INFORMED CONSENT IN NEONATOLOGY

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Abstract

Neonatology is an unpredictable specialty with increased intrinsic potential for devastating situations. Progresses in obstetrics and neonatology dramatically decreased neonatal mortality in the last decades but the same technology that saves lives may cause severe co-morbidities and may have lifetime adverse effects. Ethical and moral debates about duties and responsibilities of both physicians and parents are, therefore, continuing. *Aim:* The authors aimed to review the data in the literature regarding problems and difficulties raised by informed consent in neonatology. *Material and methods:* The authors searched the medical literature for articles and official documents discussing informed consent and related ethical, moral, and legal issues in neonatology. *Results:* A short review of the history and content of the informed consent precedes the description of the problems and difficulties of the informed content in neonatology: emotional burden, intense stress, best interest of the child, emergency situations, assuming parental responsibilities, duties of the clinicians, multidisciplinarity, prenatal consent. Other issues discussed in the paper are: situations when the informed consent is needed, potential conflicting situations, possible solutions in limiting situations, and the role of the institutional ethical committees. *Conclusions:* Physicians are invested by the medical ethical code with important responsibilities towards the patient, a burden that, in front of a newborn, may be very complex. On the other side, parents have also responsibilities for their children. Together, physicians and parents, must take the best decisions for the child even though the process may be extremely difficult in many situations in the neonatal period. Today, the complexity of the ethical issues in medical practice is universally accepted, ethics became an important part of day-to-day medical practice in neonatology, and vital decisions for the neonate's survival are based on the informed consent.

Key words: neonatology, informed consent, ethics, moral, legal, parents

Introduction

Neonatology is an unpredictable specialty and an area where nobody, never intends to harm. But the neonatal period has an intrinsic potential for devastating situations and consequences that creates the sensation of a huge injustice. The neonates are the small, most vulnerable, most protected, and most celebrated members of a society, and for the family they are the future and an unlimited potential.

The essential goal of neonatology as a specialty is decreasing the neonatal mortality. In fair and just, democratic societies life must be saved at any cost and each individual is morally entitled to be as healthy as possible and to live as long as possible. The spectacular progress registered by neonatology in the latest decades meant a dramatic decrease of neonatal mortality. It also meant decreasing the viability threshold at lower and lower gestational ages. The survival of extremely low birth weight preterm infants and of the infants with severe perinatal conditions - implying multiple invasive and risky procedures - led to the occurrence of a new category of survivors that continue to be fragile even after the neonatal period, often long time dependent on medical technologies. The reality is that the same technology that saves lives may cause severe co-morbidities and may have lifetime adverse effects[1]. All these aspects sparked, already for some time, numerous ethical and moral debates about excess therapies, viability threshold, futile treatments, initiation and withdrawal of the vital support, the best interest of the child, child's rights, parental rights, the rights and responsibilities of the medical staff.

The ethical medical code invests the physician with important responsibilities towards the patient, a burden that, in front of a newborn, may be very complex. Together with the parents, the physician must take the best decisions for the child. The process may be extremely difficult and the informed consent is a synthesis of the information representing the grounds for the most important decisions taken for the child survival.

Short history

During 1930-1940, a period when most of the therapeutic interventions were still inefficient, no informed consent existed in neonatology. After 1954, the first miraculous drugs (Penicillin) and therapies (for example, ACTH therapy for retinopathy of prematurity) occurred and still parental approval wasn't considered necessary. If Penicillin was life-saving, ACTH therapy caused growth failure and other effects secondary to increased adrenal activity.

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The issue of controlled studies was raised at that moment even tough is was generally believed that the decision to enroll a patient in a study is the resolution and the responsibility of the physician. The study protocol was broken during the first such randomized controlled study and this led to the death of one patient. Although this study related to ACTH effect in retinopathy of the prematurity was illustrative as regards the need for moral justification of the controlled studies, the medical world continued to oppose to such studies and this resistance continued to increase during the 1960s, after the informed consent occurred in medicine[2].

