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Compulsory Liability Insurance of the Entity Conducting Medical Experiments – Polemical Remarks

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Abstract: Conducting medical experiments by healthcare entities is highly necessary as it is only through such actions that we can confirm the effectiveness of new solutions, however carrying out medical experiments involves unique risks that must/should be subject to special protection. The aim of this article is to address the debatable elements contained in the Regulation of the Minister of Finance regarding the civil liability of entities conducting medical experiments. The raised concerns are intended to improve the quality of the adopted legal solutions to increase the safety of all entities and individuals participating in the process of conducting medical experiments.

Keywords: medical experiment insurance, coverage amount for medical experiment insurance, insurance company liability in medical experiments, damage settlement in medical experiments

1. Introduction

Once again, the legislator has introduced mandatory civil liability protection for healthcare entities. Civil liability involves bearing the consequences of one's own or a third party's actions. The goal in this case was to compensate for damages, which, among other things, can be caused by a tort or by the non-performance or improper performance of an obligation.

This time, insurance coverage has been extended by the legislature to entities conducting medical experiments. The issue is extremely important not only from social and insurance perspectives but also from an ethical standpoint. Additionally, the dynamic advancement of technology (e.g. in telemedicine) somewhat necessitates the use of medical experiments to protect health and treat patients with complex conditions. Civil liability involves bearing the consequences of one's own or a third party's actions. The goal, in this case, was to compensate for damages, which, among other things, can be caused by a tort or by the non-performance or improper performance of an obligation. Thus, the article considered the concept of medical experimentation, as well as the concepts of adverse events and the risks associated with them, the issue of the insurance sum guaranteed by the insurance company, and the position of the patient vis-à-vis participation in experiments and the ethical principles applicable to such conduct.

The aim of the article was to address the controversial aspects contained in the Regulation of the Minister of Finance regarding the civil liability of entities conducting medical experiments.

2. The Concept of a Medical Experiment (ME)

According to Article 21.1 of the Medical Code of Ethics (MCE), a medical experiment conducted on humans can be either a therapeutic or a research experiment.

A therapeutic experiment involves a physician introducing new or partially tested diagnostic, therapeutic, or preventive methods with the aim of achieving direct benefits for the health of the treated individual. It can be conducted when previously applied medical methods are ineffective, or their effectiveness is insufficient.

A research experiment aims to expand medical knowledge and is conducted with minimal or no risk to the subjects involved.

A therapeutic experiment is distinguished from a research experiment by its focus on achieving benefits for the health of the treated individual. In a research experiment, both sick and healthy individuals can participate. Conducting a research experiment is permissible when the risk of the procedure is sufficiently small and is outweighed by the positive results obtained.

According to Article 25, a medical experiment involving a minor is permissible. However, the participation of incapacitated persons is not allowed. Conceived children (i.e. embryos), incapacitated individuals, conscripted soldiers, and persons deprived of their liberty cannot participate in research experiments (Article 26). Furthermore, according to Article 45(2) of the Medical Code of Ethics (MCE), a physician is not allowed to conduct a research experiment involving a human embryo. Moreover, the physician conducting the research experiment is obligated to terminate it if there is an unforeseen threat to the health or life of the participating individual during its course (Article 27, paragraph 3).

Article 28 states that in connection with a medical experiment, for scientific purposes, information about the person undergoing the experiment may be used without their consent in a way that prevents the identification of that person.

The legislator clearly distinguishes between therapeutic and research experiments. However, in practice, both types of experiments can occur simultaneously.

A medical experiment is more than just a classical, repeatedly verified medical procedure.

During the COVID-19 pandemic, medical experiments with vaccines and pharmacotherapy emerged for pre-exposure and post-exposure treatment of directly infected individuals, asymptomatic infected individuals, and post-COVID-19 patients.

3. The Experimenting Entity

In compulsory insurance law, it is mentioned that there is a responsible entity for conducting a medical experiment. Such entities can be hospitals, clinics, outpatient clinics, sanatoriums, and other healthcare units. However, the legislator does not specify whether it refers to a hospital, clinic, or outpatient clinic, leaving it open to interpretation.

These entities are responsible teams of doctors (consilia) conducting a medical experiment. One can refer to the 'experimenter' ["eksperymentator"] as the entity, and also to the doctors as 'medical experimenters' ["lekarze eksperymentatorzy"] i.e. the personnel performing the medical experiment.

Another issue open to interpretation is whether the entities have the authorisation, conditions, and staff necessary to conduct medical experiments.

In general, the experimenter should have a sense of responsibility[1]: professional, qualified, specific to doctors from the perspective of the environment in which they work, as well as social responsibility (responsibility towards the institution they work for).

According to Article 27, "a person or other authorised entity granting consent for a medical experiment may withdraw it at any stage of the experiment. The physician conducting the therapeutic experiment is obligated to terminate it if there is a threat to the patient's health that outweighs the expected benefits for the patient." The above provisions do not specify the type of substitute consent, whether it is surrogate, cumulative, legal representative, or guardianship consent. It suggests that the consent giver for the experiment can be in constant communication (directly or indirectly) during the course of the therapeutic experiment.

