Introduction

1. Problem Statement

Over the past fifty years, scientific and technological progress in the biomedical field has transformed many emerging possibilities into fully developed and clinically tested health technologies.[1] They are ready to be used safely for diagnostic or therapeutic purposes on human beings. Many of them are thus eligible to become embedded in the public healthcare system, as valuable resources in schemes of medical coverage that have the potential to be extremely innovative.

Among these innovations none has found such an ample space in legal scholars' debate as those developed thanks to the convergence of reproductive medicine and genetic technology.[2] This is mainly due to the implications of their use for other moral entities, such as embryos or future generations, and thus their considerable moral weight. With regard to reproductive medicine one need only think of the constant polarisation caused by the abortion issue[3] and, in more recent times, of the impressive legal, political and philosophical debates on medically assisted procreation that have been going on ever since the birth of the first in-vitro baby

1 The notion of health technology has been chosen for the thesis due to its comprehensive scope. According to the World Health Organisation (WHO), "[h]ealth technologies include medicines, medical devices, assistive technologies, techniques and procedures developed to solve health problems and improve the quality of life", <https://www.who.int/europe/news-room/fact-sheets/item/health-technologies> accessed 9.8.2022. Article 3(l) of the EU Directive 2011/24/EU on the Application of Patients' Rights in Cross-border Healthcare, O.J. L 88/45 defines *health technology* as "a medicinal product, a medical device or medical and surgical procedures as well as measures for disease prevention, diagnosis or treatment used in healthcare".

2 In his contribution on liberal eugenics of 2001, Habermas warned against the moral weight of questions surrounding technological developments brought about by this combination of fields and stressed the need to inquire about the normative evaluation of "one day theoretically possible genetic engineering developments", although they were at the time deemed to be "completely out of reach" (author's translation), see Habermas, *Die Zukunft der menschlichen Natur: Auf dem Weg zu einer liberalen Eugenik?* (2001) p. 39.

3 Warren in Kuhse and Singer, *A Companion to Bioethics* (2nd edn 2009).

back in 1978.[4] Both the removal of embryos form the mother's womb and their in-vitro creation and selection can cause ethical concerns related to, for instance, the right to life of the embryo and its dignity as a human being,[5] the respect for the laws of nature[6] and of the personal identity and self-determination of the child.[7]

As for genetic technology, the possibility of genetic modification raises, amongst others, the concern that researchers might be "playing God"[8] as well as questions of: selection, genetic enhancement and augmentation of inequalities,[9] safety of the procedures[10] and, in case of alteration in the germline, the right to self-determination of the future generations.[11]

Ultimately, the interaction of reproductive medicine and genetic technology could allow for the full realisation of parents' natural desire to have a healthy child[12] or, according to the slippery slope argument,[13] the "engineering of the perfect baby"[14]. Until now, the combined evolution of the two fields encouraged the development and refinement of, on the one hand, long-established mechanisms of embryo diagnosis and selection, such as

4 The news of the birth of Louise Brown was reported by the media in July 1978, see Dow, 'Looking into the Test Tube: The Birth of IVF on British Television' (2019) 63(2) Med Hist p. 189. Legal and ethical discussions on IVF are still carried out with reference to her name, see Bockenheimer-Lucius, Thorn and Wendehorst, *Umwege zum eigenen Kind; Ethische und rechtliche Herausforderungen an die Reproduktionsmedizin 30 Jahre nach Louise Brown* (2008).

5 Nettesheim, 'Die Garantie der Menschenwürde zwischen metaphysischer Überhöhung und bloßem Abwägungstopos' (2005) 130(1) AöR p. 71; Habermas, *Die Zukunft der menschlichen Natur* (2001); Tooley in Kuhse and Singer, *A Companion to Bioethics* (2nd edn 2009).

6 Rostalski, *Das Natürlichkeitsargument bei biotechnologischen Maßnahmen* (2019).

7 Turkmendag, 'The Donor-conceived Child's 'Right to Personal Identity': The Public Debate on Donor Anonymity in the United Kingdom' (2012) 39(1) J Law Soc p. 58.

8 Peters, *Playing God?: Genetic Determinism and Human Freedom* (2nd edn 2003); Coady in Savulescu and Bostrom, *Human Enhancement* (2010).

9 Gyngell, Douglas and Savulescu, 'The Ethics of Germline Gene Editing' (2017) 34(4) J Appl Philos p. 498, 509.

10 ibid, p. 504.

11 Kamm, 'Moral Status and Personal Identity: Clones, Embryos and Future Generations' (2005) 22(2) Soc Phil Pol p. 283; Agius and Busuttil, *Germ-Line Intervention and Our Responsibilities to Future Generations* (1998).

12 For a reflection on the ethical issues and implications regarding the desire to conceive a healthy child, see Haker, *Hauptsache gesund?: Ethische Fragen der Pränatal- und Präimplantationsdiagnostik* (2011).

13 See Chapter 1, sec. A.3.

14 Regalado, 'Engineering the Perfect Baby' (3.5.2015) <https://www.technologyreview.com/s/535661/engineering-the-perfect-baby/> accessed 25.4.2022.

prenatal testing and preimplantation genetic diagnosis (PGD), and, on the other hand, very innovative therapeutic techniques involving genetic modifications of the embryo such as mitochondrial replacement therapy (MRT). However, both areas of technological advancement remain highly controversial and the same holds true for the decision regarding their possible inclusion in the publicly funded healthcare system.

While prenatal screening and diagnoses are currently offered within the publicly funded healthcare systems of most European countries, a "paradigm shift"[15] recently occurred with the development of innovative non-invasive prenatal testing (NIPT). This has led several states to reconsider the ethical and legal implications of wide-scale prenatal screening.[16] As for preimplantation genetic diagnosis, which offers an alternative to prenatal screening for couples that have a high risk of transmitting a genetic disease to the foetus, reimbursement through the healthcare system is not guaranteed in many countries.[17]

Mitochondrial replacement therapy, a procedure intended to prevent the transmission of serious mitochondrial diseases to the embryo, encounters the further obstacle of the international ban on germline genetic modification.[18] Only the English NHS, after Parliament passed a regulation permitting the use of MRT in 2015,[19] initially dedicated £8 million in funding over

15 Dines and others, 'A Paradigm Shift: Considerations in Prenatal Cell-Free DNA Screening' (2018) 2(5) Jrnl App Lab Med p. 784.

16 See, for instance, the debates in Germany, Heinrichs, Spranger and Tambornino, 'Ethische und rechtliche Aspekte der Pränataldiagnostik' (2012) 30(10) MedR p. 625; Hufen, 'Verfassungsrechtliche Bedenken gegen frühe Pränataldiagnostik?' (2017) 35(4) MedR p. 277 and in Switzerland, Brauer and others, *Wissen können, dürfen, wollen?: Genetische Untersuchungen während der Schwangerschaft* (2016).