Helsinki Declaration was adopted in 1964, underlining that individual needs must prevail in front of science and society needs, an important principle for medical research[3,4]. Baby Doe Regulation was elaborated in 1982 in USA, a bill that allowed withdrawal of the life support in extremely low birth weight infants and in children with increased risk for long term handicap. This bill was subsequently convicted in 1973 by another document - Rehabilitation Act -, being labeled as discriminatory and considered a violation of children's rights. A "hunting" period followed (Baby Doe Squads) for the cases in which the treatment was not offered and a storm of protests led, in 1986, to the abolishment of this act by the US Supreme Court. It was considered that the act violated the right of the US member states and it was not applied to the medical care of the handicapped children. Another bill was issued by US Congress in 1984 - Child Abuse and Treat Act -, a document that evaluated again Baby Doe Regulation guidelines and defined non initiation of needed medical treatment as child abuse and neglect and not as a discrimination[5,6].

In Europe, the first legislation referring to informed consent was issued in 2001 and was based on Helsinki Declaration (amended in 1996), United Nation Organization Declaration regarding children's rights, and The Convention for Protecting of the Human Beings Rights and Dignity Applied to Biology and Medicine (1997)[7].

Today, the complexity of the ethical issues in medical practice is universally accepted and ethics became a part of the medical practice. It is also accepted that natural rights are fundamental human rights and medical ethical principles are the ethical and moral basis of the informed consent.

What is informed consent?

Ethics implies understanding the nature of the conflicts occurring from moral imperatives and their management modalities, Medical ethics is not just a practical subject but also a branch of moral philosophy and an integrate part of a good medical practice. Ethics does not decide what is morally good and what is bad but how we should act better in the light of our duty and obligation as moral agents. Therefore, we must not forget that physicians have, towards the patients and the society, specific duties and in the center of the modern medical ethics lays the respect for patient autonomy and the fundamental principle of the informed consent derived form this autonomy[8,9]. The respect for patient's autonomy, the informed consent, and confidentiality are representing, according to some authors, key markers for an ethical medical practice and the circumstances in which these principles are not respected should be exceptional and well justified situations[9].

The informed consent represents a fundamental part of modern medical ethics implying that the patient agrees with the proposed treatment after being informed about this therapy in a fair and without restraints, including all the anticipated consequences of all the therapeutic options and their success chances: nature of the procedure/therapy, risks, benefits, alternative therapeutic options with their risks and benefits)[6,10]. Informed consent is a key element for protecting the patient well-being[9,11]. Validity of the informed consent is dependent on the quality of the presented information, understanding of the information by the patient, and the voluntary nature of this act[11].

Medical services - treatments, investigations - are ensured only if the patient or the parent/legal tutor (in the children's case) is informed and gives his informed consent. If the patient is not competent or in the absence of a legally authorized person to offer the informed consent, the medical service supplier (physicians, nurses) will offer medical services only if these are in the best interest of the patient and obeying the legal, professional, ethical and moral standards, according the manner in which they are necessary, minimizing the potential adverse reactions, and for optimizing the quality of the patient's life[7].

The informed consent may be interpreted also as a key factor for the judgment of an intervention or therapy: good/bad, proper/improper. Therefore, the informed consent must be specific to each individual patient.

There are two ways to approach informed consent:

- centered on the clinician, a modality that implies that the informed consent is of a legal type, taking into consideration what a clinician must say to the patient about the nature and risks of the therapy/intervention, a minimum necessary to protect the clinician against legal issues;
- centered on the patient, situation when all the aspects needed for an informed consent of the patient are taken into consideration; this is the real informed consent form the ethical point of view.

It is clear that informed consent has at least two aspects:

- ethical - based, as key element, on the reciprocal respect between the physician and patient, recognition of the value and integrity of the two implied parts;
- legal - with the role to exonerate the clinician of the legal consequences in some situations, representing, in fact, a defense against possible accusations.

As a communication, the informed consent can be written, verbal, or inherent (deductible form the patient's behavior)[8].

In the case of the informed refusal, the clinician must discuss the risks related to not initiating the proposed treatment/investigation, including the way the disease progresses in the absence of treatment. Knowing the consequences of the refusal gives a greater value of the informed refusal[10].

Ultimately, a correct informed consent, embracing the principles of modern medical ethics, has two goals:

- protection of the patient, offering complete information about the proposed therapy/intervention,
- protection of the physician (with some exceptions) of the legal and financial costs when correctly applying the therapy/intervention.

