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Ethics of developing autonomy in child healthcare – International and European perspectives

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DISSERTATION

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Chapter 1

Introduction

1.1. Context of the study

1.1.1. Teaching ethics in paediatrics and the emerging issue of developing autonomy in child healthcare

Not long time ago, until the early 1980s, instructing physicians to apply moral principles in their clinical work was regarded as irrelevant and even counterproductive. Medical ethics as a discipline was not to taught during their trainings. Teaching ethics to medical students, medical residents and physicians in general though, is essential for their clinical and scientific practice (Perkins, 1989, AAP, 2010).

Although ethics teaching is widely included in undergraduate medical curricula, it rarely exists in resident programs (Deonandan and Khan, 2015). Surveys among paediatricians and residency program directors in Canada and the USA underlined the importance of including medical ethics education in the clinical residency, as well as the lack of training in the current curricula (Kenny et al., 1998, Lang et al., 2009, Kesselheim et al., 2016). Increased patient and health professional movement has pointed out the importance of harmonization of medical curricula, including the teaching of ethics (Waltz et al., 2020, MacPherson and Emberley, 2017).

As pointed out by Edmund Pellegrino, a well-known bioethicist and one of the founding fathers of modern clinical ethics, teaching medical ethics to clinical residents should not only aim to develop behavioural and cognitive skills but also support character development (Pellegrino et al., 1990), emphasizing the importance of recognizing and addressing the principles of “respect for autonomy” and “beneficence” in the daily practice (Pellegrino and Thomasma, 1987). This aspect is also crucial in teaching paediatric residents, a group of physicians who are focusing on the healthcare of developing patients with varying interests, current and prospective, and a varying degree of autonomy as well as skills, decision-making competencies, cognitive skills, and legal competence associated with their developing character (Pellegrino and Thomasma, 1987, Sulmasy, 2014).

Aside from Pellegrino’s influential account of medical ethics, the so-called “four principles” approach is well established in medical ethics. Combining the most popular ethical theories, the approach of Beauchamp and Childress provides a frame for physicians to explore problems and ethical dilemmas holistically from different angles. These include the “principle of respect for autonomy”, the “principle of beneficence”, the “principle of non-maleficence” and the “principle of justice” (Beauchamp and Childress, 2019).

The “principle of respect for autonomy” grants patients competence, freedom of choice and the right to promote decision-making and self-determination (Beauchamp and

Childress, 2019). Examples from our everyday life include informed consent, as well as consideration of the will, desires, goals and values regarding a curative or preventive treatment. For instance, treating chronically sick patients according to the WHO International Classification of Functioning Disability and Health scheme, follows an autonomy-oriented paradigm of care, emphasizing the importance of social participation and including the child, actively in the decision-making making processes, regardless of age or competence (WHO, 2007, WHO, 2001).

The "principle of non-maleficence" demands that harmful interventions shall be avoided and presents, in combination with beneficence, the core of the Hippocratic philosophy (Gibson, 2016). An example of expression of this principle is the refusal to receive haemodialysis, when the patient is suffering from a severe, life-threatening chronic disease, taking into account the side effects of the treatment. On the other hand, the "principle of beneficence" underlines the duty of care, obliging the practitioner to act in the patients best interest (Beauchamp and Childress, 2019). These principles, which may often appear in conflict with each other, as well with the "principle of respect for autonomy", shall be applied only in balance with the risk-benefit ratio for the individual patient. Interventions should provide more benefit than risk (Beauchamp and Childress, 2019, Gillon, 1994).

The "principle of justice", finally, demands a fair, even and appropriate distribution of healthcare services, considering the availability of resources. Similar cases should be treated equally, while inequality should be morally justified (Daniels, 2001, Gillon, 1994).

These four principles offer a rich framework with four prima facie principles that have the same weights and need to be interpreted and applied to make ethical judgments. Although this framework has also been subject to criticism (Clouser and Gert, 1990, Jenkins, 2019, Sokol, 2008), it has been widely used in the last decades to set the frame for ethical discussion in medicine and public health, including the ongoing discussions regarding vaccination ethics. This makes it essential to include such a framework in clinical ethics teaching.

1.1.2. Vaccination and vaccination ethics

Discussions about vaccinations are an ongoing topic in health ethics and especially child health ethics and is a key part of this PhD thesis. Especially recently, that humanity finds itself racing to invent a vaccine against SARS-CoV-2, ethical discussions are important in the planning of national vaccination programs. Ethicists, public health experts, clinicians and health policy makers try to balance issues of "respect for autonomy" and freedom of choice, and the protection of both the individual and of the society from the hazards associated with preventable infectious diseases. This means that vaccination strategies should also be discussed from an ethical perspective specific to the context (Marckmann, 2008, Schröder-Bäck and Martakis, 2019).

Planning a feasible and effective vaccination program that is also ethically sound is challenging. Since the properties of each vaccine, and the disease it tackles, vary, the reasons to administer a vaccine also vary from case to case. A distinction is typically made between active and passive immunization. Passive vaccination refers to the administration of antibodies against a specific agent as secondary prevention after contracting this agent, to avoid clinical signs and symptoms of the disease or to reduce the disease-related morbidity. Typical example includes the of administration of palivizumab to reduce the burden respiratory syncytial virus (RSV) in extremely premature infants (Schröder-Bäck and Martakis, 2019, Zembles et al., 2016).

Active immunization, or vaccination refers to the provision of antigens of a specific pathogenic agent, that are applied mostly by injections, and sometimes orally or even as a nasal spray, to stimulate and enhance the antibody production against the infectious agent. A standard example, which will be discussed in the following chapters of this thesis, is the human papillomavirus (HPV) vaccination. From an ethical point of view, this is a suitable example because it is prominently discussed in public health, as well as in circles of ethicists. Vaccination scepticism is high, and the HPV vaccine is sometimes considered an optional vaccine by parents (Colgrove, 2006, Sarojini et al., 2010). HPV is a highly contagious agent and is causally associated with potentially fatal diseases, while the effectiveness of vaccination is undisputed among experts. HPV shows species specificity; eradication of HPV is possible due to the limited pathogen reservoir (IARC, 2007).

There are many reasons why HPV vaccination should be carried out. One of the most important reasons is the self-protection of the person to be vaccinated, whereby vaccination protection and vaccination risks are weighed up against each other. The risk-benefit assessment for HPV is, of course, different from that for seasonal influenza. In the latter, for instance, the effectiveness of the vaccination is somewhat lower, and the risk of disease varies depending on the age of the person (Ronco et al., 2014).

Another ethically important reason for vaccinations is third-party protection. It is about protecting those who cannot or will not be able to receive the vaccine. For example, the HPV vaccine is provided only to girls in a majority of countries. Although this challenges the “principle of justice”, vaccinating girls and increasing herd immunity against HPV may also lead to potential benefit for male adolescents, who interact sexually with their vaccinated peers (Giuliano et al., 2011). Another classic example includes the measles-mumps-rubella vaccine, which is used to vaccinate against rubella, primarily intending to protect unborn children from suffering from an extremely hazardous congenital infection, and not the person that is vaccinated (CDC, 2005).

Evidently, there are plausible reasons why a vaccination is contraindicated and cannot be provided. Immunosuppression is a typical example, e.g. in patients receiving immune modulating therapy or chemotherapy (Arvas, 2014). Age limitations may also present contraindications, since one may be too young to be vaccinated, e.g. vaccination against measles should not be applied in the first year of life, or, as in the case of diphtheria, one may be too old to receive the normal antigen dose and should receive an age-adjusted reduced dose of the vaccine antigen (Kowalzik and Zepp, 2019).

The fact that people are not vaccinated despite the lack contraindications can be due to other reasons. Patients or parents are often not well informed, are not health-competent, or there are religious or spiritual reasons that can lead to refusing vaccination (Wombwell et al., 2015, Rutjens and van der Lee, 2020). Ultimately, one goal of vaccinations is civil protection, which is ideally achieved by eradicating the disease or by attaining herd immunity. In the case of measles, a vaccination rate of 95% would result in herd immunity, and subsequently prevent the spread of measles, even if measles cases were introduced. When herd immunity is reached, there can still be ‘free riders’, who want to benefit from it without vaccinating themselves (Schröder-Bäck and Martakis, 2019). Vaccination protection at population level is often referred to as a public good, since everyone in the population benefits from it, although the population has to cooperate in order to achieve this common good (Johnson et al., 2020). In addition to infection protection, preventing economic damage and overburdening of the healthcare system are important and ethically acceptable reasons for vaccination (Marckmann, 2008). In that sense a safe and effective SARS-CoVID-2 vaccine would be, according to the principles of beneficence and justice, very welcome right now.

The National Immunisation Programme in the Netherlands includes vaccination against twelve difficult-to-treat and potentially fatal diseases, including diphtheria, whooping cough, tetanus, poliomyelitis, haemophilus influenza type B-associated disease, pneumococcal disease, hepatitis B, measles, mumps, rubella, meningococcal disease and human papillomavirus-associated disease. Standard vaccinations are aimed at specific age groups. According to the national vaccination schedule, some vaccinations are recommended to be given early in life (e.g. measles vaccination with the beginning of the second year of life and refreshed in early childhood), other vaccinations should be given relatively late (e.g. HPV vaccination in late childhood and before the first sexual intercourse) (Schurink-van’t Klooster and de Melker, 2019, RIVM, 2020).

There are some vaccines that are only relevant in early childhood and should not be administered to older people who have not been vaccinated or are even contraindicated, e.g. the pneumococcal vaccination is redundant for children from the age of five and is not recommended. In elder life, seasonal influenza vaccination is often also included in the standard vaccination programmes. Apart from individually relevant travel vaccinations, specific vaccines for occupational exposure individual risk profiles are also recommended. For instance, seasonal influenza vaccination shall be offered to chronically ill people, to healthcare workers or to employees interacting with birds (RIVM, 2020).

All states have developed their own national vaccination programs. These address the prevention issues differently, which may sound, from an evidence-based medicine perspective quite unreasonable. The significantly varying national vaccination programs across Europe present a typical example. The discussion of differences on a national level is out of scope of this thesis, however, a reflection on differences from an ethics perspective will be studied extensively in the following chapters.

1.1.3. Ethical implications of differences in the vaccination programs among Europe

On a European level, there is still no consensus regarding the ideal model of primary health care for children and adolescents in general, and for the provision of vaccines in particular. The majority of the different childhood vaccination programs and models of child health care throughout the European Union have never been appraised in terms of children's health outcomes (van der Willik et al., 2016). Similarly, children's rights to autonomy of choice may also be differently and unequally expressed or implemented in the varying childhood vaccination programs throughout the European Union. Although it is acknowledged that the child's developing autonomy should be respected, inequalities can easily be identified. For instance, differences in granting decision-making competence based on the developmental or chronological age or differences in the processes of informed consent, can raise significant ethical debates regarding the degree of respect for developing autonomy and moral equality (Wiesemann, 2016).

Once again in the case of the HPV vaccine, the implementation of the vaccination is neither harmonized nor standardized across the European Union. The vaccine is primarily offered in late childhood or adolescence, while there are differences across the states regarding the type of the applied vaccine (quadrivalent or bivalent), the age, the sex and other characteristics of the target population, the vaccination delivery strategy, as well as the need for out-of-pocket payment for the vaccine (Elfström et al., 2015). From a public health ethics point of view, the process of the HPV vaccine provision may also vary substantially across the vaccination programs in Europe, from authoritarian paternalistic, to libertarian models (Martakis et al., 2018, Wiesemann, 2016). The ethical implications of such interactions regarding the grade of respect for autonomy in healthcare of the youngest European citizens are yet to receive adequate attention among healthcare professionals and public health ethicists.

1.1.4. Vision and scientific relevance of the dissertation

Maximizing awareness and ethical skills among paediatricians, physicians and other health workers, educating and empowering parents as well as children, and exploring the social and clinical environment towards preparing it for harmonized, ethically sound child health care are the visions of this dissertation. Consequently, medical as well as public health ethics with regard to clinical decision-making in child health should be linked and studied. The central link used in this dissertation is the phenomenon of developing autonomy in childhood and adolescence, and its reflection in child healthcare, themes of high importance but nevertheless long been neglected.

Because of the high scientific and ethical relevance of vaccination policies in the daily clinical routine of child health professionals, this dissertation focuses on the field of vaccination policies, and these will be paradigmatically explored in chapters 2 to 6. Indeed, there are hardly any paediatricians or child health professionals, who have not been confronted with an ethical dilemma regarding the provision of a vaccine to a child. Balancing between ethics of personalized medicine and public health ethics, the findings of this thesis contribute to the scientific background in the field and provide a solid foundation for scientific discourse among child health professionals, children and their caregivers.

In particular, this dissertation refers extensively to policies regarding the application of two vaccines, the vaccine against seasonal influenza and the human papillomavirus (HPV) vaccine, which are used to prevent rather different yet clinically significant diseases, and which are ethically relevant both from a public health and a medical ethics perspective.

But why have these specific vaccines been chosen to be extensively studied? On the one hand, the vaccine against seasonal influenza is given to prevent epidemics of an acute, potentially fatal, infection especially among chronic patients. It is usually not included as part of the standard vaccines that children receive in childhood. Since healthy children do not really bear the burden of influenza, the main ethical principles that emerge in such cases are solidarity, justice and respect to autonomy.

On the other hand, the HPV vaccine, is provided in late childhood and adolescence to prevent sexually transmitted HPV infections and associated hazards, including HPV-driven cancer. The vaccine is often provided only to girls, although boys can also be exposed to HPV. This challenges the principle of justice. Further, the vaccine is given at an age that the patient is arguably competent to make health-related decisions, but the health system and the legislation do not grant them this decision-making competence. This raises ethical issues that challenge the principles of biomedical ethics, such as the principles of beneficence, non-maleficence and the respect to autonomy. These principles will be introduced and explored in Chapters 3 and 4 and will be studied from a European public health ethics perspective in Chapter 5.

1.2. Aims of the studies in this dissertation

Against the presented background, that ethics plays a crucial role in child health care and that vaccination is a key publicly contested field in biomedical ethics, the working **hypothesis** of this dissertation is that child health care ethics is not adequately included in the paediatric resident curricula. The working hypothesis includes, that although the respect for children's developing autonomy in paediatric healthcare, and especially with regard to national vaccination programs, could be expressed differently throughout Europe, common ethical patterns and good practices may still be identified to be transferred within the region.

The current thesis **aims** at filling this knowledge gap, by identifying expressions of respect for developing autonomy in paediatric healthcare and especially in the field of medical ethics in a European context; analysing the phenomenon of developing autonomy and creating a model for the facilitation of ethical discussion between physicians, ethicists, but also – and especially, which is innovative – including the children themselves and their families.

Specifically, the studies presented in this thesis will address the following **research questions**:

1. Teaching ethics in paediatrics:
How is medical ethics included and being taught in the medical curricula for residents in the field of paediatrics? Which problems have been reported in the literature and which solutions could be utilized to address these problems, according to the current medical teaching experience? Is the respect for children's autonomy adequately addressed in the paediatric resident curricula? (Chapter 2)

2. Principles of biomedical ethics to tackle an epidemic:
How should a vaccine to tackle an infectious disease, for instance the seasonal influenza, be offered to children or even be made obligatory to address the overall societal burden

of disease? What are the implications for the principles of respect of (developing) autonomy, justice, beneficence and non-maleficence? (Chapter 3)

3. **Developing a novel model focusing on the developing autonomy of children as patients:**

How is the developing autonomy of a child addressed in the current medical ethics and social paediatrics literature? How do the three main stakeholders interested in the well-being of their child, namely the parents, the physician and the child itself, interact to boost the child's autonomy and prospective interests? In case of lack of agreement of these three stakeholders regarding the provision of a treatment, for instance a vaccine provision, how could the discussion among them be facilitated? (Chapter 4)

4. **Exploring and identifying good ethical practices:**

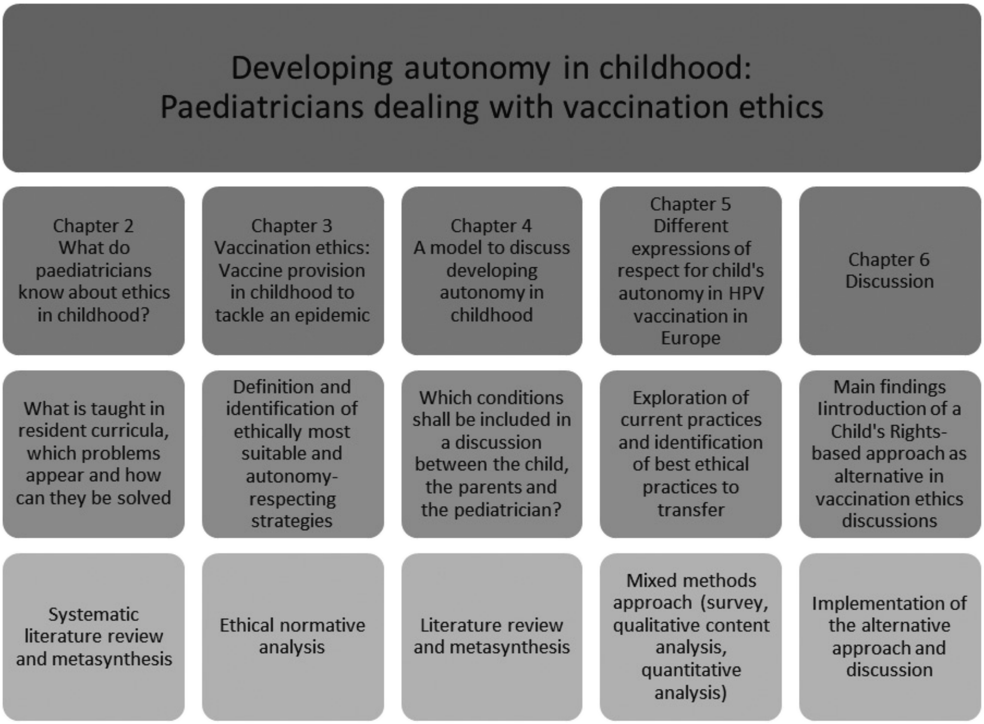
How is the respect for the children's right to autonomy of choice expressed throughout the European Union? Are there significant differences between geographic regions or individual member states of the Union? How do physicians and healthcare professionals deal with cases of lack of agreement among the three stakeholders (parents, medical team, and child) regarding the provision of the human papillomavirus (HPV) vaccine? Can any emerging ethical best practices regarding HPV vaccine provision in Europe be identified? How are they associated with the HPV vaccination rates? Could these practices be transferred to the rest of the region? (Chapter 5)

1.3. Outline of this dissertation

The thesis consists of two ethical conceptual chapters (Chapters 3 and 4) and two social sciences chapters (Chapters 2 and 5). Each of them reveals different challenges from the field of vaccination ethics and identifies and explores different levels of respect for the child's developing autonomy in paediatric healthcare and discusses them in a European and an international context. An overview of the chapters is given in Figure 1.1.

Chapter 2, titled "Teaching ethics to paediatric residents: a literature analysis and synthesis" depicts the current situation in the didactic of medical ethics among physicians specializing in child healthcare, identifies recurrent teaching patterns, portrays common difficulties and summarizes solutions to address these difficulties. The methodology used in Chapter 2 is a literature review and metasynthesis.

Chapter 3, titled "Childhood vaccination against seasonal influenza to reduce the overall burden of disease: ethical perspectives" focuses on the context of vaccination ethics. Utilizing a methodological approach currently proposed by the World Health



Developing autonomy in childhood:
Paediatricians dealing with vaccination ethics

Chapter 2 What do paediatricians know about ethics in childhood?	Chapter 3 Vaccination ethics: Vaccine provision in childhood to tackle an epidemic	Chapter 4 A model to discuss developing autonomy in childhood	Chapter 5 Different expressions of respect for child's autonomy in HPV vaccination in Europe	Chapter 6 Discussion
What is taught in resident curricula, which problems appear and how can they be solved	Definition and identification of ethically most suitable and autonomy-respecting strategies	Which conditions shall be included in a discussion between the child, the parents and the pediatrician?	Exploration of current practices and identification of best ethical practices to transfer	Main findings Iintroduction of a Child's Rights-based approach as alternative in vaccination ethics discussions
Systematic literature review and metasynthesis	Ethical normative analysis	Literature review and metasynthesis	Mixed methods approach (survey, qualitative content analysis, quantitative analysis)	Implementation of the alternative approach and discussion

Figure 1.1. Overview of the Chapters, including the main objective and research question of each chapter, as well as the methods used.

Organization, this chapter examines and addresses ethical dilemmas regarding the provision of a prophylactic seasonal vaccine in childhood to reduce the burden of influenza-related morbidity. The Hippocratic ethos, several expressions of utilitarianism such as the harm principle, perspectives from liberty and autonomy, as well as justice and solidarity perspectives are analysed in this case. Finally, decisions regarding the ethically most suitable interventions with regards to seasonal influenza vaccination programs are drawn, using a modification of the intervention ladder, a tool to facilitate ethical decision-making, proposed by the Nuffield Council on Bioethics.

In addition to next to the traditionally accepted and well-established forces of medical and parental paternalism, chapter 3 makes clear the concept of the children's developing autonomy as a new emerging force in ethical discussions in child healthcare. Chapter 4, titled "Developing child autonomy in paediatric healthcare: towards an ethical model" presents an extensive literature review in an attempt to clarify and address this emerging ethical pattern. It further sketches an ideal model including the triad of the child, as patient, the parents and the physician, interacting in a frame of justice and respecting the child's right to autonomy of choice, while acting for the child's medical good. A tool that should facilitate ethical discussion among these three actors accompanies the proposed model.

The respect, or non-respect, to children's rights to autonomy of choice is differently expressed throughout Europe. Continuing the navigation in the field of vaccination ethics, Chapter 5, titled "Human papillomavirus vaccination and respect for children's developing autonomy: results from a European Union wide study" presents the findings of an exploration of differences regarding expressions or respect for children's developing autonomy throughout Europe, using the human papillomavirus (HPV) vaccination offer as indicator. A mixed methods approach was used, utilizing an expert survey within the frame of "Models of Child Health Appraised" (MOCHA). The data analysis addresses the following themes: (i) provision of informed consent, (ii) parental and medical paternalism, (iii) relevance of the child's chronological age or maturity, and (iv) vaccination programs targeting boys. These major themes for the field of vaccination ethics are being handled differently across the region. Chapter 5 explores associations of the implemented practices with the national HPV vaccine coverage rate across the European Union, discusses and identifies the most suitable ethical approaches to be transferred and implemented across Europe.

Finally, in Chapter 6 referred to as 'Discussion' of this dissertation, the general findings of this dissertation are discussed, with an emphasis on strengths and limitations, which should foster and guide future research, provide recommendations for policy and decision-makers in the field of vaccination ethics on a national, European and international level, and also provide helpful input for ethical discussion among and between physicians, ethicists, parents and, of course, the children as patients themselves. Furthermore, a Child's Rights-based approach, proposed by the American Academy of Pediatrics, will be introduced as an alternative to discuss vaccination ethics in childhood (AAP, 2010). The approach will be compared with the Developing Autonomy approach, introduced and implemented in Chapter 4.

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Chapter 2

Teaching ethics to paediatric residents: A literature analysis and synthesis

Abstract

Background: Ethics education rarely exists in paediatric resident curricula, although ethical conflicts are common in the clinical paediatric practice. Ethics education can prepare paediatric residents to successfully handle these conflicts.

Aim: We searched for applied and recommended methods in teaching ethics to clinical and especially paediatric residents and identified recurring barriers to ethics teaching and solutions to overcome them.

Design: Literature from four electronic databases with peer-reviewed articles was screened in three phases and analysed. The literature included papers referring to applied methods or recommendations to teaching ethics to clinical residents, and on a second level focusing especially on paediatrics. An analysis and critical appraisal were conducted.

