Persons Without the Capacity to Consent

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Eugenijus Gefenas and E. Tuzaite

Introduction

Implementation of the doctrine of Informed Consent (IC) into the practice of health care has been one of the major ethical and legal shifts in the history of twentieth century medicine. The essence of this shift has been the replacement of the paternalistic ethos of the doctor-patient relationship with respect to personal autonomy based health care decision making. As a result, the principle of IC has become a basic rule to be followed in all health care related interventions with competent patients. Although there are still many problematic issues related to the implementation of IC into health care practice with capable persons (Stanton-Jean, Doucet, & Leroux, 2012), a particularly complex situation may arise when health care decision making involves persons without the capacity to consent, such as minors, people with learning disabilities, or those suffering from severe mental disorders. The complexity of this field of decision making can be attributed to the need to harmonize the traditional approach of protecting the best interest of this particularly vulnerable group of patients with the paradigm of health care based on the principle of personal autonomy and self-determination. The major international guidelines and legal instruments reflect the importance of this issue. The Universal Declaration on Bioethics and Human Rights (UDBHR) by UNESCO devotes a separate Article 7 to set general principles protecting the rights and interest of persons without the capacity to consent (UNESCO, 2005). Similarly, at the European level, the Council of Europe Convention on Human Rights and Biomedicine (The Oviedo Convention) provides an even more elaborated normative framework aiming at the protection of persons not able to consent (Council of Europe, 1997a). This instrument provides separate guiding principles with respect to different categories of incapable persons: those suffering from mental disorders, being in emergency situations, and, what is very important for this discussion, those who had their wishes expressed in the past before becoming incapable (previously expressed wishes). This chapter aims at

E. Gefenas (✉) • E. Tuzaite
Department of Medical History and Ethics, Vilnius University, Vilnius, Lithuania
e-mail: Eugenijus.Gefenas@mf.vu.lt; Egle.Tuzaite@mf.vu.lt

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analyzing the general framework of decision making with regard to persons unable to consent as well as presenting some areas of practice, where decisions are particularly complex.

Conceptual Framework of Decision Making and Incapable Persons

The concept of capacity or incapacity is closely linked to the concept of competence. In health care context being competent means the capacity to make autonomous health care decisions. A person loses his or her competence and becomes incapacitated when s/he loses such a capacity and is unable to (1) posses a set of values and goals; (2) communicate and understand information, and (3) reason and deliberate about one's choices (US President's Commission for the Study of Ethical Problems in Medicine and Biomedical and Behavioral Research, 1982). Two different meaning of a loss of competence can be distinguished. First, a narrow legal definition means a loss in court of a person's legal right to function in a particular area. Second, a broader and more common clinical use of the term means that a person can still have a legal right but is unable to make their health care decisions (Wettstein, 2005). This broader definition of competence is very important for this discussion because rather often the decisions with regard to persons unable to consent are made without their legal capacity being removed.

Different Meanings of Personal Autonomy and Protection of Incapable Persons

The system of protection of incapable persons has been recently developed within the new paradigm of medical ethics based on the principle of respect for personal autonomy. However, within the bioethics literature some interpretations of this principle have been criticized as providing insufficient background for complex health care related decisions. This criticism has been mostly directed toward a so-called minimalist-libertarian account of personal autonomy, which limits the relationship between the care giver and the cared person to noninterference rather than promoting and facilitating the decision making of the person concerned. This interpretation of personal autonomy can be criticized as reducing the relationship between health care providers and patients to simple contractual relationship of two "strangers." As such, this model neglects the caring attitude of health care provider, which is crucial when dealing with vulnerable patients.

Therefore, the alternative interpretation of personal autonomy going beyond the minimalistic-libertarian approach seems to be more relevant in many health care situations, particularly when incapable persons or other vulnerable patients are involved. This account of autonomy is emphasizing authenticity of a decision-making process (Welie, 1998). Autonomy as authenticity is implemented when decision making is based on the values and life story of the person. This is

especially relevant when people who are close to the patient and familiar with his or her personality can make choices that are congruent with the patient's values and life story. This helps to base important decisions not only on the rational and explicitly stated information but also on motivation and signs, which are not explicitly expressed by the incapable person. This component of decision making becomes increasingly important in the course of decreasing cognitive capacities of the person.