According to Article 29.1, a medical experiment can only be conducted after obtaining a positive opinion on the project from an independent bioethical committee comprising individuals with high moral authority and high specialist qualifications. The opinion is issued by resolution, taking into account ethical criteria, as well as the purpose and feasibility of the project[2].

4. The Concept of an Adverse Event and Medical Error

An adverse event (AE) is an "unintended and unexpected event in the diagnostic or therapeutic process that causes transient or permanent harm to the patient". An adverse event that could have been avoided, or could have been prevented but was not, is called a medical error. A situation in which harm occurred to the patient, but interventions were successful in preventing adverse consequences is called a 'near miss' or 'close call'. In general, medical errors can be categorised as follows (Cranovsky, 2011):

- errors of execution (failure to perform a certain action according to applicable standards),
- errors of planning (inappropriate procedure or approach for achieving the intended goal).

Both types of errors are referred to as active errors. Failure to take the necessary and appropriate action is called a 'passive error' (passive stance).

From the perspective of medical practice, errors are classified into:

- cognitive errors: relating to the application of current medical knowledge,
- execution errors: involving actions related to the physician's profession (from simple to complex),
- organizational errors: pertaining to components of the healthcare system directly dependent on physicians' decisions and requiring their supervision.

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1 Cf. E.g. (Miller, 2002, pp. 37-43).

2 Simultaneously, the Appellate Bioethical Commission, appointed by the competent minister, is responsible for considering appeals against resolutions issued by bioethical committees.

During the conduct of a medical experiment, cognitive errors may arise, which can involve:

- lack of control in performing partial tasks,
- the correctness of general anesthesia,
- previously unrecognized body reactions,
- excessive tendency towards optimistic predictions of the final outcome,
- thinking in 'all-or-nothing' categories.

In many countries, including Poland, adverse event reporting is conducted (Czarnoysky and Krajewski, 2011). The number of adverse events and their frequency depend on:

- population characteristics,
- types of procedures and methods of registration,
- adopted terminology,
- institutions responsible for analysing the effects of adverse events (Forensic Medicine Departments, Professional Responsibility Ombudsman).

In compulsory liability insurance law, there is mention of one or several events, however the legislator does not provide a specific definition of the event. While a regulation on adverse events has been published, it is extremely difficult to determine the portion of the insurance coverage from which an adverse event that occurs during the execution of a medical experiment should be recognised[3].

One event can involve a single person being harmed in a medical experiment during the period of insurance coverage.

The term 'multiple events' can refer to several injured parties, which may occur at different time periods within a specified period of insurance coverage[4], namely a collection of compensation claims.

Practice indicates that for an adverse medical event to occur, a chain of unfavourable circumstances must be present, which collectively contribute to its development.

5. Risks Associated with Medical Experiments

During the conduct of a medical experiment, unpredictable reactions of the organism can occur, which is associated with the risk of its implementation. The occurrence of an unfavourable event is often referred to as a medical incident. Procedures for handling medical incidents have been defined[5].

In the case of a medical experiment, the experimenter (physician) should be aware that they can still be subject to an adverse random event (AE) despite:

- possessing knowledge and years of professional experience;
- applying appropriate medical standards and procedures relevant to the experiment;
- performing their duties with due precision, care, expertise, and conscientiousness;
- adhering to the principles of the medical code of ethics.

However, despite the above conditions, even with very good organization and work of the medical team, there is almost always a risk of random events occurring.

When conducting a medical experiment, the experimenter should take into account the special predispositions resulting from the injured person's body and the responsibility for any harm caused (Krupa-Lipińska, 2015, p. 43 onwards) . These predispositions arise from the complex nature of the

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[3] For these purposes, let us assume that an adverse event occurs when the amount of the claim exceeds 5% of the insurance coverage limit (this is a debatable assumption). Claims below this threshold are referred to as 'shortfalls' or 'deficiencies'.

[4] In the case of insurance in the II risk class, a yearly (or shorter) period of insurance coverage is assumed.

[5] They can be improved similar to incidents that may arise in the context of implementing the provisions of the General Data Protection Regulation (GDPR), as discussed by M. Gomularz and P. Kozik, (2018, C5).

patient's body. In other words, the experimenter should assess the probability of atypical physical and psychological reactions. In legal considerations, terms such as "causal adequacy," "behaviour of an unusually weak person", "unexpected consequences", "special predispositions of the body", "susceptibility of the injured person's body", and "acceleration of the development of inherent conditions" are mentioned. Based on these considerations, the responsibility of the physician for the patient is deliberated.

The application of the term in the context of the concept of a medical experiment is ambiguous, for example[6]:

- the purpose of the medical experiment is not specified,
- "limited patient autonomy",
- "focus on direct benefits for the patient",
- "association with risk".