Results: 3231 articles were identified. 96 papers were included. The applied learning theory, the reported teaching approaches, the barriers to teaching ethics and the provided solutions were studied and analysed.

Conclusions: We recommend case-based ethics education, including lectures, discussion, individual study; regular teaching sessions in groups, under supervision; affiliation to an ethics department, institutional and departmental support; ethics rounds and consultations not as core teaching activity; recurring problems to teaching ethics, primarily deriving from the complexity of residential duties to be addressed in advance; teaching ethics preferably in the first years of residency.

Introduction

Although, until the early 1980s, teaching medical ethics was regarded as unnecessary or even counterproductive, it is now a well-accepted practice (Perkins, 1989). While medical ethics education is widely included in undergraduate medical programmes, it rarely exists in resident curricula (Vertrees et al., 2012). Surveys conducted among paediatricians in Canada and the USA (Kenny et al., 1998, Kesselheim, 2008) and among paediatric program directors in the USA (Lang et al., 2009) emphasise not only the importance of the inclusion of ethics education in the clinical residency but also the lack of training in current curricula. Needs assessment and content formulation for the topics to be included have also been reported (Taylor et al., 2009, Waz, 1995, White, 1991).

Increased movement of patients and health professionals globally pointed out the importance of harmonizing medical curricula (Breipohl et al., 2000). International medical students have shown the way, including ethics in their suggestion for a harmonised undergraduate European core curriculum (Hilgers and De Roos, 2007). We believe that medical ethics should receive the same attention in the harmonization process of postgraduate curricula.

Furthermore, even when ethics is included in the curricula, residents often fail to receive the appropriate skills to prepare them for the clinical and societal health arena. Since the need to teach ethics derives from real problems, it is important to identify and recommend good practices for ethics teaching in clinical residency (Waz, 1995).

Educational strategies are classified under three distinctive theories of learning, namely behavioural, cognitive and motivational. All three find use in medical education settings (Mohanna et al., 2010).

Regarding the teaching setting, Edmund Pellegrino, a well-known bioethicist recommended that medical ethics education should be clinical and case-based, continuous, active participatory and coordinated with the other curricular learning objectives, aiming not only to develop behavioural and cognitive skills but also towards character development (Pellegrino et al., 1990). Regarding teaching ethics to paediatricians, Pellegrino et al. emphasised on the importance of recognizing and addressing the issue of patient autonomy and beneficence in the daily practice (Pellegrino and Thomasma, 1987).

The objective of the study is twofold. Firstly, to explore the characteristics of the ethics education approaches in clinical postgraduate curricula. Secondly, to identify recurring barriers related to ethics teaching and find solutions to overcome them based on effective educational methods.

Methodology

We carried out a literature search using a mixed methods approach (Mulrow et al., 1997) and a directional content analysis (Hsieh and Shannon, 2005). Key concepts and variables were identified a priori as initial coding categories, while operational definitions for each category are determined using the existing literature and theory (Hsieh and Shannon, 2005). The studied literature was further analysed according to a model proposed by Wallace and Wray into theoretical, research, practice and policy literature (Wallace, 2006).

Data collection

The Bioethics Literature Database (BELIT), the Cumulative Index to Nursing and Allied Health Literature (CINAHL), PubMed and the Web of Science (WoS) were searched. Incorporating the main concepts of the research question, we decided to use the search terminology using Boolean Operators as follows: “teaching” OR “education”; AND “ethics”, AND “residency” OR “resident”.

We limited all searches on the basis of language (English, German, Spanish, French and Greek). The year of publication was not a limitation. The search was conducted in April 2013 using the same terminology as well as the same limitations across all databases.

The following inclusion criteria for the articles were used:

- It should be focused on medical ethics education in clinical context using or recommending educational methods and written in one of the mentioned languages.

Using broad eligibility criteria allow the inclusion of all available curricula but also the generalizability of the findings to different settings (Mulrow et al., 1997, Schiessl et al., 2016). We screened and analysed abstracts and full texts in two phases to make the search as systematic as possible and to assure that irrelevant papers were excluded. The first phase was an abstract screening. The second phase included a full text screening. Because the research team had a special focus on paediatrics ethics teaching, literature referring to paediatric residents was analysed separately.

In the study we included all articles that were available online or in hardcopy through the libraries of Maastricht University, the University of Cologne, the University of

Portsmouth and the German Reference Centre for Ethics in the Life Sciences, Bonn, Germany. We contacted directly the authors of articles that were not available through the libraries.

Data Analysis

The literature eligible for full text screening was categorised into theoretical, research, practice and policy literature (Wallace, 2006).

The teaching methods were documented, coded and analysed qualitatively according to the following themes:

1. Does the article refer to a recommendation or an applied method?
2. Is the method evaluated?
3. Which residents does the paper address? How many participants were involved?
4. Followed theory of learning.
5. Documentation of the study characteristics to be identified in every reported method. Therefore we created a register for the documentation of the following variables: duration and frequency of the educational interventions, lecturing, working in groups, working with cases and problem-based or problem-solving setting, presence of a tutor or a leader, interaction of a variety of medical and non-medical tutors, activation of prior knowledge of the participants and elaboration of the newly acquired knowledge as a group.
6. Have issues of child's autonomy and beneficence been highlighted among the studied teaching methods addressing paediatric residents?
7. Which barriers to teaching ethics to residents are reported?
8. Which solutions reported in the literature could address these barriers effectively?

Nominal variables were assigned for the operationalization of the themes. The conclusions that review papers provided were regarded as recommendations and synthesised accordingly. A critical appraisal of the studied literature was conducted. We applied methods of papers presenting qualitative research and discussion papers as suggested by Aveyard (Aveyard, 2011), Malterud and Devers et al. (Malterud, 1993, Devers and Frankel, 2001). The results were used as an analysis framework to describe and investigate different applied methods and recommendations and appropriateness to equip postgraduates with the ethical competences and skills needed.

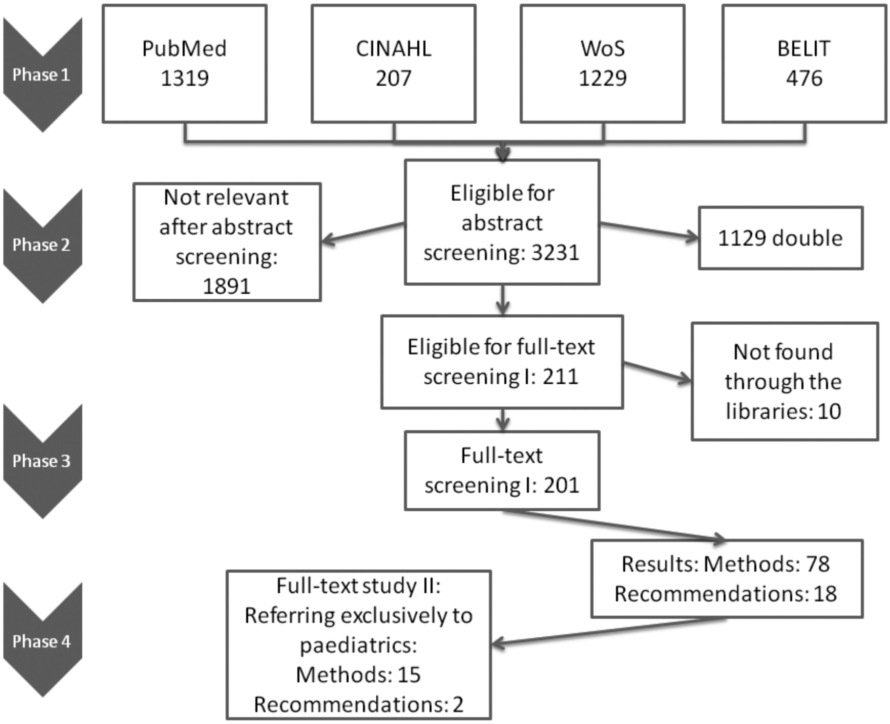
Results

We identified 3231 articles eligible for abstract screening (Figure 1). After excluding the literature that did not focus on medical ethics education through abstract screening (1891), and the articles that were identified in more than one database (duplicate articles) (1129), we identified 211 articles eligible for full-text screening. After intensive library research we accessed 192 papers. Nineteen papers were neither accessible in the searched libraries and nor available to purchase electronically. However, nine of these papers were provided directly from the authors after contacting them personally. In total 201 papers were included in the study.

78 teaching methods and 18 recommendations (96 papers) were identified as relevant for further study and scrutinised. These papers, coded as S01-S96, are documented in Table 3.

Within this sample, nine recommendations were mentioned in theoretical papers, two in policy papers, three as a result of an education needs assessment, three in practical papers and one as a recommendation of a literature review. The rest of the papers (23 research and 55 practical) presented applied methods (Wallace, 2006).

Figure 1: Flowchart of the search



Teaching methods

In total 17 papers, including three controlled trials referred exclusively to paediatric residents (Berseth and Durand, 1990, Major-Kincade et al., 2001, Kon, 2006). The reported teaching methods and recommendations of all 96 studied papers, as well as of the 17 papers referring to paediatric residents, are presented in Table 1.

We further identified four papers using the term Problem-based learning (PBL) (Schmidt, 1983) and another four referring to seminars based on problem-solving setting. Approaches for the activation of prior knowledge have been reported or implied in 64 papers (67%), while elaboration of the acquired knowledge as a group was reported in 45 papers (47%). Working with cases was reported in 88% of the 96 papers, teaching in small groups in 65%, having regular meetings in 73%, recruiting professional ethicists in 71% and having tutors or moderators in 75% of the papers. Although a standard PBL was applied only in a few methods, PBL elements kept repeating in the studied curricula.

The importance of using case-based medical ethics teaching has been reported by a randomised controlled trial among family medicine residents. Although there was no significant difference in the level of knowledge acquired from the two study groups, physicians who received case-based lectures and team meetings were more confident in the post-test in comparison to the ones who received only lecturing (Sulmasy et al., 1993).

Berseth et al. conducted a controlled trial among paediatric and non-paediatric residents in a paediatric intensive care unit, using a method that followed both the behaviourist and cognitive theory. The method, including lectures and discussions, concluded that the paediatric residency itself affects significantly the development of ethical attitudes, so that formal medical ethics training should be conducted during the first years of the paediatric residency to avoid the maturation effect (Berseth and Durand, 1990).

The relevance of the ethical problem of the balance of child's autonomy and beneficence has been highlighted in ten out of the seventeen ethics teaching methods addressing paediatric residents, while Opel et al. emphasised the introduction of principlism and casuistry as methods of ethical analysis in the paediatric ethics education (Opel and Olson, 2012).

Barriers to teaching medical ethics to paediatric residents

We identified a series of recurring barriers to teaching ethics (Table 2). Time constraint was the main problem reported against implementing ethics education in residency program. The complexity of residential duties poses barriers which include dealing

Table 1. Teaching methods

Reported methods	General literature (N=96)	Paediatric lit. (N'=17)
Lecturing	46%	53%
Case-presentations	61%	53%
Discussions	31%	24%
Consultations	8%	6%
Seminars with problem-solving setting	31%	41%
Ethics rounds in the unit	14%	11%
Grand ethics rounds	14%	11%
Multimedia and web-based approaches	16%	6%
Literature study	14%	-
Written assignments	9%	6%
Role playing and standardized patients	17%	24%
Thematic congresses	3%	-
Discussing with patients' parents, home visits, resident support groups and mentoring have been reported		
PBL elements reported (96 papers)		
Activation of prior knowledge	67%	
Elaboration of knowledge as group	47%	
Working with cases	88%	
Teaching in small groups	65%	
Having regular meetings	73%	
Recruiting professional ethicists	71%	
Having tutors or moderators	75%	
Studied papers referring to paediatric residents (N' =17)		
Presenting recommendations		2 / 17
Presenting applied methods, following:		15 / 17
combination of cognitive and behaviourist theory		9
cognitive theory		3
behaviourist theory		2
combination of cognitive and motivational theory		1
Applied methods presented in research papers:		6 / 15
Case studies		3
Controlled trials		3
Applied methods presented in practice papers:		9 / 15
Highlighting issues of child's autonomy and beneficence:		10 / 17

with medical emergencies, offsite-rotations and scheduling difficulties. Additional core reported barriers for teaching ethics are a lack of continuity of attendance and lack of interest, diffuse scepticism or negative attitudes from the clinicians or clinical residents towards ethics education. Next to these barriers, lack of funding and material resources, lack of institutional and departmental support, support of the relevant directors, lack of cases for discussion from the clinic's own clientele, and finally the limited effect of a previous ethics teaching experience in the clinic were reported as major barriers. The maturation effect on the formation of ethical attitudes of the paediatric postgraduate education itself was an interesting additional element regarding teaching ethics to paediatric residents.

Solutions to overcome these barriers

In order to address these problems, we analysed and synthesised solutions published in all studied papers. The barriers and their respective solutions are stated in the following paragraphs and presented in Table 2.

We first addressed the problem of time constraint. It was not clear if the ethics teaching should take place during or after the working hours. Resident time constraints can be addressed with ethics rotations, short, regular, usually monthly, meetings, teaching during a residential outpatient block, whole-day seminars, or residential courses.

Interactive sessions with short pre-session readings, teaching the use of algorithms and special ethics tools, teaching using a 'resident-as-teacher' approach and the collaboration of different clinics for the formulation of a common ethics curriculum seem to increase the effect of the methods and the interest of the residents. Similar effects were reported utilizing logotherapy and music.

Working with cases from the residents' own experiences was reported as increasing the credibility of the method and the interest of the participants. Using ethics cases from medical journals rather than from ethics journals in the form of "journal clubs" addresses the problem of shortage of relevant educational cases. Both clinicians and ethicists should be involved in the preparation of the cases to be taught so that the cases are not only relevant to the clinic but also include cases of reimbursement or justice issues.

Trainee attendance and participation continuity was higher in programs that provided food during the ethics training, which shall not be sponsored by pharmaceutical companies. During the formal ethics training residents should be free from medical duties. Salary increase or promotion for the participants was suggested in one paper, while a detailed process about the procedure for planned absences, including notification of the instructor and make-up assignment was implemented in a method applied in psychiatric residents.

Table 2. Barriers and solutions to teaching ethics to residents

Barriers	Solutions
Time constraint (S43, S59)	Ethics rotations (S18), or training sessions during or after the working hours (S74). Short (S42, S87) regular (S47, S70) meetings, whole-day seminars (S52, S32), residential courses (S54).
Complex residential duties (S08)	Pre-session readings (S53). Training during outpatient blocks. Free-of-duty participants (S16). Salary increase, promotion (S40). Support from the director of the clinic (S60, S25, S32, S16, S40, S41)
Maturation effect of paediatric residency (S22)	Formal ethics teaching in the first years of residency (S22)
Limited participation, lack of continuity of attendance and lack interest (S43, S08)	Interactive sessions (S54). Use of algorithms (S84). Resident-as-teacher approach (S94). Use of music (S04, S58) Provision of aliments (S67, S55, S31, S68), non-pharmaceutical funding (S74). Collaboration of different clinics (S54). Make-up assignment in case of absences (S37)
Scepticism of physicians towards ethicists (S08)	Active involvement of both professions to the preparation of the training (S23, S16) Commitment of the residency educational director and the tutors (S20, S49, S31, S62, S32, S37, S48)
Lack of faculty and personal resources (S25)	Affiliation to an ethics department institutional and departmental support, recruitment of trainers, tutors (S60, S25, S32, S16, S40, S41)
Lack of resources institutional or departmental support (S25)	Funding from the clinic or the hospital, importance of institutional and departmental support (S60, S25, S32, S16, S40, S41) Cooperation with other clinics (S54) Emphasis given from leading medical organizations and respective associations (S42) Development (S64, S81) and constant use (S63, S91) of teaching material
Lack of "interesting" cases (S23, S62)	"Journal clubs" (S42, S62) Cases suggested by ethicists and physicians, incl. the residents to be trained (S23, S16) Include cases from the residents' own experiences (S34, S45) Involvement of patients' parents (S60, S42)
Limited effect of previous teaching experiences (S09)	Thorough planning of training before intervening (S09)

The codes in brackets refer to the article codes and are available in the online published material.

Institutional and departmental support in the form of staff recruitment, funding and dedication of conferences, rounds, consultations and in general time to teaching ethics was reported as essential for an effective teaching program. The emphasis given to formal residential ethics curricula from leading medical organizations and respective associations was also reported as a significant promoting factor.

Effective ethics consultations were also reported to positively influence the success of formal ethics teaching. Additionally, the constant presence of an ethicist in the patient wards and the active participation in the rounds was reported as effective for ethics education.

The participation of patients' parents in the ethics education was reported as a factor influencing ethics teaching in paediatric residents. Opel et al. (Opel and Olson, 2012) emphasised that paediatric bioethics education shall be based on three steps: identifying the dilemma, describing methods of analysis and acquiring knowledge of additional resources, a method similar to the standard PBL approach .

Finally, the professional ethics education and personal commitment of the educational director, the moderators and tutors and the development of individual material and the consequent use of established study material were important to achieve continuity and success of the program.

Discussion

Our study revealed that the behaviourist and the cognitive theories of learning independent or in combination are used as main educational approaches in clinical and especially in paediatric ethics education.

Previous studies show that essential features related to medical ethics education are interactions between medical and non-medical professionals and an assessment of application of acquired knowledge by trainees. This study confirms this finding. Ethics teaching should take place preferably in small groups of trainees that meet regularly and participate actively under the supervision of an instructor or tutor, affiliated to an ethics department. In line with Pellegrino et al. (Pellegrino et al., 1990) we conclude that medical ethics education should be clinical, case-based and continuous, aiming to skill and character development.

Considering these features, it seems that an ideal ethics teaching model should be based on the cognitive theory (Hrynchak and Batty, 2012). According to this theory a teacher provides guidance and facilitation of a trainee's learning experience. Teaching is understood to involve providing opportunities to expose inconsistencies between learners' current understandings and new experiences (Hrynchak and Batty, 2012). The educational method of PBL is based on the cognitive theory. Considered as an effective method to develop professional skills, to endow functional knowledge and motivation for continued self-directed learning (Vernon and Blake, 1993), PBL could be implemented to serve the objectives of medical ethics education (Miles et al., 1989).

Further, opportunities should be provided for developing new schemes and learning should be active. Relevant problems and group interaction should be included, and enough time should be provided for reflection on new experiences (Kaufman, 2003). Clinical ethics rounds and consultations are complementary but should not be the core teaching activity.

Pellegrino et al. emphasised the importance of the coordination of ethics education with the other curricular learning objectives and residential activities. The complexity of the activities within the diverse working environment presents barriers to teaching medical ethics. There are recommendations that teaching in paediatrics may preferably take place in the first years of residency and that the patients' parents may be effectively involved in ethics teaching.

The main barriers related to clinical ethics teaching, as identified in the studied literature, constitute problems deriving from the complexity of the residential duties and the time constraint, from the lack of participation and interest from the side of the residents, but also from an inadequate institutional or departmental support. Since limited effect of previous teaching experiences has been reported as another important problem in teaching ethics to residents, a thorough preparation of the teaching setting and planning of the interventions addressing effectively the recurrent problems is of major importance.

Limitations

The study findings are insightful and direction-setting. However, there are limitations to this study. Although the sampling method was systematic and comprehensive, teaching methods published in journals not included in the searched databases or not written in the studied languages, have been excluded from the study. Additionally, ten articles meeting the inclusion criteria could not be found and therefore they were excluded from the study. We may have also missed articles that addressed the issue without it being mentioned in the abstract. This study did not take into account non-educational strategies promoting ethics within medical education. Having clearly stated sampling criteria and analysis tools, we regard the study as reproducible.

We should be cautious in generalizing the results on populations with different characteristics of the ethics culture. Moreover, we should take into consideration that the relevance of a reported teaching method does not have to do only with the quantity of the fulfilled criteria, but primarily with the quality of each of the characteristics.

We conducted a systematic critical appraisal of the studied literature. However, the barriers and relevant solutions were documented as mentioned in the literature, without focusing on the level of evidence of the paper that the information derived from. The level of potential influence of each barrier in ethics teaching is unclear.

Conclusions

Although we shall be cautious with the generalization of the results on populations with different characteristics of the ethics culture, the results of this study may be used as a guide of elements to be included and factors to be addressed to establish a successful and effective formal ethics education program for clinical residents.

The ethics education should be based on the cognitive theory of learning using small group case-based or problem-solving teaching and learning, lectures, mini-lectures, discussion and provision of resources to improve one's theoretical background through optional individual study.

Thorough planning of the educational setting with regard to recurring barriers related to teaching ethics to residents is crucial for a successful ethics teaching program. Cases should be selected by trainers or trainees. The meetings should be supported financially and institutionally from the department or clinic direction. Such a model also reflects the recommendations of Pellegrino et al. for case-based, cognitive teaching methods in ethics education. PBL may present a serious alternative teaching process against the traditional teaching methods. The inclusion of ethics cases that address issues of patient's autonomy and the balance with paternalism aiming for beneficence, as suggested by Pellegrino et al., but also the majority of the studied teaching methods, is highly recommended.

