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Ethical decision making in neonatal intensive care: adaptation of EURONIC research protocol in Greece

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Summary

Purpose of investigation: To address the lack of research regarding the bioethical decision making process in neonatal intensive care in Greece and provide a comparative basis with international research. *Materials and Methods:* The research protocol of the widely acknowledged *European Project on Parents' Information and Ethical Decision Making in Neonatal Intensive Care Units* (EURONIC) was adopted and implemented in order to: a) record clinical practices, b) assess healthcare professionals' ethics concerns, and c) investigate the clinical, demographic, and cultural factors linked to the bioethical decision making in neonatal intensive care in Greece. *Results:* The process of cultural adaptation and implementation of the EURONIC research protocol is described while special attention is given to issues of entry to the field, recruitment, and informed consent procedures and ethics approvals as well as 'lessons learned' which could potentially inform further implementation of similar research. *Conclusion:* Despite the acknowledged need for relative research, this is the first research protocol for ethical dilemmas in neonatal intensive care in Greece.

Key words: Neonatal intensive care; Ethical dilemmas; Healthcare professionals; Greece.

Introduction

Preterm birth, an important complication of pregnancy, is linked, internationally, to increased likelihood of neonatal morbidity and mortality during the perinatal period. Thus, preterm birth is considered a key factor in understanding the etiology of fetal and neonatal fatalities [1-5]. Births of extremely preterm (< 28th week) or very preterm (28 to < 32 weeks) babies, with extremely low (< 1000 grams) or very low (< 1,500 grams) birth weight and births of babies with health problems continue to be considered inevitable despite the rapid developments of medical knowledge and technology in perinatal medicine and care. Furthermore, such births are followed by increased neonatal morbidity and mortality, long-term neurological, cognitive and behavioural disorders of children, and multiple hospitalizations [6-15].

However, epidemiological findings such as the above, raise significant bioethical dilemmas: a) Should life support of a neonate who is born at the limits of human viability or suffers from a serious disease and who, based on epidemiological data, is expected to die shortly, begin? b) Does such a newborn benefit, and to what extent, from provision of care which artificially extends their life while simultaneously causes pain and suffering? c) Does a newborn benefit, and to what extent, from the provision of "aggressive" intensive care when the prognosis for their survival or the development of a serious neurodevelopmental disorder is highly unfavourable? In other words, in cases in which the weighing between benefit and harm from the care provided is not clear and the balance between the two is easily overturned, a major bioethical dilemma is raised, a dilemma which further relates to issues of beginning and end of life: Should support of human life begin and continue at all costs and in all cases or should limits be applied to the invasive practices that keep newborns alive or should their health condition be left to take its course without interventions?

The difficulty in weighing benefit and harm in the provision of intensive care to extremely/very preterm babies, with extremely low/very low birth weight, and babies or newborns with serious health problems is intensified since it is not possible to positively determine: a) human viability, b) the exact diagnosis, outcome, and prognosis of a disease or the complications of extremely preterm birth and c) the effectiveness of the provided treatment and care [16].

Although medical decisions which touch upon the beginning and end of human life are always ethically challenging, they are not *per se* unique to the provision of neonatal intensive case. In the case of newborns, however, who have no way of formulating and expressing opinions and preferences, much less decide for their lives, as would be the case with adults for example, ethically charged "life

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and death" decisions weigh heavily upon healthcare professionals and parents.

Nevertheless, a commonly accepted approach to bioethical dilemmas in neonatal intensive care can neither be uniformly applied in all clinical cases nor is available among healthcare professionals. On the contrary, significant differences are recorded within respective guidelines, scientific recommendations, and national laws [17-19]. Furthermore, healthcare professionals' attitudes, opinions, and practices vary widely and tend to depend upon the structural, clinical, legal, financial, religious, historical, and cultural conditions of each country. Indeed, research shows that the country of origin is the most important differentiation parameter in bioethical decision making in neonatal intensive care [17, 19-21].

