The Biomedical Engineer's Pledge 1.0

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Abstract:

The professional practice of biomedical engineering can lead to severe consequences. These potential consequences do not differ from those expected in the exercise of the medical profession. Hence, the ethical framework of biomedical engineers (BMEs) should not differ substantially from the ethical framework of medical doctors (MDs). In medicine, an element that is perceived as symbolic but essential in the formation of the ethical conscience of MDs is the “Hippocratic Oath”. The “Hippocratic Oath”, or its modern adaptation, the “Physician's Pledge”, is a brief not legally binding solemn declaration of ethical commitments that medical students take as a rite of passage in their final year or just after graduation. In other healthcare professions, such as nursing or pharmacy, sometimes the “Hippocratic Oath” is also taken. However, in its different versions, the “Hippocratic Oath” contains aspects that would not apply to the field of biomedical engineering and, therefore, its adoption without adaptations would be inappropriate. We have drafted a “Biomedical Engineer’s Pledge” aiming at strengthening the ethical awareness of future biomedical engineers. It consists of a preamble sentence, ten promises, and a concluding sentence. Top priority is given to the first promise, which combines the fundamental principles of beneficence and non-maleficence.

1. Introduction

Biomedical engineering is a relatively recent profession in which principles and techniques from different branches of engineering (e.g., mechanics and electronics) are integrated together with principles and techniques from biology and medicine to provide solutions for healthcare, primarily for diagnostic and therapeutic applications. The first university departments and graduate biomedical engineering programs were established in the US in the 1960s. And, although the first BScs in biomedical engineering appeared soon after, also during the 1960s, they were not widespread until decades later [1]. The comprehensive 2017 World Health Organization (WHO) report "Human resources for medical devices, the role of biomedical engineers" indicates that in 2015 the number of biomedical engineers was above 115,000, distributed in 129 countries [2].

The professional practice of biomedical engineering can lead to consequences of great severity that can affect the quality of life and survival of persons. These potential consequences do not differ from those expected in the exercise of the medical profession. Thus, the ethical framework of biomedical engineers (BMEs) should not differ substantially from the ethical framework of medical doctors (MDs). Regrettably, ethical aspects in biomedical engineering programs are addressed irregularly, and in general scarcely. Some programs only deal with ethical aspects anecdotally, while others include courses in which entire lessons are devoted to ethical aspects (e.g., in bioethics or in research ethics) [3], [4].

In medicine, an element that is perceived as symbolic but essential in the formation of the ethical conscience of MDs is the "Hippocratic Oath", whose uncertain origin dates back to ancient Greece [5]. The "Hippocratic Oath", in its ancient versions, or in its contemporary adaptation by the World Medical Association (WMA), the "Physician's Pledge", also referred to as the WMA Declaration of Geneva [6], is a brief not legally binding solemn declaration of ethical commitments that medical students take as a rite of passage in their final year or just after graduation.

In other healthcare professions, such as nursing or pharmacy, sometimes the "Hippocratic Oath" is also taken. However, in its different versions, the "Hippocratic Oath" contains elements that would not apply to the field of biomedical engineering and, therefore, its adoption without adaptations would be inappropriate.

In our view, a very attractive feature of taking the "Hippocratic Oath" is that it constitutes an activity of low academic load that effectively strengthens the ethical awareness of the students.

In the past, calls were made for the implementation of a "Hippocratic Oath" for BMEs [7], and some initiatives aligned in this direction have been carried out, such as dissertations with ethical guidelines for BMEs [8], ethical codes by biomedical engineering societies [9]–[12], and solemn declarations by engineering students "to serve as ethical engineers" [13] or "pledge to professionalism" [14], even including performing very ceremonial acts involving tokens such as rings [15]. Remarkably, France has recently introduced a mandatory research integrity oath for obtaining a PhD [16]. However, to the best of our knowledge, nothing resembling an oath or pledge specifically aimed at biomedical engineering students has ever been published. In view of this, we decided to draft a pledge comparable to the "Hippocratic Oath" applicable to biomedical engineering, the "Biomedical Engineer's Pledge", with the participation of a diverse team of individuals, including students, academics, researchers, professionals at companies, physicians, experts on regulatory issues and experts on applied ethics.

