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Case study

Outside the hospital: cancer monitoring with apps

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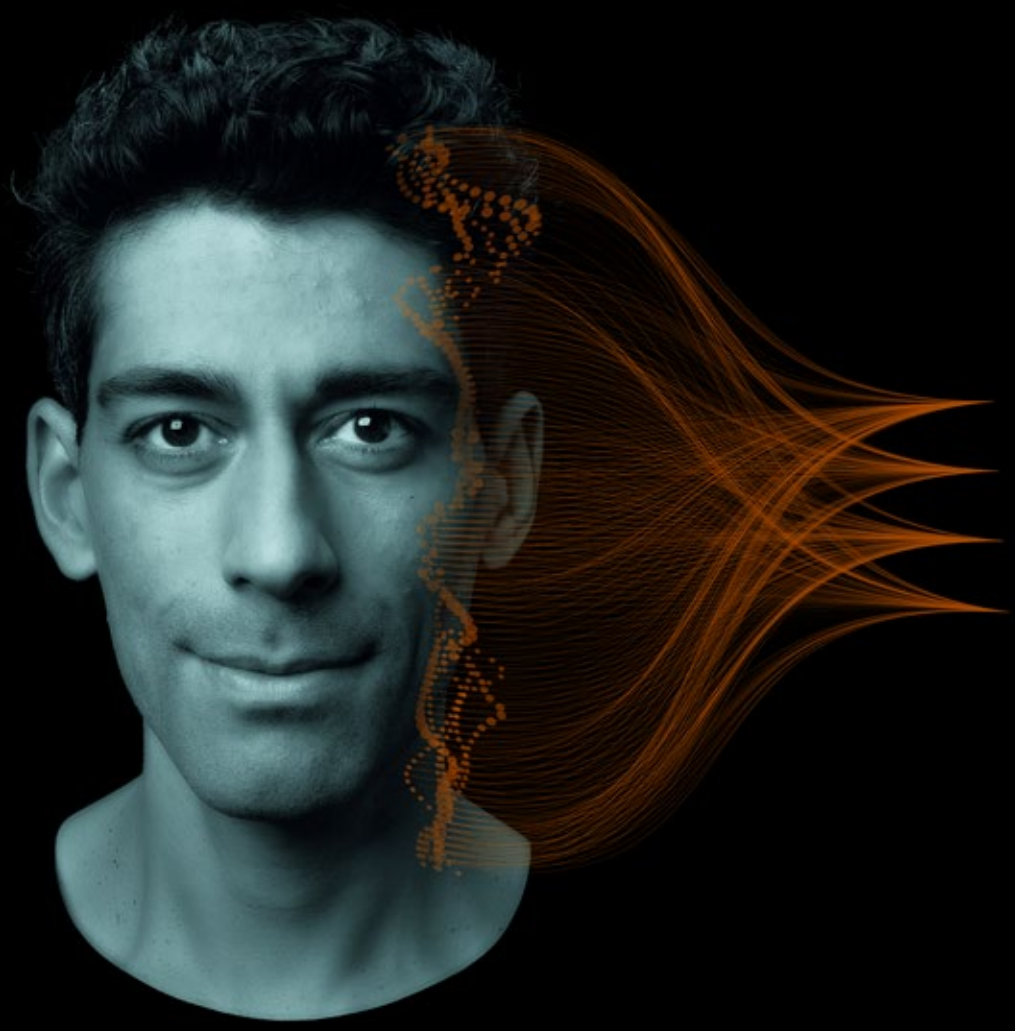

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Foreword by ECG Management Consultants – a Siemens Healthineers Company

Siemens Healthineers strives to understand the broader changes taking place in healthcare and how they may bring in changes to improve working practices, and to share these insights with our community.

One of the transformative developments changing every facet of the healthcare industry landscape is digitalization. Digital transformation has been redefining our lives for several decades now, and the recent pandemic has served to accelerate many of these changes. It is essential that healthcare providers, patients, and all stakeholders understand the scope and breadth of these changes, and learn how to use them for their benefit – to expand precision medicine, transform care delivery and improve the patient experience.

In the article below, part of a series, written by the Economist Intelligence Unit (EIU) and based on extensive first-hand research, we are exploring how digitalization trends are impacting our world. The article explores how systematic remote monitoring of patient symptoms, well-being, and quality of life using digital apps can facilitate proactive treatment management and improve clinician-patient communication. At the same time, it has the potential to improve survival rates and decrease hospitalization and emergency room visits. According to a recent Journal of Hematology Oncology and Pharmacology (JHOP) study, nonadherence to treatment regimens (such as medication adherence) has been associated with worse outcomes, increased physician visits, higher hospitalization rates, longer hospital stays, and lower survival rates. Patient Reported Outcomes (PRO) systems can provide care teams with a useful tool to collect data relevant to treatment management and recovery support, routinely monitor symptoms, automate timely interventions and analyze outcomes in cancer patients. This data driven approach can ultimately help healthcare providers in their journey toward building a learning health system.