Table 3. Systematically reviewed literature

Code	Title	Authors	Journal	Year
S01	Ethics seminar for interns and residents.	Holman EJ.	Md State Med J.	1966
S02	Teaching medical ethics: an experimental program.	Veatch RM, Gaylin W.	J Med Educ	1972
S03	Program report: teaching medical ethics. Helping medical students face ethical issues.	Veatch RM.	Hastings Cent Rep.	1972
S04	Ethics/human values education in the family practice residency.	Keller AH.	J Med Educ.	1975
S05	Teaching medical ethics: University of Nijmegen, The Netherlands.	De Wachter MA.	J Med Ethics	1978
S06	Ethics teaching on ward rounds.	Carson RA, Curry RW Jr.	J Fam Pract.	1980
S07	A model for teaching ethics in a family practice residency.	Self DJ, Lyon-Loftus GT.	J Fam Pract.	1983
S08	Pediatric ethics rounds: an evaluation -- the impact of ethics rounds on clinical decision-making is worthy of further exploration.	Ladd, Rosalind Ekman; Forman, Edwin N.	Rhode Island Medical Journal.	1985
S09	Teaching of bioethics within a residency program in obstetrics and gynecology.	Elkins TE, Strong C, Dilts PV Jr.	Obstet Gynecol.	1986
S10	Teaching ethics on rounds: the ethicist as teacher, consultant, and decision-maker.	Glover, Jacqueline J.; Ozar, David T.; Thomasma, David C.	Theoretical Medicine.	1986
S11	Teaching medical ethics to medical students and GP trainees.	Boyd K.	J Med Ethics.	1987
S12	Teaching medical ethics in perinatology.	Fleischman, Alan R.; Arras, John	Clinics in Perinatology.	1987
S13	Teaching and evaluation of interpersonal skills and ethical decision making in pediatrics.	American Board of Pediatrics. Medical Ethics Subcommittee	Pediatrics.	1987
S14	Teaching clinical medical ethics: a model programme for primary care residency.	Arnold RM, Forrow L, Wartman SA, Teno J.	J Med Ethics.	1988
S15	Introductory course in biomedical ethics in the obstetrics-gynecology residency.	Elkins TE.	J Med Educ	1988
S16	The development of a medical ethics curriculum in a General Internal Medicine Residency Program	Wartman SA, Brock DW.	Acad Med	1989
S17	Evolution of clinical ethics teaching at the University of Pittsburgh.	Frader J, Arnold R, Coulehan J, Pinkus RL, Meisel A, Schaffner K.	Acad Med	1989
S18	Ethics education at Northwestern University Medical School.	Bresnahan JF, Hunter KM.	Acad Med	1989

Code	Title	Authors	Journal	Year
S19	A workshop to foster medical humanism in residents.	Tarail M, Friedman S.	Acad Med	1989
S20	Teaching medical ethics during residency.	Perkins HS.	Acad Med	1989
S21	An ethics curriculum for teaching emergency medicine residents.	Moskop JC, Mitchell JM, Ray VG.	Ann Emerg Med.	1990
S22	Evaluating the effect of a human values seminar series on ethical attitudes toward resuscitation among pediatric residents.	Berseth CL, Durand R.	Mayo Clin Proc.	1990
S23	Teaching clinical ethics.	Pellegrino ED, Siegler M, Singer PA.	J Clin Ethics	1990
S24	Ethics education for psychiatry.	Moffic, H. Steven; Coverdale, John; Bayer, Timothy	Journal of Clinical Ethics.	1991
S25	Sensitizing residents to moral issues by case discussions.	Durbin PT, Engel JD, Blacklow RS, Wellenbach BL.	Acad Med.	1991
S26	Role-playing for teaching ethics in emergency medicine.	Nelson MS, Eliastam M.	Am J Emerg Med.	1991
S27	An approach to teaching ethics in child and adolescent psychiatry.	Sondheimer, Adrian; Martucci, L. Claire	Journal of the American Academy of Child and Adolescent Psychiatry.	1992
S28	Storytelling as a method for teaching values and attitudes.	Hensel, William A.; Rasco, Teresa L.	Academic Medicine.	1992
S29	Ethics training for residents at the University of Calgary	Doig, C. J.; Burgess, M.; Brownell, A. K. W.; Flagler, E.; Kinsella, T. D.	Clinical and Investigative Medicine	1992
S30	Advanced training in biomedical ethics: a curriculum in clinical specialty programmes.	Jennett, P.A.; Crelinsten, G.L.; Kinsella, T.D.	Medical Education.	1993
S31	A randomized trial of ethics education for medical house officers.	Sulmasy DP, Geller G, Levine DM, Faden RR.	J Med Ethics.	1993
S32	Ethics training for residents.	Kinsella D, Lockyer J, Brownell K.	Acad Med.	1993
S33	The status of ethics education in obstetrics and gynecology.	Cain JM, Elkins T, Bernard PF.	Obstet Gynecol.	1994
S34	An Educational Intervention in the Surgical Intensive Care Unit to Improve Ethical Decisions	Holloran, Suzanne D.; Starkey, George W.; Burke, Peter A.; Steele, Glenn; Forse, R. Armour	Surgery	1995
S35	Ethik in der Medizin in der neuen AeAppO - was Studierende sich wuenschen.	Baitsch, Helmut; Gommel, Michael; Kohler, Elke; Sponholz, Gerlinde; Stroessler, Michael	Zeitschrift fuer medizinische Ethik	1995
S36	Ethics curriculum for internal medicine residents.	Wymer A, Kendrick B.	Acad Med.	1996

Code	Title	Authors	Journal	Year
S37	Fifteen years of teaching psychiatric law and ethics to residents	Hassenfeld, IN; Grumet, B	ACADEMIC PSYCHIATRY	1996
S38	Clinical ethics teaching in psychiatric supervision	Roberts, LW; McCarty, T; Roberts, BB; Morrison, N; Belitz, J; Berenson, C; Siegler, M	ACADEMIC PSYCHIATRY	1996
S39	A curriculum for teaching clinical ethics in neonatal-perinatal medicine.	Davis DJ, Doucet H.	Ann R Coll Physicians Surg Can	1996
S40	Ethically based medical decision making in the intensive care unit: residency teaching strategies.	Crausman RS, Armstrong JD 2nd.	Crit Care Clin.	1996
S41	Ethics education for medical house officers: long-term improvements in knowledge and confidence.	Sulmasy DP, Marx ES.	J Med Ethics.	1997
S42	An approach to teaching ethical, legal, and psychosocial aspects of gynecologic oncology in a residency program.	Strong C, Miller BE, Photopoulos GJ, Smiley LM.	Obstet Gynecol.	1997
S43	An ethics curriculum for the pediatric residency program. Confronting barriers to implementation.	Diekema DS, Shugerman RP.	Arch Pediatr Adolesc Med.	1997
S44	Teaching Medical Ethics to Orthopaedic Surgery Residents	Wenger, Neil S.; Liu, Honghu; Lieberman, Jay R.	Journal of Bone and Joint Surgery, American Volume	1998
S45	Teaching clinical ethics to orthopaedic surgery residents.	Wenger NS, Lieberman JR.	Instr Course Lect	1998
S46	Analysis of clinical bioethics teaching in pediatric surgery residency.	Robin ML, Caniano DA.	J Pediatr Surg	1998
S47	Medical ethics curriculum for surgical residents: results of a pilot project.	Angelos P, DaRosa DA, Derossis AM, Kim B.	Surgery	1999
S48	Description of an ethics curriculum for a medicine residency program.	Silverman HJ.	West J Med.	1999
S49	A longitudinal ethics curriculum for medical students and generalist residents at the Medical College of Georgia.	Carter BS, Roberts A, Martin R, Fincher RM.	Acad Med.	1999
S50	An approach to educating residents about palliative care and clinical ethics.	Fins JJ, Nilson EG.	Acad Med.	2000
S51	Long-term outcomes of the New Pathway Program at Harvard Medical School: a randomized controlled trial.	Peters AS, Greenberger-Rosovsky R, Crowder C, Block SD, Moore GT.	Acad Med.	2000

Code	Title	Authors	Journal	Year
S52	The path to professionalism: cultivating humanistic values and attitudes in residency training.	Markakis KM, Beckman HB, Suchman AL, Frankel RM.	Acad Med.	2000
S53	Ethical issues in the managed care setting: a new curriculum for primary care physicians	Wright, SM; Carrese, JA	MEDICAL TEACHER	2001
S54	Teaching medical ethics to experienced staff: participants, teachers and method.	Nilstun T, Cuttini M, Saracci R.	J Med Ethics.	2001
S55	Training pediatric house staff in evidence-based ethics: an exploratory controlled trial.	Major-Kincade TL, Tyson JE, Kennedy KA.	. J Perinatol.	2001
S56	Talking medicine: a course in medical humanism--what do third-year medical students think?	Lypson ML, Hauser JM.	Acad Med.	2002
S57	Clinical ethics in rehabilitation medicine: core objectives and algorithm for resident education	Sliwa, J.A.; McPeak, L.; Gittler, M.; Bodenheimer, C.; King, J.; Bowen, J.	American Journal of Physical Medicine and Rehabilitation	2002
S58	Listening to music: the case for its use in teaching medical humanism.	Newell GC, Hanes DJ.	Acad Med.	2003
S59	A bioethics curriculum for the pediatric residency program: experience of a university hospital	Moreno Villares JM, Gómez Castillo E.	An Pediatr (Barc).	2003
S60	Teaching professionalism to residents.	Klein EJ, Jackson JC, Kratz L, Marcuse EK, McPhillips HA, Shugerman RP, Watkins S, Stapleton FB.	Acad Med.	2003
S61	Building professionalism and communication through active small-group sessions.	James WD.	Eur J Dermatol	2004
S62	Incorporating ethics education into the radiology residency curriculum: a model.	Oljeski SA, Homer MJ, Krackov WS.	AJR Am J Roentgenol.	2004
S63	Teaching medical ethics: implementation and evaluation of a new course during residency training in Bahrain.	Al-Jalahma M, Fakhroo E.	Educ Health (Abingdon).	2004
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3

Chapter 3

Childhood vaccination against seasonal influenza to reduce the overall burden of disease – Ethical perspectives

Abstract

Introduction: Childhood immunisation against seasonal influenza promises to reduce the burden of disease through herd immunity. The option of intranasal vaccination seemed to offer a more acceptable vaccination for children, as they are perceived to be less invasive. Yet, intranasal vaccines have been recently proven not to be as effective as presumed. In Germany, contradictory recommendations of the Standing Committee on Vaccination (STIKO) first, to use and then, in October 2016, not use these vaccines have been issued for the 2016-2017 season, whereas recommendations not to use them were already issued in the USA (CDC, ACIP). This controversy spurs the discussion of immunisation programmes for children again. Despite studies discussing the effectiveness of a comprehensive immunisation programme targeting children also in the German and wider European context, an accompanying ethical discussion is missing.

Methodology: We discuss several policy options from different key ethical perspectives that are widely used in public health: if seasonal influenza vaccination should be intensively offered to or even made mandatory for children to decrease the societal burden of the disease.

Results: Various ethical perspectives reflect the question how to balance individual autonomy, personal benefit and population benefit differently.

Discussion: A convincing justification to suggest immunisation policies has to balance norms anchored in different ethical theories. There are good reasons to offer immunisation programmes against seasonal influenza to children, using a voluntary, possibly incentive-based approach.

Key words: vaccination, children, influenza, ethics, autonomy, chronic diseases

Introduction

Seasonal influenza poses a substantial burden of disease, significantly increasing the number of hospitalizations and deaths, especially among patients with chronic conditions at any age (Nowak et al., 2015). Active annual immunization using up-to-date influenza strains is a relevant practice among these populations. Increasing the seasonal vaccine use is a major WHO goal (Kieny et al., 2006).

Higher immunisation rates against seasonal influenza could be achieved with a variety of policies, extending from a recommendation to specific groups to annual vaccination of the general population, through programmes that may include nudges, incentives or mandates. A mandatory annual vaccination among children appears promising in achieving herd immunity. Indeed, such a programme has been introduced among Japanese school children in 1977 and was continued until 1987 (Reichert et al., 2001). Reichert et al. report that 37.000–49.000 deaths were annually avoided corresponding to one avoided death for every 420 immunized children, concluding that the mandatory seasonal vaccination of school children provides protection against influenza and reduces mortality among elder populations. Emerging criticism and lawsuit allegations of adverse side effects that did not outweigh the vaccination benefits, lead to the loss of public confidence in the program. Ultimately, the programme was discontinued and herd immunity lost (Reichert et al., 2001).

Next to the standard trivalent inactivated influenza vaccine (TIV), a novel, intranasal, live attenuated influenza vaccine (LAIV) has been currently discussed as a non-invasive alternative for childhood vaccination programmes (Carter and Curran, 2011, McGuire et al., 2016), bringing the topic back on the agenda for the German and European context (McGuire et al., 2016, Rose et al., 2014). However, LAIV did not have the effectiveness that was presumed (Rose et al., 2014), and was recommended by the American Advisory Committee on Immunization Practices (ACIP) not to be used in the season 2016/2017 (Grohskopf et al., 2016). The German Standing Committee on Vaccination (STIKO) first recommended the intranasal vaccination, despite the different recommendation by CDC/ACIP, but changed the recommendation status in October 2016 (der STIKO, 2016). Recommendations might differ in the coming seasons, depending on the circulating influenza virus strains to be expected. Therefore, the question of using childhood influenza immunisation to achieve herd immunity and thus also to protect risk groups like the elderly and chronically ill is current and pertinent. Until now the ethical dimension has been neglected in discussing the topic.

While the discussion is ongoing, we want to approach the question from an ethical perspective. Thus, we ask: Should seasonal influenza vaccination be offered to or maybe made obligatory for children to tackle the overall societal burden of disease?

Methodology

We will frame the issue and ask what appears ethically convincing, utilizing principles that are also regarded as relevant by the WHO for the methodical study of infectious disease outbreaks (WHO, 2016). Indeed, we are developing a coherentist argument that not only refers to one ethical theory but to several principles, theories and approaches. Our aim is to come to a convincing convergent conclusion in the tradition of "reflective equilibrium" (Daniels, 1996) that coherently integrates normative insights of different ethical approaches when developing a judgment and drawing conclusions. The ethical approaches referred to in our argumentation are chosen on different grounds: First, they are chosen according to the authors' experience in giving ethical trainings to members of public health services across Europe (incl. Germany). Most of these ethical approaches have been repeatedly mentioned as starting points of public health service professionals for their argumentations in the context of immunisation programmes. Second, this choice also reflects systematic and introductory discussions of public health ethics. Several scholarly works also refer to the same range of principles and theories when discussing ethics in a pluralist context (Stapleton et al., 2014, Holland, 2015) but also in papers formulating ethical policy advice or being suitable directly for public health practitioners (Capron, 2007, Faden and Shebaya, 2016, Nuffield-Council-on-Bioethics, 2007, WHO, 2016). Thus, our choice of approaches intends to relate to real-world discourses of public health ethics within the public health community, while referring explicitly to the most used approaches in the field. We furthermore argue in a systematic fashion for the choice of approaches. Indeed, one could also rather directly choose public health ethical tools of which many exist (Willison et al., 2014, Lee, 2012). However, none of these tools – except the "intervention ladder" of the Nuffield Council (Nuffield-Council-on-Bioethics, 2007) that is also used here – is widely used, yet. Although many of the tools also implicitly or explicitly refer to the here applied approaches, we indeed want to go back to the original approaches given that in our experience they are more often referred to in public health practice and service, and so to directly connect them to the arguments of the actors in public health service.

First, we start with the Hippocratic Ethos that – in our experience across Europe – is still being used as normative reference point by public health physicians. The core normative sentence of the Hippocratic Oath is: „I will prescribe regimen for the good of my patients according to my ability and my judgement and never do harm to anyone".

Physicians and their judgement play a central role, not the patients' will. The idea of bringing about best consequences for the patient is often confused with Utilitarianism, which could better be summarised as "Doing greatest possible good to the greatest number". Classical act-utilitarianism states that an act is right if, and only if, it raises the net amount of the overall good. Despite adding a social dimension to the bilateral consequentialist thinking of the Hippocratic tradition, it is said that utilitarianism is the standard normative theory of public health (Powers and Faden, 2006). Miettinen (Miettinen, 2005) claims in a hedonistic fashion that "public health actions should serve to maximize the aggregate happiness", while Mackenbach (Mackenbach, 2005) argues that utilitarianism provides public health professionals "with a quantitative method for determining what is a good, and what is a wrong decision".

Utilitarianism is a founding theory of the so-called "harm principle" of John Stuart Mill, a core norm in the widely used Nuffield Council on Bioethics report (Nuffield-Council-on-Bioethics, 2007). According to Mill "the only purpose for which power can be rightfully exercised over any member of a civilized community, against his will, is to prevent harm to others" (Mill, 1859). The principle pronounces the importance of individual liberty against paternalistic action, as Mill assumed that granting liberty leads to prosperity and thus increases the overall good. However, it also shows where the limits of respecting liberty should lie. As such, it is an important norm in public health ethics and specifically in this context (Bioethics, 2007). The key concern of limiting liberty is also reflected in the public health ethical tool of the "intervention ladder"(Nuffield-Council-on-Bioethics, 2007). In this tool, the gradual weighing of the norm of liberty against interests in maximising population health is disentangled. Here it is reflected that the more coercive the state gets in interfering with the liberty of its people – e.g. making choices of getting immunised or not – the more the state has the burden of proof of justification that the limitation of liberty is justified (Nuffield-Council-on-Bioethics, 2007). With its focus on the incremental loss of individual liberty, however, the ladder is very narrow with regard to its ethical concerns (Dawson, 2016). Nevertheless, such a tool is helpful to structure interventions and to draw one's attention to at least some relevant normative tension. But it is not sufficient, and we only regard it as one approach that needs to be combined with other approaches and perspectives to reach convincing conclusions.

Liberty – and the harm principle as well – stands against paternalism and against instrumentalisation of individuals for the greater good: "Individuals are ends and not merely means; they may not be sacrificed or used for the achieving of other ends without their consent" (Nozick, 1974). Using force to benefit others, including taxes to finance public health services, is not acceptable. Force is unacceptable even to paternalistically benefit the person forced, what Hippocrates might still allow. On the other hand, charitable actions or other expressions of free choice meant to contribute to the good of others are acceptable.

The focus on the social and population level is missing in individualistic ethics like Hippocrates or the harm principle, while on the other hand the utilitarian social ethics perspective is also not fully convincing as it would disregard aspects of equality and individual rights as intrinsically morally relevant. Therefore, the principle of justice, a further corrective of both utilitarianism and liberty, systematically developed against the deficits of these approaches, shall be considered (Powers and Faden, 2006). Justice is of particular importance in public health dealings with questions of health inequalities and inequities. Justice asks what "we owe each other in the protection and promotion of health" (Daniels, 2008). One could argue that public institutions are obliged to promote fair equality of opportunity. Health significantly contributes to the opportunity range for people and thus justice requires protecting health and meeting health needs. These opportunities should be real and equal, so that people can *really* do and choose what they prefer to be and pursue a good life (Nussbaum Martha, 2006). The normative demands of justice are largely compatible with the value of solidarity that normatively understood pronounces that people carry "costs" commonly to support each other and thereby assist particularly those in need (West-Oram and Buyx, 2016). Solidarity thus supports the collective action when facing common threats (Dawson and Jennings, 2012), e.g. immunization programmes against seasonal influenza that demand relatively little "costs" from everyone participating but are potentially lifesaving for particular weak members of society, like children, the elderly and otherwise chronically ill persons (WHO, 2016).

The relations among and the systematic enfolding of these approaches show why the choice of these theories is not arbitrary or simply eclectic but indeed represents a range of ethical theories and principles that are (rightly) prominent and used complimentarily in public health ethics. To only use a tool focussing on questions like a checklist would not connect so foundationally to the discourses already lead in the context of the ethics of infectious disease control.

Results

To what actions would these ethical approaches guide policy makers to decide about childhood immunization strategies for seasonal influenza? In the following, we will see how the individual approaches would respond to our question at stake. In the discussion, then, we consider all these judgements and approaches and reflect what justifications would flow from them. We will discuss how we can weave them together in a coherentist manner to come to a convincing and convergent judgement that also is valid in a pluralist context.

Hippocratic perspective

Hippocratic physicians check what consequences an action has but only for their patient and then try to avoid harm and do good to this one patient. Prioritisation or instrumentalization of patients for the benefit of others is unacceptable (Veatch, 2000). The social good, justice and patient autonomy are also irrelevant. When it is to avoid harm, the iatrogenic harm to the individual patient is meant in the Hippocratic tradition. The idea of avoiding harm through preventing the disease spreading relates more to Mill's harm principle. Unlike for Mill, paternalistic action, including "nudging" patients for their individual benefit is acceptable (Thaler and Sunstein, 2009). Compulsory immunisation would be acceptable on grounds of paternalism, not for the social good (Veatch, 1987).

A strict Hippocratic physician would prefer to give a nasal spray over a shot, if this is less harmful and discomforting – but would be as effective. After a risk-benefit assessment focusing only on the good of the one patient the Hippocratic physician would weigh the indication for the individual. The immunisation can only be acceptable if it protects the child–and it is irrelevant whether it protects others or not. Thus, a Hippocratic physician would not be a mere executor of mass immunisation programmes. Also, the will of a child, or the parents, is no reason to vaccinate, no matter how it is financed. In other words, Hippocratic physicians would only administer a vaccination if they think it benefits the one patient they currently deal with.

Utilitarian perspective

Utilitarianism focuses aggregate consequences. If all consequences can be considered, utilitarianism, can give clear answers (Singer, 2015). The claim that evidence-based decision making for vaccines follows rule utilitarianism (Field and Caplan, 2012) is not surprising since it underlines that actions are right if and only if they follow a rule that promises utility maximisation. However, it also assumes the premise that health maximisation is contributing to the maximisation of the overall good. In utilitarianism, outcomes are judged on the long run: health maximisation and all costs are to be taken into account. Thus, even compulsory measures can be acceptable based on evidence: "If wide uptake of a vaccine can leave an entire population disease-free, the case for overriding personal autonomy by requiring universal compliance is substantially strengthened" (Field and Caplan, 2012).

Assessing costs and benefits, vaccination fee for service can be allowed or demanded. But if fee for service would not lead to sufficient coverage, paid immunisation programmes can be preferred. The role of vulnerable groups could be limited, since they per se have no special status. Rather, one has to ask: What is their contribution to social utility? One could easily conclude that saving children has priority, as they can lead more happy and healthy years, contributing to overall utility maximisation. Even though social fear and distrust is to be a avoided, as they are detrimental for overall utility, a strict utilitarian has to consider if it is more cost-beneficial to not immunise against seasonal influenza at all, if healthy young people benefit less from being immunised, while higher mortality among older and multi-morbid people save costs to the society. Indeed, prioritising people promising to contribute more to the overall utility may lead to frivolous conclusions.

Perspectives from Liberty and Autonomy

A strong counter position to utilitarianism is libertarianism. Strict libertarians would argue: Elderly, pregnant women and chronically ill can go for immunisation themselves. If this is not possible it is indeed their bad luck. Vulnerable people can hope for voluntary support or charity action but claiming rights to support is not acceptable. Since one may never force someone to get immunised to benefit someone else, compulsory programmes are not acceptable. State financed immunisation programmes recruiting people for immunisation on 'opting in' are unacceptable because 'others' are forced to finance this. Therefore, only free choice and fee for service is acceptable. Setting transparent and not manipulative incentives, whose costs are covered by voluntarily collected funds and not by forced taxes, are also acceptable. The different levels of balance in liberty and state intervention and coercion are reflected in the Nuffield Council on Bioethics "intervention ladder" (Nuffield-Council-on-Bioethics, 2007) (Table 1). Focusing only on liberty and ignoring other normative approaches that are relevant in a pluralist society (Dawson, 2016) the tool could hardly be a sufficient ethical approach as it is. Therefore, for this paper we are following a more pluralist and coherentist approach integrating also other values but liberty and common good.

Libertarians, however, claim to protect the autonomy of individuals by making autonomy trump any utility or beneficence-driven perspective (Nozick, 1974), overlooking that autonomy could be differently interpreted. In fact, it is very plausible that the Kantian autonomy would not support libertarian "hands off" policies as mentioned above. It wants people to act on the principle of universalisability and there are duties to support

Table 1. Intervention ladder as proposed by the Nuffield Council on Bioethics adapted by authors regarding seasonal influenza immunisation programmes that include children

Step	Possible interventions with regard to seasonal influenza immunisation programmes
(1)	implement no special interventions, including no financing of requested immunisations, but only monitor the situation
(2)	educate the population with leaflets or information campaigns and appeal to participate in (publicly financed) immunisation programmes
(3)	enable choice by educating pro-actively and personally via public health services or paediatricians
(4)	nudge towards the immunisation by e.g. offering immunisation as standard package at paediatrician visits (allowing for an opt out)
(5)	pay incentives for immunisation, e.g. by paying immunisation premiums to parents or children (e.g. textbook vouchers)
(6)	implement disincentives, e.g. having to pay flu treatment out of pocket
(7)	restrict choice by e.g. making another requested treatment at the paediatrician only available when also immunising
(8)	leave no choice but to obligatorily immunise children to protect society, including the elderly

others in need. Indeed, free-riding and benefitting from herd immunity while not being vaccinated is wrong, because if everyone would free-ride, preconditions for autonomy are undermined (O'Neill, 2002).

And, even more, is the parents' will or liberty identical with the child's will or liberty? We accept that parents decide for the good of their children, unless a lot of harm would otherwise be done to them. But what is the role of children's developing autonomy? What if they are empathetic and want to protect the vulnerable by promoting herd immunity? Should they be permitted to receive vaccination against their parents' will? Although including children in assent processes is common, a recent study of their competence to consent hinted that children older than twelve years of age may be judged as competent to be involved in informed consent – and not only assent – processes (Hein et al., 2015). Questions around child autonomy are still developing and need more research, conceptualisation and public discussions, especially in the context of seasonal influenza vaccination.

Justice and Solidarity Perspectives

The vision of this perspective is health for everyone, as far as possible. Endorsing egalitarian concepts, special attention is given to those who are worse off, especially if not through any fault of their own. This includes vulnerable groups. There might, unlike in utilitarianism, be special ethical worry about "free riders" and for those that have been previously discriminated against (Field and Caplan, 2012, Powers and Faden, 2006).