17 In Germany, the exclusion of PGD from statutory health insurance has been confirmed by the Federal Social Court (*Bundessozialgericht*, BSG) in BSG, 18.11.2014 - B 1 KR 19/13 R.

18 The ban appears in Art. 13 of the Convention on Human Rights and Biomedicine of the Council of Europe and is reiterated in the national legislation of several countries. The Swiss Constitution states, for instance, that « [t]oute intervention dans le patrimoine génétique de gamètes et d'embryons humains est interdite » (Art. 119, al. 2). Moreover, the UNESCO Universal Declaration of the Human Genome and Human Rights lists germline interventions as practices "contrary to human dignity" (Art. 24).

19 The Human Fertilisation and Embryology (Mitochondrial Donation) Regulations 2015.

five years[20] for mitochondrial donation, thus allowing licenced clinics to ensure integrated NHS care for patients at high risk of transmitting serious mitochondrial disease.[21] The prohibition of germline genetic modification also affects the possible implementation of genome editing by CRISPR/Cas9 in human embryos, which would enable the correction of mutations responsible of serious genetic disease in future children. Although several ethical and safety concerns related to these procedures hinder any clinical implementation at the present time, the question of their possible funding by public healthcare systems in the foreseeable future has already been raised.[22]

Since the health technologies described above are of a deeply controversial nature, the issue of their coverage or reimbursement in the public healthcare system is often likely to fade into the background of legal debates. The use of health technologies developed from a combination of reproductive medicine and genetic technology presents deep ethical dilemmas, and the immediate legal response to their emergence is often to impose criminal law restrictions according to the precautionary principle.[23] In this sense the legal debate's focus is primarily on the constitutional acceptability of these prohibitions and on whether the use of such technologies is compatible with individual rights and constitutional principles. These discussions often fail to address fundamental questions concerning the possible implementation of those procedures in the healthcare system – particularly questions regarding the state's positive obligation to guarantee the social right to equal access to healthcare through a publicly funded system.

Nonetheless it is important to address this point. In fact, not only must states decide whether ethically controversial techniques shall be permitted,

20 NHS England, 'NHS England to fund ground-breaking new mitochondrial donation clinical trial' <https://www.england.nhs.uk/2016/12/mitochondrial-donation/> accessed 22.4.2022.

21 Gorman and others, 'Mitochondrial Donation: From Test Tube to Clinic' (2018) 392(10154) Lancet p. 1191.

22 See, for Germany, the speculations maybe by Bern, *Genome Editing in Zeiten von CRISPR/Cas* (2020) pp. 191-ff. and Deuring, *Rechtliche Herausforderungen moderner Verfahren der Intervention in die menschliche Keimbahn* (2019) pp. 413-ff. reaching opposite conclusions, on the possible reimbursement of human genome editing within the existing rules of the German Social Law Code (SGB) Book V.

23 Andorno, 'The Precautionary Principle: A New Legal Standard for a Technological Age' (2004) 1(1) JIBL p. 11.

but also whether they should receive public funding, with funds being raised via taxation or contributions.

In light of the high costs of innovative health technologies it can be argued that a refusal of public coverage would effectively amount to a prevention of their use and distribution, especially amongst less affluent patients. As a matter of fact patients' access to innovative healthcare technologies is primarily determined by their inclusion in public healthcare coverage or insurance schemes.[24]

The choice of including ethically controversial health technologies in the public healthcare system not only has a substantive effect on a positive right to health, but also carries a certain symbolic value and has an impact on their acceptance by the community as a whole. This was also recognised by the German Constitutional Court in its second abortion decision.[25] The Court pointed out that the inclusion of certain medical procedures, such as abortion, in the statutory health insurance's benefit basket conveys an evaluation by the state that is liable to influence the population's perception towards them.[26] In fact, granting public funds through social benefits creates the impression that the state takes a positive stance towards the relevant health service. Conversely, withholding health insurance benefits conveys the idea that the procedure is not a standard one and is disapproved of or even condemned by the legal system.[27] According to the Court reimbursement decisions are thus capable of influencing public values. In addition the Court emphasised how an endorsement through the social insurance system is likely to "ease the conscience" of the people who are

24 Several studies investigate the diffusion of certain innovations after their introduction in the public health insurance or public coverage, see, for instance in the case of non-invasive prenatal testing, Vinante and others, 'Impact of Nationwide Health Insurance Coverage for Non-invasive Prenatal Testing' (2018) 141(2) Int J Gynaecol Obstet p. 189.

25 BVerfG, 28.5.1993 - 2 BvF 2/90, 2 BvF 4/90, 2 BvF 5/92 (BVerfGE 88, 203 - *Schwangerschaftsabbruch II*). An English translation is available at https://www.bundesverfassungsgericht.de/SharedDocs/Entscheidungen/EN/1993/05/fs19930528_2bvf000290en.html> accessed 9.8.2022. More on this judgment at Chapter 1, sec. B.I.2.b.

26 BVerfG, 28.5.1993 - 2 BvF 2/90, in BVerfGE 88, 203 (319).

27 Starck, 'Der verfassungsrechtliche Schutz des ungeborenen menschlichen Lebens. Zum zweiten Abtreibungsurteil des BVerfG' (1993) 48(17) JZ p. 816, 822. In the opinion of the court, however, the refusal to grant funding is "only limitedly" (*nur begrenzt*) suited to convey a negative view, see BVerfG, 28.5.1993 - 2 BvF 2/90, in BVerfGE 88, 203 (319).

close to the patient and share their responsibility in deciding to carry out the procedure.[28]

In other words, decisions regarding the public coverage or reimbursement of ethically controversial technologies tell us something about their acceptability and compatibility with a society's selection of values and contribute to a determination of "the kind of community we want to be".[29]

As a result, while the inclusion of a new health technology in the healthcare system's benefit basket is always the result of an assessment process characterised by uncertainty,[30] dealing with ethically disputed technologies adds another element of concern to the reimbursement decision. Further reflection is allegedly desired on possible moral harm resulting from their use or on the potential impact of their diffusion on the ethical values of a society.[31] Hence it could be argued that coverage decisions should be open to moral reflection and guarantee compliance with ethical standards and this applies particularly in the field of genetics and reproductive medicine.