Informed consent in neonatology

The neonatal period is the period between birth and 28 days of life. Starting the half of the XXth century, the neonatal care received "a more and more ethical aspect" due to progresses noted in obstetrics and neonatology. The neonatal period is a special one, with extremely vulnerable population of patients, with specific problems, and patients that cannot defend themselves, cannot express their whishes and rights, and cannot offer informed consent. The anatomical and physiological aspects of the neonate correlated with the specific pathologies of this period are increasing the mortality risk and the risk for handicaps, affecting the future growth and development, including sensorial risks. The newborn and its care implies the emotional involvement of all the individuals participating in this care, both parents and medical staff, physicians and nurses. When the neonatal pathology and the technology necessary to treat the neonatal conditions (incubators, ventilators, monitors, etc.) intervene in the relationship between the child and its family the parental anxiety increases and the communication between clinicians and parents becomes more difficult.

In neonatology, the informed consent, even raising unique issues, aims to inform and imply the parents in taking the important decisions regarding the treatment of the child[12]. In neonatology, there are at least four situations that are ethically critical: obtaining the informed consent for treatment and investigations, the newborn's quality of life, the optimal palliative approach of the critical cases, and equitable distribution of limited resources of a society so that each newborn would benefit of these resources. For multiple reasons, the informed consent dogma has a limited applicability in neonatology.

Modern neonatology is marked by numerous changes, mostly by the progresses and performances of the neonatal intensive care. In the modern medical bioethics, the autonomy of the patient is a central element: the adult has the right to refuse the medical interventions and therapies offered by physicians[8]. In neonatology, the patient - the neonate - has not the ability to take decisions rendering the parents to take decisions in the best interest of the child. It is already well established the fact that, at birth, the parents have the right to be involved in decisions every time when optional therapies or investigations are necessary, so that informed consent of the legal caregivers became, in the latest years, a norm of conduct in neonatology[5,7]. Obviously, the patient's autonomy principle is not accepted by all the patients. In a survey conducted by Zupancic et al.[13], many patients preferred the medical advice against the decisional autonomy, only 27% of the patients wishing to take independent decisions regarding the informed consent.

In neonatology, problems and difficulties are occurring starting straight from the subject of informed consent, and, obviously, the problem of its fairness and validity raises. First of all, the newborn, the subject of the informed consent in neonatology, is not able to take decision for himself. The parental stress can be major in the case of the preterm infants and newborns admitted in the neonatal intensive care unit. Concerned, excited parents, frightened for the child's life may often feel physically and psychically powerless, incapable to take a decision. In this situation, asking the informed consent increases even more the stress level[8,14,15].

Another great difficulty encountered by physicians while obtaining a valid informed consent is the emergency. Neonatology is an emergency specialty, often the birth occurring after a stormy pregnancy or delivery history or the newborn's status may change abruptly, needing emergency diagnostic or therapeutic interventions. In such critical situations, the parents are forced to assume the responsibility of taking major decisions for another individual. According some authors[16], in such major stressful situations, the understanding of the situation by the caregivers is limited and informed consent cannot be practically obtained. The danger that parents will choose a path to follow based on their own preferences arises form this situations. These personal preferences may not reflect the best interest of the child and the informed consent is contradicting its own goal - the best interest of the child. Other parents, under the burden of the stress and need to hear good news about their child, let themselves to be overwhelmed by the situation, and, mostly when they lack previous experiences to lay on, are tempted to allow the physician to take the decision, being unable to process the offered information. As showed by Modi[17], the human response to disease if often very complex and not rarely less rational and in the case of the parents their capacity to take autonomous informed decisions is affected. Even more, most often the parents are not prepared for the emotional, moral and intellectual stress of the neonatal pathology and this may also be one of the reasons of the understanding and accepting difficulties of the situations[15]. In front of incertitude and risk, the term "objective" losses its value and meaning.

