INFORMED CONSENT: FROM HISTORIC ROOTS TOWARDS THE RED LINE OF MODERN CRISES IN INFECTIOUS DISEASES

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Stages of the informed consent (IC) process, being the instrument for protecting the rights and dignity of the research subjects, ideology and essence development during the crises in medicine have been studied on the example of the infectious diseases. Special emphasis has been placed on the 100-year national history of the informed consent ethical and legal principles development. The review of information process content and logistic improvement (individual, public, delayed and broad IC) during vaccine testing and vaccination in emergency settings has been provided. Implementation of the WHO programmes aimed at eradication of preventable infections (polio, measles) illustrates the coherence of adherence to awareness-raising ethical standards with the success of epidemic control. The development of preventive vaccination ethical algorithm and the practice of its use during the epidemic crises have a significant predictive value for organization and control of using the vaccines during the pandemic.

Keywords: informed consent, history and development informed consent, IC in vaccine research, IC in vaccination for emergency reasons.

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КОНЦЕПЦИЯ ИНФОРМИРОВАННОГО СОГЛАСИЯ ОТ ИСТОРИЧЕСКИХ КОРНЕЙ ДО КРАСНОЙ ЛИНИИ СОВРЕМЕННЫХ КРИЗИСНЫХ СИТУАЦИЙ В ИНФЕКЦИОННОЙ ПАТОЛОГИИ

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Проведено изучение этапов процесса развития идеологии и содержания информированного согласия (ИС) как инструмента защиты прав и достоинства участников исследований и в кризисных ситуациях в медицине, на примере инфекционных заболеваний. Специальный акцент сделан на более чем 100–летний период отечественной истории становления этических и правовых принципов формирования информированного согласия. В отдельном разделе дан обзор совершенствования содержательной и логистической характеристики процесса информирования (индивидуальное, общественное, отсроченное и широкое ИС) при испытании вакцин и проведении вакцинации в чрезвычайных ситуациях. На примере реализации глобальных программ ВОЗ по ликвидации управляемых инфекций (полиомиелит и корь) продемонстрирована сопряженность следования этическим стандартам информирования и достижения успеха противоэпидемических мероприятий. Создание этического алгоритма вакцинопрофилактики и опыт его применения в кризисных эпидемических ситуациях имеет важное прогностическое значение при организации и контроле применения вакцин в период пандемии.

Ключевые слова: информированное согласие, история и совершенствование форм ИС, ИС при исследовании вакцин, ИС при вакцинации в чрезвычайных ситуациях

Вклад авторов: Кубарь О.И. — историко-архивное изучение и обзор становления и развития этики исследований в России; анализ специфики информированного согласия при исследовании вакцин и разработка этического алгоритма контроля чрезвычайных эпидемических ситуаций. Бичурина М.А., Романенкова Н.И. — проведение комплекса вирусологических и эпидемиологических исследований в формате Субнациональной лаборатории ВОЗ по ликвидации управляемых инфекций.

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Responsible adherence to the norms of law and morality (ethics) is a historically justified constant of public health system management and regulation. However, we need to acknowledge that adherence to normative and ethical principles is essential in the context of logistic changes resulting from new challenges related to scientific progress or global health emergencies. In the circumstances, due respect to human dignity, rights and fundamental freedom truly plays a crucial role, and the ethics reaches the level of the conflict of interest resolution and the benefit/risk/damage balance criterion. The priority role of ethics, in turn, requires continuous improvement of multidisciplinary and pluralistic dialogue between all parties concerned based on objectivity, openness and trust.

Achieving the doctor-patient mutual understanding, where special responsibility belongs to information exchange and the parties' consent, is the universal instrument that ensures protection of human dignity throughout many centuries of the history of medicine.

The cultural diversity features importance for the information process building led us to appeal to the base of this phenomenon documentation in Russia, as well as to the dynamic changes in development in the specific context of extreme pressure on the healthcare systems associated with control and management of infectious diseases.

METHODS

Methodological approach used in our study consisted in exploratory research and consistent reporting of the informed consent development and implementation in Russia covering

the periods of imperial Russia, USSR and modern Russian Federation. Archival documents, legal acts and printed matter issued from 1902 to date were revised 1, 2]. The national and international legal acts, including the guidelines for good clinical practice (GCP), UNESCO and WHO documents developed with the author (having the status of the WHO expert and the UNESCO IBC member) assistance, were analyzed in order to demonstrate the dynamic changes in the informed consent development and implementation features during clinical trials and the use of vaccines [3, 4, 5]. Special attention was paid to investigation of the WHO programmes aimed at eradication of polio, measles, rubella and congenital rubella [6, 7, 8, 9]. The section on assessing the IC role in eradication of preventable infections is based on methodological resources of the WHO guidelines and direct experience of such programmes implementation within the framework of managing the polio/measles/rubella WHO subnational laboratory [10, 11, 12].