The aim of incorporating ethical reflection into the decision-making process has been pursued on different levels. Ethical analysis has been recognised as a possible component of health technology assessment (HTA) procedures. These consist in systematic evaluations of properties, effects and impacts of health technologies[32] with a view to informing policy making in healthcare and, in particular, to supporting the healthcare system's reimbursement decisions.[33] Subject to the assessment is a broadly defined class of health technologies, including: drugs, medical devices, medical and

28 BVerfG, 28.5.1993 - 2 BvF 2/90, in BVerfGE 88, 203 (320), according to which those who are close to the pregnant woman may also feel relieved because they will perceive procedures for which social security benefits are granted as normal and lawful.

29 An expression borrowed from Brownsword and Wale, 'Testing Times Ahead: Non-Invasive Prenatal Testing and the Kind of Community We Want to Be' (2018) 81(4) Mod Law Rev p. 646.

30 Indeed, aspects of clinical effectiveness, quality, safety and cost-effectiveness are often unclear and need to be carefully evaluated in an assessment procedure.

31 This twofold uncertainty is illustrated by Beyleveld and Brownsword, 'Emerging Technologies, Extreme Uncertainty, and the Principle of Rational Precautionary Reasoning' (2012) 4(1) Law Innov Technol p. 35.

32 WHO Definition to be found in WHO Executive Board, 'Health Intervention and Technology Assessment in Support of Universal Health Coverage: Report by the Secretariat' (14.1.2014) EB 134/30 <https://apps.who.int/iris/handle/10665/172848> accessed 9.8.2022. See, also, Widrig, *Health Technology Assessment* (2015) pp. 48-ff.

33 *Inter alia,* Luce and others, 'EBM, HTA, and CER: Clearing the confusion' (2010) 88(2) Milbank Q p. 256, 271; Drummond and others, 'Key Principles for the Improved Conduct of Health Technology Assessments for Resource Allocation Deci-

surgical procedures, diagnostic tests, biologics (e.g. blood products and gene therapies), equipment and support, and organisational and managerial systems.[34] Although HTA is traditionally aimed at evaluating clinical and economic aspects, the need to include ethical principles within its normative criteria has been widely argued for.[35] Allegedly this would inform decision makers of the ethical concerns linked to the use of a health technology and of the possible ways to implement it in a manner that is consistent with the prevailing societal ethical values.[36]

Moreover, many countries have already envisaged the involvement of ethics committees on different levels of decision making. Ethics committees established at the national level can be consulted by the government or legislature on any legislative or regulatory action that might entail ethical concerns.[37] Other *ad-hoc* committees may be foreseen by specific laws as safeguarding mechanisms that can issue concrete guidelines and advisory opinions. Alternatively, they can oversee the compliance with legal standards through a requirement that they must sanction the performance of specific procedures. In Germany, examples are provided by the local

sions' (2008) 24(3) J of Inter Tech of Health Care p. 244, 247; Widrig, *Health Technology Assessment* (2015) p. 45.

34 Available on the International HTA Glossary, at <http://htaglossary.net/technology> accessed 25.4.2022. See also Goodman, *HTA 101 Introduction to Health Technology Assessment* (2014) p. II-1.

35 See, *inter alia,* Grunwald, 'The Normative Basis of (Health) Technology Assessment and the Role of Ethical Expertise' (2004) 2(2-3) Poiesis Prax p. 175; Reuzel and others, 'Ethics and HTA: Some Lessons and Challenges for the Future' (2004) 2(2-3) Poiesis Prax p. 247; Lucivero, *Ethical Assessments of Emerging Technologies: Appraising the Moral Plausibility of Technological Visions* (2016); Have, 'Ethical Perspectives on Health Technology Assessment' (2004) 20(1) Int J Technol Assess Health Care p. 71; Hofmann, 'Why Ethics Should Be Part of Health Technology Assessment' (2008) 24(4) Int J Technol Assess Health Care p. 423; Widrig, *Health Technology Assessment* (2015) pp. 248-ff.

36 Giacomini, Miller and Browman, 'Confronting the Gray Zones of Technology Assessment: Evaluating Genetic Testing Services for Public Insurance Coverage in Canada' (2003) 19(2) Int J Technol Assess Health Care p. 301; Castro and others in Marsh and others, *Multi-criteria Decision Analysis to Support Healthcare Decisions* (2017).

37 This is the case of the German Ethics Council (*Deutscher Ethikrat*), the Italian Committee for Bioethics (*Comitato Nazionale per la Bioetica,* CNB), the French National Consultative Ethics Committee for health and life sciences (*Comité consultatif national d'éthique*). The function of the UK-based Nuffield Council of Bioethics is slightly different, see later at Chapter 3, sec. C.II.3.a. On the roles of national ethics committees, see Vöneky, *Recht, Moral und Ethik: Grundlagen und Grenzen demokratischer Legitimation für Ethikgremien* (2010) pp. 233-ff.

Ethics Commissions for Preimplantation Diagnostics[38] and the Genetic Diagnostic Commission envisaged by § 23 of the Genetic Diagnosis Act (*Gendiagnostikgesetz*, GenDG).[39]

It is interesting to note that the EU Directive on the application of patients' rights in cross-border healthcare explicitly acknowledges that the public healthcare systems of the Member States may have made different ethical assessments of certain healthcare technologies.[40] Recital 7 of the Directive provides that "[n]o provision of this Directive should be interpreted in such a way as to undermine the fundamental *ethical* choices of Member States".[41] This clarification was introduced precisely to ensure that the directive would not oblige States to reimburse the costs of health services considered ethically controversial, such as in vitro fertilisation (IVF), if they are not funded in the Member State of origin.[42] The term 'ethical choices' is not defined by the Directive and remains relatively ambiguous.[43] In any case, it is assumed that the decision on whether or not to publicly fund a health technology also depends on an ethical, not just legal, assessment of it.

In sum, there is evidence that reimbursement decisions by the public healthcare system are not only the result of clinical and economic evaluations, but are also considered to depend on the ethical evaluations of relevant decision-makers.

Ethical concerns might enter the decision-making process even in an undisclosed or indirect way.[44] This has been the case with the Italian national and regional policies on heterologous IVF. After the Italian Constitutional Court had declared unconstitutional the prohibition of the use of

38 See Embryo Protection Act (*Embryonenschutzgesetz*, ESchG) § 3a(3) no. 1, as well as Chapter 2, sec. A.I.3.d.

39 Taupitz in Schliesky, Ernst and Schulz, *Die Freiheit des Menschen in Kommune, Staat und Europa: Festschrift für Edzard Schmidt-Jortzig* (2011) p. 829.

40 Although the focus of this thesis is not directly on EU law, the latter still plays a fundamental role as part of the legal order of individual European states.

41 7th recital, Directive 2011/24/EU. Emphasis added by the author.

