

Legislation regulating availability of breast cancer treatment with particular focus on prophylactic mastectomy

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Abstract: Breast cancer is one of the most common diseases in the Polish society. In 2015, around 17,000 Polish women were diagnosed with this type of cancer. A comparison of relative survival rates for different European countries shows that the Polish oncological care system is inefficient in terms of breast cancer treatment. Women in Poland have substantially lower chances of surviving the first five years after being diagnosed than women in most other European countries.

An inspiration, and at the same time the main theme of the paper is assessing the availability of a controversial treatment, i.e. risk-reducing mastectomy, to patients at high risk of breast cancer. The primary goal connected with this issue is an analysis of breast cancer prevention in Poland in light of applicable provisions of law and, in a broader context, availability of oncological services in the scope of breast cancer prevention and treatment in Poland.

The following research methods were adopted in the implementation of the above mentioned objectives: non-systematic review of the PubMed medical database, review of literature and other available sources of information, including press releases, conference materials and online sources. Furthermore, relevant acts of law have been selected and analysed, with the use of a pre-specified glossary of key terms.

Cancers are becoming an increasingly big issue. Every year the incidence rates are higher, and in consequence the number of patients receiving cancer-related benefits grows. The current legal regulations governing the availability of cancer-related benefits seem to be insufficient.

Key words: mastectomy, BRCA, preventive mastectomy, availability, legislation, health benefits, breast cancer, Angelina Jolie effect.

Introduction

Breast cancer is one of the most common diseases in the Polish society. In 2015, around 17,000 Polish women were diagnosed with this type of cancer [1]. It is estimated that in 2025 it will be around 21,000. A comparison of relative survival rates for different European countries shows that the Polish oncological care system is inefficient in terms of breast cancer treatment. Women in Poland have substantially lower chances of surviving the first five years after being diagnosed than women in most other European countries. In accordance with statistical data for the years 2000–2007, the odds for survival of women with breast cancer for a year from diagnosis were over 4 percentage points lower than the European average, and after 5 years from diagnosis, these odds were lower by over 10 percentage points. Effectiveness of diagnosing and treating breast cancer is determined by numerous factors. Apart from quality and effectiveness of treatment (which are dependent on the healthcare system organisation), one of the main factors is organisation of prevention [2]. One form of primary prevention is bilateral risk-reducing mastectomy (breast amputation), which reduces the risk of cancer in 90–95% patients with deleterious mutations in the BRCA1 gene or the BRCA2 gene.

Given the growing prevalence and increasingly younger age of patients, breast cancer is becoming a social and economic problem, negatively affecting not only the lives of individual patients and their families, but also, on a national scale, healthcare economics and broadly understood economic problems [2].

In recent years, national campaigns promoting health and the debate in the media sparked by Angelina Jolie's statement about having undergone risk-reducing mastectomy resulted in thousands of Poles searching for information about genetic determinants of cancer and the possibilities of undergoing a similar surgery. The media published a lot of information and the public television and other channels would broadcast documentaries dedicated to this issue (The news of the surgery was first broken in The Times on 14 May 2013 and was followed by coverage of this news in most news outlets around the world).

The National Programme for Combating Cancer offers patients with family history of breast cancer (such as having a mother, sister, and/or daughter who were diagnosed with breast cancer or mutations in the BRCA1 or BRCA2 genes) impacting the risk of developing cancer, to take preventive measures. The standard procedure is considered increasing the frequency of prophylactic tests (mammograms carried out every 12 months) and broadening the range of the tests conducted. Prophylactic

mastectomy is among the suggested solutions. In Poland there are 100,000 women with the BRCA1 gene mutation (which increases the risk of developing both breast cancer and ovarian cancer). However, so far the mutation has been detected in only 5,000 women. Only approx. 10% of them opted for risk-reducing mastectomy (2013 data) [3]. Deciding to go forward with the surgery is often a choice of the lesser evil, where the available options are maiming a (still) healthy body and not reducing the risk of developing the disease which had already affected other family members. The choice is the more difficult as it regards the body parts which are perceived as attributes of femininity, both in terms of canons of beauty and social roles they are associated with (being a mother). Given this context, it seems that the woman's decision to undergo the procedure is the most challenging stage of the entire process, requiring psychological preparation and support offered to the patient by both her loved ones and the healthcare professionals. Should these conditions be met and should the woman opt for the (medically indicated) surgery, then — which is indicated by an analysis of the provisions of law and interviews with healthcare professionals — patients might have trouble finding healthcare centres which perform such services. Furthermore, provisions do not specify when a patient is entitled to such benefits — what likelihood of developing cancer in the future would guarantee the right to such a procedure.

Objective of the paper

An inspiration, and at the same time the main theme of the paper is assessing the availability of a controversial treatment, i.e. risk-reducing mastectomy, to patients at high risk of breast cancer. The primary goal connected with this issue is an analysis of breast cancer prevention in Poland in light of applicable provisions of law and, in a broader context, availability of oncological services in the scope of breast cancer prevention and treatment in Poland. The paper analyses the legal conditions governing this area of healthcare, with particular focus on prophylactic mastectomy.

An objective connected with an important research question, i.e. the reasonableness of the procedure, and in consequence the right to such a benefit in Poland, is indicating the existing legal regulations regarding availability of oncological care, as well as indicating implemented legislative changes aiming at increasing availability of such benefits to cancer patients.