The moment when parents are approached for offering the informed consent is a moment of intense excitement and stress. The more intense is the maternal stress level, the more reduced is the real value of the informed consent. Zupancic et al [13] showed that a quarter of the participants in a survey about the informed consent in newborns would have preferred to be approached during pregnancy and not after birth. But even the prenatal informed consent is entailed to many question signs: in the case of the pregnant women asked for informed consent regarding peridural anesthesia during labor 33% of them did not remembered having this discussion at 48 hours after delivery irrespective if the informed consent was written or verbal[13]. A better rate of recall about informed consent discussions was obtained only in mothers approached during parental school lessons[13]. The value of informed consent obtained during labor is considerably diminished by the labor and delivery stress[3,5]. The authors are cautioning the antenatal informed consent is popular but may overwhelm the parents with information that are not necessary and in the case of

increased risk pregnancies may increase the pressure felt by parents[18-20]. Lack of the fetal legal rights is another major problem of the prenatal informed consent[3].

After birth, obtaining the informed consent from the mother may be hampered by particular situations as:

- postnatal transfer of the child to superior level units - raises legal problems mostly when the transfer was not done before delivery, in utero, even if a safe prenatal transfer could have been done[8]
- maternal postpartum complications: mother under anesthesia for cesarean section, or treated with psychotropic drugs or receiving medication affecting the decisional capacity, mother with major conditions, etc.[8]
- psychical and psychological maternal complications due to newborn's conditions - postpartum depression, feelings of guilt[15]
- changes of the familial relationships under stress pressure (between parents, between the parents and brothers, etc.)[15]
- limited technological, material, and human resources influencing the neonatal standards of care, creating inequities.

Obtaining the informed consent process must be based on sufficient, simple, easy to understand information, explaining concepts, potential risks, benefits, and implications of the decisions taken into informed consent. The validity of the informed consent may be subjected to discussions anytime the communication between clinicians and parents is poor due either to incorrect, incomplete, difficult to understand (medical slang), complicated (unexplained scientific concepts or too many information) offered by clinicians, or to difficulties of understanding secondary to language barrier, educational or intellectual deficiencies of the parents[8,14,15,21]. Therefore, it is important that clinicians take into account the results of the study developed by Zupancic[13] that showed that factors determining the parental preferences for a certain decision are related mostly to the process of the informed consent and not to the personal character of those participating in taking decisions.

Sometimes the parents don't even understand the concept of informed consent and other times they just don't want to completely assume the responsibilities of taking decisions[21,22]. In other situations, the physicians that want to impose what they consider as necessary treatment are assuming the decision irrespective if they ask or not the informed consent[8]. Such a paternalist behavior, a norm some decades ago, persistent as dominant up to nowadays especially in the case of futile medical interventions, situations when clinicians may override the informed consent, often with success[8]. Between futility and patient's autonomy there is a grey zone, a territory where the medical staff and the patient are discussing, negotiating, and compromising, the best model for solving potential conflicts. Such a grey zone is, in neonatology, resuscitation at the viability threshold, under 24 weeks of gestation[8].

Unrealistic parental expectations may also create difficulties of understanding and accepting the offered information during informed consent process and denial responses as a defense reaction in front of a very serious situation[15,21]. Another problem of the informed consent in neonatology is related to its content[9]. The correctitude and validity of informed consent may be influence by social, cultural, religious, gender (as in Roma population), familial norms or pressures[14,15,21]. All these norms may influence familial understanding about good/bad, correct/incorrect, possible/impossible.

Another problem of the informed consent is linked to the multidisciplinarity imposed by complicated cases, asking for solutions from a team of different specialists. Conflicting situations and misunderstandings between the team members are often arising in these situations, most often due to individual prestige, authority, priority of action, each individual role in the team, language, or even knowledge about the involved related specialties. Not rarely, the obstetricians opinion dominates in front of parents, among others because an older relationship between parents and the obstetrician and due to trust gained by the specialist in the eyes of the family. Also, in relation with other specialties, the neonatologist gains ground during postnatal period. Ideally, the relationship and communication between the members of the multidisciplinary team should not negatively affect the communication with the parents and with informed consent[15].

Many discussions existed in the latest years in the medical world due to numerous ethical, moral, and even legal issues raised by informed consent in neonatology. For instance, in situations where discordances between clinicians and parents that cannot be solved exist, the parents have the legal right to consent or not to the therapies applied to their child but this right is not an absolute one when it is judged in the light of the best interest of the child, including in situations where parents are unjustifiably asking for supporting the child's life[22]. United Nations Organization Convention for child rights clearly defines the society's responsibilities to support parents in applying their believes from the position of main persons responsible for the well-being of their child[23]. Legal courts may be solicited in conflicting situations in order to align the moral values of the professionals to those of the society. But the medical staff should have the right to decide when and where their professional knowledge is used and, in situations when these knowledge are causing unacceptable distress the medical staff should be allowed to withdraw their medical services. At least theoretically but also from a legal point of view, the parental right to decide for the child is not as strong as their right to decide for themselves. In the case of the minors, the standard of the best interest of the child dominates but the place for each decisional threshold is often subjective and the success of the treatment is defined in terms of survival or subsequent disabilities[6].