RESULTS

Examining the origins of the informed consent institutions formation in Russia was the initial phase of our study, which defined our interest to understand the dialectic of relationship between law and ethics in medicine. The task ahead was to assess the contingence and mutual influence of historical moral foundations underlying national bioethics based on the experience of implementation in critical epidemic situations. These developments had a special resonance and were of key relevance in the context of the COVID-19 pandemic, under which both national sovereignty conflicts and specific morality of national consciousness had become apparent [13].

In that regard, it is extremely important to note the moral high ground of the medical profession peculiar for Russian statehood that is reflected in a series of historical and cultural papers [14, 15, 16, 17]. Of particular note is some written evidence of moral and legal regulation of communication, which has been presented earlier in a special series of reviews [1, 2].

According to chronology of the research, the first available publication was concerned with the moral regulation of health activities based on the example of the trial of Dr. Modlinsky, who was found guilty of "*failure to ask the patient for consent*" by the Criminal Cassation Department of the Senate of the Russian Empire [published in the "Legal Drama" magazine, 1902, No. 2]. This example suggests that it was legally recognized obligation to obtain the patient's consent to medical intervention in Russia in the early 20th century, and the regulatory framework existed for sanctions related to non-compliance with this legal rule. The principle of morally graded attitude to the fact of patient's was obligatory too, as was clear from the comment given by professor of criminal law Tagantsev: "*the patient's consent is powerless to grant impunity in all cases of healing*" (published in the "Law" magazine, 1902, № 12) [1, 18, 19].

The truly unique paper by Dr. B.V. Dmitriev "*Thyroid Gland Transplantation Case and Legal Issues Related to Such Transplantation*", published in 1917, is the irrefutable proof of the legal recognition of the medical research involving human subjects in the imperial Russia [20]. This paper presents the full list of major ethical requirements for conducting such surgical interventions, among which is the obligation to inform both donors and recipients about all the potential consequences of medical intervention. The requirements for the donor's physical and mental health are also emphasized, as well as the need for the "*transient and mild nature of injuries*", guaranteed by the doctor. The text of the note written by the female patient E.P., presented in the paper by Dr B.V. Dmitriev, is of historical value. The note is blatantly obvious to be contingent with the current standards for the ethically acceptable elements of the contemporary IC process [20, p. 628]. The original text of the note contained the list of items common to all up-to-date international instruments on bioethics, such as confidentiality, respect for autonomy, risk awareness, respect for freedom and voluntariness of decision-making, and the need to consider the social and psychological maturity of the person being the research subject. All of the above defines our point of view that this note is essentially the first fully valid example of the patient informed consent form, possibly not only in Russia [2].

Legal sufficiency and completeness of this fact are substantiated by the concept developed by A.F. Koni, one of the most respected Russian lawyers, who stated that there was no criminal activity in selling organs for medicinal purposes [20, p. 629–630]. The legally recognized contract between the donor and the recipient, containing provisions for exclusion of *"minors, mentally retarded people, and people being in the state of artificially induced excitement*", was indispensable for the legality of such an action; furthermore, the concept stipulated that the decision on participation had not had to be provoked by "*psychological coercion, deception, seduction, profit, or authoritative suggestion*", i.e. in modern terms the decision had to be free and informed.

Thus, the analysis of the relationship between ethics and law in the early 20th century Russia suggests that the humanistic ideas of voluntary, confidentiality, and informed nature of the research subject decision-making took place together with the responsibility and mercy of the physician-scientist and regulations in force. This highlighted the rich moral heritage and bioethics potentiality of Russia [14, 17].