The modern system of legal protection of incapable persons has been developed following the broader interpretation of personal autonomy rather than the minimalist-libertarian one. The authenticity based account of personal autonomy allows developing a more flexible set of measures assisting a person who is starting to lose decisional capacity. Such a system of legal protection is elaborated in some international recommendations based on a set of principles to be followed when it is necessary to organize protective measures for an incapable person (Council of Europe, 1999). First, the protection provided for a person concerned should be based on respect for the wishes and feelings, including previously expressed wishes, which is of paramount important when decision-making capacity of the person is getting increasingly compromised by the disease. Second, prominence should be given to the welfare and interest of the person to counteract the sometimes existing tendencies to use assets of the person to benefit other parties. Third, the principle of subsidiary or minimum necessary intervention should be followed, which means that protection has to be established, if and only if it is unavoidable in the circumstances. It also means that preference should be given for any less formal arrangements that might be used rather than formal ones, and for any assistance that might be provided by family members. Finally, the proportionality of the measure to be applied means that protection needed should correspond to the degree of capacity of the person concerned and tailored to the individual circumstances of the case (Council of Europe, 1999). All the mentioned principles are important to understand the limits of the traditional system of protection. The problem is that some countries still have a rather traditional approach toward the protection of incapable persons. This approach can be characterized as rather rigid. In this traditional system, the measure applied deprives a person concerned of almost all legal capacity to make decisions and is coupled with the appointment of the guardian who is supposed to represent the incapable person in all the matters of life. As a result, it is mainly based on deprivation of legal capacity rather on the attempt to involve the incapacitated person into his or her own care-related decision making, which is a key feature of the alternative modern approach based on a broader concept of personal autonomy (Gefenas, 2004).

Normative Principles of Protecting Incapable Persons in Health Care Context

There have also been some more specific principles developed with regard to medical interventions on persons not able to consent. In the European context,

the Oviedo Convention provides a rather comprehensive framework for these principles summarized in its Article 7 (Council of Europe, 1997a). References will be made to this and other legal instruments and guidelines to make this framework explicit.

First of all, another person or a body substituting the decision making of the incapable person should be introduced when such a necessity arises following the subsidiary rule mentioned above. It means that the authority to consent is being transferred to somebody who represents the interests of the person unable to consent. For example, the intervention on the minor may only be carried out with the consent of his or her parents. In cases of incapable adults, the substituted decision makers should be legal representatives or any person or body provided for by law. It should also be noted that before making a decision, the representative should get the same information that would have been given to the person concerned if s/he was capable.

Second, the guidelines require to involve the person himself, as far as possible, into the process of his or her health care decision making. This principle is relevant to both minors as well as adults whose capacity starts to diminish due to a mental disorder. In case of minors, it helps to ensure that their opinion is to be regarded as an increasingly determining factor in proportion to their age and capacity for discernment. This means that in certain situations and depending on the nature and seriousness of the intervention as well as the minor's age and ability to understand, the minor's opinion should increasingly carry more weight in the final decision. This principle is also enforced by the Article 12 of the United Nations Convention on the Rights of the Child (United Nations [UN], 1989). The involvement of the person who has lost or is losing the decision making capacity in respect to health care can also be achieved by referring to his or her previously expressed wishes, life goals and values. This is an especially important issue in the context of this discussion and it will be addressed in a separate section.

Third, the general framework also usually specifies the type of intervention to be authorized in terms of risk/benefit ratio. For example, according to the Oviedo Convention the only interventions to be authorized on behalf of incapable persons are those that are supposed to bring them direct benefit. In general, the higher the benefits of the intervention, the more stringent capacity criteria are required from the person whose capacity is being questioned to refuse such an intervention, for example, in case of refusing potentially life-prolonging interventions. This tendency has been called "sliding scale" of competence evaluation (Wettstein, 1995).

Complexity of Implementation and Remaining Controversies

Although a consensus has been achieved with regard to the general principles mentioned above at the international level, this general framework is not always easily applied in practice. The difficulties arise because sometimes these principles can contradict each other or because their interpretation contains some level of unavoidable ambiguity. For example, the requirement to take into account

previously expressed wishes can come into conflict with the views of representatives or medical staff with regard to the best interest of the person concerned. In other cases, such as decisions on reproductive choices of minors, it is not always clear if the representative should have a final word on the issue or the teenager can make her own choice. The following most controversial areas of decision making will be analyzed in this chapter:

- Recent tendencies to implement previously expressed wishes in practice
- Complex reproductive choices by minors and people with learning difficulties
- Compulsory hospitalization and treatment of people with mental disorders
- Research on incapable persons

Previously Expressed Wishes

As has already been noted, previously expressed wishes are one of the most basic means to implement the principle of respect to personal autonomy in the field of health care with regard to people unable to consent. This is why the concept of previously expressed wishes is included into the international ethical and legal guidelines presented in this chapter. Article 7 of the UDBHR by UNESCO does not explicitly mentions this concept; however, it refers to the need to involve a person concerned to a greatest extent possible in the decision-making process. At the same time the Article 9 of the Oviedo Convention makes it explicit that "[t]he previously expressed wishes relating to a medical intervention by a patient who is not, at the time of the intervention, in a state to express his or her wishes shall be taken into account" (Council of Europe, 1997a).

