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INNOVATION ACTIVITIES IN PERSONAL DATA MANAGEMENT IN MEDICAL ENTITIES[1]

Summary

Purpose – The purpose of the article is to present the essence of innovation and possible innovative activities affecting the increase in the efficiency of personal data management in medical entities. The article analyses the impact of selected institutional aspects on innovative activities that can be undertaken by medical entities to increase the efficiency of personal data management.

Research method – The article was prepared on the basis of a review of selected literature on innovation, secure processing of personal data, as well as the author's own observations.

Results – As a result of the advancement of information technology in medicine, new data processing possibilities are created. The complexity of processes and procedures for processing personal data increases and that jeopardises their security.

Implications / recommendations – Effective, innovative resource allocation is necessary, which determines the security of personal data being processed.

Key words: medical entity, personal data, innovations

JEL Classification: D02, D23, L25

1. Introduction

Medical entities managing patients' personal data have to meet specific quality requirements with respect to the medical services offered by them. Quality standards of their operation, subjected to specific regulations, are assessed both by the institutions which finance medical services, as well as patients themselves. The criteria of such assessment include the accuracy of medical diagnosis, type of applied therapy and actions taken in the field of prophylaxis as well as adherence to doctor-patient privilege or respect for patients' dignity. Medical entities process personal data of special importance concerning state of health and including medical data such as genetic and biometric data particularly used in personalised medicine.

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The development of information technology leads to new unprecedented risks related to the loss, damage, accidental destruction or unauthorised use of such data. As a result, innovative personal data management is becoming a crucial area of operation in the sector of medical entities with respect to patients' well-being. Therefore, the principal purpose of this research is to present the essence of innovation and possible innovative activities, which have an impact on the increased efficiency of personal data management by medical entities.

2. Mechanism of personal data management by medical entities

Personal data management means the usage of resources and undertaking the action of processing data required during the process of rendering medical services. The fundamental document regulating personal data processing is the Regulation (EU) 2016/679 of the European Parliament and the Council of 27 April 2016 on the protection of natural persons with regard to the processing of personal data and on the free movement of such data and repealing Directive 95/46/EC (General Data Protection Regulation), commonly referred to as GDPR [Regulation of the European Parliament..., 2016, p. 1].

Pursuant to art. 4 par. 1 of GDPR, personal data means any information relating to an identified or identifiable natural person. An identifiable natural person is one who can be identified directly or indirectly in particular by reference to an identifier such as a name, an identification number, location data, an online identifier or other factors specific to the physical, physiological, genetic, mental, economic, cultural or social identity of the natural person.

In art 4 par. 2 of GDPR, data processing means any operation or set of operations which is performed on personal data such as collection, recording, organisation, structuring, storage, adaptation or alteration, retrieval, consultation, use, disclosure, dissemination or otherwise making available, alignment or combination, restriction, erasure or destruction.

Benefits related to personal data management, due to the nature of such activity, are not measured with profit, but with achieving utility resulting from meeting the following criteria [Krówczyński, 2017]:

- processed data confidentiality, that is protection from access of unauthorised persons,
- processed data availability, that is providing access to data at the time when data is required,
- adequacy of data necessary to make a decision but not exceeding the scope necessary for such a decision,
- data integrity, which allows for their unambiguous presentation for the requirements of the process of rendering medical services,
- data settlement, that is functionality which allows for an unambiguous identification of the data processing person.

Personal data protection in the management process is a method of data processing which protects it from disclosure or making it otherwise available to unauthorised persons, processing in breach of the law, or modification, loss, damage or destruction.

Personal data management in the economic sense includes activities and resources necessary for its processing to satisfy specific medical needs of patients (achieving specific utility) and providing its security.

Activities and related resources necessary for personal data management include:

- maintenance and development of tele-technical infrastructure,
- development and updating of formal and legal, as well as organisational principles for rendering medical services (regulations, procedures),
- contracting with and supervising people authorised for personal data processing,
- current operational activities within the scope of rendered medical services,
- training and advisory with respect to personal data processing and protection.

Taking into consideration the scope of listed activities, personal data management performed by medical entities generates high costs. The requirements related to the appointment of a Data Protection Officer (DPO), risk assessment obligation, reporting violations to the Personal Data Protection Office induce a number of changes in the operation of entities rendering medical services. Nowadays, personal data management has a special importance due to the progression and comprehensive computerisation of healthcare services, which is carried out by the Centre for Healthcare Information Systems (CSIOZ) as part of the EU project [Wierzbicka, 2014; Gawrońska-Błaszczyk, 2013; Nojszewska, 2011; Suchecka, 2010]. Every medical entity using IT systems has to meet high technological, legal and supervision requirements [Banyś, Łuczak, 2014]. Traditional personal data processing is usually less expensive and simpler, since it does not require any technologically advanced infrastructure and complicated servicing. Therefore, personal data management must be based on innovative allocation of in-house resources, which would assure higher effectiveness of data use and at the same time secure exceptional standards of rendered medical services.