In addition to strengthening the ethical awareness of biomedical engineering students, we believe that the adoption of the "Biomedical Engineer's Pledge" may bring other beneficial results such as a greater knowledge and appreciation, by society at large, towards biomedical engineering and a stronger collegiality between biomedical engineers and other health professionals. Furthermore, it can be a source of pride for biomedical engineering students and their families.

2. Methods

The prerequisites for the "Biomedical Engineer's Pledge" were initially defined by two members (A.I. and G.R.) of Universitat Pompeu Fabra (UPF), in consultation with two members (María Casado and Itziar de Lecuona) of the Bioethics and Law Observatory (OBD) of the University of Barcelona (UB), and a member (T.A.) of the Applied Ethics Group of the Institute of Philosophy of the Spanish Research Council (CSIC). A drafting committee of three members (A.I., G.R. and T.A.) was in charge of writing the first draft of the pledge.

It was decided to draft the pledge using as initial model, both formally and conceptually, the 2017 version of Declaration of Geneva, known as the "Physician's Pledge", of the World Medical Association (WMA) because of its widespread use and because it is considered "the contemporary successor to the 2500-year-old Hippocratic Oath" [6].

The 2017 version of the "Physician's Pledge" consists of a preamble sentence, 12 specific promises, and a concluding sentence. In total, in its English version it has an extension of 208 words. For formal

resemblance, it was decided that the “Biomedical Engineer’s Pledge” would follow the same structure. It was also decided that it would have a similar extension.

In addition, it was decided to avoid grandiloquent or archaic expressions to bring the language in the “Biomedical Engineer’s Pledge” close to the language used by young biomedical engineering students. It was also decided to use gender inclusive language for the Spanish and Catalan versions, in accordance to the United Nations guidelines [17], and to place the female gender first in the title (“Compromiso de la ingeniera biomédica y del ingeniero biomédico”) in accordance to a reality (women in undergrad biomedical engineering programs are about to be the majority [18]) and also in accordance to the generalized desideratum of increasing the portion of female students and professionals in engineering [19]). (It was possible to draft the English version using gender neutral language.)

While some aspects in the “Physician’s Pledge” had to be disregarded because they would not apply to biomedical engineers, it was decided that some other aspects, not explicit in the “Physician’s Pledge”, had to be explicitly included in the “Biomedical Engineer’s Pledge”:

1. Integrity and responsibility concepts.
2. Avoidance of fraud against patients.
3. Safeguarding of patient data.
4. Minimization of animal experimentation.
5. Protection of human participants in clinical trials.
6. Environmental and economic sustainability.
7. Universal health coverage.

After a few iterations among the members of the drafting committee, it was resolved that the number of specific promises could be limited to ten, and it was decided to establish this feature as a requisite of the pledge. In this way, it is possible to refer in a strict etymological sense to the pledge as a “decalogue”. In addition, this establishes an association to the decimal numeral system, of historic importance in engineering [20].

Another substantial structural feature also emerged during the initial iterations: the pledge could be drafted as an initial, and of top priority, promise combining the fundamental principles of beneficence and non-maleficence followed by a general promise of integrity and responsibility followed by specific promises that can be understood as particularizations of what it means to act with integrity and responsibility.

After the first draft (version 0.1) was concluded, invitations to participate in redrafting the pledge were sent to a diverse pool of present and past collaborators and graduate and undergraduate students. (The invited undergraduate students were the class delegates of biomedical engineering at UPF.) The vast majority (>95%) of the contacted individuals accepted the invitation to participate. The team (n =46) thus formed is diverse in multiple dimensions: gender (female (17), male(29)), nationality (15 countries, 4 continents), age (from 19 to 74 years), academic fields (engineering (28), medicine (6), veterinary (2), other biomedical fields (5), law (2) and philosophy (2)), professions (students, academics, scientists, R&D engineers, regulatory experts, and executives) and institutions (universities, research centers, large companies, and small companies).

The draft of the pledge and a description of the project were shared among the team members via a shared virtual folder in Google Drive. For one month the team members were able to voluntarily add comments to the draft and discuss these comments. After that, a revision committee of five members (A.I., G.R., T.A., L.B-F. and A.J.A.) analyzed the comments and the discussions and produced a new draft of the pledge.

The new draft (version 0.2), together with a justification of the performed amendments, were again shared among the team members for a second round of comments and the discussions for three weeks. Then, the revision committee analyzed again the comments and the discussions and produced the final draft of the pledge in English (version 0.3), Spanish and Catalan. The grammar of these final versions was revised to produce the release versions (version 1.0).