42 van Hoof and Pennings, 'Extraterritorial Laws for Cross-border Reproductive Care: The Issue of Legal Diversity' (2012) 19(2) Eur J Health Law p. 187, 194; Frischhut, '"EU": Short for "Ethical" Union? The Role of Ethics in European Union Law' (2015) 75(3) ZaöRV p. 531, 548.

43 Frischhut, '"EU": Short for "Ethical" Union? The Role of Ethics in European Union Law' (2015) 75(3) ZaöRV p. 531, 558.

44 Taupitz in Schliesky, Ernst and Schulz, *Die Freiheit des Menschen in Kommune, Staat und Europa* (2011) pp. 827-ff.

donor gametes in IVF (so-called heterologous IVF), laid down by Article 4(3) Law no. 40/2004,[45] some regional administrations attempted to limit the use of a technology that they still considered undesirable. They limited or altogether prevented its funding by the Regional Healthcare System.[46]

This case shows that the consideration of ethical concerns in the decision can become problematic if it is intended to ensure that the provision of healthcare follows the ethical agenda of a political majority. The rather broad margin of appreciation granted to state institutions in shaping the benefit baskets entails the risk that the decisions might be taken on the basis of particular ethical, religious or ideological convictions. This allows the ideological opposition of the majority towards a technology to manifest itself in the refusal to fund it. If so, reimbursement choices that are based on ethical considerations would carry a problem of legitimacy in modern democratic societies. These societies are characterised by broad ethical pluralism, meaning that their members have different axiological beliefs and conceptions of the moral good.[47] This holds true both in terms of different ethical assumptions – deriving from different moral intuitions proper to each individual – and in terms of their concrete significance on the desirability of certain technologies.[48]

Within this framework this dissertation endorses the view that the adoption of a position of ethical neutrality is imperative for the legitimacy of state action and is an essential element of a pluralistic society.[49] Ethical neutrality is intended to guarantee that state actions are justified on grounds that can be accepted by the society as whole, and not on ideological or religious convictions shared only by a political majority.[50] According to this

45 In its judgment no. 162/2014.

46 Iadicicco, 'La lunga marcia verso l'effettività e l'equità nell'accesso alla fecondazione eterologa e all'interruzione volontaria di gravidanza' [2018](1) Rivista AIC p. 1, 29-ff. On this case, more information at Chapter 1, sec. II.2.b.

47 John Rawls refers to this circumstance as "the fact of pluralism", see Rawls, 'The Idea of an Overlapping Consensus' (1987) 7(1) Oxf J Leg Stud p. 1, 4.

48 See Vöneky and others, *Legitimation ethischer Entscheidungen im Recht: Interdisziplinäre Untersuchungen* (2009) p. 4.

49 Zotti in Vöneky and others, *Legitimation ethischer Entscheidungen im Recht: Interdisziplinäre Untersuchungen* (2009) p. 104.

50 Onida in Tedeschi, *Il principio di laicità nello stato democratico* (1996) p. 87; Valentini, 'La laicità dello Stato e le nuove interrelazioni tra etica e diritto' [2008](June) Stato, Chiese e pluralismo confessionale p. 1; Huster in Albers, *Bioethik, Biorecht, Biopolitik: Eine Kontextualisierung* (2016) p. 64.

principle it would be illegitimate for the majority to preserve and enforce its ethical or religious position by regulatory means.[51]

Although it is controversial in many respects,[52] the thesis will argue that the principle of the ethical neutrality of the state has an essential core element that can be widely agreed upon. Namely, that individuals in a constitutional state cannot suffer interferences with their fundamental rights, such as the right to health, if these can be only justified on the basis of particular ideological, ethical or religious considerations.[53]

2. State of Research

Much has been written about the emergence of innovations in healthcare and the legal and ethical concerns that arise from their implementation in the public healthcare system. More broadly, there is no lack of studies analysing the relationship and interplay between law and (bio)ethics with regard to the developments in modern biomedicine.[54] Many scholars advocate that law in the biomedical field should be open to ethical reflections.[55] Some of these scholars examine the role and legitimation of ethical committees in the public healthcare system.[56] Others have investigated the prin-

51 Korený, 'From a Tolerant to an Ethically Neutral State' (2016) 26(2) Human Affairs p. 409, 187; Huster, *Die ethische Neutralität des Staates* (2nd edn 2017) p. 106.

52 Huster in Albers, *Bioethik, Biorecht, Biopolitik* (2016) p. 67. Recently, a heated discussion about the validity of the neutrality requirement in German constitutional law arose at the conference of the *Vereinigung der Deutschen Staatsrechtslehrer*, which took place in Mannheim from 6 to 9 October 2021. The discussion is published in 'Aussprache und Schlussworte' [2022](81) VVDStRL p. 355.

53 Huster, *Die ethische Neutralität des Staates* (2017) p. 117.

54 See, *inter alia*, Piciocchi, 'Bioethics and Law: Between Values and Rules' (2005) 12(2) IJGLS p. 471; Casonato in Casonato and Piciocchi, *Biodiritto in dialogo* (2006); Vöneky and others, *Legitimation ethischer Entscheidungen im Recht* (2009); van der Burg in Kuhse and Singer, *A Companion to Bioethics* (2nd edn 2009); Vöneky, *Recht, Moral und Ethik* (2010); Spranger, *Recht und Bioethik: Verweisungszusammenhänge bei der Normierung der Lebenswissenschaften* (2010); Vöneky and others, *Ethik und Recht - Die Ethisierung des Rechts/Ethics and Law - The Ethicalization of Law* (2013); Huster in Albers, *Bioethik, Biorecht, Biopolitik* (2016).

55 Vöneky, *Recht, Moral und Ethik* (2010); Casonato in Valdés and Lecaros, *Biolaw and Policy in the Twenty-First Century* (2019).

56 Amongst others, Fateh-Moghadam in Voigt, *Religion in bioethischen Diskursen: Interdisziplinäre, internationale und interreligiöse Perspektiven* (2010); Videtta in Rodota, Zatti and Ferrara, *Trattato di biodiritto: Salute e sanità* (2011); Poscher in Vöneky and others, *Ethik und Recht - Die Ethisierung des Rechts/Ethics and Law - The Ethicalization of Law* (2013); Hermerén, 'Accountability, Democracy, and Ethics Committees'

ciple of the ethical neutrality of the State in the context of authorising new health technologies or in relation to the role of ethics in public health.[57]

Furthermore, several scholars have turned their attention to the health technology assessment process: since the beginning of this century researchers have investigated the inclusion of ethical values in the normative basis for the decision making process in health technology regulation and reimbursement decisions.[58] Although HTA is traditionally conducted with a view to safety, quality and cost-effectiveness criteria, many studies argue that these guiding principles are nowadays no longer sufficient for a full assessment of innovative products. A responsible implementation of novel medical products and procedures demands that ethical issues be addressed in the decision making process. Scholars acknowledged that, in order to be eligible for public coverage, an innovative healthcare technology must be judged to be consistent with the ethical standards or prevailing values in society. However, most of the relevant research in the field is not legal research. Rather it is conducted from a Science and Technology Studies (STS), bioethical or philosophical standpoint. As a result little or no attention centres on the legal significance of the inclusion of ethical evaluations within the public decision making procedure. In particular, one might wonder whether and to what extent the consideration of ethical aspects in the assessment process could – legally and legitimately – be relevant to the final decision.