This article is the fourth in a series of that will present original insights based on exclusive research and interviews with global healthcare leaders, prepared by the EIU. Complementing this, Siemens Healthineers has analyzed survey data, prepared by the EIU, to further explore future digital transformation in hospitals. For more information on Siemens Healthineers Insights, please visit: **siemens-healthineers.com/insights-series**

Asif Shah Mohammed
Principal, ECG Management Consultants

Executive summary

Benefits

- Patient monitoring apps can provide real-time data on cancer patients, thereby enabling much faster feedback loops between individuals and their healthcare teams.
- Clinicians can develop personalised cancer care plans that respond to patient behaviours and support better management of adverse events related to treatment.
- Cancer apps could support a reduction in healthcare costs arising from preventable hospital admissions.
- They can help to improve a patient's quality of life by allowing them to become participants in co-creating their care and opening the door for shared decision-making.

Challenges

- Reimbursement pathways for mobile health tools have traditionally been a barrier to implementation, but leveraging beyond the pandemic could accelerate adoption into clinical pathways.
- Healthcare providers need to invest in ICT infrastructure that can rapidly translate data from apps into actionable and meaningful insights for clinicians – without becoming an additional administrative burden.
- Providers will need to invest in different skills for digital workflows, or new roles will be required within healthcare settings, to support the digital patient journey.
- Confidence in these tools could be achieved with the use of digital formularies.
- Healthcare providers and developers will need to continue to work together to prioritise the standardisation of apps so that they are interoperable across health systems. As regulations differ across geographies, this will require taking into account factors including different IT architecture, connectivity requirements, and data sharing and communication standards.

Outside the hospital: cancer monitoring with apps

Introduction

Advances in smartphone technology, healthcare provider information and communications technology infrastructure has enabled the development of new clinical pathways involving app-based remote patient monitoring. Patient monitoring apps allow patients with chronic diseases to report on their condition from outside of the hospital – where they spend most of their time – putting the patient, rather than the hospital, at the centre of the care pathway.

A high society-wide level of smartphone penetration has presented a large market for developers, with apps now used in clinical practice for chronic disease management in diabetes, chronic kidney disease, congestive heart failure and oncology.[1, 2, 3, 4] However, up until the covid-19 pandemic struck, the development of technological capabilities within healthcare had largely outpaced the capacity to implement many novel remote patient monitoring apps as part of real-world practice.[3]

The covid-19 pandemic initiated a rapid reorganisation of healthcare delivery systems, raising awareness of these digital tools that physicians can use to provide care outside hospitals. Chronic disease monitoring apps vary widely in their functionality but increasingly rely on patients to capture health data that can help inform clinical decision-making. This has enabled a high degree of patient-centricity, varying from enabling behavioural nudges from clinicians to providing real-time updates to care teams with on-demand care capabilities for patients.

In this case study we explore the use of remote monitoring, particularly in oncology. We review recent health system developments, challenges to implementation of these digital tools and the emerging opportunities for their sustainable use throughout health systems.

Beyond remote appointments, recent digital health advances in oncology have centred on capturing validated patient-reported outcomes (PROs) in the home environment. PROs capture patient-reported health data on symptoms, response to treatment and its effect on daily living, in the process providing physicians in clinic with a retrospective view of these metrics over the preceding week or month, thus supporting clinical decision-making. According to Trevor Royce, assistant professor and oncologist at the Lineberger Comprehensive Cancer Centre at the University of North Carolina (UNC) at Chapel Hill, PROs "are now a well-established subspecialty in cancer treatment, and there is real momentum behind a move to more sophisticated monitoring" of these metrics, including with mobile apps.

"PROs are fast becoming the standard of care and evidence of their use may in fact improve survival in some patients," says Dr. Royce, citing research demonstrating increased "time-on-therapy" and overall one-year survival for cancer patients treated at UNC-Chapel Hill and Memorial Sloan Kettering Cancer Centre in New York City.[5] The evidence also provides an economic argument backing the use of PROs, in the form of an 8% reduction in emergency room visits and a 14% reduction in hospitalisations for cancer patients.[6]

Mobile apps can provide a more valuable, real-time dataset by enabling a much faster feedback loop between patients and their care teams. Increased reactivity allows for deeply personalised cancer care plans that respond to patient behaviours, in addition to better management of adverse events related to treatment, a reduction in healthcare costs arising from preventable hospital admissions and ultimately improved patient quality of life. These apps provide an avenue for patients to become participants in co-creating their care pathway and open the door for shared decision-making, which may have other behavioural benefits in terms of adherence.