In this respect also a concrete research task was set forth: demonstrating gaps in legal regulations with regard to access to the medical procedure in question, i.e. prophylactic mastectomy. Furthermore, the objective of this paper is demonstrating limitations in the use of cancer-related services, with particular focus on women with strong family history of cancer who wish to reduce the risk by undergoing preventive mastectomy.

Research methods

The following research methods were adopted in the implementation of the above mentioned objectives: non-systematic review of the PubMed medical database, review of literature and other available sources of information, including press releases, conference materials and online sources. Furthermore, relevant acts of law have been selected and analysed, with the use of a pre-specified glossary of key terms. The paper also draws on statistical data included in resources published by the Central Statistical Office and on epidemiological data registers, i.a. the National Cancer Database. Google Trends was used to assess the frequency of searches for “mastectomy” and “BRCA” in recent years.

Results

Sources of the right to healthcare

In accordance with the hierarchy of sources of law, deliberations on legal regulations in healthcare should start with the basic law, i.e. access to healthcare specified in the highest-ranking normative act in Poland — the Constitution [4]. Article 68 of the Constitution clearly stipulates that: “everyone has the right to healthcare”; this means that access to this fundamental resource is not reserved exclusively for Polish citizens, but for everyone staying in the Republic of Poland; however, it should be noted that this provision does not refer to the question of financing services at all.

Further stipulations in the afore-mentioned Article 68 specify the State’s obligations. Firstly, public authorities have a duty to provide citizens with equal access to healthcare benefits financed from public funds — in this respect the Constitution refers the reader to specific provisions stipulated by the relevant acts of law. Secondly, Article 68 of the Constitution specifies groups of people who should be provided with “special healthcare”. Those groups include: children, pregnant women, the disabled and the elderly. Another obligation imposed on public authorities consists in combating epidemiological diseases and preventing consequences of environmental degradation.

Acts of law constitute the next source of law in the hierarchy of legal instruments right after the Constitution. The basic legal regulation in the field of availability of healthcare is the Act on healthcare services financed from public funds [5]. Its provisions regulate the tasks of public authorities with regard to ensuring equal access to benefits, or the group of people who have the right to benefit from healthcare services financed from public funds. The beneficiaries entitled to services are specified in Article 2 of the Act and they include: individuals covered by common health insurance and citizens who meet specified financial criteria. Specific norms indicate that the Polish law provides for a number of statutory conditions which introduce the

right to use free-of-charge services by specified groups of people who are not ensured — they are clearly indicated in the Act.

Chapter 2 of this Act specifies the tasks of the public authorities with regard to their obligation to ensure equal access to healthcare services. This obligation, imposed on the authorities by the Act, should be implemented in four areas. Firstly, the public authorities should “create conditions for the healthcare system to function in” by implementing the principle of equal access to healthcare services. Another area is the obligation to conduct systematic analyses and assessments of the society’s healthcare needs and the factors impacting the change of those needs. These modifications might result from changes in the demographic structure or changeable epidemiological factors in a given area. The third group of tasks relates to the broadly-understood prevention and health promotion, the main goal of which is to create appropriate conditions for keeping the society in good health. Prophylaxis and health promotion can be implemented by the public authorities i.e. by creating health programmes. The last area of tasks refers the allocation of funds collected by the State for the purpose of financing healthcare services.

Articles 7–9 of the Act on services [4] stipulate that the tasks of local governments include the obligation to ensure equal access to benefits in the following areas: development and implementation, as well as evaluation of the effects of health programmes, informing the executive body higher in the local government hierarchy about the implementation of health programmes, as well as activating local communities with regard to health promotion and health education.

The municipal self-government’s competence to issue administrative decisions regarding confirmation of the right to use healthcare services financed from public funds for individuals who are uninsured under the common social insurance is an example of a task delegated from the central level to a basic territorial entity. It is worth pointing out that the municipality’s own tasks with regard to healthcare include also “meeting the community’s collective needs” (article 7 of the Act of 8 March 1990 on local self governments, Journal of Laws of 1990 No. 16. item 95). In relation to the powiat self-government, its competence in terms of healthcare have been defined as the implementation of public tasks “beyond the municipal nature” (article 4 of the Act of 05 June 1998 on powiat self governments), and with regard to the largest territorial self-government entities, tasks consisting in health promotion and healthcare were described as “voivodeship-level tasks” (article 14 of the Act of 05 June 1998 on voivodeship self governments). Such an imprecise, hierarchical approach to the ensuring access to healthcare can on the one hand motivate territorial self-government entities to cooperate, however on the other hand can result in treating the issue like a hot potato.

The tasks of a voivode (i.e. territorial governmental administration entity) in terms of ensuring equal access to healthcare services consists in particular in the

need to secure healthcare in the voivodeship (region governed by the voivode), as well as assessment of obligations enforced on territorial self-government entities and reporting implementation of health programmes in the voivodeship to the minister competent for health.

