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Non official translation of the summary of the report "The Quantified Human. Ethical Aspects on Self Monitoring by Wearbles and Health Apps."

Summary

In this report, the Swedish National Council on Medical Ethics (Smer) summarises the project it initiated on self-monitoring using wearable technology and health apps. The main purpose of Smer's work has been to unearth the potential ethical problems that are raised, provide recommendations for decision-makers contemplating introducing and using this technology in the healthcare system, and bring the ethical issues up for debate in society.

In this report, *self-monitoring* means an individual measuring personal data such as health, exercise and sleep using wearable equipment. The measurements can be taken by smartphones or watches, activity-tracking wristbands, clothing or other products containing sensors. *Health app* refers to different types of health, lifestyle and medical apps (applications) usually distributed and downloaded via the internet. People often upload the data that has been measured. This can then be combined with data from other internet-based communication services.

Most self-monitoring apps are consumer products. These include activity-tracking wristbands capable of measuring the number of steps taken, sleep habits and pulse rate, and apps to avoid or increase chances of pregnancy. There is also equipment used by parents to measure the physiological data of their baby or small child, such as breathing rate, body temperature, movement, pulse rate and oxygen level.

Other more advanced wearable technology is used clinically in the healthcare system as diagnostic and treatment tools. This can involve measurements in diabetes, epilepsy or migraine patients, or to monitor mental health or post-traumatic stress.

The overall aim of self-monitoring through wearable technology and health apps can be said to be promoting good health. The technology can be used in public health work and by individual patients to:

- encourage healthy behaviour (primary prevention),
- reveal early signs of illness,
- track the course of an illness to increase understanding and improve treatment (secondary prevention, i.e. reducing the risk of relapse and preventing an illness from worsening and leading to disability and a lower quality of life),
- improve diagnostics and treatment.

The rules governing this use vary depending on the purpose of the self-monitoring, the area of application and who is measuring the data. The ethical issues also vary, as do the reason for public intervention, regulations and undertakings.

This area is changing rapidly. Even just a few years ago, over 165,000 health apps were available for download. Studies today show promising effects for various types of activity-tracking wristbands and other wearable technology, including helping to increase physical activity and acting as a tool for people with diabetes to control their blood sugar levels. However, only a few of the health apps currently available have been developed on the basis of scientific evidence and ethics.

Wearable technology with sensors to measure individuals' health data is likely to become a natural and integrated part of the healthcare system. Data will increasingly be analysed automatically in real time, using artificial intelligence.

Rapid development brings major opportunities but also risks. One key issue is what needs to be done to make the most of the positive contribution to health that this trend and the increasing use of self-monitoring can offer, while avoiding or minimising the risks.

The technology, the products and their usage are a global phenomenon. Sweden is investing to become the best in the world at using the opportunities opened up by digitalisation in health care. Smer considers that attaining this aim is conditional upon ethical issues being an obvious point of departure and an integrated

element in working to attain it. It is also essential that attention is paid to ethical aspects in European and global cooperation on health and that relevant steps are taken at the international level.

Ethical issues and conflicting values

Self-monitoring using wearable technology highlights conflicting values concerning privacy, self-determination, informed consent, safety, justice, gender equality and trust. Issues concerning human dignity and the way human beings are viewed are also raised. These values can be interpreted in several ways; they are interrelated and there may be conflicts within and between different values.

Relevant actors include current and future patients and their patient organisations, relatives, care staff, healthcare organisations, individuals, companies and outside the healthcare sector (employers, the justice system, insurance companies, schools, etc.) and society in general.

Examples of a number of values, interests and goals that become relevant and which may conflict with each other when self-monitoring using wearable technology and health apps are listed below:

– The interest of the individual in
  - gaining an understanding of and knowledge about their health and their illness
  - feeling in control of their health and illness
  - getting good care (tailored to the individual)
  - having the freedom to live free from control and the demand to self-monitor
  - protecting their self-determination
  - protecting their personal privacy.
– The interest of the healthcare sector in
  - improving health and developing tools to improve the quality of care
  - monitoring, predicting and promoting health in the population

- using resources more efficiently
- encouraging patient engagement in their health and participation in health care.

– Other interests at the level of society in using health data for
  - research and development on how health can be promoted and potential health risks prevented, and illnesses diagnosed and treated
  - monitoring, analysing and forecasting health and illness for health care and social planning
  - other purposes not directly linked with health or health care.

