Teknologirådet

MOBILE SELF TESTS

Until now, medical diagnosis has been expensive and has been performed in laboratories, hospitals and doctors' surgeries. With the aid of mobile self tests, people can take measurements themselves, analyse them and receive advice on follow-up.

Diagnosis with a smartphone

These days, most people have a smart-phone with sensors and data processing capacity, and diagnostic health apps are being developed at a rapid pace.

Test and observe

The smartphone has a built-in camera, flash and accelerometer and can easily be connected to camera lenses and instruments. This means that people can do the following themselves:

- **Measure body functions,** such as temperature, blood pressure, oxygen saturation, breathing frequency and heart rate.
- **Take picture** of wounds, ears, eyes and skin moles, for example.
- **Do biochemical tests,** to measure blood sugar, vitamins and viruses, for example.

Interpret and recommend

The test results are digital and can be sent to health personnel who can interpret them. Interpretation will increasingly be done using computer programmes. The smartphone has access to powerful calculation resources, both locally and in the cloud. This means it can compare the test results with other information, assess the risk of illness and give advice on how the user can self-treat and prevent illness and whether the doctor should be contacted.

One example is the Watson computer programme, which analyses and understands natural language and images. Watson has now been trained to interpret medical data. It can assess the risk of illness by comparing the user's symptoms and self-measurements with knowledge gained from millions of medical research articles and technical literature.

MOBILE SELF TESTS

- Can perform medical tests and measurements, interpret the results and suggest a diagnosis with the aid of an app on the smartphone
- Are sold directly to consumers without using the health service as an intermediary
- Can help to improve prevention and the early detection of illness
- Can take some of the load off the health service by establishing a digital frontline
- Require new policies for patient safety, integrity and improved use of resources

Innovation from the user

Medicines are developed in stages, with detailed clinical studies before the product launch. Digital self tests, on the other hand, are constantly tested by users throughout the course of development. The mobile platform makes it easy to recruit users, collect data on experiences and distribute new, improved versions. Research and product development go hand in hand, and the products become better the more they are used.

John Hopkins hospital has developed a mobile app with which people with epilepsy keep a log of attacks and possible triggering causes, medicines and side effects in order to manage the illness better. Because the users can share the log and data from sensors that measure pulse and movement with researchers, they can help to develop more advanced versions. The ambition is initially to be able to detect attacks and eventually they hope to be able to predict attacks.

There are other tools that help researchers to recruit test subjects and collect data from sensors and health apps for medical studies. On the day the research app "My Heart Counts" was launched, it was downloaded by 11,000 people. It would normally take researchers a very long time to recruit as many users. This means that rapid innovation is possible, based on clinical trials from real user situations.

What can we expect in the next few years?

The Norwegian Board of Technology has performed an analysis of mobile self tests on the market and in research laboratories. There are already self tests on the market that enable people to self-diagnose hypertension (high blood pressure), discover heart fibrillation, continuously measure blood sugar and analyse urine samples. People can take pictures of their skin, eardrums and retinas and send them to a doctor for assessment.

We have also seen the growth of home tests. For example, The Doctors Laboratory in the United Kingdom offers home testing for a variety of blood tests such as iron, blood sugar, vitamins and hyper- and hypothyroidism. With the Babylon Health mobile app, users can order test kits and send blood samples back to the laboratory for analysis. The results can be read from the mobile app within three days, after a doctor has reviewed them.

There is reason to believe that within five years people will be able to measure their own cholesterol and vitamin D, diagnose asthma and COPD and record cramps with epilepsy. The 10-year forecast is that people will be able to measure proteins and DNA/RNA, so that they can self-diagnose anything from hormonal imbalance to HIV.

Significance for health policy

Diagnostic health apps have the potential to support the ambition of the Coordination Reform to "prevent more, treat earlier and coordinate better". More people will have the opportunity to discover illness and the risk of illness earlier and begin prevention or treatment more quickly. Some of the load can be taken from the health service because people perform part of the diagnosis themselves and treatment can potentially be simpler, cheaper and less extensive.

A market for diagnosis

Diagnostic health apps are marketed and sold directly to consumers without using the health service as an intermediary. A diagnosis can however give the right to treatment by the health service.

Even though the health authorities cannot directly control the offer and use of diagnostic health apps, it is still possible to influence this development in other ways. Patient safety, integrity and the correct use of resources will be important considerations.