Tasks of the government administration have also been defined in relation to the two chief bodies: The Minister of Health and Minister of Finance [6]. The competences of the minister responsible for health are defined as the obligation to implement and participate in education on the prevention and resolution of problems caused by the negative impact of social and environmental factors on the health of Polish residents (article 11 of the Act of 27 August 2004 on health care services financed from public funds). The tasks of the Minister of Health include also: consultations with the voivodeship governments in order to assess the availability of health services, financing of health programmes and tertiary care services, cooperation with third sector organisations as well as control and supervision of the financial plan of the National Health Fund in cooperation with the Ministry of Finance (article 231 of the Act of 27 August 2004 on health care services financed from public funds). It is noteworthy that provisions of the Act impose an obligation on the National Health Fund to "ensure continuity of the provision of healthcare services" (article 11 of the Act of 27 August 2004 on health care services financed from public funds), thus specifying in more detail the stipulations of Article 68 the Constitution of the Republic of Poland.

Article 15 of the Act includes a catalogue of groups of services available to beneficiaries under the common social insurance. These groups include the following areas: primary care, outpatient specialist care, hospital care, mental health care and substance abuse treatment, rehabilitation, nursing care benefits and long-term care services, dental treatment, spa treatment, supply of medical devices, medical rescue, palliative care, tertiary care services, health programmes, drugs and foodstuffs for special nutritional uses (article 15 of the Act of 27 August 2004 on health care services financed from public funds). Given the subject of the paper, it is worth noting that in Article 57 of the above-mentioned Act, oncologists are among those specialists to whom a referral is not required. This means that the decision-maker attempts to ensure the widest possible access to the basic service which is a consultation with qualified healthcare professionals.

The contents of the various groups of guaranteed services under the National Health Fund insurance are specified in the so-called "regulations on the guaranteed service package". The study takes into account areas which can be classified as cancer-related. The first such act of law is the Regulation of the Minister of Health of 6 November 2013 on the scope of secondary outpatient treatment [7]. The Regulation includes provisions on requirements imposed on healthcare providers who provide specialist consultations in the field of oncology, haematology and surgical oncology.

These requirements relate to: the number of healthcare professionals and their training, the medical equipment, as well as the capacity to perform specific tests and medical procedures.

The Regulation of the Minister of Health of 6 October 2015 amending the Regulation on guaranteed health services in inpatient treatment (Regulation of 22 November 2013) is another executive act to the Act on healthcare services [8]. Appendix 1, which contains a list of services guaranteed in the field of oncology, specifically medical procedures related to breast cancer (which is the main area of interest in this study) includes a broad catalogue of guaranteed services.

Services included in the guaranteed services package include procedures such as: unilateral subcutaneous mastectomy/implant, other unilateral subcutaneous mastectomy, bilateral subcutaneous mastectomy/implant mastectomy-other, total mastectomy, bilateral simple mastectomy, bilateral total mastectomy, extended simple mastectomy-other, modified radical mastectomy, simple mastectomy including axillary lymph nodes, bilateral extended mastectomy, radical unilateral and bilateral mastectomy, breast amputation, unilateral insertion of prosthetic implant, exchange of an expander for breast endoprosthesis, breast reconstruction with skin-muscle flap in two versions: pedicle flap or microvascular free tissue transfer, reconstruction or repair of nipple, review/removal of breast implant, insertion of expander into a breast, as well as breast expander prosthesis [9].

Unfortunately, existing provisions lack precise regulations on prophylactic mastectomy — it does not seem justified for the mysterious term “mastectomy — other” to refer to this type of healthcare service, or at least it does not seem to be a good solution, as it is characterised by exceptional conditions and preventive nature. This procedure, although indicated from a scientific point of view as a method of preventing breast cancer, is not standard procedure in the case of Polish patients given the afore-mentioned imprecise provisions of normative acts.

An amendment of the Act on healthcare services financed from public funds became effective on 01 January 2015 [10]. The amendment of the Act on healthcare services provides i.a. for a modification of the previous manner of financing healthcare services. Another important legislative change was the imposition of new obligations on general practitioners. The goal of the changes was primarily to improve the availability of healthcare services. The justification for the amendment specified in particular the need to improve standards of care provided to cancer patients, improve waiting lists and the process of contracting healthcare services, as well as improve the functioning of the National Health Fund.

The change included in particular the introduction of a new group of patients — cancer patients. Separate lists, apart from the previous waiting list, have been introduced for this group. The objective of introducing this regulation is primarily to shorten the waiting times for healthcare services required by cancer patients, as well

as meeting the deadlines imposed by the legislator on general practitioners in terms of waiting times for cancer diagnostics. It is also important to ensure comprehensive care in the course of particular stages of diagnosis and treatment. For that reason it was specified that healthcare providers who undertake to carry out a full diagnostic process have priority in receiving a contract with the National Health Fund. Not more than 9 weeks should pass between the day on which a patient is entered into the waiting list for a specialist consultation and the final diagnosis. A person, in whom a GP or specialist doctor suspects cancer, will be entitled to the so-called fast-track diagnostics. In accordance with the Act, not more than 8 weeks should pass between the GP consultation and the diagnosis. Currently healthcare providers are obliged to carry out the necessary diagnostic tests to confirm or exclude cancer and begin treatment in the case of the patient tests positive within 8 weeks (7 weeks in 2017). This is the time to carry out preliminary diagnostics, in-depth diagnostics, qualify the patient to treatment through a team of specialists and commence treatment. Pursuant to the Order of the President of the NFZ No. 79/2014/DSOZ on determining the terms of concluding and performing contracts on secondary outpatient care, a healthcare provider carrying out preliminary cancer diagnostics is obliged to finalise it within 35 days from the date the patient was entered into the waiting list; in-depth cancer diagnostics should be carried out within 28 days.

