Embracing Change: Learnings From Implementing Multidimensional Digital Remote Monitoring in Oncology Patients at a District General Hospital During the COVID-19 Pandemic

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A combination of newer treatments, better diagnostics, and earlier interventions means more people live with and are treated for cancer than ever before.[1] Although in terms of scientific breakthrough, this is clearly positive, clinical pathways and the systems in place to deliver these treatments have not much changed for 20 years. Embracing technology must be part of the solution to improve efficiency, to safely deliver treatments and improve patient's experience with oncology care.[2,3]

The COVID-19 pandemic has forced this issue to the forefront.[4,5] Increasing staff sickness and clinical assessments largely over the phone, using innovative technology, particularly in the outpatient setting, should now be a must.

Our oncology unit consists of a 20-bedded inpatient ward, 20-chair chemotherapy delivering unit, outpatient department, and acute oncology–specific receiving unit. It is associated with a main hospital site and benefits from subspecialty advice with any level II or III care required. Our vision is for each oncology patient undergoing anticancer treatment to have vital signs and circadian metrics monitored continuously over the entirety of their oncology care. This can be achieved through a multidisciplinary integrative approach involving clinicians of different specialties, nurses, healthcare professionals, and biomedical engineers.

There is rapidly growing evidence demonstrating the predictive value of large patient-generated data in anticipating deterioration, optimizing care, and guiding treatment changes.[6-10] Although the bioinformatics predictive methodology rapidly develops, building systems on existing older technology is becoming a major bottleneck to success. Developing environments that allow validated easy-to-use devices and applications to complement busy service departments without becoming additional time burden is key to a viable useful solution.

We plan to develop a three-phase process to attain our ambitions. We present the first phase here. Forty-eight randomly selected patients with cancer were given a wearable device (Garmin Vívosmart 4[11]) connected to a bespoke smartphone application "Nitrogen by Aparito" (iOS and Android compatible), designed by the MedTech company Aparito[12] and funded by NHSX Techforce 19 and SMART Cymru as part of their COVID response fund for a specific duration of 2 weeks.[13] Nitrogen is a version of the Atom5 platform (Fig 1). Vívosmart 4 is an off-the-shelf lifestyle watch that records heart rate, accelerometer, ambient light, and pulse blood oxygen saturation (SpO_2). The performance of this device has been compared with similar consumer activity trackers in studies assessing outcomes related to physical activity, sleep, and heart rate, with overall satisfactory results.[14-16] Nonetheless, Vívosmart 4 used here is one of the few armbands equipped with a pulse oximeter, which we reputed chiefly relevant with regard to COVID-19 symptomatology and remote surveillance.[17,18]

Twenty-six participants were male and 22 female. Each of them completed informed consent. Patients' average age was 65 years (range, 31-80 years). As a group, they reflect a real-life cohort expected to attend an oncology outpatient department.

Phase I coincided with the COVID-19 peak in the United Kingdom (April 2020). As this was a proof-of-concept project attempting to outline the feasibility of rapidly implementing tailored patient monitoring, we selected COVID-19–based patient-reported symptoms highlighted by Public Health governing bodies at that time.[19] Specifically, Nitrogen presented once daily yes/no questions on new/worsening cough, breathing difficulties, fever/temperature, unusual/worse than usual fatigue, and general well-being. The patients could also tick the symptoms they were experiencing from a pre-established list including body aches/chills, nausea, vomiting, appetite/smell/taste loss, and abdominal pain. Objective measurements of spot-check SpO_2 and continuous heart rate and physical activity were collected using the wearable device. Any