Nevertheless, in numerous countries, Greece being among them, healthcare professionals practice their work and take their bioethically challenging decisions in the face of absence of specific guidelines and legal provisions. It is further often the case that in numerous countries, issues of neonatal intensive care are not readily debated in public nor included as subjects of scientific research augmenting, thus, ambivalence and uncertainties in healthcare professionals' decision making [22]. Consequently, in countries in which regulation is limited and research is scant, as it is the case with Greece, research which investigates the dilemmas raised, the decision making processes, and the solutions adopted in issues of neonatal intensive care is of paramount importance. Equally important is the need for research findings comparable to findings of research in other countries. In order to fill these research gaps, a study was undertaken in order to investigate the way neonatal intensive care ethics concerns are conceptualized and addressed by healthcare professionals in Greece. The overall goal of the study was threefold: a) assess the ethical acceptability of clinical practices which set limits to the provision of neonatal intensive care, b) investigate the factors that delineate the ethical acceptability of such limitations, and c) provide an empirical basis for comparisons between Greece and other countries.

To better serve the purposes of this study, is was decided to use as the basis for the present study an existing, tested for its validity and reliability, internationally acknowledged research protocol such as the one used in the "*European Project on Parents' Information and Ethical Decision Making in Neonatal Intensive Care Units* (EURONIC): staff attitudes and opinions", an European Commission funded research program implemented in the period 1996-1997 in 11 countries [23, 24].

EURONIC's goal was to investigate ethical decision making in neonatal intensive care. Research undertaken in EURONIC addressed the social, cultural, legal, and ethical framework [25], as well as the attitudes, perceptions, and ethical decision making practices of Neonatal Intensive Care Unit (NICU) healthcare professionals in 11 countries [24]. Structural and operational organization of NICUs, the legal and regulatory framework and provisions, as well as scientific and professional associations' guidelines and directives, when available, were also addressed [23]. Consequently, EURONIC's research goals and the research goals of the present study were aligned.

EURONIC has been proven to be a rather influential research program. It has served as a methodological model for several international research projects [26-29], has contributed to the formation of guidelines [30] and even more so, to the scientific and policy discourse on the ethics of neonatal intensive care limitations and newborns/infants euthanasia [30, 31].

Implementing the EURONIC protocol allows the present study to generate data and findings from a country not originally included in the project comparable to data and findings from other countries. Furthermore, exploring the ethical decision making of Greek NICU professionals within the specific socio-cultural characteristics of Greek society (i.e. extended ethnic, linguistic and religious-Eastern Orthodox Christians-homogeneity) contributes to a more comprehensive mapping of neonatal bioethical dilemmas and decision making at the international level.

The purpose of the present article, thus, is to describe the different steps and procedures followed in the process of adjusting the original tools to the needs of the Greek study. To the extent that the Greek study aims at producing data and findings comparable to data and findings in other countries, this paper is aimed as a first step in establishing the basis of comparability.

Implementation of research protocol

The initial step in the implementation of the research protocol and the design of the study was the acquisition of permission to use EURONIC's data collection "tools". Specifically: the "Staff Questionnaire" consisting of the "Questionnaire for medical staff" and the "Questionnaire for nursing staff" and the "Unit Description Questionnaire". These questionnaires were used not only for the purposes of the EURONIC project [20, 23, 32-35] but in other international studies as well [26-28]. To better serve the goals of the present study, it was decided to adjust the EURONIC program questionnaires to the reality of Greek neonatal intensive care.

Pr. M. Cuttini, as the coordinator of the research program, was conducted and informed in writing of the study's aims and goals. Her permission was asked for the translation, cultural adaptation, and adjustment of the project's questionnaires to the institutional, clinical and cultural characteristics of Greece. Permission was given in writing and the English version of the original questionnaires were provided by Pr. M. Cuttini.

