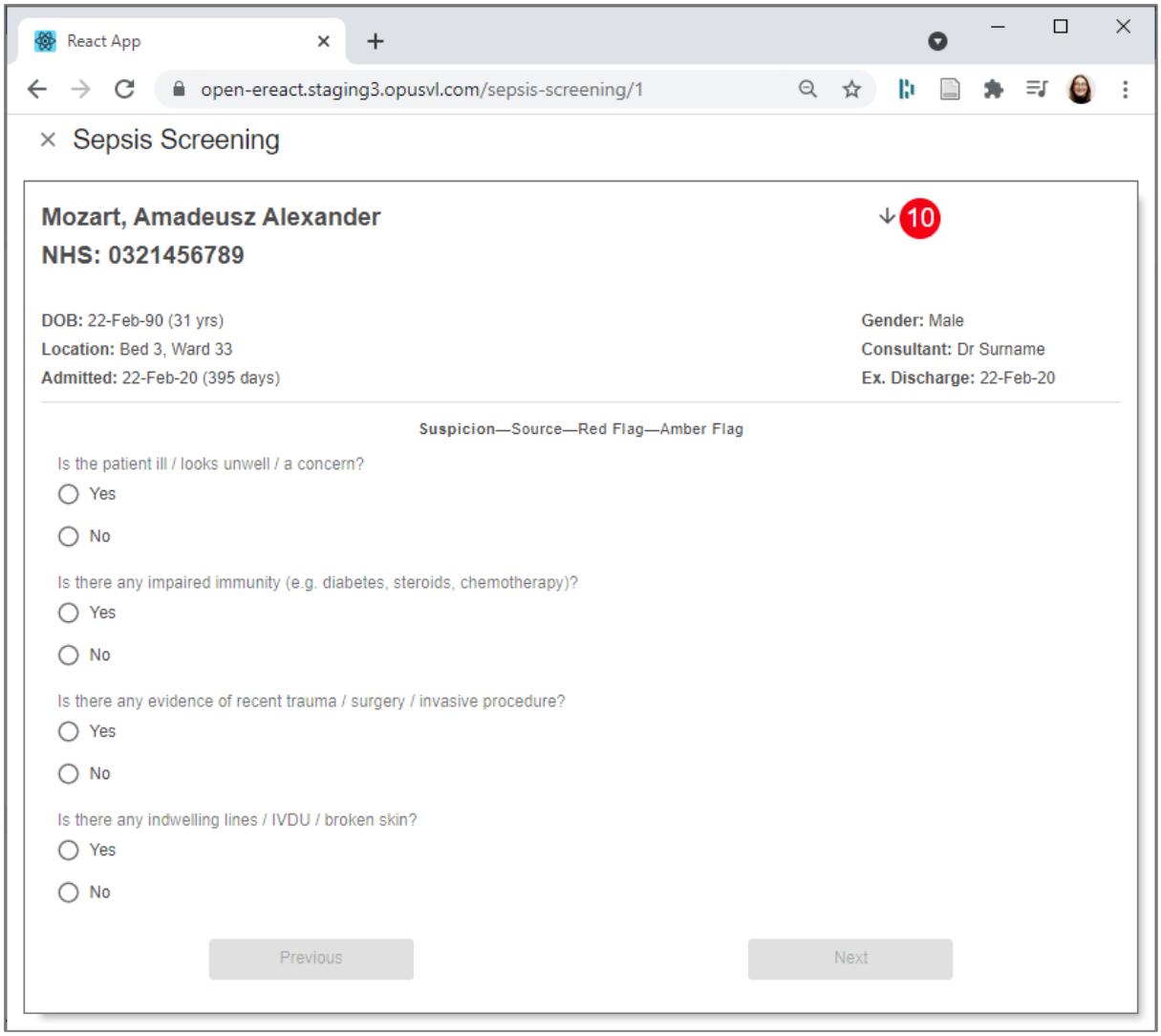


Figure 13: Sepsis screening

Some participants from a mental health background were not sure what constituted a Red Flag and suggested that possible Red Flags could be listed prior to the drop-down Red Flags list that appear if the user selects 'Yes' (see Figure 14). This would support staff who may not deal with Sepsis Screenings on a routine basis.

> *"Are there any Red Flag factors present? I don't know what that means… I guess that it depends on one's level of familiarity with the language." (Participant 6)*

> *"Where are the Red Flag factors so you can see them?" (Participant 9)*

> *"Yeah I think because otherwise you say oh I don't know, I don't know what the red flags for that are, so I might just say no and miss those. So you have a box on the right hand side with [would-be] factors there and then say, you know, greyed out and then if you click yes, then you can fill them in. Or, yeah, or just grey out that bottom box, so grey out where it says tick all that apply, just grey that out and then if you tick yes it allows you to fill it out. If you tick no, then it just disappears, because I think a lot of people wouldn't necessarily know off the top of their head what the red flags would be and some nurses might just be like, well I don't know so I'll*

just say no because it means they don't have to fill as much in."
(Participant 11)

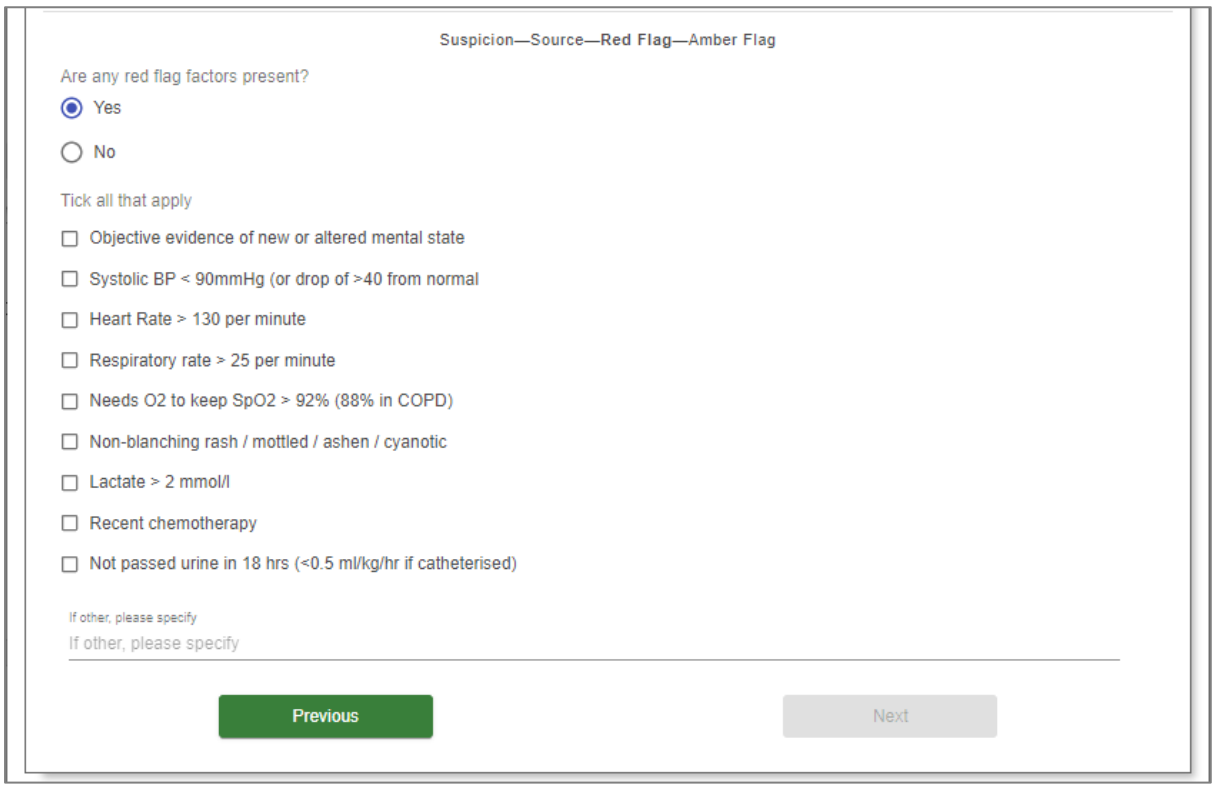


Figure 14: Sepsis red flag factors

Two participants suggested some layout changes to the Sepsis Screening summary screen to make it easier for the clinician to read, interpret and action (see Figure 15).

"So it's come up now with an amber flag, sepsis, further review required. So that's a bit confusing because every word has a capital and then the sentence is over three lines. So it doesn't read very well, but it gives good advice." (Participant 8)

"Yeah that's good, I'd probably put, where it says start sepsis six, I'd probably put start on a separate line. Maybe put like red flag for sepsis and the next line now start sepsis six or something just because of the way it reads, it's a little bit confusing maybe. Yeah because then it just makes it a bit more obvious that it's a certain instruction, now start sepsis six."
(Participant 11)

The presence of information regarding next actions based upon the participants NEWS2 score, or Sepsis Screening summary was very important to participants, and is discussed in more detail below in the 'Patient Safety' and 'Escalation Instructions' themes.

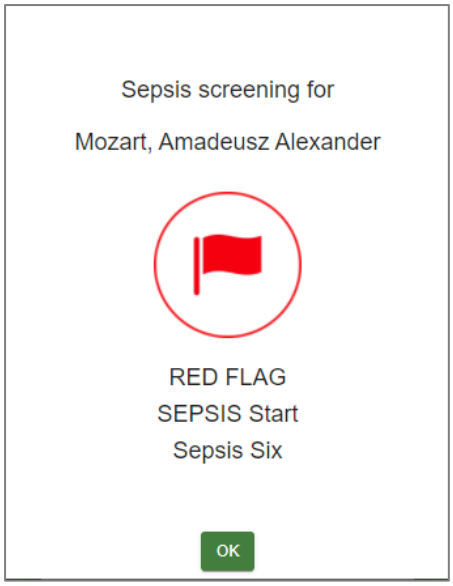


Figure 15: Sepsis Screening summary screen

Usability - Data (presentation, interpretation and quality)

Patients were presented with the patients observation history via the graphs and charts in the 'Vital Signs' section of the Patient Summary. Overall, the graphs and tables were easy to read and interpret, although some changes were suggested for individual graphs to further improve usability and interpretation , and these are discussed graph by graph in more detail below.

> *"So I would expect to see organised chaos if that makes sense. Looking at this, I've got a lot of data exactly where it needs to be. Just like on a physical document but a lot easier for me to read." (Participant 5)*

Dates and corresponding data within the graphs and tables was presented oldest (left) to newest (right), with participants agreeing this is how they would expect to read a graph, and that it mirrored the existing NEWS2 paper charts.

> *"The oldest reading on the left the newest reading on the right… Yeah I'd say that's the easiest way of scoring it, yeah." (Participant 4)*

> *"I think that would follow any charts, including you know, normal temperature chart or anything like that. Yeah. That makes sense." (Participant 6)*

> *"I quite like on the existing NEWS charts, the graphs themselves have a colour coding don't they? There's sort of a white band in the middle, and then they go yellow and then red depending on what they score." (Participant 8)*

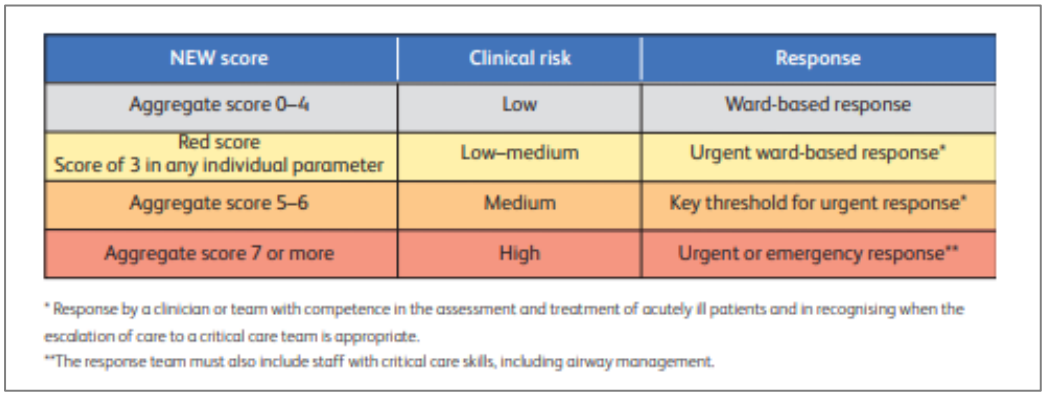
Participants also liked the colour coding (yellow, white, red) on the graphs, and that it reflected the colour coding on the NEWS2 forms with which they were familiar. One participant suggested that to make it easier for newly trained staff or students, a key to the colour coding, such as the key from Royal College of Physicians (2017), would be useful (see Figure 16).

> *"I don't quite know what that is. Is it – hold on, I'm not too sure, because there's hold on there's no colour kinda key. If they were scoring when they*

were 16, then why are they not scoring – if that was white it would go in yellow, I'm not too sure what that means." (Participant 3)

"I like the colour coding, which was good for the different levels of risk." (Participant 7)

"We have a lot of first year students, you know, who've never done them before and we have to train them how to read them and how to make sure they're done properly and things like that… I think if you just had a little thing what the colours are for them, which is on, it's on the paper one." (Participant 10)



NEW score	Clinical risk	Response
Aggregate score 0–4	Low	Ward-based response
Red score Score of 3 in any individual parameter	Low–medium	Urgent ward-based response*
Aggregate score 5–6	Medium	Key threshold for urgent response*
Aggregate score 7 or more	High	Urgent or emergency response**

* Response by a clinician or team with competence in the assessment and treatment of acutely ill patients and in recognising when the escalation of care to a critical care team is appropriate.
**The response team must also include staff with critical care skills, including airway management.

Figure 16: NEWS2 colour coding key with recommended escalation response from Royal College of Physicians (2017)

Some patients from a mental health setting did not recognise that the colour coding reflects the colour coding on the paper NEWS2 form, although they were able to still interpret the risk level based upon colour.

"Well I don't know what [the colours] mean to start with, so white means okay, red means its really bad and yellow means… why is it yellow and not amber?" (Participant 5)

Patients had mixed views regarding their personal preferences on whether they preferred to use the graphs or tables to interpret a patients observations history, but overall there was an appreciation of having the choice of both tables and graphs. For some the graph was preferable regarding observing the overall trend for the patient.

"…To be honest, I don't like the graph, I think it's a bit too, it looks way more complicated than what it is, whereas if you look at the table, you've just got resps, sats, and it's just dead easy to look at." (Participant 4)

"I prefer the graphs. For me, cognitively, I've no idea why, it seems to make more sense to me. Whereas other people just might like the clarity of a clear scoring box… but me, my mind seems to follow the trend better when I can see the graph moving – for me. But look you know, the choice of both is brilliant isn't it? …So, for me I prefer [the graphs] but I can imagine my wife [a nurse], she'd much prefer it in this table." (Participant 5)

"Me personally it would be the tables, I think… I find the table a bit more easy to read than the graph, but that's my personal thing I would imagine." (Participant 6)

"…For things like blood pressure and heart rate, the trend is really much more important I think with those things." (Participant 8)

"Probably the tables are easier. The table's more like the paper format that we use that the moment, you know, see I can pick a chart up and it's recorded very similar, you know, there's just a few differences." (Participant 10)

"I like them both to be honest with you, I think they're both really good and really useful, so you've got a visual representation across the board so you can see, you've got a table with the numbers in." (Participant 9)

"I think the graph gives you a good instant oversight of what's been happening, the table gives you a bit more of a broad side by side oversight maybe of what's been happening. So, I find it easier to read and see what's happening on a table with the stats and the oxygen levels, in terms of the respiratory rate and the oxygen levels maybe." (Participant 11)

Participants liked that the tables displayed the series of NEWS2 scores pertaining to the patient (although this field had not been populated for the purposes of the prototype). Participants wondered if this would be a running total NEWS2 score, or individual NEWS2 score for the particular parameter in question.

"So, I'm gathering where it says NEWS2 at the bottom… you said when it's live it will have a NEWS2 score, is that a running score or is that just a score for these parameters?" (Participant 9)

Some participants found the individual observations on the graph difficult to read without zooming in, however this was not an issue on the tablet devices due to the ease with which they could pinch and zoom in on particular observations.