Advance Directives

The concepts of "document of prior instructions" or "advance directives" have been used to refer to implementation instruments of previously expressed wishes of incompetent patients (Council of Europe, 2011). This section will only focus on the advance directives which deal with those health care and treatment options that the person would like to receive while s/he is still alive and will not deal with the decisions about the use of body and organs after death.

Two major models (or their combination) of advance directives can be distinguished in this context. These are living wills and continuing powers of attorney (World Health Organization [WHO], 2004). Living wills are written legal documents which allow people to convey their wishes about the life-sustaining procedures ahead of time. They usually include instructions on withholding or withdrawing the treatment. For example, a person can express his/her wishes by signing the, "do not resuscitate" (or DNR) order when admitted to the hospital. However, living wills are not limited to treatment refusals. They can also be used to advance a wish that a particular type of treatment will be continued (Council of Europe, 2011).

On the other hand, the model of continuing powers of attorney is based on the choice of a person who is supposed to make health care decisions on behalf of someone who loses the ability to do so. Usually attorneys are relatives or close friends and it can be argued that this model has a significant advantage comparing to the living will because it can provide a "personal voice" clarifying the patient's preferences. This is especially important in those cases when written instructions are ambiguous, or there are unexpected developments in the situation that have not been addressed by the patient (Council of Europe Steering Committee on Bioethics (CDBI) [CDBI], 2008). It can also be noted that this model provides the granter an opportunity to appoint one more person to supervise how the attorney performs his/hers duties (Council of Europe, 2009).

The increasing importance given to advance directives in both legal instruments and academic literature is related not only to the changing paradigms of health care provider – patient relationship, where the paternalistic culture has been gradually replaced by the value of personal autonomy and the practice of informed consent. The importance of integrating previously expressed wishes into the clinical decision making and the need to introduce the practice of advance directives also reflect intensive technological advancements of modern medicine and life-sustaining technologies. These developments not only help to save human lives. They can also contribute to the continuation of physical survival of patients for prolonged periods of time without their capacity to make decisions about their own health care for the rest of their lives.

Implementation Difficulties

It should be noted, however, that the changes in ethical and legal paradigms have not yet been fully implemented in many countries in the world. In this respect, the situation is somewhat better in the USA, where the percentage of people with an advanced directive is far higher than in European countries, where only a tiny minority of the Council of Europe's 800 million citizens actually have advance directives (Council of Europe, 2011). For example, in the USA the advance directives have been expressed by around 22 % of all patients (raging from 32.1 % of surgery patients vs. 17.7 % of medicine patients), living wills being the most frequently chosen type of advance directives (Morrell et al., 2008).

In many European countries, it is still unusual to base clinical decision making on previously expressed wishes. Many states are just starting to recognize the importance of advance directives. For example, in some countries such as Austria, Belgium, Finland, Germany, Hungary, the Netherlands, Spain, Switzerland, and the United Kingdom advance directives are made legally binding. More specifically, in Austria it is obligatory to take the advance directives into account if a few criteria are met: the physician's consultation has been provided, the procedure of advanced directive has been supervised by a lawyer, the refused treatment is described in detail, and the document has been signed not more than 5 years ago (CDBI, 2008). However, in many other European countries specific provisions concerning the

advance directives are not legally binding or there is a lack of laws on this particular matter. It is argued, that the reason for such a slow integration of previously expressed wishes into the legislation of some European countries has been the advisory character of the provision of the Article 9 of the Oviedo Convention, which only states that patient's "wishes shall be taken into account" rather than being followed. In other words, according to this article European countries are not required to assign the advance directives a legally binding status (CDBI, 2008). More details on the advisory nature of this provision are provided in the Explanatory Report of the Oviedo Convention, which states that "[. . .] taking previously expressed wishes into account does not mean that they should necessarily be followed.[. . .] when, for example, they were expressed long time before the intervention or medical technology made a significant progress since the time when the advance directive was signed" (Council of Europe, 1997b).

There can also be other obstacles to build an efficient system of advance directives. For example, in some countries patient autonomy is taken more seriously, while in the other countries the paternalistic model of decision making still prevails. Furthermore, the economic situation in the country can also play an important role. This is especially the case when the most basic health care services are hardly available for the country's population. For example, it has been argued that in transition European countries, like Ukraine, interest in this kind of arrangements is very limited due to the fact that people are mostly preoccupied with access to basic services in the context of severe scarcity of health care services available (Council of Europe, 2011).