App quality and the move to further regulation

Apps are not always regulated to a level similar to that associated with healthcare products such as pharmaceuticals or medical devices. The line between wellness and medical care can be difficult to tread, although apps with an intended medical purpose are seen as medical devices and so are regulated in line with those regulations.

Recently, regulators such as the European Medicines Agency, the US Food and Drug Administration (FDA) and the UK's Medicines and Healthcare products Regulatory Agency have sought to define more closely the specific guidance on what software does, and what does or does not fall under the "medical devices" umbrella.[7, 8, 9] Globally, medical devices are classified according to risk rating, which also determines the level of evidence required for a device to be supported in different markets.[10] Medical devices and related accessories must be classified into one of four classes, based on the perceived risk of the device to the patient or user: Class I (low risk), Class IIa (medium risk), Class IIb (higher risk) and Class III (highest risk).

In the EU, the Medical Device Regulations came into effect in May 2020, further tightening the risk rating criteria assigned to medical devices thereby increasing requirements for supportive clinical evidence. According to Anne Bruinvels, founder of Px Healthcare, a company that develops mobile health solutions – including an app to support breast cancer patients and their clinicians – "the EU has moved in a way that all apps need to essentially move up one level from medical device Class I to Class II, which at the same time makes [medical app use in healthcare] hopefully also sustainable." In 2019 the UK's health technology assessment body, the National Institute for Health and Care Excellence (NICE), released a classification framework to provide producers of digital health technologies with targets for evidence generation, as well as to support reimbursement decisions.[11]

Remote patient-monitoring apps, and so-termed digital therapeutics, are generally classified at the higher end of classification frameworks (Class II-III), requiring more extensive clinical and cost-effectiveness evidence, and mandating that developers must meet strict data privacy and protection guidelines. Dr. Bruinvels believes that this is necessary to help protect patients from apps that are harmful while making it easier for clinicians to choose evidence-based technology. "What we really need is to have an authorised body – either NICE or another entity – that is funded to make sure that the right apps are visible to the clinicians who can recommend them," she says.

In parallel, Germany, France and the Netherlands have developed new reimbursement pathways to incentivise the use of apps through diagnostic-related groups, which some payers use to determine the cost of patient care by hospitals.[12, 13, 14] The aim is to financially reward healthcare providers for adopting these workflows. Elsewhere, countries such as Belgium have developed national health app repositories, while the UK's National Health Service (NHS) has developed a list of apps that it thinks can help patients to manage their conditions.[15, 16] In Germany, from late 2020 doctors will be allowed to "prescribe" apps like they can pharmaceuticals from an evidence-based list of approved platforms.[17]

In terms of cancer-specific platforms, patients can find apps that encourage medication adherence as an outpatient, capture PROs and log symptom management during chemotherapy, and promote community interaction post treatment.[12] But with around 150 cancer apps available to patients in the UK and the US, it can be a challenge to determine which is best.[18, 19, 20] A centralised formulary that is managed by national bodies – such as in the UK, Germany and Belgium – increases the visibility of the most appropriate, regulator-approved, clinically supported apps. Embracing the idea of a certified digital formulary can both reward developers who provide high-quality, cost-effective solutions that are interoperable across providers and enable health systems to realise further cost efficiencies through bulk purchasing and pricing.[21]

In the US efforts have been made to speed up the approval process. In March 2020, as the severity of the covid-19 pandemic worsened, policymakers relaxed privacy and reimbursement policies to promote telemedicine and remote patient monitoring.[22] The US previously tried to hasten the speed to market of high-quality apps in 2019 with a "pre-certification" programme for mobile health (mHealth) products. This programme sought to review software developers and their quality-assurance systems, rather than the products themselves.[23] The FDA has also founded a Centre of Excellence for Digital Health with the objective of modernising the regulatory approach to digital health. Dr. Bruinvels is supportive of such changes: a "more flexible approach to regulation could be helpful for these apps, which can change much more frequently than a drug or medical device," she says.

Clinicians have a large role to play in app use

Even if more high-quality apps are brought to market, their benefits can only be realised if they are used where both patients and providers see the value in them. Despite recent developments, a 2019 study showed a significant implementation gap in patient utilisation rates of mHealth in oncology; only 30% of patients reported using these tools.[24] To a large extent, closing this implementation gap will rely on clinicians, as the relationship between patients and their physicians means that the use of apps is highly dependent upon a physician's recommendation.

Clearing regulatory hurdles is only the first step to acceptance to securing buy-in from physicians. The integration of tech within existing clinical pathways is the real challenge, says Dr. Royce. Physicians expect the data and insight produced from remote patient-monitoring apps to be easy to access and seamlessly integrated with electronic health records (EHRs), this reducing the administrative burden. Empirically, however, most oncology apps are not integrated with EHRs.[15]

According to Dr. Royce, one common hurdle to integrating new technology is the design of EHRs. "Software is often designed to support [patient] billing and not necessarily around patient care," he says. "Many providers feel like they have to do a lot of form filling and they don't always appreciate the direct value in [some of these apps]." Developers must be prepared to co-design their apps with these stakeholders if they are to achieve implementation and radically change care pathways.