Translation and cultural adaptation of the questionnaires

Given the focus of the research on healthcare profes-

sionals, the guidelines for translation and cultural adaptation of questionnaires provided by the American Association of Orthopaedic Surgeons (AAOS) Outcomes Committee [36, 37] were followed. Thereupon, the six stages of the suggested procedure were implemented as follows: initially, each questionnaire was translated from English into Greek by two different healthcare professionals familiar with medical terminology in both languages. These persons were independently of one another (1st stage). The two translations of each tool were compared by the research team and the first version of each questionnaire in Greek was drafted (2nd stage). These drafts were then back-translated (from Greek into English) by two different healthcare professionals, other the persons mentioned above, who were not aware of the original English version of the questionnaires and worked independently of one another (3rd stage). Ambiguities in terms, and differences in rendering the meaning and content of the words were examined by the research team against the original English version of the two tools and decisions were made as to the most appropriate wording. Additionally, the internal structure and cohesion of both questionnaires was examined and decisions were made as to the instruments relevance to the Greek situation. As a result, 12 questions from the original "Unit Description Questionnaire" were included in the "Staff Questionnaire". These questions related to processes of providing information, announcing the prognosis/diagnosis to parents, and engaging them in ethical decision making, as well as convening of the medical team/board. Taking into consideration the possibility that NICUs as well as Hospitals may not have established standardized protocols that are followed in each and every case requiring intensive care, and aiming further at registering not only the actual procedures followed, but the way these procedures are perceived and affect ethical decision making for individual healthcare professionals, the present authors decided that such questions would be more accurately addressed if included in the "Staff Questionnaire". Consequently, the "Staff Questionnaire" used in this study contained a total of 70 questions (58 questions from the original "Staff Questionnaire" and 12 from the original "Unit Description Questionnaire"). On the other hand, the "Unit Description Questionnaire" developed for this study contained 39 instead of the original 51 questions, which related mainly to the number of births in each Hospital, birth weight, and number of admissions per year, number of shifts, on duty personnel, follow up after discharge, etc. At the end of this process, a second draft of both questionnaires was developed (4th stage).

The next step of the procedure of cultural adaptation of the research tools (5th stage) required testing each tool for cohesion, comprehension by participants and cultural interpretation of the translated terms, and the potential need for alternative formulations of the questions included. Consequently, the questionnaires were pilot-tested in a sample of healthcare professionals (five paediatricians and ten midwives/nurses) with experience in neonatal intensive care. These persons were not included in the study sample because they were working at NICUs which did not meet the study selection criteria. Pilot-test participants were asked to answer the questions and comment on the context, wording and meaning of the items and questions included in the questionnaires. The pilot implementation of the study tools contributed to the detection of errors and omissions and resulted in the amendment of the wording of ten questions of the "Staff Questionnaires", in order for the questions to be more understandable by research participants. Finally, the procedure as a whole, as well as, the final version of the data collection tools, were assessed and evaluated by 2 faculty members in the institution of affiliation of the second author of this article, acting as supervisors and consultants to the research (6th stage).

The need for a further adjustment to the "Unit Description Questionnaire" emerged, however, during data collection. Rarely if ever was the "Unit Description Questionnaire" as drafted, completed, and returned. Consequently, and in order to collect as accurate and reliable information as possible, even at the minimal level, on equipment and human resources a short Questionnaire, a new "Unit Description Questionnaire" was developed (in Greek) which contained seven questions referring mainly to equipment and personnel. This short Questionnaire was then answered by the Director of Supervisor of each of the NICUs in the sample.

Description of questionnaires

As a result of the previously described process, data collection in the current study was based on two different questionnaires: the "Staff Questionnaire" consisting of the "Medical Staff Questionnaire" and the "Nursing Staff Questionnaire" which was addressed to healthcare professionals, and the "Unit Description Questionnaire" which was addressed to the Director or the Supervisor of each of the Units included in the sample.

The final version of the Questionnaires for NICU staff, following the original EURONIC project tools adopted and adjusted for the needs of the current research is an anonymous, self-administered questionnaire surveying staff views, attitudes, and self-reported practices related to provision of neonatal intensive care. The "Unit Description Questionnaire" is also self-administered and completed by the NICU Director descriptive of the Unit.

"Staff Questionnaire" (for both, the Medical Staff and Nursing Staff) is divided in five parts. In the first part, information on the professional profile of participants is collected. Respondents are asked questions related to their current position, work and professional responsibilities, experience, and potential engagement with research activities.