The legislator does not specify that the entire diagnostic process must be carried out in one medical centre. This means that comprehensive cancer care can include both public and private facilities. Additionally, the legislator provided for a possibility to create consortia by smaller facilities to enable ensuring the required services or subcontract some diagnostic tests to external entities. All healthcare providers who are able to guarantee patients "high-quality, comprehensive care" can access the fast-track cancer diagnostics system. Furthermore, those providers must ensure that the services in question are carried out within the deadlines specified by the legislator.

Provisions of the amendment to the Act provide for a possibility of cancer patients receiving healthcare services without the need to be entered into regular waiting lists. This course is available to patients who have been issued a special document — Cancer Diagnosis and Treatment Chart (Polish: Karta Diagnostyki i Leczenia Onkologicznego, DiLO). General practitioners and doctors operating in secondary outpatient or inpatient clinics have the right to issue DILO charts. The Act clarifies what the DiLO chart shall include (Article 32b).

Firstly, personal data of the patient, and in the case of a person without full capacity to perform legal acts, also data of the legal or actual guardian. Secondly, designation of the service provider, along with the date on which the documents were drawn up, data on the patient's symptoms, diagnostic tests, referrals to specialists,

oncological diagnostics and diagnosis. Furthermore, DiLO contains data assessing the quality of the oncological diagnostic procedure. The document also contains the cancer treatment plan. Every DiLO has a unique number allowing for identification of the patient.

Creation of the Cancer Diagnosis and Treatment Chart (DiLO) equipped general practitioners with the right to refer patients to cancer diagnostics in order to diagnose a cancer disease (Article 32a). It is noteworthy that the doctor's privileges depend on the cancer detection rate, specified in the Act as the Individual Cancer Detection Performance Rate (IWSRN). Only healthcare providers whose IWSRN rate is at least equal to or higher than the Minimum Cancer Detection Performance Rate (MWSRN) specified by the Ministry of Health have the right to refer patients to healthcare services bypassing regular waiting lists. Other general practitioners are obliged by the Act to undergo training in the field of early detection of cancer; the costs of the training are borne by the GP. GPs are informed about their IWSRN value and the possible failure to achieve MWSRN by the Regional Branch of the National Health Fund. The minimum cancer detection rate is 1/15 [11]. It is important to note that from the moment the GP is informed that he/she does not meet the requirements until a certificate confirming the training is submitted in the Regional Branch of the National Health Fund, the GP is not authorised to issue DiLO charts.

Practice guidelines for prophylactic mastectomy and genetic testing

Prophylactic mastectomy is indicated as one method of reducing the risk of breast cancer in women whose family history indicates increased likelihood of developing the disease. Research demonstrates that in the event a woman is diagnosed with mutations in the BRCA1 or BRCA2 genes, this procedure can reduce the risk of developing the disease in the future. The objective of prophylactic mastectomy is avoiding development of the disease in the most at-risk group, whereas the prophylactic of this method is unmatched with any other methods. This effect can be achieved by removing the portion of tissue where cancer develops most commonly. Zeigler *et al.* indicate that breast cancer develops in only 1% of women who opted for prophylactic mastectomy [12].

As already indicated, the intervention in question should be performed on women strongly motivated to opt for radical steps by a family predisposition or the presence of mutations, as it is a body-mutilating procedure which, like every surgery, is associated with risks. The specific nature of the procedure is strongly connected with psychology and sexuality — the body part, which has always been associated with femininity in both the sexual context and the image of a breastfeeding mother, is voluntarily mutilated.

The procedure can be particularly indicated in women, in whom nodular and mammographically dense mammary glands are observed. The reason for the procedure being particularly advisable in this group is the fact that such a tissue structure makes it difficult to make a diagnosis at an early stage [13]. It is worth noting that in very at-risk women, implementing preventive measures in the form of self-exams, frequent medical examinations and mammography does not offer the same level of certainty as prophylactic mastectomy. We are left with an unresolved question of whether this group of women should have the right to this service under the public system even if the attending doctor is against such a procedure.

The benefits described above resulting from clinical trials have been proven in a document published in June 2013 by the National Institute for Health and Care Excellence (NICE) entitled "Familiar breast cancer" [14]. With regard to prophylactic mastectomy, the document discussed conducting risk-reducing mastectomy in both women whose family history indicates an increased risk of developing the condition, as well as women, in whom family history is not a factor increasing that risk. Given the radical nature of the procedure, NICE guidelines recommend it only in a small number of patients identified with the highest risk of developing the disease. Authors of the document recommend that the woman be managed by an interdisciplinary team of professionals including, apart from an oncologist and oncological surgeon, also a geneticist, psychologist and sexologist. The document also underlined how significant it is for future patients to obtain the support of those patients who have already undergone the procedure. It is particularly important to reduce fear by arranging conversations with individuals who have already had similar experiences.

Guidelines included in the document underline the significance of preparing an individual action plan for each patient, including discussing the risks and benefits resulting from the procedure. The discussion in question should touch upon both the odds of the disease developing in the case the procedure is not carried out and the odds of it developing even despite of opting for the procedure. In the case unilateral mastectomy is planned, the patient should be informed about the likelihood of cancer developing in the other breast. The conversation should also include the potentially negative impact of mastectomy on the appearance and sexuality resulting from the different feeling when touching the breast or its changed appearance. NICE guidelines also recommend that a member of the interdisciplinary team should discuss the issue of performing breast reconstruction as soon as possible. The objective of the procedure is improving the quality of life of patients.