Many of these interests may be in conflict with each other. For example, the interest of the healthcare sector in improving efficiency using digital technology may conflict with the individual's interest in obtaining good (person-centred) care tailored to the individual.

The individual's requirement that their privacy be protected may conflict with the interest of the healthcare sector in accessing data on patients for care and research. The individual's interest in protecting their private sphere and safeguarding their self-determination may come into conflict with the interest of the healthcare sector in developing tools to improve quality and efficiency.

When health data is used by actors outside the healthcare system, additional conflicts of interest can arise. For example, employers can use health data to improve health and safety and working conditions, but they can also use the information to increase surveillance and control of their employees.

If data from health apps is used to set insurance premiums, a financial incentive for healthy behaviour can be created. At the same time, there is a risk of greater inequality – some find it harder to obtain insurance, while others may be offered insurance at a price they cannot afford. The Council of Europe has drawn up a recommendation on the treatment of health data for insurance purposes. The Council recommends that Member States implement the provisions (see section 6.3.1.).

The table below summarises the benefits and disadvantages of self-monitoring from the perspective of the actor concerned.

Benefits and risks are distributed differently between the different actors. One problem is that knowledge of the advantages and how great they are for one party or another is uncertain and there are many knowledge gaps.

Summary of potential benefits and disadvantages of self-monitoring using wearable technology

Table 1 **Healthy people using self-monitoring to improve their health**

Potential benefits	Potential disadvantages
Encourages healthy behaviour	Sense of being monitored and mental burden
Can lead to better health, quality of life and greater self-esteem	Can lead to exaggerated focus on a "healthy" lifestyle, physical ideal and perfect behaviour
Provides greater awareness and control of own body and own behaviour	The person has no control over their "own" data, risk of breach of privacy and inappropriate use of the data by a third party

Table 2 **People using self-monitoring in cases of illness (or suspected illness)**

Potential benefits	Potential disadvantages
Generally healthy behaviour is encouraged	Risk of a negative sense of control and surveillance
Early discovery of illness and a better understanding and management of one's illness	Risk of medicalisation and exaggerated focus on measurement
Beneficial medical effects in long-term illness with better treatment results and reduced risk of complications	Risk of incorrect measurements and misinterpretation of recorded values
Greater independence and reassurance	Risk of an excessive sense of responsibility
Greater self-confidence, greater control over own body and the illness	Risk of unauthorised access to self-monitored measurements
The patient gains a stronger position in the health service	Risk of breach of privacy and inappropriate use of data by a third party
Cooperation and exchanging knowledge online between patients carrying out self-monitoring	

Table 3 The health service and healthcare staff

Potential benefits	Potential disadvantages
New, efficient tool in population-oriented preventive work	Greater burden on the health service due to false alarms from self-monitoring and a greater need to discuss the results of self-monitoring which is not justified from a health or medical point of view
Meetings with more independent patients which improve the quality of care	Data fixation, risk that the real patient will be overshadowed by the digital version
Reduced burden on the health service when self-monitoring replaces tests and when patients are better able to understand and manage their illnesses themselves	Fragile scientific basis for care initiatives as a result of self-monitoring
The option of self-monitoring can relieve the burden on the health service, contributing to better management of staff and economic resources	Lack of evidence on the effects of self-monitoring in different types of illness and different patient groups, with difficulties prioritising

Table 4 Other actors

Potential benefits	Potential disadvantages
Tools for the actors' core operations (e.g. tackling crime, insurance, different stakeholders' development of products and services [may be but does not need to be commercial activity], research, employer's responsibility and duty)	Use for purposes that were not intended, sometimes to the clear disadvantage of the person concerned (=lack of informed consent or risk of greater inequality [e.g. insurance premiums])
Individual adaptation of duties/work environment/school conditions	Breaches of privacy, surveillance
Financial incentives for healthy behaviour	No control over "own" data

Standpoints

Sweden is investing to become the best in the world at using the opportunities opened up by digitalisation in health care. Smer considers that attaining this aim is conditional upon ethical issues being an obvious point of departure and an integrated element in working to attain it. It is also essential that attention is paid to ethical aspects in European and global cooperation on health and that relevant steps are taken at the international level.

The individual and the patient

Protect the self-determination, autonomy and privacy of the individual

Self-monitoring in the care service may be a good tool for the patient to gain greater control over their health and illness, their care and their treatment. When self-monitoring is considered, individual circumstances should be taken into account. Motivation is key. Particular attention should be paid to risks, including medicalisation and the risk of different forms of mental illness.

