

# SELF-TESTING AND ITS IMPACT ON HEALTHCARE



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**For over three decades, home tests for measuring glucose, cholesterol, a hormone that is indicative of pregnancy and blood pressure have proven their efficacy and laid the foundation for consumer trust in test kits and devices. Routine at-home testing for COVID-19 has added to the general public's comfort with self-testing, increasing the acceptability of, and demand for, home-use kits and health-related devices.**

Besides disease-related testing, the health and wellness segment of at-home testing is experiencing significant growth as consumers, especially millennials and GenZ are increasingly taking responsibility for optimising their own health<sup>1</sup>. This includes tracking heart rates and steps with brands such as London-based X-Wrist<sup>2</sup> and measuring sleep and optimal rest with wearables and smartphone apps. Demand in the women's health category, which includes fertility, perimenopause and post-menopause testing, is growing significantly with companies such as Chepstow-based Forth<sup>3</sup> leading the way. Of the consumers who monitor their own health, over three quarters have said that the results have led them to change their behaviour with the younger generations being the most likely to make changes.

For the past five years<sup>4</sup> and especially post-pandemic, access to self-testing kits and technology has been expanding. This is now a rapidly growing industry which runs in parallel with traditional testing by healthcare professionals and analytical laboratories. Today, self-tests and devices can be purchased in-store, online and from pharmacies, and measurement

or sample taking is done without the input of a healthcare professional. Measurements and samples taken are either processed at home or sent to a laboratory, and may offer screening, diagnosis, monitoring, or information about the risk of a disease. In some cases, tests are directly interpretable by the user (consumer), while the results of others are communicated to an



expert for interpretation and to judge if a further intervention is required.

The development of new tests is aided by advances in sensor technology, data interpretation, AI and the application of the Internet of Things to clinical/biological systems. This will greatly increase the scope of diagnostics and enable the consumer to make informed decisions about their health and wellness and allow consumers to take more responsibility for their own health.

However, in 2018, some UK doctors warned that at-home testing could trigger a need for additional primary-care consultation as consumers were likely to self-diagnose based on a single result rather than having the complete clinical picture<sup>5</sup>. Nonetheless, those same doctors indicated that the benefits of self-testing would improve patient health and well-being, provided that there are adequate regulatory systems in place to assess the suitability of tests and technology, and that tests come with high-quality, easy-to-understand information about their performance and interpretation. Further afield in the USA, a Deloitte review found that the opportunity for a patient to self-test at home, instead of a doctor's surgery, saves time and money<sup>6</sup>. This was recently confirmed by a review in the *Journal of Health Economics* which indicated that self-testing, device-assisted telehealth reduced care costs by 7%<sup>7</sup>.

It is our contention that the increased development and use of self-testing for infectious (e.g., COVID-type) and non-infectious (e.g., diabetes, cardiovascular disease, cognitive decline) diseases, as well as general health and wellbeing, will help in the early detection and preventative treatment of

disease and in optimisation of health status. This will support the deployment of healthcare resources to facilitate more effective use of these increasingly scarce resources and allow consumers to self-manage their health for beneficial outcomes.

## INNOVATION

Self-testing for disease states, health and wellness is a new frontier that is consistent with the evolution of the virtualisation of industries like banking, travel and shopping. The first question that must always be answered is whether the new product is a medical device or a 'wellness' device? Or does it cross the boundary between the two?

Innovation offers significant opportunities in self-testing through the miniaturisation of technology, application of Artificial Intelligence and app development. Consider the Apple Watch that records heartbeat and rhythm using their ECG app, and the lightweight Aktia<sup>11</sup> bracelet that records an average of over 70 blood-pressure readings per week without the need for a cuff. Cognitive behavioural therapy (CBT) apps like the FDA-approved AspyreRx<sup>TM</sup> for type 2 diabetics help patients to make and sustain meaningful lifestyle changes, and to connect these changes in behaviour to improvements in blood sugar and other biometrics<sup>12</sup>.



However, the self-testing arena presents more challenges than other tech industries. These challenges involve regulatory scope and product definition, and product safety and quality, amongst others. Furthermore,

devices for self-testing have to be intuitive and simple to use as in most cases, they will be used and perhaps interpreted by untrained individuals. Doctors are also reluctant to accept results from devices that are

## SELF-TEST TECHNOLOGY EVOLUTION

Self-test technology has evolved from finger-prick tests for glucose monitoring to those that can detect infectious diseases. Cuffs for blood pressure monitoring are being replaced by bracelets with embedded optical technology; and lateral flow devices have progressed from the detection of human Chorionic Gonadotrophin (hCG) in urine, in the case of pregnancy tests, to confirm the presence or absence of a target analyte from blood, serum, saliva, sweat and urine samples.