Statistics show that the number of prophylactic mastectomies is on the rise. A comparison of the number of bilateral risk-reducing mastectomies among US residents in the years 1998–2005 indicates an almost two-fold increase in the number

of procedures performed [15]. Researchers indicate that the increased number of procedures is attributable to: an increase awareness of genetic determinants of breast cancer, improving availability of genetic testing, as well as the constant development of plastic surgery offering increasingly advanced techniques of breast reconstruction. When discussing the situation in Poland, it is this aspect — the possibility of performing breast reconstruction integrated into the prophylactic mastectomy procedure, financed in full from public funds, which is questionable.

Ethical issues regarding performance of prophylactic mastectomy are experienced not only by patients troubled with taking the difficult decision on reducing the risk of developing cancer in the future at the cost of mutilating their body in the present. Doctors, who, by referring to conscience clauses, do not wish to mutilate a (presently) healthy woman may experience some moral dilemmas in connection with carrying out the surgery [16]. Other concerns voiced following Angelina Jolie's announcement of her prophylactic mastectomy. Concerns related to the Angelina Jolie effect regarded increased costs associated with genetic testing and the carrying out of surgeries. Concerns regarding the economic burden related mainly to situations where women without family history of cancer wish to test their genes [17]. The question arises whether or not such a right — to test for genetic predispositions in order to exclude them — should be enjoyed by every woman?

Polish experience in terms of the correlation between mutations in BRCA genes and prophylactic mastectomy have been presented in a study entitled: "A survey of preventive measures among BRCA1 mutation carriers from Poland" [12]. A study conducted at the beginning of the 21st century in Szczecin presents the types of preventive measures taken by women who were informed that they are carriers of gene mutations. Patients who tested positive for gene mutations were asked to participate in a survey 18 months after the test results and provide information about whether they took any action to prevent development of the disease.

Apart from prophylactic mastectomy, the list included actions such as: removal of ovaries, commencement of treatment with tamoxifen, the use of oral contraceptives, breastfeeding for a period of over a year, as well as carrying out regular mammography and MRI examinations. Of 414 respondents, 117 women were classified as individuals who should consider opting for prophylactic mastectomy. The results indicate that this option was chosen by only six women. This means that Poles' interest in this way of reducing the risk of breast cancer is not significant, which, as mentioned before, may be due to various factors: concern about how the procedure might affect the woman's appearance, the partner's support, a change of feeling, the fear of the surgery and its unpredictable consequences. The guidelines about prophylactic and treatment of breast cancer are described in details in the table below.

Table 1. Guidelines for genetic testing and prophylactic mastectomy.

Country	Guidelines	Year	Genetic testing	Recommendations	Reimbursement
Poland [18]	Breast Cancer	2013	Offering genetic testing to people at high risk of developing breast cancer.	1) Person with a personal history of breast cancer referred to tertiary care 2) Counselling 3) Genetic testing for BRCA1, BRCA2 4) Three options: risk-reducing bilateral mastectomy, risk reducing bilateral salpingo-oophorectomy, pharmacology prophylactic	Yes* Yes
United Kingdom [19]	Person with a personal history of breast cancer: assessment and management in tertiary care	2015	Offering genetic testing to people with a 10% likelihood of carrying a BRCA1/2 mutation.	1) Person with a personal history of breast cancer referred to tertiary care 2) Genetic testing for BRCA1, BRCA2, TP53 mutations 3) Counselling 4) Three options: risk-reducing mastectomy, risk reducing bilateral salpingo-oophorectomy, treatment options for people who are TP53 mutations carriers	Yes* Yes
United States [20]	BRCA-Related Cancer: Risk Assessment, Genetic Counseling, and Genetic Testing	2013	Women with an increased risk of having a BRCA mutation based on a family history of breast, ovarian, fallopian tube, and/or primary peritoneal cancer should be referred to a genetics professional.	1) Person with a personal history of breast cancer referred to tertiary care 2) Counselling 3) Genetic testing for BRCA1, BRCA2 4) Counselling 5) Three options: Breast cancer chemoprevention, risk-reducing mastectomy, prophylactic oophorectomy.	Yes* Yes

Recommendations for the management of early breast cancer in women with an identified BRCA1 or BRCA2 gene mutation or at high risk of a gene mutation.	<p>Women with an increased risk of having a BRCA mutation based on a family history of breast, ovarian cancer and have a more than 10% likelihood of a gene mutation. Or if unaffected by cancer have more than a 20% likelihood of a gene mutation.</p> <p>* at high risk of developing breast cancer. » Medicare, Medicaid and private insurances (e.g. Aetna). Thirty-two states offer reimbursement for testing, although the specific criteria for coverage can vary, and may not provide coverage for asymptomatic individuals (Medicaid).</p> <p>^ Prophylactic surgery, both mastectomy and oophorectomy, is covered by several insurance companies, but was, and still is, not a widespread practice (2015).</p>	<p>2013</p> <p>1) Person with a personal history of breast cancer referred to tertiary care 2) Counselling 3) Genetic testing for BRCA1, BRCA2 4) Counselling 5) Three options: breast cancer chemoprevention, risk-reducing mastectomy, salpingo-oophorectomy.</p>	<p>Yes*</p>
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Evidence-based information on prophylactic mastectomy