In Article 22 of the Medical Experimentation Code (MCE), it is stated that "a medical experiment may be conducted if the expected therapeutic or cognitive benefit is of significant importance, and the anticipated outcome from this benefit, as well as the purpose and method of conducting the experiment, are reasonable in light of current knowledge and consistent with the principles of medical ethics".

This provision introduces further conditions for the legality of the experiment. In the commentary on this article, attention is drawn to:

- the ambiguity of the term "expected benefits" and its evaluation over time;
- the meaning of "reasonableness";
- the definition of "current state of knowledge" and the sources of scientific information;
- how to proceed when there is deterioration in health instead of benefits after the experiment;
- the principles of medical ethics governing scientific research.

In Article 23, it is stated that "a medical experiment is conducted by a physician possessing appropriately high qualifications". However, there are also controversial remarks concerning what exactly constitutes "high qualifications." This may refer to factors such as specialisation, scientific achievements, or experience. The article does not specify the methods of evaluating these qualifications (e.g. by the Bioethical Commission).

Article 24 states that "1) The person who is to undergo a medical experiment must be informed in advance about the objectives, methods, and conditions of conducting the experiment, expected therapeutic or cognitive benefits, risks, and the possibility of withdrawing from participation at any stage of the experiment, and 2) In the event that an immediate termination of the experiment could pose a danger to the life or health of the participant, the physician is obligated to inform them about it.". This provision requires the patient to be provided with full and understandable information about the experiment that is planned to be conducted, including informing their close relatives. Withholding information from the patient about the experiment is prohibited, even if the conducting physician (or medical team) is not entirely certain about its success. In most cases, there is a risk and a threat to the patient's health when conducting medical experiments.

In every experiment, one encounters the complexity of medical processes. composed of a series of partial actions (procedures). The risk of a medical experiment increases with its innovative nature, the individuals participating during the experiment, the procedures used, undesired reactions of the organism, and delayed reactions of the physicians. It is only during the conduct of the medical experiment that one sees the disparity between the knowledge possessed and the knowledge required, which can ultimately determine its success.

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[6] For a detailed analysis, see (Kopeć, 2016, chapter 4: Eksperyment medyczny, p. 625).

W legal literature, there is a broad discussion about the phenomenon of "counter-type risk," which refers to the risks associated with ordinary risk. This particularly applies to the protection of human life. In this context, the principle of "caution in conducting the experiment" is examined, as well as the permissibility of risk, especially concerning medical research experiments and the "counter-type risk of innovation." This involves the acceptability of hazardous actions, the conduct of research experiments for the first time, and the application of 'socially adequate' methods" (Kubiak, 2007, pp. 115-123).

In this context, the phenomenon of the experimenter's culpability is discussed in case of adverse events for the patient.

It is worth considering the use of medical experiments in the terminal phase of life (end-of-life care). During this period, there are many characteristic features of the patients, such as susceptibility to malignant tumors (Sykes, 2009, pp. 70-76).

Indeed, it is worth noting that in medical experiments, the experimenter may rely on intuition[7]. This phenomenon involves utilising one's own ability or insight in the decision-making process.

The discontinuation of costly, risky, extraordinary, or disproportionate medical procedures may be justified. This is the refusal of so-called "persistent therapies,"[8], which involves using extraordinary medical procedures (technical devices, pharmacological means) to artificially sustain the life functions of a patient afflicted with an incurable disease, thereby delaying their death[9].

Indeed, in practice, there are situations where doctors decide not to pursue persistent therapy and may choose to withhold or withdraw certain medical procedures.

It is debatable whether a doctor can abstain from ineffective therapy against the patient's request. Nonetheless, discontinuing persistent therapy requires adhering to the following principles:

- human life is the highest good for a person;
- human dignity should be preserved;
- it should ensure a natural and dignified death for the patient;
- neither shortening nor prolonging human life;
- it is the autonomous decision of the patient;
- the patient's wishes expressed in the 'living will' inform the doctor about their desires;
- the doctor makes decisions in accordance with their knowledge and conscience clause.

It is important to note that for the purpose of conducting experiments, specialists from outside Poland are often invited, which also has implications for insurance risk.

6. Relation: Patient – Medical Experiment

Let us now look at the relationship between the patient and the entity undertaking to help the patient through a medical experiment. From the experimenter's perspective, among others, the following conditions should be met (Kościelska, 2006, pp. 96-107):

- act with full awareness and voluntariness (the idea of the experiment),
- anticipate potential consequences,

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[7] Intuition has various meanings. According to the Dictionary of Psychologists by Arthur and Emily Reber, intuition is "understanding or knowing something in a direct and immediate way." Scholars dealing with this topic describe it as the "conscious effect of unconscious thinking," the sixth sense, clairvoyance, a manifestation of supernatural abilities, the "mysterious voice coming from beyond us," or "a mind that hurries.". According to Einstein, "Thinking without intuition is empty. Intuition without thinking is blind." For details, see (Krzemionka, 2015, pp. 52-57).