The second part of the questionnaire records healthcare professionals' views on the ethics issues raised in the pro-

vision of neonatal intensive care and their attitudes towards withholding or withdrawing intensive care overall, as well as in cases with specific medical characteristics. Furthermore, in this part of the questionnaire participants are asked to assess the practices and procedures followed in the respective Unit regarding the decision making process, the involvement of parents in decisions about withholding or withdrawing care to neonates. They are also asked to assess the existing regulation and provide their views on potential need for regulatory changes. Most of these questions are Yes/No questions or questions in which participants are asked to select from among a list of provided statements. A number of statements describing specific ethical positions such as the value of human life, the worth of life with disabilities, the cost of health care services, the relation between ethics, and legal regulation are also included in this section. Respondents are asked to state their agreement or disagreement to each of these statements on a five-point Likert scale.

In the third part of the questionnaire healthcare professionals are asked to describe the course of action they would select if they were required to treat specific cases. Respondents are provided with a short description of three clinical cases (a vignette) and statements on the potential course of action from which they have to select. Case studies relate to intensive care provision to: a) extremely preterm newborns, b) full term newborns with unfavourable prognostic information due to severe perinatal asphyxia, and c) newborns with severe congenital anomaly (of physical and not mental nature). The case scenarios follow those provided in the original EURONIC project [23].

In the fourth part of the questionnaire the participants are asked to share personal experiences by recalling specific cases in which they were directly or indirectly involved and which raised ethical concerns. For these cases respondents are prompted to report on the decision making process and the actions taken. Socio-demographic characteristics of participants are recorded in the fifth part of the questionnaire.

The "Unit Description Questionnaire" developed for the needs of this study included only questions soliciting information and documenting technical characteristics (equipment available e.t.c.) and human resources at each of the NICUs in the sample.

Population and sampling

Two different populations were of interest in this study: NICUs operating in Greek Hospitals and healthcare professionals (medical doctors, midwives, and nurses) working in these Units. Based on education, training, work and professional rights and duties, the above mentioned healthcare professionals are directly involved in the provision of neonatal care and thus, critical decision making related to it. In other words, healthcare professionals working in NICUs are the professionals most likely to face bioethical dilemmas in the provision of neonatal intensive care. Additionally, and to the extent that the context in which healthcare professions provide neonatal intensive care is hypothesized in this study to play an important role in the content of bioethical dilemmas and in the solutions to these dilemmas, studying the immediate structural environment, the NICUs, is a mandate for the purposes of this study. Consequently, two different sampling procedures, different for each population were followed. These procedures are described below.

NICU sampling: Following the EURONIC protocol implemented in the case of small countries [23], it was decided that all public hospitals of the country with an operating NICU were to be approached and asked to participate in the study. A readily available list of NICUs did not exist at the time research tool place and had to be developed. In response to a written request to the Ministry of Health official data were provided. Additional information and clarifications related specifically to NICUs operating in University Hospitals were needed and these necessitated personal on-site visits to the Ministry of Education & Religious Affairs. The above process resulted in a list of 21 Hospitals with a "Preterm Unit" and nine with a "Specialized NICU".

The terms "Preterm Unit" and "Specialized NICU" are literal translations of the Greek terminology used to describe Hospital Units providing neonatal care and/or neonatal intensive care. The terminology and the related classification deviates, at least to some extent, from the international standard terminology and classification of such Units. Consequently, and in order to apply inclusion criteria in a reliable and comparable way, the level of care provided in each of these Units needed to be clarified and confirmed.

Directors (or acting Directors as the case was in a number of the Units) were contacted by telephone and asked to clarify, verify, and provide details in relation to the care provided in their Units and the equipment and human resources available in their Units. Getting in touch with these persons and obtaining all the necessary information required, in almost all of the cases, repetitive attempts and numerous telephone discussions, and follow ups. During this prolonged, time and effort consuming process, which further dictated special attention to matters of assurance and trust, it was revealed that inconsistencies existed between the information officially registered with the relevant Ministries (for example: type of care provided and availability of technical and human resources) and the reality of operation of NICUs. Although in varying degrees, such inconsistencies and deviations were anticipated and observed in the implementation of the EURONIC project in other countries as well [23]. At the end of this process, a final list with detailed, accurate, and up-to-date information on the care provided, the equipment and the human resources available in each Hospital Unit in the country in which neonatal care is provided was generated. This list was used for the implementation of the inclusion criteria.