According to systematic review and meta-analysis, bilateral prophylactic mastectomy and prophylactic bilateral salpingo-oophorectomy were both associated with a decreased breast cancer risk in BRCA1/2 mutation carriers RR 0.114 [95% CI: 0.041; 0.317], RR 0.552 [95% CI: 0.448; 0.682] respectively. Furthermore, contralateral prophylactic mastectomy significantly decreased contralateral breast cancer incidence in BRCA1/2 mutation carriers RR 0.072 [95% CI: 0.035; 0.148]. Of note, prophylactic bilateral salpingo-oophorectomy was associated with significantly lower all-cause mortality in BRCA1/2 mutation carriers without breast cancer HR 0.349 [95% CI: 0.190; 0.639] and those with breast cancer HR 0.432 [95% CI: 0.318; 0.588]. In addition, all-cause mortality was significantly lower for patients with contralateral prophylactic mastectomy than those without, however, bilateral prophylactic mastectomy was not significantly associated with reduced all-cause mortality [23].

Cochrane systematic review (2010) shows that bilateral prophylactic mastectomy should be considered only among those women at very high risk of disease. There was insufficient evidence that contralateral prophylactic mastectomy improved survival [24].

The Zendejas *et al.* concluded that contralateral prophylactic mastectomy is cost-effective, compared with surveillance, for patients with breast cancer who were younger than 70 years. Compared with surveillance the incremental cost-utility ratio (incremental cost per QALY gained) for contralateral mastectomy was \$4,869 for 45-year-old women, \$6,896 for 50-year-old women, \$9,237 for 55-year-old women, \$17,333 for 60-year-old women, \$28,213 for 65-year-old women, \$62,750 for 70-year-old women, and \$93,400 for 75-year-old women [25].

Bilateral prophylactic mastectomy reduces breast cancer risk in BRCA1/2 mutation carriers to approximately 2%, and breast cancer fatality rate to less than 10% [26]. Prospective data have shown radical mastectomy including the nipple areola complex to be the most efficient surgical technique for reducing breast cancer risk [27].

Several studies have shown a steady increase in contralateral prophylactic mastectomy rates, but data regarding trends in bilateral prophylactic mastectomy are less common. Table below shows genetic risk for developing breast cancer. Data presented in table below based on clinical trials and systematic reviews [28–30].

Table 2. Risk for developing breast cancer [31]

Genetic risk factors	
Factor	Absolute Lifetime Risk
BRCA1	81%
BRCA2	85%
P53	24%
PTEN	25%

Controversies, media attitude to preventive mastectomy

On 14 May 2013, Angelina Jolie, a famous actress and social activist announced in the columns of the most widely read newspaper in the world that she had undergone prophylactic mastectomy [32]. The reasons for taking this decision were twofold: the fact that she had been identified as the carrier of a BRCA1 gene mutation and her strong family history of cancer. Her mother developed cancer in her forties and died at the age of 56 [31]. Press releases published after the bilateral risk-reducing mastectomy was announced stated that the main motivator for taking such drastic measures was the fear that it might prove impossible to continue being a mother for her six children. The actress revealed that the estimated risk of her developing cancer was 87%.

Jolie's statement published in The New York Times also describes the preparations to the surgery and the procedure itself. The actress wrote that the medical procedure was initiated on 2 February 2013. That is when the first surgery, nipple-sparing mastectomy, was performed. Two weeks later, the major surgery, i.e. a bilateral mastectomy, was performed. In the course of the procedure, breast tissue where cancer could potentially develop was removed. Temporary breast fillers were introduced during that surgery. After another 9 weeks, the patient underwent breast reconstruction and the proper implants were introduced [33]. Both the procedure and the recovery are very extended processes — particularly as the patient is a healthy person. Therefore overall costs are not only limited to costs of the procedure itself, but also include social costs.

In the article dated 14.05.2013, The Times compared Angelina Jolie to Betty Ford, the first lady who in the 1970s was the first such person to speak openly about her mastectomy [31]. It was estimated that a celebrity informing the public about her surgery can significantly affect women's awareness of breast cancer. The celebrity's attitude and the interest expressed by mass media may impact increasing knowledge on the procedure itself and the disease in general, as well as the significance of prevention and genetic testing.

Half a year after the announcement made by Angelina Jolie about her risk-reducing procedure, a group of researchers carried out a survey among 2572 respondents. The purpose of the study was to check the Americans' awareness of the procedure which the actress underwent, as well as to see if they understood the reasons for that procedure. Findings of the survey indicate that approx. 75% of respondents have heard of prophylactic mastectomy as the procedure which a person they know from headlines was subjected to. Unfortunately, only less than 10% of the respondents were able to name the risk factors which prompted Ms Jolie to opt for the procedure. The results of the survey suggest that despite of the fact that respondents are aware of the actions taken by Angelina Jolie, they do not understand the reasons for those actions, i.e. family history and the BRCA gene mutation [34].

In what has been termed the “Angelina effect,” there was a dramatic increase in the number of women seeking referrals for genetic testing. Interestingly, a survey of US adults demonstrated that while 75% of respondents were aware of Angelina Jolie’s bilateral mastectomies, fewer than 10% were able to interpret her risk of developing breast cancer compared to a woman without a BRCA gene mutation [35].