[8] Persistent therapy is characterised by:
- incurring high treatment costs,
- causing disproportionately intense suffering,
- limiting the functionality of the patient,
- neglecting basic nursing procedures (feeding, pain relief).

[9] For details, see: (Kiedy lekarz może pozwolić umrzeć choremu, 2009, pp. 167-177).

- always maintain a conservative approach (have a cautious and careful attitude),
- have the ability to choose not only the method of conducting the experiment but also the use of medications.

In terms of consciousness, the experimenter should possess a sufficiently large and up-to-date medical knowledge, potential, and imagination, and accurately diagnose the patient's condition before the experiment. In the event of adverse medical events, the experimenter should have the ability to assess (perceive) their actions and foresee the complicity of other individuals (collectively) in carrying out the medical experiment. Additionally, they should avoid making 'childishly simple mistakes' that would indicate a lack of expertise.

6.1. Self-assessment of the patient before making a decision to participate in a medical experiment

The person who is ill strives by all means to recover, to minimise the damage to their health (on their own body). The person is aware of the situation they are in and finds it difficult to adapt to it. They perform a self-assessment of their self-image, self-worth, origin, position in the family, interpersonal functions in society, and in their professional work, and reputation[10]. The pressure of the above constructs and attributes is very strong and increases with the patient's age. Additionally, factors such as emotions, beliefs, comparing one's own situation with similar cases of illness in other people, also have an impact. Impulsive functions come into play (stress, anxiety, restlessness, depression, pain, suffering, lack of self-control, decreased effectiveness of actions, and even suicidal thoughts, aggression). In light of such self-evaluation, the burden of making a decision to undergo a medical experiment falls on the patient, caregivers, and family members.

Frustrations arise from blaming (responsibility) previous doctors or pharmacists for diagnoses or not recognising circumstances that caused the current condition (putting blame on others). This is not accompanied by an element of self-evaluation, self-reflection, or acknowledgement of one's own shortcomings.

The source of self-esteem comes from experiences in previous stages of life, acquired skills, and random events (such as a fire, accident, divorce, death of a loved one, achieving social status, wealth, or possessions). This can be referred to as explicit self-esteem. In addition to that, there may be hidden self-esteem associated with fears, risks, and defense mechanisms.

The patient, who possesses knowledge about their illness, symptoms, and suffering, undergoes self--evaluation of their own person, their 'self', equipped with the knowledge acquired during the course of previous treatments and information from other individuals with similar ailments (a process of social comparisons)[11]. They must adapt to the requirements of the situation they find themselves in. Their self-evaluation corresponds with emotions, shaping their own self-worth, reduced effectiveness in actions, and a unique sociometry of internal self-value. Being in a situation of health risk, they decide to undergo the medical experiment by signing the appropriate document and acquainting themselves with the potential consequences after the experiment. This decision is based on faith in success and trust in the experimenter.

The patient's consent (declaration of will) is required for undertaking ME. The signature must fulfill conditions such as being legible and made with a permanent means, including the full name of the patient, and it should be done with full awareness after being acquainted with the document being signed[12].

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[10] For details, see: (Ossowska, 2013, pp. 147-163). It is worth noting that a scale of self-assessment is readily available: (Łaguna et al., 2007, pp. 164-176).

[11] The source of one's own 'self' derives from their past life experiences and interpersonal relationships.

[12] However, insurance practice presents many circumstances in which obtaining written consent is challenging, such as the lack of hands, signatures in Russian or Arabic languages, or witnesses not present at the time of signing. In such cases, the doctor should suspend the experiment (Kubiak, 2019, pp. 130-135).

Article 25 stipulates that the written consent of the subject is required for participation in the medical experiment. In cases where it is not possible to obtain written consent, "consent expressed in the presence of at least two witnesses" is considered equivalent. In the case of a minor or incapacitated person, the consent of their legal representative is necessary for the medical experiment. Additionally, in practice, there may be various situations involving a period of reflection on the proposed experiment, issues of self-awareness, unconscious individuals, helpless persons with limited legal capacity in urgent situations (due to the patient's condition).

Special attention is given to therapeutic experiments involving pregnant women (Article 26). In such cases, participation in medical experiments is allowed only if they are free of risk or danger to both the mother and the child.

From practice, it is known that a medical entity can conduct numerous experiments on any human subject. Thanks to many experiments, the medical entity gradually gains more experience, and as a result, its experiments become increasingly safer.

Indeed, it is reasonable to agree with D. Birnbacker that *the greater the knowledge of distant potential harms and the more numerous the possibilities of preventing these harms, the greater the burden of responsibility for the future lies on human actions and omissions*[13].

Both the patient – and above all, the experimenter – should be aware of the quality of life after the medical experiment[14].