The informed consent in neonatology - when it is necessary

The informed consent means, in its essence, informing the patient or its legal representative about the risks and benefits of the proposed medical intervention or therapy and about alternative therapeutic options. But, especially in neonatology and in the case of a sick neonate and in preterm infants, very often, the therapeutic procedures are implying

also significant risks, sometimes on long time. Even more, any procedure, any therapy may have, sometimes, hundreds of associated risks. And, in case of the drugs some may consider the adverse effects as risks associated to that therapy. Therefore, the medical world agrees that into the informed consent only the relevant risks for the physician's specialty and those with the greatest severity and/or frequency must be described (for example, risks occurring with great incidence are those arising in more than 3% of the cases, while complications as death, palsy, cerebral lesions occurring in more than 1% of the cases are considered severe risks)[10]. Clinicians must pay attention to the risks presented in the informed consent process, mostly to the mode in which they communicate these risks to the patient. Informed consent must prepare the patient for adverse effects and also help him chose the best option for him, including the option to refuse the proposed therapy and the consequences derived from this refusal.

In newborns, the informed consent must encourage the parents to imply themselves in taking decisions regarding the child's health. Ideally, these discussions must take place before birth but, in most of the cases, this is rarely possible. Most of the times, the parents are approached immediately after delivery for explaining the routine care, immunizations, and screening tests for the neonates without special problems or for presenting a diagnosed condition and therapeutic options in preterm infants and sick newborns. Whenever changes are occurring in the child's condition, changes of the therapy may be needed and the parents may need to be approached again with new therapeutic options, ideally before applying them (for example, the need for catheterization, phototherapy, ultrasound scans, treatment of complications, etc.). In emergency situations the parents must be informed as soon as possible after applying urgent treatments.

Not all the procedures performed in newborns need parental informed consent but there are certain situations when informed consent must be obtained any time when the situation is not an emergency: type of milk for feeding, feeding modality, immunizations, vitamin K administration, screening tests, blood withdrawal, antibiotic therapy, administration of drugs, including infusions, phototherapy, vascular catheterizations - peripheral and central -, oxygen therapy, non-invasive and invasive respiratory support, ultrasound scans, special radiological procedures (as contrast agents administration, magnetic resonance imaging, computer-tomography, etc.), blood or blood-derived products transfusions, any surgical procedure, any innovative procedure or therapy, participations in studies or research, resuscitation at viability threshold, organ donation, autopsy[10,22,24].

When presenting the risks related to the proposed therapy/procedure, the clinician must avoid formulations as "among the described risks there are ..." or "the risks include but are not limited to ...", formulations that are in a way elusive an may conduct to patient refusal (scared by too many risks) or lack of attention form a patient refusing to know the risks. Some authors are recommending not only documentation of the informed consent but also documentation the attitude of the patient during discussion[10].

Informed in neonatology - potentially conflicting situations

Disagreements between clinicians and the newborn's caregivers - parents of legal tutors - may occur in various situations. Most often, such conflicts are seen in the following situations:

- clinicians and parents have different opinions regarding the continuation or cessation of life support in extreme situations;
- personal interpretations or influence of religious groups (for example opposing blood or blood-derived products transfusion in the case of Jehovah witnesses);
- different interpretation of the autonomy principle when parents may believe that they have a better perception compared to physicians as regards the best interest of the child (for example, immunizations);
- differences in evaluation the future status of the newborn on medium and long term, mostly as regards the quality of life, between the parents and physicians (for example, in conditions affecting the quality of life, such as Down syndrome).

Informed consent in neonatology - possible solutions

The informed consent is not valid if it does not respect the principles of modern medical ethics:

- the best interest of the patient (including life preservation, removal of suffering);
- "non malefience" principle (do not harm);
- patient's autonomy (the patient or his tutor are regarded as moral agents, with duties and obligations, able to understand and take ethical decisions);
- equity principle (fair allocation of medical resources)[5,8,9,25].