Patient safety and quality

A number of mobile self tests that can provide results that are as good as, or even better than, professional equipment, partly because of the frequency of testing, could provide a better overall picture.

But at the same time, there will also be examples of self tests of poorer quality. False negative results might lead to illness not being discovered in time, while false positive results might create unnecessary worry and increase the pressure on the health service.

The CE label is no guarantee

Mobile health apps that are to be used for diagnostic or therapeutic purposes on people are regulated by the EU directive on medical equipment. Products that meet the requirements of the directive may be granted the CE label and thus gain access to markets in the EEA.

However a CE label is no guarantee of quality. A critical review of a clinical study of a CE-labelled skin mole app showed that it overlooked cancer in 18% and over-diagnosed 51% of users. In the same survey, skin specialists overlooked only 3% and over-diagnosed 15%.

Another issue with CE labelling is that a number of suppliers state that the purpose is training or entertainment, so as to circumvent the requirements for regulation, even when the equipment is actually being used for health purposes. One of the reasons they do this is that the process of CE labelling is very demanding of resources.

It is the actual use of mobile self tests that is decisive for patient safety. Uncertainty about the results from self-measured health data could potentially have great consequences for the individual and lead to the unnecessary use of resources.

Need for quality labelling

There is a need for further quality assurance of mobile health apps, regardless of how the manufacturer defines their purpose. A labelling scheme could help individuals and health personnel to choose health apps that are safe, reliable and of great precision.

Norway already has SKUP, which is a Scandinavian scheme for testing laboratory equipment for the primary health service. This is widely used by Norwegian GPs. Health authorities in Andalusia in Spain have introduced an optional and free labelling scheme for mobile health solutions for all types of health-related apps. By 1 May 2016, they had approved 15 health apps and approximately another 30 were undergoing the approval process. A labelling scheme for Norwegian conditions could draw on the experience of these initiatives.

Since the costs for the health service of follow-up the

tests are potentially high, and a labelling scheme could stimulate the use of safe solutions, this would suggest that the authorities should subsidise a labelling scheme.

Privacy and data security

In order to create good diagnostic apps, data is required. Health data is valuable for research and also has great commercial value, including for the insurance industry, for developing medicines and for personalised advertising.

However, privacy is maintained in very different ways in the health apps. An American survey of 211 diabetes apps showed that four out of five had no personal protection policy, which meant that the users' health data could be shared without users being aware of this.

In the new information streams that are developing and growing, it is difficult for the ordinary citizen to know who they are sharing information with and what purposes it is being used for.

The EU has created draft guidelines for personal protection in mobile health apps. The guidelines propose a framework for:

- clear consent
- third-party use of data
- requirements for deletion
- security

The EU guidelines provide a good starting point for maintaining personal data protection for Norwegian citizens. However the guidelines allow for self-declaration by suppliers. A third party could give an independent assessment in order to ensure that personal protection is maintained at all stages of the flow of information. The EU requirements for personal protection should therefore be incorporated into the proposed labelling scheme.

A digital front line

Digitalisation could turn citizens into active participants in the design and delivery of health services. Norway is already at the top of the European charts for the use of the internet for health purposes. There is reason to expect that many people will use diagnostic health apps to check their symptoms at home before consulting a doctor.

The citizens do the job

People doing the job of performing their own health tests could save time and receive a better service. They could also remove some of the load on the health service, since fewer people would consult a doctor unnecessarily.

However there is also a risk of the opposite effect: that the health apps will recommend users to contact their doctor so as to be on the safe side, and the tests will be performed again. This could increase the load on the health service.

If the doctor can directly make use of the assessments of the mobile apps and so avoid having to start the process again from the beginning, consultation time can be reduced. This assumes a model in which the user, the mobile app and the doctor interact in making a diagnosis.

One interesting example is the mobile app Babylon Health, which has 250,000 users in the United Kingdom and Ireland. The app asks questions about symptoms and asks about the user's self-measured health information. If the risk of illness is discovered, the user is offered a digital consultation with a doctor, and if needed more home tests in order to arrive at a final diagnosis. In Highland and Eastwood in the United Kingdom, users can have digital consultations with GPs in the public health service (the NHS). Babylon Health has an ambition to reduce the time taken by doctors by up to 80 per cent by handing more and more to the user and the mobile app.