"If you do pinch it's easier to see, if you expand it…So I can see that now, I can see it's eighty-five, but if you leave it on normal you can't really see it. That's my eyes, that's not the fault of the program, no that's okay, that's okay." (Participant 9)

Views related to the specific graphs, rather than the graphs overall are discussed below.

Graphs and Tables – Saturation and Respiration (A&B)

The A&B tab in the Patient Summary displays data regarding the patient's saturation and respiration observations to the user (Figure 17). Overall, people found the graphs easy to interpret, although there was some initial confusion regarding the use of different symbols for oxygen saturation (used to differentiate between the different saturations scales for patients on air and oxygen)

"And then just obviously the 70 in red, I can see the 70 there has obviously got a little warning sign there to show; well I assume that you know obviously because it's quite low. And then I assume then they've gone into oxygen because then that's turned to a square. I think it's a bit confusing with the different symbols and the different colours as well like I'm not sure, I think you know I'd have to be looking back and forth as to what that kind of meant, especially because we're going from a circle and a square and then to like a diamond and, is it a hexagon?... Yeah. So anyway that would be a little bit confusing because I'd be like wondering what the

difference was and then maybe I wonder if people would pick up that there's a difference between being in oxygen and being in air with doing that as well so I think that it looks like quite busy, like there's a lot going on." (Participant 1)

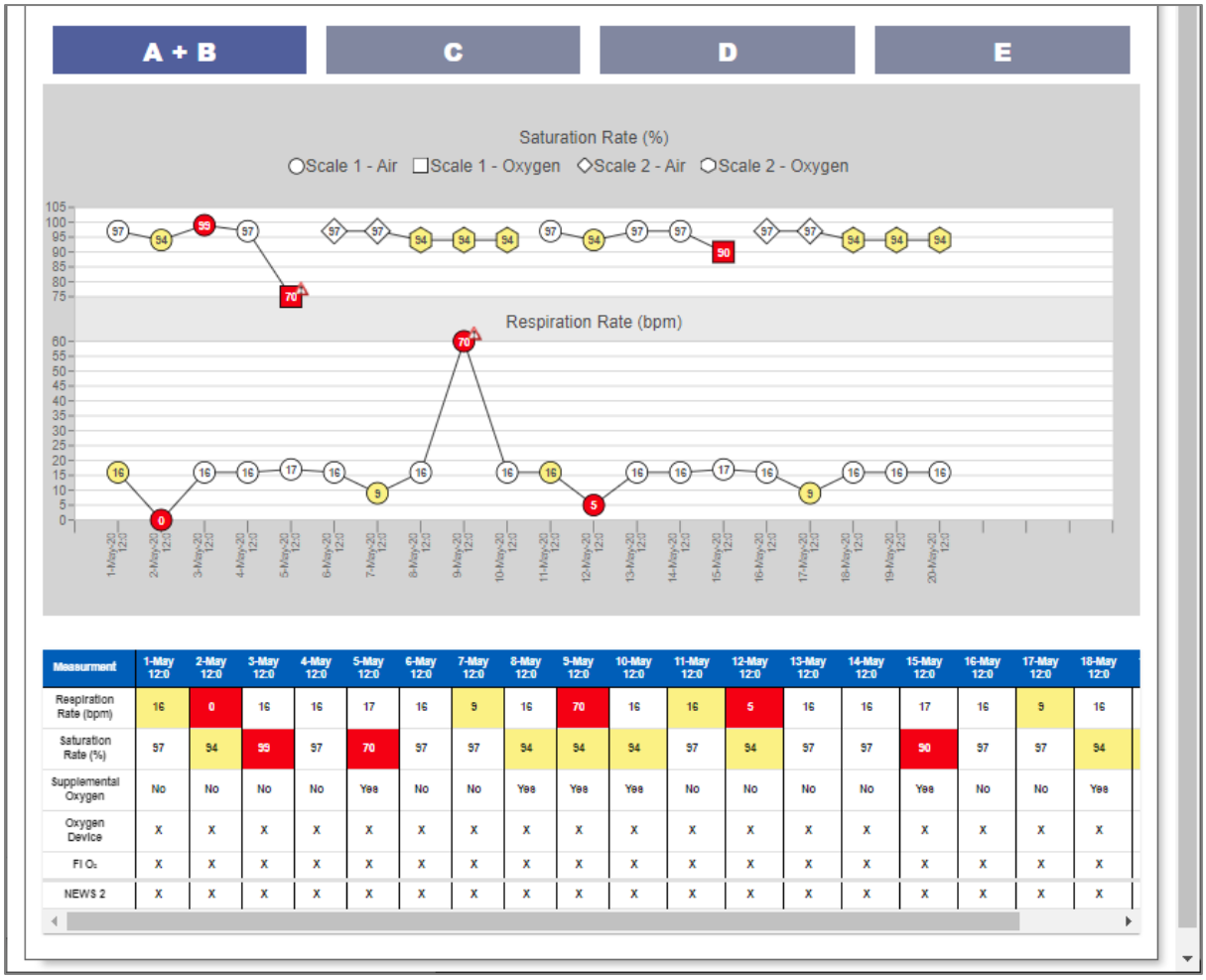
"Not that that's an issue I just think the only thing is the shapes of that I don't like because I find that confusing why there's different shapes for scale one and scale two, I'm not sure what they are." (Participant 1)

"Yes. Saturation rate percentage, scale one oxygen, scale two air, scale two oxygen, so what does that mean? So you've got scale one, so where's the explanation of the scale? What is scale one, and what is scale two?" (Participant 2)

"Okay, so we've got the sats rate over a twenty day period … I don't, ah, and the resps, sorry, right, so that's resps, I was going to say if I was that person who's got 0% sats…. Right, okay, so … yeah, I mean when I first looked at them I thought, I was a bit like woah, what the hell, but now I'm looking at it it's quite clear. So first night they were sixteen and ninety seven, yeah, and zero and ninety-four, okay. Can you click on, no, I was just thinking can you click on where the resps are red and the sats are red, do you click on them to get further information." (Participant 4)

"Okay. So in terms of the first part, I'm looking at A and B, which is the highlighted area, A and B. I like the graph. I think it's very visual and I think it helps give me a view of that scaling of how somebody's respiration saturation rates are and the fact that it's colour coded helps you see trends or concerns. So where you've got amber and red. And it's quite a spiky profile, isn't it, in terms of saturation rate and also respiration rate. I'm not so sure about the box. I know it does clearly tell me what it is. But I think when I look at it, other than the fact that it's colour coded squares of amber and red, I'm not so sure, I'd have to read that more to get a flavour of the picture of what's happening. So when I looked at the graph, I'm clearly seeing the scores are within the amber or red areas here, but it's absolutely clear from the point of looking at it visually. In terms of the chart and the square at the bottom I have to read that to see what that means. So I have to do a different bit of interpretation around it." (Participant 6)

"Can I just ask you, back on A&B, so saturation rate percentage you've got scale one here, scale two, what do they mean the boxes, you've got a circle, square, diamond? ***[Researcher: So it's just to indicate…]*** *Oh, I've got you…* ***[Researcher: what different scale they're on… whether they're getting the additional oxygen supplementation.] …****Yeah, now I can see that… now I've looked at it properly." (Participant 9)*



Measurment	1-May 12:0	2-May 12:0	3-May 12:0	4-May 12:0	5-May 12:0	6-May 12:0	7-May 12:0	8-May 12:0	9-May 12:0	10-May 12:0	11-May 12:0	12-May 12:0	13-May 12:0	14-May 12:0	15-May 12:0	16-May 12:0	17-May 12:0	18-May 12:0
Respiration Rate (bpm)	16	0	16	16	17	16	9	16	70	16	16	5	16	16	17	16	9	16
Saturation Rate (%)	97	94	99	97	70	97	97	94	94	94	97	94	97	97	90	97	97	94
Supplemental Oxygen	No	No	No	No	Yes	No	No	Yes	Yes	Yes	No	No	No	No	Yes	No	No	Yes
Oxygen Device	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X
FI O_2	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X
NEWS 2	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X

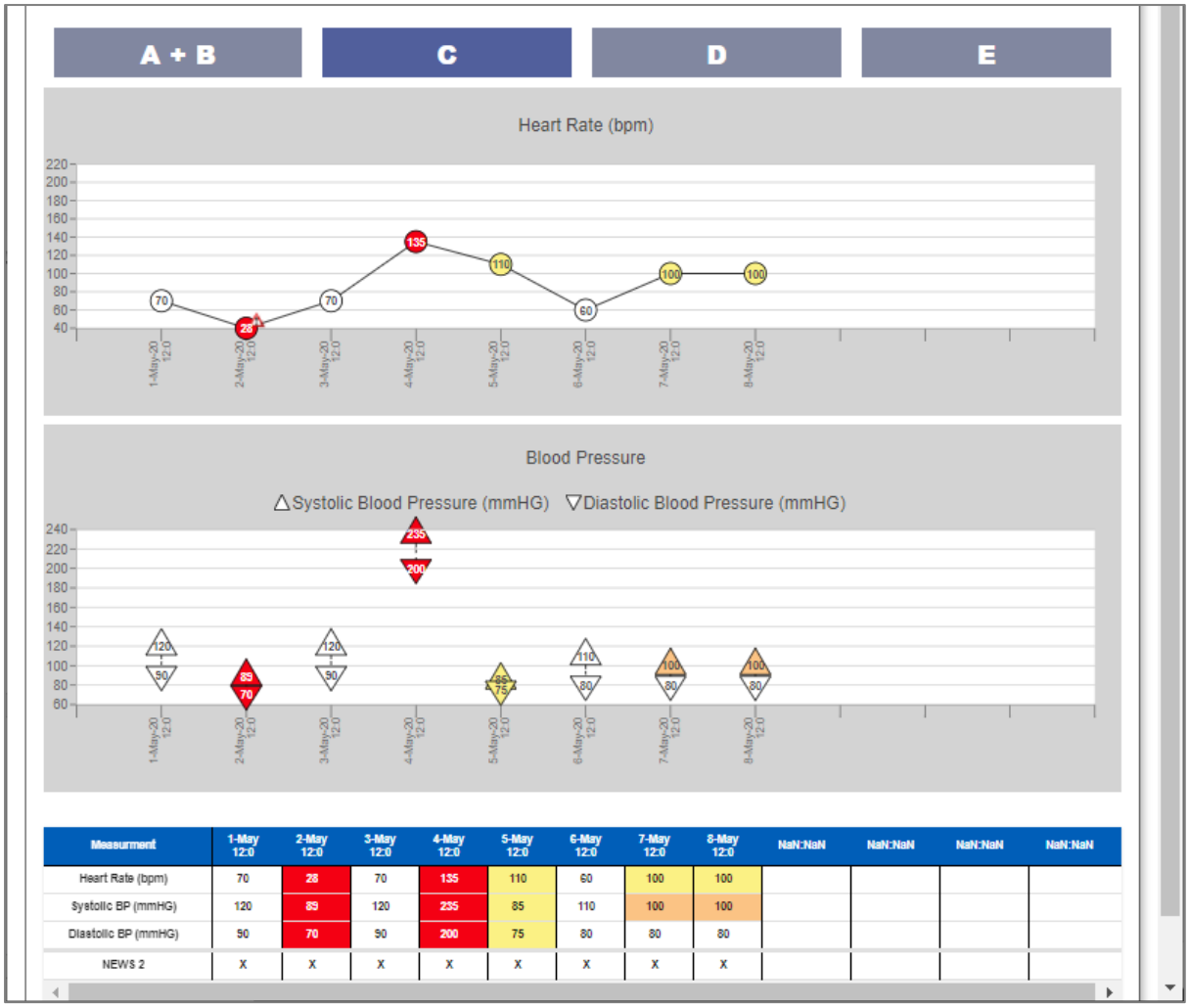
Figure 17: Graphs/tables A&B - Saturation and respiration observations

Graphs and Tables – Heart rate and blood pressure (C)

Participants liked the heart rate graph and thought it was clear and unproblematic and had no suggestions for further improvements (Figure 18).

"In terms of the heart rate, I like the graph." (Participant 6)

"It's quite clear." (Participant 7)



Measurment	1-May 12:0	2-May 12:0	3-May 12:0	4-May 12:0	5-May 12:0	6-May 12:0	7-May 12:0	8-May 12:0	NaN:NaN	NaN:NaN	NaN:NaN	NaN:NaN
Heart Rate (bpm)	70	28	70	135	110	60	100	100				
Systolic BP (mmHG)	120	89	120	235	85	110	100	100				
Diastolic BP (mmHG)	90	70	90	200	75	80	80	80				
NEWS 2	X	X	X	X	X	X	X	X				

Figure 18: Graphs/tables C - heart rate and blood pressure

Views were mixed on whether the blood pressure graph was easy to read.

> *"Blood pressure… it's simple to read, yes… the blood pressure is normally the one that looks messy [on paper charts], it's not in any form … some people draw lines between them, some people just dot them, and when you physically write them in, the boxes again are normally quite small… So, it's nice to see that data organised correctly." (Participant 5)*

> *"…I don't like the blood pressure triangles. I find them a bit distracting… Funnily enough I prefer the square charts underneath in terms of that, and it may just be because it's an unusual graphic of a triangle… it doesn't catch my eye and I'm not quite sure, I'm kind of having to stare at it looking at the numbers in the blood pressure graph… I'm looking at the [table] underneath… with the colour coding that's telling me, you know, where heart rate is a concern and [blood pressure]." (Participant 6)*

> *"I think if it followed the same format [as the previous graphs], if we went back to A&B, although it's got circles and squares… and hexagons … that's quite helpful… And then in terms of the blood pressure, I think if it was using circles or as in [A&B] it would probably have a more streamlined presentation." (Participant 6)*

For some participants, the blood pressure graph was overall easy to interpret, except for observations where the diastolic and systolic observations were close in number (see Figure 19). Although, it was recognised that this would not happen often in practice and the table was there as a back-up to ensure the correct reading, or alternatively one could pinch and zoom on the graph to see the observation more clearly.

"The blood pressure things… look a bit clunky, I think. I suppose in practice, they're not really going to overlap like that because you're unlikely to have a blood pressure of 85 over 75, but it looks a bit clunky when the triangles start to overlap and things… I'm not sure what the alternative would be there really… it's cosmetic really isn't it, the numbers are there aren't they." (Participant 8)

"You've got your two triangles interlocked… That's telling me that the diastolic and the systolic are very close to each other… I could go to the charts underneath couldn't I and have a look at what it was… Oh yes, I can zoom in, I was gonna say can I zoom in and I can, that's even better yeah, I like that, I've got really bad eyes, so I have to zoom in… It's not impossible [to get a reading like that in practice], it would be quite frightening if it did, but there's nothing you can do about that." (Participant 9)

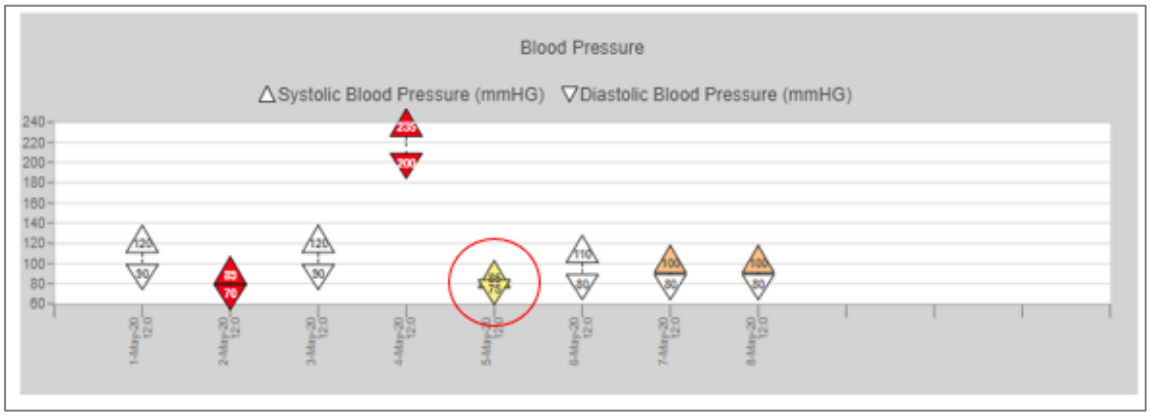


Figure 19: Blood pressure graph display where diastolic and systolic readings are close.