The patient needs to be given objective information about criteria and the consequences of self-monitoring of health data. The patient must also have understood this information and not have been the victim of coercion or pressure when giving their consent. Informed consent is essential for the patient being able to make well-founded decisions. Where relevant, the patient should be informed that self-monitoring may provide a) surplus, b) unforeseen information that the patient might not wish to know. In light of this, the patient should be given an opportunity to decide whether they want to be aware of unforeseen information or not.

There must always be an opportunity for the patient to refuse to use wearable technology for self-monitoring.

Caution when using self-monitoring for children and young people

Caution should be observed in the use of self-monitoring using wearable technology and health apps for children.

Using self-monitoring arouses questions about the child's right to personal privacy, self-determination, and possible medical and psychological risks concerning the child's development, self-image and body image. The design and use of the products needs to be adapted to the child's age and maturity. Children and young people should be involved in the process of producing new products adapted to them.

It should be considered whether others, such as preschool or school personnel, should in general have access to health data

generated by mobile self-monitoring tools that may be privacy-sensitive.

Advantages and disadvantages need to be discussed and carefully observed when using different types of activity-tracking wristbands in preschools as we know too little about the effects of their use in children and young people. The purpose of the monitoring, how use is structured and the attention paid to the age and wishes of the child is of great importance.

The healthcare system

Training in working methods to benefit from data

Self-monitoring can be a valuable contribution to healthcare initiatives to promote and facilitate physical activity in the prevention and treatment of disease (FYSS).

To be able to benefit from data from self-monitoring in its preventive and treatment work, health care needs to develop its working methods and its communication with patients who want to self-monitor. Among other things, training initiatives on the new technology are needed (for the care professions and patients/citizens) to exploit the potential of self-monitoring in the individual treatment situation, safeguard the patient's self-determination and develop person-centred care.

It is important on the one hand to incorporate the patient's experiences, including their self-monitored data. On the other hand, health care needs to ensure that the digital patient is only used as an aid to seeing the real patient and not vice versa. Self-monitoring must be seen as a means of improving information between the real patient and the healthcare staff.

Privacy, data security and quality

When self-monitoring is used in health care, the care provider must ensure that the data is collected and fed back to the patient subject to the same confidentiality as other patient information. The starting point should be that the health service is responsible for ensuring that collected data is protected. Care providers have a

responsibility to solely recommend certified products which meet stringent demands in terms of quality and data protection. They also need to assure themselves that data cannot be spread to a third party.

When apps and wearable technology are used in the healthcare system, there are particular opportunities to comply with requirements on privacy and data security. As a purchaser, the care provider can require that the seller fulfils certain fundamental conditions on privacy and data security. Contracts can include opportunities for sanctions if the requirements are not met. Equivalent requirements can also be put in place regarding functionality and data quality.

The Swedish e-Health Agency is developing the "Health for me" service. This may be an important element in work to foster circumstances in which self-monitoring can be carried out with safeguards in place, and in which demands can be set for the health apps connected to "Health for me". The service may form a safe, long-term place to store all information on an individual's health, provided that the service is developed in a way that will provide rigorous protection for sensitive personal data.

To provide care safely, the care provider must be familiar with the products used in the healthcare system, i.e. how the products are to be maintained and used and how the results are to be interpreted. The care provider must also ensure that the user understands how the product is used so that the results from the product are reliable. It is important that the care provider monitors that the product is fit for purpose. The quality work conducted by the care provider should include giving both patients and care staff sufficient training in handling the equipment and the data generated. This is, in principle, nothing new for the care sector from an ethical or practical viewpoint, although the scope will increase tangibly once health apps are included in care provision.

Responsibility and priorities of the healthcare system

When a person engages the healthcare service, the care provider has a responsibility to address signs of problems, whether they are from physical or mental symptoms, or from self-monitoring. How

the signs are handled primarily depends on how great one judges the need for action (e.g. investigation) to be.

When health care is considering introducing or rejecting a self-monitoring method, the ethical principles of the ethical platform for setting priorities in health care must be followed. The need and the benefit are then assessed on the basis of the severity of the condition, and on the basis of the effects that self-monitoring has. The strength of the scientific evidence for the method being beneficial and not causing harm must also be factored in, as must the costs.