When discussing the historical perspective, we should highlight the ethical and legal regulation of medical and biological research in the former USSR. Studying the legal instruments available revealed that already in the first years of the Soviet power's existence the Act of the RSFSR dated December 1, 1924, "*On the Professional Work and Rights of Medical Workers*" clearly specified the need for "*the patient's consent, in particular when conducting surgical procedures*", and the fact that "*in individuals under 16 or mentally disabled individuals*" the "*consent of their parents or guardians*" was essential. The Resolution of the Scientific Medical Council of the People's Commissariat of Health Care of the RSRSF "*On the Conduct of Study of New Medicines and Medical Methods Associated with Risk for the Life and Health of Patients*", issued in 1936, was unique [21]. The reasons and grounds for such instrument development and acceptance were explained in detail in the paper by private associate professor IYa Bychkov "*On the Issue of Legal Regulation of Medical Experiments Involving Human Subjects*" [18]. It is important to note the compliance of experimental procedure with modern requirements in terms of scientific data validity and preliminary survey on animals; informed consent of the research participant; requirements for high physician-scientist qualification and his/her responsibility towards the study participant. Among the historic documents reviewed, the USSR legislation in the area of "*crimes against humanity*" applied during the trial of the former military officers of the Imperial Japanese Army, charged with the development and use of bacteriological weapons, conducted by the Military Tribunal of the USSR in December 1949 in Khabarovsk (Article 1 of the Decree of the Presidium of the Supreme Soviet of the USSR of April 19, 1943), deserves special attention [1].

In general, historical recollection suggests that in varying political and socio-economic situations during the studied period, national health care was based on the sense of morality

and responsible approach to scientific research involving human subjects. Later, in the course of improving the research and educational potential, as well as the harmonized integration of modern Russia in the development of global bioethics, the full-fledged legal framework for ethical issues in medicine and biology was formed [17].

This provision is extremely important at the current stage of the health care development, especially in emergencies requiring accomplishing the goals of global interaction and solidarity, such as elimination of infections and epidemic management during the pandemic. In both situations, preventive vaccination and the associated element of "*dual loyalty*" to the rights of the individual and of society are of key importance [9]. In this regard, correct presentation of the complex of ethical awareness and actions in the above-mentioned conditions requires understanding of contemporary structure and conceptual changes in the informed consent process with the focus on testing and using the vaccines.

Investigation and analysis of contemporary informed consent framework was the next important stage of the study. The existing standards of the informed consent as a primary mechanism for the protection of the rights of biomedical research participants include a number of essential elements, such as the fact of obtaining the voluntary IC, guaranteed accessibility of information, as well as objectivity and specific nature of the process in vulnerable populations. The other essential factors ensuring protection of the research subject rights are as follows: review/approval by the ethics committee (EC), and conformity with national law [4, 5, 23-27].

Since this paper directs by testing and using the vaccines, the significant elements of the informed consent process specific for this area are especially important. In general IC protects the freedom of individual choice and ensures respect for the individual's autonomy. These qualities assume special importance during studies showing no immediate and direct effects, which include vaccine trials. Under the circumstances, the IC should provide clear and true information not only about the study, but also about the possible alternatives. IC should ensure the possibility of dynamic discussion of the questions raised by the study participants (before/in the course of/after the study). During the vaccine trial, potential participants have the right to receive the advice about the risk of infection and any steps that could be taken to reduce the risks. The correctness of this fact has been unequivocally confirmed by testing the vaccines against such infectious diseases as COVID-19.

The social aspect of the perception that the informed consent is a two-way communication process that also involves voluntary consent, given by the participant, and the IC, received by the researcher, is very important. The structure of the IC information block should be discussed in detail, which includes, but is not limited to information about the goals, methods, funding sources, possible conflict of interest, and institutional affiliation of the researcher, expected benefits, potential risk/discomfort, and access to study results. The IC process should not be considered as one-off and static process, since the researcher must once again provide the up-to-date information and obtain the new IC from the participants in case of significant changes occurring at any stage of the study. Certainly, it is necessary to ensure the potential participant's ability to understand the information, which is directly related to the presentation of characteristics mentioned in the IC (in the mother tongue, with no medical terms), to the person's maturity, educational level and beliefs, as well as to the researcher's ability and willingness to create an environment of trust.

When conducting contemporary research, introduction of the new format, the so-called "broad" IC, should be taken into account. Broad IC involves consent to storage/future use of biological specimens that remain after the study and are used for other purposes. Broad IC stipulates that it can be withdrawn using the informed refusal procedure, which in turn includes a number of issues discussed below. Prior understanding of the refusal acceptability by the participants is required; moreover, the information sufficient to make such a decision should include the possibility to withdraw the previously submitted broad IC, and confidence in the participant's availability for the refusal procedure. There are special provisions for individuals unable to submit the IC at the beginning of the study (e.g., children). In this case, the procedure of obtaining the individual IC or the refusal of the previously submitted by the children's guardians broad IC is specified for the situation of acquiring full legal capacity in the future. The fact of the broad IC acceptance must necessarily be reviewed and approved by the EC. There are several exceptional situations where the ethics committee might not necessarily require the individual IC to the future use of the retrospective study data. Such situations are as follows: the study is impossible in case of refusal; the study is of great social significance; the study poses minimal risk for the subject or the community, the subject belongs to. However, even in these situations, safeguards for information confidentiality protection ensured by anonymized or encoded data exchange, or limited access to data for the third parties, is an essential component.