In the 21st century, an analysis of the frequency of searches of keywords or phrases in the most popular search engine — Google serves as an adequate tool for measuring the society’s interest in a specific issue. For that purpose, the Google Trends tool (in search of the words “mastektomia”/“mastectomy” and “BRCA”) was used to analyse the society’s interest in mastectomy. The results presented below regard searches performed worldwide and more specifically — in Poland.



Fig. 1. Interest in mastectomy among Google users, source: www.google.pl/trends [36].

The chart shows the important events which could account for spikes in the searches for the issue in question presents the interest in mastectomy among Google users between 2005 and the present. Individual events have been marked with letters of the alphabet, starting from the most recent one and ending with the earliest one, chronologically speaking. The event marked with the letter C is particularly noteworthy. Pursuant to data published by Google Trends, it is in May 2013, i.e. the month when Angelina Jolie announced that she had undergone prophylactic mastectomy, that the term “mastectomy” was searched for most often. It should be noted that she was not the first celebrity to reveal to the public that she had had such a surgery. Prior to that event, in January 2013, (event marked with the letter D) this information was made public by Miss America, Allyn Rose, and in December 2011, (event marked with the letter F), Giuliana Rancic, an Italian television anchor. “Mastectomy” was searched the most in the United States, as well as the Philippines, Canada, Singapore, Australia, New Zealand and the UK.

Fig. 2 presents the search of the same term by Polish Internet users. The tendency for Poland is similar to that for worldwide searches. The peak for Poland was also in May 2013.

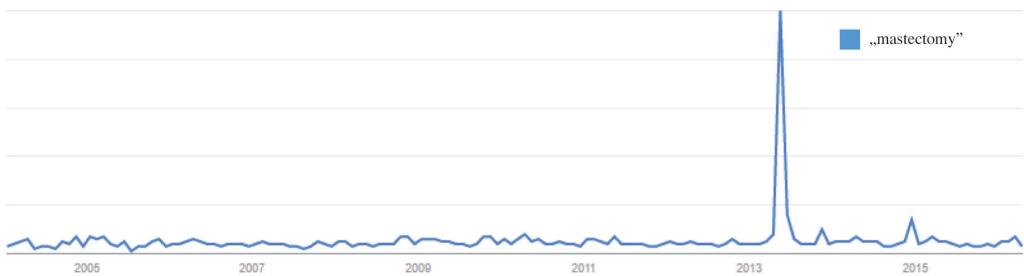


Fig. 2. Interest in “mastectomy” among Polish Google users, source: www.google.pl/trends [37].

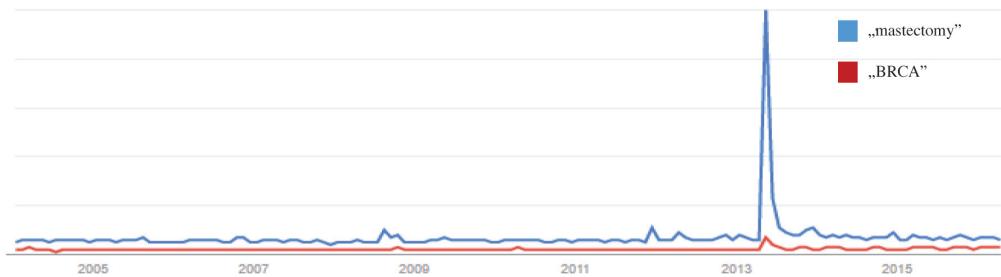


Fig. 3. Interest in “mastectomy” and “BRCA” genes among Google users, source: www.google.pl/trends [38].

A comparative analysis of the searched phrases: “mastectomy” (blue) and “BRCA” (red) illustrated above indicates a correlation between Angelina Jolie’s announcement about her risk-reducing mastectomy and the increase in the search for information about genes impacting the prevalence of the disease.

Statistics show that the surgery gained widespread attention in 2013 when actress Angelina Jolie revealed she had it done after learning she carried a gene mutation that put her at extremely high risk of developing breast cancer. According to a study published in the Journal of Plastic Reconstructive Surgery, contralateral prophylactic mastectomy is on the rise — from 39 to 207 per 1,000 mastectomies between 1998 and 2008 in United States [39].

According to National Cancer Data Base, for women of all ages, rates of contralateral prophylactic mastectomy increased, from 1.9% in 1998 to 10.2% in 2011 ($p < 0.001$), with higher rates in women ≤ 45 years old, rising from 3.7% in 1998 to 26.2% in 2011 ($p < 0.001$) in the United States [40].

Retrospective analysis of hospital episode statistics from England indicates that among women without breast cancer, the number who had a bilateral mastectomy increased from 71 in 2002 to 255 in 2011 (annual incidence rate ratio 1.16, [95% CI: 1.13; 1.18]). Moreover, rates of immediate breast reconstruction roughly doubled and reached 90% among women without breast cancer in 2011 [41].

It should be emphasized that in Poland about 40 percent of women eligible for a free mammogram had it in 2015 and only 20 percent of women did cytology. Marcinkowska *et al.* present reasons for low women attendance at mammography screening. Based on discussions, four main groups of low attendance reasons were identified: social (lack of knowledge about prophylactic mammography), economical (inability to give up a day's work), psychological (fear) and administrative (problem of obtaining referrals). Free of charge access to mammography would increase attendance only if the physicians would routinely inform their patients about necessity of regular breast examination [42].