Ultimately besides the app themselves being high quality, effective and easy to use, physicians need to be reimbursed for providing the services offered through their use. The covid-19 pandemic may have accelerated changes in the reimbursement landscape, but regulators and payers must seek to prolong these changes and incentivise the development of a health-in-the-home ecosystem that would ensure sustained use of related technology.

Another issue for integration of these tools is that not all apps are developed to a common standard. To rectify this, tech and healthcare industry players (including Apple, a health technology firm, Cerner, and the US-based Mayo Clinic) have begun to develop common information standards and implementation guides. Working under the Fast Health Interoperability Resources (FIHR) banner, this initiative aims to ensure that the data produced by apps is both portable and interoperable around health systems.[25] In May 2020 the Cures Act Final Rule, which implements interoperability-related provisions of the 21st Century Cures Act (2016), adopted FIHR standards for API interoperability.[26]

Unfortunately, given the varying stages of digital maturity within health systems, progress is likely to be uneven. The UK's NHS offers one example: given historical underinvestment in ICT and the fact that some hospitals in the NHS will not be paperless until 2027, there will be substantial lead time before the true benefits of these initiatives are seen at a system level.[27] There is concern that issues around accessibility may actually worsen health disparities by limiting the use of new digital platforms to those sections of society that can afford the most recent technology.[28] Developers will need to work with health system end-users to ensure that their apps can be used online and offline and across platforms if they are to address basic connectivity and accessibility issues.

Patients and behavioural change

Remote patient monitoring addresses many unmet needs for patients, including by surmounting geographical barriers. But cancer is a particularly personal and distressing diagnosis, and many patients will inevitably maintain a preference for face-to-face encounters.[18] "There certainly are patients that really want to avoid coming into the hospital at all costs, but a lot of patients still just want to see us in person," says Dr. Royce. "Perhaps 25% of visits are now virtual and the rest are in person, with the number of virtual [visits] decreasing the further that we get from March 2020."

There is much evidence demonstrating that patient compliance – that is, the sustained engagement of patients with treatment plans – poses an enduring challenge to the use of medical apps.[29, 30] Medical apps require patients to embrace increased agency and ownership of their cancer management, as well as committing to ongoing behavioural compliance.

Sustained behaviour change can be difficult to achieve, and doing so involves striking a delicate balance that embraces user-centred design. For example, behavioural economics suggests that people react differently to nudges and alerts based on the time of day, and survey fatigue is one factor that can limit patient involvement in app use, ultimately impacting the reliability of the data gathered.[31] More detailed research is needed in this space to help understand which service models are preferred by patients, and which improve patient outcomes alongside cost and clinical effectiveness.

Opportunities

Dr. Bruinvels says that, on a systems level, medical apps provide an opportunity to focus on patient outcomes rather than processes. By collecting real-world data and processing these data through advanced analytics, health systems have the opportunity to move towards value-based reimbursement models and "N of 1" care. Cancer apps do this by providing data to better track a patients course on a clinical pathway. Treatment regimens can thus be measured based on the care team's ability to keep patients on their pathway – by improving day-to-day quality-of-life, toxicity management, and survivorship – or be quickly modified to a more appropriate intervention for that patient.

For Dr. Royce, medical apps lift the veil of secrecy that can enshroud the design and monitoring of a patient's care pathway. They do so by improving communication with care teams and allowing increased patient engagement, thus positively impacting patient outcomes and delivery of care. Apps also present opportunities to private systems for broader chronic disease management, where payers can incentivise improved behavioural compliance and the efficient use of services through reduced premiums or co-payments for those engaged with digital care plans.

To enable such new service designs, the organisation of care teams may need to adapt to be more service oriented and digitally able.[32] Dr. Royce refers to a reorganisation of care delivery that involves new tasks such as calling the patient beforehand and making sure that they have the right instructions to successfully partake in telehealth or remote monitoring. Dr. Bruinvels agrees with this idea, while suggesting that new roles may also be required for apps to reach their potential. "To free up clinical resources and make sure that these new ideas can be implemented, service management roles are necessary to manage the implementation of these pathways," she says.

To boost confidence in the role of apps in cancer care, physician and patient behaviour could be incentivised through the availability of digital formularies and guidelines on how apps can fit more naturally with existing care pathways. Although apps are not designed to replace face-to-face care, the covid-19 pandemic has provided the impetus for healthcare providers and app developers to consider a greater role for such tools within care pathways.

This case study was led and edited by Elizabeth Sukkar of the Economist Intelligence Unit.

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