To be included in this study, a NICU had to meet the following criteria: 1) capacity to provide routine care to newborns with extremely low/very low birth weight (< 1,500 grams): at least 20 admissions per year, 2) capacity of mechanical ventilation provision, if necessary, 3) availability of neonatologists/paediatricians 24 hours a day on duty in the Unit, and 4) no transfer of babies to other higher level units for medical reasons [23].

Inclusion criteria were met by 17 NICUs which offered tertiary medical care to newborns and belonged to 15 National Hospitals. Thus, 17 NICUs were retained. All Units agreed to participate in the research. Consequently, in Greece, similarly to other countries included in the EURONIC program (e.g. Luxembourg, the Netherlands and Sweden) all NICUs which met admission criteria were included in the study.

Healthcare Professionals' sampling: An exhaustive list of all healthcare professionals working in each of the 17 NICUs included in the sample was prepared based on information provided by the Heads of Units. For reasons of convenience (mainly accessibility), it was decided to exclude from the list all personnel who for any reason was on leave of absence. This process resulted in a total number of 495 healthcare professionals (medical doctors, midwives, nurses) who during the time of data collection were working at the selected NICUs. These, constituted the pool of potential participants. Each of these professionals were invited to participate in the study. Of these, 251 (71 doctors, 98 midwives, 82 nurses) responded positively (response rate 50.7%) and constituted the sample of the study. Recruitment of participants, data collection processes, as well as informed consent procedures, confidentiality issues, and issues of entry to the field are discussed in the following section.

Entry to the field, recruitment and ethics

The subject of the current study, ethical decision-making in neonatal intensive care is *per se* a sensitive issue. The fact that participants are asked to recall specific cases and report their own actions undertaken within the context of their professional responsibilities as staff members of specific organization units increases the sensitivity of the matter. Furthermore, research took place in organizational units with rather controlled, if not restricted access, allowed only to few and identifiable persons (i.e. parents, the unit's medical and nursing staff), hierarchically structured, further integrated in a larger organization such as a Hospital. In that respect, the daily operation of these Units could potentially be disrupted by the presence of 'outsiders' such as a researcher. Consequently, the current study raised a number of ethics concerns which needed to be carefully observed: entry to the filed (i.e. approvals and permissions to carry out research in each of the hospitals and each of the NICUs), participants' informed consent, protection of respondents' identity, non-identification of participating NICUs. Confidentiality issues were particularly pronounced in the current study to the extent that respondents were asked to recall specific actions and potentially reveal sensitive information regarding their personal actions, other healthcare professionals' actions, and overall Unit practices which even carried the potential to be on the limits of legal and ethical acceptability. Of paramount importance, thus, was on the one hand to safeguard ethics issues, and on the other to establish and maintain relationships of trust between the researcher, participants, and participating organizations.

As a first step, a formal request of approval and permission to entry the field and contact research was submitted in writing to the Administrative Board and the Scientific Committee (the bodies responsible to approve research ethics and allow access to Hospital premises for research) of each of the 15 Hospitals which met the inclusion criteria. One of the Hospitals required additional clarifications which were provided to the President of the Scientific Committee of the Hospital through telephone. All 15 Hospitals approved the research in writing.

As a second step, permission to conduct research was sought from the Directors of the NICUs included in the sample. Explicit consent and permission from the Directors of NICUs was a *sine qua non* condition in implementing the research and in adhering to principles of research ethics for a number of reasons. First, the Committees' permission did not cover Directors' approval to conduct research in the Unit. Second, given that the research addresses issues related directly to the operation of each Unit, Directors could be hesitant in allowing such research to take place. Consequently, their consent and approval was necessary. Third, their full and without reservations consent and approval of the research was a necessary safeguard against potential undue pressure to staff members to either participate or not participate in the research. Thus, each of the NICUs Directors was briefed orally, in person, for the goals of the research, the way it was to be carried out and the handling of research ethics issues. During the briefing questions asked and concerns raised by the Directors were answered and addressed. At the end of the briefing session an information letter containing all relevant information was handed to the Directors. In a number of instances, a follow-up telephone briefing was held to provide further clarifications as required by Directors.

