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CASE STUDY 3: AITOPYA

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Innovation, Sustainability, and the Future of Healthcare

The use of artificial intelligence technologies within the healthcare setting is expanding, bringing challenges and triumphs, and disrupting the way healthcare is delivered. Clinical decision support systems are one such use of AI technology, which aim to use intelligent systems to solve complex problems and incorporate this into clinical decision making. This case study will explore the journey of a clinical decision support system in Sweden, from identifying a role for such innovation to evaluation and regulation challenges, guided by the experience of BYON8, an emerging health technology company within this space.

BACKGROUND

The Open Comparisons in Public Health study (OCPH) in Sweden, 2019, demonstrated an overall good level of health and health outcomes across Sweden. However, it also highlighted ongoing disparities between population groups. Life expectancy inequality correlates with inequalities in education, income levels, living conditions and environmental development levels, i.e. rural versus urban environments [1]. There is a share of the population whose health needs are reportedly unmet due to cost or distance to facilities [2]. Of the roughly 250 new primary healthcare centres that have been established in Sweden within the past decade, the majority of these have been in larger centres and cities, causing a demonstrated negative effect on geographical equity [3].

Inequity between differing socioeconomic backgrounds also continues to be an issue in the Swedish healthcare system and translates into unmet health needs. Studies have indicated that economically vulnerable people in Sweden are less likely to seek healthcare and that a significant number of this group self-report financial reasons for refraining [4]. The OCPH demonstrated that the most significant factor having an impact on health inequalities in Sweden was education level, which is used as a measure of socioeconomic status by Sweden's public health department [1]. Life expectancy and self-reported health measures also correlate with higher and lower socioeconomic scores between municipalities.

CHALLENGE-DRIVEN DESIGN

Understanding the challenges facing the Swedish healthcare system provides the base for which to analyse the burgeoning healthcare technology industry that exists in Sweden. There are numerous medical AI companies developing and introducing products into both the domestic and international healthcare markets, with varying stated aims and motivations.

One such technology is a product called AITOPYA, "a digital medical service powered by artificial intelligence" [5] developed by the Stockholm-based technology company BYON8. This type of AI can be categorized as a clinical decision support system, as well as a telemedicine tool, with the product aiming to act as an assessment, triage and diagnostic assistant.

The current version of AITOPYA collects patient health data, which is then provided to a medical professional along with diagnostic suggestions. Health professionals are then able to either provide self-care advice, organize a remote consultation, or advise the patient to attend a healthcare facility in person. In this way, AITOPYA aims to function as a health assessment tool, diagnostic tool and health information storage service with both patients and healthcare providers as the end-user targets. Figure 1 provides a flow diagram of this process, which resembles other clinical decision support systems on the global market.

The motivations for designing AITOPYA were discussed during an interview with a long-standing member of BYON8's senior management team. The founders, while working as medical doctors, identified numerous challenges in the Swedish healthcare system that they believed a new technology could effectively target. Telehealth products in countries with similar remote population challenges, such as Australia, had already demonstrated a positive impact on health service access and delivery, while evidence from the United States demonstrated that these technologies reduced socioeconomic disparity and improved cost effectiveness [6], [7]. The objectives of AITOPYA are threefold: to improve equity of healthcare access in Sweden by removing financial and geographic barriers to care; to reduce the burden on healthcare facilities by lowering the amount of 'unnecessary' clinic visits; and to improve the use of human resources by automating or semi-automating processes such as administration.