3. Essence and type of innovation, sources of financing

The concept of innovation (from Latin *Innovatio* – renewal) – understood as an implementation in an organised way of a new or improved solution to economic practices with respect to a product, process, marketing or organisation – was introduced to economic deliberations by Schumpeter. According to him, an innovation means [Schumpeter, 1960]:

- an introduction of a new product, which consumers are not familiar with yet, or a new type of a specific product,
- an introduction of a new production method, which has not been practically tested yet in a given branch of industry,

- gaining a new source of raw materials or semi-finished products, independently from the fact if such a source exited before or it had to be specially created,
- opening a new market, where the given branch of industry was not introduced before in a country, irrespective of the fact if such a market existed before or not,
- conducting a new organisation of a specific industry, for example, creating a situation of a monopoly or breaking a monopoly.

An identical or similar definition of innovation can be found in numerous publications. According to Porter, innovation is the application of new ideas which are supposed to bring economic benefits; technological improvements, better methods or ways of producing a certain object. He stresses the central role of technological innovations in the long-term economic growth [Porter, 1990]. According to Kotler, innovation means goods, services or ideas, which are received as new, even if they existed before [Kotler, 1994]. According to Drucker, innovation is a specific idea of entrepreneurship [Jończyk, 2011]. The Act on some forms of support for innovative activity [Act, 2008] in article 2 defines innovative activity as one which includes the development of a new technology and its implementation related to the production of new or considerably improved goods, processes or services. The Main Statistical Office defines innovative activity as a total of research, technical, organisational, financial and commercial activities, which actually lead or intend to lead to implementation of innovations [*Działalność innowacyjna*…, 2013]. According to the methodology of The OECD and Eurostat, innovation means an implementation of a new or considerably improved product (goods or services), new or considerably improved process, new marketing method or a new organisation's methods with respect to business practices, work place organisation or relations with the external environment [*Oslo Manual*…, 2005]. Innovation activities can be conducted by a company on its own territory (in-house) or it may be in the form of procuring goods or services from the external market [Matusiak, 2005].

Among many criteria for innovation classification, the basic distinction was proposed for example by The OECD and Eurostat [*Oslo Manual*…, 2005]:

1. Product innovations concerning goods and services. They involve changes to implement a new product or improve an existing one. They may result from the application of new know-how, technology, combining existing technologies or their new application.
2. Process innovations concerning the manufacturing process. They involve improvement of the production process making it more effective, less hazardous for the environment or improving working conditions.
3. Organisational innovations concerning organisation of work and/or production. They involve new ways of work organisation and creating external relations. They result in increased work efficiency, as well as an improved health and work safety environment. They may involve the outsourcing of services or production, or cooperation with universities with respect to research and development of new technologies.

4. Marketing innovations concerning changes to marketing strategy. They may influence pricing strategy, product promotion, creative image modification or creating new demand on the market.

Apart from economic factors (investments, cost, risk), innovative activities are influenced also by other components, such as cognitive (knowledge), psychological (creative destruction), social (relations), cultural and historic (models of social relations) and organisational (organisational culture) [Okoń-Horodyńska, 2016].

Medical entities managing personal data use various sources of financing for the needs of innovation activities. They may include their own funds or sources of financing via family or friends. Individual investors (business angels) also provide possibilities for financing. They are natural persons providing financial capital and possess the relevant knowledge, capital, business and technical experience required. Usually they focus on companies which are at the initial stage of their development and represent a high level of innovation, but are also at a high risk level. Therefore, a high rate of return from capital is for them an extraordinary bonus for the high risk related to the undertaken investments [Szydłowski, 2013].

Another form of financing is available from venture capital funds. It is a form of financing which provides for mid- or long-term equity stakes. It is addressed mostly to small and medium-sized companies which are not listed on the stock exchange, but have a strong growth potential. Shares or stakes in such companies are acquired with the intention to sell them later, which generates the return of invested capital plus potential profit [Głodek, Gołębiowski, 2006].

Bank loans can be another source of financing for innovation. They are popular in case of investments, but in case of innovative activities they are not granted so often due to their higher risk, longer time of implementation and difficulty to assess effectiveness of such activities [Brzeziński, 2001].

European funds are another form of financing for innovative activities. From 2014 to 2020, over EUR 15 billion has been designated for pro-innovation policy. The main source of support for innovation is the Smart Growth Operational Programme, European Funds for Computerisation and regional programmes for individual voivodeships [*Program…,* 2014-2020]. Business entities may use the funds from the programme for the development of new innovative products and/or services, and also for their introduction to the market.

Innovation activity may be also financed by regular (mostly the stock exchange) and irregular financing market (off-exchange/OTC or multilateral trading facility – MTF). The NewConnect alternative market is a dynamically developing market in this sector. It promotes companies who start their operations in the field of such innovative technologies as: biotechnology, IT, environmental protection, ICT or renewable energy [Zapotoczna, 2013, pp. 171-191]. Apart from unquestionable benefits resulting from the application of such solutions (attractive conditions for obtaining loans, higher status, organisational improvements), the main challenge related to it is the high cost, which includes administrative and court fees, remuneration for advisors, as well as cost of marketing and promotion [Wojtowicz, 2013, pp. 151-167].