Graphs and Tables – Blood glucose and pain score (D)

The blood glucose graphs were very easy for people to interpret (Figure 20).

"Oh, that's simplistic." (Participant 5)

One participant suggested highlighting very low blood glucose levels (in addition to very high) in red. Blood glucose levels are not currently part of the NEWS2 calculation therefore do not have a NEWS2 colour code convention.

"I don't know, I would have assumed that the colours would have depicted for the scoring for the NEWS score, so the early warning score, but then I wouldn't understand why the 99 there would be in red because that's normal so I would've thought that would've been clear." (Participant 1)

"So I'm seeing the [blood glucose], three, one, what would be a good idea is anything below four we need to… it might be an idea – anything below four, turn it red… If you're a Clinical Support Worker you might not know

what the values are, and red means danger to me. So, anything below four red and anything above seven red… At least then they're gonna take it to the [senior staff] and say 'this is red, I'm not sure'… I do all the training for them so you get a lot of confusion from some of the [Clinical Support Workers], but they're the ones that are doing the obs and it does worry me a little bit… If I'm being honest, it's the lower ones I worry about which is hypoglycaemia and they're the ones that deteriorate a bit quicker. Hyperglycaemia usually you've got a bit of notice before you have to start treating, so I think whatever's out of range needs to be red." (Participant 9)

On the other hand, a few participants found the pain score graph easy to interpret, but others required more time to interpret it correctly, and differentiate the scores in the resting and moving states.

"Pretty clear I would say." (Participant 7)

"Pain score I'm not that familiar with, believe it or not. My wife [a nurse] is though… For a pain score, I can see these symbols at the top, resting, moving, both… Okay well I didn't know a lot about that and that makes sense to me, so considering nobody explained it and I just looked at a graph, that's a good sign." (Participant 5)

"I can see that it's coded with circles and triangles, I find that a bit busy, I find that difficult to work out." (Participant 6)

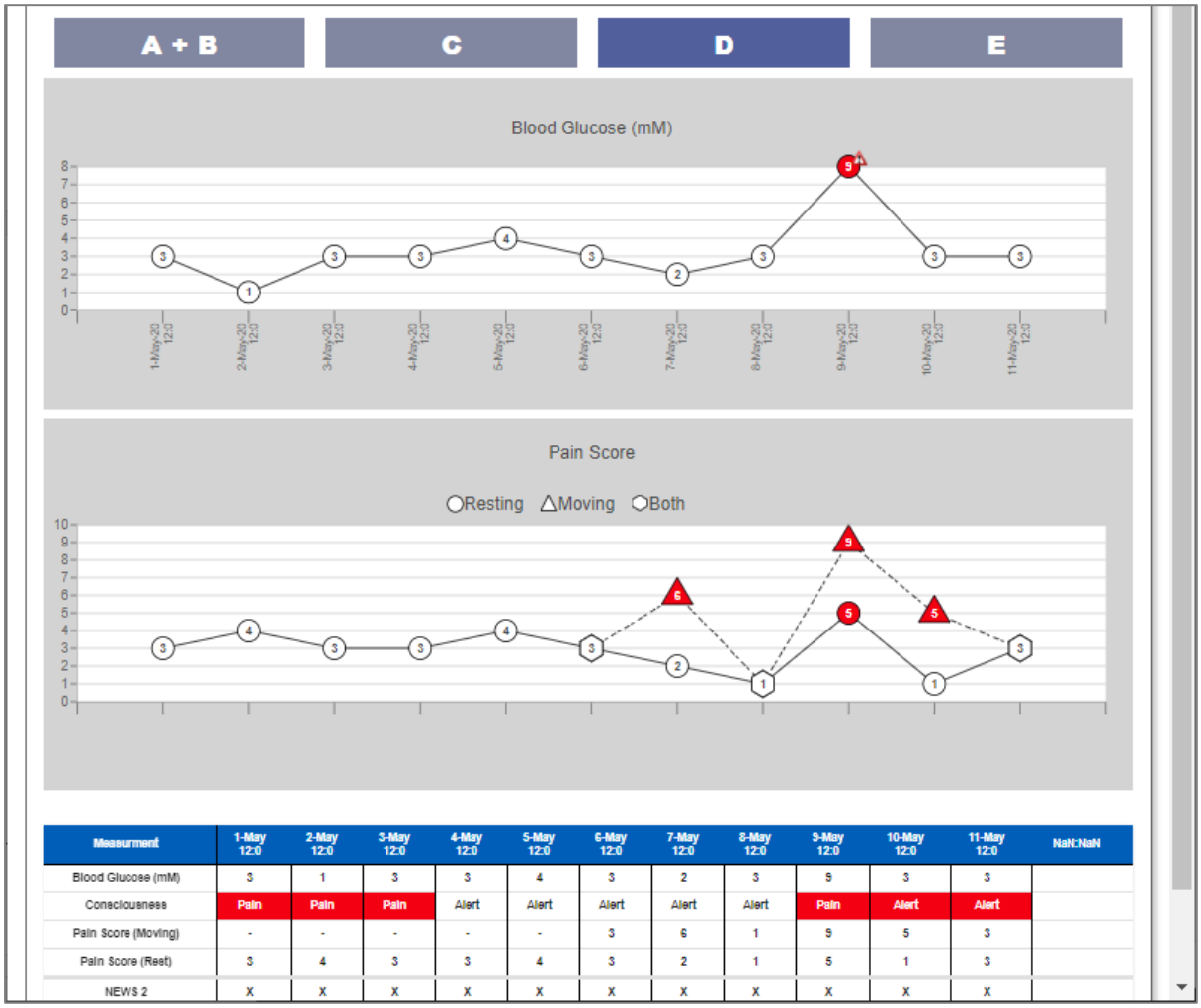
"…Pain score is getting complicated now… It's not immediately obvious what it means, I can see different shapes, there's circles, there's hexagons and triangles. There's a key at the top, so resting, moving, both, okay. It's a little hard to spot the difference between the hexagon and the circle at a glance, so I don't know, maybe a square or something would be better… I'm going to guess that the dotted lines connect to the moving scores and the circle and the solid lines connecting the resting scores because it seems that the dots connect from triangles and both, I'm assuming that's the difference." (Participant 8)

"Excellent, yeah… you've got your high score six, so anything above five, that's great, but they flash up as red… Red danger so hopefully I'm hoping the [Clinical Supports Workers] will action that and they'll take it to the staff nurse… That's good." (Participant 9)

"So, pain score, so I'm trying to work out what the red bits mean, so that's going from 3 resting and moving to 6 to 1, so that looks a bit confusing when it goes sort of the right hand side of the pain score. I think you have to sort of have to sit and try and work out what's going on there for a few minutes. And I'm not quite sure what it's supposed to be saying. So, it looks like you're going from, that middle point where it says a pain score of 3 on both resting and moving, then it's – what are the dotted arrows supposed to mean?... I mean, if there wasn't that 2 in between the 3 and the 1, I might say that the patient had been moving between those two time points and that's why they've gone to a higher pain score, so I'm not sure what the 2 is supposed to represent in between those or the 6. (Participant 11)

The pain score graph was also missing the dates and times at which the observations were taken, which was picked up by participants.

"Just looking at that graph I wouldn't have a [timeframe] about what period that was in when the pain was changing so I think I'd need to know something about that." (Participant 6)



Measurment	1-May 12:0	2-May 12:0	3-May 12:0	4-May 12:0	5-May 12:0	6-May 12:0	7-May 12:0	8-May 12:0	9-May 12:0	10-May 12:0	11-May 12:0	NaN:NaN
Blood Glucose (mM)	3	1	3	3	4	3	2	3	5	3	3	
Consciousness	Pain	Pain	Pain	Alert	Alert	Alert	Alert	Alert	Pain	Alert	Alert	
Pain Score (Moving)	-	-	-	-	-	3	6	1	5	5	3	
Pain Score (Rest)	3	4	3	3	4	3	2	1	5	1	3	
NEWS 2	X	X	X	X	X	X	X	X	X	X	X	

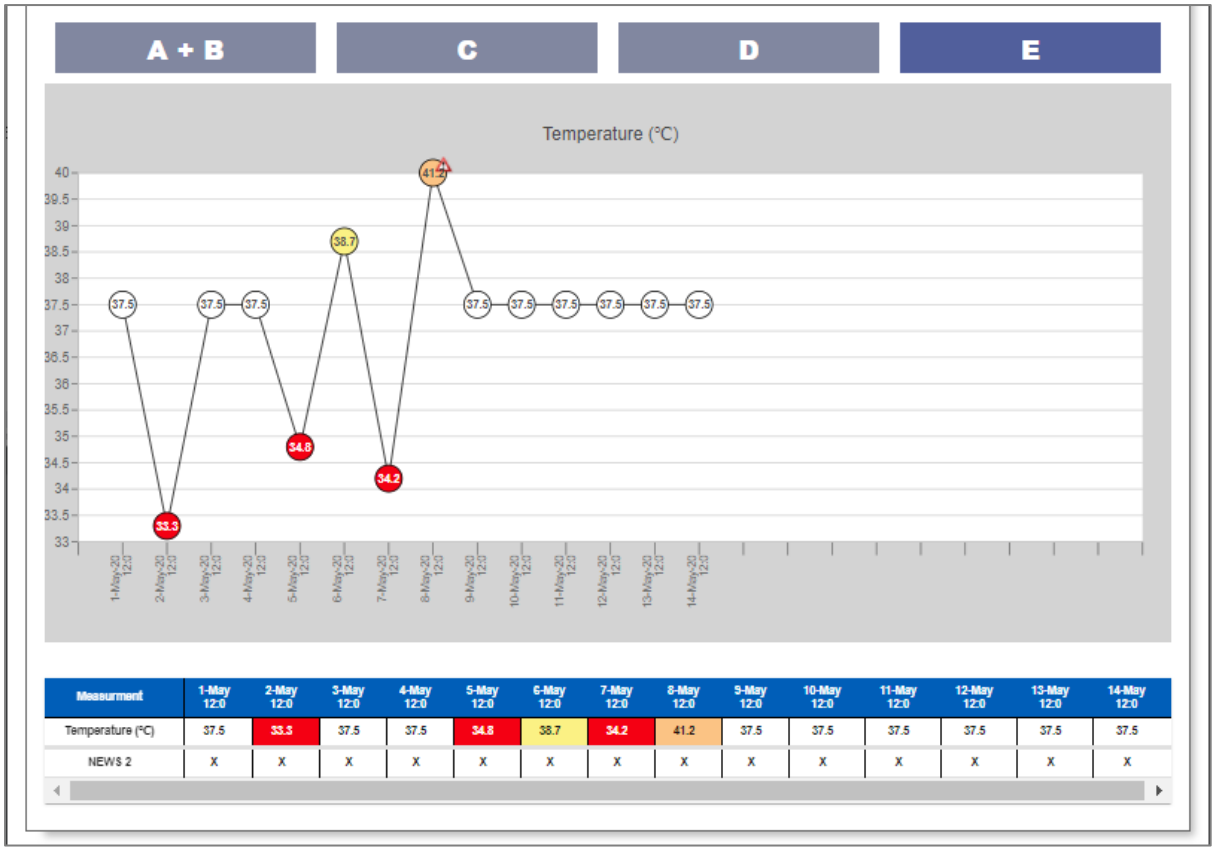
Figure 20: Graphs/tables D - Blood glucose and pain score

Graphs and Tables – Temperature

The temperature graph (Figure 21) was very easy to understand for all participants.

"Yeah, very simple, easy to understand." (Participant 5)

"Quite easy to understand that isn't it for temperature? …So that will help pick up sepsis no problem." (Participant 9)



Measurment	1-May 12:0	2-May 12:0	3-May 12:0	4-May 12:0	5-May 12:0	6-May 12:0	7-May 12:0	8-May 12:0	9-May 12:0	10-May 12:0	11-May 12:0	12-May 12:0	13-May 12:0	14-May 12:0
Temperature (°C)	37.5	33.3	37.5	37.5	34.8	38.7	34.2	41.2	37.5	37.5	37.5	37.5	37.5	37.5
NEWS 2	X	X	X	X	X	X	X	X	X	X	X	X	X	X

Figure 21: Graphs/tables E - Temperature

There were some concerns that the extreme temperature values should be colour-coded red, not orange, however this colour coding is in line with NEWS2 scoring systems. It was noted that these extreme temperatures were highlighted with an exclamation mark on the eREACT V2 graph, which may draw further attention to a very extreme value whilst still being in keeping with the NEWS2 colour coding (see Figure 22).

> *"...There's a …temperature of 38.7 and that's only yellow and I'm surprised that's yellow. That would be a pretty good going pyrexia… and I thought… it should be red by the time you're at 38.7… and then I've also noticed the one that's 41.2, which probably isn't compatible with life and is only orange, yet with an exclamation… Which does draw some attention to it." (Participant 8)*

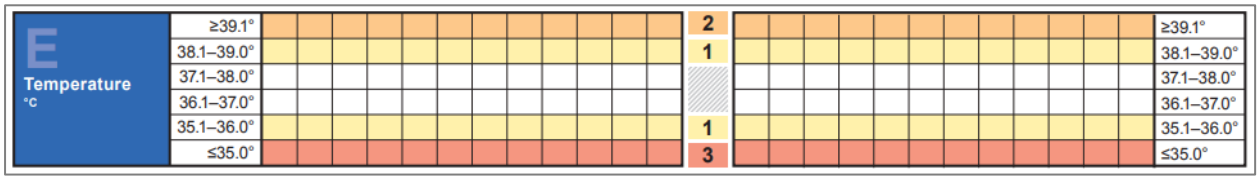


Figure 22: NEWS2 temperature colour coding – from Royal College of Physicians (2017)

Benefits of eREACT V2

Data quality

All participants agreed that the eREACT V2 app had the potential to improve quality of patient observations and data held about patients. Just by storing the patient details (i.e., name, date of birth, etc) reduced likelihood of error as this information does not need to be re-entered for each new form that is used.

> *"…it's got all the relevant details that you need, otherwise you'd have to write them on which we normally do you know, we write them on all the forms so it's clear… and there's limited room for error really because all the details are already in the app I think." (Participant 10)*

The use of the scrolling wheels to input data rather than free typing was seen as key to reducing mis-typed data therefore improving data quality.

> *"You know with a scroll wheel you make less errors, you know, less mistypes, because you can only hit the numbers that are relevant." (Participant 5)*

> *"I like the wheels because you're not having to type out the numbers, you just go to the right number." (Participant 7)*

The automatic calculation of the NEWS2 algorithm further reduced the capacity for error, which was also enforced by the ability to view and edit observations after reviewing the Patient Summary screen.

> *"It's about getting the scoring right. Believe it or not you know, the scoring isn't always accurate when you look at someone's obs form, and you're looking at it and you're going, how did you score that?" (Participant 5)*

> *"…That's good actually 'cause it'll make them, it's like a summary isn't it so it will make them have a look at it and make sure they've done it properly… Obviously you've got to be careful when you start putting in obs in that they're the right obs, but you've got that summary screen so you can check it… I like it because it's very clear, and it's in ABCDE, so it's not all in one, you can see it's broken down into categories, and I like that because it's very clear to see if you have made a mistake," (Participant 9)*

Being digital, the eREACT V2 application also reduces the likelihood of patient data going missing on the ward.

> *"…That's the other thing when you're on the ward is actually finding the paper-based systems as well, even when you're there in person a lot of the time, you'll say 'okay, where's the NEWS2 chart?' and they'll go, 'Oh I'm not sure, [someone else] might have it, she was off down that way in the ward'." (Participant 8)*

The graphs displaying observations over time would also indicate to clinicians the date and time of the last observations for each patient – something that due to user error is not always present in paper charts.

> *"…We find with the paper copy, they miss like the time out or something like that you know, and when you go to do the next set you've got no way*

of finding out when they did the last one, and they can't remember." (Participant 10)

To improve data quality further, one participant argued the ability to mark when a particular observation has not been taken or if there is data missing about a patient would be useful, for example if the patient does not have a GP or fixed address.