For international studies, it is necessary to take into account the developer/sponsor obligation to return all specimens/data to the country of research, as well as to share all the potential results and benefits. It should be noted that the broad IC is also applicable in cases, when the materials collected could be potentially used for the common good during the subsequent research, the exact nature of which is usually unknown at the time of collecting the materials. This does not allow for the information block specifying, and makes broad IC the acceptable alternative [5]. The latter issue is no doubt substantial from the social and epidemiological point of view; therefore, it might be applicable in emergencies, such as elimination of infections and the pandemic.

In the format of this discussion, it is significant that the broad IC to storage of biological specimens envisages certain limitations concerning their future use, and must include information about the goals, conditions and period of storage, as well as the details of the access policy and the means of raising awareness about the use of biomaterial (i.e., the use for the subject's health with subsequent destruction, the use for the well-known research projects, or storage for the inconclusive purpose). Such alternatives provide basis for introduction of the new term, the "tiered" IC, allowing one to choose the appropriate setting for the storage of his/her biomaterial.

Thus, in view of the foregoing, it is obvious that, when performing ethical review of the new vaccine trials, special attention should be paid to the issues of the collected biological specimens and/or data carriers (medical records) future use. As mentioned above, the researcher's responsibility extends to obtaining the appropriate IC. Responsibility of the EC extends to reviewing supplementary or broad IC, as well as to ethical evaluation of the fact and the grounds of the biological specimens collection (including the commercial purposes), storage period, broadness and the terms of acceptability during the future research projects.

The issue of the researcher and sponsor obligations to ensure the subject's right to compensation or necessary

additional medical care merits a separate discussion. Furthermore, the procedure and the measure of compensation for study (e.g., new vaccine trial) participation should be reviewed, justified and explained to participants. It should be emphasized that the compensation does not provide for the mandatory financial component, and can be implemented via free medical care during the study, as well as via access to a number of services: insurance, examination, health education. Special types of compensation are possible when conducting research involving volunteers. However, it must be borne in mind that the compensation cannot be used as a means of pressure or coercion for decision making during the IC process anyway. A solution to the issue of the fact and form of compensation (or the fact of no compensation) is a subject of ethical review performed by the EC. It should be taken into account that the participants have a right to free treatment and compensation in the event of harm (physical, psychological or social), directly related to participation in the study. The nature and measure of the compensation, including the cases of disability and death, should be detailed in the IC information block and are the special subject to review by the EC. It should also be emphasized that the right to compensation for caused damage/harm is, on top of everything else, of great moral importance in maintaining the clinical trials credibility.

The fact that all the aforementioned data are fully applicable to individuals capable of making decisions independently due to their mental status, age and social background is an important logistical issue. When dealing with vulnerable populations, the IC process is addressed to the study participant's legal representative (parent, guardian or other authorized person). According to GCP ethical standards, the research involving vulnerable populations can be conducted only on behalf of such individuals provided that the research is aimed at getting immediate or potential benefits, the study cannot be conducted in other populations, and the risk and discomfort related to study participation are insignificant compared to the expected benefits. Special regime of conducting the studies involving various vulnerable populations is defined in each case based on the universal ethical principles, which include respect for cultural and social diversity, and are recognized by law allowing for special conditions for protection of individuals unable to give the informed consent. The arguments advanced here may produce a significant resonance when testing and using the vaccines during the epidemic crises, when the high coverage levels of vaccination with potential enrollment of individuals with different social status have to be achieved [5, 24].

It is evident from the above that within the focus of this study aimed at defining the features of IC in case of infection outbreaks in order to prevent or eliminate the outbreaks by vaccination, the socially significant aspect of the studies involving large populations (among them the vulnerable groups) is particularly important. Such studies make it possible to accomplish important tasks of fast knowledge-building, building public trust, and overcoming practical difficulties in specific circumstances. However, these tasks should be carefully balanced against the scientific validity of the study and the guarantee of respect for the participants' rights. The facts of speeding up the review, and application of EC action priority evaluation in emergency situations are envisaged and permitted under these circumstances [13].