Contemporary medicine has extraordinary capabilities for treating and prolonging human life. These therapies require significant financial resources and scientific research. In the past, the concept of ordinary and extraordinary medical means was introduced. An ordinary medical means is considered to be a treatment method that:

1) is financially accessible to the majority of people in a given country,
2) does not cause excessive and prolonged suffering to the patient,
3) provides a sufficiently high probability of cure.

An extraordinary medical means is one that:

1) is very expensive, surpassing the financial capabilities of the patient, family, and ordinary healthcare service;
2) may lead to serious and unfavourable organic or psychological consequences;
3) offers a small chance of cure. The use of such means is the right of the patient.

The present approach is based on distinction between proportional and disproportionate medical means[15], examined both from objective and subjective perspective and criteria.

7. The Sum Insured and the Insurer's Liability in an Insurance Company

The concept of the sum insured is rarely defined by the authors of numerous publications. The common definition of the sum insured from the perspective of insurance practice comes down to determining the maximum amount of liability of the insurance company for events that occur during the insurance coverage period[16].

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13 Quoted after (Nowak, 2002, p. 219).

14 For more details, see: (Dziurawicz-Kozłowska, 2002, pp. 77-99; Kleszkowska-Gruding, 2007, pp. 209-213; Stenden and Okła, 2007). It may also be useful to note the availability and support of the International Society for Quality of Life Research.

15 W. Bołoż, quoted after: (*Życie w ludzkich rękach*…, 1997, p. 138 onward; Wróbel, 2009).

16 The sum insured pertains to liability insurance in property and personal insurance.

The sum insured, in its content, is the equivalent of the insurance amount in various types of property and personal insurance. It is worth noting that in the definition of the sum insured, it is mentioned that an insurance event should occur. The concept of an insurance event is broader than that of an insurance accident. In practice, it is assumed that an insurance event may encompass multiple insurance accidents[17].

The conclusion of a civil liability insurance (OC) contract does not imply that the insurer's liability arises simultaneously with that moment, as these two events usually occur at different times and cannot be equated. The insurance company may be liable for events that occurred before the insurance contract was concluded, may not be liable for a certain period, and may be liable even after the termination of the contract if the insured event occurred during its validity period (Małysz, 2001, p. 14).

The last paragraph of the above statement pertains to the payment of damages for losses that have occurred but have not been reported. The amount of these compensations can be estimated using various methods. It is important that in the case of new types of civil liability insurance for different social groups, one is unable to accurately predict future compensation payments, thus one can only speak in terms of estimated amounts. Since it is not known (or whether these will even occur) when these losses will be reported to insurance companies and the size of the claims they may involve, the task of the sum insured is to cover these damages. Therefore, the legislator rightly establishes in many cases a minimum sum insured that would fully cover future compensation and benefits caused by the insured.

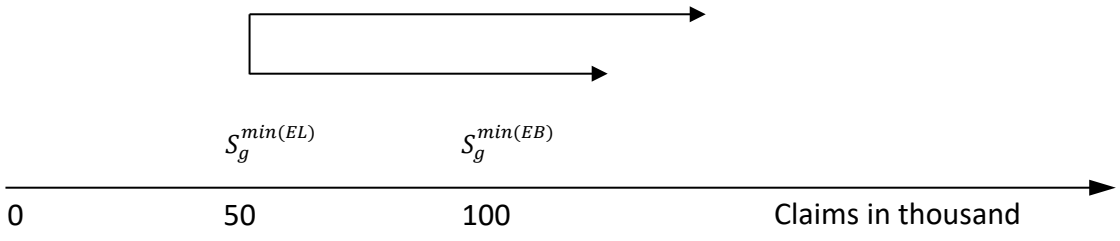
It may seem that human life has no predetermined limit. However, the legislator sets certain limits on insurability for risks occurring in medical experiments. Despite not knowing the ultimate size of the claims that may arise after conducting a medical experiment, the law proposes minimum insurance limits for the discussed risk through minimum sums insured. The legislator foresees that insurability limits may shift over time, depending on factors such as the awareness of injured patients, but it only establishes the lower limit of insurability.

In This case, the legislator has determined two minimum guaranteed sums:

- 50 thousand euros for a therapeutic experiment,
- 100 thousand euros for a research experiment.

In light of the above, this fact can be interpreted as follows: 1) the legislator assumes that claims arising from a research experiment are considered to be more dangerous (twice as much) than those from a therapeutic experiment; 2) claims from the injured parties resulting from a research experiment may be higher than those from a therapeutic experiment ; 3) conducting a research experiment is more risky than a therapeutic experiment.

One can illustrate this schematically as follows:



where: $S_g^{min(EL)}$ – the minimum insurance coverage amount for a therapeutic experiment, $S_g^{min(EB)}$ – as above, but for a research experiment.

[17] Consider a simple example of an event involving the collision of multiple vehicles simultaneously (pile-up), which can be insured with one or many different insurance companies.