Even if the assessment authorities were given a legal basis for the consideration of ethical aspects in their decision making process, it is uncertain whether public coverage could legitimately be denied on the basis of purely

(2015) 1(2) Law Innov Technol p. 153; Faulkner and Poort, 'Stretching and Challenging the Boundaries of Law: Varieties of Knowledge in Biotechnologies Regulation' (2017) 55(2) Minerva p. 209.

57 Huster in Kopetzki and others, *Körper-Codes: Moderne Medizin, individuelle Handlungsfreiheiten und die Grundrechte* (2010); Strech, Hirschberg and Marckmann, *Ethics in Public Health and Health Policy: Concepts, Methods, Case Studies* (2013).

58 *Inter alia,* Grunwald, 'The Normative Basis of (Health) Technology Assessment and the Role of Ethical Expertise' (2004) 2(2-3) Poiesis Prax p. 175; Have, 'Ethical Perspectives on Health Technology Assessment' (2004) 20(1) Int J Technol Assess Health Care p. 71; Giacomini, 'One of These Things is Not Like the Others: The Idea of Precedence in Health Technology Assessment and Coverage Decisions' (2005) 83(2) Milbank Q p. 193; Hofmann, 'Why Ethics Should Be Part of Health Technology Assessment' (2008) 24(4) Int J Technol Assess Health Care p. 423; Lucivero, *Ethical Assessments of Emerging Technologies* (2016); Castro and others in Marsh and others, *Multi-criteria Decision Analysis to Support Healthcare Decisions* (2017).

ethical concerns. The perception of certain technologies as ethically controversial would give rise to more legal barriers for their publicly-funded implementation and therefore in hurdles to patients' prompt access to innovation. The legitimacy of this effect has not yet been investigated from a legal point of view. No study has assessed whether the decision-makers could legitimately operationalise an ethical position to limit patients' access to certain health services. As far as legal scholarship is concerned, research focuses primarily on the impact of innovations in healthcare on the fundamental rights of the individual and on human dignity, self-determination and privacy.[59] The emphasis remains mainly on whether it is constitutionally acceptable to prohibit the use or the provision of certain health services.

Undoubtedly the study of the compliance of health technologies with individual rights and constitutional principles is of particular interest and offers stimulating insights and reflections. Nevertheless, this approach leaves out fundamental questions concerning the coverage and reimbursement of these medical services in a publicly funded healthcare system.

The work of some German scholars must be mentioned separately. Although only in relation to specific instances, these have indeed inquired whether there is a legal basis for the consideration of ethical issues in the statutory health insurance's reimbursement decision.[60] The contributions on the subject mainly focus on medically assisted procreation.[61] However, these studies have not yet adopted a comparative approach. Being limited to a single country, they do not give insights into whether different normative frameworks may determine different outcomes in terms of the relevance of ethical considerations in reimbursement and coverage decisions.

59 See, for instance, Jasanoff, *Reframing rights: Bioconstitutionalism in the genetic age* (2011); Santosuosso, Goodenough and Tomasi, *The Challenge of Innovation inLlaw: The Impact of Technology and Science on Legal Studies and Practice* (2015); Lucchi, *The Impact of Science and Technology on the Rights of the Individual* (2016); Castaing, *Technologies médicales innovantes et protection des droits fondamentaux des patients* (2017).

60 Huster, 'Der Gemeinsame Bundesausschuss als Ethikbehörde?' (2017) 35(4) MedR p. 282.

61 Huster, 'Die Leistungspflicht der GKV für Maßnahmen der künstlichen Befruchtung und der Krankheitsbegriff' (2009) 62(24) NJW p. 1713; Rauprich in Bockenheimer-Lucius, Thorn and Wendehorst, *Umwege zum eigenen Kind; Ethische und rechtliche Herausforderungen an die Reproduktionsmedizin 30 Jahre nach Louise Brown* (2008); Rauprich, *Die Kosten des Kinderwunsches: Interdisziplinäre Perspektiven zur Finanzierung reproduktionsmedizinischer Behandlungen* (2012).

On a more general note, the question of the relationship between law and morality or law and ethics has been subject to deep philosophical investigations and debates at least since Kant's reflection on the function of the legal system in relation to the moral autonomy of the citizens.[62] This literature, emerging also from the debate between positivists and natural law theorists,[63] offers a fruitful basis for concretising the principle of ethical neutrality and for embedding it in a more comprehensive theory of the state.[64]

3. Research Objectives and Methodology

As outlined above, public coverage and reimbursement decisions about ethically controversial technologies have to meet two contrasting demands. On the one hand, some commentators highlight the need to include ethical evaluations in the decision making process in order to address moral uncertainty. On the other hand, it cannot be denied that contemporary democratic societies require state authorities to reach a decision that is acceptable to individuals with different, and often opposite, moral stances and ethical principles. An examination of these conflicting positions is all the more needed in light of the innovation to be expected in this field in the near future.[65]

62 Kant, *Metaphysic of Morals: Divided into Metaphysical Elements of Law and of Ethics* (1799) pp. 11-ff and 26-ff.

63 See Chapter 1, sec. A.II.2.a.

64 Stefan Huster warns that the answer to the question of whether public health insurance should assume the costs of ethically controversial procedures cannot be simply answered by a mere reference to a principle of secularity or religious-ideological neutrality. The discussion must be accompanied by a more detailed concretization of this principle and its embedding in a comprehensive theory of the state, see Huster in Albers, *Bioethik, Biorecht, Biopolitik* (2016) p. 69.