Unless there is guarantee that everyone, who would benefit from the vaccination can get it financed, fee for service vaccinations are not preferable. Rather, publicly financed immunisation programmes would be preferable.

The capability approach of social justice focuses on the moral importance of the freedom to achieve well-being, understood in terms of people's capabilities, opportunities to do and be what they have reason to value (Nussbaum Martha, 2006). Thus, this theory draws attention to those who cannot make a choice themselves because they either may not be vaccinated due to their immune status or they do not grasp for example the implications of choice. In the latter case, emphasis would be given on real informed choice. This goes beyond information campaigns, referring rather to empowerment and health education. The capability approach of justice also reflects again to the value of solidarity (Prainsack and Buyx, 2012, van den Hoven and Verweij, 2013) .

Compulsory programmes could be acceptable if needed to protect people including those who cannot protect themselves. Yet, other non-compulsory measures have to be explored first, underlining the right of exercising self-determination (Powers and Faden, 2006). Even though paternalistic and compulsory measures might be acceptable for proponents of liberal justice theories, these interventions would always have the burden of proof of being necessary to achieve real equality of opportunity.

Discussion

We would like to use the normative insights gained from the different ethical approaches, to respond to the question at hand. We are stating a coherent ethically informed argument in line with our considered moral judgment as follows:

In the Hippocratic Ethos we find convincing that professionals have obligations towards individuals. If we trust individual physicians, we expect them to act in our interest and do not harm us. If they have the benefit of others in mind, they should at least be explicit and non-manipulative about it.

The utilitarian calculus reminds us convincingly that there are ethical reasons to maximise health, promoting utility in the society by avoiding harm related to infectious diseases. Thus, to reduce the societal burden of disease is good, but not the only moral point to consider. In fact, if it were, this could lead to solutions that restrict individual autonomy and societal equity. Any action undermining autonomy has the burden of proof. Yet, this includes the duty to protect autonomy of others and points to the high value of all individuals, to which justice conceptions also point, including vulnerable and disadvantaged groups.

What still puzzles us is the role of developing autonomy and the will of children that may be in conflict with their parents' choice. In our opinion, involving children in decision making can promote their developing autonomy and moral development. Considering children as morally equal to adults already from the infancy, the idea of "agenting child" (Wiesemann, 2016) has been not only neglected in immunisation discussions but also in research so far. Lastly, children benefit from the immunisation – they do not get sick, they do not miss days in school – even though for healthy children seasonal influenza has mostly no negative long-term effects.

Of course, one needs to address parents' needs and questions. This can be done during the encounter of the health care workers with parents and children. Here, children's opinion can also be heard and be considered in shared decision-making. In this setting health care workers need to address the value of herd immunity. One also has to critically keep in view that "non-immunisation" could become the new "smoking", those who would not immunise their children must not be stigmatised.

Thus, what options for immunization strategies exist, and which do we find convincing? Considering and adapting the Nuffield Council on Bioethics "intervention ladder" (Nuffield-Council-on-Bioethics, 2007), we identified strategies with regard to seasonal influenza immunisation programmes that are displayed in Table 1. Unlike the Nuffield Council on Bioethics, we not only want to focus on the more or less of liberty in the argumentation (Dawson, 2016) but also want to integrate the other norms and values as well.

We are convinced that there are good ethical reasons for offering a childhood vaccination programme to protect the whole society (reflecting justice, solidarity and partly also utilitarian thinking). This should be voluntary, meeting "real choice" conditions: Those who counsel on immunisation should stimulate the capabilities for choice. In Germany those would be the paediatricians. Thus, public health agencies should empower paediatricians, parents and children to make real deliberate decisions. In this context, the role of the children and their preferences shall not be ignored. This is a promising, rather autonomy supporting strategy (Marckmann et al., 2015) and thus also appears to be proportional (Schröder-Bäck et al., 2009). Thus, step (3) is ethically convincing.

If voluntary programmes do not achieve high immunisation rates – for instance of 75% according to the WHO (Kieny et al., 2006), appropriate incentivisation or nudges could be of added value (Constable et al., 2014, Wildner, 2016). In other words, next to step

(3) we see (5) as being promising for herd immunity but not too autonomy-limiting and thus the least restrictive alternatives (Schröder-Bäck and Martakis, 2015). Furthermore, investing extra resources (e.g. for incentives like book vouchers or so) or using nudges is still compatible also with the value of solidarity. Only if these approaches do not show to be effective in real life, compulsory measures may be considered.

Conclusions

Childhood vaccination programmes may significantly lower the societal burden of disease while particularly protecting vulnerable groups through herd immunity. However, policy development needs ethical reflection. We have applied the ethical theories, principles and approaches that are – according to our observation – most widely used in public health while discussing childhood immunisation programmes ethically. This does not withstand that also immunisation programmes among adults and the elderly should be strived at. We are convinced that non-compulsory immunisation programmes focussing a capability for choice and programmes using incentives or nudges are ethically defendable. We suggest further research to explore how the child's developing autonomy shall be considered in such decisions, where the risk is small, but the overall benefit can be substantial. Here, interdisciplinary work combining psychological and ethical analysis can be helpful.

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4

Chapter 4

Developing child autonomy in paediatric healthcare: towards an ethical model

Abstract

The changes initiated by the new National Civil and Commercial Code in Argentina underline the paediatric task to empower children's and adolescents' developing autonomy. In this paper, we have framed a model describing autonomy in child healthcare.

We carried out a literature review focusing on i) the concept of autonomy referring to the absolute value of the autonomous individual, and ii) the age-driven process of competent decision-making development.

We summarised our findings developing a conceptual model that includes the child, the paediatrician and the parents. The paediatrician-child relationship is based on different forms of guidance and cooperation, resulting in varying levels of activity and passivity. Parental authority influences the extent of autonomy, based on the level of respect of the child's moral equality.

Contextual, existential, conceptual, and social-ethical conditions shall be considered when applying the model to facilitate dialogue between paediatricians, children, parents and other actors.

Introduction

The changes initiated by the new National Civil and Commercial Code bear significant implications in the paediatric routine, according to the Subcommittee of Clinical Ethics of the Argentinean Paediatric Society (SAP) (SAP, 2016). Children and adolescents are regarded competent regarding decisions relevant to their health from the age of thirteen, while informed consent and assent of the child are gaining importance in the paediatric practice. Along with other national paediatric societies, SAP has underlined the paediatric task to empower child autonomy (SAP, 2016, Gahr, 2015). In this paper we have focused on the concept of "respect for autonomy" and the relevant challenges in paediatric healthcare (Beauchamp and Childress, 2019, O'Neill, 2002a).

First, it is contested from which age autonomy is sufficiently developed for children's decisions to be respected. Second, the classical dipole (physician–patient) is replaced by a triangle of actors (child/adolescent, paediatrician, parents) (Carse and Nelson, 1996). This is similar to challenges with autonomy when dealing with less autonomous adults, represented by guardians (Elliott et al., 2009). In our case though, autonomy is still developing.

Thus, the objective was to present a model depicting developing autonomy in child healthcare. This is meant to be useful to understand normative implications of child autonomy and to facilitate discussion.

Methods

We conducted a literature search and carried out a directorial content analysis (Hsieh and Shannon, 2005). We examined concepts and models that have strongly influenced the conception of autonomy, including the topic of paternalism, defined as overruling autonomy for a person's assumed benefit. We documented relevant information in a corpus and studied the data using digital methods of qualitative analysis, following three study themes: paediatrician-child, parent-child and paediatrician-parent relationship. We limited our study in situations that include these actors interacting within a frame of justice, where legal, human rights-based and distributive justice (Gillon, 1994) as well as the public health good (O'Neill, 2002b) are respected.

Further, the model was developed synthesizing the key findings (Figure 1). The model underwent several phases of refinements, including a presentation at the meeting of the German Research Foundation's (DFG) Network: "Children's well-being and child-

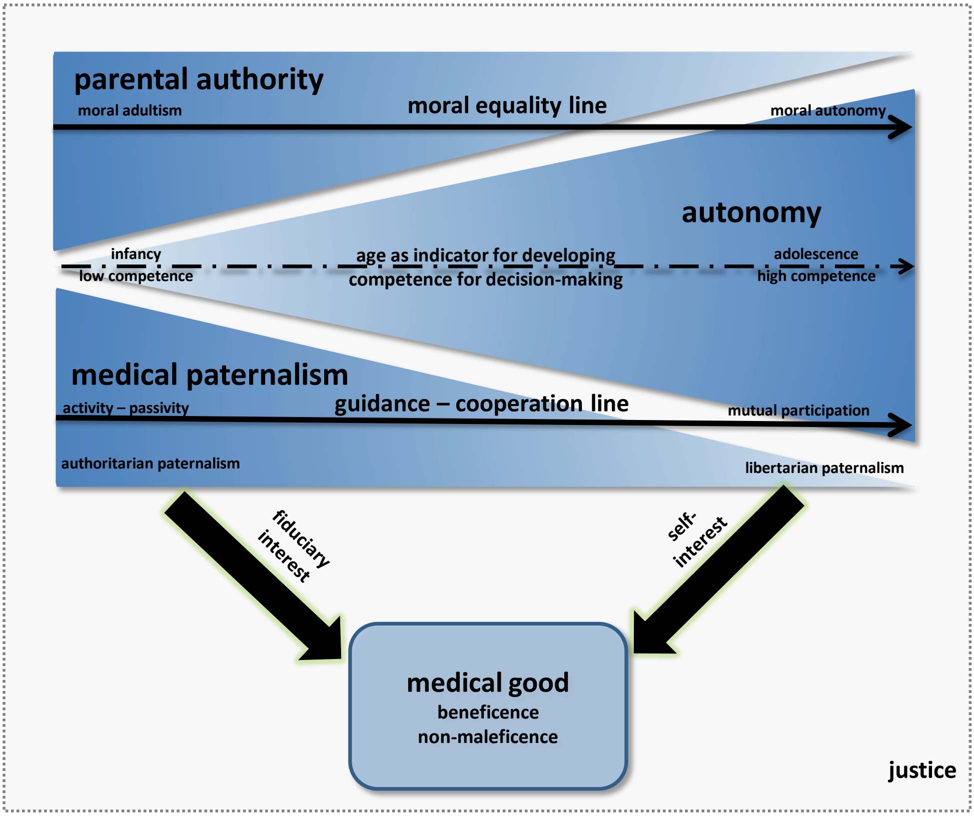

Figure 1. Conceptual model for developing autonomy in child healthcare.

protection: An analysis of the normative principles of children's well-being" on October 4th-6th 2016 in Göttingen (Germany) (Bagattini, 2017).

Results

In the following we presented what we found to be relevant to the study question, ordered according to four themes: a. autonomy and the child's moral completeness, b. the parental role, c. the paediatrician's role and d. beneficence and the medical good.

How complete is complete?

Autonomy development includes increasing levels of self-governance. Thorough decisions, self-reliance and balancing parental pressure and peer pressure are key elements of this process (Russell and Bakken, 2002). Several authors argue that autonomy and wholeness for the paediatric patient have not been achieved yet. This may be explained either by radical theories that deny the child's moral worth (Giubilini and Minerva, 2012, Schapiro, 1999, Tristram, 1996) or through the theory of minimal autonomy, which absolutise the importance of chronological age (Jaworska, 2009). The age-driven character may resemble to Piaget's controversial theory of cognitive development (Piaget, 1983). Interestingly, recent studies on children's decision-making competences suggest that individuals from the age of twelve years shall be judged as competent to provide informed consent (Hein et al., 2015a). Thus, intelligence could complement age as key factor in children's competence to consent to research (Hein et al., 2015b).

Besides, the principle of 'moral equality' presents a revolutionary approach. Indeed, the principle of 'respect to autonomy' not only equalises the moral worth of the child of any age and the parents, but also of humans of all ages. The parental role is established on the child's natality, on which the child's trust follows and is safeguarded by the parents' respect and love, guiding them to fulfill the child's needs. Denial of the child's moral worth, unintended (child neglect) or intended (child abuse) signals a betrayal. Rather, an agenting child can only be raised once the child's moral autonomy is respected by the parents (Wiesemann, 2016).

Does authority make a parent?

Parental authority and family interests influence the extent of a child's autonomy. For instance, overprotective parenting has been reported to weaken the child's capacity for developing autonomy, with varying effects according to the child's age and degree of physical and cognitive abilities (Affdal et al., 2015). Considering the relevance of age and intelligence for cognitive development of children, such overprotective parenting styles can only be counterproductive (Hein et al., 2015b). On the contrary, open discussions within the family and participation in family focus groups – sometimes even leading to the children questioning their parents' choices – can be an important means of developing autonomy (Nichol et al., 2011).

Parenting styles vary from absolute authoritarian paradigms (Tristram, 1996, Giubilini and Minerva, 2012) to stewardship (Brennan and Noggle, 1997) and libertarian concepts (Wiesemann, 2016). The first ones, comprising expressions of moral adultism, may even conclude that children are parental property, and parents for instance may even decide if their infants should keep living (Giubilini and Minerva, 2012). Modern libertarian parenting concepts, however, are based on the principle of trust and the respect of the child's equal moral worth (Wiesemann, 2016).

The role of the paediatrician

The dynamic paediatrician-child relationship is based on guidance and cooperation. Thus, the paediatrician may show a higher or lower level of authority, resulting in stronger or weaker forms of medical paternalism, from authoritarian, coercive, limited, to libertarian (Strasser, 1988).

According to traditional paternalism models, the physician acts for the patient's good (beneficence) and is qualified to act on behalf of the patient, even without the patient's consent or in opposition to his or her uttered will. A passive patient merely recognises the physician's authority (Komrad, 1983). However, the paradigm shift to a less paternalistic medical behavior leads to varying levels of activity and passivity of both actors. In this context, paternalism can be directly associated with the extent of the child's autonomy. Authoritarian paternalism is less likely to boost decision-making competences. Libertarian paternalism though, is the force that intensively facilitates mutual paediatrician-child participation in decision-making, maximizing the child's capacity to be autonomous (Karlsson, 2007). Pellegrino underlines that the paediatrician-patient relationship is about restoring lost wholeness and autonomy (Pellegrino and Thomasma, 1987). Indeed, the paediatrician not only should facilitate a restoration, but also stimulate the further autonomy development, especially because illnesses existentially limit children's autonomy.

Further, informed assent and consent are important tools deriving from libertarian paternalism, facilitating pedagogically the child's agenting role (Kuther and Posada, 2004, Rossi et al., 2003). This role is based on the fact that children are capable of moral feelings at every age, and can act in accordance with them in ways that others can understand and share (Wiesemann, 2016). Thus, the paediatrician has an obligation to explain using age-appropriate terminology and to ask for assent of competent children and adolescents (Sibley et al., 2016).

Furthermore, paediatricians co-coordinate the parent-child interaction (Simpson, 2014). Focusing on the child within its family, paediatricians facilitate the interdisciplinary work needed to assist autonomy-strengthening parenting (Harrison et al., 1997). This shall not lead to a compensating rise of medical paternalism. Apart from obligations to the "emerging adult", paediatricians have obligations towards the parents, including openness to discussion, consent or even negotiating responsibilities among family members, or the care-giving team and the parents (Sibley et al., 2016, Kloep and Hendry, 2010). Thus, rights deriving from parental authority, rights of new parents and the child's autonomy need to be well balanced when juxtaposed (Goering, 2009).

Finally, the paediatrician's role is critical in cases of absolute irreconcilability between parents and children. Indeed, it is crucial to have the right to request an intervention of the local agency for child and youth welfare, to consult an ethics committee, or even to initiate a legal intervention (SAP, 2016). Paediatricians though, do not always enjoy adequate societal and legal support, that would allow them to utilise such tools (Gahr, 2015).

Medical good

Beneficence and non-maleficence (Pellegrino and Thomasma, 1987) are argued to be drivers for paternalism. In healthcare setting, child, physician and parents are freely interacting for the medical good of the first (Wiesemann, 2016). Thus, all actors aim at the maximisation of net benefits and minimisation of net harms dictated by different motives. Fiduciary interest is the driving force of the paediatrician and the parents, while self-interest is the respective child's motive (O'Neill, 2002a).

Drawing the model

The terminology describing autonomy development varies in the literature, depicting differences in the stance of academicians. In fact, the terms 'future' and 'developing' autonomy are often used interchangeably. In our opinion, this is not fully correct. 'Future' autonomy is static, illusionary, ignoring the child by simply referring to the adult-to-be. Deriving from moral adultism, it does not represent the kind of autonomy that should be prioritised. On the contrary, 'developing' refers to a dynamic process leading to autonomy through trust and care, guidance and cooperation. Aim should not be the mere preparation for an autonomous adulthood, but the safeguarding of autonomy every step of the way from infancy, through adulthood.

Further, two main and somehow contradicting ideas associated with autonomy are depicted in the literature. First, reflecting the idea of Kantian autonomy, the concept of autonomy refers to the absolute value of the autonomous individual (Wiesemann, 2016). The second one reflects the age-driven process of competent decision-making development, as presented by Beauchamp and Childress (Beauchamp and Childress, 2019).

Thus, is chronological age that relevant for the autonomy development? In our opinion, the child's developmental age, summarizing the factors of age and cognitive development, could be the key to assess the development of functions associated with autonomy, such decision-making competences. For this reason, we have included both ideas in the model (Figure 1) using the moral equality axis, pronouncing that all children have the same moral value despite their different competences, as well as the "developmental age"-driven decision-making competence axis. Future research shall consider the children's developmental, and not chronological age, utilizing appropriate assessing tools.

Attempting to graphically display different levels of paternalism against the extent of autonomy, utilizing a guidance-cooperation line as the main axis, we realised that libertarian paternalism shall be the paradigm to actively promote the children's developing autonomy. Paediatricians shall cooperate with the parents to empower young patients in their voyage to autonomy.

While applying the model, a series of conditions needs to be addressed. Pellegrino classified them as contextual, existential, conceptual, and socio-ethical (Pellegrino and Thomasma, 1987). Relevant emerging topics to be considered are summarised in Table 1.

Implementation

In the following two cases that pronounce different aspects, we have exemplified autonomy-related challenges, discussing them along the different constructed conditions as laid out in the model.

Case 1: Influenza vaccine

> *Veronica is a ten-year-old girl. Her best friend Mariella, a patient with spinal muscle atrophy (SMA) type III, suffers often from critical infections of the lower respiratory tract. Veronica always visits Mariella during her hospital stays. Veronica wishes to receive the intramuscular seasonal influenza vaccine, because she is convinced that increasing herd immunity is critical for patients like Mariella. Her parents are skeptical about the vaccination.*

*Contextual conditions***:** The paediatrician shall first address issues of context variability. The disease itself may be relevant for Veronica. Nevertheless, the consequences among healthy children are limited. The vaccine side-effects are harmless, including mild infections of the respiratory tract and fever, most probably not threatening her developing autonomy. Alternative intranasal vaccines have not been proven effective. Providing evidence-based information will rule our health literacy problems. The decision-making competences of the child and parents may be examined using standardised tools. The literature suggests that a ten-year-old child is not always competent to reason wisely in this context.

*Existential conditions***:** On the other hand, Veronica's exposition to influenza-related hazard among SMA patients has increased her awareness. During the discussion with Veronica the paediatrician ruled out doubts regarding her decision-making competence. Chronological age is apparently not the leading dimension.

Table 1. Exemplary conditions to be addressed when applying the model

Contextual conditions	• Context variability: - Nature of the disease, curability, urgency, prognosis and consequences for the child's developing autonomy. - Properties of the offered diagnostics or therapy and consequences for the child's developing autonomy. - Alternative therapies or diagnostic methods to be offered and consequences for the child's developing autonomy. • Health-literacy level of the child and the parents. • Decision-making competences of the child and the parents. • Consider the pitfall of false generalisations.
Existential conditions	• How the disease itself may change the ideas and the decision-making competence of the child and the parents. • How the treatment as well as the alternative treatments may change the ideas and decision-making competence of the child or the parents. • The effect of prior knowledge or exposition to the disease or therapy on the health-literacy level of the child and the parents. • Consider institutional or societal differences that have implications on the transferability of a treatment or therapy in another setting.
Conceptual conditions	• Paradigm shift: from cure to care and how is it applied in the case. • Respect for non-maleficence, if not for beneficence of the child and the family. • Respect for evidence-based medicine when setting indications.
Socio-ethical conditions	• Are there concerns that the individual good, the medical good are suffering from the common good? • Are there concerns regarding the interest of the parents? • Are there concerns regarding the motives of the child? • Are there concerns regarding the exposition of family history or third-party information? • Are there ethical concerns about the financing of the treatment or diagnostics? Who bears the cost? • Is there a case of absolutisation of autonomy? • Is there the case of acting without respecting the frame of justice (legal, human rights-based and distributive)?

Veronica is a healthy individual, thus, no relevant concerns regarding the vaccination emerge. According to national recommendations, the vaccine should be provided annually to all children from the second till the sixth year of life.

*Conceptual conditions***:** The case most definitely addresses the paradigm shift from cure to care. The vaccination can effectively increase herd immunity and Veronica's good is not in danger.

> *Further, Veronica's parents express concerns regarding her school absenteeism. It looks like Veronica has often failed attending school in the last weeks. Currently her school attendance is regular. The mother is worried, that Veronica may get fever and need to stay*

> *at home following the vaccination. Veronica may fail to finish the class, in case the school absenteeism emerges again.*

Socio-ethical conditions: The paediatrician shall thoroughly address school absenteeism that endangers Veronica's developing autonomy. No concerns about the parents' interest are raised. Veronica's motives though, shall be re-evaluated, probably discussing with her alone. Veronica regrets failing to visit school and confirms solidarity as her only motive. She would be happy to receive the vaccine during winter holidays, so that she may not need to miss school because of an infection following the vaccination.

Veronica wants to finance the vaccine herself, using pocket money she and Mariella have collected. Except from the fact that the paediatrician now knows about Mariella's condition, there is no additional concern regarding the exposition of family history or third-party information. The frame of justice has always been respected.

Thus, we would conclude that the mutual participation of the paediatrician and the child according to the relationship of guidance-cooperation, led to a compromise, that boosts Veronica's autonomy, since her school participation has not been endangered and that she financially contributes for the treatment. The parents' concerns have been taken into serious consideration and were resolved efficiently. Their final decision reflects an acceptance of Veronica's agenting function.

Case 2: HPV vaccine

> *HPV-driven cancer is frequent in women of reproductive age. Since 2011 the HPV vaccine is offered as part of the national vaccination program in Argentina and the coverage rate is high.(Patel et al., 2016) Wenzeslava is a fifteen-year-old migrant girl from Bulgaria. Her family moved to Argentina a few months ago. Her parents wish that she receives the vaccine. She refuses though, arguing that she is not sexually active yet. In a private talk with the paediatrician, she admits being scared of potential side-effects. Wenzeslawa has heard that a girl in Bulgaria developed a lethal Wegener's granulomatosis after HPV immunisation. Although there was no causal relation between the two events, vaccination criticism in the media has strengthened the already high vaccine skepticism(Petrova et al., 2015) in Bulgaria.*

The conditions to be addressed have been summarised in Table 2.