"…A lot the time you can't get a full set of obs. If it's a patient… in psychiatry, there's all sorts of reasons why you might not… like you might have someone with autism who doesn't tolerate the blood pressure cuff, or you might have someone in seclusion or restraint and you can check a pulse but you're not going to get a full set of obs, so I guess it's a shame to not be able to record anything when you've only got a partial set of obs really isn't it? …You could even maybe have a couple of options. So, in the same way that… a lot of drug charts have a numbering system where one means patient refused, two means not indicated, or not available, maybe you could just have a couple of options for the nurses to select because that forms part of the evidence… if there ever is any problem and anything happens then it's documented then isn't it?" (Participant 8)

The participant then argued that missing patient details should be flagged if no data is entered to remind staff to track down this information to input later to avoid problems in future.

"…One [software] was insisting on GP details, which when you meet someone out of hours, it's the least of your concerns isn't it? Fair enough when you're thinking of discharge and we need to know who to send the discharge letter to and who's going to prescribe, but in the middle of the night, when they're being admitted, it's not the problem. And so the nurses had a dummy thing, which was like Doctor Z that was just a made up doctor but the problem is then that it's not flagged at all and it's forgotten about for the rest of the admission and it's only when you're coming to discharge and they're starting to plan that then someone realises, you know, 'oh we actually have no idea who the GP is still'. So yeah, I agree. I think being able to enter it blank with a sort of a red line saying 'warning no GP details' is much better because it will keep people reminded. So yeah, I think having some sort of plan for when information is missing and how you can still open accounts would be really helpful." (Participant 8)

Patient Safety

All participants agreed that the eREACT V2 application would support improvements to patient safety. Much of the improvements to patient safety come from the enhancements in data quality in the theme described above, as well as improvements coming from increased quantity of data (which would not lead to an increase workload – see theme below), and centralisation of data in one place, rather than multiple folders, as well as improved accuracy of scoring.

"Yeah, do you know what, again, I would say in comparison to – if I was comparing it, so in comparison to a paper document, I do believe it probably could inform patient safety because you've got the alert coming up and telling you what to do instantly." (Participant 3)

“[It would affect patient safety] only positively, yeah. I mean, if you saw more information, more accurately, clearer, easier to access, because these are the issues that exist with the other paperwork, there are too many mistakes, there’s too many bits missed off… When you’re trying to read it, it’s not clear enough, so the problems that exist with …the old way… then this identifies and corrects all of those. So, it could only be positive.” (Participant 5)

“I think the positives of it is that you can have it centralised.” (Participant 6)

"…It's going to give the on-call doctors a lot more information at the touch of a button which is going to be very helpful because we simply, we don’t get it or it's very time consuming to get the information… When you're busy and you're having to sit and wait two minutes while they [get the patient information], there's a temptation to say 'okay, fine… I'll come and review them in half an hour', which nine times out of ten is fine but every now and again there might be something vital that you do need to know. So, I think it is going to help patient safety significantly." (Participant 8)

"…Paper versions are so unsafe; it depends on the user and who's writing the obs down. I've seen so many weird and wonderful ways of recording obs… I think we should start; we should be using apps for deteriorating patient observation 'cause it takes away the mistakes." (Participant 9)

“So, on paper I audit every year, and I do five random patients per ward, and I go through it like a fine tooth comb, and I’ve been seeing lots of mistakes. Particular mistakes have been scoring wrong. So we had a patient die a couple of years ago because she was scored as… four, and it should’ve been a six, but when I did the investigation of what happened we had a look at it and the patient should’ve scored six, so that meant they would have gone to A&E earlier, and when it was finally started the patient was too far gone to be honest with ya, and as much as I like paper I think apps is gonna stop that.” (Participant 9)

The use of the colour coding conventions within the graphs and tables and the highlighting of risk within eREACT V2 were also cited as aspects of the application that will improve patient safety. One participant described how using the app would support use of the correct patient care pathways.

“I think it would make patient care safer because it would tell me straight away that that is something that needs to be done. And I would say, you know, as a qualified nurse, I’d be getting my medical colleagues to come and do a medical review of the patient. So, I think it helps in terms of operational usage, it clearly helps look at the pathway of patient care.” (Participant 6)

"It just shows you whether they've deteriorated you, know." (Participant 10)

The inclusion of the Sepsis Screening within the app also supports enhancements to patient safety in terms of awareness and clinical actions to take.

“I think having anything that can help you kind of screen for sepsis is a good thing.” (Participant 6)

"Very good, it gets missed out a lot… I think that would help because, especially the sepsis screening as well, that should… because it's not actually on the paper copy [of NEWS2], it's a separate form altogether, and sometimes when somebody's seriously ill you haven't got time to be running around with a piece of paper, you know, that you don't use all the time, whereas this [sepsis screening] will be on there." (Participant 10)

Staff workload and saving time

Most participants felt after some time (e.g., with minimal training to use the software) eREACT V2 would save time and reduce staff workload.

"I think initially, as it's new, it will take time for people to get familiar with it. But I think overall, I think it's responsive and I think once you know where you're going and what to do, it'll be really quick." (Participant 6)

Ease of access to patient information and not needing to trace pens, folders, or forms to record patient observations would also save staff time.

"It would save time." (Participant 4)

"I think it would [save time] actually… because it's so quick and there's no sort of flapping about trying to find the right paperwork, or have you got a pen, you know, all these silly little things that you don't think of but on a ward, the amount of times you lose a pen, and you've got to do somebody's obs… trying to find a pen, they're like gold dust, you know so something like this it would be brilliant." (Participant 7)

Other benefits

It was felt that if other NHS trusts or health and care organisations (e.g., care homes) took up the software, it would enable easier sharing of patient information (as mentioned above).

"So, if the idea would be eventually for every part of the NHS to use this app, it would be good because the results coming from say a nursing home to a hospital via a paramedic, they'd all be there online wouldn't they?" (Participant 7)

Comparison to current methods

All participants agreed that eREACT V2 compared favourably against both existing paper and digital systems (e.g., SEND, SystmOne, CareNotes, VitalPAC). Firstly, participants argued that eREACT V2 would be easier to complete than the paper-based NEWS2 form, reducing the mistakes made from writing down observations.

"…I don't know if you've seen the NEWS2 form, but the boxes are really, really small, so if you fill in say blood pressure, it can sometimes… it can look like something else because someone's tried to squash it into a tiny little box, and this would obviously stop that from happening." (Participant 4)

"When you're looking at those things [paper form], they look scrappy, they look messy, they've got errors all over. They're also in tight spaces." (Participant 5)

"Filling little boxes in with pens and the possibility of making mistakes is easy, you know, but this is really clear… There's no sort of flapping about trying to find the right paperwork, or have you got a pen." (Participant 7)

As described above in 'Data Quality', eREACT V2 was seen to be superior to paper-based systems by ensuring correct calculation and interpretation of the NEWS2 score.

"It's about getting the scoring right. Believe it or not you know, the scoring isn't always accurate when you look at someone's obs form, and you're looking at it and you're going, how did you score that?" (Participant 5)

"So, on paper I audit every year, and I do five random patients per ward, and I go through it like a fine tooth comb, and I've been seeing lots of mistakes. Particular mistakes have been scoring wrong. So we had a patient die a couple of years ago because she was scored as… four, and it should've been a six, but when I did the investigation of what happened we had a look at it and the patient should've scored six, so that meant they would have gone to A&E earlier, and when it was finally started the patient was too far gone to be honest with ya, and as much as I like paper I think apps is gonna stop that." (Participant 9)

For the doctors, they saw eREACT V2 as being able to improve the quality of handovers with staff and would help clinical staff to manage large numbers of patients.

"Speaking in terms of psychiatry and myself, we often cover multiple sites. A lot of the rotas I worked on as a Senior House Officer, you're covering two, sometimes three hospitals and so you get phone calls from the nursing staff and the psychiatry nurses as well, they're brilliant with psychiatry, they're not trained as physical health nurses, and oftentimes the handover that you get isn't the same standard that you'll get from a physical health nurse, where you'll get a clear SBAR [Situation/Background/Assessment/Recommendation], you will have all the information to hand… You'd get a phone call 'Oh Mr So and So is not so well, his NEWS are off', and they'd give you the score, they'd say his NEWS are six now, but then you'd say 'Okay, what's your scoring on?' and they'll go 'Oh it's pulse and blood pressure' and you go 'Okay what were the numbers?' and they'd go 'Oh I don't know… Margaret bring me the chart'. And it takes a lot more time basically for you to get all the information. So being able to remotely, if they ring and speak to me, and I can just, in a few taps on the iPad see all the numbers, see all the patterns, and then also get information about the patient… what his comorbidities are… that'd be really really helpful." (Participant 8)

The ability to keep track of a high case load without the requirement of multiple pieces of paper and folders was also seen as an advantage.

"In my job, you know, I often go onto a ward and you could have twenty people, all with very complex behavioural needs and behavioural issues… with quite complex health concerns too… and there's twenty folders, and you're relatively new to a ward and some says 'Right, read those folders there, you'll be looking after these people today. And you literally read one folder and utterly forget what was in that folder when you move onto the next one; you're required to retain so much information all at once in a very

short space of time. A device like this just gives you a really quick reference to the things you need most… So, if I had one of these, I could literally walk up to [my patient] and tap a couple of buttons and it would come right back to me." (Participant 5)

Clinical staff also felt that eREACT V2 would keep patient data safe, 'in one place', and avoid the problems inherent in misplacing paper-based observations.

"I prefer it because it's digital… It's not paper, I think papers get lost and you know, things can go missing, so this is all in the one place." (Participant 4)

"Also… How data is then stored, you know, so paper ends up just sat in an in-tray waiting to be filed or stamped. I just think this is… it's got to be a better way, you know, from someone who likes to deal with things that are instinctive…. I don't see the comparison in which one is better, the paper is so outdated that something needs to change." (Participant 5)

The only aspect in which a digital approach to eREACT V2 attracted criticism was if hardware required to run eREACT V2 failed, for example, if devices are not charged, or the Wi-Fi is not working. However, it was recognised that this issue is not exclusive to eREACT V2 and much of these risks can be managed by the users themselves.

I think the negatives of it is the system, the data entry system fails, and you lose that data so there needs to be something around back-up, but also if, worst case scenario, your iPads aren't charged, and then you can't complete the task, then you revert back to paper format and that would be my only worry if you have two systems running… But it's really down to users… make sure that the iPad is charged and that it remains operational to be able to do those observations, otherwise you may end up with people doing paper forms." (Participant 6)

With regards existing digital systems (e.g., SystmOne, CareNotes, SEND, VitalPac), participants also viewed eREACT V2 favourably with participants describing eREACT V2 as a simpler, more intuitive system.

"So, I've worked in a lot of places where we use a lot of electronic notes-based systems. And as I say, I think they're probably a lot more complicated." (Participant 8)

"I've been involved in two trials of [different apps], I mean this is better… This is the third app now… This is the better one by the looks of it… This is the best app we've had now out of the three that I've seen." (Participant 9)

"The last app we saw… it was really good, it was so complex, but it could manage beds, and you could assign Clinical Support Workers, and staff nurses to these patients and… I did a two-hour training session and I'd come out with a headache. This isn't like that, and I like that, I like the fact that all you can see is your beds, and your patients in those beds… and that's the way it needs to be, it needs to be simplified… It's straightforward, and that's what I've been asking for for years, just straightforward, we just said it needs to be what it says on the tin, we don't need it to make the tea and do everything else really either, so it's doing what it says, NEWS2." (Participant 9)

"It seems a bit clearer, and not as much, it was quite difficult [another application] we piloted really, and there was a lot of information that didn't really need to be there." (Participant 10)

Implementation

Regarding the potential implementation or roll out of the eREACT V2 software, participants said they would be happy to use the software in its current form but discussed aspects to be considered to make implementation as successful as possible, highlighting training needs, the type of devices that could be used along with some minor changes to the software, and ideas for future developments of eREACT V2.

One participant wondered how easy it would be to set each staff member up with an account with which to log into the software.

"…Maybe for nursing or ward managers, whoever actually opens the accounts and things like that, that's another matter. I have no idea how easy that would be." (Participant 8)

Clinical staff also wondered how the application could be used for auditing purposes and keeping track of the staff member recording each set of observations.

"[On paper systems] There's no signatures or anything to say who completed them, but it would be on your tablet [with eREACT V2] wouldn't it? …And that it's been completed properly, 'cause we find with the paper copy they miss like the time out, or something like that you know, and when you go to do the next set you've no way of finding out who did the last one, and they can't remember." (Participant 10)

There was a concern that implementation might be difficult where there are a high number of staff with low digital literacy, or an aversion to using new technology, however one of the participants who self-declared low confidence in the use of technology felt that she still found eREACT V2 easy to use and would be happy to use it.

"A lot of our nurses are very against technology, well Clinical Support Workers, more the Healthcare Assistants, they just didn't wanna know and that was on the iPad as well, that was one of the biggest things, was it's too difficult to use." (Participant 9)

"It was all clear and straightforward what you had to do. I'm not very good on electronic things." (Participant 10)

Training

All participants agreed that very little training, such as a one-hour training session, would be required to successfully use the application. Most participants stated that running through eREACT V2 during the online usability testing sessions allowed sufficient time and exploration to confidently use the application and something similar would be enough for training. Some participants also suggested just having some time to explore the software in their own time, with a 'dummy version' like the one used during the think-aloud sessions, would be enough to feel confident to use the software in practice. The only situation where training would take more time would be if a session on NEWS2 training were to be included.

"I think you could have a day's training, maybe, I think you've got to… it depends who you're training because if you're training students, you'd have to do all the background to NEWS2 and what it means and do a

whole session and then go in to show them how it works and the possibilities and the same for Sepsis Six, it depends on what depth you need to go to and who you're addressing it to." (Participant 2)

"I don't think there would be an awful of training. I think if they, even if they did it very similar to this, like where they had certain patient examples, and they just explained everything as they went through, I wouldn't think they needed a lot because the computer is analysing what those results are so that's supposed to be the safety issues, the safety for nurses that if they complete this, it tells them what to do." (Participant 3)

"Well, I feel like I could navigate round [the app] now, but I think probably for people who aren't very tech savvy it might take a little bit longer, but you know, like an hour's session." (Participant 4)

"I personally, you know, if you've got a Samsung Notebook at home, I probably could have figured most of this out, if not all of it, if I was dealing with obs. To go through it effectively and quickly… I mean you can't really go that wrong, can you because there's only a couple of options you can tap in and you're not wrecking anything by tapping any of it… It's hard to make a mistake if you know what I was saying. So if I press the wrong button I would only be going back, you know. So, how long [to learn how to use it?] Half an hour? I don't know, a one to one with someone on your ward, it will take you just a few minutes." (Participant 5)

Well I hadn't looked at this before [the online usability session] and I would say that I've found it a very useful and interactive process just doing it with you now. So I think in terms of getting people familiar with it, I'd say no more than an hour, but I think it's about using it, once you've had the training, it's about using it." (Participant 6)

"It's laid out in a relatively intuitive way and the bits that I wouldn't necessarily know straight away, they're very easy to learn, they're things I'd need to be shown once and then I'd know… I've worked in a lot of places where we use electronic notes based systems, and as I say, I think they're a lot more complicated… in terms of my point of view from just using it, I think it would probably need twenty minutes training. I don't think it would be very much at all. It's very intuitive software." (Participant 8)

"I don't think it'd take much, I really don't, I don't think there'd be much training needed… From what I've seen it's easy to use anyway, it's been nice you [the researcher] sitting there… but I think I could have done it [on my own] to be honest with you, with a bit of playing… you can't break it can you?" (Participant 9)

IT Platforms – Computing devices

Participants discussed which platforms and computing devices they would prefer to use with eREACT V2 in practice when recording patient observations. Several participants suggested a handheld portable device, such as a smartphone or tablet, whereas other participants suggested a desktop computer or laptop. The type of device preferred depended upon the participants role in the patient's care – support workers solely preferred handheld devices, and nurses and doctors spoke of handheld or desktop/laptop devices depending on whether they were working in the office or on the ward.