65 See, as mentioned above, the developments in human gene editing promised by the CRISPR/CAS 9 technology. The announcement of the birth of the first children with edited genomic dates to the 25th of November of 2018 (for some consideration on this case, see Greely, 'CRISPR'd Babies: Human Germline Genome Editing in the 'He Jiankui Affair'' (2019) 6(1) J Law Biosci p. 111) and a possible future removal of the ban on germline editing has already been envisaged, *inter alia*, in Neri, 'Embryo editing: a proposito di una recente autorizzazione dell'HFEA' [2016](1) BioLaw Journal – Rivista di BioDiritto p. 261; Baertschi, 'CRISPR-Cas9: l'interdiction de la thérapie génique germinale est-elle devenue inappropriée?' (2017) 10(2) Bioethica Forum p. 41; Gregorowius, 'Human Genome Editing and the Need for Regulation and Deliberation' (2017) 10(2) Bioethica Forum p. 71; Sykora and Caplan, 'The Council of Europe

Against this background, the present dissertation inquires whether ethical concerns are and can legitimately be taken into account in reimbursement and coverage decisions of different public healthcare systems. The normative framework of the investigation follows from an analysis of the question of the separation between ethics and the law, both from a descriptive and a prescriptive point of view. From a legal-sociological angle, pluralism is a factual basis of modern societies. Starting from this assumption, a legal-ethical perspective demands that, in a pluralistic society, only values that are considered acceptable and relevant by virtually al members of society can be a legitimate basis for legal regulations. Accordingly, the main hypothesis that the state shall adopt a position of ethical neutrality will be justified by reference to the legal and constitutional background. Adopting a constitutional law approach, the state obligation of neutrality will be traced back to its constitutional embedding in the different jurisdictions.

By conducting two case studies an in-depth appreciation will be gained of the concrete mechanisms governing reimbursement decisions of ethically controversial technologies. This case study approach offers insights into the extent to which ethical concerns concretely played a role in relevant decision making processes, concerning both the regulation and the public funding of some of the most recently debated innovations in the field of reproductive medicine and genetic technology.

The analysis of the case studies will be conducted from a variety of angles. From an epistemological perspective, the aim will be to critically compare the ethical patterns of argumentation with the legal-constitutional background, and their influences on the regulation of controversial technologies in the public healthcare system. From the perspective of the separation of powers, the interaction between the legislative, executive, and judicial branches will be explored. This is complemented by a broader institutional perspective, through which the interaction of state powers with other entities including various stakeholders, civil society, ethics committees and other commissions will be observed. In doing so, the study will take into account the different regulatory frameworks of the various jurisdictions, such as the individual conceptions of constitution and state, as well as the different models of healthcare systems.

Should not Reaffirm the Ban on Germline Genome Editing in Humans' (2017) 18(11) EMBO reports p. 1871.

As mentioned above, progress in the fields of medicine and genetic technology can be considered emblematic of all ethical concerns in healthcare. Therefore the chosen cases consist of innovative technologies intended to prevent the birth of a child with specific genetic disorders or chromosomal anomalies. Namely: preimplantation genetic diagnosis (PGD) and non-invasive prenatal testing (NIPT).[66]

Unlike classic IVF procedures these technologies do not simply aim to satisfy the parents' desire to have a child, but rather involve the selection of embryos and foetuses that are not affected by severe health conditions. This makes them more ethically controversial than IVF, as they are linked to issues of eugenics and abortion. At the same time, as PGD is always performed in conjunction with IVF, issues relating to fertility treatments more generally will have to be addressed indirectly. The choice of conducting two case studies follows from the need to address two equally relevant aspects in the current investigation. The first is that ethical concerns may lead the state to prohibit a health technology through the criminal law. This has the effect that the technology will not be allowed into the public healthcare system either. The second aspect is the decision on public financing. While the first point is well illustrated by the PGD case, the second aspect is more prominent in the case of NIPT.

The dissertation adopts a comparative method. The choice of this method is partly motivated by the specific desire to learn how different states deal with ethically controversial health technologies. Comparative law serves to better grasp, understand and evaluate the law,[67] both in terms of its internal functional mechanisms and in terms of the role that the legal system plays in democratic societies. Moreover, the added value of a comparative study lies in the potential to reveal, through comparison with other countries, ethical and religious influences on the law that might otherwise remain concealed.

For the purposes of addressing the research question the comparative method is instrumental for understanding how the relationship between ethics and law is constructed from different constitutional premises. I hypothesise that the principles of the constitutional order of different jurisdictions will provide an indication as to how the spheres of ethics and

66 For more details on the functioning of the two technologies, see Chapter 1, sec. A.I.3.b.

67 Zacher in Zacher and Schulte, *Methodische Probleme des Sozialrechtsvergleichs: Colloquium der Projektgruppe für internationales und vergleichendes Sozialrecht der Max-Planck-Gesellschaft* (1977) p. 22.

law should relate to each other. Constant progress in medical technology enables us to understand and potentially influence biological processes to an unprecedented extent, without social normative systems such as ethics, morality or the law necessarily being able to keep pace with these innovations. When deliberating on the use of and access to innovative health technologies different value systems collide with each other. Disagreements must ultimately be reconciled in a legally binding way to ensure the maintenance of a pluralist society. This resolution must balance patients' autonomy and access to innovative technologies, as well as the right to health and life respectively. The legal comparison will shed light on the ways in which different jurisdictions, with different constitutional and institutional settings, deal with the emergence of ethically controversial health technologies against the background of diverging and pluralist views.

It is the search for the functional equivalents that is at the core of comparative legal research.[68] Following the functional method, social law is particularly well suited for comparative research, since it is often based on specific social policies that address concrete social needs or objectives.[69] The case of health is even more striking, as all states will be faced with the emergence of the exact same technologies and will have to assess them according to their own normative background. The strong interdependency between the legal and political system within modern welfare states enables the identification of functional equivalents within different legal orders: while the objectives remain the same, the solutions to problems often differ. The comparative perspective allows identifying those functional equivalents, carving out the peculiarities of the respective social systems and, what is more, determining the extent to which the differences between the constitutional orders are effectively relevant in shaping positive law.[70] It is hypothesised that the way a public healthcare system is shaped and regulated, together with its constitutional setting and the involvement of different legal instruments and actors, can influence the space in which ethical considerations can play a role in decisions on the public funding of health technologies.

68 Zweigert and Kötz, *Einführung in die Rechtsvergleichung auf dem Gebiete des Privatrechts* (3rd edn 1996) pp. 33-ff; Michaels in Reimann, Zimmermann and Michaels, *The Oxford Handbook of Comparative Law* (2006) pp. 340-ff.

69 Becker in Becker, *Rechtsdogmatik und Rechtsvergleich im Sozialrecht I* (2010) p. 21.

70 ibid, p. 22.