A Norwegian digital front line could mean that citizens contact their GP via an app on the mobile phone. The app systematically asks questions about general state of health and symptoms and receives self-measured data. It can provide recommendations for follow-up and assess whether a doctor should be consulted.

Sharing of test results

It is a prerequisite that citizens can consent to the sharing of self-measured data with the various bodies within the health service and decide what purposes the data can be used for in the health service. The least comprehensive option for sharing data with the health service can be proposed as the default setting.

The health service could also use self-measured health data for treatment, research and public health. The users of public health services should therefore also be asked about sharing data for such purposes.

Preventive health checks

Digital diagnostic tools can be used preventively, before the user is aware of symptoms. If the use of self testing is left to the market, this could lead to social imbalance in the use of health services and to resources being redirected from priority health areas. This would indicate that the authorities need to work proactively. Consideration must be given to citizens' integrity and their right to decide what health information and tests they will be exposed to by government authorities.

The health authorities in the United Kingdom offer all residents aged between 40 and 74 a free health check every five years. They expect that every year this could savne 650 lives, prevent 1,600 heart attacks and strokes and prevent 4,000 people from developing type 2 diabetes. However, performing such health checks is expensive, since they require consultation at

a doctor's surgery.

When people perform health checks themselves, preventive programmes can be initiated at less public expense. The health authorities should continuously assess whether mobile self tests that have good clinical results should be included in such programmes.

Health checks for selected groups

The more precisely a segment can be defined, the greater the probability of reaching the right risk group and of finding genuine positive results. General health checks for all give a risk of more false positive results and thus increased pressure on the health service. Here, consideration of perceived health pressure need to be weighed against the potential health benefits. The health authorities can take this into consideration by allowing for both passive and active consent.

For many illnesses, the risk factors are linked to non-sensitive information such as age, gender and place of residence. For example, all women over 50 are currently offered a mammography examination.

Health checks that are based on non-sensitive information can be offered to all citizens who fall into an illness risk group. To increase the probability of these being performed, they can be based on passive consent, i.e. that people must advise if they do not wish to receive such offers (opt-out). The authorities could also consider subsidising such health checks.

One example might be routine checks for artrial fibrillation. An ECG meter on a smart-phone can measure as precisely as the ECG machines used in doctor's surgeries. According to a number of experts in Norway, 700 strokes a year could be prevented if people aged over 65 were routinely checked for artrial fibrillation. The health service can ensure that everyone over 65 has easy and cheap access to ECG apparatus on the smart phone, receives the ECG readings and makes a risk assessment. If there is a risk of artrial fibrillation, the user is notified and given recommendations for further action.

Personalised health checks

The health service will gain access to a considerable quantity of health information when all citizens receive their electronic medical records, which is the ambition of "One citizen – one record". Sharing self-measured data and other health information in this medical record will further reinforce this.

RECOMMENDATIONS

» Health policy should immediately facilitate the development and use of diagnostic health apps in Norway.

» The health authorities should establish an optional and subsidised labelling scheme for all types of health apps in order to promote quality solutions and personal data protection.

» The health authorities should establish a digital front line when people contact their GP. Both individuals and the health service can save time and resources, while the system will be improved.

» All citizens should receive offers of health checks for better prevention of illness, based on non-sensitive information such as gender and age. These could include, for example, an offer of regular ECG examinations for those aged over 65 to prevent strokes. Those who do not wish to receive such offers must actively deregister themselves.

» Those who so desire should be offered personalised health checks. This would require them to actively register and give their consent to sharing sensitive health information with the health service.

» People should be encouraged to share self-measured data with the health service, so as to improve diagnosis, treatment, research and public health.

With this type of data, the authorities can more precisely identify persons with an increased risk of illness and offer them personalised health checks that they can perform themselves. This would potentially provide faster and more precise diagnosis and would facilitate better prevention.

As well as involving the use of sensitive health data, this will provide health information that the patient should decide whether he or she wishes to be exposed to. Personalised health checks should therefore be based on active consent (opt-in). This means that those who wish the health authorities to contact them with offers of health checks when they are at risk of an illness must give their explicit consent and state the types of illness about which they wish to be contacted.

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The Norwegian Board of Technology is an independent advisory organisation for technological evaluation.