As mentioned above, a prerequisite of this study was to create and maintain a milieu of trust, reliability, and security, which would allow every healthcare professional to fully and genuinely consent to participate in the study after being thoroughly informed. Towards this goals, personal communication and availability of the researcher, to provide detailed information, answer all questions and give all assurances of confidentiality, and identity protection was of paramount importance. Thus, to the extent possible, each Unit's personnel (except those on leave) was contacted in person, on site, by the first author of this paper, was briefed

on the research and handed an information sheet detailing the purpose and objectives of the study, the content of their participation, the process of data collection, as well as the method of protecting their identity and ensuring the anonymity and confidentiality of their data and opinions expressed. Additionally, potential participants were provided with the informed consent form, the questionnaire to be completed, and a return envelope with no distinguishing or identifying marks.

When personal contact was not possible, given rotations, distance, and location of Unit, the information sheet, the informed consent form, the questionnaire, and the return envelope was handed to potential participants by the NICU Director or the Head Midwife/Nurse of the Unit. The information sheet contained contact information of the person each potential participant could contact for further clarifications.

Questionnaires were self-administered, anonymous, and they included no indication of the participant's identity. Respondents were further instructed not to mark any personally identifying information on the questionnaire. After completing the questionnaire, they were instructed to include the questionnaire and the signed consent form in the envelop provided and seal the envelop. In order to facilitate data collection, a person responsible for collecting the completed questionnaires was identified in each Unit. All such persons were instructed not to open the sealed envelopes. All return envelopes were received sealed and intact. Upon reception each questionnaire was assigned a serial number and a code indicative of the NICU to which the participant worked. In addition to the above, statistical analysis of the data was performed for all NICUs combined and in aggregate form. Similarly, an in accordance with the information provided to the participants, findings were to be presented only in aggregate form and no mention was to be made to individual participants' professional position, gender or any other identifying characteristics. Furthermore, under no circumstances were references made to be specific, identifiable NICUs. Furthermore, in order to guarantee protection of participants' identities even in the original EURONIC questionnaires, collection of socio-demographical data was scarce. Finally, the lists provided by the NICU Directors, the signed informed consent form, and the NICU codes were kept separately from the questionnaires in a locked cabinet to which only the first researcher had access.

Discussion

Survival of extremely/very preterm newborns with extremely low/very low birth weight or of full term babies suffering from a serious disease/congenital anomaly is precarious and even today morbidity rates are still high. Lack of precision in predicting the long term consequences of prematurity or determining the potential adverse impact of intensive neonatal care [16] in many cases renders the balance between benefits and harms very difficult. Combined with the epidemiological reality of prematurity, these uncertainties raise significant bioethical dilemmas with regards to initiation, continuance, and withdrawal of neonatal intensive care. Healthcare professionals involved in the provision of neonatal care are frequently faced with these dilemmas in their everyday professional life. International empirical studies, however, show that neither a single nor a commonly accepted approach is available for healthcare professionals to implement and follow. On the contrary, a multitude of approaches and even guidelines and recommendations exist while the particular legal, economic, religious, historical, and general cultural conditions of every country appear to impact significantly upon the content of the dilemmas, the decision making process, and on the solutions provided to ethical concerns raised in the provision of intensive care to neonates.

Unlike other countries in which issues of neonatal intensive care are debated and documented, such matters have received only scant attention in Greece. Similarly, clinical practices involving bioethical decision making in the provision of neonatal intensive care have not been recorded as part of a study to date.

To fill this gap, a study was designed which, for the first time in Greece, records: a) the bioethical concerns raised in neonatal care of babies suffering from serious diseases or born at the limits of human viability, b) bioethical decision making processes related to persons (neonates) who, by default, cannot formulate and express an opinion much less make decisions for themselves, c) clinical practices of neonatal intensive care, d) healthcare professionals' views and attitudes on the ethics and the practice of neonatal intensive care, e) their moral stance towards the value and quality of life, f) the impact of the social, cultural, ethical and legal framework upon critical decision making in relation to initiating, continuing, limiting, withholding or withdrawing invasive practices, and g) the moral and ethical assessment of such practices.