If these hypotheses are correct, then the comparative analysis, by following the perspectives mentioned above, should be able to identify which elements can legitimately contribute to deliberations dealing with ethical concerns in healthcare. The capability of legal systems to preserve pluralism by adopting a position of ethical neutrality, which will be developed in the theoretical chapter, is intended both as a measure of legitimacy and a standard of comparison.[71]

In addition the thesis will provide historical insights on how the current national rules came to being, bearing in mind that health law constantly develops against the background of emerging health technologies.[72]

Every comparison demands selecting jurisdictions with "wise restraint"[73] and with a view to addressing the research question. With these purposes in mind, the jurisdictions chosen for the comparison are Germany, Italy and England. Since health is a devolved matter and each country in the United Kingdom has an independent publicly funded national health service, the chosen jurisdiction is England and not the entire UK. However, some constitutional considerations apply to the United Kingdom as a whole. For this reason, the dissertation will refer to the UK where most appropriate while keeping in mind that the investigation of the case studies remains focused on the English National Health Service (NHS).

The country selection was based on several considerations. First of all, the pool of legal systems has been limited to European countries. This is, on the one hand, because of their common tradition of gradual emancipation of law from religion[74] which resulted in the development of a theory of separation of law and ethics that will form the theoretical background for this research. This thesis seeks to investigate both the differences and commonalities amongst constitutional orders that strive, to varying degrees, to ensure that legal and constitutional values are determined and pursued independently, without reference to particular religious beliefs. On the other hand, the existence of a publicly funded healthcare system covering

71 Michaels in Reimann, Zimmermann and Michaels, *The Oxford Handbook of Comparative Law* (2006) pp. 372-ff.

72 On social law as a developing subject, see Zacher in Zacher and Schulte, *Methodische Probleme des Sozialrechtsvergleichs* (1977) pp. 66-ff.

73 Zweigert and Kötz, *Einführung in die Rechtsvergleichung auf dem Gebiete des Privatrechts* (1996) p. 40 (author's translation). See also Constantinesco, *Rechtsvergleichung: Band 2: Die rechtsvergleichende Methode* (1972) p. 49.

74 Böckenförde in Böckenförde, *Recht, Staat, Freiheit: Studien zur Rechtsphilosophie, Staatstheorie und Verfassungsgeschichte* (2006).

the majority of the population was considered a necessary requirement for establishing relevancy to the investigation. States based to a large extent on private health insurances were excluded on this account. The three selected jurisdictions all offer publicly funded universal healthcare. In Italy and England, the National Health Service offers universal healthcare free of charge to all residents.[75] In Germany, although the healthcare system is characterised by a coexistence of private and public insurance, around 90% of the population is covered by the public statutory health insurance.[76] Membership in the statutory health insurance is generally compulsory, with the exceptions listed in § 6 SGB V. Individuals who are not compulsorily insured in this system, however, have an obligation to stipulate an insurance with a private health insurance fund.[77] Civil servants fall under a particular regime and are therefore also listed in the category of subjects who are not mandatorily insured.

Secondly, jurisdictions have been selected according to their different legal and constitutional understanding of the right to health and of the concepts of illness and medical treatment. Here, the hypothesis is that the notions of illness or health might have an influence on the kind of health services that fall within the scope of the public healthcare system, and can thus be included in its benefit basket. The legal understanding of the right to health or physical integrity is supposed to be relevant in determining the individual's entitlement to health services.

Both Italy and Germany adopt a very substantial, albeit partially different, concept of the right to health. In Germany, Article 2(2) of the Basic Law protects the right to life and physical integrity. However, a fundamental right to claim access to healthcare benefits is not encompassed by this Article.[78] The Basic Law thus leaves a wide margin of appreciation to the

75 For England, see the National Health Service Act 2006 sec. 1. The Italian National Health Service was established in 1978 by Law no. 833/1978, which replaced the previously existing insurance-based system.

76 Data for 2021 available at Bundesministerium für Gesundheit, 'Daten des Gesundheitswesens 2021' <https://www.bundesgesundheitsministerium.de/fileadmin/Dateien/5_Publikationen/Gesundheit/Broschueren/220125_BMG_DdGW_2021_bf.pdf> accessed 25.4.2022.

77 § 193(3) German Insurance Contract Act (*Versicherungsvertragsgesetz*, VVG).

78 Nonetheless, some obligations derive for the legislature by the principle of the social state enshrined in Article 20 of the Basic Law. See Steiner in Spickhoff, *Medizinrecht* (3rd edn 2018) para. 16; Di Fabio in Dürig, Herzog and Scholz, *Grundgesetz: Kommentar* (2021) para. 94.

legislature.[79] Very narrow exceptions to this have been developed by the case law of the Federal Constitutional Court for the medical treatment of life threatening diseases.[80] Legal scholars have also pointed out that the broad definition of health endorsed by the World Health Organisation (WHO)[81] does not fall within the scope of Article 2(2) of the Basic Law.[82]

In Italy, Article 32 of the Constitution provides the protection of health as a fundamental right of the individual. Unlike in Germany, this constitutional provision also covers the social aspect of the right to healthcare. The constitutional definition of health is repeated in Article 1 of Law no. 833/1978 establishing the National Health Service. Moreover, unlike Germany, Italy openly endorses the broad WHO definition of health.[83] As the case studies will show, due to influential interpretations in the legal scholarship and the jurisprudence of the Italian Constitutional Court, the protection of the right to health has proven of great importance in the Italian constitutional order.

In England, on the contrary, patients' rights to healthcare services are mainly procedural.[84] While patients do not usually have the right to claim a specific health service from the NHS, they are able to hold NHS bodies accountable for following certain procedural standards that can be checked via judicial review.

79 Steiner in Spickhoff, *Medizinrecht* (2018) para. 16.

80 BVerfG, 6.12.2005 - 1 BvR 347/98 (BVerfGE 115, 25) so-called '*Nikolaus*' decision. See, *inter alia*, Kingreen, 'Verfassungsrechtliche Grenzen der Rechtsetzungsbefugnis des Gemeinsamen Bundesausschusses im Gesundheitsrecht' (2006) 59(13) NJW p. 877; Huster, 'Anmerkung: BVerfG, Beschluss v. 6. 12. 2005 – 1 BvR 347/98' (2006) 61(9) JZ p. 466; Becker in Steiner and others, *Nach geltendem Verfassungsrecht: Festschrift für Udo Steiner zum 70. Geburtstag* (2009); Steiner in Spickhoff, *Medizinrecht* (2018) para. 17.

81 According to which "health is a state of complete physical, mental and social well-being and not merely the absence of disease or infirmity", see Preamble to the Constitution of WHO, as adopted by the International Health Conference, New York, 19 June - 22 July 1946, available at World Health Organization, 'Basic Documents' (2020), p. 1. <https://apps.who.int/gb/bd/pdf_files/BD_49th-en.pdf> accessed 25.4.2022

82 Rauschning, 'Staatsaufgabe Umweltschutz' [1979](38) VVDStRL p. 168, 179; Starck in Mangoldt, Klein and Starck, *Grundgesetz: Kommentar* (7th edn 2018) para. 193; Kämmerer and Kunig in Münch and Kunig, *Grundgesetz: Kommentar* (7th edn 2021) para. 116; Rixen in Sachs, *Grundgesetz: Kommentar* (9th edn 2021) para. 150.