Previously Expressed Wishes in the End of Life Care

The importance of advance directives should be particularly emphasized in end of life care situations with persons unable to consent. Here there are two interrelated issues to be discussed: first, involvement of patients and their relatives in particular medical end of life decisions (MELDs) that might have a life-shortening effect; second, controversy of associating the advance directives with euthanasia.

According to the EURELD study conducted in six European countries, rather often MELDs are shared neither with patients nor with their relatives. For example, in Italy and Sweden, countries representing culturally rather different regions of Europe, MELDs were not discussed with the patient or with the relative in more than 50 % of cases (van der Heide, Deliens et al., 2003). It should be stressed that these figures applied to both competent and incompetent patients and showed how important advance directives can be in these highly sensitive and stressful situations. The reason why the doctors try to escape from communicating and sharing their decisions with relatives or patients can be their reluctance to overburden relatives (in case of incompetent patients) or the consideration that even competent patients would not be able to fully comprehend the situation. The advance directives seems to be a relevant solution to overcome both of the mentioned obstacles as this would make possible a decision making respectful to personal autonomy of the patient.

The association between advance directives and euthanasia should also be addressed. It has been pointed out that this association is unfortunate because active termination of life is forbidden in the vast majority of European countries (Council of Europe, 2011). In addition, as has been shown by the EURELD study, administering, supplying or prescribing drugs with the explicit intent to hasten the death on patient's explicit request (which are the most common criteria of active voluntary euthanasia), appeared to be also one of the least frequent types of decision. It occupied a very small portion of MELDs as reported in the studies available, e.g., 1 % of deaths or less in Denmark, Italy, Sweden, and Switzerland as compared to nontreatment decisions such as withdrawing or withholding medication (or forgoing hydration and/or nutrition), which in some countries (e.g., Switzerland) reached as much as 28 % of all death cases (van der Heide et al., 2003). Therefore, the introduction of advance directives can help to ensure that no form of unconsented medical end of life treatment decision is taking place, which is still the existing practice in many countries as shown above. It can also enable a person to explicitly express the wish to not take or omit some actions with the intention to shorten his or her life.

There have been important recent European developments that can bring positive changes in this field. First, the Council of Europe Committee of Ministers issued a special Recommendation CR/Rec (2009)11 on the principles concerning continuing powers of attorney and advance directives for incapacity. This document laid down basic principles on the role of attorney, the procedure of her/his appointment and the circumstances when her/his rights come into force (Council of Europe, 2009). Second, and more specific to this discussion on advance directives in the field of health care, the Council of Europe is adopting a Resolution and Recommendation on "Protecting Human Rights and Dignity by taking into Account Previously expressed Wishes of Patients" (Council of Europe, 2012). Hopefully, this can be an important impetus to further encourage the European countries to take steps in this field.

Reproductive Issues in Minors and People with Learning Difficulties

As has been already shown in the previous sections of the chapter, it is currently accepted that minors and people with learning difficulties should be involved in the decision making about their health care as much as this is possible in the circumstances. However, the involvement of people unable to consent in the decision making on their reproductive health issues can be more complicated because of societal taboos surrounding the sexuality of the intellectually disabled. As has been noted, due to this reason even studies concerning their contraception and moreover their sterilization may be difficult to carry out and when carried out, biased by low participation rates (Servais et al., 2004). However, the denial of the problem does not eliminate it. On the contrary, if the issue of reproductive choices fell beyond the scope of legal regulations and public discourse, nobody can guarantee that the best interests of the incapable people are really served and their rights are protected.

Use of Contraception and Termination of Pregnancy in Minors

The complexity of reproductive health policies in relation to minors arises predominantly because of the tension between the rights of the minors and those of their legal representatives. According to Article 16 of the United Nations Convention on the Rights of the Child every child has the right to privacy (UN, 1989). This right can also justify those cases when legal representatives are not asked for authorization of the minor's decision and the practice of teenage contraception seems to be particularly relevant case to be discussed in this context. For example, the issue of prescribing contraceptives without authorization of legal representatives became widely discussed in the UK in the 1980s when Mrs Gillick wrote to her area health authorities forbidding medical staff to give contraceptive or abortive advice or treatment to any of her four teenage daughters without her consent. This case culminated in the well-known Gillick judgment of 1985 when the House of Lords ruled (by the narrowest of majorities) that doctors can in certain cases prescribe contraceptives for girls under 16 without parental consent (Dyer, 1985).

The supporters of Mrs. Gillick position usually argue that the policy of confidential counseling allows teenagers to engage in risk taking behavior and insist that information about the use of contraceptives should be disclosed to the parents because the minor's ability to give a valid informed consent can be compromised by the minor's immaturity and the lack of life experience. This may make minors vulnerable to exploitation and external coercion and therefore decision making in such a sensitive field should be overtaken by legal representatives who are believed to act according to the best interests of the minors.