Fair and gender-equal care

Once self-monitoring is introduced in the healthcare system, there is a risk that different groups of patients will not have the same access to the new technologies. Differences may arise due to gender, age or socioeconomic circumstances. To counteract this, there should be a focus on education and information for potential patients and the healthcare professions. Any inequity can also be tackled via analyses and feedback to the healthcare service. It can also be reduced with user-friendly adaptation of the technology for different types of illness and to patients in varying circumstances. Development and exchanging experiences on these issues is important, particularly in the bodies covered by the Swedish Association of Local Authorities and Regions (SALAR).

Products that are prescribed should mainly be offered within the remit of the public undertaking to counteract inequality of access to advanced healthcare products and differences in health.

Care on equal terms should also be guaranteed to those patients who for various reasons do not receive access to – or do not want to have – the technology. This group of individuals should be offered alternatives as far as possible.

Society and the State

It is important to be alert to whether a greater focus on self-care can lead to a shift in values in society towards a far too rigorous assumption that the individual is responsible for their own health

and illness. In the long run, this could lead to stigmatisation and discrimination against individuals, which may affect human dignity and a humanist view of people.

Initiatives to attain targets in public health policy must always be preceded by ethical analysis. Initiatives that make it easier to change to and stick to a healthier lifestyle can bring benefits for individuals as well as society. However, initiating different behavioural initiatives to "nudge" citizens in the "right" direction is not ethically unproblematic.

The State has an important duty to protect personal data and respect the privacy of the individual. This concerns values, such as the individual being able to trust that sensitive information will not be misused, and feeling reassured in their daily life. The privacy aspects should continually be highlighted and considered so as to enable acceptable development for all actors involved. There may be grounds to consider whether there is a need for additional restrictions regarding certain treatment or use of personal information in the form of health data outside the health and medical sector.

Furthermore, it is likely that there will be a greater need for supervision of health apps and wearable technology in the future, in order to ensure compliance with the rules. This concerns the reliability of the products, their being used in a way that is safe for patients, and handling sensitive personal data.

Promoting research, development and evaluation

It is important to promote initiatives and multi- and interdisciplinary research to develop products, methods and working methods for self-monitoring. This is needed in order to exploit the opportunities of the new technology and avoid – or find solutions for – potential ethical problems as early as the development stage when creating new wearable technology and health apps. Greater dialogue between researchers and developers, potential users, staff and decision-makers is important.

The rise in methods and products for self-monitoring has been rapid for particular diseases and for measuring particular physiological or medical characteristics, but not for others. There

may be grounds to particularly support development for priority groups on the basis of the ethical platform for setting priorities in health care. The State has opportunities to influence development via its agencies, such as its innovation agency Vinnova, the Swedish eHealth Agency and research councils. The Swedish Association of Local Authorities and Regions (SALAR) also has an important strategic role in future development. Furthermore, the R&D activities of county councils and municipalities can be involved in development and evaluation, as can knowledge centres at national and regional level.

There is a need for randomised, controlled, medical and other studies, and for interdisciplinary research to analyse different groups' use of self-monitoring and the short and long-term effects of these on the health and quality of life of individuals. The knowledge obtained from these studies can be used to develop methods to encourage day-to-day physical activity in the long term and make this easier for different target groups for reasons of prevention and treatment.

The need for evaluation and research applies to medical, behavioural and psychological effects. There is a need for broad sociological and humanist research aimed at gaining a deeper understanding of and knowledge of the advantages and disadvantages of the new technology, and any problems it raises. The hitherto limited but now rapidly increasing research into self-monitoring in health care needs to be collated in systematic knowledge overviews, which could be a task for the Swedish Agency for Health Technology Assessment and Assessment of Social Services (SBU) and the Health Technology Assessment units of county councils/regions.

Other actors

App developers

Smer considers that app developers have an important responsibility in terms of ensuring that privacy protection and data protection are built into the design of the app. Information to individuals on the processing of personal data must also be improved such that users are able to make an informed choice.

The app should also be designed such that it does not collect more data than is necessary for the intended function, and data should not be stored for longer than necessary. The user should easily be able to delete collected data from the database.

It is extremely important that the app development companies are aware of and follow the rules that exist in terms of safety and quality requirements governing their products, whether or not these are medical technology products.

Employers

Employers' opportunity to demand that employees use wearable technology for monitoring should be strictly limited. The same also applies to the employers' opportunity to read the collected data. This is an area with potential for greater value conflicts in the future. Developments in this area should therefore be carefully monitored.