83 Formally transposed into the Italian legal system with the legislative decree no. 1086 of 4 March 1947. More on the Italian constitutional concept of health in Chapter 1, sec. B.II.2.a.

84 See Newdick in Nagel and Lauerer, *Prioritization in Medicine: An International Dialogue* (2016) pp.124-ff; Lock and Gibbs, *NHS Law and Practice* (2018) p. 317.

Thirdly, countries have been selected according to how 'restrictive' or 'permissive' their legislation on ethically controversial healthcare services tends to be, especially in the field of reproductive technologies. This, admittedly approximate, distinction offers another indication for the ethical background of the countries and their attitude towards ethical concerns in healthcare. The hypotheses about the legislative tendencies in the three jurisdictions will be verified in the case studies. As a first assessment it can be noted that Germany has adopted legislation which is especially protective of the human embryo.[85] A precautionary attitude in the field of reproductive medicine likely results from the paramount importance of the inviolable right to human dignity in the Basic Law. Italy also tends to have a particularly restrictive regulation, given its broadly Catholic background and the influence this manages to exert on politics.[86] In contrast, England has proven to be a leading pioneer in fertility treatments and embryo research. Both the first IVF baby[87] and the first child conceived using IVF combined with PGD were born in England,[88] marking milestones in the field of reproductive medicine.

A shared touchstone that illustrates these distinctions is proved by the different attitudes shown by the three states in drafting and adopting the 1997 Oviedo Convention of the Council of Europe on Human Rights and Biomedicine.[89] In particular, Germany and the United Kingdom adopted diametrically opposed positions regarding ethical questions linked to the issues addressed by the Convention.[90] Both countries refused to sign the document, albeit based on opposite objections. While the Convention was

85 The regulation of fertility treatment is indeed contained in a Law titled "Embryo Protection Act" (*Embryonenschutzgesetz*). See Chapter 2, sec. A.I.1.

86 See the influence of the Catholic Church on the approval of Law no. 40/2004 and following referendum. More on this in Chapter 2, sec. B.I.1.

87 Louise Brown was born in Lancashire, see Dow, 'Looking into the Test Tube' (2019) 63(2) Med Hist p. 189, 192.

88 The first PGD procedure resulted in healthy pregnancies were conducted in London in 1990, see Handyside and others, 'Pregnancies from Biopsied Human Preimplantation Embryos Sexed by Y-specific DNA Amplification' (1990) 344(6268) Nature p. 768.

89 Convention for the Protection of Human Rights and Dignity of the Human Being with regard to the Application of Biology and Medicine: Convention on Human Rights and Biomedicine (ETS No 164).

90 Council of Europe, Steering Committee on Bioethics, 'Preparatory Work on the Convention on Human Rights and Biomedicine' (Strasbourg 28.6.2000) CDBI/INF (2000) 1 <https://www.coe.int/t/dg3/healthbioethic/texts_and_documents/CDBI-INF%282000%291PrepConv.pdf> accessed 25.4.2022

considered too 'permissive' by the German representatives, the British delegation deemed it excessively restrictive on the freedom of research.[91] The analysis of the *travaux préparatoires* reveals that Germany was of the opinion that "in some areas [...] such as embryo protection [...] German law ensures a higher standard" than the Convention.[92] Italy, on the other hand, has signed and (almost) ratified the Convention.[93]

Finally, countries were chosen in which the legislative and societal debates on the technologies adopted as case studies here varied in scope and intensity. Public debates, or the absence of them, may offer insights into the perception of the community and the legislature towards coverage and reimbursement decisions of ethically controversial health technologies.

For these reasons, the three chosen jurisdictions offer a good variety of institutional and normative frameworks surrounding the protection of health and the regulation of access to reproductive technologies. At the same time comparability is ensured, both due to the common European context and through a shared understanding on the separation of ethics and law.

4. Overview of the Structure

In the first chapter, the relationship between ethics and the law is illustrated in both a descriptive and a normative way. Selecting the principle of the state's ethical neutrality as a normative criterion is explained and justified through a legal theoretical and a constitutional reflection. In doing so

91 Wachter, 'The European Convention on Bioethics' (1997) 27(1) Hastings Cent Rep p. 13; Raposo and Osuna in Beran, *Legal and Forensic Medicine* (2013) pp. 1406-ff.

92 Council of Europe, Steering Committee on Bioethics, 'Preparatory Work on the Convention on Human Rights and Biomedicine', Strasbourg 28.6.2000 CDBI/INF (2000) 1, p. 136. See also Schulze-Fielitz in Dreier, *Grundgesetz: Kommentar* (3rd edn 2013) para. 8.

93 The Convention was indeed ratified with law no. 145/2001, but has not yet deposited the instrument of ratification. Therefore, it does not appear on the Council of Europe's list of countries that have ratified the Convention, available at <https://www.coe.int/en/web/conventions/full-list?module=signatures-by-treaty&treatynum=164>, accessed 24.4.2022. This omission has no apparent reason. On this point, see Penasa, 'Alla ricerca dell'anello mancante: il deposito dello strumento di ratifica della Convenzione di Oviedo' (2007) Forum di Quaderni Costituzionali <https://www.forumcostituzionale.it/wordpress/images/stories/pdf/documenti_forum/paper/0007_penasa.pdf> accessed 25.4.2022; Goffin and others, 'Why eight EU Member States Signed, but Not Yet Ratified the Convention for Human Rights and Biomedicine' (2008) 86(2-3) Health Policy p. 222, 225–226.

the chapter examines whether this principle has a more limited scope of application in an area of state action, such as the implementation of the positive dimension of the right to healthcare, which is characterised by a broad degree of discretion.

Chapter 2 and 3 contain the investigation of the processes that accompanied the implementation of PGD and NIPT in the public healthcare systems of the selected countries. These chapters offer insights into the role that the ethical and religious factors played in the regulation as well as in the reimbursement and coverage decisions on the chosen technologies. Moreover, the instruments used for regulation are assessed and categorised into substantial and procedural tools. The involvement of different actors is carefully evaluated.

The resulting reflections will converge in the concluding analysis, which combines the outcome of the case studies with the normative background and considers whether the current situation in the three countries is compatible with a state obligation of neutrality of justification. The conclusions look at the different factors that have amplified or limited the room for the consideration of ethical concerns in the different countries. A final assessment is made regarding the legitimacy of considering ethical concerns in public funding decisions on health technologies. The conclusions are accompanied by some observations on how to improve the ways of coping with ethically controversial technologies in an ethically neutral state.