"I think an iPad would be better… If you're looking at putting them on the wards they'd have to have dedicated iPads specifically for that because often… you've got maybe two or three computers on the ward, they might be being used by people, if you need to put obs down straight away you don't want to be writing it down on a scrappy piece of paper and possibly losing it… you'd need quite a few iPads probably on the wards." (Participant 4)

"Would it be confined to one type of device? I mean, it's pretty good on this [tablet], it would be as good on a Smartphone or laptop. I think maybe not a laptop so much because you don't get too much chance to use it. We're pretty limited on laptops and computers, so getting to a computer especially for a support worker isn't easy. I think it would have to be some sort of handheld device, so you can actually fill it in as you're doing the observations." (Participant 7)

"I would prefer it on a mobile phone because [tablets] are quite bulky to carry around. You can't put it in your pocket which you need to be able to do really when you're on call. I find anything I can't put in my pocket gets left on the side and then sooner or later I'm going to leave it somewhere." (Participant 8)

"Sometimes we struggle to get on a computer in the office, and at the moment [due to Covid-19], we can only have three [people] in the office, so if we had Clinical Support Workers and nurses checking the information we'd have to have iPads… You can take them out while they're doing the observations, they can have them out with them can't they like they do with the file, the written ones." (Participant 10)

Hybrid laptop/tablet devices were noted as useful by one participant.

"For [another digital obs system] we're using Lenovo laptops, but they're Yoga laptops. It's a fifteen inch screen, which is useful, and obviously once we start using it they can do their admissions next to the patient because it's all touchscreen, you don't have to be in the office for eight hours like they are now." (Participant 9)

Participants highlighted the importance of protecting the devices from damage when being used on a busy ward.

"For me it would be a tablet. But then I think of the cost and the damage that will come to tablets… For instance, I've been worried about having this thing in my house because my kids might break it… They're not cheap, they're a few hundred quid aren't they? …So trying to keep them operable without it becoming expensive… I bought myself a really, really good [case], I suggest you do the same for these… They just have to be really well protected." (Participant 5)

"Also I worry with things like tablets, they're easier to drop aren't they… if you're having a busy shift and you're using it as you're walking down a corridor … you've just not got as good a grip with one hand… and what would you do then if you're on call and you've just smashed your tablet, you're knackered aren't you?" (Participant 8)

One participant warned they had experienced problems with Apple devices and an apparent incompatibility between the NHS Electronic Staff Record and Apple devices.

> *"We tried iPads in the past and it was a nightmare with them. It was basically because iPads are tied up by Apple aren't they, so we found with Android devices you've got a lot more usability with them, with iPads, sometimes the, especially with some of the Clinical Support Workers using them, sometimes they'd take the password [which was] supposed to be linked with the Electronic Staff Record password that they use normally, and a lot of times they were locked out, so we were just throwing out the iPads and saying we're going back to paper." (Participant 9)*

And of course, there was the importance of the practicalities of having systems in place to ensure the devices are always working, for example, devices always charged and ready for use.

> *I think the negatives of it is the system, the data entry system fails and you lose that data so there needs to be something around back-up, but also if, worst case scenario, your iPads aren't charged, and then you can't complete the task, then you revert back to paper format and that would be my only worry if you have two systems running… But it's really down to users… make sure that the iPad is charged and that it remains operational to be able to do those observations, otherwise you may end up with people doing paper forms." (Participant 6)*

Regarding the day-to-day practicalities of using digital devices, participants were concerned whether eREACT V2 would still work if there was no access to Wi-Fi, as this might ease of use on a day-to-day basis in hospitals with poor Wi-Fi coverage.

> *"The Wi-Fi sometimes gets a bit, it depends, different areas that you go to it's not as good as it should be… It's because of where we are, our building's very old." (Participant 10)*

Suggested changes and further developments

Participants suggested a range of changes and additions to eREACT V2 that would make ongoing implementation and success of the application more likely, as well as suggestions for future modules and development of the application.

Participants wondered if the software would record who took each set of observations for audit purposes or to check accuracy of data.

> *"There's no signatures or anything to say who completed them [with paper observations], but it would be on your tablet wouldn't it?" (Participant 10)*

They were also keen to exploit the potential to share digital information more easily than paper based information be leveraged within the eREACT V2 app, whether that is by the ability to share patient information with other organisations also using the eREACT V2 app, or by being able to print out patient information from eREACT V2 to share with organisations still reliant on paper or ambulance services that needs to get obs quickly.

> *"So if the idea would be eventually for every part of the NHS to use this app, it would be good because the results coming from say a nursing home to a hospital via a paramedic, they'd all be there online wouldn't they?" (Participant 7)*

"Say we have someone who's really ill and we get an ambulance for them [mental health trust], and they say 'Have you got a copy of the NEWS2?' …if we didn't have a copy of it we wouldn't be able to give it to them… Is there any way to print them off?' …When we [used another digital application]… We still used the paper copy as a back-up which was a bit of a nuisance." (Participant 10)

Interoperability of eREACT V2 with other systems (such as electronic patient records) was also viewed as important to successful implementation.

"Where these technical devices and so on tend to fall or drop off later, is when they're… separately used… The ones that generally last are the ones that link to each other. It's a slippery slope isn't it, because then you start using all this specific software, then you bring in something else and you think, oh you know what, all that software, all those computers et cetera, those devices we brought for that software…" (Participant 8)

Additional patient information

Participants suggested further patient information that would be useful to include in next iteration of the application, for example, learning or physical disability or mental health status, reason for admission, allergy status, and treatment plan.

"If he had a disability or something here then that would be useful again to flag up or fill in any like safeguarding if using, that would be helpful to have all that on the main page that you've information straight away." (Participant 1)

"What the plan for the treatment is." (Participant 10)

"The only thing that might be important is if they had a learning disability …at the top of it there would be a risk identified… that would say learning disability, or drug abuse, you know, anything like that… or any mental health problems. I was just thinking if someone's dealing with a patient on the ward it would obviously be quite important that they know that." (Participant 4)

"Whether you could have something on that initial screen [Patient List] about, sort of a snapshot, one line about what their sort of problem is or reason for admission or what have you." (Participant 6)

"I'm thinking allergy status, so I think with allergies now, especially in mental health wards, allergies, they are missed sometimes." (Participant 9)

Addition of further information to graphs, including pain medications to see if there was a difference to the pain score, as well as contextual information regarding the pain score, were also suggested.

"A very common thing on call is pain relief, patients in pain and you often haven't met them before so being able to see how the pain is over time and can you correlate this with 'this medication was added then – did it help, did it not?'" (Participant 8)

"I guess what I would expect from a chart is to tell me something, just to answer the question, but at the moment, I'm not sure what it is, so if the

question was at what point was the pain level different for [the patient], I'd be saying it changed at some point in a day, where he had one rating at two and one rating at six… And obviously there are times when it's the same when they're resting or moving. So I think that gives you the data, but it doesn't tell you the context of why it might be different, so you need to have something in there." (Participant 6)

It was argued that information regarding a patient's Do Not Attempt Resuscitation (DNAR) status, and whether conversations had been had regarding a DNAR order could be included in escalation instructions following a set of observations, but also in the 'Independent Living and Escalation Assessments' section (currently not fully populated in the prototype version).

"Including whether there's a DNAR or whether the discussion has been had as well… my girlfriend's a doctor as well and it drives her mad… she's like not only is there not one there but there's no reference to it in the notes as to whether it's actually been considered because… you don't know then if someone's had the chat and decided not to, or whether it's just not been thought of, which puts you in a sticky situation out of hours when you don't know the patient and you're trying to make decisions… Independent Living and Escalation Instructions… Would this include information about DNARs and things as well then in this section?" (Participant 8)

Although not currently populated in the prototype version of eREACT V2, participants agreed that the inclusion of the biochemistry, haematology, microbiology tabs were important (Figure 23).

"So you've got vital signs, biochemistry, haematology – so have we got blood results in here as well?" (Participant 6)

"As a clinician what interests me so if somebody's observations are off what are the bloods telling me, so that is a good idea if can put that in there, especially if medics are looking at it." (Participant 9)

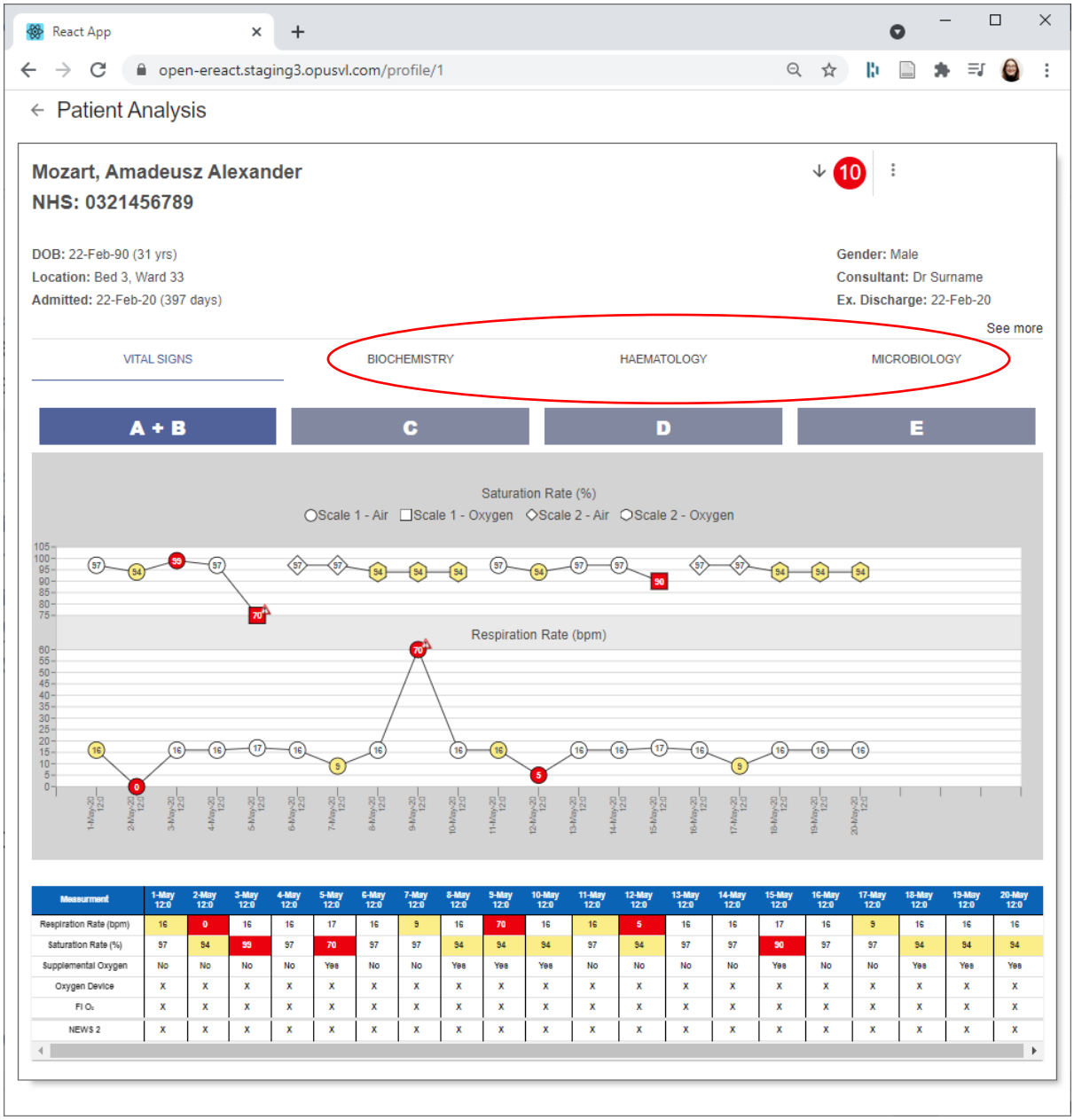


Figure 23: Biochemistry, haematology, microbiology tabs

Add on modules and local customisations

With regards future developments, add-on features or modules to support customisation for local contexts, some participants highted the potential of using Open Source Software for adjustments or improvements depending on hospital or department needs.

> *"Just hopefully there's scope for adjusting it to a hospital's needs which would help." (Participant 11)*

One participant recommended considering the inclusion of adapted paediatric charts, and the use of height and weight rather than BMI due to medication titration based on weight in paediatric patients.

> *"Yeah, yeah. Whereas the height and the BMI, that wouldn't really matter maybe so much as if that was more kind of like in this section here but the weight definitely would need to be a bit earlier on. Also, in paediatrics we*

don't tend to use BMI as much. We have percentile charts that they plot their weight and height on, so obviously that comes in the form of a chart so I don't know if that's something that would be electronic eventually." (Participant 1)

The ability to record further information regarding blood glucose, for example, insulin given, food intake, etc. was also seen as important for diabetic patients.

"Blood glucose is good, I mean this is probably [filled] on it so much further down the line for it to be developing as open source but it might be nice at some point to be able to add in sort of events along the blood glucose mark, so insulin deliveries and meals and stuff like that but again that's not your classic NEWS 2 chart, so that would be something that probably a hospital might add in themselves." (Participant 11)

A few participants also stated that inclusion of the Glasgow Coma Scale (GCS) in addition to the AVPU would be useful, particularly in settings where head injuries, or use of certain medications may be common.

"I definitely need to see, we will need to see GCS… A link from AVPU to GCS… I know it's not national, but in mental health we have anti-psychotics, we have people coming in drunk, and AVPU doesn't pick that up very well, GCS does… Also we use a lot of rapid [tranquilisers], the rapid tranquilisation is sedation for patients that are really poorly, mentally poorly, so you might have someone's who's really aggressive… Sedation is a respiratory depressant …The ones that are in rapid tranq we move to a different [NEWS2] booklet, there is constant monitoring." (Participant 9)

"…We do the Glasgow Coma Scale on the back [of the paper NEWS2 chart] if someone's had a head injury." (Participant 10)

"I mean GCS doesn't normally come into the NEWS 2 to be honest so it probably won't, it would be okay unless, you know, it would be nice if there was an option to add GCS, again that sort of goes into the …. and that would include a GCS, not just an AVPU. So I think, you know, as a basic NEWS 2 chart that would be fine but I think there should be some sort of option built into it at some point for the nurses to add in a separate type of monitoring and that could probably come in when you're on the patient overview section. So you could probably just tick which types of observations the patients could have and then you have a standard set of obs which is what we're seeing here and then just add in, does the patient need neuro obs? Yes. Is a patient on a sliding scale for insulin? So more insulin obs, yeah. And then that might add in your extra insulin charts." (Participant 11)

One participant suggested some trusts may require Body Maps to record symptoms, pain and injuries.

"We also have a body map included in the bits of paper, I kind of would have expected a body map on this as well… that doesn't necessarily mean in the wider part of where they should be used that would be necessary." (Participant 5)

To improve patient safety further, participants argued that escalation instructions should be provided within or following the Patient Summary, similar to the basic escalation instructions provided on the paper NEWS2 form (see Figure 16).

> *"You should be able to click on that and it will come up and then escalation status, there's nothing there, it just says escalation status." (Participant 2)*

> *"It doesn't really have any information about escalation status… I don't know whether this comes later or not, but the NEWS2 charts have a sort of algorithm suggesting to the nursing staff what action they need to take. Is that incorporated in the app somewhere? …I mean, nursing staff might disagree because they might know what to do and they might say it makes it more clunky and whatnot. But I think for newer nursing staff or staff that are maybe doing a bank shift and covering a ward they're not familiar with, it'd be useful for them to be the access to that algorithm. So maybe just a link to it, or you know, you could have a little button saying suggested actions or something where it's not going to get in the way for experienced nurses who know 'I need to call the doctor'." (Participant 8)*

> *"At the moment it's given me a [NEWS2] score but no direction of what to do with that score… Any app [should provide escalation instructions]… if you score above seven in acute it's advanced airway techniques, it's senior medics, it's the registrar on call isn't it?" (Participant 9)*

One participant suggested that clicking on high numeric values within the graphs and tables could also provide a pop-up with escalation instructions.

> *"See where on the graph it says 41.2 and it's flagging up that obviously that's a really high temp… But it doesn't give the option to click it… Like if that was on the NEWS2 form… there's kind of actions on the back of it what would tell you what to do, whereas this… it's flagging it up because it's really high but then it doesn't give you actions like the form does." (Participant 4)*

> *"[The Patient Summary] …so it's got the A, B, C, D, E, NEWS2 scores, then it's telling you at the bottom clinical risk is medium, but I don't know when I click confirm whether its going to then give me, like on the NEWS2 scoring tool it gives you a low, medium and high clinical risk, and it tells you what to do in that instance… It's medium risk so what do I need to do?" (Participant 4)*

Participants highlighted that the Sepsis Screening in the prototype version did include the escalation instruction of starting the Sepsis Six process.