Insurers

Handling of personal data generated from self-monitoring in the insurance industry can involve serious risks to personal privacy and also cause harm to the individual in other ways. It should be investigated whether certain requirements should be set on the insurers' use of health data for insurance purposes, in line with the recommendations of the Council of Europe (See Personal data protection on the Council of Europe website). Examples of restrictions proposed by the Council of Europe include:

– Health-related personal data should only be processed for insurance purposes subject to conditions, including that the data is relevant, of good quality and the processing is proportionate to the risk;
– health-related personal data obtained in the public domain, such as on social media or internet forums, should not be permitted to evaluate risks or calculate premiums;

– health-related personal data should not be processed for insurance purposes without the insured person's free, express and informed, written consent;
– there should be adequate safeguards for the storage of health-related personal data (not stored longer than necessary, limited access, etc.);
– it is essential that people with results from self-monitoring that deviate from what is normal for people of the equivalent age, etc. are also offered insurance at a reasonable price. Otherwise there is a risk that some people will be faced with no opportunity to obtain insurance protection.

Proposals

To tackle the actual and potential ethical problems discussed in this report, Smer sees the following needs for initiatives in the future:

Digitisation ethics strategy

The Government and SALAR's joint "Vision for e-health 2025 – common starting point for digitisation of social services and health care" will be supplemented by a digitisation ethics strategy for Swedish health care. Such a strategy should also cover self-monitoring through wearable technology and health apps. The Government's instructions and mandates to affected agencies that concern self-monitoring using wearable technology and health in any way should always include an ethical analysis requirement. It is also essential that attention is paid to ethical aspects in European and global cooperation on health and that relevant steps are taken at the international level.

Proposed mandate to agencies

– It is proposed that the Public Health Agency of Sweden be tasked with investigating how common self-monitoring is in different groups of the population, and the effects such monitoring is

judged to have in the short and long-term on behavioural changes that encourage health through changed habits, such as physical activity.

– It is proposed that the National Board of Health and Welfare, which has been tasked with reporting information on the development of health and welfare technology in municipalities for several years, be tasked with also monitoring the use of self-monitoring and health apps in health care.

Forum for ethical analysis

The agencies concerned should consider jointly creating a digital ethics forum/council.

Initiatives for medical, ethical and health economics evaluation

Development within the field will demand major initiatives in the future for medical evaluation of individual certified apps and products. Initiatives are needed on the part of researchers, as well as affected agencies such as SBU.

Prevent problems with fairness and gender equality

More training initiatives and initiatives to develop products with inclusive design should be initiated to ensure that vulnerable groups also have access to new technology. (In)equality in access to the new technology should be monitored, e.g. by developing quality registers.

Training initiatives

When self-monitoring products are used in the healthcare sector, the care provider has a responsibility to ensure that both staff and patients receive sufficient training in how the products are handled and in interpretation and use of the data.

Innovation and development

Initiatives are needed to encourage the development of innovative products and multidisciplinary exchanges to find solutions to potential ethical problems with wearable technology and health apps as early as the development stage. Furthermore, there is a need for better dialogue between researchers and decision-makers.

Forums for cooperation between county councils, municipalities and developers

It is important to create more forums for cooperation on ethical issues between county councils, municipalities, patients/users and developers, such that products are developed on the basis of the needs of patients and the healthcare sector and in a way that complies with ethical requirements.

Consumer information and education

Wearable technology has the potential to become a new effective instrument in promoting public health. An ethical digitisation strategy for the healthcare sector (see above) should have the aim of increasing awareness among citizens regarding the advantages and disadvantages of these technologies and of the problems that can arise. The Swedish Consumer Agency could play a key role in this respect.

Initiatives to limit the spread of sensitive personal data

The Government should investigate whether there are gaps in current regulations (including the EU's new Data Protection Regulation) regarding protection of personal data collected from monitoring and self-monitoring using wearable technology and health apps. If such gaps are discovered, it should also be investigated how these can be closed so as to achieve better individual privacy protection.

Social debate

Self-monitoring raises a number of fundamental ethical dilemmas. Many of them are extremely relevant to the whole of society. These include issues surrounding the way human beings are viewed, identity, justice, self-determination and privacy versus control and surveillance. Society must continue to conduct a robust debate on these ethical issues. Smer has an important role to play regarding use in the healthcare system, but the debate on use of self-monitoring by the general public must also be brought to a wider audience.