Cluster studies may be considered an acceptable form of the research. Such studies provide for enrollment of distinct groups (for example, schools, hospitals, other institutions or departments, i.e., the clusters) that are subject to randomization in order to investigate various means and methods of medical interventions. Conducting such studies requires specifying ethical approaches: clearly defined individual study participant, defining the nature of the influence on other individuals or community, the need to obtain the IC from the community representatives, as well as consideration of the degree, to which the IC or refusal to give the IC can justify or compromise the study results. Arrangement of such studies always faces the need to address the ethically significant issue of the control group eligibility, and the need to discuss the project with independent experts. An example of specific ethical conflict can be introducing the new infection control procedure (vaccination) in one cluster without modifying the procedures in the control cluster; this situation is analogous to the use of placebo, which could trigger the need for post-marketing surveillance of the vaccines. Meanwhile, there are always the conditional measure and the level of decision making capacity. For instance, when a school is selected as a cluster, the students' parents cannot give the consent to randomization of the school, attended by their children, for the vaccination programme, or to exclusion of the school from the cluster. However, they can accept or reject their children's participation in the vaccination programme [5].

In the current context of conducting research and practical arrangements for the preventive vaccination, it is necessary to take into account the new technologies, such as Internet (social media, websites, chat rooms), which, apart from the clearly considerable benefits (accessibility, communication speed), pose additional risks for establishing and maintaining confidentiality. The need for confidentiality primarily extends to keeping secret information, making it possible to determine the participant's identity, and other information subject to non-disclosure provisions from the unauthorized persons. Moreover, when conducting the study results analysis in terms of potential data disclosure impact on the possibility of the data use for discrimination of certain groups and human communities, it is essential to follow the principle of confidentiality. Assurance of confidentiality during epidemiological research involving the use of Internet (both for mailing and research data acquisition/ storage, depending on the specific conditions and levels of protection) requires mandatory inclusion in the text of the IC with subsequent approval or refusal both of the designated authorities together with the ethics committee, and the used website owners [4, 5, 12].

In spite of the fact that our study is focused primarily on the crucial role of the informed consent being a vital force in the protection of the rights of the research subjects, it should be strongly emphasized that this goal can be achieved only under the full complex of ethical support, which includes, in addition to the IC, independent review by the EC, and the recently developed third element, public accountability. Negative, inconclusive, and positive results must be published or made available to public in any other way. Such format is intended to maximize the research benefits, reduce social tension by disclosure of risk/harm, reduce the time required for decision making, increase the resource allocation efficiency, avoid overlapping, conduct an independent evaluation, and contribute towards building trust on the part of the society as a whole [5].

Therefore, only the three-component ethical element of vaccination that includes IC, and independent social feasibility recognized by society, demonstrates openness, timeliness, objectivity and relevance. In view of the above, we must point out that this exact supranational and interdisciplinary approach largely determines current trends in the development of biomedical ethics; it also allows for seeking justice in distribution of benefits/damage/ costs/risks, resulting from scientific and

technological progress in biomedicine, among countries. In this context, the trends in global bioethics become more and more evident. Global bioethics focuses not only on individual, but also on social values, intended to reveal the ethical nature of socially significant settings and situations, which should obviously include preventive vaccination.

In terms of ethics, the area of using the vaccines during health emergencies is the most important focus of creating the unified ethical approach. Extreme conditions during such situations are comparable to research, as they are related to unknown and unpredictable circumstances. In such a case the issue of providing authoritative information, as well as of conscious acceptance and response to information both in the individual and the society as a whole, becomes crucial for success.

DISCUSSION

Examining the role of the informed consent in the WHO infection elimination programmes is the key element for understanding the informational aspects of the research. The authors' direct participation in the WHO programmes aimed at eradication of a number of preventable infectious diseases (polio, measles, rubella, and congenital rubella) made it possible to determine the true role of the correct information process development, as well as to identify the features of the IC structure and forms in the context of the large-scale international events. May 13, 1988, the date of the 41st World Health Assembly (WHA) Resolution adoption, should be considered the official start of the polio eradication programme. The Resolution urged all countries to coordinate their efforts in order to eradicate polio by the end of 2000 [6–8]. Since the programme was considered critically important, the requirements for high-coverage vaccination against polio, conducting clean-up immunization in populations with low immunization coverage, and maintaining highly effective polio surveillance until the end of the programme entered into force. The global efforts great force was ensured by the following: involvement of 200 countries, territories and regions; participation of 20 million volunteers; vaccination coverage of more than 2 billion children. In terms of ethics, it was important that the polio eradication programme sociopolitical and economic components were based on the principles of international solidarity, social responsibility, and respect for cultural, historical and religious diversity. We conducted comprehensive study of the ethical algorithm for global infection elimination and presented the results in a series of papers [10–12]. Within the framework of this study, it was important to examine and define the predictive value of the ethical block information component.