> *"I've pressed next, so Red Flag, sepsis, start Sepsis Six." (Participant 6)*

Participants also argued for tailored escalation instructions depending on the setting or patient. For example, if a patient has a DNAR order, or in mental health settings where a rapid response team or the equipment required for the Sepsis Six process may not be available, therefore calling for an ambulance would be a more appropriate escalation.

> *"Including whether there's a DNAR or whether the discussion has been had as well… my girlfriend's a doctor as well and it drives her mad… she's like not only is there not one there but there's no reference to it in the*

notes as to whether it's actually been considered because… you don't know then if someone's had the chat and decided not to, or whether it's just not been thought of, which puts you in a sticky situation out of hours when you don't know the patient and you're trying to make decisions." (Participant 8)

"So where it says Sepsis Six …in mental health we don't do the Sepsis Six, the only one we can do is oxygen… We'd have to get them to acute… So staff would probably say 'What is the Sepsis Six?' and have them listed… They might take it do a medic and say 'we've got sepsis'…if so we need to take them to A&E… [We have] to rewrite our clinical response because the national ones are more acute driven." (Participant 9)

Participants were also keen to see alerts sent to appropriate members of the clinical team should a patient be at risk of deterioration, or if a new set of observations were overdue.

"Will it come through to, you know if one of the Clinical Support Workers is out on the floor and they're doing the observations, would the alert come through to the staff nurse on another [device]? …That's what happened [with another software we piloted], the score used to come as an alert to us in the office… So it didn't get missed, especially if there was another set [of observations] were due again, 'cause some of the people are hourly if they're very poorly… Usually at that point we're out on the floor with the staff anyway, but you know… Well you do have to go and answer the phone and things… you have to leave them and you have to go looking for things… sometimes you've got that many tasks to do that you forget… Even for the Clinical Support Workers, 'cause they end up doing personal care and things and they probably put their iPad down somewhere." (Participant 10)

Summary of main findings

This project aimed to explore perceived usability and acceptability of the eREACT V2 eObs prototype application with a range of clinical staff via a think-aloud evaluation incorporating an online cognitive walk-through methodology (Beer et al., 1997; Lewis & Rieman, 1994), to ensure the prototype was optimised with regards end-user needs (Bradbury et al., 2019). Eleven healthcare practitioner participants from across the UK were recruited to the think-aloud usability testing, representing a range of roles who would be expected to interact with an eObs system and included Clinical Support Workers (n=2), Nurses (n=6), Doctors (n=2) and a Clinical Training Manager (n=1). Participants had a variety of experience with paper and digital Obs systems (see Table 1). A range of platforms were tested to assess usability.

Overall, participants found eREACT V2 very easy to use and navigate, describing it as clear and intuitive. Participants found the Patient List screen straightforward and clear, and liked the presentation of the first screen within the application. One participant noted how it was preferable to log-in and be presented with the patient list straight away – unlike other digital applications which may require a number of 'clicks' to access a patient list. Participants were able to easily search for and locate individual patients by their names. Navigation between screens was mostly intuitive, although participants did not expect to have to press the back button twice to navigate back from searching to patient to the Patient list.

All participants were unable to identify the function of the Patient Sort button, although once the purpose was explained to them, they found it easy to sort their patient lists and agreed

that the three options of NEWS2 score, observation frequency and patient name were useful. Suggestions for additional sort options included gender and ward/hospital area.

Participant's preferred sort method tended to depend upon their role in the hospital, with nurses and clinical support workers having a preference towards search by NEWS2 score or observations frequency, and doctors preferring to search by patient name or by ward, although they may use the sort list to prioritise patients by NEWS2 score when on-call.

Some minor usability issues arose when exploring the Patient Information. For example, all participants felt that the presence of the three dots within the information carousels suggested that the screen should be swiped, rather than the dots clicked or tapped, as per other device and software conventions, and some participants had difficulty identifying the expand icon to see further details for each information carousel.

Participants found the process of entering observations very easy, although there was some confusion over the correct button to press to begin the process. Participants who tested the application using a PC had some issues with the wheel bouncing when trying to enter data. Although the application was designed for use with tablets, some participants argued that some clinicians may wish to use the application on a PC rather than a handheld device, although this would be more likely to be a doctor who is reviewing patients rather than entering observations. Some patients did not immediately notice that they had to complete tabs C and D&E to enable the pressing of the 'Finish Observations' button. There was concern by some that being forced to enter a full set of observations could be a barrier in some care events, for example where a patient refused to have particular observations taken, and there should be an option to record such an event. Following completion of their patient's observations, participants were presented with a summary of the patient observations and NEWS2 scores, which participants found clear, and they appreciated the automatic calculation of the NEWS2 score, and the option to edit individual scores in the case of a mis-entered observation.

Participants found the sepsis screening easy and intuitive to complete. The presence of the Sepsis Screening option presented at the end of the Patient Summary would be a prompt to run the Sepsis Screening after each round of patient observations. Some participants from a mental health background were not sure what constituted a Red Flag symptom, and suggested that possible Red Flags could be listed prior to the drop-down Red Flags list that appear if the user selects 'Yes'. This would support clinical staff who may not deal with Sepsis Screenings on a routine basis.

Regarding the graphs and tables within the app, overall participants found that these were easy to read and interpret, although some changes were suggested for individual graphs to improve usability and interpretation further, in particular for the blood pressure and pain score graphs. Participants also liked the colour coding on the graphs, and that it reflected the colour coding on the NEWS2 forms with which most of them were familiar, although there were some participants (mostly those from a mental health nursing background) who were less familiar with the NEWS2 colour coding conventions with the graphs followed.

All participants agreed that the eREACT V2 app had the potential to improve quality of patient observations and data held about patients. Just by storing the patient details (i.e., name, date of birth, etc) reduced likelihood of error as this information does not need to be re-entered for each new form that is used. The use of the scrolling wheels to input data rather than free typing was key to reducing mis-typed data therefore improving data quality. The automatic calculation of the NEWS2 algorithm further reduced the capacity for error, which was further enforced by the ability to view and edit observations after reviewing the

Patient Summary screen. Being digital, the eREACT V2 application also reduces the likelihood of patient data going missing, which can happen with paper files and folders. As well as improvements to patient safety coming from improved data quality, participants felt that eREACT V2 would enhance patient safety by supporting centralisation of data in one place, rather than multiple folders, as well as improved accuracy of scoring. The use of the colour coding conventions within the graphs and tables and the highlighting of risk, and inclusion of a sepsis screening tool further enhances patient safety.

Most participants felt that after becoming familiar with eREACT V2 it would save time and reduce staff workload due to ease of access to patient information and not needing to trace pens, folders, or paper forms to record patient observations all contributing to the saving of staff time.

All participants agreed that eREACT V2 compared favourably against both existing paper and digital systems. Firstly, participants argued that eREACT V2 would be easier to complete than the paper-based news form, reducing the mistakes made from writing down observations, and thus support calculation of correct NEWS2 scores. For the doctors, they saw eREACT V2 as being able to improve the quality of handovers with staff and would help clinical staff to manage large numbers of patients. The ability to keep track of many patients without the requirement of multiple pieces of paper and folders was also seen as an advantage.

The only aspect in which a digital approach to eREACT V2 attracted criticism was if the hardware required to run eREACT V2 should fail, for example, if tablets are not charged, or the Wi-Fi is not working. However, it was recognised that this issue is not exclusive to eREACT V2 and much of these risks can be managed by the users themselves. With regards existing digital systems (for example, SystmOne, CareNotes, SEND, VitalPac), participants also viewed eREACT V2 favourably with participants describing eREACT V2 was a simpler, more intuitive system.

Regarding the potential implementation or roll out of the eREACT V2 software, participants said they would be happy to use the software in its current form but discussed areas to be considered to make implementation as successful as possible, highlighting training needs, the type of devices that could be used along with some minor changes to the software, and ideas for future developments of eREACT V2.

There was a concern that implementation might be difficult where there are a high number of staff with low digital literacy, or an aversion to technology, however one of the participants who self-declared low confidence in the use of technology felt that she still found eREACT V2 easy to use and would be happy to use it.

All participants agreed that very little training, such as a one-hour training session, would be required to successfully use the application. Most participants stated that running through eREACT V2 during the online usability testing sessions allowed sufficient time and exploration to confidently use the application and something similar would be enough for training. Some participants also suggested just having some time to explore the software in their own time, such as a dummy version like the one used during the think-aloud sessions would be enough to feel confident to use the software in practice.

Participants discussed which IT platforms they would prefer to use with eREACT V2 in practice when recording patient observations. Several participants suggested a handheld portable device, such as a smartphone or tablet, whereas other participants suggested a desktop computer or laptop. The type of device preferred depended upon the participants role in the patient's care – support workers solely preferred handheld devices, and nurses

and doctors spoke of handheld or desktop/laptop devices depending on whether they were working in the office or on the ward.

Participants suggested a range of changes and additions to eREACT V2 that would make ongoing implementation and success of the application more likely, as well as suggestions for future modules and development of the application, including:

- Ensuring recording of who takes each set of observations for audit purposes
- Support information sharing with other NHS organisations
- Ensuring interoperability of eREACT V2 with other products and systems
- Include further patient information, for example, learning or physical disability or mental health status, reason for admission, allergy status, treatment plan, pain medications, contextual pain information, DNAR status, information pertinent to diabetics (e.g., food and insulin given)
- The ability to record further information regarding blood glucose, for example, insulin given, food intake, etc. was also seen as important for diabetic patients.
- Development of paediatric chart modules
- Include the Glasgow Coma Scale
- Include Body Maps to record symptoms, pain and injuries
- Include clear escalation instructions following the completion of a set of observations (where escalation is appropriate)
- Allow customisation of escalation instructions
- Build in alerts to relevant team members where escalation is required.

Recommendations for eREACT V2 improvements

Recommendations described previously (for the first iteration of the prototype) within the project are detailed in Appendix 1. Following the analysis of the think-aloud usability data for Participants 4-11, the following recommendations for further development of eREACT V2 are made:

- Do not make any significant changes to the overall design, layout and presentation of the application: *Overall participants found eREACT V2 clear and intuitive to use*
- Continue to present the patient list as the first screen the user is presented with: *Participants liked that they could immediately access the patient list, rather than having to navigate to the list via a number of clicks*
- Investigate potential reasons for one of the participants having usability issues when using the keyboard to search for a patient by name (the keyboard and cursor disappeared from the search box): *Although the researchers could not replicate this issue, it should be kept in mind throughout the development process to ensure it was a 'one off' problem*
- Consider allowing users to navigate from the Patient Summary back to the overall Patient List via one click of the back button, or by clicking the X button: *Currently one click of the back or X button takes the user back to the search bar alone, when they expected to be taken straight back to the Patient List*
- Redesign the patient sort button: *Users' first impressions of the Patient Sort button were that it would present them with a NEWS2 form*
- Consider adding the following sort options for users: gender, ward, hospital: *Participants felt that in some contexts these options may be more useful, for example, when using eREACT V2 on a ward round*

- Allow participants to swipe through the information carousels in case of using handheld devices: *All participants felt that the presence of the small dots suggested that the screen could be swiped*
- Consider redesigning the expand icon within the information carousels: *Not all participants were quickly able to identify the expand icon*
- Consider removing the See More/See Less button and present height, weight and BMI as standard: *Although participants found the extra information useful, they did not feel that it was enough information to warrant the option of minimising the information*
- Reconsider 'Create Patient Care Event' language and button design: *Not all participants were able to quickly and correctly locate this button to begin their patient observations, and some found the language confusing, however it was also argued that they would soon learn the correct button via training*
- Keep the wheel method of entering data: *All participants found the wheel easy to use, and cited the benefits of wheel use, including improved data accuracy*
- Ascertain and fix the cause of the blood pressure wheel operating slower than the other data entry wheels: *All participants found the blood pressure wheel slow to use, and some participants suggested that this may become frustrating on a day-to-day basis*
- Explore usability issues regarding wheel use on laptop and desktop computers. *Although eREACT V2 has been optimised for tablet use, some participants suggested they may want to use laptop or desktop devices, depending on the task in hand*
- Provide the option to record if particular observations are unable to be taken (including the reason). *Participants described examples of times where they may not be able to take a full set of observations from a patient, for example, if the patient refuses)*
- Consider changing the layout of text used in the Sepsis Screening, or providing options for users to customise text font and size: *One participant found the text within the Sepsis Screening difficult to read*
- Provide a list of Red Flag factors prior to clicking 'Yes' to "Are there any red flag factors present?": *Not all participants were familiar, or could remember the full list of red flag factors*
- Rearrange text on the Sepsis Screening summary to read: RED FLAG/SEPSIS/Start Sepsis Six: *Participants felt the current layout left the summary and escalation instructions difficult to read*
- Keep the NEWS2 colour coding conventions in the graphs and tables: *Participants liked that the colour coding was familiar and reflected that on the NEWS2 paper forms*
- Keep both the graphs and the table: *Participants liked the choice of either graph or table, depending on the particular parameter they were looking at, or their personal preferences*
- Consider changing the shape used in the blood pressure graph (e.g., from triangles to squares or circles): *Some participants found the blood pressure graph difficult to interpret, particularly where the diastolic and systolic numbers were close in number*
- Highlight low blood glucose (below 4.0 mmol/L) readings via red colours in the same convention as high blood glucose readings: *One participant highlighted that low blood glucose readings are also dangerous and needs to be highlighted as well as high blood pressure readings*

- Some advice or training may need to be provided regarding the pain score graph: *Some participants took time to be able to interpret the graph correctly and differentiate the scores in the resting and moving states despite the presence of the key.*
- Add dates and times to the graph axis for the pain scores: *Participants noted that there were no dates and times on the axis*
- Allow users to submit incomplete sets of observations or patient information, but providing them with the option to record the reason why a full set was not taken (e.g., patient refused, data not available). *Participants highlighted that sometimes they are not able to take a full set of observations for a variety of reasons, and this should not preclude them from being able to submit observations for the data they do have*
- If users are able to submit incomplete observations or patient information, include a feature that will remind users to enter the data when it becomes available (particularly so for patient information, for example GP details): *Participants recognised that there was a risk that users could forget to enter patient information at a later date*
- Ensure that the app is able to function and save data locally when the user is unable to access Wi-Fi: *Participants highlighted that many hospitals do not have blanket Wi-Fi coverage across all wards*
- Ensure the process to create new accounts for users is as simple and quick as possible: *Participants were concerned that this task can increase workload for the member of staff tasked with setting up new accounts*
- Ensure the application records which users uploads which set of observations for audit purposes: *Participants recognised that this would be a useful feature for audit and patient safety purposes*
- Ensure eREACT V2 works on a range of devices, including laptops and smartphones. *Participants discussed how they would want to use eREACT V2 on a variety of devices, depending upon the task they were conducting, for example, tablets or smartphones would be used in ward rounds, but users may prefer to use a laptop or desktop device for reviewing patient observations*
- Encourage customers to purchase protective equipment for their devices: *Participants were concerned that tablets and smartphones have a high individual cost per item, and may get dropped frequently in a busy ward environment*
- Explore potential incompatibility between the NHS Electronic Staff Record system and Apple devices: *One participant had experienced such incompatibility problems, and thus preferred Android devices*
- Incorporate functionality to share data from eREACT V2 digitally, or via paper (this may be done by including information on how to print the screens in training sessions): *Participants spoke of how they would need to share latest observations and the NEWS2 score when transferring patients, and that they would need digital and paper-based ways of doing this depending upon which organisation the patient was being transferred to*
- With regards future developments of eREACT V2, ensure interoperability with other systems where possible: *Participants spoke of their frustration with other software systems which would not work with other systems, or became obsolete following the introduction of a new system*
- Include further patient information within the application, for example: learning or physical disability status, mental health diagnoses, reason for admission, allergy status, treatment plan, DNAR status, whether a DNAR status conversation has taken place: *Participants were keen to see this information within the eREACT V2 app*

- Allow inclusion of data regarding pain medications administered to patients within the pain score graphs: *Participants wanted to be able to correlate the patient's pain scores with interventions such as pain relief*
- Include or develop a separate module for use in paediatric wards: *Paediatric wards have different early warning systems (PEWS) and would need to see these incorporated into the app, or a separate module developed*
- Allow recording of further information regarding blood glucose (e.g., insulin or food taken): *Participants saw this as important for the care of diabetic patients*
- Include the Glasgow Coma Scale within eREACT V2: *Participants argued that this was useful in additions to AVPU, and particularly useful in settings where head injuries or the use of certain medications (e.g., tranquilisers) may be common*
- Include Body Map charts to allow clinicians to record symptoms and pain: *One participant from a mental health trust suggested this may be useful and would remove the need for separate sheets of paper to record symptoms via the Body Map*
- Include escalation instructions where appropriate in the NEWS2 summary which follows the completion of a set of observations: *Participants argued that this would improve patient safety further, and argued that the escalation instructions should be customisable to local contexts*
- Incorporate an alert system to send alerts to appropriate members of the clinical team should a patient be at risk of deterioration, or if a new set of observations were overdue: *It was argued that this would improve patient safety further and reduce the risk of a set of observations being missed*

Conclusion

Despite challenges to the methodology because of the Covid-19 pandemic, the usability testing has added value to clinical development of the application by suggesting recommendations for improvements and future developments. The testing has also highlighted the successes of the application developed so far, with regards to it being intuitive, it will support the improvement of patient outcomes, and requires little training from front-line staff working with patients who are at risk of deteriorating. These successes are likely due to the user-centred philosophy in which the application was developed, working with key stakeholders from the outset (doctors, nurses, patients, researchers, designers, Open Source software specialists).

