The paper introduces the multidisciplinary HUNIC project, which is partly based on the EURONIC study. The objective of the HUNIC study is to assess the attitude and opinion of healthcare providers in Hungarian NICUs about end-of-life decisions, the decision-making process, parental communication, to analyse the differences between HUNIC results in 2015-2016 and EURONIC results in 1996-1997, to compare the attitudes of neonatologists and neonatal nurses, and to identify factors that might affect those attitudes and opinions. A further important objective of the HUNIC study is to compare these attitudes and opinions of neonatal care providers with their personal work experience, educational background in the bioethics field, social support, work and life satisfaction, burnout, health behaviour and psychosocial health. This paper aims to present the methodology of an extensive, complex, and multidisciplinary survey (HUNIC) within the framework of the EURONIC.

**Keywords:** neonatal intensive care, ethics, end-of-life decision making, well-being of health workers, study design

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1. Introduction

Preterm birth and infant mortality rates are commonly used indicators of a country’s social and economic development, while the perinatal mortality rate may indicate the quality of perinatal care, as well (Kim & Saada 2013).

Parallel to the rapid development of medicine and, in particular, the practice and technology used in obstetrical and neonatal care, such as the application of antenatal corticosteroids, surfactant, and sophisticated ventilation techniques, the mortality rates of prematurely born infants have significantly dropped (Goldenberg et al. 2008; Saigal & Doyle 2008; Crump et al. 2011) and survival rates of very preterm (i.e. <32 weeks of gestational age) and extremely preterm (i.e. < 28 weeks) infants have increased in high-income countries (Blencoe et al. 2012; Costeloe et al. 2012). Mortality rates for very preterm infants differ across European regions (Sereni et al. 2014), but regional variation was not explained by the variation in very preterm stillbirth rates (Draper et al. 2017).

The percentage of premature births in Hungary in 2010 was 8.9% of the total livebirths; the preterm birth rate in Hungary has changed relatively little in the past few years (Balla & Szabó 2013).

In a seminal paper published in 1982, Campbell stated that the withholding or withdrawal of treatment is a complex question, as it does not only raise medical, but also legal, ethical, and moral dilemmas (Campbell 1982). Subsequently, several studies examined the issue of resuscitation of babies with extremely low gestational age and/or birth weight by surveying both doctors and parents. (Ambrósio et al. 2016; Duffy & Reynolds 2011; De Leeuw et al. 2000)

The EURONIC (European Neonatal Intensive Care) study was the first to explore ethical decision-making in a large representative sample of Neonatal Intensive Care Units (NICUs) in 11 European countries (Estonia, France, Germany, Hungary, Italy, Lithuania, Luxembourg, the Netherlands, Spain, Sweden, and the United Kingdom) in 1996-97 (Cuttini et al. 1997). The objective of the EURONIC project was to study and compare parental visiting, communication, and participation in the ethical decision-making process in NICUs in relation to the social, cultural, legal, and ethical backgrounds of the participating countries. The EURONIC study structured questionnaires to record data on the organization and policies of the NICUs (Unit Description Questionnaire) and to measure physicians’ and nurses’ opinions, attitudes, and practices (Staff Questionnaire) (Cuttini et al. 1997). The main results of this study suggested that attitudes of physicians and nurses varied widely among countries and that legal, ethical, religious, and cultural issues also played an important role in neonatal ethical decision-making. Country-specific factors were more relevant than characteristics of individuals or NICUs (Duffy & Reynolds 2011; Rebagliato et al. 2000; Cuttini et al. 2004). Compared to colleagues in other countries, Hungarian physicians appeared less willing to limit intensive care for ethical reasons and to involve parents in decision-making. Similarly to Italian and Estonian physicians, when confronted with the birth of

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a depressed 24 weeks’ preterm infant, Hungarian doctors (45%) would resuscitate and start intensive care even if they knew that, once started, intensive care would not be withdrawn whatever the prognosis (Duffy & Reynolds 2011). More recently, EURONIC was replicated in Ireland (Samaan et al. 2008) and partially in Turkey (Bilgen et al. 2009).

Clinicians, ethicists, philosophers, lawyers, and politicians have been debating neonatal decision-making issues, but agreement is difficult to achieve. In the last decades, however, the opinion of parents has acquired prominence and, besides this, researchers tried to include aspects such as the proper use of medical technology (availability of resources), law, and social attitudes (Balla & Szabó 2013; Rebagliato et al. 2000; Cuttini et al. 2004; Samaan et al. 2008; Bilgen et al. 2009; Cuttini et al. 1999; Orzalesi 2010; Orzalesi & Cuttini 2011; Einaudi et al. 2013).