While older technology is still extensively used, innovation has expanded the range of home tests and devices available as well as what can be monitored, measured, detected and diagnosed.

### Some examples include:

- Lateral Flow tests use body-fluid samples to detect hormones, infectious diseases and drugs.
- Finger-prick tests that detect infectious diseases and allergens are interpreted at home, while those for genetic screening can be sampled at home and then sent away for laboratory testing.
- Larger blood samples and swabs can be taken at home and sent away for laboratory testing. In the UK, the rapidly expanding London Medical Laboratory can perform most phlebotomy tests. Similarly, Forth,<sup>8</sup> in Wales, focuses tests related to women's health and wellbeing.
- Swabs taken at home for faecal occult blood are sent away and tested by the NHS for colon cancer.
- Implantable Continuous Glucose Monitoring devices to help manage blood sugar levels for diabetic children, adults, athletes and people needing care and supervision.
- Optical technology, similar to that used in wrist-based heart-rate monitors, measure blood pressure day and night.
- Home-use ECG devices can detect heart rate irregularities, which is especially beneficial for those high-risk patients with congenital heart disease or a history of atrial fibrillation.
- Apps use mobile-phone camera technology to measure oxygen saturation or post-operative recovery after orthopaedic surgery.
- Tytocare's Home Smart Clinic is a hand-held medical device that enables a remotely-guided virtual consultation with a doctor. It reduces total cost of care, delivers 59% more accurate diagnoses than traditional telehealth solutions, and resolves 98% of visits without necessitating an in-person appointment<sup>9</sup>. It is now used by various NHS Trusts<sup>10</sup>.

unfamiliar to them, for example using photoplethysmographic data<sup>13</sup> vs. inflating cuff measurements for blood pressure. In addition, where healthcare professionals (HCPs) charge for tests, self-testing using at-home kits and devices may have a negative financial impact on their practices, which could cause friction between developers and HCPs in the short term.

Wearables, both medical devices and wellness devices, provide sufficient impact on health and wellness for *Nature, Scientific Reports*<sup>14</sup> to have published an entire collection on their development.

## CYBERSECURITY CHALLENGES

The Deloitte 2020 Survey of US Health Care Consumers found that more US consumers are using technology to monitor their health, measure fitness, and order prescriptions, and that they are willing to share their data with healthcare providers and researchers, and even tech developers<sup>15</sup>. Fitness and health apps and devices may store name, address, locations, health records and banking information – valuable content in a world where data is currency. Hackers and cybercriminals may target data servers, connection signals (Bluetooth, Wi-Fi), devices or smartphones<sup>16</sup>. Cyber-attacks on healthcare are increasing. At CPX London it was revealed that in May 2023 there were 1383 cyber-attacks in healthcare per week, compared with 797 weekly in May 2022<sup>17</sup>. The former US Vice President, Dick Cheney had his heart implant device altered to prevent cyber-attack<sup>18</sup>.

## REGULATION

A major consideration is how regulators will deal with new self-testing technologies and services marketed directly to consumers.

Regulators must ensure that patient safety and a high standard of care is maintained. Significant strides are being made by regulators in the acceptance of new technologies as medical devices. For example, the MHRA now have a pathway for Software as a Medical Device (SaMD) in response to the development of new technologies.

But can regulators keep up with the pace of innovation? At recent medical technology conferences, businesses indicated that they are unable to get regulators to approve their products on the basis that the regulators simply do not understand the technology. While the challenge of regulators keeping up with technology is by no means exclusive to the UK, it is an issue that has the potential to limit innovation and discourage investment<sup>19</sup>.

The growth in the market for polygenic risk scores (genomic testing to determine the susceptibility of an individual to disease) which are marketed direct to consumers, has led to calls for the Food and Drug Administration in the US to review its policies on scrutiny and enforcement of direct-to-consumer tests that are available without a health care professional as an intermediary<sup>20</sup>.

## DEVELOPING UK PLC

The global At-Home Testing Market Size was valued at USD 16.7 billion in 2021 and is estimated to surpass USD 45,582.24 million by 2031, growing at a CAGR of 10.5% from 2022 to 2031<sup>21</sup>.

In 2021, Core Medical Technology<sup>22</sup> in the UK, which includes the developers of self-tests, employed approximately 113,000 people and generated GBP23.6 billion in revenue. This is driven extensively by SMEs which make up 77% of the UK

Life Sciences; indicating that the UK is well placed to take advantage of the global opportunities created by the self-testing market.

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