In practice, it may turn out that the insurance coverage amount set by the insurance company for a therapeutic experiment can be higher or equal to the minimum insurance coverage amount for a research experiment.

$$S_g^{EL} \geq S_g^{min(EB)}.$$

The legislator did not specify whether it refers to the consequences of a single event or multiple events in both medical experiments.

The legislator did not specify whether the minimum insurance coverage amount applies to a single experiment or multiple ones.

Hence, in Poland, one can find specialist hospitals for the treatment of certain diseases (e.g. the burns treatment hospital in Siemianowice Śląskie)[18].

According to the regulations on compulsory insurance, the legislator has determined that the sum insured is the upper limit of financial liability. This means that the insurance company cannot settle claims for an amount greater than the agreed sum insured. Most cases in liability insurance comply with the above provisions, however, in insurance practice, one encounters situations where the claims of the injured parties exceed the sum insured specified in the insurance policy. Already at the stage of creating claims reserves, one can see that securing the claims of the injured parties (e.g. through court judgments) may exceed the sum insured. In a particular case, when calculating the present value of a lifetime annuity awarded to the injured party, one must be aware of such situations. This is especially relevant in cases of injured parties in medical experiments on patients, where such instances may occur frequently. In such cases, the sum insured should include the amount of the present value of the lifetime annuity paid to the injured parties.

To protect against the exhaustion of the sum insured, insurance companies introduce voluntary excess insurance while maintaining the same scope of liability as in the compulsory insurance. The contract can be concluded at any time, regardless of the duration of compulsory coverage[19].

To address such situations, the legislator introduced the Act of 19 July 2019, on special entitlements for victims in the event of exhaustion of the guarantee sum established on the basis of provisions in force before 1 January 2006 (Journal of Laws of 2019, item 1631). According to this act, the victim is entitled to claim a pension from the Insurance Guarantee Fund (IGF). The Fund pays the pension based on the recognition of the victim's claim (Article 5, paragraph 4), settlement reached with the victim, or a court judgment[20]. In this way, the legislator protects the financial situation of severely injured individuals, including compensation for suffering and long-term care.

The introduced law does not resolve many specific circumstances, for example (Zdyb and Dziekoński, 2020, pp. 56-57):

- whether "the insurer's liability has been completely excluded or whether it still exists in parallel and complementarily to IGF's liability";
- whether "the condition for the claim arising against IGF is prior knowledge by the claimant of the insurer and then the claimant's lawsuit being definitively dismissed";
- whether the claim is valid when the claimant had no knowledge of the insurer at all.

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[18] The above-mentioned observation is significant for assessing insurance risk and, consequently, for calculating the insurance premium.

[19] The risk is the possibility of not achieving success in pursuit of a goal despite having correctly adopted assumptions to achieve that goal.

[20] The legislator does not specify the parameters of the pension being paid.

The law does not indicate whether IGF's liability is limited to the difference between the guarantee sum from the IGF Act and the benefits previously paid by the insurer. Therefore, there is a fundamental doubt about the amount of the guarantee sum covered by IGF's liability.

Furthermore, the content of the law does not clearly indicate whether the provisions cover annuities from insurance contracts that expired before the entry into force of the law or whether they do not cover contracts that expired before the law's entry into force.

In the latter case, it is necessary to anticipate (estimate) potential adjustments to the amount of life annuity paid to the injured party in the future.

Additionally, the insurance company is obligated to monitor the person receiving the annuity to prevent them from receiving additional benefits from other sources[21]. The insurance company has the responsibility to inform the injured party about the expected depletion of the sum insured in advance.

It is also noteworthy that in many regulations of the Minister of Finance, various types of costs related to claims settlement are covered within the scope of the sum insured. These costs include:

1) covering the expenses of remunerating experts appointed by the policyholder, with the insurer's consent, to determine the circumstances and extent of the damage,
2) reimbursement of necessary costs aimed at preventing the increase of the damage and financial claims if justified by the circumstances of the specific event,
3) covering the costs of legal proceedings settled with the insurer's consent,
4) covering the costs of conciliation proceedings incurred by the policyholder, conducted with the insurer's consent (par. 10 of the aforementioned regulations).

It should be noted that the provisions of the mentioned regulations do not limit the amount of the above-mentioned additional costs that the insurance company is obliged to cover under the liability insurance policy. The insurance company is also obligated to cover these costs even if, together with the compensation, they exceed the sum insured specified in the insurance policy.

8. Ethics of Medical Experiments

The conduct of medical experiments (ME) requires the application of ethical norms. Among many norms, obtaining informed consent from the patient for conducting the experiment is essential. The principle that "every person has the right to decide their own fate" applies. Usually this right is exercised by individuals with full legal capacity, however, in medical practice, there are situations where others must provide consent on behalf of the patient; this applies to physically and mentally disabled individuals, minors, those with different beliefs, individuals who are not capable of giving consent, or those who use sign language (Czarkowski, 2014, p. 91 onward). In such cases, parents, authorised individuals, or guardians should give their consent on behalf of the patient. In legal terms, this is referred to as "substitute consent," "cumulative consent" (or double consent), or "parallel consent." There are also cases where a study may be conducted without obtaining prior consent.