The practice of neonatal intensive medicine, and especially end-of-life care, poses many ethically and legally difficult situations that can increase staff work related distress, together with factors such as workplace policies, resources, expectations and climate (Oh & Gastmans 2015; Prentice et al. 2016; Larson et al. 2017; Chuang et. al. 2016; Mohammadi et al. 2016; Dodek et al. 2016). For nurses, professional autonomy can be an important issue, but increasing professional autonomy may lead to increased moral distress (Sarkooj Jabalbarez et al. 2017).

Despite the important changes in the Hungarian healthcare system since 1989, including a reformed health insurance system, the increased presence of high-quality private health care, a new and comprehensive healthcare act resulting from fundamental political, social, and economic changes, there are still many inherited problems (e.g. lack of tools and equipment, paternalism in healthcare), as well as new ones such as heavy and stressful workload, very low staff salaries, and shortage of healthcare workers. These difficulties may intensify the psychological and somatic symptoms of burnout among Hungarian health workers (Piko 2006; Feith et al. 2008; Kovács et al. 2010; Győrfy & Adám 2013; Győrfy et al. 2014; 2016).

In Hungary, no recently published data on the neonatal staff’s attitudes or opinions regarding neonatal ethical decision-making are available, despite the fact that Hungary enacted the Hungarian Act CLIV of 1997 on Health (HAH; 1997. évi CLIV. törvény), which comprehensively sets forth the rights of patients. The HAH rules narrow patients’ rights, e.g. the right to self-determination, the right to be informed, the right to refuse health care, the right to become familiar with their medical records, and the right to file complaints in a protective legal system; but the Hungarian health care system is still not ready for this legal reform. Because of this, the number of medical malpractice lawsuits against healthcare providers has considerably increased. Act V of 2013 in Hungarian Civil (2013. évi V. törvény a Polgári Törvénykönyvről) Code implies stricter rules, because healthcare providers’ opportunities to be exempt from legal proceedings have become limited by the new law (Bárzó 2015).

On the one hand, our study, the Hungarian Research Project on Ethical and Legal dilemmas in the practice of Neonatal Intensive Care Units (HUNIC), focuses
on legal and ethical decision-making in Hungarian NICUs, which is still a current issue in special cases where medical treatments cannot achieve a favourable patient outcome. This question is especially interesting because of the changed legal (HAH) and healthcare environment. Withholding or withdrawing life-sustaining therapies in neonatal care are forbidden by Hungarian legal norms, and therefore, physicians have no opportunity to make end-of-life decisions with or without parents in a fatal or severely brain-damaged status. HUNIC studies social support, work and life satisfaction, burnout, health behaviour, and psychosocial health by relating them to moral and legal dilemmas due to serious work-related moral distress.

The HUNIC studies have some unique characteristics:

1. To our knowledge, there was no national study using the same questions on neonatal ethical decision-making at different points in time (1996–97 and 2015–16) to explore changes in attitudes and views of the healthcare personnel, and then distributed to all Hungarian neonatal staff in NICUs III.
2. In the HUNIC study, the use of standardized questionnaires exploring different aspects of the professional and personal life of responders will allow an in-depth exploration of the factors influencing ethical opinions and a better understanding of the relationship between ethical decisions and professional burnout.

This paper aims to present the methodology of our extensive, complex, and multidisciplinary survey (HUNIC) within the framework of the EURONIC.

2. Objectives

The main objective of the HUNIC study is to assess the current attitudes and opinions of the healthcare providers in Hungarian NICUs about end-of-life decision-making and compare these results with those obtained in the same country by the EURONIC project in 1996–97. Additionally, we aim at describing the work-related stress of the NICU staff and exploring its relationship with decision-making attitudes and experiences.

3. Methods

3.1. Sampling and sample size

Our target nationwide research population included neonatal physicians and nurses in Hungarian NICUs. As with EURONIC, so also the HUNIC study focused only on the highest level NICUs (level III NICUs), since they encounter the highest number of high-risk infants in their routine care.

All Hungarian level III NICUs (20 units) were invited to participate in the HUNIC study in 2015/16, and all of them accepted the invitation (Figure 1).
The 16 NICUs that participated in EURONIC are included in the HUNIC study, but some of the original 16 NICUs have been closed since 1996-97 and new ones were established.