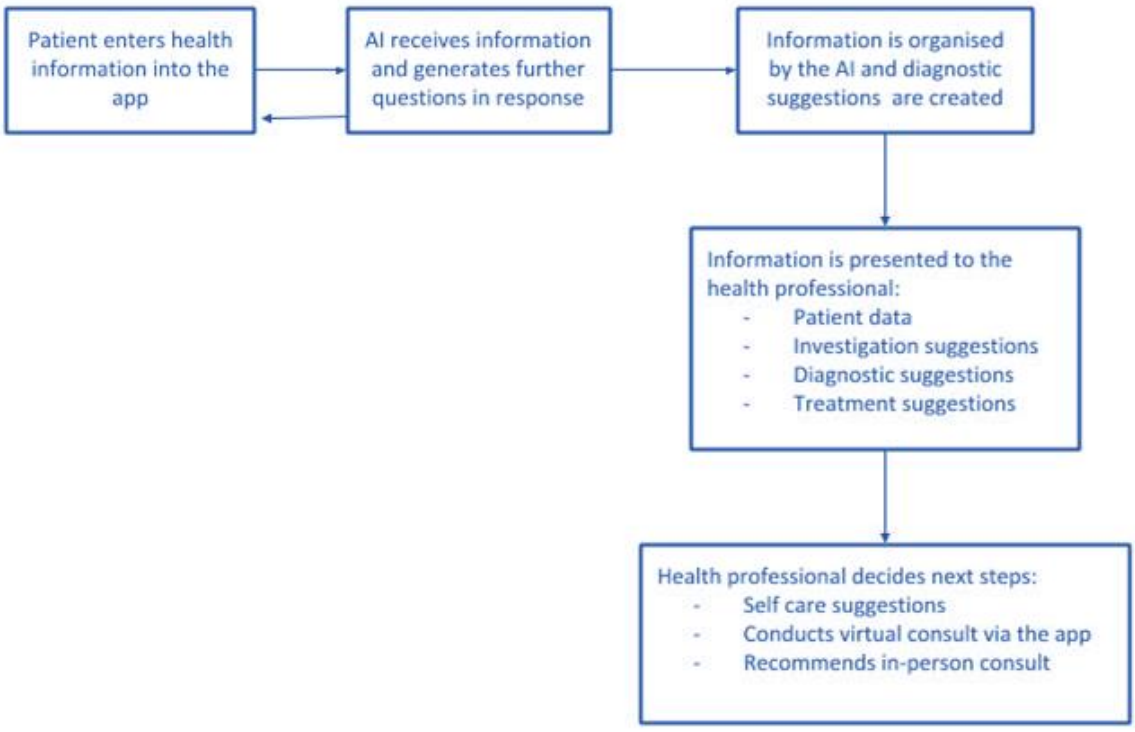

Figure 1 - AITOPYA's clinical decision support flow.

BYON8 is not alone in identifying these areas as potential targets for innovative solutions. Other major companies in the Swedish digital healthcare market include KRY, Min Doktor and Doktor.se, all app-based medical consultation products. They have stated goals to improve evidence-based access inequalities and reduce inefficiencies within the system [8], [9]. The major difference between BYON8 and these primarily telemedicine-based products, however, is the use of AI as a clinical decision support or triage tool; something KRY is developing but has not yet publicly trialled [10]. This has implications for evaluation as risks, effectiveness, efficiency and so forth differ between AI and telemedicine technologies. This is also the case when considering regulatory issues where telemedicine technologies fit more neatly into existing 'health-tech regulations' and individual practitioner regulations [11]. The concept of AITOPYA was first pitched in 2015 at LiU Innovation at Linköping University, where the company received support in patent, development and funding. Seeing potential in the product, they entered into their first collaboration with LiU Holding at this time [5]. In April 2018 the company was accepted into an AI Accelerator Program run by Tieto, a Nordic IT services company co-financed by Vinnova, Sweden's governmental innovation agency. The aim of this accelerator was to help health start-ups penetrate healthcare, by providing coaching in business development aspects of the products [12]. They have since partnered with healthcare clinics within Sweden, as well as in Uganda where they have recently launched. According to Crunchbase, Byon8 has received a total of $878,000 USD in funding across two venture rounds in 2018 and 2019 [13] .

EVALUATION AND TESTING

Globally, there is limited information or data publicly available on either an independent evaluation or internal testing of medical AI products. To complicate the situation, there are also inconsistencies of opinion in regards to what elements are important to evaluate, and what constitutes robust or appropriate methods of testing [14], [15].

Key aspects of symptom checker or clinical decision support AI that should be rigorously evaluated, and how, is discussed and contested in the literature. Suggestions for evaluation fall into two categories: testing undertaken during design to evaluate algorithm performance and validate systems' knowledge; and testing in clinical settings to validate utility, efficacy, qualities of information, system and service, and overall impact on health outcomes [16], [17], [18], [14]. However, there are still disagreements between what constitutes acceptable methods and results, what the clinical 'endpoints' in evaluation are, and how ongoing surveillance will evolve [14]. Additionally, the increasingly prevalent ethical issues of clinical decision support AI are not able to be measured. Such issues include transparency and explainability (or the ability for patients and doctors to understand how algorithms have arrived at end decisions), patient privacy and information management, accountability and conflicting role identities between physicians and developers [19], [20], [14].