Discussion

When discussing access to healthcare services, in oncology in particular, one should first consider the specific situation of a cancer patient. It is because in this group of patients, ensuring full diagnostics as soon as possible is of key importance. Naturally, individual neoplastic diseases differ in terms of disease progression, however, when compared to other conditions, cancer is characterised by significant dynamics and rapid progression.

Legislative changes in relation to the improvement of access to oncology can be referred to British solutions included in a document published in September 2000 entitled "The NHS Cancer Plan" [43]. The British have indicated that nobody should be forced to wait longer than one month to commence treatment when his/her health condition is qualified as an "urgent" case. The only exception is a situation where good clinical practice indicates a reason for extending that period, or the procedure is subject to the patient's decision.

Authors of The NHS Cancer Plan assume reducing the waiting time to receiving treatment from the moment of diagnosis for all types of cancer to a maximum period of one month. The waiting time between the patient's first contact with a doctor to commencing treatment should not take more than two months. Both adopted objectives were to be met by 2005. For breast cancer treatment, the standard was indicated as a maximum of 1-month waiting for the commencement of treatment from the final diagnosis.

A report of the Watch Health Care Foundation dated 2016 regarding changes in availability of guaranteed healthcare services used in fighting cancer indicates that in the case of a patient without a DiLO chart, the total waiting time, from the moment a first suspicious lesion is detected in the course of a self-exam or a screening test (e.g. mammogram) to the commencement of breast-conserving surgical treatment with additional CT of pelvis minor and abdomen is 6 months (4.4 month without in-depth diagnostics). It is noteworthy that in January 2015, the average waiting time was 5.6 months, and in May and January 2015 — 9 months [44]. Unfortunately, the

subsequent part regarding up to 2 months waiting time to commence treatment from the first GP visit indicates that the Polish healthcare system still has a long way to go to meet the standards specified in the UK guidelines. A case study of a woman diagnosed with breast cancer included in the Foundation's report indicates that the waiting time was actually 3.7 months at the beginning of the year. A verification of the current waiting time allows to conclude that the system is not prepared to implement the stipulations of the "oncological package" nor meet European standards.

An analysis of the Poles' opinion on availability of healthcare services indicates that the limitations encountered most often by patients are the significant waiting times to consult a specialist and undergo diagnostic tests. In the case of patients with suspected cancer, given the fact that the disease progresses rapidly, a streamlined diagnostic process is of utmost importance. Unfortunately, a Polish cancer patient must wait for months to get a final diagnosis and start treatment.

It is difficult to assess the waiting times for preventive mastectomy, given the fact that patients must wait for the procedure even in the case of mastectomies performed when cancer has already developed. It is also difficult to assess the impact of the Angelina Jolie effect on the number of procedures performed in Poland, as no register of such procedures is kept. However there are no doubts as to the fact that Jolie's declaration increased awareness of the problem both in Poland and globally. It can be assumed that it prompted millions of women to seek information about that topic.

The main interest focused on the types of procedures performed and the impact of genetic determinants on the risk of developing cancer. Unfortunately, the line representing the tendency indicates that the interest in the problem was only temporary, it also demonstrates that a person's economic status was strongly correlated with the tendency to search for information about the subject (data based on Florida cancer registry) [45]. The information noise encountered by a Pole who might be interested in undergoing the surgery is also very worrisome. On the one hand, she is informed of the benefits of taking such actions and the possibilities to carry out the surgery, and on the other hand she encounters difficulties when looking for entity which would perform such a healthcare service. As a result, it is often the case that individuals determined to undergo the procedure opt for financing it out of their own pocket.

Conclusions

Cancers are becoming an increasingly big issue. Every year the incidence rates are higher, and in consequence the number of patients receiving cancer-related benefits grows. The current legal regulations governing the availability of cancer-related benefits seem to be insufficient.

An analysis of the current waiting times allows to conclude that Polish patients will not reach European standards for a long time; before the Polish healthcare

system reaches the standards set forth by decision-makers, it should be subjected to substantial reforms. This is particularly true in the context of the subject discussed in this paper. An analysis of the current legal regulations indicates a lack of detailed solutions in terms of prophylactic mastectomy. Despite indications for the procedure as one of the ways of preventing breast cancer among women with strong family history of cancer and mutations in the BRCA1 and BRCA2 genes, patients who wish to undergo this procedure under insurance provided by the National Health Fund encounter access difficulties. For that reason women often decide to opt for services offered by the private sector. However, the procedures in question are costly and hence, due to financial constraints, out of reach of some women.

There is no extensive discussion about mastectomy in Poland; although there are amazon organisations for women who underwent mastectomies, they bring together women who were subjected to the procedure due to cancer being detected, and not for the purpose of risk-reducing. Since we have the capacities to determine the risk of developing cancer, shouldn't we consider a broader use of not only prophylactic mastectomy, but also make genetic tests more available to women with a clear family history of cancer? From the perspective of the healthcare system, we should also consider economic aspects in these case, as possibly the high costs of prevention might actually be lower than the costs which could be expected sooner or later anyway (this applies in particular to women with the risk of developing cancer dangerously close to 100%). In practice it is a rare situation in healthcare where we can not only determine the risk quite precisely, but also have significant chances of preventing it.

Conflict of interest

None declared.

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