For both studies, all part- and full-time physicians (N = 183) and nurses (N = 462) were asked to participate (not including staff on pregnancy, maternity, longer health or training leave). Table 1 shows the response rates by time of data collection and professional role.

Table 1
Respondents and responses rate in level of NICU III and the year

| Year     | Level of NICU (Total number of NICUs in Hungary) | Number of respondents and response rate | Number and proportion (%) of staff |
|----------|-------------------------------------------------|----------------------------------------|-----------------------------------|
|          |                                                 | No. of respondents                     | Doctors                           |
|          |                                                 |                                      | Nurses                            |
| 1996-97  | Level NICU III (16 NICUs)                       | 120                                    | 213                               |
|          |                                                 | 94%                                    | 90%                               |
| 2015-16  | Level NICU III (20 NICUs)                       | 111                                    | 284                               |
|          |                                                 | 61%                                    | 61%                               |
The information collected at each participating NICU III included the number of intensive care beds, the annual number of total and VLBW admissions; the mortality rates of infants with birth weight less than 1500 grams/year and NICU III with birth centre and/or surgeon.

3.2. Research instruments

We used a self-administered -structured questionnaire with mostly closed-ended and some open-ended questions to survey the attitudes and practices of the health care personnel. The questionnaire included selected sections of the EURONIC questionnaire in the original Hungarian version, and was complemented by a set of validated standardised scales (Beck & Beck 1972; Bech al. 1996; Caldwell et al. 1987; Appels & Mulder 1988; Table 2).

Table 2
Standardized scales which were used for the HUNIC study

| Standardized scales in the HUNIC study |
|---------------------------------------|
| • Beck Depression Inventory–Short Form (39) |
| • WHO (Ten) Well-Being Index (40) |
| • Social support (41) |
| • Fatigue Symptom Inventory Interference Scale–Short Form (42) |

Overall, the HUNIC questionnaire included the following parts:
1. Basic socio-demographic information: sex, age, marital status, length of partnership, number of children, intended child in future, religion, preterm infant in the family (14 items).
2. Work experience and career: special qualification, work status, part-time job and work experience in health care and in neonatal intensive care (8 items).
3. Communication, graduate and postgraduate experience, mourning practice (13 items).

We asked responders whether palliative therapy, breaking bad news, helping to die, and mourners had been part of their graduate and postgraduate training and whether the respondent felt that he/she had sufficient knowledge in these areas. These questions were part of a former research carried out in Hungary among doctors, nurses, and medical students. (Hegedűs et al. 2001; 2002). We also asked about the degree of emotional burden caused by breaking bad news (Otani et al. 2011). We complemented the HUNIC
questionnaire with the open-ended question on mourning practice, about remembering a perinatal loss (e.g. light a candle for the child) in NICU.

4. Selected parts from EURONIC Staff Questionnaire (103 items):
   a) Staff attitudes, opinions, feelings about non-treatment decisions in neonatal intensive care; role of parents, physicians, nurses, ethics committees and the law; desirability to change current legislation and/or to issue specific guidelines; and
   b) Three case histories regarding: 1) extreme prematurity (revised because of elapsed time with gestational age of 23 weeks (compared to 24 weeks), and heart rate 40/minute without spontaneous breathing as additional information; 2) severe asphyxia in a term baby (including of a hypothermia treatment in the first three days and MRI examination as added information); and 3) severe physical congenital malformation with no brain involvement (CUTTINI et al. 1997).

5. Respondents’ self-reported health, health and risk behaviour, social support, well-being, depression (77 items):
   a) The following – self-constructed – questions were included in the HUNIC questionnaire, all measured on a five-point Likert-type scale:
      • How often do you consider changing your field of work due to emotional stress in the workplace?
      • Typically, after how much time do you become emotionally attached to the neonate or suffer distress because of the condition of the patient? (five-item scales – where 1: less than one day; 2: one-three days; 3: four-seven days; 4: more than one week; 5: no emotional attachment to a patient).
      • Health/risk behaviour, well-being of respondent in terms of daily routine (wake up rested; awareness of health-damaging behaviours; healthy diet; have a breakfast regularly; eat at least four times a day; optimistic about his/her day); doing sports regularly; taking psychoactive substances (sedative; barbiturate; cigarette; coffee; painkiller; energy drink; alcohol).
   b) Professional difficulties in their private life and work by family life cycle theory (FRANZORI 1976), crisis theories (AGUILERA & MESSICK 1974), family system theory (SEGDWICK 1974), including: financial problems, choosing a partner, partnership problems, difficulties with planned child/children, childrearing problems, conflicts in the workplace based on family difficulties, family conflicts based on work difficulties, career plans, professional tasks, studies, conflicts with colleagues and the leader, conflicts with a family member of a patient.
   c) Satisfaction with personal life situation as a wife/husband/partner, as a colleague, as a family member providing financial background to their family, and as a man/woman who has a healthy lifestyle – factors which are based on the theories of role model and family pattern
impact on behaviour (Godé 1981) and social support system theory (Welch 1987).