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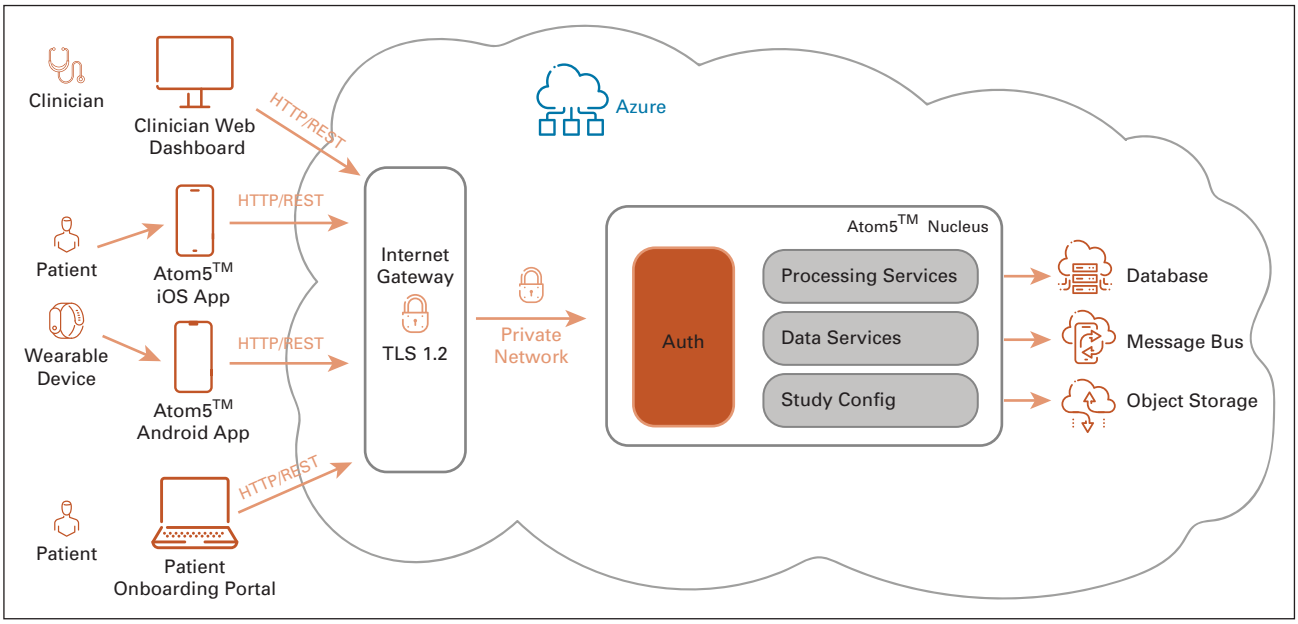

FIG 1. Technical architecture of the Atom5 platform used in this deployment. The data flow and storage is illustrated in the cloud, with encryption at transfer and rest depicted. Auth, authorization; TLS, Transport Layer Security.

identified potential COVID-like symptoms were assessed daily for subjective deterioration through the mobile application with an alert and notification sent to patients to complete. Vital sign measurements from the device and patient-reported symptoms were collated and displayed within a central easy-to-use web-based dashboard for responsible clinicians and healthcare professionals to assess.

Forty (83%) of the patients who were consented ultimately recorded data, demonstrating that the application was an accessible technology solution for the majority of patients. In general, the patients demonstrated a high engagement with completing the questionnaire, recording symptoms for a median of 9 days. The monitoring duration varied from 1 to 14 days depending on the patients' consent date during the project timelines (a fortnight). Overall, there was a positive commitment to the process, and this was confirmed by an impressive median adherence rate of 89%, comparing favorably with other similar COVID-19–specific or general cancer digital solutions.[20-22]

Physiological metrics were monitored by the wristband worn day and night for the continuous measurement of heart rate, the motion intensity patterns, and the nightly assessment of SpO_2. Additionally, patient-triggered snapshot measurements of SpO_2 were possible during daytime.

When evaluating our target population before amendments for phase II of our plans, one of the most notable reasons for not engaging was user-operator related. Of the twelve patients who had minimal use of the application, the majority struggled to activate the Bluetooth connection on their mobile phone to allow linking the application to their wearable device or mistakenly used the Garmin Connect App, which prevented clinicians from receiving the data on the Nitrogen app. As a result, data were collated from the wearable devices of 34 patients (71%). Patients showed slightly less engagement with the wearable device's use than with the symptoms questionnaire, as reflected by the median adherence to device's use of 79%. The most commonly reported difficulty was related to the device screen being too small for patients to read and navigate the display. Another key engagement issue was the expressed wish by the majority of patients to being able to track their own data directly on the application. Patients encouraged the development team to adapt and develop version II. Thirty-one patients were still using the technology at week 5 and 21 at week 13 without any prompting, reminder, or further intervention from the clinical team.

Overall, the response to the remote monitoring technology was greatly positive. A short feedback survey conducted in a self-selecting subgroup of 22 patients revealed that the patients were overall satisfied with both the application and wearable device. On a Likert scale from 0 (not at all) to 10 (very much), the patients rated the easiness of the application's use with an average score of 8.3, and of 6.9 to the wearable device's utilization. Furthermore, the patients felt comfortable with using the application on their phone to communicate their symptoms (average: 9.3) and with carrying a wearable device to share their physiological metrics with their doctors (average: 8.7). The feedback regarding the device screen, the onboarding process, and the desire to self-monitoring being included have been used to inform the development for phase II.

Developing bespoke monitoring systems for individual patients undergoing systemic anticancer therapy will become standard of care eventually. Our first phase implemented rapidly during the viral crisis has offered us valuable insight into the practicalities of implementing a system as we move to more comprehensive deployments.