The opponents of this position may respond that the involvement of parents into the counseling procedure do not necessarily increase the welfare of the minor. For example, if the family relations are complicated and parents or guardians are informed about their child's request for contraception, this can make teenagers life in the family unbearable due to excessive control exercised upon the social environment of the child. Furthermore, it seems that confidential consultations have the potential to reduce the unintended pregnancy and abortion rates because some surveys have shown that as many as 59 % of teenagers would discontinue use of specific sexual health care services if their parents were informed that they were seeking prescribed contraceptives (Reddy, Fleming, & Swain, 2002).

The role of health care professionals seems to be very important in this context because they can act as moderators between teenagers and their parents in this complex and controversial area of personal relationships. In fact, sensitive and professional counseling can resolve raising tensions and encourage communication between the parties involved. Due to this, physicians are strongly recommended to help adolescences to see the potential advantages of improved communication with their parents (Ford, English, & Sigman, 2004).

However, despite the importance attributed to the confidentiality issue in health care provider – minor relationship, the health care providers do not necessarily share the same opinion. In some countries, physicians do not regard the confidentiality as the issue of utmost importance in the field of adolescences' medicine.

The study carried out among Swiss doctors revealed that maintaining minors' confidentiality was ranked considerably lower than such issues as psychosomatic/functional symptoms, eating disorders, or depression-anxiety and was not considered to be a priority topic in adolescent medicine training (Kraus, Stronski, & Michaud, 2003). Furthermore, a resent Lithuanian study in this field showed that when consulting on general sexual issues, more than 70 % of the Lithuanian general practitioners stated that they would respect their minor patients' confidentiality. However, nearly the same percentage said they would inform parents in cases of sexually transmitted infections or pregnancy (Jeruseviciene et al., 2011).

The termination of teenagers pregnancy is probably the most sensitive and controversial issue in this discussion. Whose decision must be followed in case of disagreement between the pregnant minor and her parents? A tendency to give priority to the opinion of the minor has been observed in many European countries and the USA. However, there are opposing views expressed toward this prevalent tendency as well. For example, in Britain teenage girls are allowed to have an abortion without their parents consent, however, some time ago a mother whose daughter secretly had a chemical abortion publicly criticized this law claiming that if she had known what was happening she would have been able to change her 14 years old daughter mind (Mother angry at secret abortion, 2004). On a state level some countries, such as Slovakia, enforced the legislation to require parental or guardian consent in case of termination of pregnancy in minors. This shows a fundamental and hardly commensurable disagreement between the worldviews of those who hold different positions on this matter (Gefenas, 2012).

Sterilization of People with Learning Difficulties

Policies to regulate reproductive choices of incapable adults have a long and controversial history. The racial hygiene politics and eugenics movement in Nazi Germany is probably the best known, but not the only example of such a policy in the twentieth century. In fact, during the whole post–World War II period till about the 1980s, the sterilization laws were in force in many countries of the world. For example, in 1997, one of the most influential Swedish newspapers disclosed information about a sterilization program carried out between 1935 and 1975 leaving more than 60,000 Swedes being sterilized including people with learning difficulties. The sterilization law existed in Denmark as well. From 1934, when this particular law was adopted, until 1968, 5,579 mentally disabled people were sterilized in this country (Broberg & Roll-Hansen, 2005).These policies were largely associated with eugenic intentions to reduce the incidence of learning disability in general population, which appeared to be based on a mistaken belief that this goal can be achieved by eliminating the opportunities for intellectually disable people to reproduce (Howard & Hendy, 2004). Even though the understanding of mental disability has undergone significant changes in recent years, the issues concerning the reproductive health of incapable people remain controversial and difficult to handle.

In many countries, women with learning difficulties are still rarely involved in decisions about their contraception arguing that these issues are too complex for them to understand. In this situation, the reproductive questions have been dealt with in a paternalistic manner and contraception presented as a preventive measure to assure that in the case of the sexual assault the unintended pregnancy is avoided. Sterilization of mentally disabled people is regarded to be the most reliable method of contraception. Although it is regarded as the last measure which should be taken only if the more conservative methods of birth control do not work, it is rather widespread and mainly applied to sexually active women. Although it is difficult to single out a concrete disability which could increase the possibility of sterilization, people with Down syndrome seems to be the group most often exposed to contraceptive sterilization. This is probably due to the fact that this genetic condition can be transmitted to the offspring with 50 % of probability. In addition, women with Down syndrome are commonly considered as very social and affectionate, which also make them more vulnerable in intimate relationship (Servais et al., 2004). However, the level of capacity of people having this syndrome can be very diverse, which makes the decision on their sterilization sensitive.