4. Types of implemented innovations in personal data management at medical entities

Due to the transfer in utilising full digital documentation, personal data management within medical entities usually depends on the type and scope of application of the information and communications technology (ICT) infrastructure. It includes for example:

- terminal equipment, such as computers, scanners, printers, monitors,
- office software for specialised diagnostics, recording and transmitting the course of treatment,
- data bases,
- access equipment,
- transmission equipment (switches, patch boards, cabling).

Patients' personal data stored in electronic format is processed in management systems for: patients (in medical and administrative aspect), pharmacies, other medical materials, and also rendered medical services [Strzelecka, 2015]. New Information and Communication Technologies (NICT) include all communication media (internet, wireless networks, bluetooth, satellite, cell or land-line telephones, communication of sound or image), equipment and devices for data recording (flash drives, CD/DVD discs, tapes), also equipment and applications allowing for medical data processing [Pawłowska, 2015]. As a result of such activities, a physician receives complete, reliable information delivered in specific time and personalised for the needs of treatment of a given patient.

Examples of innovative ICT solutions in the subject field include medical imaging, cardio surgery and dynamically developing telemedicine. Patient's medical data, consulted at the same time by doctors in various medical centres in the world, allow for a remote control of complicated surgeries. With respect to personal data management, the innovative aspect of ICT solutions improves data access and raises their adequacy level. In turn, it improves treatment efficiency, while the treatment cost per patient is reduced. Innovative ICT solutions accelerate transfer of diagnostic tests, increase the control level of service providers with respect to re-financing of rendered medical treatment, limit medical mistakes, and as a result also the number of patients' claims [Strzelecka, 2015].

Information and communications innovations focused on processes and organisation in ICT systems constitutes new solutions which integrate individual systems with public service platforms in the field of healthcare. They accelerate data circulation, enhance access and provide higher standards of security during data processing. Cloud computing solutions and hybrid systems are examples of innovations in medical data storage. Innovation also concerns hardware, as well as the organisation of information online between the physician and the patient (remote medical consultations), enhanced communication between a physician and a medical entity or monitoring patient's physical activity [Ziuziański, Furmankiewicz, 2014, pp. 61-74].

An important area of organisational innovation which also incurs process changes is subcontracting medical services (outpatient clinics, diagnostics) to other medical entities. Organisational innovations also include joint procurement and usage of diagnostic equipment and software on the basis of co-administration of a patients' personal data. Innovation additionally affects the scope of rendered services (extension, consolidation, transfer). Offshoring (relocation to another country) of medical services similarly is an increasingly frequent phenomenon; it is related to the relocation of patients' personal data to another country.

Organisational innovation in personal data management also incurs changes in the system of supervision over personal data processing, including modification of the scope of tasks and responsibilities of specific jobs. Such changes correspond to the procedures for quality enhancement (auditing, recording, adjustments, corrective and preventive actions). Innovations also affect techniques and methods of personal data management. They optimise functional and legal organisational structure of the branch including the positions (e.g. HR, Legal Department, Quality Management Officer, Data Protection Officer, IT Administrator, Public Relations Manager, Healthcare Manager, Medical Director).

Marketing innovations concern the creation of cutting-edge information channels which reach potential or existing patients with information about the privacy policy and the scope and type of processed personal data.

The purpose of all innovative actions in personal data management is to enhance the positive image of a medical entity on the market of medical services. Such enhancement can be achieved by improving the quality of services, rendering them in a shorter time and at a relatively lower cost. Achieved results are in particular outcomes of the application of the Blue Ocean Strategy (BOS) that is reducing the operational costs with concurrent increase of innovativeness [Szydłowski, 2013].

5. Conclusions

Dynamic development of IT technologies defined new standards in personal data processing. The existing EU institutions force medical entities to introduce new innovative technologies for personal data processing or adjust existing functionalities to the binding regulations in that respect.

Analysis of the importance of innovation in the area of personal data management by medical entities should include not only the technological development of IT infrastructure but also the organisational and economic development of those entities. Innovation may include various areas of operation such as diagnostics, treatment methods, auxiliary services for patients, or methods of settlement of medical services. Innovations in each of those areas translate into higher effectiveness of personal data management, and as a result into higher standard of treatment.

The need to optimise the cost of rendered medical services and meet the increasing quality standard requirements leads to further innovation in the area of

personal data management. Innovation in personal data management in the context of existing institutional conditions is not a question of a choice; it has become an obligatory requirement. Popularisation of innovation, frequently based on cost-benefit analysis, translates into a more rational allocation of required resources.

Financial resources constitute a necessary factor to develop innovative activities in the field of personal data management. Funds may come from various sources. Although there are multiple options in that respect, the main challenges still include their availability, high price and investment risk.

Apart from the economic, technological and organisational aspects, the creation of innovation in personal data management requires an organisational culture of a medical entity, which facilitates the management of know-how in personal data processing for its safe and adequate application in diagnostics and treatment.

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