The ethical principles for conducting medical experiments have been elaborated (W trosce o godność człowieka…, 2019, pp. 235-257). The most important principles include:

- unforced consent of the patient to participate in the experiment;
- the experiment should be designed and prepared based on previous experiences and with the involvement of qualified medical personnel;
- it should not cause adverse medical events (psychological and physical);
- adequate medical equipment preparation by supporting staff;

[21] Furthermore, it should be noted that the validity of the established reserves is monitored by the Financial Supervision Authority, the Treasury Chamber, and other institutions.

- the possibility to interrupt the experiment if it poses a threat to the patient's health. In the case of harm to individuals, compensation should be provided, including that from civil liability insurance;
- the obtained results should be published in appropriate publications.

In the case of an Adverse Event (AE) occurring during the Medical Experiment (ME), the following actions should be taken immediately:

- secure the patient's basic life functions,
- seek to limit damage to organs,
- preserve evidence for later analysis,
- notify relevant medical institutions about the unsuccessful experiment and the circumstances and causes of its occurrence,
- identify any "secondary victims" of the medical experiment, such as nurses or anesthesiologists.

In fact, it is crucial to emphasise that any intervention by a medical practitioner in the human body carries civil and tort liability. At the same time, the issue of "conscientious objection" is raised in literature. If a subject conducting a Medical Experiment (ME) takes on its implementation, they should adhere to the Hippocratic principle of "first, do no harm." This principle is so general that it is challenging to derive detailed norms (recommendations) directly from it for the person taking action.

In the Constitution of the Republic of Poland, Article 53 paragraph 1 speaks of freedom of conscience. The concept of 'freedom of conscience' has already been the subject of numerous publications (Hanc, 2016, pp. 21-50), including some controversial theses. In this case, the principle of conscience clause applies to entities conducting medical experiments as an "external attribute of constitutional freedom". Simultaneously, in foreign and Polish medical literature, the issue of "right to conscientious objection" is discussed (Różyńska, 2015, pp. 1-23, 27), referring to situations where a physician refuses to perform certain medical procedures due to their conscience (Pawlikowski, 2015, pp. 120-125).

According to the European Convention on Bioethics, every medical intervention should be carried out based on the principle of consent from the person concerned, which should be voluntary and fully informed. Before performing a medical intervention, the person concerned should receive appropriate information about the purpose and nature of the intervention, as well as its consequences and risks. The person concerned has the right to withdraw their consent freely at any time.

9. Problems of Damage Settlement

In liability insurance, it is said that the coverage limit should be set at a level that encompasses the full civil liability of the insured for the damages caused. This is of particular importance because the purpose of such insurance is, in essence, to protect the interests of the injured parties. The question arises about the definition of full civil liability, which refers to the complete financial compensation for the consequences of the insured event.

The question arises whether one can determine full compensation for the consequences. In practice, such a situation may occur when the injured party does not report further financial claims due to the suffered harm to health.

From the perspective of creating reserves for reported and unreported claims, the insurance company needs to establish reserves at a safe level and calculate their present value as of the valuation date.

Additionally, to calculate the reserve for unreported claims, the chain ladder method is required. Calculating reserves for annuities (stream of payments) is more complex. These annuities are life annuities and take into account debatable parameters such as:

- the probable future life expectancy of the injured party,
- the annuity payments (in advance or in arrears) at specified time intervals,

- the debatable interest rate (discount rate),
- the fixed or time-varying amount of annuity payments (adjustments to the payment amount).

It is not possible to have a simplified claims settlement process consisting of only some absolutely necessary steps that would minimise the time and effort required by the insured to obtain compensation. However, there are several advantages to consider:

- short waiting period for compensation,
- reduced claims settlement costs,
- optimal utilisation of the insurer's employee involvement in claims handling.

The object of personal injury is the injured person[22].

The main goal of personal injury recovery should be to achieve the maximum therapeutic effect while maintaining a rational level of costs. In other words, the optimal path to recovering the lost life values for the injured party.

A personal injury adjuster is a manager who coordinates the individualised process of restoring lost life values, utilising interdisciplinary knowledge. At the same time, in the insurance industry, one observe an annual increase in compensation claims.

The reasons for increased compensation claims from the injured parties are as follows:

- increasing awareness of patients undergoing medical experiments;
- awareness shaped by media, environment, narrative medicine, and health education;
- seeking compensation in the form of money or specific services, such as rehabilitation, for the damage suffered;
- the process of restoring lost life functions through medical procedures;
- monetary compensation is provided in cases where it is not possible to restore life functions.

During the compensation process, it is necessary to gather all precise and imprecise information and structure it accordingly.

Structured information is used when:

- the injuries are more complex, requiring greater expert knowledge and experience in the process of compensation;
- the individual scale of values is difficult to determine (e.g. hand amputation);
- monetary compensation cannot fully restore the lost life values;
- the valuation of the lost life values is exceptionally challenging and usually leads to limited satisfaction.