The comparison of sterilization rates of people living in social care institutions versus those staying with their family members in the community helps to reveal some prevalent tendencies in this field. It might seem that opportunities to control fertility of people living in institutions are more favorable than for incapable people staying in the community. This feature can be explained by the fact that nowadays intellectually disabled people are more integrated into the society which provides them with more opportunities to start sexual activities. At the same time, however, this makes them more vulnerable to sexual offenses. It can be predicted therefore that sterilization rates should be higher for noninstitutionalized population of incapable people. However, the Belgian study revealed the opposite tendency where living in an institution was associated with an increased probability to be sterilized (Servais et al., 2004). This tendency seems to point to the need to revise the existing institutional policies as they might better serve the interests of the institutional employees rather than the interests of the incapable persons themselves.

Compulsory Hospitalization and Treatment of People with Mental Disorders

Coercive measures applied to people suffering from mental disorders are another ethically sensitive issue to be addressed. Images of chaining psychiatric patients to the walls of the asylums or medicating political dissidents with high doses of neuroleptics can hopefully be regarded as historical examples not to be repeated in modern psychiatry. Indeed, methods of treatment and the models of patient-doctor relationships showed in the Oscar wining movie “One Flew Over the Cuckoo’s Nest” are hardly imaginable in contemporary society. Nowadays, it is universally accepted that people with mental disorders, including those unable to consent to particular health care interventions, are entitled to the same civil, social,

political, and cultural rights as the rest of the population. However, even in the twenty-first century, reports on keeping psychiatric patients in net beds or just chaining them to their beds are published (Sailas & Wahlbeck, 2005; WHO, 2008). There is still disagreement among different representatives of the society and professionals about the proper use of restraints and coercive measures in general. Therefore, this section surveys the most important principles guiding coercive measures to be applied to psychiatric patients with limited capacity.

Basic Normative Framework

The major changes in the field have been brought by integrating psychiatric practice with basic human rights principles in the second half of the twentieth century. The Universal Declaration of Human Rights (UN, 1948) can be considered to be the first international human rights instrument paving the way to more specific documents enforcing the rights of people with mental disorders, such as Convention on the Rights of Persons with Disabilities (UN, 2008) or the Council of Europe Recommendation Rec(2004)10 concerning the protection of the human rights and dignity of persons with mental disorder (Council of Europe, 2004a). The latter document provides a detailed normative framework on involuntary measures applied in the field of psychiatry. According to this document two basic conditions should be satisfied in order to apply coercive measures, such as involuntary hospitalization, with regard to people with mental disorders. First, involuntary hospitalization is only justified when the existence of mental disorders is recognized or its assessment is required to determine whether a mental disorder is present. Second, it must be very likely that mental disorders can cause a risk or a serious danger to the person concerned or a serious danger to other persons (Article 17, part i & ii). In addition, the Council of Europe Recommendation (Article 17, part iii) also emphasizes that the intention of the involuntary placement should always include a therapeutic purpose. Two specific distinctions are important in this context, namely, the distinction between involuntary hospitalization and involuntary treatment, as well as the distinction between formal versus informal involuntary hospitalization.

Distinction Between Involuntary Hospitalization and Involuntary Treatment

Although it is often thought that the need of compulsory hospitalization also includes mandatory treatment, the forced hospitalization does not necessarily imply the involuntary medication. A person involuntarily admitted to the institution should be provided with several treatment choices and should be free to choose any of them. Among these choices and despite being forcibly admitted to the hospital the person should retain the right to refuse the medical treatment proposed. The Explanatory Memorandum to Recommendation Rec(2004)10 (Article 17, paragraph 133) states that “therapeutic purpose” of hospitalization should not be equated with medical

treatment. For example, a person diagnosed with schizophrenia can choose to experience hallucinations (such as hearing voices) instead of taking medications because of their short and long-term side effects (Council of Europe, 2004b).

The distinction between forced placement and forced medical treatment has not been made until the late 1970s. Due to the human rights movement in psychiatry this approach has remarkably changed in the USA and Europe leading to a clear separation between involuntary hospitalization and involuntary treatment. It should be noted, however, that some European countries still do not define in their laws involuntary placement and treatment as separate modalities, which seems to also imply that in these countries the decision of forced hospitalization means an approval for forced medication of psychiatric patients against their expressed resistance (Dressing & Salize, 2004).