In addition to mapping the landscape of provision of neonatal intensive care in the country, this study further aimed at providing data and findings comparable to other countries with the further aim of contributing to the broader scientific research and debate of the issue. To meet the above goals, an existing, tested for its reliability and applicability in numerous countries, research protocol was implemented. The EURONIC research protocol, thus, was adjusted to the socio-cultural characteristics and care provision realities of the country. Additionally, the majority of NICUs in the country were included in the study and almost all healthcare professionals (with the exemption of those on leave) serving in these were invited to participate in the study aiming at compiling a sample as representative as possible. The process of adjusting and implementing this research protocol is detailed in the present article. This way, on the one hand, the validity of the current study can be as-

sessed while on the other "lessons learned" in this process become available for consideration in future similar research at country and international level.

Issues related to public administration were among the first to show their importance in the implementation of the research design. The fact that various types of hospitals and for varying functions fell under the jurisdiction of different Ministries impacted on the accuracy of the available data related to equipment, human resources, and operation of NICUs. Thus, relevant data on NICUs not only had to be collected and compiled through a multitude of avenues (use of provided data and personal communication with administrative staff of various Ministries), but required further clarification and verification at Unit level in order to safeguard accuracy of NICUs' sample selection.

The Head of Units' stance was also of critical importance to the implementation of the research. Although none denied access to the Unit and a number of them facilitated in various ways data collection, their availability to answer specific questions about the operation of the Unit was very limited. Because of that, the "Unit Description Questionnaire" of the original study was restricted to containing only minimal operational information. Although an undeniable prerogative of all research participants, the lack of response by the Head of Units may be linked to operational issues rather than personal decisions. It may be the case for example that their work load, time constraints, and level of responsibilities, common to all, defined their availability and level of commitment to research participation and facilitation. At the same time, however, this observation reaffirms the importance of keyholders in research implementation as well as the dynamic nature of research design and implementation.

Issues of entry to the field and gaining trust from participants and organizations have been addressed in the detail in the sections above. Still however, it is important to note that these issues are of particular importance in cases where multiple levels of organizational hierarchies are involved as is the case in this research. Furthermore, issues of trust are of particular importance in research addressing subjects participants are not familiar with (this research is the first on the issue in the country) and at the same time touch upon sensitive issues. The researcher's personal communication, explanations, and reassurances have often, in the context of this research, proven critical in recruiting.

Conclusion

The issue of neonatal intensive care has not been investigated until now in Greece, despite the fact that a number of healthcare professionals involved in its provision face critical, ethical dilemmas as part of their everyday professional life. The present study aims at filling this research gap and providing not only a mapping of the situation in the country but also data and findings comparable at the international level.

Among the contributions of this study is further the fact that it is based on a population with cultural characteristics not previously addressed in similar studies. That is, the traditionally rather strong religious affiliation to Orthodox Christianity as is the case in Greece. It is more than likely that decision making touching upon the beginning and end of life is strongly and related to assessments over the value of life and/or quality of life are strongly influenced by religious dogmas. Furthermore, this study takes place during the country's severe economic crisis. It is likely that the new economic reality impacts significantly upon health care provision decisions. This study aspires to provide the international scientific discussion on bioethical decisions relating to neonatal care with empirical data from a country with different cultural background compared to the rest of the countries having presented similar data to date. The different steps followed in the implementation of the research design which allows the collection and analysis of these data have been presented in this paper in order to provide grounds for validation and potentially facilitate further implementation at country and international level.

Notes

This research was partially used for the fulfilment of requirements for a Doctoral Dissertation in the Bioethics Post Graduate Programme of the University of Crete. Members of the Dissertation's supervising committee acted as supervisors and consultants of the research during the development of the methodology, the adjustment of the questionnaires, and partially the data collection process.

Based on the information provided by NICUs' Directors, it was found that babies from almost all Units in the country are transferred to the NICUs of the country's major Paediatric Hospitals located in Athens for major surgeries and screening or in the event the peripheral Units exceed their capacity. Strictu senso then, only two of the country's NICUs met this fourth criterion. Nevertheless, on the one hand the way Cuttini *et al.* [23] define this criterion allows for certain exemptions to the 'no-transfer of babies' rule. On the other hand, if this criterion was applied in a very restricted way then only two NICUs could be retained in the sample. This would further mean that the number of healthcare professionals from which the sample would be selected would be reduced, as well compromising thus, the reliability of statistical analysis and potentially research confidentiality.

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