In this case we identify issues of health illiteracy, fear induced by anti-vaccination attitudes in media, regarding a vaccine against a sexually transmitted agent, problems regarding the intercultural interaction, language barriers and probably lack of trust towards her new

Table 2. Case study: HPV vaccine

Contextual conditions	• HPV-driven cancers present a serious risk for an often not adequately curable condition, that can be effectively prevented with the HPV vaccine. • The vaccine coverage is high in Argentina. It is expected to lead to a significant increase of the herd immunity in the coming decades. • Prevention of vaginal transmission, e.g. using condoms, often does not prevent from oropharyngeal manifestations. • Sexual inactivity or abstinence is presented as alternative from the girl herself. However, this alternative is definitely restrictive for her future personal and social development, as well as her developing autonomy. • In this case, health illiteracy-driven fear is the apparent problem. • The private talk with the paediatrician is a very important tool to be utilised in such cases.
Existential conditions	• There is no underlying condition or prior experience that could influence the girl's decision-making competence or level of autonomy. • Wenzeslawa has no prior exposition to HPV-driven diseases. She has been exposed though to false information regarding potential side-effects of the vaccine. • There are apparent societal differences between the two settings. The HPV vaccine is a successfully implemented program in Argentina, but this is not always the case in a lot of other countries. Problems in the communication or lack of trust, associated with the intercultural character of this paediatrician-patient interaction need to be addressed very thoroughly.
Conceptual conditions	• The respect for non-maleficence of the girl is crucial. Wenzeslawa needs to be reassured, that the side-effect she is scared for is not associated with the HPV vaccine. However, she shall be informed about all true side-effects, including the extremely rare serious ones. • The prevention of HPV-driven cancers reflects the respect for beneficence as well as for evidence-based medicine. • Apparent paradigm shift from cure to care. Wenzeslawa shall not be vaccinated for the sake of performing the treatment immediately. She shall understand the personal and societal benefits of this decision and she may receive it in the future. • Negotiation with the girl could be a useful tool.
Socio-ethical conditions	• There are no concerns that the individual good, or the medical good are suffering from the common good. • There are no concerns regarding the interest of the parents or the motives of the child. • There are no concerns regarding the exposition of family history or third-party information. • There are no concerns about the financing of the treatment or diagnostics. • There is no case of absolutisation of autonomy and the frame of justice has always been respected.

paediatrician. All these shall be thoroughly addressed by the paediatrician. The parents understand the indication and back the treatment. On the other hand, Wenzeslawa's argument of not being sexually active yet, shall not be ignored. The girl is in an age that she is regarded, and most probably she is, competent of taking such decisions.

A negotiation seems appealing. The paediatrician shall inform about vaccine benefits and risks and plan an appointment to re-evaluate the situation for instance six months later. It shall be underlined that it is absolutely advisable for her to be immunised by the time she intends to be sexually active. The parents shall be already informed that in such a case, the vaccine may be applied even without their involvement.

Conclusions

We introduced a model to explore issues of developing autonomy and the tension with paternalism, driven by both paediatric and parental authority. This model shall support the interdisciplinary dialogue between involved actors, such as paediatricians, public health practitioners, ethicists, parents as well as the children themselves. Contextual, existential, conceptual, and socio-ethical conditions should be critically considered when applying the model.

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5

Chapter 5

HPV vaccination and respect for children's developing autonomy: Results from an EU wide study

Abstract

Introduction: Children's rights to autonomy of choice are differently expressed throughout Europe. We explored differences regarding expressions of respect for children's autonomy throughout Europe, using the procedure of HPV vaccination offer as indicator.

Methods: We used a mixed methods approach, utilising an expert survey within the frame of "Models of Child Health Appraised" (MOCHA), among all thirty EU and European Economic Area states. A questionnaire was designed using vignettes regarding the vaccine provision. Thirty MOCHA country agents were invited to respond from June 2017 to April 2018.

Results: In total, 28 country agents responded. We studied the following themes: i. provision of informed consent, ii. parental and medical paternalism, iii. relevance of the child's chronological age or maturity, iv. vaccination programs targeting boys. These are being handled differently across the region. We explored associations of these implemented practices with the national vaccine coverage rate across Europe.

Conclusions: We used the processes of HPV vaccination to study child's autonomy, the paradigm change towards libertarian paternalism and issues of sex-equity. Interestingly, greater respect for children's autonomy tends to be associated with medium or high vaccination coverage rates, and lower respect with lower rates. Respect and empowerment seem to have practical as well as moral benefits. Identifying and transferring the most suitable ethical approaches is crucial and should be strengthened.

Key words:

Vaccination, Papillomavirus Vaccines, Child Health, Europe, Personal Autonomy, Vaccination Coverage

Introduction

Currently, there is no consensus in Europe regarding the ideal model for the provision of primary health care for children and adolescents. The majority of the different existing models of primary child health care throughout the European Union have never been appraised in terms of children's health outcomes (van der Willik et al., 2016). It remains unclear, to what extent children may or may not be receiving optimal health care. Consequently, their entitlement to optimal health, as supported by the United Nations Convention on the Rights of the Child (Unicef, 1989), is rather unknown. It is for this reason that the Models of Child Health Appraised (MOCHA) project has been instigated (Blair, 2017).

Children's rights to autonomy of choice may also be differently and unequally expressed or implemented throughout the European Union. It is widely acknowledged that the developing autonomy of children in health care should be more respected and accepted (Gahr, 2015, Martakis et al., 2018). Inequalities in children's autonomy can easily be identified within the primary health care models for children and adolescents. For instance, differences in granting competence in decision-making based on the developmental or chronological age, differences in the process of informed consent, as well as the processes to be followed in cases that a health service is denied by children or their parents, can raise significant ethical debates regarding the degree of respect to child's developing autonomy (Martakis et al., 2018, EU-FRA, 2017) and moral equality across Europe (Wiesemann, 2016).

A major task of primary health care is to ensure vaccinations to prevent diseases in the population. Vaccination programs for human papillomavirus (HPV) immunization have been offered across Europe since 2007 (Elfstrom et al., 2015) following recommendations from the European Centers for Disease Prevention and Control (ECDC) (Hamers et al., 2008). Unlike in many countries internationally, including the United States, in the majority of the European countries, HPV vaccines are commonly offered to girls in late childhood or adolescence. The implementation of the vaccination, however, is neither harmonized nor standardized across the European Union (Elfstrom et al., 2015). There are several differences across the states including the type of applied vaccine (quadrivalent or bivalent), the age and other characteristics of the target population, the vaccination delivery strategy, as well as the need for out-of-pocket payment of the vaccine (Elfstrom et al., 2015).

From the point of view of public health ethics, very little is known regarding the quality of the interaction between the child or adolescent receiving the HPV vaccine and the physician or nurse administering it. Thus, processes of vaccine provision may vary substantially across the national vaccination programs in Europe, from authoritarian paternalistic models, imposing a passive role on the child, to libertarian models, where mutual participation of both actors is needed (Martakis et al., 2018).

Study aims

Aim of this paper is to explore differences regarding issues related to different expressions of respect for children's developing autonomy throughout the European Union. The procedure of HPV vaccination can be regarded as an indicator for developing autonomy. In Europe the vaccine is commonly offered to girls in late childhood and adolescence, although boys may also benefit. Arguably, at this stage of the life course, cognitive development and decision-making competences of young people are approaching that of adulthood, and thus at least the consent of the person receiving the vaccine, next the consent of the legal guardians, should be requested (Hein et al., 2015). By this stage, young people should also be taking responsibility for their own health and salutogenic behavior. Furthermore, the vaccine protects against an infection that can also be sexually transmitted. Issues related to the right of sexual self-determination of children and adolescents, and associated conflicts in the relationship with their parents, can complicate the implementation of vaccination programs in different European settings. Finally, we aim to explore associations between expressions of respecting child's autonomy and the HPV vaccine coverage rate (VCR) across Europe.

Methods

Study design

National vaccination programs principally utilize primary health care facilities and services to achieve a universal vaccine offer. Currently, within the frame of the Models of Child Health Appraised (MOCHA) project, an interprofessional network has been formed, linking scientific partners with a Country Agent in each one of the thirty European Union and European Economic Area member states, supplying data to answer precise questions. This is aimed at mapping and appraising the field of primary health care services offered to children in Europe. This study was an expert survey performed within the framework of MOCHA, using a mixed methods approach, combining tools of quantitative and qualitative research. We finally explored associations between expressions of respect to child's developing autonomy in the different vaccination approaches in Europe and the national HPV VCR, as currently reviewed by Sheikh et al (Sheikh et al., 2018).

Sampling

The recruited experts included the MOCHA Country Agents (http://www.childhealthservicemodels.eu/partnerlisting/country-agents/), a professional network with diverse professional qualifications, collaborating within the frame of the MOCHA Project. This group of experts is a key methodological feature of the MOCHA project (Brenner et al., 2017, Kuhne et al., 2017). These individuals are local experts in child health in each country who have access to professional networks in order to answer research questions on a range of topics. The specific field of expertise included social pediatric experts and child health professionals, affiliated with one of the thirty participating academic institutions. In total thirty MOCHA country agents from the following thirty European Union and European Economic Area member states were invited to participate in the survey: Austria, Belgium, Bulgaria, Croatia, Cyprus, the Czech Republic, Denmark, Estonia, Finland, France, Germany, Greece, Hungary, Iceland, Ireland, Italy, Latvia, Lithuania, Luxemburg, Malta, the Netherlands, Norway, Poland, Portugal, Romania, Slovakia, Slovenia, Spain, Sweden and the United Kingdom.

Data collection

Data collection and validation took place with the help of the MOCHA Country Agents. We designed a questionnaire, which underwent several rounds of revision based on scientific feedback from the MOCHA task working group, the project's scientific managing team, and an independent Expert Advisory Board, to confirm rationale, relevance and clarity. The questionnaire included a combination of closed questions with specific response categories as well as deepening open-ended questions. MOCHA agents were asked to complete the questions on the basis of their expertise, or in other cases, to gather data from other national experts to respond to the study items. For the sake of transparency, the questionnaire is provided as supplement file (Kuhne et al., 2017). From June–December 2017 the MOCHA country agents from thirty European states were invited to respond to the questionnaire.

The questions related to national policies on respecting children's choices and therefore their autonomy in the national primary health care model. Concerning national law, the MOCHA Country Agents were asked to provide, wherever possible, links to the relevant pieces of legislation.

The Country Agents were further asked to refer to national policies or strong guidelines issued by a health professional or cross-sectoral body on the right of choice or refusal of treatment in childhood and adolescence and to provide the respective link if possible. Further, possible differences of legislation associated with the children's chronological age or the child's decision-making competences were documented. Regarding the issue of medical paternalism, we asked the MOCHA Country Agents, if the physician can overrule a child's choice to receive or refuse to treatment in daily practice in their country**.**

We further explored and exemplified ethical issues regarding the respect for children's developing autonomy, based on an ethical model developed by the lead author (Martakis et al., 2018), using a vignette referring to the provision of the HPV vaccine in girls. Finally, we included a similar vignette referring to the provision of the vaccination to a boy in countries where this was routinely offered, and who thus might wish to be immunized too.

All data were centrally collected and validated by the collaborating scientific partners of the MOCHA project. When clarifications were needed, the MOCHA coordinators directly contacted the country agents, who were asked to review and eventually revise their response.

Data analysis

We carried out a directorial qualitative content analysis (Hsieh and Shannon, 2005), examining concepts and models referring to the following study themes:

i. provision of written informed consent or assent from a child or adolescent or their legal guardians, to receive, request or refuse a treatment, and more specifically the HPV vaccine
ii. issues related to parental as well as medical paternalism
iii. association of the level of autonomy with the children's chronological age or with their decision-making competence
iv. reporting of HPV vaccination programs targeting boys.

We finally explored correlations between different practices applied throughout Europe regarding the themes i., ii., and iii. and the national HPV vaccinate coverage rates. A quantitative descriptive analysis was further used to study the results. The maps in this paper were created with mapchart.net. Atlas.ti–version 16.0 (ATLAS.ti Scientific Software Development GmbH, Berlin, Germany).

Results

Focal points of twenty-eight European states: Austria, Bulgaria, Croatia, Cyprus, the Czech Republic, Denmark, Estonia, Finland, France, Germany, Greece, Hungary, Iceland, Ireland, Italy, Latvia, Lithuania, Malta, the Netherlands, Norway, Poland, Portugal, Romania, Slovakia, Slovenia, Spain, Sweden and the United Kingdom responded by providing national data.

HPV vaccine is offered to girls in late childhood and early adolescence in all participating countries, starting from nine years of age in Austria and Germany. The study of different approaches regarding HPV vaccination in Europe revealed a series of emerging ethical issues. This vaccine is offered to girls through national vaccination programs; however, although generally accepted as safe and beneficial by regulatory authorities, it is sometimes not well accepted in certain population groups, and some public opinion has expressed concerns, including claims of short or long term adverse effects. For example, the HPV vaccine is part of the „National program primary prevention of cervical cancer in the Republic of Bulgaria 2017-2020". After successful program start, the death of a teenager of a long-term systemic disorder two months after immunization, lead to public scepticism and the program was terminated, despite there being no causal relation between the two events.

Our findings have been classified according to four study themes: ethics of provision of informed consent, issues related to parental or medical paternalism, issues associated with the children's cognitive development or findings directly related with the respect for developing autonomy and issues regarding HPV vaccination programs targeting boys. These results are presented in the following paragraphs.

Provision of informed consent

Regarding vaccine provision, written consent is required in the majority of the countries (Figure 1). Although written consent for the vaccine provision is required in the majority of the European states, the person who is responsible to provide informed consent, child or parents, differs substantially (Figure 1). Indeed, the girl's sole written consent is sufficient for vaccination in Finland; an additional parental consent is needed in the Czech Republic, Estonia, Poland, Portugal and the UK. Parental written consent, instead of the girl's consent, is needed in Austria, Bulgaria, Croatia, Cyprus, Denmark, Hungary, Germany, Lithuania, Malta, Norway, Romania, Slovakia and Sweden. Finally, in Greece, Iceland, Ireland, Italy, Latvia, the Netherlands and Spain the vaccine is provided without request of consent, but a parental refusal may deny application.

Issues related to parental or medical paternalism

If the girl requests an offered HPV immunization but the parents refuse consent, she can be immunized in the Czech Republic, Finland, Germany, the Netherlands, Portugal, the UK and in late adolescence in Austria, Denmark, Ireland and Poland (Figure 2). On the other hand, if the parents or guardians request immunization, but the girl objects, she will still be obliged to receive vaccination in Croatia, Cyprus, Italy, Latvia, Lithuania, Norway, Romania and Slovakia. A negotiation with the physician would be the rule in some states, such as Bulgaria, Greece, Hungary, Iceland and Ireland, while a court decision is needed for being vaccinated in the Czech Republic and Poland (Figure 3).

Regarding medical paternalism, it seems that physicians may overrule a child's choice without going to court in Austria, the Czech Republic, Denmark, Estonia, Ireland and Portugal, in case the child has not reached a chronological or developmental age threshold and thus, children may receive the treatment against their will.

Chronological age, maturity and their association with the respect for autonomy

First, we examined the legal situation regarding the right of children to consent or assent in receiving or refusing the HPV vaccination in different European states. National law and policies on the right of children to choose or refuse treatment, even when this is advocated by the parents or their doctor, were reported in Austria, the Czech Republic, Denmark, Estonia, France, Finland, Germany, Ireland, the Netherlands, Norway, Poland, Portugal, Spain, Sweden and the United Kingdom.

Regarding differences of legislation associated with chronological or developmental thresholds to grant children and adolescents a decision-making capacity, we identified a variety of approaches across Europe. Indeed, an age limit of 14 years of age to grant decision-making competence has been set in Austria and Portugal, 15 years of age in Denmark and Finland, of 16 years of age in the Netherlands, Norway, Poland and Spain, and of 18 years of age in Estonia. On the contrary, the grade of development of decision-making competences is the relevant criterion in the Czech Republic, Germany, Sweden, the UK and Spain (for ages 12-16 years). After confirmation of the maturity of the decision-making competences in an examination of mental competency, the child is granted the right to accept or refuse a medical treatment. This is often not the rule in life-threatening conditions.

HPV vaccination programs targeting boys

Unlike some countries such as the United States, vaccinating boys against HPV is still not the norm in Europe, though this is increasing. In the second semester of 2017 the vaccine was offered to boys regularly in Austria, Croatia, the Czech Republic, Poland and Slovakia (Figure 4). The ethical issues referring to the children's rights to receive or refuse treatment, as well as the grade of parental or medical paternalism did not differ from the ones referring to girls of the same age in these states (Figure 4). In June 2018, the Standing Committee on Vaccinations of the Robert Koch Institute announced a plan of launching a vaccination program targeting boys in Germany (RKI, 2018).

Correlation with the national HPV vaccine coverage rate

We explored associations of the studied vaccine practices with the HPV VCR across Europe, as reported by Sheikh et al (Sheikh et al., 2018). The VCR data of only 11 countries, out of the 28 recruited in our study, were available (Table 1). We classified the countries according to their HPV VCR in three categories: low rate (<40%), medium rate (40-75%) and high rate (>75%). Due to the small sample, an analysis using inferential statistics was not possible. However, as table 1 depicts, higher VCR was often achieved in countries with less paternalistic approaches (not vaccinating against child's will), such as Spain, Sweden and the UK.

Discussion

Developing autonomy, parental and medical paternalism

The study of HPV vaccine practices in Europe revealed significant differences in practices in primary health care services targeting children throughout the European Union. The child's developing autonomy, parental authority and medical paternalism are differently weighed and respected.

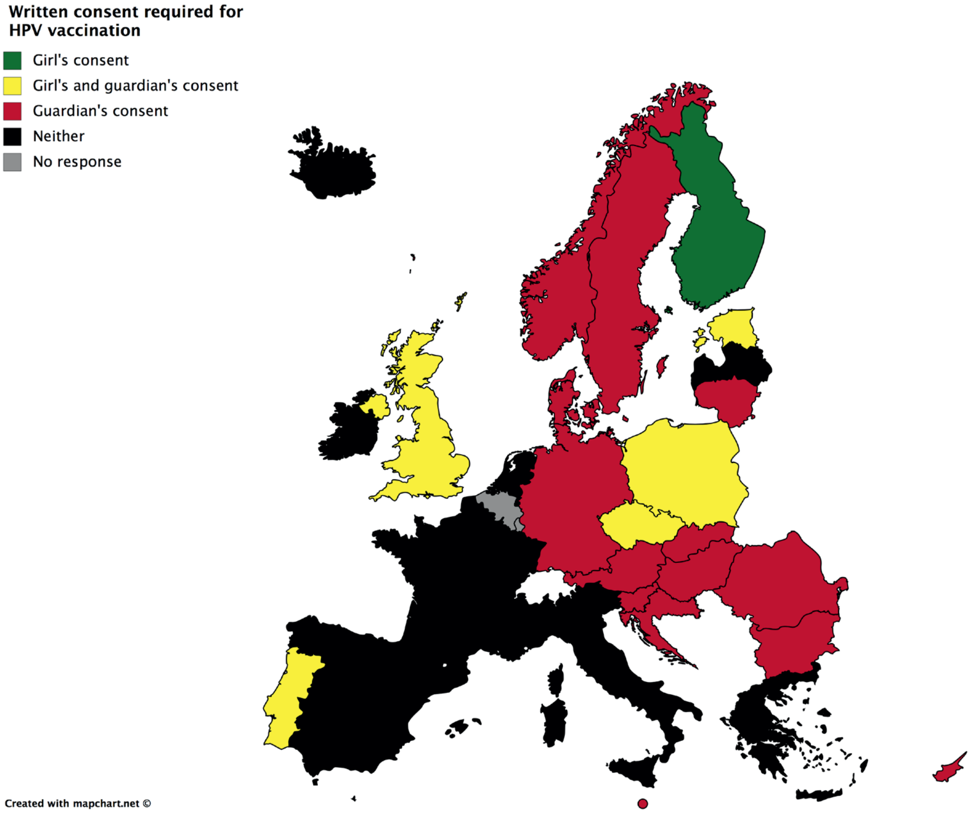
Children's developing autonomy is a dynamic process that should be facilitated throughout their life (Martakis et al., 2018). In practice, as seen from the legislation and practices regarding the provision of the HPV vaccine in the different states, a large number of European children are assessed as competent or incompetent to meet health care choices usually according to their chronological and sometimes developmental age. The chronological threshold also varies across Europe, since adolescents are often legally entitled to decision-making in different ages. The developmental age is currently primarily taken into consideration in a few countries, but such approaches are not standardized yet.

The grade of parental authority deriving from more or less paternalistic paradigms of parenting also emerge in the HPV vaccine case. It is clear (Figure 1) that with the exception of Finland, parents are the ones expected to decide in Europe if a child shall be immunized or not, either through processes of informed consent, or simply not choosing to opt-out of this option, in countries where written informed consent is not required.

Furthermore, in cases where there is disagreement between the girl and her parents, the expected outcome differs throughout Europe. In the European South, parental refusal would be prioritised, ignoring the child's will to receive the HPV vaccine (Figure 2), while the girl's refusal would only be respected in some countries, such as Malta

Table 1. Association of the HPV vaccine coverage rate (VCR), according to Sheikh et al. (2018) and the procedures related to respect of the child's developing autonomy across Europe. L: low VCR (<40%), M: medium VCR (40-75%), H: high VCR (>75%), NR: Not reported, NA: not applicable (no national program)

Country	HPV Vaccin'n Rate	Written informed consent needed?	If the child provides consent and the parents don't (child autonomy)	If the parents provide consent and the child doesn't (paternalism)
Austria	NR	Guardian's	Vaccination	Court decision
Belgium	55.5% M	NR	NR	NR
Bulgaria	14.1% L	Guardian's	No vaccination	Vaccination
Croatia	NR	Guardian's	No vaccination	Vaccination
Cyprus	NR	Guardian's	No vaccination	Vaccination
Czech Republic	NR	Both	Vaccination	Court decision
Denmark	NR	Guardian's	Vaccination, after 14 y.	Vaccination, until 14 years
Estonia	NR	Both	No vaccination	No vaccination
Finland	68.8% M	Child's	Vaccination	No vaccination
France	19.1% L	No	Vaccination	No vaccination
Germany	42.5% M	Guardian's	Vaccination	No vaccination
Greece	27.0% L	No	No vaccination	Negotiation
Hungary	NR	Guardian's	No vaccination	Negotiation
Iceland	NR	No	No vaccination	Negotiation
Ireland	NR	No	Depending on chronological age	Negotiation
Italy	70.1% H	No	No vaccination	Vaccination
Latvia	NR	No	No vaccination	Vaccination
Lithuania	NR	Guardian's	No vaccination	Vaccination
Malta	NR	Guardian's	No vaccination	No vaccination
Netherlands	53.0% M	No	Vaccination	No vaccination
Norway	NR	Guardian's	No vaccination	Vaccination
Poland	23.0% L	Both	Vaccination, after 14 y.	Court decision
Portugal	NR	Both	Vaccination	NR
Romania	NR	Guardian's	No vaccination	Vaccination
Slovakia	NR	Guardian's	No vaccination	Vaccination
Slovenia	NR	Guardian's	No vaccination	Vaccination
Spain	79.0% H	No	No vaccination	No vaccination
Sweden	80.0% H	Guardian's	No vaccination	No vaccination
UK	85.9% H	Both	Vaccination	No vaccination



Created with mapchart.net ©

Figure 1. Written consent required for HPV vaccination for girls in Europe. HPV: human papillomavirus.

and Spain (Figure 3). In Western Europe, the norm would favor the girl's will. A well-defined legal and ethical framework guiding the interaction of all actors (parents, child, professional offering the vaccine) should safeguard that loss of parental trust in this unique case would not substantially influence the interaction of the actors for the child's medical good. The situation is more diverse in Northern and Eastern Europe.