The testing has also clearly demonstrated the potential for the eREACT V2 app to support improvements to data quality, patient safety and staff workload. Participants embraced the concept of eObs despite as a group having relatively little experience, and appreciated the potential of Open Source to more easily support local customisations and the development of future bespoke modules.

Future research could involve usability and 'think-aloud' testing of further iterations, and post-Covid utilising the Coventry University Healthcare Simulation Area to conduct further testing of the eREACT V2 application in a high ecological validity setting to fully ascertain the benefits of the application whilst being used in a simulated patient care pathway.

In conclusion, with some minor amendments to further improve usability and intuitiveness, eREACT V2 is an Open Source application with the potential to transform patient care, and to improve workflow and workload for healthcare practitioners.

References

Aakre, C. A., Kitson, J. E., Li, M., & Herasevich, V. (2017). Iterative User Interface Design for Automated Sequential Organ Failure Assessment Score Calculator in Sepsis Detection. *JMIR Human Factors*, *4*(2), e14. https://doi.org/10.2196/humanfactors.7567

Adelman, J. S., Berger, M. A., Rai, A., Galanter, W. L., Lambert, B. L., Schiff, G. D., Vawdrey, D. K., Green, R. A., Salmasian, H., Koppel, R., Schechter, C. B., Applebaum, J. R., & Southern, W. N. (2017). A national survey assessing the number of records allowed open in electronic health records at hospitals and ambulatory sites. *Journal of the American Medical Informatics Association*, *24*(5), 992–995. https://doi.org/10.1093/jamia/ocx034

Alsohime, F., Temsah, M.-H., Al-Eyadhy, A., Bashiri, F. A., Househ, M., Jamal, A., Hasan, G., Alhaboob, A. A., Alabdulhafid, M., & Amer, Y. S. (2019). Satisfaction and perceived usefulness with newly-implemented Electronic Health Records System among pediatricians at a university hospital. *Computer Methods and Programs in Biomedicine*, *169*, 51–57. https://doi.org/10.1016/j.cmpb.2018.12.026

Anton, F., & Anton, S. (2016). Implementing the Patient Clinical Observation Sheet as a Service in Hospitals. In T. Borangiu, M. Dragoicea, & H. Nóvoa (Eds.), *Exploring Services Science* (Vol. 247, pp. 693–702). Springer International Publishing. https://doi.org/10.1007/978-3-319-32689-4_53

Ash, J. S., Sittig, D. F., McMullen, C. K., Wright, A., Bunce, A., Mohan, V., Cohen, D. J., & Middleton, B. (2015). Multiple perspectives on clinical decision support: A qualitative study of fifteen clinical and vendor organizations. *BMC Medical Informatics and Decision Making*, *15*(1), 35. https://doi.org/10.1186/s12911-015-0156-4

Bansler, J. P., Havn, E. C., Schmidt, K., Mønsted, T., Petersen, H. H., & Svendsen, J. H. (2016). Cooperative Epistemic Work in Medical Practice: An Analysis of Physicians' Clinical Notes. *Computer Supported Cooperative Work (CSCW)*, *25*(6), 503–546. https://doi.org/10.1007/s10606-016-9261-x

Beal, M. D., Kinnear, J., Anderson, C. R., Martin, T. D., Wamboldt, R., & Hooper, L. (2017). The Effectiveness of Medical Simulation in Teaching Medical Students Critical Care Medicine: A Systematic Review and Meta-Analysis. *Simulation in Healthcare: The Journal of the Society for Simulation in Healthcare*, *12*(2), 104–116. https://doi.org/10.1097/SIH.0000000000000189

Beer, T., Anodenko, T., & Sears, A. (1997). A Pair of Techniques for Effective Interface Evaluation: Cognitive Walkthroughs and Think-Aloud Evaluations. *Proceedings of the Human Factors and Ergonomics Society Annual Meeting*, *41*(1), 380–384. https://doi.org/10.1177/107118139704100184

Benthin, C., Pannu, S., Khan, A., Gong, M., & for the NHLBI Prevention and Early Treatment of Acute Lung Injury (PETAL) Network. (2016). The Nature and Variability of Automated Practice Alerts Derived from Electronic Health Records in a U.S. Nationwide Critical Care Research Network. *Annals of the American Thoracic Society*, AnnalsATS.201603-172BC. https://doi.org/10.1513/AnnalsATS.201603-172BC

Blijleven, V., Koelemeijer, K., Wetzels, M., & Jaspers, M. (2017). Workarounds Emerging From Electronic Health Record System Usage: Consequences for Patient Safety, Effectiveness of Care, and Efficiency of Care. *JMIR Human Factors*, *4*(4), e27. https://doi.org/10.2196/humanfactors.7978

Boehm, M. (2019). The emergence of governance norms in volunteer-driven open source communities. *Journal of Open Law, Technology and Society*, *11*(1), 3–39.

Bradbury, K., Steele, M., Corbett, T., Geraghty, A. W. A., Krusche, A., Heber, E., Easton, S., Cheetham-Blake, T., Slodkowska-Barabasz, J., Müller, A. M., Smith, K., Wilde, L. J., Payne, L., Singh, K., Bacon, R., Burford, T., Summers, K., Turner, L., Richardson, A., … Yardley, L. (2019). Developing a digital intervention for cancer survivors: An evidence-, theory- and person-based approach. *Npj Digital Medicine*, *2*(1), 85. https://doi.org/10.1038/s41746-019-0163-4

Cresswell, K. M., Bates, D. W., Williams, R., Morrison, Z., Slee, A., Coleman, J., Robertson, A., Sheikh, A., Avery, T., Blake, L., Chuter, A., Slight, S. P., Girling, A., Lee, L., Lilford, R., McCloughan, L., Mozaffar, H., & Schofield, J. (2014). Evaluation of medium-term consequences of implementing commercial computerized physician order entry and clinical decision support prescribing systems in two 'early adopter' hospitals. *Journal of the American Medical Informatics Association*, *21*(e2), e194–e202. https://doi.org/10.1136/amiajnl-2013-002252

Dahl, Y., Alsos, O. A., & Svanæs, D. (2010). Fidelity Considerations for Simulation-Based Usability Assessments of Mobile ICT for Hospitals. *International Journal of Human–Computer Interaction*, *26*(5), 445–476. https://doi.org/10.1080/10447311003719938

Dalal, A. K., Schnipper, J., Massaro, A., Hanna, J., Mlaver, E., McNally, K., Stade, D., Morrison, C., & Bates, D. W. (2016). A web-based and mobile patient-centered "microblog" messaging platform to improve care team communication in acute care. *Journal of the American Medical Informatics Association*, ocw110. https://doi.org/10.1093/jamia/ocw110

Dixon, B. E., Simonaitis, L., Goldberg, H. S., Paterno, M. D., Schaeffer, M., Hongsermeier, T., Wright, A., & Middleton, B. (2013). A pilot study of distributed knowledge management and clinical decision support in the cloud. *Artificial Intelligence in Medicine*, *59*(1), 45–53. https://doi.org/10.1016/j.artmed.2013.03.004

Finkel, N., & Galvin, H. (2017). Electronic Health Records: Medication Decision Support for Inpatient Medicine. *Hospital Medicine Clinics*, *6*(2), 204–215. https://doi.org/10.1016/j.ehmc.2016.11.007

Flick, U. (2014). *The SAGE Handbook of Qualitative Data Analysis*. Sage.

Green, J., & Thorogood, N. (2018). *Qualitative Methods for Health Research*. SAGE.

Jamieson, T., Ailon, J., Chien, V., & Mourad, O. (2017). An electronic documentation system improves the quality of admission notes: A randomized trial. *Journal of the American Medical Informatics Association*, *24*(1), 123–129. https://doi.org/10.1093/jamia/ocw064

Jensen, S., Lyng, K. M., & Pnøhr, C. (2012). The role of simulation in clinical information systems development. *Studies in Health Technology and Informatics*, *180*, 373–377.

Kendall, J. E., Kendall, K. E., & Germonprez, M. (2016). Game theory and open source contribution: Rationale behind corporate participation in open source software development. *Journal of Organizational Computing and Electronic Commerce*, *26*(4), 323–343. https://doi.org/10.1080/10919392.2016.1228360

Kopanitsa, G. (2017). Integration of Hospital Information and Clinical Decision Support Systems to Enable the Reuse of Electronic Health Record Data. *Methods of Information in Medicine*, *56*(03), 238–247. https://doi.org/10.3414/ME16-01-0057

Kossman, S. P., Bonney, L. A., & Kim, M. J. (2013). Electronic Health Record Tools' Support of Nurses' Clinical Judgment and Team Communication. *CIN: Computers, Informatics, Nursing*, *31*(11), 539–544. https://doi.org/10.1097/01.NCN.0000432122.79452.7b

Krousel-Wood, M., McCoy, A. B., Ahia, C., Holt, E. W., Trapani, D. N., Luo, Q., Price-Haywood, E. G., Thomas, E. J., Sittig, D. F., & Milani, R. V. (2018). Implementing electronic health records (EHRs): Health care provider perceptions before and after transition from a local basic EHR to a commercial comprehensive EHR. *Journal of the American Medical Informatics Association*, *25*(6), 618–626. https://doi.org/10.1093/jamia/ocx094

Kushniruk, A., Nohr, C., Jensen, S., & Borycki, E. M. (2013). From Usability Testing to Clinical Simulations: Bringing Context into the Design and Evaluation of Usable and Safe Health Information Technologies. Contribution of the IMIA Human Factors Engineering for Healthcare Informatics Working Group. *Yearbook of Medical Informatics*, *8*, 78–85.

Larsen, E., Fong, A., Wernz, C., & Ratwani, R. M. (2018). Implications of electronic health record downtime: An analysis of patient safety event reports. *Journal of the American Medical Informatics Association*, *25*(2), 187–191. https://doi.org/10.1093/jamia/ocx057

Lee, Y., Park, Y. R., Kim, J., Kim, J. H., Kim, W. S., & Lee, J.-H. (2017). Usage Pattern Differences and Similarities of Mobile Electronic Medical Records Among Health Care Providers. *JMIR MHealth and UHealth*, *5*(12), e178. https://doi.org/10.2196/mhealth.8855

Legaz-García, M. del C., Martínez-Costa, C., Menárguez-Tortosa, M., & Fernández-Breis, J. T. (2016). A semantic web based framework for the interoperability and exploitation of clinical models and EHR data. *Knowledge-Based Systems*, *105*, 175–189. https://doi.org/10.1016/j.knosys.2016.05.016

Leminen, S., Westerlund, M., & Nyström, A.-G. (2012). Living Labs as open-innovation networks. *Technology Innovation Management Review*, *September 2012*, 6–11.

Lewis, C., & Rieman, J. (1994). *Task-centred user interface design*. Lewis & Rieman.

Lundell, B., Lings, B., & Syberfeldt, A. (2011). Practitioner perceptions of Open Source software in the embedded systems area. *Journal of Systems and Software*, *84*(9), 1540–1549. https://doi.org/10.1016/j.jss.2011.03.020

Manaktala, S., & Claypool, S. R. (2017). Evaluating the impact of a computerized surveillance algorithm and decision support system on sepsis mortality. *Journal of the American Medical Informatics Association*, *24*(1), 88–95. https://doi.org/10.1093/jamia/ocw056

Metelmann, B., & Metelmann, C. (2016). Medical simulation center as a model for testing mHealth concepts in prehospital emergency medicine. *2016 Federated Conference on Computer Science and Information Systems (FedCSIS)*, 1423–1426.

Miller, A., Moon, B., Anders, S., Walden, R., Brown, S., & Montella, D. (2015). Integrating computerized clinical decision support systems into clinical work: A meta-synthesis of qualitative research. *International Journal of Medical Informatics*, *84*(12), 1009–1018. https://doi.org/10.1016/j.ijmedinf.2015.09.005

NCEPOD. (2007). *Emergency Admissions: A Journey in the Right Direction? A report of the national confidential enquiry into patient outcomes and death (2007)*. NCEPOD. https://www.ncepod.org.uk/2007report1/Downloads/EA_report.pdf

Nguyen, L., Bellucci, E., & Nguyen, L. T. (2014). Electronic health records implementation: An evaluation of information system impact and contingency factors. *International Journal of Medical Informatics*, *83*(11), 779–796. https://doi.org/10.1016/j.ijmedinf.2014.06.011

NHS Health Research Authority. (2017). *Is my study research?* http://www.hra-decisiontools.org.uk/research/

NICE. (2017). *Sepsis recognition, diagnosis and early management: NICE Guideline NG51*. London: NICE. https://www.nice.org.uk/guidance/ng51

NICE. (2020). *National Early Warning Score Systems that alert to deteriorating patients in hospital. Medtech Innovation Briefing (MIB205*. NICE. https://www.nice.org.uk/advice/mib205/resources/national-early-warning-score-systems-that-alert-to-deteriorating-adult-patients-in-hospital-pdf-2285965392761797

Perry, J. J., Sutherland, J., Symington, C., Dorland, K., Mansour, M., & Stiell, I. G. (2014). Assessment of the impact on time to complete medical record using an electronic medical record versus a paper record on emergency department patients: A study. *Emergency Medicine Journal*, *31*(12), 980–985. https://doi.org/10.1136/emermed-2013-202479

Pimentel, M. A. F., Redfern, O. C., Gerry, S., Collins, G. S., Malycha, J., Prytherch, D., Schmidt, P. E., Smith, G. B., & Watkinson, P. J. (2019). A comparison of the ability of the National Early Warning Score and the National Early Warning Score 2 to identify patients at risk of in-hospital mortality: A multi-centre database study. *Resuscitation*, *134*, 147–156. https://doi.org/10.1016/j.resuscitation.2018.09.026

Ratwani, R., Fairbanks, T., Savage, E., Adams, K., Wittie, M., Boone, E., Hayden, A., Barnes, J., Hettinger, Z., & Gettinger, A. (2016). Mind the Gap: A systematic review to identify usability and safety challenges and practices during electronic health record implementation. *Applied Clinical Informatics*, *07*(04), 1069–1087. https://doi.org/10.4338/ACI-2016-06-R-0105

Rehmann, A. J., Mitman, R. D., & Reynolds, M. C. (1995). *A Handbook of Flight Simulation Fidelity Requirements for Human Factors Research* (DOT/FAA/CT-TN95/46). Article DOT/FAA/CT-TN95/46. https://trid.trb.org/view/1542465