d) Standardized scales (Beck & Beck 1972; Bech al. 1996; Caldwell et al. 1987; Appels & Mulder 1988).

e) Social or and professional support by NICU colleagues with possible discussion because of neonate loss, mourning, near-death dilemmas, different professional opinion of neonate’s treatment, and choice of communication method with the patient’s relatives (three item scales – where 1: yes, every time; 2: yes, sometimes; 3: never). The types of discussion: official meeting with several colleagues, official meeting with head, official meeting with a colleague, private conversation with the head in the workplace, private conversation with a colleague in the workplace, unofficial meeting with colleagues in a private place, informal conversation with parents, informal conversation with laymen, friends (three-item scales – where 1: yes; 2: no; 3: not every case).

4. Data collecting procedures

Data collection for the HUNIC study was conducted between April 2015 and January 2016 using printed, paper-based questionnaires that were distributed to all Hungarian neonatal staff in NICUs III (N = 645). The questionnaires were anonymous.

The questionnaires were distributed in blank envelopes that were sealed after completion of the questionnaire. The local coordinator was not allowed to open the sealed envelopes to read the questionnaires, nor was any other person from the NICU. The data are to be presented only in aggregated form and neither single respondents nor the units will be identified in any report.

Completion of the questionnaire was taken as indication of consent to use the data. The Research Ethics Committee of the Hungarian Medical Research Council approved this study (No.: 9991-3/2015/EKU (62/2015.).

5. Methods, statistical analyses

Ordinal and multinomial logistic regression will be used to test the associations of socio-demographic characteristics with ethical and legal issues measured by the survey. Odds ratios (ORs) and 95% confidence intervals (CIs) will be obtained to estimate effect strength for each variable to the target variable. R statistical software (3.4.1) and IBM SPSS Statistic (v20) software will be used for analyses.

We will also apply the network-based Bayesian multilevel analysis of relevance (BN-BMLA) method to model the complex interdependencies of all variables by estimating a posteriori probabilities of direct relationships between them (Antal et al. 2014). The complex model is represented by a directed graph whose nodes are the variables and whose weighted edges correspond to the direct relationships between
the given variables. The weight of the edges is the posterior probability of the corresponding direct relationship.

6. Discussion

In the last twenty years, advances in neonatal medicine have dramatically improved neonatal survival. Still, despite the survival of an increasing number of preterm infants, several of them suffer from long-term impairments, which is a huge challenge for neonatal providers and infants’ families, as well. The ethical dilemmas, the conflict with legal norms associated with withholding/withdrawing treatment are evident.

Hungary enacted the new healthcare law in 1997, after the EURONIC survey. The new regulations of health care in the post-socialist transition resulted in enormous changes in the attitudes and roles of patients, relatives, and health professionals. The physicians’ fears of malpractice lawsuits, the practice of defensive medicine, the role of the media, and the everyday difficulties in the health care sector may create a negative impact on health workers’ mental well-being and everyday life. In this changed situation, our main question is whether these new frameworks have affected the attitudes reported by NICU physicians and nurses in the last two decades.

The limitations of this study should be acknowledged. Although all Hungarian level III NICUs’ staff were invited to take part in the HUNIC study and the response rates are appropriate to reach correct conclusions, there are differences in response rates between EURONIC and HUNIC studies. Although we did not focus on examining the possible causes of response rate differences, a trend in the last decade towards decreasing response rates in research has been reported in other countries as well (BILGEN et al. 2009; BARUCH & HOLTOM 2008; KLEIN et al. 2017) An additional explanation may be that the HUNIC study included a larger number of questions compared to EURONIC.

We feel that neonatal clinical areas benefit from the comparative results and our study may lead to the development of new common guidelines and special multidisciplinary courses for neonatal providers.

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