High-quality governance is an essential cornerstone of this approach if it is to be accepted long term. Although such big data are likely to provide valuable insights into patients' clinical outcomes, their privacy must not be sacrificed in a bid to achieve this, and as such, the protection of this personal patient-generated data is vital. In our phase I deployment, Information Governance approval and patient onboarding were all achieved within 2 weeks; this process could well have taken upward of 2 months before the COVID-19 pandemic. The facilitation of speedier decision making and implementation are hugely topical aspects that have allowed significant progress in our monitoring plans, and we hope that they remain in health care after COVID-19.

Some of the major limitations and therefore learning points of our first phase were based on the assumption of what is patient IT literacy. We assumed that patients knew how to connect to Wi-Fi, navigate an app store, and use Bluetooth connectivity. Although these issues were by no means the norm, they did highlight a potential disenfranchised group whom we need to support and cater for.

Finding the balance of using key clinicians time and collecting meaningfully actionable data means that our future infrastructure budgeting will change. Redesigning of workflow will allow nonclinical staff with dedicated time to onboard initially less capable patients and upskill those with an interest while enabling trained and experienced healthcare professionals to focus on analyzing and triaging trends highlighted by the data.

In conjunction with this, finding a balance between a validated minimally invasive device that is easy to use for a patient with poorer eyesight and less fine motor dexterity was probably our biggest ongoing concern.

Since being able to visualize their own data was of major interest to patients, we believe that the addition of this feature to future rollouts will be likely to increase participation's length and patient's engagement. Notwithstanding, it is important to strike the balance between empowering and not overwhelming patients with information. Not to be overloaded with questions was another highlighted aspect by the participants. These are not novel insights into patient's habits and requirements for digital monitoring studies.[23,24]

Monitoring devices can be either lifestyle and/or consumer or medically certified. Inherently, health professionals veer to medically registered devices because of absolute need for accurate, reliable, and repeatable data to justify clinical decisions. Patients, however, are much more likely to provide longer periods of data monitoring with a lifestyle and/or consumer device given its focus on being easy-to-use, esthetically pleasant, and practical.[25,26]

There are several examples of validated, or undergoing clinical trials, novel medical devices. These devices are aimed explicitly to be clinically accurate but often designed for a short-term assessment period and as such come with more taxing fitting conditions.

Manufacturers of lifestyle devices, particularly in the COVID-19 pandemic era, are moving into an economic space capitalizing on the general population's desire for medical monitoring. They are teaming with large research institutions; examples include the Scripps Research Translational Institute with FitBit's DETECT health study[27] and Stanford Healthcare Innovation lab who are working with multiple lifestyle devices including Fitbit, Garmin, Samsung, Apple, and Oura.[28,29]

In our initial case series, we noticed several staff members and patients in good health condition recording low saturations that were up to 10% lower compared with readings found using in-hospital medical grade devices. This highlighted the absolute need to carefully deploy chosen devices in validating study as a prerequisite before any use in a decision-making capacity.

Despite the growing interest in mobile sensing in oncology[3] and with COVID-19,[18,30] and the multiple smartphone apps and digital platforms for symptom monitoring in patients with cancer,[31-35] most COVID-19–specific monitoring in patients with cancer worldwide has been using mainly patient-reported symptoms and not passive biosensing.[36-40]

With this blurring between the more traditionally designed medical devices and the rapidly evolving lifestyle trackers, justifiable scientific validation becomes critical. One important feature from our initial study suggested that patients have a wide reference range of what they consider easy to use. We believe that a combination of offered devices will lead to the most comprehensive, individualized, and long-term engagement—likely in the form of watches and/or armbands,[41] rings,[42] transdermal patches,[43] or even integrated solutions using multiple dedicated sensors.[44,45]

Our series informally gather the key staff members' opinion of efficiency. Although trial processes are inherently inefficient cited by the initial onboarding of patients, there was a general buy-in that optimizing this technique is a progressive step and dedicated nursing support has been funded to investigate streamlining a protocol.

As our series moves through phase II (recruiting targeted acutely unwell patients to monitor their progress as inpatient and outpatient) and phase III (general new patient recruitment), assessment, reliability, and quality checks of the monitoring device with medical grade specifications will be critical to success. Phase II will additionally look to

compare the vital signs measured on standard medically accepted and certified observation machines based in the unit used for the development of the NEWS score[46] with our device(s). Improved versions of the application will evolve over the phases as we optimize patient-specific queries and incorporate cancer-specific pathways and other aspects that support our multidisciplinary team (specialist cancer nurses, physiotherapists, nutritionists, and clinical psychologists) to provide a holistic, tailored, and integrative support for our patients with cancer.

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