Formal Versus Informal Involuntary Hospitalization

One more issue to be addressed here is the inconsistency between legal regulations for involuntary placement and application of these regulations in practice. This inconsistency can be analyzed as a distinction between formal involuntary hospitalization and so-called informal involuntarily hospitalization, where patients sign the admission forms for voluntary hospitalization, however, cannot leave the institution whenever they want. This can be demonstrated by remarkable variation between frequency of compulsory admissions into psychiatric institutions in the European Union countries. The frequency of involuntary hospitalizations can vary from 218 involuntary placements per 100 000 population in Finland, 175 in Austria, 114 in Sweden to 11 in France or just 6 in Portugal (Salize & Dressing, 2004). Due to the fact that the ratio of persons with mental disorders in population in Europe cannot be so different, one possible explanation of this phenomenon is that admissions to the hospital are formalized in a significantly different way. Health care providers can avoid compulsory admission due to complex legal procedures, such as obligatory court's hearing or search for patient's representative. Scarce personnel and financial recourses at the health care institution can also be the reason of escaping the formalities of mandatory hospitalization. The problem is that these tendencies raise a question about the safeguards to protect patients' rights in these complex situations because de facto involuntary patients are left without the safeguards, which should be provided for them in the institutions for mentally disordered people unable to consent (European Committee for the Prevention of Torture and Inhuman or Degrading Treatment or Punishment (CPT) Standards & CPT/Inf/E [CPT], 2011).

Research on Incapable People

Conducting research activities on participants who are not capable to understand and consent to these activities is nowadays regarded as one of the most complex and controversial areas of research ethics. After all, modern history of research ethics

has emphasized the fundamental importance of informed consent. This principle has been placed on the top of the list of ten requirements of the Nuremberg Code – the first international instrument condemning the Nazi experiments and paving the way for the development of research ethics. In addition, as has been already shown above, the principle of informed consent has replaced traditional paternalism and marked a paradigm shift in the history of medical ethics and health care provider-patient relationship.

The problem is that research on persons unable to consent has to actually "bypass" this basic research ethics benchmark, which since the Nuremberg Code has been incorporated into the most important research ethics guidelines and legal instruments. Therefore, some alternative mechanisms of protecting incapable research subjects had to be developed. The historical overview of the evolution of these alternative models of protection reveals some complex features of establishing what is nowadays regarded as widely accepted ethical and legal algorithm to conduct research on incapable persons. The Article 7 part B of the UDBHR by UNESCO is a good example of this algorithm. It is important to note that this framework of research on incapable persons is also enforced by other important international instruments such as Article 17 of the Oviedo Convention and the Guideline 9 of the International Ethical Guidelines for Biomedical Research Involving Human Subjects (CIOMS). Although there exist some differences between the mentioned documents, the convergence of the main provisions is remarkable as compared to the regulations in some other areas of health care on persons unable to consent presented in this chapter.

It can be useful to briefly explain this two-step model of involving incapable persons into research project. As the first step, the guidelines require to limit research to only those projects where:

- The results of the research have the potential to produce real and direct benefit to the health of incapable research participant.
- Research of comparable effectiveness cannot be carried out on individuals capable of giving consent.
- The necessary authorization has been given specifically and in writing.

In case it is not possible to comply with the first step criteria, the second step of the framework is formulated as an exceptional scenario for research that does not have the potential to produce results of direct benefit to the health of the person concerned. Such a research can only be allowed if the following additional conditions are met:

- The research has the aim of contributing, through significant improvement in the scientific understanding of the individual's condition, disease, or disorder, to the person concerned or to other persons in the same category of disease or disorder.
- The research entails only minimal risk and minimal burden for the individual concerned.

In all circumstances the person concerned must not object to the participation in the project.

Two important features of developing the current ethical framework of research on incapable persons will be discussed. First, the liberalization tendency in the post-Nuremberg evolution of the research ethics codes: after an earlier absolute ban of

research on persons unable to consent, there are now provisions of research without the direct benefit. Second, a possible explanation will be provided for the emergence of the current ethical framework of research on incapable persons by referring to balancing or rather compensating the inability to get informed consent with other ethical principles and safeguards (Gefenas, 2007).

Two Steps of Liberalization

It can be claimed that modern research ethics started as a reaction to the horrors of Nazi human experiments, where adults and children became involuntary victims of activities, to which they would have never consented. The Nuremberg code responded to these atrocities in a radical way – it only legitimized research on those who were able to give informed consent. Paradoxically, this would have stopped the development of treatment and diagnostic interventions for many categories of patients unable to consent. That is why the Declaration of Helsinki made a step toward the softening of this very strict position in 1964 and introduced a distinction between so-called therapeutic research and nontherapeutic research (World Medical Association, 1975). This distinction made it possible to conduct so-called therapeutic research or research with the direct benefit for incapable people assuming that authorization from their representative was secured.