Medical paternalism is a third force and a further emerging ethical issue regarding vaccine administration in Europe. First, we discovered that providing information to patients and parents and expecting written informed consent to provide a vaccine, is not always necessary in some European states, primarily in the European south (Figure 1). Secondly, overruling a child's decision, even of one who is competent to meet a decision based on developmental criteria, is still acceptable in a large part of the European Union. Thirdly, the physician may function as a negotiator in cases of disagreement between children and their parents. This may actually facilitate a solution to the problem, since the physician is required to provide valid information regarding the vaccination to

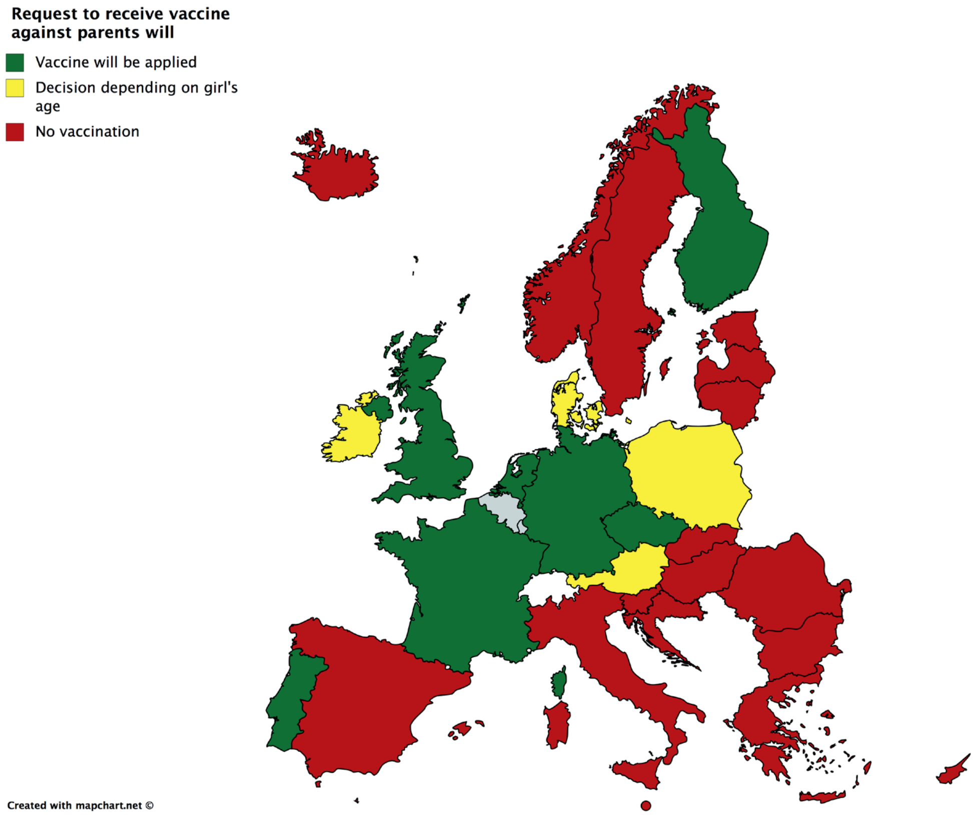


Figure 2. Request of a girl to receive vaccine against parents' will.

both children and parents by facilitating discussions among all actors. Deriving from libertarian paternalism theories, such an approach not only respects, but can also constructively boost the children's developing autonomy (Martakis et al., 2018).

The age at which the vaccine is offered introduces a further ethical issue, regarding the level of parental or medical paternalism in the different European states. Thus, the vaccine is offered already with the ninth year of life in Austria and Germany, two states that show one of the most and least paternalistic patterns respectively. On the other hand, in the UK, a country where the level of maturity and not the chronological age signalizes the decision-making competence, the vaccine is only offered with the 14th year of age, and thus indirectly enabling girls to consent for the vaccine application regardless of parental consent. Offering the vaccine with a delay of a couple of years may seem to be boosting children's autonomy, however. We should keep in mind though, that the vaccination shall be provided before the treated individuals are sexually active. Thus, a delayed application in late teenage years, an age in which many adolescents are already

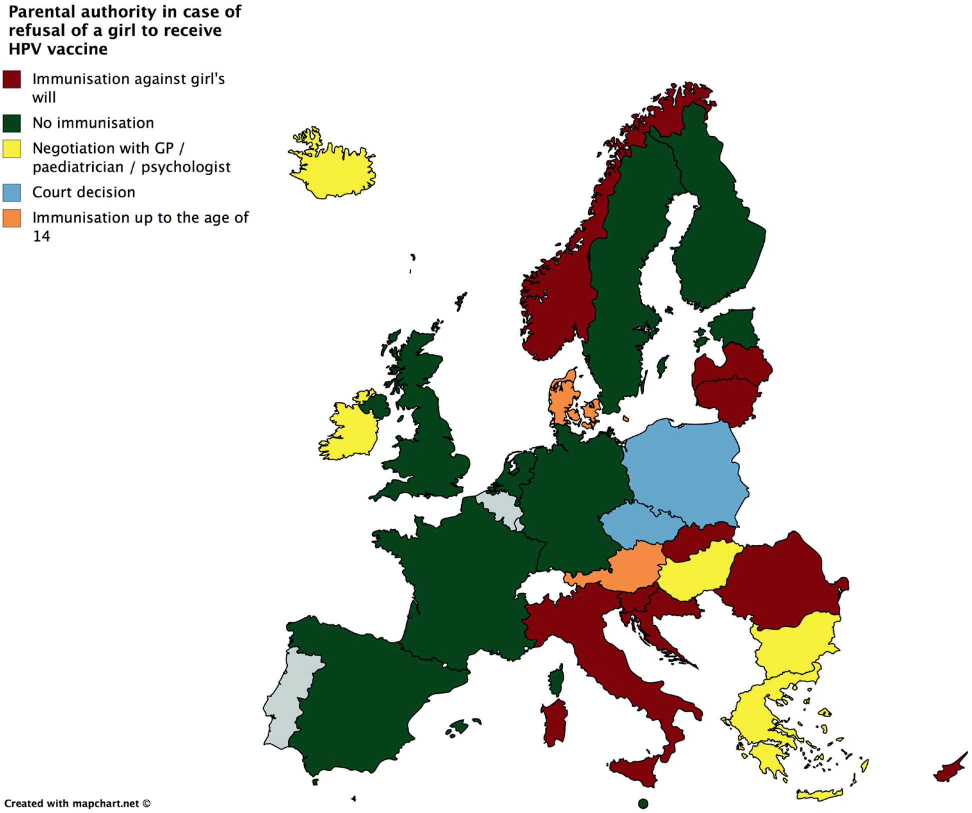


Figure 3. Parental authority in case of refusal of a girl to receive HPV vaccine.

sexually active, may indeed jeopardize the effect of the vaccine and the child's medical good.

Immunizing boys against HPV

From a public health ethics perspective, the case of the HPV vaccine raises issues of cost-effectiveness, as well as sex-equity issues. Meanwhile it is scientifically clear, that the application of the vaccine to male adolescents is to protect against HPV-related forms of penile, oropharyngeal as well as anal carcinomas (Gulland, 2016). This intervention is especially protective among men who have sex with men (Wise, 2017). Additionally, the increase of herd immunity may also be an additional motive to be immunized against HPV. However, issues of cost-effectiveness and arguments the vaccination of females is adequate to protect men, have led to recommendations against the universal vaccination of teenage boys. Such recommendations are not based on scientific evidence (Wise, 2017).

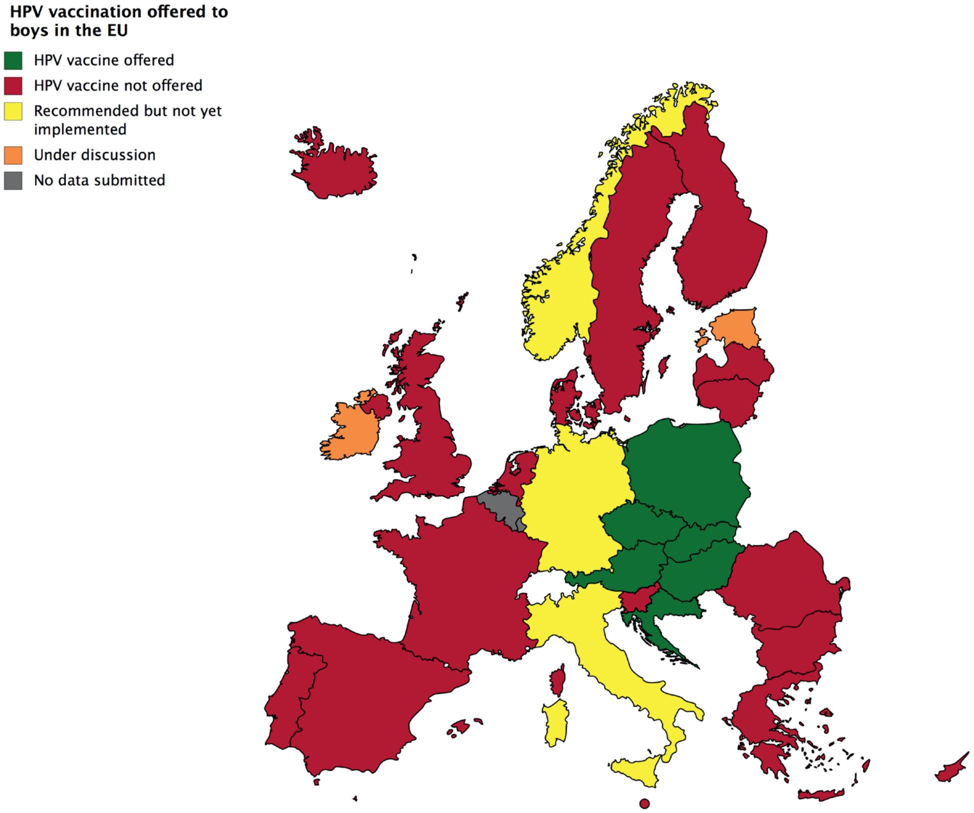


Figure 4. HPV vaccination offered to boys in Europe. Data as in June 2018

Elfström et al (Elfstrom et al., 2015), based on a questionnaire-based data collection conducted from May 2012 until May 2014, reported no organized vaccination programs targeting boys in Europe. The vaccine was available to males from high-risk populations, who actively asked for an immunization, and were usually expected to finance it out-of-pocket, raising sex-equity issues (Elfstrom et al., 2015). In 2017, however such programs have already been implemented in Eastern Europe, as depicted in Figure 4, while the vaccination has already been recommended in Italy and Norway, and recently also in Germany. Extended discussions among all relevant actors, including youth organizations and the vaccine manufacturers, shall be held on an international and regional level, to explore realistic alternatives regarding the financial coverage of the intervention, as well as the facilitation of other determinants of diffusion, dissemination and implementation of the treatment in the rest of the European Union (Greenhalgh et al., 2004).

Identifying and transferring best practices

The United Nations Convention on the Rights of the Child presents an ethical frame in which access to healthcare services shall be facilitated and preventive measures shall be offered in childhood and adolescence (UNICEF and Rights, 1991). According to the Convention, the right of children to access primary healthcare, including preventive health services is indisputable (Article 24), while educating parents and children regarding child health is essential (Article 24). Further significant ethical conditions include: steering the parenting style towards more libertarian patterns (Article 14 of the Convention), empowering children through offering health education (Article 17), treating children and adolescents with disabilities, or chronic conditions equivalently to healthy ones (Article 23), while distinctions of any kind based on sex are not acceptable (Preamble).

From an ethics perspective, the transferability of good ethics practices in child healthcare and the harmonization of policies with respect to the child's developing autonomy are crucial within the European Union (Schloemer and Schroder-Back, 2018). To enable transferability, it is important to consider contextual conditions in the different countries, particularly the characteristics of the target populations, such as health education and literacy of families and their usual way of cooperation with providers of the vaccination. For some countries, the transfer of good ethics practices will need changes of the procedures of vaccination. This requires the analysis of environmental conditions, such as available resources for service delivery and the expertise of providers with regard to ethical practices. However, there are several facilitating aspects for transferability of good practices in the European Union. Providing health education regarding a vaccine to be offered to children and their parents and requesting written consent or assent, are already common practices in many national vaccination programs across Europe and could be easily spread throughout the European Union. The emerging role of the pediatrician as negotiator in cases of disagreement between the child and the parents also reflects a paradigm change, framing a potential standardized ethical role of the physicians treating children and adolescents.

The exploration of associations of the level of respect for the child's autonomy and the HPV VCR across Europe revealed that average or above performing countries tend to follow less authoritative and paternalistic approaches for the vaccine provision (Table 1). Interestingly, the country with the best VCR performance, the UK, also follows most autonomy respectful paradigms (vaccination of a consenting child, even without parental consent).

In the case of the HPV vaccination offer in Europe it seems ethically most appropriate to implement an approach including the following elements:

- Educate children and parents regarding the vaccine provision and involve them all in informed consent processes.

- Grant decision-making competence to children and adolescents depending on their maturity.
- In cases of refusal to treat, consider offering the vaccine to older children and adolescents, who have most probably reached maturity. However, the vaccine should be applied before the individuals are sexually active.
- Involve the pediatrician as negotiator in cases of disagreement between children and parents.
- Do not restrict the provision of health education to children with disabilities, including diseases affecting cognition.
- Offer the vaccine to children and adolescents of both sexes.

Limitations

Expert surveys may be helpful for national data collection, however are associated with a probable bias and thus a relevant limitation for the study (Collins and Evans, 2007). Thus, such data could partially be not representative for a population of a country, or could not reveal differences between different regions of a country. However, the study of data of the European Union Agency for Fundamental Rights for the EU countries, published in November 2017, mapping the minimum age requirements concerning the right of the child to consent to medical treatment without parental consent in the EU, did not show significant differences, when compared to the results of our expert survey (EU-FRA, 2017). Thus, we regard the validity and reliability grade of the collected data as satisfying.

Such a study design regarding an understudied topic presents important advantages, since the expertise and experience of the recruited professionals provide valuable insight for understanding the diversity among the European states, for future research and for developing recommendations worth transferring regionally and internationally.

Conclusion

The procedure of HPV vaccination is an interesting indicator for studying emerging ethical issues in European public health, such as the child's developing autonomy and the paradigm change towards more libertarian forms of parental and medical paternalism, as well as issues of sex equity. Interestingly, but not surprisingly, greater respect for children's autonomy tends to be associated with medium or high vaccination coverage rates, and lower respect with lower rates. Respect and empowerment seem to have practical as well as moral benefits. Identifying and transferring the most suitable ethical approaches is crucial and should be strengthened

Identifying and transferring the ethically most suitable approached in European models of health care is crucial and shall be strengthened in the coming years. Educating children and their parents regarding vaccines and implementing written consent approaches that would include and respect the child’s autonomy are already existing practices that should be further spread throughout Europe. This would also facilitate a paradigm change in the physician’s role, evolving into an advocate for the child’s autonomy development and empowerment, and a negotiator in cases of disagreement between children and their parents.

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6

Chapter 6

Discussion

The hypothesis of this dissertation was that respect for the children's developing autonomy in paediatric healthcare especially with regards to national vaccination programs, may be expressed differently across Europe. Despite the differences, common ethical patterns and good practices may still be identified and transferred across the region. While the paediatrician's role may be decisive in addressing ethical dilemmas regarding the respect for developing autonomy in childhood, it is unclear if ethics teaching is adequately included in their resident curricula.

From the previous chapters of this thesis, it has been made clear that the expressions of respect for the developing autonomy of paediatric patients, children or adolescents, in a healthcare setting differ significantly across the European Union (Martakis et al., 2019). Children and adolescents are often regarded more or less equal to adults on a cognitive or moral level and are treated significantly differently (Wiesemann, 2016). The exploration of such ethical patterns can be conducted using plausible examples from the field, such as the seasonal influenza vaccine provision in childhood to provide herd immunity and tackle a potential pandemic, or the case of the human papillomavirus (HPV) vaccine in chapters 3 and 5 respectively. Qualitative content analysis and partial quantification of the data may also lead to the identification of good ethical practices that could be worthy of transfer across the European region, in an attempt to harmonise the health care provided to the youngest European citizens (Martakis et al., 2019, Schloemer and Schroder-Back, 2018).

The role of the paediatrician as the primary health partner of children and adolescents in many member states, and of the respective primary care physician treating children in some other states of the European Union, has transformed in the last decades. From being authoritarian figures, they have become an advocate for these young patients. However, physicians bearing such a role with associated responsibilities, often lack ethics education that would help them to reflect on standards and the normative scope of their responsibilities. Ethics education is often ignored or inadequate in the paediatric resident curricula, and does not contain adequate tools for reflection (Martakis et al., 2016). Two extensive literature reviews have been performed and presented in the previous chapters. The first underlines the need to teach ethics to paediatricians and ways to overcome crucial problems in the implementation of ethics teaching during the paediatric clinical residency (Martakis et al., 2016). The second enables the framing of the phenomenon of developing autonomy in child healthcare and presents a model of a relatively simple clinical ethics tool, to facilitate discussion between paediatricians, parents and of course the child itself, in cases of disagreement (Martakis et al., 2018).

This thesis does not venture to offer solutions to all normative, ethical problems regarding health or vaccination in childhood. It is, however, one of the first endeavors to address the emerging issue of developing autonomy in child healthcare, using the example of vaccination in a diverse cultural setting in the European region. The main research findings of the thesis are summarised, followed by a discussion of the results and the newly introduced tools as well as pitfalls during the implementation of the model of developing autonomy. Children's rights approaches will be introduced as an alternative to the model of developing autonomy to discuss ethics in child healthcare. This analysis comprises of a comparison of the two approaches, and some of the cases already presented in this thesis will be revisited. Limitations of the studies included in the thesis will be summarised in the respective sub-chapters, followed by suggestions for future research, especially in light of the ongoing SARS-Covid-2 pandemic.

Main findings

This thesis consists of two conceptual (Chapters 3 and 4) and two empirical chapters (Chapters 2 and 5), each addressing different aspects of the described problem. Following the introductory chapter, Chapter 2 describes the context, underlining the lack of ethics teaching in paediatric clinical education. Since these child health experts, who shall later advocate for their young patients, are not familiar with ethical theories, norms and ethical analysis, there is an existential need to provide them with knowledge and tools to support them in their role.

The third chapter introduces the concept of child vaccination ethics within the field of public health ethics, presenting a series of essential ethical principles, norms and approaches in ethics discussions between physicians, patients and their caregivers. The chapter contains a description of different expressions of authority and respect for the individual's autonomy when providing a vaccination in childhood to increase herd immunity (Martakis et al., 2017). The example used in this chapter was the implementation of influenza vaccination programs in childhood to tackle seasonal influenza epidemics across the world. This example may be considered an allegory to the much-anticipated SARS-Covid-2 vaccine and will be discussed further.

Chapter 4 is a core chapter of the thesis. A model of the emerging principle of respect for developing autonomy in child healthcare is presented in this chapter, as well as an account of the different expressions of respect for autonomy in clinical practice. Two cases are used to illustrate the implementation of the model, one related to the seasonal influenza vaccine in childhood and another related to the HPV vaccine in adolescence.

Finally, in Chapter 5 the case of the HPV vaccine is revisited in a European context. This chapter depicts significant practical differences in the expression of respect for developing autonomy in child healthcare across Europe. The association of different expressions of respect with different vaccination coverage rates across the European Union formed the basis of identification of best practices from a public health ethics view. The best practices could be transferred across the region in an attempt to harmonise the healthcare services offered to the youngest European citizens.

An overview of the main findings of this thesis is shown in Figure 6.1.

Teaching ethics in medicine

Changing paradigms in the way healthcare, including child healthcare, is provided, is challenging the practice of clinicians, health workers and researchers. They face constant dilemmas in their interactions with patients and their caregivers. A code of moral reasoning is needed to address such dilemmas. Thus, ethics, as the "moral reasoning for actions" in biomedical sciences, is and should continue to be a fundamental element of medical practice (Beauchamp and Childress, 2019). However, addressing such dilemmas requires professionalism and consistency in moral reasoning, and health professionals need to be trained to be able to handle the provided ethical theories, norms and tools and apply them in their medical routine.

This is the added value of establishing and teaching ethics in medicine. Our children need to be treated by health professionals who reflect on a situation explicitly using well-established ethical theories, communicate with colleagues, patients and their relatives in a consistent and professional way, and accept the burden of proof of their own actions.

Ethics teaching during paediatric postgraduate education

In order to map the situation regarding ethics teaching during the paediatric residency, an extensive systematic literature review of four databases (Pubmed, CINAHL, BELIT, Web of Science) was performed. From the identified 3.231 papers, 211 articles were eligible for full-text screening.

Only few ethics teaching programs could be identified in the literature. The teaching approaches identified were classified into those following cognitive, motivational or behaviorist theories of learning, or combinations of these. The study revealed that the behaviorist and the cognitive theories of learning, independently or in combination, are commonly used as primary educational approaches in paediatric residential settings.

Case-based and problem-oriented approaches that focus on the activation of prior knowledge have been successfully used in trials and provide an alternative to traditional lecturing. Teaching in small groups and including a tutor instead of a lecturer, has also been favored in the literature. Interactions between medical and nonmedical

Developing autonomy in childhood:
Paediatricians dealing with vaccination ethics

Chapter 2
What do paediatricians know about ethics in childhood?

Ethics teaching in paediatric resident curricula is not adequate.

Recommendations:

- case-based teaching, including lectures, discussion, individual study
- regular teaching sessions in groups, under supervision
- affiliation to an ethics department, institutional and departmental support;
- ethics rounds and consultations not as core teaching activity.

Recurring problems derive primarily from the complexity of residential duties and should be addressed in advance.

Teaching ethics preferably in the first years of residency.

Chapter 3
Vaccination ethics: Vaccine provision in childhood to mitigate an epidemic

Policy development needs ethical reflection.

Childhood vaccination programmes shall be performed next to programmes targetting adults and the elderly.

An intervention ladder as proposed by the Nuffield Council on Bioethics regarding seasonal influenza immunisation programmes that include children has been developed.

Non-compulsory immunisation programmes focussing on capability for choice and programmes using incentives or nudges are ethically defendable.

Further research is needed to explore how the child's developing autonomy shall be considered in such decisions, where the risk is small but the overall benefit can be substantial.

Chapter 4
A model to discuss developing autonomy in childhood

Introduction of a model and a tool to explore issues of developing autonomy in childhood and the tension with paternalism (parental or medical), to facilitate the dialogue between paediatricians, public health practitioners, ethicists, parents and children.

Conditions to be discussed, when applying the model:
- Contextual
- Existential
- Conceptual, and
- Socio-ethical.

Chapter 5
Different expressions of respect for child's autonomy in HPV vaccination in Europe

Respect for autonomy differs significantly across Europe.

Greater respect for autonomy associated with medium or high vaccination coverage rates.

Transferring best ethical approaches should be strengthened

Recommendations:
- educate child / parents
- involve child in the informed consent process
- grant decision-making competence depending on maturity and not age
- in case of refusal to treat, offer vaccine later
- the paediatrician shall negotiate in cases of disagreement
- do not restrict provision of health education to children with disabilities
- offer vaccines to both sexes

Figure 6.1. Overview of the main findings of the thesis

professionals, an affiliation with an ethics department, and the assessment of the knowledge acquired by paediatric residents are essential features. This would actually prioritise the cognitive-, and not the behaviourist theory of learning, according to which teachers provides guidance and facilitation of the learning experience.

Chapter 2 reports a series of recurring problems to teaching ethics to paediatric residents, such as time constraints, and the complexity of residential duties themselves. This includes off-site rotations, dealing with emergencies, and unpredictable working plansleading to scheduling difficulties, or a lack of continuity of attendance. Diffuse scepticism, negative attitudes, and a profound lack of interest of the residents towards ethics education are some other hurdles. In addition, a lack of resources funding and material resources, a lack of institutional and departmental support, lack of cases for discussion from the clinic's own pool of patients, and finally the limited effects from previous teaching experiences in the clinic have been reported as major barriers. The maturation effect on the formation of ethical attitudes of the paediatric postgraduate education itself was identified as a barrier, which highlights the need for early initiation of ethics teaching in the paediatric postgraduate curricula.