In neonatology, other extremely important principles are: respecting the child's rights (by the clinicians, parents, and society), medical knowledge of the clinicians, and professional deontology[15].

Actually, the informed consent occurs in the context of understanding and trust between clinicians and parents and is determined by three elements: a substantial informational process of the parents, ability of the parents to take correct decisions for their child, and the capacity of the parents to freely take decisions, without coercive pressure from the physicians.

Ethically, the informed consent aims to offer easy to understand information and choosing a therapeutic conduct by the patient or by his legal representatives. For the parents, their ability to make a real informed choice implies a systematic approach of the informed consent as regards the moment, the content, and the communication modality. After open discussions, the parents must be guided to decide the best for the child's health. Tripp et al[22] are distinguishing several types of relationships between clinicians and parents that may burden the informed consent (Table no 1.). Based on the parental typology, the physician must be prepared to use one of the attitudes described in the table to reach a common decision for the best interest of the

child. The principles of the modern bioethics are recommending physicians to avoid paternalist attitudes and to try to imply the parents in taking decisions[26]. Clinicians attitude in discussing with parents is important, empathy being a major element. Physicians must guide and support the parents with calm and empathy, avoiding to set themselves as child's tutors[15].

Clinicians have also to avoid sliding on the path of simplified ethical questions, situation that minimize the relationship with the patient to the principles derived from Hippocrates oath[22]. Older and more experienced physicians can be involved in the discussion as counselors, facilitators, or even negotiators[22].

Table no. 1. Types of relationships between physician and parent[22]

	Physician's style			
	Informative	*Interpretative*	*Deliberative*	*Paternalist*
Parental values	Well defined, fixed, known by the parent	Rudimentary, conflicting, needing clarification	Open to revision by moral discussions	Objective, originating from the physician
Duties of the physician	Offering relevant information and implementing the option chosen by the parent	Clarifying and interpreting the relevant values of the parent, informing the parent and applying the option chosen by the parent	Showing and convincing the parent about the most important values and applying the option chosen by the parent	Promotion of the best interest of the child independent of the parents
Parental concept about autonomy	Chose and control of the medical care	Good understanding of the medical care	Moral self development related to medical care	Consent to objective values
Physician's concept about his own role	Competent technical expert	Counselor or advisor	Friend or educator	Tutor

The open and honest character of the discussions between clinicians and parents represents a good prerequisite for avoiding conflicting situations during informed consent in neonatology[22]. Also, the principles of respecting individuals and of responsibility are other two essential points for a valid informed consent. Repeating information (if there is time) allows avoiding misunderstandings and prevents unrealistic expectations of the parents. It also prevents confusions, suspicions, and overt hostility of the parents. Repeated discussions offer a better knowledge of the dialog partners and a better evaluation of both parts as regards the physician's rationale and integrity, creating a basis for objective informed consent[26].

In situations known before birth, communication between obstetrician, anesthesiologist, neonatologist, and other specialists that may be involved in the care of the neonate is essential for avoiding overwhelming the parents with multiple and not always concordant information.

Documenting (written in the patient chart) the discussion about risks and the informed consent is legally helpful for the physician and parent. The parent may loner deliberate and may ask for more information when he/she reads the information verbally presented[10,24]. Brochures, flyers, algorithms, audio tapes, computerized programs, interactive videos, prognostic tables stratified on gestational age in the case of preterm infants are helpful and recommended[13,24]. Such standardized information may help parents to take the best decisions for their children, decisions that, in neonatology, during an intense emotional moment, are often a too heavy burden on the parents' shoulder.

Informed consent in neonatology - the possible role of ethical committees

The role of ethical/bioethical medical committees of the medical institutions is unsure as regards obtaining informed consent. In order to reduce the risk of unsafe and unreasonable parental decisions, the physicians may call these committees for their quality of ethical counselors and for solving ethical disputes with parents[5]. Ethical medical committees may be useful for training the medical staff and patients (including parents) on the relevant ethical principles, development of medical ethical policies and standards in medical institutions, and applying in practice of the recommendations issues. Also, these committees must represent a support forum for the medical staff facing difficult ethical decisions[26].

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