Royal College of Physicians. (2017). *National Early Warning Score (NEWS2): Standardising the assement of acute illness severity in the NHS. London: Royal College of Physicians*. Royal College of Physicians. https://www.rcplondon.ac.uk/projects/outputs/national-early-warning-score-news-2

Sieverink, F., Kelders, S., Poel, M., & van Gemert-Pijnen, L. (2017). Opening the Black Box of Electronic Health: Collecting, Analyzing, and Interpreting Log Data. *JMIR Research Protocols*, *6*(8), e156. https://doi.org/10.2196/resprot.6452

Skyttberg, N., Vicente, J., Chen, R., Blomqvist, H., & Koch, S. (2016). How to improve vital sign data quality for use in clinical decision support systems? A qualitative study in nine Swedish emergency departments. *BMC Medical Informatics and Decision Making*, *16*(1), 61. https://doi.org/10.1186/s12911-016-0305-4

Slight, S. P., Eguale, T., Amato, M. G., Seger, A. C., Whitney, D. L., Bates, D. W., & Schiff, G. D. (2016). The vulnerabilities of computerized physician order entry systems: A qualitative study: Table 1. *Journal of the American Medical Informatics Association*, *23*(2), 311–316. https://doi.org/10.1093/jamia/ocv135

Slovis, B. H., Nahass, T. A., Salmasian, H., Kuperman, G., & Vawdrey, D. K. (2017). Asynchronous automated electronic laboratory result notifications: A systematic review. *Journal of the American Medical Informatics Association*, *24*(6), 1173–1183. https://doi.org/10.1093/jamia/ocx047

Subbe, C. P., Gao, H., & Harrison, D. A. (2007). Reproducibility of physiological track-and-trigger warning systems for identifying at-risk patients on the ward. *Intensive Care Medicine*, *33*(4), 619–624. https://doi.org/10.1007/s00134-006-0516-8

Tsoukalas, A., Albertson, T., & Tagkopoulos, I. (2015). From Data to Optimal Decision Making: A Data-Driven, Probabilistic Machine Learning Approach to Decision

Support for Patients With Sepsis. *JMIR Medical Informatics*, *3*(1), e11. https://doi.org/10.2196/medinform.3445

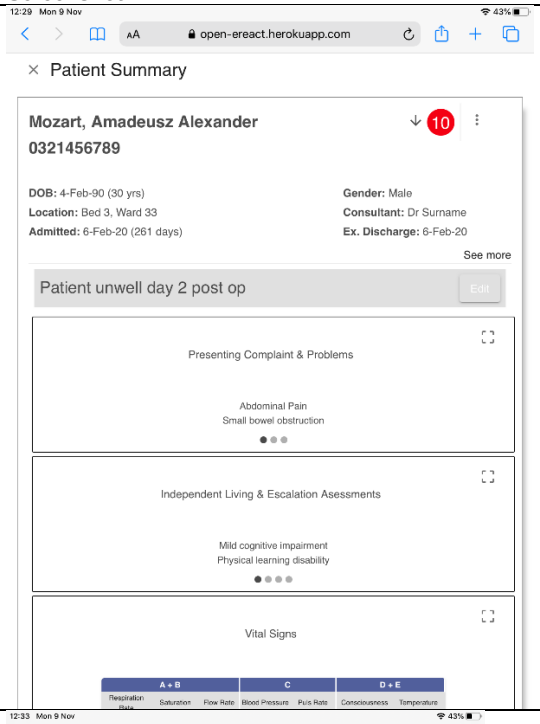
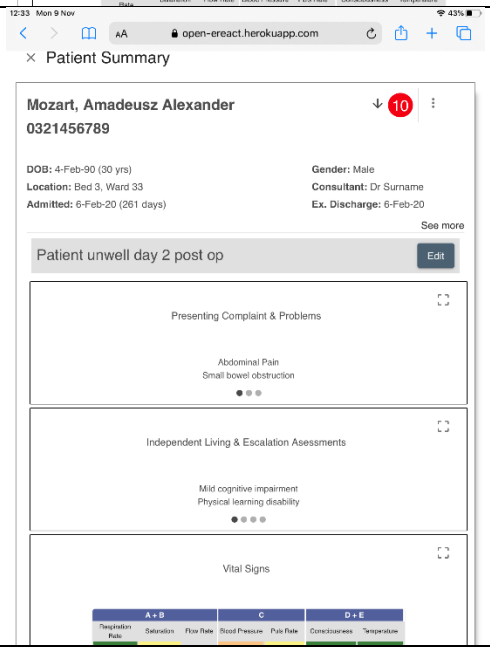
Wilbanks, B. A., Berner, E. S., Alexander, G. L., Azuero, A., Patrician, P. A., & Moss, J. A. (2018). The effect of data-entry template design and anesthesia provider workload on documentation accuracy, documentation efficiency, and user-satisfaction. *International Journal of Medical Informatics*, *118*, 29–35. https://doi.org/10.1016/j.ijmedinf.2018.07.006

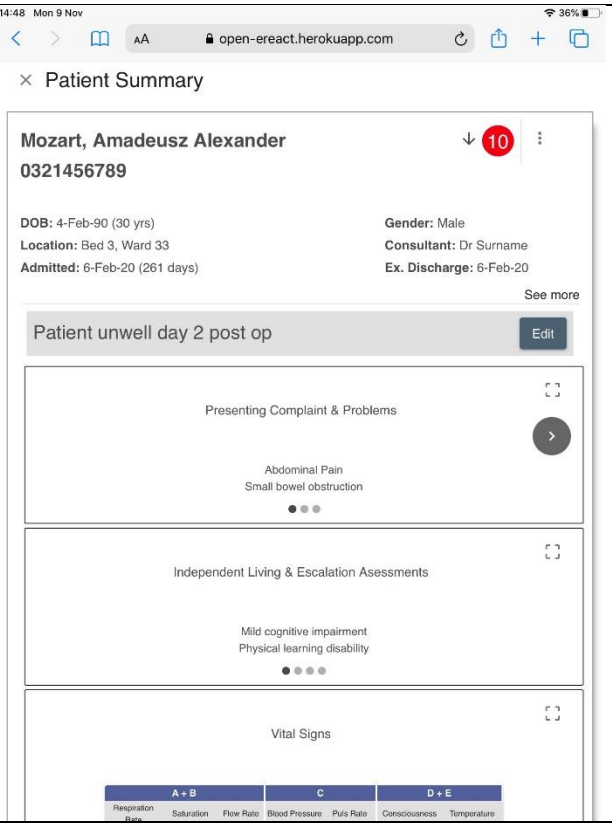
Wilson, S. J., Wong, D., Clifton, D., Fleming, S., Way, R., Pullinger, R., & Tarassenko, L. (2013). Track and trigger in an emergency department: An observational evaluation study. *Emergency Medicine Journal*, *30*(3), 186–191. https://doi.org/10.1136/emermed-2011-200499

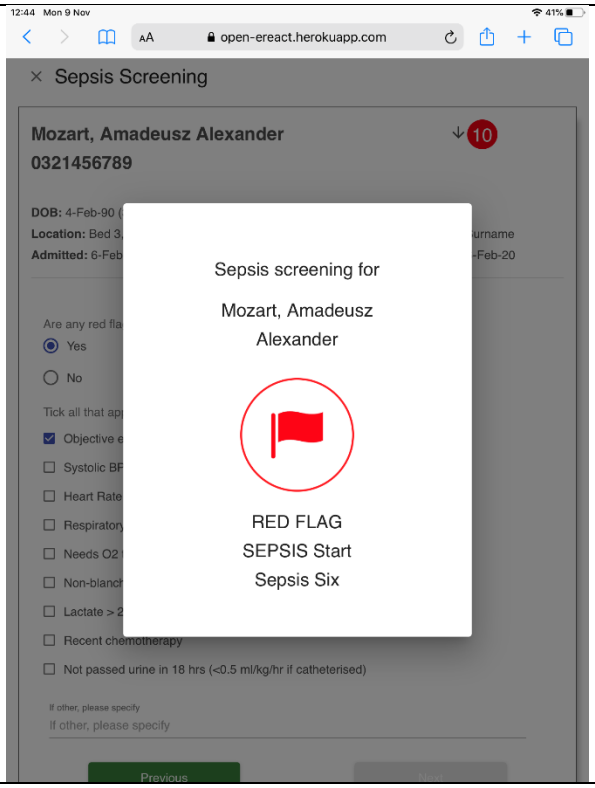
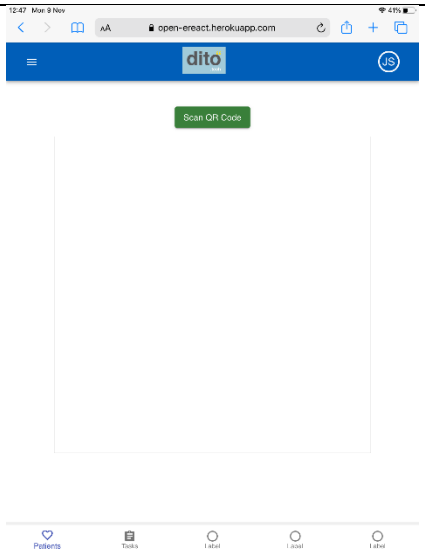
Wong, D., Bonnici, T., Knight, J., Gerry, S., Turton, J., & Watkinson, P. (2017). A ward-based time study of paper and electronic documentation for recording vital sign observations. *Journal of the American Medical Informatics Association*, *24*(4), 717–721. https://doi.org/10.1093/jamia/ocw186

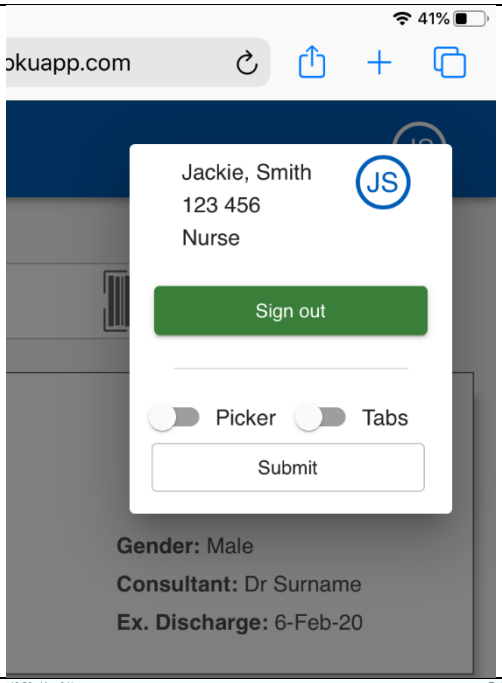
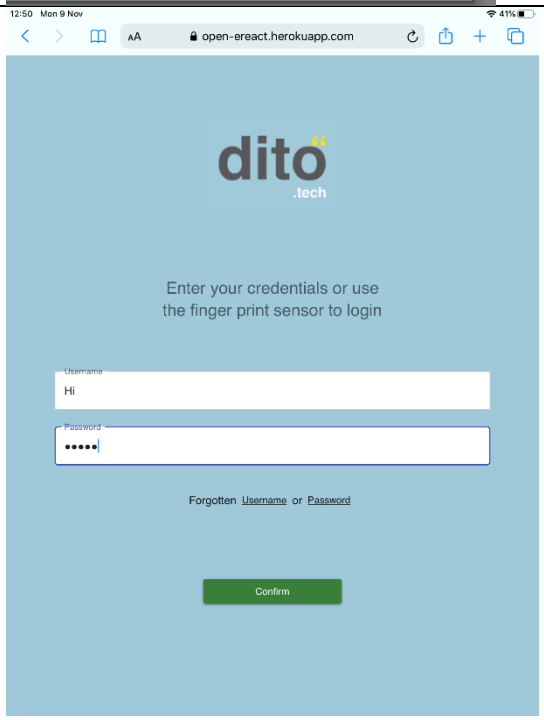
Appendix 1

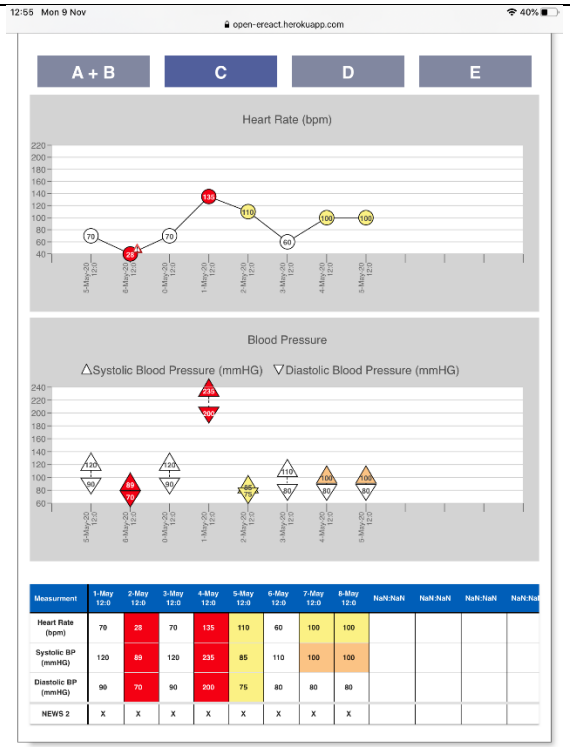
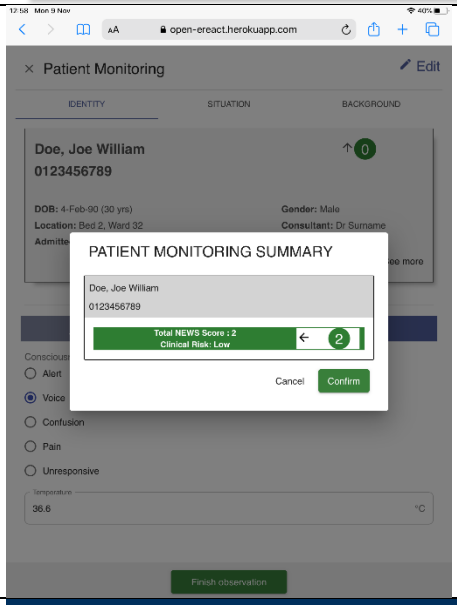
Usability issues identified after pilot testing

Issue identified	Description	Suggestion	Screenshot
Edit button doesn't do anything	On Mozart, A A, the 'patient unwell day 2 post op' edit button doesn't do anything		
Dots for additional information difficult to click	Dots for additional information on the sections 'procedures & progress', independent living… etc) are difficult to click to see additional information	Swipe left/right function and/or arrows on the edges to click	

Arrows in circles for moving left and right appear randomly/briefly	Arrows in circles for moving left and right on the detail boxes on patient summary page appear randomly/briefly when you click on the side		
Clicking back on the browser	If you click back on the browser (safari) it goes back to the patient list. I was on the 'patient situation & background section for Mozart, so back should have gone back to Mozart's patient summary page rather than all patients. It works fine to click the back arrow within the application itself.		
Scrolling through numbers for blood pressure	When there are two numbers to scroll through if you scroll systolic first and have a long way to scroll it also changes diastolic. It takes a long time to scroll through to get the right number.		

Sepsis screening result flashes up	Sepsis screening result flashes up really quickly so not able to read it.	Needs to stay on as long as needed	
No other patient records	When clicking on any patient on the patient home screen, it goes to Mozart.	Need to go to each individual patient records.	
No back button on the scan page	No back button on the scan page. I needed to use back on browser or click patients <3		

What does picker and tabs do?	On the top right nurse account details button (JS). What does picker and tabs do? They don't seem to do anything.		
There's no GO button on the keyboard when putting in username and password.	There's no GO button on the keyboard when putting in username and password. You have to close the keyboard to then click confirm on the app screen.		 (screen shot didn't capture the iPad's keyboard)

Dates for heart rate in wrong order	Dates for heart rate observations are in the wrong order on the patient analysis C page.		
Entering patient obs anything changed? **(+ ppt1, p13, line 302-309)**	After you've entered the patient obs its not clear if anything changed or if all the same	See **all entered details** on summary including up, down, same arrows to indicate changes.	
EWS (sort) not clear **(ppt 1, p2, line 46-60)**	Its not clear that the EWS button is to be able to sort… Should there also be an option to sort ascending and descending?	Could just have 'sort by' with the up and down arrows or 'sort by: EWS'