10. Insurance Premium

Calculating insurance premiums is a crucial aspect of compulsory insurance. A necessary condition for determining the premium is the access to reliable and credible statistical data. Unfortunately, public statistics do not provide any information about the quantity and types of medical experiments (ME) conducted. There is also a lack of data concerning the number and causes of ME in which patients' lives were endangered or adverse medical events occurred. These data gaps make it difficult to calculate the value of damages caused to patients due to errors, negligence, and flawed conceptualisation of ME procedures.

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[22] Using the trend adopted by the World Health Organization, it can be simplified to state that the subject of personal injury involves a wide range of losses in the catalog of material and non-material values, both measurable and immeasurable, and often difficult to identify.

It is worth noting that the insurance company must calculate the premium in such a way as to be 95% certain that it will cover all claims and costs related to this insurance. Such a high level of certainty is connected to unpredictable damages that may occur outside the insurance period but result from events that took place during the coverage. Additionally, it accounts for the exhaustibility of the coverage limit.

Research in the essence of insurance risk aims to construct an ideal model applicable to even the most challenging risks in insurance. Within this context, the issue of the economic interest in insurance arises, which means ensuring the profitability of both parties in the insurance relationship. On the insurer's side, not only financial requirements (e.g. solvency margin, capital holdings) must be met, but also organizational ones. In this context, insurance for the entity conducting medical experiments as a product can be realized by financially strong insurance companies. According to Vaughan, insurability criteria include factors such as a large number of exposed individuals, clearly defined losses, and the consequences of risk must be random and accidental in nature.

11. Conclusion

Currently, only six Insurance Companies in Poland offer liability insurance (OC) for entities conducting medical experiments. These companies are: TUiR Allianz, STU Ergo Hestia SA, Inter Polska TU SA, Wiener TU SA, PZU SA, and TUW PZUW. Recently, Uniqa also had such an offer, but it is most likely withdrawing, or at least suspended offering it. Among these insurers, TU Wiener SA has the most general agreements covering multiple experiments, making it the leader in this market.

Despite many concerns shown above (in terms of: *determination of the concept of adverse event and accumulation of events, *identification of potential risks, *determination of the level of liability of the insurer through the guarantee sum, *insurance premium and claim settlement process, as well as in the *position of the patient in the medical experiment with the assessment of ethical principles), including the concerns regarding the amount and sufficiency of the sum insured, Insurance companies do not record significant (or even any) claims related to conducted medical experiments. This is important because, unlike claims arising from medical activities conducted by hospitals, the number of claims is increasing. Currently, there is probably no hospital that has not received any claims from its medical activities.

Nowadays, insurance companies do not have to defend themselves against the exhaustion of the sum insured. They are only liable up to the amount of the sum insured, and any claims exceeding this value become the responsibility of the medical entity and the injured party. Only an aware medical entity (e.g. informed by a broker) seeks and enters into mandatory liability insurance for its medical activities along with the so-called excess insurance. In practice, about 90% of medical entities opt for this "excess" insurance. However, this is a result of claims related to medical activities and not medical experiments.

Nevertheless, along with social changes and an increase in awareness among individuals participating in medical experiments, it appears necessary to pay attention to the elements that form the basis for effective protection against the consequences of risks inherent in medical experiments. It can be assumed that as a consequence of these changes, there will be a rapid increase in claims directed at organizers of medical experiments, similar to those arising from medical activities. Therefore, the adopted legal solutions should be the best possible and leave no room for doubt.

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Obowiązkowe ubezpieczenie odpowiedzialności cywilnej podmiotu przeprowadzającego eksperymenty medyczne – uwagi polemiczne

Streszczenie: Prowadzenie eksperymentów medycznych przez podmioty lecznicze jest bardzo potrzebne, gdyż tylko dzięki takim działaniom można potwierdzić skuteczność nowych rozwiązań. Z drugiej strony jednak prowadzenie eksperymentów medycznych cechuje wyjątkowe ryzyko, które musi/powinno być objęte szczególną ochroną. Celem artykułu jest ustosunkowanie się do dyskusyjnych elementów zawartych w Rozporządzeniu Ministra Finansów dotyczącym odpowiedzialności cywilnej podmiotów przeprowadzających eksperymenty medyczne. Przedstawienie wątpliwości ma służyć poprawie jakości przyjmowanych rozwiązań w systemie prawnym po to, aby zwiększyć bezpieczeństwo wszystkich podmiotów i osób uczestniczących w procesie prowadzenia eksperymentów medycznych.

Słowa kluczowe: ubezpieczenie eksperymentów medycznych, suma gwarancyjna dla ubezpieczeń w eksperymentach medycznych, odpowiedzialność gwarancyjna zakładu ubezpieczeń w eksperymentach medycznych, likwidacja szkody w eksperymentach medycznych