Based on literature, a series of solutions and recommendations to overcome the aforementioned educational barriers have been reported. To address time constraints, ethics teaching should take place in the form of short, regular, monthly meetings during or at the end of clinical shifts, and preferably supported with financial reimbursement. Ethics rotations, whole-day seminars, or residential courses may be viable options in some settings. Interactive sessions with short pre-session readings, teaching how to implement ethics algorithms and special ethics tools, referring to the trainee's own cases, ideally using a 'resident-as-teacher' approach may increase didactic credibility and thus, the interest of the participants. When no 'interesting' own cases are available, journal clubs are an ideal alternative. Institutional and departmental support in the form of human resources and funding for ethics teaching are essential. Food and beverages sponsored by the department should also be provided during the sessions. Finally, the inclusion of paediatric patients and their caregivers in ethics teaching has also been reported as positive for the learning process.

The analysis of the content of ethics teaching in the paediatric curricula revealed that the majority of the reported educational programs emphasised on the principle of beneficence. Studies also referred to issues of respect for patient's autonomy, especially during adolescence. Although no clear guidelines are available, a general recommendation from Opel et al underlines that paediatric ethics education should be based on three steps: 1) identifying the dilemma, 2) describing ethical principles and methods of analysis, and 3) acquiring knowledge of additional resources (Opel and Olson, 2012). An obvious pre-requisite is that the paediatric residents are familiar with ethics norms and principles and have a series of, ideally simple tools to analyse and discuss an emerging ethical dilemma.

Results from evaluations of teaching processes is scarce and not well documented in literature. On the other hand, the impressions of the trainees participating in such teaching programs has been reported as rather satisfactory (Martakis et al., 2016).

Vaccine provision in childhood to tackle an influenza pandemic

Chapter 3 uses a vaccination case study to describe a series of ethics norms and principles essential to clinicians dealing with ethical dilemmas in public health and child healthcare. Vaccination ethics presents a field in which paediatricians are directly involved, given that immunisations take place primarily in paediatric practices in many European states.

In the case of seasonal influenza, there are several policies ranging from recommendations to specific groups to annual vaccinations of the general population. Programs to increase the vaccination coverage rate (VCR) may include nudges, incentives or even mandates. The Japanese experience during the 1970's and 1980's showed that mandatory annual vaccination of children seems promising in achieving herd immunity (Reichert et al., 2001). Ethical considerations regarding the absolutizing of beneficence though, led to the discontinuation of this Japanese vaccination program in 1987. According to epidemiological projections, such a mandate would actually avoid 37000–49000 deaths annually, primarily among the elderly, at the rate of one averted death for every 420 immunised children. The introduction of a less-invasive intranasal although less effective influenza vaccine, as well as outbreaks of new highly contagious viral agents related with lower respiratory infections, such as the SARS-Covid-1 outbreak in 2003 and the recent SARS-Covid-2 pandemic, have brought the topic back into the European public health agenda (Martakis et al., 2017).

From a public health ethics point of view, Chapter 3 discusses the option of reducing the societal burden of influenza-related harm through the offer of a less invasive influenza vaccine to children. Justifications of immunisation policies have to take into account norms anchored in different ethical theories. The theories, principles and norms introduced in Chapter 3 are as follows:

- The Hippocratic ethos: an outdated but ethically relevant normative reference for physicians. The oath underlines the importance of the principles of non-maleficence and beneficence in treating an individual patient. It does, however, ignore the common good. The Hippocratic ethos is highly influenced by paternalism, defined as overruling autonomy for a person.

- Utilitarianism: another paternalistic and rather authoritarian approach, highlighting the principles of non-maleficence and beneficence. Instead of focusing on individuals though, utilitarianism prioritises the common good. It emphasises that an act is right if, and only if, it raises the net amount of overall good.

- The Harm principle: a rather non-paternalistic norm, which takes into account the significance of autonomy and liberty of the individual but defines limits for both liberty and authoritarianism. The underlying principle states that 'the only purpose for which power can be rightfully exercised over any member of a civilised community, against his will, is to prevent harm to others'.

- Libertarianism and other perspectives emphasizing Liberty and Autonomy: approaches standing against paternalism or instrumentalisation of individuals for the greater good. Such perspectives regard force to benefit others as unacceptable.

- The principle of Justice: presents a corrective of both utilitarianism and liberty, systematically developed against the deficits of those approaches. This principle focuses on health inequalities and inequities, declaring that "we owe each other in the protection and promotion of health".

There are good reasons to offer immunisation programs against seasonal influenza to children to increase herd immunity. Nudges, incentives, mandates, and different levels of enforcement may be used to support such programs. It is important for child health experts, including paediatricians, to be able to define and distinguish between different levels of enforcement. An important, autonomy-oriented tool is the intervention ladder as proposed by the Nuffield Council on Bioethics (Table 3.1) (NCB, 2007). This tool summarises and classifies interventions towards one public health goal based on autonomy and liberty. Although the intervention ladder is a rather one-dimensional ethical tool focusing primarily on autonomy, it presents an ideal first-line tool for clinical child healthcare experts to address ethical dilemmas of individual cases or entire populations of children and adolescents.

Although the main goal of the chapter is to introduce clinically relevant ethical theories and norms for paediatricians, the case provides recommendations for a seasonal influenza vaccination in childhood. This thesis recommends non-compulsory immunisation programs focusing a capability for choice and programs using incentives or nudges that are ethically defendable. In parallel, immunisation programs targeting adults and the elderly are also needed.

A crucial point in child health ethics that could not be adequately discussed using the aforementioned theories and principles is the role of the children's developing autonomy and the respect for their will, especially in cases of conflict with their parents' choice.

This highlights the need for a model and a tool to facilitate the discussion of issues of children's developing autonomy, between physicians, parents and children themselves. Such a model and tool should be easy to interpret and implement. The following chapter, Chapter 4, presents an extensive literature review that led to the development of a model for developing autonomy in child healthcare and a tool to aid discussions among the three main actors, the paediatricians, the caregivers and, most importantly, the children themselves.

Developing autonomy in paediatric healthcare

Chapter 4 is a conceptual chapter presenting the findings of an extensive literature review on 'developing autonomy' in child healthcare. The review includes sources collected systematically from four databases (Pubmed, CINAHL, BELIT and the Web of Science), well-known and established ethics literature referring to the four principles of healthcare ethics, as well as further literature identified using a snowball method. The terms and Boolean operations used to identify the systematically reviewed part of the literature were ("developing autonomy" OR "future autonomy") AND ("child" or "children"). The year of publication was not a limitation.

After directorial content analysis, findings that refer directly to child autonomy or to the antagonistic force of paternalism (medical or parental) have been studied under the following three themes: the paediatrician-child relationship, the paediatrician-parent relationship and the parent-child relationship. The subsequent metasynthesis led to the framing of a conceptual model containing a variety of expressions of respect, or disrespect for the developing autonomy in child healthcare. The model has been presented in Figure 4.1, it is applicable for medical as well as public health practice (Martakis et al., 2018).

To apply the model in solving an ethical dilemma, for instance in case of a disagreement regarding consent for a treatment between children and their parents, a series of issues or conditions have to be addressed. Pellegrino and Thomasma have classified these into contextual, existential, conceptual and socio-ethical (Pellegrino and Thomasma, 1987), and has been used in this thesis. Table 4.1. presents a rather exhaustive list of these conditions.

Chapter 4 also includes the discussion of two cases from the vaccination ethics field, demonstrating the implementation of the model and the accompanying tool in clinical paediatric practice. Both cases describe a lack of agreement between the children and their caregivers regarding the provision of informed consent to receive a vaccination. The first case refers to the topic of offering the seasonal influenza vaccine in childhood to increase herd immunity and subsequently solidarity, as introduced in Chapter 3.

The second refers to the provision of the HPV vaccine in adolescence and unveils an ethical discussion addressing issues of respect for the child's developing autonomy, the paradigm shift from authoritarian to libertarian forms of paternalism, as well as issues related to the right of sexual self-determination in childhood and adolescence. This topic has been discussed further in the following chapter.

Autonomy-driven approaches are not the only ones available or suitable for ethical discussion in child healthcare. Children's rights and moral equity-based approaches may also be successfully implemented. In the discussion section of this thesis, the presented cases will be revisited using an argumentation deriving from a children's rights approach (Goldhagen et al., 2015, Wade et al., 2015).

Expressions of respect for child's autonomy in healthcare in Europe and transferability of good ethics practices: The HPV vaccine case

Once again in chapter 5 the focus is on the case of the HPV vaccination. In this empirical chapter, the already presented case in Chapter 4 along with a series of other cases exploring expressions of respect or disrespect for the children's developing autonomy, are revisited as vignettes of a pan-European survey.

Tackling the lack of consensus regarding an ideal model for the provision of primary health care for children and adolescents throughout the European Union requires the systematic appraisal of all existing national child healthcare systems, services and policies in terms of health outcomes (van der Willik et al., 2016). The EU Models of Child Health Appraised (MOCHA) project aims to address this (Blair and Alexander, 2017). The MOCHA project was funded by the European Union's Horizon 2020 research and innovation program under grant agreement no. 634201.

Within the MOCHA project an inter-professional network has been formed, linking scientific partners in each one of the thirty member states of the European Union and the European Economic Area. These agents have been supplying data to answer precise questions related to the primary health care services provided to the youngest European citizens. The study presented in Chapter 5 was an expert survey performed within the MOCHA framework. A mixed methods approach was used in the analysis, combining tools of quantitative and qualitative research. Finally, associations were drawn between expressions of respect or disrespect for the child's developing autonomy in the different national vaccination approaches in Europe, and the reported national HPV vaccination coverage rates (Sheikh et al., 2018). These associations were used to identify good ethics practices that could also lead to an increased vaccination coverage rate, when transferred across Europe. Explorative analyses revealed that countries with above-average coverage rates tend to follow less authoritative and paternalistic approaches for vaccine provision (Table 5.1.).

Chapter 5 argues for the inclusion of the following empirically good ethics practices in the European national vaccination programs:

- Improve health literacy about vaccines aimed parents and children, to whom a vaccine is to be offered.

- Grant decision-making competences to children depending on the level of maturity and not on age.

- In cases of refusal to treat, the paediatrician shall consider postponing the offer to a future visit, and ideally already set a timeframe for that visit.

- The paediatrician shall act as negotiator in cases of disagreement between the child and the caregivers.

- Offer adequate information on vaccines to children and adolescents suffering from cognitive or developmental conditions.

- Offer vaccines to children and adolescents regardless of their sex.

Holistic considerations of the contextual and existential conditions, as presented in Chapter 4, are crucial to enable transferability to different countries. Particularly significant are the characteristics of the target populations, such as health literacy and their usual way of cooperation with providers of the vaccination. In some cases, the transfer of good ethics practices requires changing the procedures of offering a vaccination. An analysis of environmental conditions, such as the available resources for service delivery and the expertise of health service providers with regard to ethical practices, is required (Schloemer and Schroder-Back, 2018).

However, there are already several facilitating aspects for transferability of good practices in the EU. For instance, providing health education to children and their parents and requesting written consent or assent are often common practices in many national vaccination programs across Europe and could easily be implemented throughout the EU. Also, the emerging role of the paediatrician as ethical negotiator and liaison, especially in cases of disagreement between the child and the parents, reflects a paradigm change (Martakis et al., 2019). The paediatrician in the 21st century carries an ethical duty to empower children and adolescents to form strong future generations of European citizens, and to advocate for their developing autonomy in healthcare, within what may be considered conservative, even patriarchal societies. The vision of this thesis is to prepare clinicians for this role.

The ethical model presented in this thesis is an autonomy-oriented tool. Social paediatricians have often pointed out that such approaches are less practical and ignore children's rights (Goldhagen et al., 2015, AAP, 2010). In the subsequent parts of the discussion section, the HPV case presented in chapters 4 and 5 will be revisited using a different, Children's Rights-based approach (Wade et al., 2015). Reaching conclusions aligning with the ones expressed in chapters 4 and 5, for instance when discussing about the HPV vaccine provision, would be crucial for confirming the validity of the introduced ethical approach. Such conclusions should be seen as extensions of the child health ethics discussion offering normative perspectives for future research in a culturally diverse and pluralistic academic and public health context.

Children's Rights and the Principles of Biomedical Ethics

Before introducing a Children's Rights-based approach to discuss child healthcare ethics, it is essential to define children's rights, as summarised in the United Nations "Convention on the Rights of the Child" (Wade et al., 2015, UN, 1989). The integration of the principles of the United Nations "Convention on the Rights of the Child" into child healthcare practice provides powerful strategies to respond to the causes of health disparities in childhood (UN, 1989). The articles of the "Convention on the Rights of the Child" defines children's rights in the context of their cultural, economic, social and civil-political societal status, redefines childhood and children's well-being, and establishes a template for advocacy. Respect for the child's dignity and equity are the two founding concepts of the articles of the "Convention on the Rights of the Child". Child's rights advocacy and health care equity have been included as core elements of the paediatric clinical practice agenda of the American Academy of Pediatrics (AAP, 2010). In the following paragraphs, the ethically most relevant articles of the "Convention on the Rights of the Child", as ratified by all UN nations with exception of the United States of America, will be summarised and will be associated with the principles of biomedical ethics they address, as these have been presented in the Introduction.

Article 2 of the "Convention on the Rights of the Child" operationalises the principle of equity and depicts the moral value of non-discrimination. It is comparable to the ethical principle of Justice. According to Article 2, discrimination of any kind irrespective of the child's or the caregivers' "race, colour, sex, language, religion, political or other opinion, national, ethnic or social origin, property, disability, birth or other status", is unacceptable.

Discrimination may be direct or indirect. Direct discrimination includes the denial of treatment of children with a chronic, life-limiting disease, on the grounds of perceived lower life quality, or the denial of access to health for financial reasons, or the denial of access to prevention and reproductive health services for youth, without receiving parental consent. Denying the HPV vaccine to a girl who wants to be vaccinated against parental will, described in this thesis, is a vivid example of direct discrimination.

Indirect discrimination happens when a policy, law or action leads, often unintentionally, to the exclusion of or harm to particular populations of children. Laws and policies that allow environmental hazards or fail to regulate development can significantly affect children's health and well-being. This may include certain global trade policies. Paediatric hospitals or healthcare facilities that may be inaccessible to children with motor impairment, or services that are not adequately advertised or available in a language understandable to a migrant child, are some other examples of indirect discrimination. Such issues have been discussed in the cases presented in chapter 4 of this thesis.

The ethical principle of Non-Maleficence is depicted in Article 6, the one referring to the right to life and optimum development of the child to the maximum extent possible. This shall be recognised and ensured by the state and is crucial to the implementation of the "Convention on the Rights of the Child" as a whole. Combined with Article 24 on the right to health and healthcare services, Article 6 plays an important role in the provision of child healthcare and paediatric services.

Article 3 of the "Convention on the Rights of the Child" can be associated with the ethical principle of beneficence, as it focuses on the best interests of children in all actions concerning them. This includes actions undertaken by the private or public sector, courts of law, legislative bodies or administrative authorities. However, Article 3 does not grant children autonomy or decision-making rights; these are granted automatically in adulthood. Accordingly, adult caregivers, usually the child's parents, are charged with ensuring that the child's best interests are considered in all decisions. The function of the parents to defend the child's best interests is also underlined in Article 18 of the "Convention on the Rights of the Child", which reinforces the parental responsibility of raising the child and the duty of the states to support parents to do so (Lansdown et al., 2015).

The ethical principle of respect for the children's developing autonomy is only introduced in Article 12 of the "Convention on the Rights of the Child". This article refers to the right to “be heard”, a right that shall be ensured by the state, if the child is capable of forming his or her own views in accordance with age or the level of maturity.

The right applies regardless of the level of linguistic or mental abilities of a child. In cases of communication difficulties, the adults are the ones that bear the duty to make concepts understandable to children, using for instance child-centric language. Adults also have the responsibility of ensuring that children’s opinions are freely expressed, respected and seriously considered. After a decision is taken, children shall receive feedback about how their view has been considered in the decision-making process.

Article 12 is profoundly significant and is the most challenging ethics concept in the “Convention on the Rights of the Child”. Article 12, in combination with Article 13 and 17 referring to informed consent, has massive implications for the paediatric practice and the provision of child healthcare services. Table 1 depicts the association of core rights principles of the “Convention on the Rights of the Child” consisting of four ethics principles as described by Beauchamp and Childress, according to the American Academy of Pediatrics (Beauchamp and Childress, 2019, AAP, 2010).

Table 1. Linking the Children’s Core Rights Principles to Principles of Biomedical Ethics (AAP, 2010)

Children’s Rights Principles	Biomedical Ethics Principles
Article 2: Non-discrimination	Justice
Article 3: Best interests	Beneficence
Article 6: Survival and development	Non-maleficence
Article 12: Providing children a voice and listening to them	Autonomy

As already mentioned, parents also hold rights under the “Convention on the Rights of the Child”. Articles 3 and 5 define their role as right-holders with responsibilities of parenthood, a right to be respected and supported by the state. The state should educate parents and provide them with the capacity to perform these duties. Article 7 refers to the right of the child to know his or her parents and be cared for by them. Other important parental rights (Lansdown et al., 2015) are the right to family relations without unlawful interference (Article 8), the right to privacy of the family (Article 16), the right to non-separation from the parents unless it goes against the child’s best interests (Article 9) (Archard and Skivenes, 2009), the right to family reunification (Article 10), the right to provide guidance in the exercise of religion, conscience and freedom of thought (Article 14), and the development of respect to parents through education (Article 29).

Children’s and parents’ rights sometimes seem as being at odds with each other (Wardle, 1995), and is cited as the reason for the failure of the United States to ratify the “Convention on the Rights of the Child” (Kilbourne, 1998). While the views of children and their caregivers align in a majority of cases, there are some instances where conflicts arise that need to be addressed and resolved. Such conflicts often lead to ethical considerations and dilemmas and should be discussed using a child’s rights perspective and an ethics perspective.

In such a setting, the role of paediatric bioethics in serving the child’s best interests is two-fold, advocating for the child’s developing autonomy and rights on one side, and ensuring respect for parental rights on the other.

The Children’s Rights-Based Approach to discuss ethics of the American Academy of Pediatrics

To fulfil their ethical and advocating role paediatricians have some available tools for use in clinical practice to deal with children’s rights and health assessments in childhood (AAP, 2010, Hagan et al., 2007, Vaghri et al., 2011, Ben-Arieh, 2008, Unicef, 2006). However, given the lack of basic ethics education in their resident curricula, they often ignore them or fail to utilise such tools when are confronted with ethical dilemmas. On the other hand, such tools often do not show ethics specificity, and since paediatricians often are not even familiar with basic health ethics terminology, they often fail to use them in the correct context.

This emerging need within a changing healthcare paradigm has been underlined by the American Academy of Pediatrics, which appeals for a different ethics training among paediatricians (AAP, 2010). To bridge this gap, the American Academy of Pediatrics developed a Health Equity and Children’s Rights Approach for paediatricians to facilitate discussion in ethical and children’s rights contexts (AAP, 2010). The tool consists of an inventory of children’s rights, along with a human rights’ taxonomy, and one of the four principles of biomedical ethics, namely “justice”, “respect for autonomy”, “non-maleficence” and “beneficence”.

According to this model, children’s rights classified as economic rights include the provision of an adequate standard of living, social security and protection from economic exploitation, which are in turn associated with the ethics principle of Justice. Examples of social justice issues that affect the children’s well-being and health include access to quality housing and pre-kindergarten, early learning resources, sufficient educational resources and recreational activities, child-friendly neighbourhoods, land use that considers the children’s best interest, child and infant-friendly hospitals supported with adequate budgets and appropriate physician and health care service reimbursement, affordable and convenient transportation, safe workplace conditions for adolescents, freedom from gender discrimination and the provision of all appropriate resources for differently abled children (AAP, 2010).

Social human rights in childhood include the promotion of a child's best interests, protection of life, survival, development, provision of education, securing play and free time, provision of a family life or some efficient alternative care, provision of the best possible health and access to health, the right to reunification of the family and the fullest inclusion of children with disabilities and in despair, as well as supporting parents to ensure the protection of children's rights. This group of social rights has been associated with the principle of beneficence.

Protective rights are associated with the principle of Non-Maleficence. These include protection from abuse and exploitation, from harmful drugs, trafficking and armed conflict, as well as secondary and tertiary prevention in the form of provision of rehabilitation after abuse or neglect.

Finally, the tool of the American Academy of Pediatrics makes a link between civil, political and cultural aspects of human rights with the principle of Respect for Autonomy. Children have the right to be heard and taken seriously, right for privacy and information, right to respect for their physical and personal integrity, and the right to be treated with respect within the justice system. Children should be able to enjoy freedom of religion, of association and expression and have the right for respect for language, culture and religion, and to stay away from traditional practices that are likely to be prejudicial to children's health. Civil and political rights that can be attributed to the respect for autonomy are the freedom from discrimination in the exercise of rights, freedom from all forms of violence, torture, or other cruel, inhuman or degrading treatment, as well as the right for due process in the law and the right not to be detained arbitrarily . The complete tool, as published by the American Academy of Pediatrics is presented in Table 2.

Finally, the Child's Rights approach also includes five indicators to be addressed to facilitate ethics discussion between the children, the parents and the paediatricians (AAP, 2010). These are associated with the four ethics principles and will be discussed in the following subchapter of the thesis.

Revisiting the HPV vaccine case from a Children's Rights perspective

Chapter 4 introduced the model of developing autonomy in paediatric health care and a tool to facilitate ethical discussion regarding issues related to autonomy development in childhood and adolescence. The case of the HPV vaccination from Chapter 4 will be revisited using the aforementioned Health Equity and Children's Rights Approach of the

Table 2. Linking the Taxonomy of Children's Rights (AAP, 2010) to the Principles of Biomedical Ethics

Taxonomy of Rights	Inventory of Rights	Principles of Biomedical Ethics
Economic	Adequate standard of living	Justice: distributive and allocative
	Social security	
	Protection from economic exploitation	
Social	Promotion of a child's best interests	Beneficence
	Life, survival, and development	
	Best possible health and access to health care	
	Education	
	Play	
	Family life or alternative care	
	Family reunification	
	Fullest social inclusion for disabled children	
	Support for parents to ensure protection of children's rights	
Protective	Protection from abuse and exploitation	Non-maleficence
	Protection from armed conflict	
	Protection from harmful drugs	
	Protection from trafficking	
	Rehabilitative care after abuse or neglect	
Civil and political	Heard and taken seriously	Autonomy
	Freedom from discrimination in the exercise of rights	
	Freedom of religion, association, and expression	
	Privacy and information	
	Respect for physical and personal integrity	
	Freedom from all forms of violence, torture, or other cruel, inhuman, or degrading treatment	
	Due process in the law	
	Recognition of the importance of treating the child with respect within the justice system	
	Not to be detained arbitrarily	
Cultural	Respect for language, culture, and religion	Autonomy
	Abolition of traditional practices likely to be prejudicial to a child's health	

American Academy of Pediatrics (AAP, 2010, Martakis et al., 2018). The assessment of this case using the Children's Rights Approach could lead to recommendations of action for health professionals, which may be similar to the recommendations expressed in Chapter 4 using the "developing autonomy" model. This exercise serves as a validation of the model introduced in the Chapter 4 of this thesis.