Currently, there is no data publicly available from any evaluations BYON8 has completed or are carrying out, and no information regarding testing and redesign that occurred before the clinical implementation of AITOPYA. It was highlighted in an interview that BYON8 had internally validated the product to a level they were comfortable with over the course of 6 years; however, information on this validity testing is not available. Current testing in-vitro is underway, which includes usability tests and an end-user study, conducted via a think-aloud method, focus group interviews and surveys of end-users including both healthcare professionals and patients. This testing is occurring internally, and no public data is yet available. AITOPYA has also launched in three clinics across Uganda, with researchers from the sciences department at Victoria University planning to evaluate the use of an AI tool in the Ugandan context by testing the "applicability, feasibility, effectiveness and efficiency of AITOPYA" [21].

To meet EU regulatory requirements, AITOPYA will need to complete a clinical evaluation which will be scientifically reviewed and made publicly available. There are currently no AI-specific regulations within the EU; instead medical AI systems are governed by the harmonized regulations for medical devices, the MDR, to which new changes come into effect in May 2021. Currently, to receive the CE Marking, demonstrating compliance with these regulations, a medical device must produce a quality management system (QMS) and technical file in compliance with ISO 13845. Additionally, a clinical evaluation report must be prepared and contain clinical investigation results and analysis, demonstrate clinical benefit and clinical safety, include sensitivities and specificities if relevant, include risks and provide validation against the intended purpose of the device [22]. However, it is the manufacturer's responsibility to specify the level of clinical evidence needed to conform with these regulations, leaving room for interpretation. Additionally, the data produced does not need to be published or meet 'peer review' standards. The new EU regulations have attempted to improve scientific rigour and transparency, subjecting Notified Bodies (organizations who conduct the scientific review) to stricter assessments and increasing clinical evidence requirements from manufacturers [22]. The clinical reports and information submitted, in addition to other previously internal reports and checks, will also become publicly accessible and therefore open to wider scrutiny.

In contrast to the EU, the US Food and Drug Administration (FDA) does have specific guidelines for AI use in the medical setting, and despite being outside FDA jurisdiction, the regulatory affairs team at BYON8 state they will be referring to these guidelines as they raise specific issues and standards to consider. They also use the "key lines of enquiry for healthcare services" of the UK Care Quality Commission (CQC) as a guideline for service quality expectations, and refer to feedback from Babylon Health's CQC inspection reports as a similar medical AI service [23].

MEASURING IMPACT

The stated aims and methods in which companies like BYON8 aspire to change the healthcare environment are more difficult to evaluate than some of the aspects of testing discussed above. Improving healthcare access disparities related to cost and geography, improving use of human resources and reducing health system inefficiencies are parameters that can be time consuming and technically difficult to measure. It can also be difficult to correlate changes in these measurements with a single intervention, and it often requires significant periods of time to allow for observable change. Globally, there is little systems level evaluation or data yet. Emerging evidence at facilities level supports the hypothesis that the use of AI to either assist or independently complete administration tasks reduces physician time spent on this work, improving efficiency across human resources and costs [24]. Additionally, there is a growing knowledge base assessing changes in health access following the introduction of medical AI and telemedicine products in certain locations. Much of this knowledge exists within low-resource settings, with evidence from both India and China demonstrating an improvement in healthcare access and quality in rural areas where previously either no healthcare or untrained and informal healthcare workers existed [25]. This knowledge, however, could reasonably be applied to the role AI can play within a developed country when similar challenges are being addressed.

While the literature discusses testing and evaluation of medical AI safety quite extensively, the long-term health system impacts of this technology are not widely discussed. This is understandable due to the relative fledgling nature of the technology and more immediate requirements to create a safe and effective system before implementation is considered.

CONCLUSION

Inequities in health outcomes and healthcare delivery persist in high-income and well-resourced countries such as Sweden. Healthcare systems that we consider advanced and resilient continue to face issues with rising costs and overburdened facilities. These challenges pose an opportunity for innovative solutions, based on a demonstrated impact of telemedicine and other health technologies in similar settings in conjunction with emerging information from AI systems with similar objectives in different settings. Regulatory and evaluation issues will be the initial hurdles to face, to ensure first and foremost the safety of such technologies. Understanding the impact of wider systems and the role AI may play in healthcare systems such as in Sweden is likely to be a much longer-term realization.

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