This was not, however, a sufficient condition allowing conducting early phase research where benefits for individual research participants can only be very limited. Therefore, the second step toward the liberalization of this type of research was introduced in the 1990s when research without direct benefit to the persons concerned was allowed by international codes and legal instruments under strict protective conditions described above.

Balancing Approach

The first liberalization tendency was followed by the attempt to "compensate" the impossibility to apply the principle of informed consent with other ethical principles and values involved in ethical decision making. Careful consideration of the risk and benefit ratio has been the most important one for this discussion: there is always a correlation between the capacity to consent and a justifiable risk/benefit ratio in the documents presented in this chapter.

For example, the level of risk that is tolerated in research on capable persons is higher than that allowed in research on incapable or other vulnerable groups: The Oviedo Convention only allows research with "real and direct benefit" on incapable people, while allows a higher level of risk by introducing the concept of "acceptable risk" in nontherapeutic research on capable persons. Similarly, the CIOMS Guidelines say that the risk presented by such intervention must be reasonable in relation to the knowledge to be gained (see Guideline 8). However, the CIOMS guideline 9 requires following the "low-risk" standard with incapable research participants.

Minimal risk or low-risk standard is probably one of the most important and complex principles to be followed in the field of research on incapable persons because it reveals both the conceptual differences between different definitions as well as variations in applying these definitions in different societies. For example, according to Article 17 of the Oviedo Convention the "minimal risk" standard is defined as "a very slight and temporary negative impact on the health of a person concerned." Paragraph 100 of the Explanatory Report to the AP to the Oviedo Convention provides examples of the interventions that might be considered as those not exceeding the minimal risk standard. These examples are among others: taking saliva, urine; taking small additional tissue samples during operation; taking a blood sample (capillary, peripheral vein); sonographic examinations, one X-ray exposure, or one exposure using magnetic imaging without a contrast medium.

The CIOMS guidelines introduce even more complex and liberal scale of balancing. Guideline 9 refers to the "low-risk standard": the risk that should not exceed the risk attached to routine medical or psychological examination of incapable persons. However, CIOMS Guideline 9 also provides a more liberal standard, the so-called slight or minor increase above such risk when there is (a) overriding scientific and medical rationale for such an increase and (b) research ethics committee's (REC) approval. The Commentary to Guideline 9 explains that there is no agreed definition of what the "slight or minor increase" is. However, it says that its meaning is inferred from the RECs' reports that provide such examples as, additional lumbar punctures or bone-marrow transplantation.

There are also other complexities that arise when conducting research on persons unable to consent. For example, the requirement to take into account the objection of the person concerned can beg the question what type of objection should be considered as a sufficient ground to stop or not to start participation in the research project. Research in emergency situations can also be mentioned as raising additional concerns. First, because in the emergency situations it can be very difficult to find a representative (e.g., a family member) who is supposed to authorize the involvement of the person in the research project. Second, because emergency medicine research also raises discussion on the alternative models of consent replacing the "real time" IC procedure. For example, different options have been proposed for these "modified" forms of consent in the emergency medicine research. One option can be "advance" consent given before the intervention when the person is still capable to make decisions. Another and more practicable option can be "retrospective" consent, which is given when a person regains the decision making capacity. However, this type of consent also raises serious concerns because it is given after a person has already started or completed participation in the research project.

Concluding Remarks

It should be acknowledged that since the second half of the twentieth century, there has been a significant progress in the protection of rights of persons unable to consent to medical interventions. Massive sterilization campaigns including among

others people with mental disorders or learning disabilities, chaining psychiatric patients as a means of restraint, "treating" political dissidents with damaging doses of psychotropic medications and sticking them the label of "sluggish schizophrenia" – all these will hopefully remain sad historical medical practices and will never return to the field of medicine.

The positive changes in attitudes and practices with regard to people unable to consent have been mainly achieved in the process of developing international and national regulations based on fundamental human rights instruments adopted in the post–World War II period. In some areas, such as research on incapable persons or the involuntary measures in the field of psychiatry, these regulations reached a remarkable level of convergence. It should be noted, however, that despite the mentioned positive developments, there are still many problematic open question. Many countries are still rather slow to follow with the implementation of some important internationally established principles. For example, respect for previously expressed wishes and advance directives have not yet been implemented in the national regulations of many countries. In addition, despite the presence of relevant regulations, there are still some controversial practices going on, such as the use of coercive measures in psychiatry or sterilization of some groups of population, which should attract more attention and studies in order to develop strategies of how to better protect the interests of the most vulnerable group of people – persons without or in a process of losing their decisional capacities.

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