The case reads as follows:

> *HPV-driven cancer is frequent in women of reproductive age. Since 2011 the HPV vaccine is offered as part of the national vaccination program in Argentina and the coverage rate is high (Patel et al., 2016). Wenzeslava is a fifteen-year-old migrant girl from Bulgaria. Her family moved to Argentina a few months ago. Her parents want her to receive the vaccine. She refuses though, arguing that she is not sexually active yet. In a private talk with the paediatrician, she admits being scared of potential side effects. Wenzeslava heard of a girl in Bulgaria who developed a lethal Wegener's granulomatosis after HPV immunisation. Although there was no causal relation between the two events, vaccination criticism in the media has added to the already high vaccine scepticism in Bulgaria (Petrova et al., 2015, Martakis et al., 2019).*

- According to the Children's Rights-based approach, proposed by the American Academy of Pediatrics (AAP, 2010), the first question and indicator to be addressed is if there is a morally defensible system of resource allocation for the treatment.

In this case, the answer would be a yes. There are no issues regarding the rights to social security, economic exploitation or adequate standard of living. The frame of justice, allocative and distributive, are being respected.

- The second and third indicators to be addressed are if the children feel that they are respected and if they consider themselves participants in their environment.

These points refer to Wenzeslava's rights for "participation", and "to be heard" and they are both associated with the Principle of Autonomy. Indeed, the patient is heard during the conversation in the presence of her parents, as well as in a private talk with the paediatrician. Investing time to explain and to clarify issues of misinformation or health illiteracy are crucial to addressing child's rights, including the rights for privacy and information. It is reasonable to assume that the language barrier could be an obstacle for the child to exercise her rights of freedom of expression. However, her confidence to have a private talk with the paediatrician reveals rather adequate communication and, perhaps, language skills.

In the case presented in Chapter 4, the paediatrician decided to postpone the vaccine provision to a future date, accepting Wenzeslava's arguments that she is not sexually active yet and does not plan to be so in the coming weeks. This decision respects the girl's physical and personal integrity and rules out the phenomena of physical "iatrogenic violence" that can occur if the vaccination was performed against her will. Issues associated with Children's Rights within the justice system are not raised in this case.

- The fourth indicator to be addressed is if the participants of the policy-making process act with charity and kindness.

Both the parents and the paediatrician are keen on promoting the child's best interests and in making sure the rights for life, survival and healthy development are well respected. Wenzeslava is most likely to enjoy a healthier sexual and personal life later, when the risk for harmful, oncogenic sexually transmitted diseases is significantly lower. Educating Wenzeslava about the HPV-related harms and clarifying the complete lack of correlation between granulomatosis and the HPV vaccine are crucial. Planning for a new appointment to discuss the option of vaccination at a future date would be an appropriate course of action.

Among others, this will assure a healthier family life for her and her future partner(s) and perhaps result in better social inclusion; complete sexual abstinence can impact social inclusion. If we regard the sexual exploration of one's own, and the partner's body as physiological experiences in adolescence and youth, a time-bound second visit to administer the vaccine also respects the "right to play" of the adolescent.

- Is the dictate of non-maleficence adhered to in the decisions made related to the child?

Wenzeslava used to think that a vaccine is a harmful drug. Once this issue is clarified, all protective rights of the girl are respected. Finally, parental rights, as expressed in the "Convention on the Rights of the Child" were adequately respected by the paediatrician in this case.

Similarities, differences, strengths and limitations of both approaches

Similar conclusions were reached with the two approaches, namely the Children's Rights-based approach of the American Academy of Pediatrics, and the Developing Autonomy model, as introduced in Chapter 4. Postponing the vaccination to a future planned appointment before the beginning of her sexual activity might be justified both from an ethics as well as from a children's rights perspective.

Postponing vaccine provision is in accordance with the “principle of respect for autonomy”, as well as Article 12 of the “Convention on the Rights of the Child”, since Wenzeslava’s opinion has been taken into consideration.

The appointment for vaccine provision should be scheduled at the end of the current consultation. Considering that the benefits of vaccination are clear, this element will uphold the “principle of beneficence”. It also serves Article 3 of the “Convention on the Rights of the Child”, with the child’s “best interest” at heart.

Ensuring the vaccination is provided before the beginning of Wenzeslava’s sexual life is crucial, so that the right for survival and development is respected. This is depicted in Article 6 of the “Convention on the Rights of the Child” and is a clear instance of the ethical “principle of non-maleficence”.

Wenzeslava is young enough such that healthcare providers and insurance providers do not question delaying the vaccination, and she is not discriminated from her sexually inactive peers. Neither Article 2 of the “Convention on the Rights of the Child” nor the “principle of justice” are violated.

This approach also ensures parental rights as described in the “Convention on the Rights of the Child”. Articles 3, 5, and 18 defining the roles and responsibilities of parenthood are upheld. The paediatrician has educated the child and her parents and has empowered them to make joint decisions on vaccine provision.

Similar conclusions arrived at using the two approaches vouches for the validity of the model of developing autonomy, introduced in chapter 4 of this thesis. This adds to the value of the model of developing autonomy as an instrument for paediatricians and other clinicians dealing with the ethical dilemmas of childhood, especially issues of the child’s developing autonomy and the balance between parental rights, and ethical forces of paternalism.

Interestingly, the Health Equity and Children’s Rights tool proposed by the American Academy of Pediatrics links a series of rights traditionally regarded as “Justice” issues, with the principles of respect for autonomy and beneficence. Examples include the right to education and play, family life or alternative care, family reunification, social inclusion in cases of disability, support for parents to ensure their role as protectors of children’s rights, the freedom from discrimination in the exercise of rights, the freedom from all forms of violence, torture, or other cruel, inhuman or degrading treatment, and the right for due process in the law and the right not to be detained arbitrarily.

From an ethics perspective, this is a limitation of the Children's Rights approach, and raises questions about its construct validity and specificity to address delicate ethical dilemmas focusing on respect for the child's developing autonomy. This is even more crucial in cases where the will of the children and their caregivers do not align. Such issues may not be adequately captured in an approach based on the "Convention on the Rights of the Child", a legal document focusing more on beneficence and justice, and respecting parental rights.

On the other hand, references to children's rights are often easier to understand and discuss with the child and the parents. This is one of the limitations of the model of developing autonomy, which is probably less practical, considering that it contains philosophical ethics terminology.

This thesis does not venture to establish the superiority of one approach over the other. The two approaches complement each other, and both should be used in daily practice. Ideally, both approaches should be included as part of the ethics education of the paediatric resident curricula.

Limitations

This section contains a summary of the limitations of the individual study elements presented in the previous chapters, and the thesis as a whole.

A major methodological limitation of the systematic review metasynthesis, presented in chapter 1, is that the barriers and solutions presented were documented as mentioned in the literature, without considering the level of evidence of the included primary studies. Differences between the barriers on teaching ethics were not assessed. Furthermore, the proposed solutions were not derived from programs implemented exclusively in paediatric resident populations but included other physicians as well. This methodological limitation may be attributed to the limited availability of literature for the systematic review.

There were methodological limitations to the survey data presented in chapter 5. Part of the collected data were extracted from an expert survey. While such surveys are helpful to collect national data, they are associated with probability bias and do not capture regional differences within a country (Collins and Evans, 2007). However, as already mentioned, a study using similar data from the European Union Agency for Fundamental Rights for EU countries did not reveal significant differences when compared to the results of the survey conducted within the framework of the MOCHA Project (EU-

FRA, 2017). One could argue that the study of the association of the vaccination coverage rate as a dependent variable, with different ethical patterns in health policies across Europe (independent variable), may have ignored confounders of vaccination coverage. The results of this novel methodology were extensively peer reviewed and presented in congresses, including at the Annual Meeting of the International Society for Social Pediatrics and Child Health 2018 in Bonn, Germany. The role of confounders in associations of vaccination coverage rate and ethical patterns in health policies should be addressed by future research in the field.

The ethical analysis presented in this thesis follows a specific perspective, namely an autonomy-oriented point of view, which subsequently led to the development of an autonomy-oriented ethical tool. Social paediatricians have often pointed out that such approaches are less practical and often ignore children's rights (Goldhagen et al., 2015, AAP, 2010). To address the shortcomings, one of the main cases presented in this thesis was revisited using a Health Equity and Children's Rights-based approach. Comparable conclusions (Wade et al., 2015) were reached, proving the validity of the developing autonomy model and demonstrating that children's rights are, in fact, being considered.

In keeping with the concerns raised by social paediatricians, personal experience has underlined difficulties of presenting to this less practical tool to an audience. A simple description of the proposed tool in a scientific congress typically needed at least thirty minutes, primarily because of the lack of ethics knowledge among physicians. Children's rights approaches, on the other hand, are often self-explanatory and intuitive. This poses a major limitation of the tool and the dissertation as a whole. An online training module accompanying the tool to help new users navigate through the different conditions and dimensions could mitigate this limitation.

Outlook

Due to the paradigm change from iatrocentric to patient-centred healthcare, the principle of respect for the still-developing autonomy in childhood and adolescence has emerged as a new and interesting ethical topic. This principle is to be considered if not addressed in every interaction of the paediatrician with the child. The model introduced in this thesis serves this purpose.

The study of this principle becomes more challenging in two instances – when there are disagreements between the child and his or her caregivers, or when the cognitive and decision-making competences of a child or adolescent are impaired because of an underlying condition. Future research by social paediatricians and paediatric ethicists should include children with chronic conditions that affect their language, motor and cognitive skills. The author of this thesis is currently conducting such a study exploring the development of decision-making competencies in children with cerebral palsy in the University Children's Hospital of Cologne, Germany (University of Cologne, Ethics Commission Approval Number: 17-283).

The scope of the dissertation can extend to include other treatments, clinical decisions and contexts where the triad of actors (child, caregivers, and physicians) try to balance the clashing forces of autonomy and paternalism. While this dissertation has prepared the ground for the use of vaccinations through participatory decision-making, while other situations can be much more challenging. Empirical research of comparison of the respect for developing autonomy in medical versus non-medical contexts can help understand the differences between general, medical and public health ethics.

Finally, an important and rather relevant issue to be addressed in future research is the extent to which children's developing autonomy should be considered in an epidemic or a pandemic. In chapter 2 the hypothetical implementation of a seasonal influenza vaccination in childhood to increase herd immunity has been discussed from an ethics perspective. The recent COVID-19 pandemic has shown that such situations are not far from reality. Children can be carriers of a virus, meaning they usually do not suffer from the disease. Contact with carriers can be dangerous to the weaker populations of the society. This has led to a complete lockdown of schools and any kind of facilities for children. While these measures – and the exit strategy of widespread lockdowns – are highly contested, vaccination of children is likely to contribute to achieving herd immunity and getting back to "normal life".

Are lockdowns the only way to deal with the problem? Have the restrictive measures changed the course of the pandemic? Were these measures ethically justified? Have the restrictive measures curtailed children's right to education, play, personal integrity and social inclusion, to what extent and at what cost? What are the consequences for children's physical and mental well-being? Since the measures differ substantially across Europe, is there a pattern in the expression of respect to the children's developing autonomy across Europe during the pandemic? What will happen when a SARS-CoViD-2 vaccine becomes available? Which step of the intervention ladder of the Nuffield Council on Bioethics, as presented in Chapter 2, will be implemented?

This thesis is not arguing for an absolutizing of the children's developing autonomy; this would have been rather illusionary. The children, though, are not our future only (Dabrock, 2020). Children need to be heard. They need to be informed and given the opportunity to participate in their environment.

Concluding remarks

Expressions of respect for the developing autonomy of paediatric patients, children or adolescents, in a healthcare setting differ significantly both on an individual as well as on a population level. Examples from the field of vaccination ethics have been presented and discussed in this thesis. In this context, the paediatrician treating an individual patient or a paediatric population as a whole shall function as an advocate for the autonomy development of children. This becomes crucial in case of lack of alignment of the will of children and their caregivers in a healthcare setting.

Ethics as the "moral reasoning for actions" should continue to be a fundamental element of medical practice and education. The purpose of teaching ethics in the clinical and scientific practice is to create health professionals who reflect on a situation morally, who reason explicitly using appropriate ethical theories, who can talk to colleagues, patients and their caregivers consistently and professionally, and who can accept the burden of proof of their own actions.

Unfortunately, paediatricians lack often ethics education and are, thus, not familiar with the theory of ethical principles. They do not know how to utilise simple ethical tools to address emerging ethical dilemmas and thus, do not recognise the value and perspective of autonomy and children's rights. This thesis offers a series of medical ethical principles and norms for the clinician to use. The thesis presents a novel model and tool for clinicians to discuss issues of developing autonomy with the children and their parents. In the discussion section of this thesis the Children's Rights-based approach was used to address similar ethical dilemmas. The similarity of the conclusions reached using the two approaches confirms the validity of the developing autonomy model.

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Valorisation Addendum

The aim of this addendum is to summarize ideas and suggestions for knowledge and value creation in practice, which can be generated from the presented thesis.

Indeed, three main ways of value creation deriving from the results of this thesis are suggested:

1. Solving didactic and administrative problems when teaching ethics to paediatricians

Teaching ethics in paediatric residents, underlining the emerging issue of developing autonomy, is a main appeal in this thesis. Results of the research of the thesis are relevant to address relevant recurrent problems in teaching ethics in evidence-based resident curricula.

Thus, time constraint, lack or resources, problems due to complex residential duties or maturation effect of the residency, lack of continuity of attendance or interest, scepticism could be effectively overcome using a thoroughly planned ethics curriculum, which shall be adequately supported and funded by the department direction. Indeed, inadequate quality or limited effect of previous ethics teaching experiences present a very important problem when dealing with clinical residents. This thesis summarizes relevant didactic barriers in teaching ethics to paediatric resident and provides medical teachers with potential solutions to address them.

2. Providing paediatricians and child healthcare professionals with a tool to address developing autonomy in their daily routine

This thesis introduced a novel ethical model to address dilemmas associated with the grade of respect, or lack of respect, for the children's developing autonomy, in a healthcare setting. Not many practical tools and models have been published towards this direction, with a main alternative the Children's Rights-Based approach presented by the American Academy of Pediatrics (AAP) (AAP, 2010). The tool presented in this thesis should function complementary to the approach of the AAP and could be actually more effective for the discussion of cases in which there is a lack of alignment in the decisions of children and their parents in a child healthcare setting.

The model has been presented in the Annual Meeting of the International Society for Social Pediatrics and Child Healthcare, 27-29 Sept. 2018, Bonn, Germany as well as in the annual conference of the project "Children's well-being and child-protection: An analysis of the normative principles of children's well- being", 4-6 Oct. 2016, Göttingen, Germany and received very positive feedback. The model has already been cited in peer-reviewed papers. Finally, the publication of this chapter in English and

Spanish language, in a bilingual, open-access journal, can further increase the impact of the presented model and tool. The tool is already in use in research among paediatricians and ethics master students in Latin America.

3. Identifying transferable health ethics practices related to vaccination strategies in Europe

It is obvious that the study of contextual factors is crucial for the transferability of good ethics practices in different settings. Harmonization of these practices within Europe will need changes of the procedures of healthcare practices, including vaccination programs. This thesis portraits ethical dilemmas regarding respect to the child's developing autonomy, emerging in different vaccine settings, including the initiation of a general seasonal influenza vaccine in early childhood, as well as the treatment with a vaccine preventing the transmission of sexually transmitted agents (HPV) in late childhood. Different methodologies have been implemented in order to reach conclusions that could function as ethical guidelines to facilitate harmonization of ethics practices in child healthcare services in Europe. Results of the research presented in this thesis are relevant for policy makers and other respective ethical actors, functioning nationally, regionally and internationally. The International Society for Social Pediatrics (ISSOP) has already been used as a platform to disseminate the findings of this thesis, while the association of parts of the thesis with the EU MOCHA Project (Models of Child Health Appraised) (Blair, 2017) can multiply the impact of these findings in identifying and implementing good ethics practices in Europe and internationally.

Offering a clear overview of the phenomenology of autonomy development in childhood and adolescence can provide a robust fundament to support an ethics-based interaction between children, parents and physicians and can also serve as relevant background for child ethics research. Indeed, the study group has currently initiated the implementation of an ethics approach in treating a German cohort of paediatric patients with cerebral palsy with botulinum toxin and has extended the research field including the assessment of decision-making competences, as suggested by Hein et al (Hein et al., 2019). This patient cohort includes children with congenital postural and movement disorders, who partially suffer from intellectual disability. The comparison of decision-making competences among patients with or without cognitive dysfunction may reveal relevant findings regarding different patterns of autonomy development in childhood and adolescence of these patients. The approach has been welcomed by the patients, their parents, as well as the acting physicians.

All in all, the paradigm change underlining the importance of respect to autonomy in paediatric patients, as well as the lack of education of the physicians to respond to this emerging need, are the main underlying values and appeals this thesis brings forward. The thesis does not only identify the problems, but also provides solutions and approaches to address them successfully.

Finally, influenced by the spirit of this thesis, but also of similar literature referring to the role children may play in vaccination programs in times of a pandemic, a group of academicians, including the author of this thesis, prepared a policy brief with ethics recommendations for a potential Sars-CoV-2 vaccine, regarding the prioritization of health workers, children and vulnerable groups (Schröder-Bäck et al., 2020). The Policy Brief aimed at health policy advisors, public health institutions and health policy makers on different levels of governance within Germany and Europe. It has been submitted to the German Standing Committee on Vaccinations, the WHO Europe and the European Commission, receiving very positive feedback.

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Summary

The hypothesis of this dissertation is that respect for the children's developing autonomy in paediatric healthcare, especially with regards to national vaccination programs, may be expressed differently across Europe. Despite the differences, common ethical patterns and good practices may be identified and transferred across the region. Although the paediatrician's role may be decisive in addressing ethical dilemmas regarding the respect for developing autonomy in childhood, it is unclear if ethics teaching is adequately included in their resident curricula.

The thesis consists of two ethical conceptual chapters (Chapters 3 and 4) and two social sciences chapters (Chapters 2 and 5). Each of them reveals different challenges from the field of vaccination ethics, identifies and explores different levels of respect for the child's developing autonomy in paediatric healthcare and discusses them in a European and an international context.

Chapter 1 provides an introduction to the field of vaccination ethics and defines the research questions and hypothesis. Chapter 2 presents a systematic literature review and metasynthesis, regarding paediatric resident ethics curricula and depicts the current situation in the didactic of medical ethics among physicians specializing in child healthcare. It identifies recurrent teaching patterns, portrays common difficulties and summarizes solutions to address these difficulties

Chapter 3 focuses on the context of vaccination ethics. Utilizing a methodological approach currently proposed by the World Health Organization, this chapter examines and addresses ethical dilemmas regarding the provision of a prophylactic seasonal vaccine in childhood to reduce the burden of influenza-related morbidity. The Hippocratic ethos, several expressions of utilitarianism such as the harm principle, perspectives from liberty and autonomy, as well as justice and solidarity perspectives are analysed in this case. Finally, decisions regarding the ethically most suitable interventions with regards to seasonal influenza vaccination programs are drawn, using a modification of the intervention ladder, a tool to facilitate ethical decision-making, proposed by the Nuffield Council on Bioethics.

Next to the traditionally accepted and well-established forces of medical and parental paternalism, Chapter 3 focuses on the concept of the children's developing autonomy as a new emerging force in ethical discussions in child healthcare. Chapter 4, further, presents an extensive literature review in an attempt to clarify and address this emerging ethical pattern. It also introduces an ethical model including the triad of the child, as patient, the parents and the physician, interacting in a frame of justice and respecting the child's right to autonomy of choice, while acting for the child's medical good. A

tool that should facilitate ethical discussion among these three actors accompanies the proposed model.

The respect, or non-respect, to children's rights to autonomy of choice is differently expressed throughout Europe. Continuing the navigation in the field of vaccination ethics, Chapter 5 presents the findings of an exploration of differences regarding expressions or respect for children's developing autonomy throughout Europe, using the human papillomavirus (HPV) vaccination offer as indicator. A mixed methods approach was used, utilizing an expert survey within the frame of the "Models of Child Health Appraised" Project (MOCHA). The data analysis addresses the following themes: (i) provision of informed consent, (ii) parental and medical paternalism, (iii) relevance of the child's chronological age or maturity, and (iv) vaccination programs targeting boys. These themes are being handled differently across the region. Chapter 5 also explores associations of the implemented practices with the national HPV vaccine coverage rate across the European Union, discusses and identifies the most suitable ethical approaches to be transferred and implemented across Europe.

In Chapter 6, the Discussion of this dissertation, the general findings of this dissertation are discussed, with an emphasis on strengths and limitations. This should foster and guide future research, provide recommendations for policy and decision-makers in the field of vaccination ethics on a national, European and international level, and also provide helpful input for ethical discussion among and between physicians, ethicists, parents and, of course, the children as patients themselves. Furthermore, a Child's Rights-based approach, proposed by the American Academy of Pediatrics, is introduced as an alternative to discuss vaccination ethics in childhood and is compared with the "developing autonomy approach", introduced and implemented in Chapter 4. The similarity of the conclusions reached using the two approaches, confirms the validity of the "developing autonomy approach".

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Curriculum Vitae

Kyriakos Martakis was born on July 22nd, 1984 in Chios, Greece. After receiving primary and secondary education in the city of Chios, he studied Medicine at the Aristotle University of Thessaloniki, Greece and the University of Cologne, Germany, where he acquired scientific and clinical skills. During his medical student years, he was actively involved, and he later headed the Hellenic Medical Students International Committee (HelMSIC), a national medical student organization, and member of the International Federation of Medical Students' Associations (IFMSA) and the European Medical Students' Association (EMSA). Following his interest in Public Health, he organized local, national and international health promotion projects, he participated in the regional and international activities of the IFMSA Standing Committee on Public Health (SCOPH), which he later headed as Director (2007-2008) and Liaison Officer on Public Health (2008-2009). He participated in the 60th World Health Assembly, where he drafted and presented a statement on Alcohol Policies.

After finishing his medical studies in 2008 he specialized in paediatrics at the Hospital of the City of Chios (2008-2009) and at the Department of Paediatrics of the University Hospital of Cologne (2009-2014). Further, he completed fellowships in Paediatric Palliative Care (2015), Paediatric Neurology and Social Paediatrics (2015-2018) at the Department of Paediatrics and the Centre for Prevention and Rehabilitation (UniReha GmbH) of the University Hospital of Cologne.

His experience in research includes studies on the development of spinal reflexes and pain circuits in human infants, as well as the monitoring and neurorehabilitation using spinal reflexes of children with chronic posture and movement disorders. He received the doctorate title with honours (suma cum laude) from the University of Cologne, after defending his doctoral thesis on pain perception among very premature infants in 2015. He completed his postdoctoral studies at the University of Cologne, focusing on neurorehabilitation using spinal reflexes in children with movement disorders, and received the title of Associate Professor (Privatdozent) in Paediatrics from the University of Cologne, in July 2020.

Next to his clinical career, and following his passion for public health, he pursuers Masters in European Public Health, at the Department for International Health of the Faculty of Health, Medicine and Life Sciences, Maastricht University, Maastricht, The Netherlands from 2012 to 2013. The treatment of chronic sick, and physically or socially challenged children has led to the development of his genuine interest in child health ethics. This driving force met the respective passion of PD Dr. phil. Peter Schröder-Bäck, his supervisor and mentor in the field, leading to the present PhD, an academic work focusing on autonomy development in child healthcare in Europe. He also worked as researcher at the Department for Health Economics of the Faculty of Economics and Management of the University of Cologne, Cologne, Germany from 2014 to 2015.

Currently he is working as paediatric neurologist, social paediatrician and researcher at the Department for Paediatric Neurology and Social Paediatrics of the Justus-Liebig University, Giessen, Germany and the Department for Paediatric Neurology and Social Paediatrics of the University Hospital of Cologne, Cologne, Germany, where he also holds the title of Associate Professor in Paediatrics.