Thus, correct and successful implementation of the programme, apart from coherence at the global level, correct recording, and the use of scientific and economic resources, was definitely impossible without the civil society support. Engagement with society necessitates the implementation of appropriate educational measures, equal access to training of personnel, and availability of specific public information. All decisions and acts should target different audiences and groups of people, different in social, cultural and religious composition. Efforts in education and raising public awareness during implementation of the infection elimination programme dictate adherence to the ethical principles of openness, objectivity, honesty and accessibility. Moreover, rapid investigation of the population reaction to measure implementation is required, together with the rapid response. Such type of monitoring is intended to restore a just information risk-benefit balance, prevent misinformation and confusion, and, as a consequence, ensure mutual trust and solidarity with society. Shaping the population attitudes by sensitizing to objectives and methods of the polio eradication programme worldwide can be considered a good example of adequate information policy. This is conclusively demonstrated by the modalities of the Polio National Immunization Days implementation in India. A huge amount of operational activities took place during 6 immunization days officially declared by the country, including opening of 640,000 vaccination centers, involvement of 2.3 million vaccinators and 137,000 curators, visits to 191 million households, which ensured vaccination of 172 million children [10, 11]. In terms of ethics, when implementing such large-scale measures, special attention should be paid to development of the information block, as well as to efforts to obtain the informed consent to participation of general public using a differentiated approach to vulnerable populations and guaranteeing the right to the protection of privacy and confidentiality. During implementation of the whole range of global measures aimed at polio eradication, adaptation and actualization in different countries and populations were achieved through country visits and the analysis of follow-up data obtained for acute flaccid paralysis, as well as through comparison with data of regional reference laboratories and communication with national technical partners. The inclusion of the "Institutional Memory and Lessons Learned" programme mechanisms was essential. The programme provided for information types differentiation, as well as screening of quality and significance of information blocks by the use of more detailed subnational database containing data on epidemiology of other preventable infections. Only the whole range of the listed above measures could ensure transparency and accessibility of information about the organizational and operational efforts of the national system in the course of polio eradication.

Thorough review and analysis of events, that took place at the stage of acceptance and implementation of the new WHO global measles, rubella and congenital rubella elimination initiative, provided extensive and convincing data supporting our previous conclusion made after investigation of the polio eradication programme ethical algorithm [9, 12]. The compulsory measures to provide the two-time postponement of implementation of the WHO strategic plan for elimination of these infections at national, regional and global levels (from 2010 to 2015 at the first stage, and from 2015 to 2020 at the second stage) owing to non-synchronous preventive measures clearly demonstrate the fundamental importance of the joint efforts of all systems of information management, governance and control of epidemic process for achieving the effect. Implementation of measures in various parts of the world in the populations with different cultural, social, religious, economic and psychological status requires commitment to the ethical principles of human vulnerability recognition, respect to cultural diversity and inviolability of the person, as well as equality, justice, equal rights and pluralism. This resource of ethical filling should clearly be taken into account and should dominate in achieving the public and individual informed consent with guaranteed free informed decision making. At the same time, data integrity ensures efficient functioning of all scientific research elements, both in laboratory practice and in vaccine improvement [12]. The tangible achievements may be based on the ethics of transnational interaction practices, the compliance with which contributes to sharing new technologies, as well as on professional training and bioethics data [3].

CONCLUSION

Thus, ensuring the humanitarian success of the infection elimination measures requires building the ethical component of the programme and inclusion of this component into plans and operational documents as an integral part in order to achieve ethical integrity of decisions and actions at all levels of governance. The existence of ethical standard obliges all the parties involved to maintain and develop the relationship of solidarity, personal and social responsibility, justice, openness and accountability within the civil society at the professional, state and interstate levels.

In general, summing up the interdisciplinary analysis of the informed consent value for achievement of epidemiological welfare, there should be a clear recognition of the feasibility of compliance with its humanistic essence together with recognition of the need for considering the best ways to follow the IC process during the pandemic crises.

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