Finally, the team members were requested to individually endorse the pledge and a public website was created (https://www.upf.edu/web/biomedical-engineers-pledge) on November the 4th, 2022, where the pledge in English, Spanish, and Catalan and the list of endorsements were published together with a very brief explanation of the pledge. It was decided to license the pledge under a Creative Commons Attribution-NoDerivatives 4.0 International License. It was also decided to allow future endorsements, both individual and institutional (instructions provided at the website).

3. Result and discussion

3.1. The "Biomedical Engineer's Pledge"

(The numbering of the specific promises is not intended to be read.)

I solemnly declare that as a biomedical engineer:

1. I will hold paramount the safety, health, and well-being of patients, research participants, coworkers, healthcare workers, and the public.
2. Upholding the above, I will exercise my profession with integrity and responsibility.
3. I will do my best to ensure the autonomy and dignity of patients and research participants.
4. I will ensure the proper safeguarding of patient and research participant data.
5. I will not discriminate on the grounds of age, sex, sexual orientation, gender identity or expression, disease, functional diversity, origin, racial status, religious beliefs, political affiliation, social class, or any other identity factors.
6. I will not participate in patient deception or fraud against them.
7. I will share my scientific and technical knowledge, and I will not use it to violate human rights.
8. I will promote the replacement, reduction, and refinement of the use of animals in research.
9. I will contribute to the environmental and economic sustainability of healthcare and to universal health coverage.
10. I will demonstrate to my teachers, colleagues of any discipline, students, and to the society at large, the respect and gratitude that is their due.

I understand and commit myself freely and publicly to these principles.

3.2. Argumentation and explanations

In essence, the "Biomedical Engineer Pledge" adapts the contents of the "Physician's Pledge" to the field of biomedical engineering while explicitly introducing some additional aspects (e.g., avoidance of fraud against patients and minimization of animal experimentation). As in the case of the "Physician's Pledge", the "Biomedical Engineer Pledge" can be fitted to the general bioethics framework of the Four Principles devised by Beauchamp and Childress: beneficence, justice, non-maleficence, and respect for autonomy [21]. However, the four general principles are not considered equally important in the pledge: non-maleficence and beneficence are given top priority.

Section by section, the pledge is justified in detail in the following paragraphs. This argumentation is not only intended to justify the wording of the pledge, but it is also intended to explain it and to show how the pledge would guide the biomedical engineers in their professional decisions. In addition, a few case studies or ethical dilemmas are sketched to illustrate how to apply the pledge.

Preamble ("I solemnly declare that as a biomedical engineer:")

Although the pledge is primarily intended to be taken as a rite of passage by students around their graduation, the preamble sentence is intentionally short and generic to allow the use of the pledge in different scenarios (e.g., before graduation, at the graduation ceremony, just after graduation, many years after graduation…). In former versions of the "Physician's Pledge", a student-oriented preamble ("At the time of being admitted as a member of the medical profession:") was used. A similar sentence was considered when discussing the first version of the pledge. However, it was disregarded for allowing the flexible use of the "Biomedical Engineer Pledge".

It is worth noting that the pledge is not intended to be a prerequisite for graduation. It is a non-legal binding declaration intended to be taken voluntarily.

It should be noted that this sentence indicates that what follows is declared "as a biomedical engineer". Thus, the actions and decisions outside the professional sphere of biomedical engineering are not affected by the pledge. The pledge is not intended to be a moral compass for personal behavior.

First promise ("I will hold paramount the safety, health, and well-being of patients, research participants, coworkers, healthcare workers, and the public.")

This promise, or principle, combines the fundamental principles of beneficence and non-maleficence, which are encompassed by the classical formulation by Thomas Aquinas "bonum est faciendum et malum vitandum" that means "good is to be done and evil to be avoided" [22].

The wording of this promise is based on the first principle in the Canadian Medical and Biological Engineering Society (CMBES) Code of Ethics, which "defines expectations of individuals in the profession": "[CMBES members shall] Hold paramount the safety, health and welfare of the patient, public and coworkers" [11]. The first principle of the CMBES, in turn, appears to be based on the first

"fundamental cannon" of the National Society of Professional Engineers (NSPE) Code of Ethics for Engineers [23]. In essence, besides switching the person (from third person, the CMBES members, to first person), the only differences between this first promise of the pledge and the first principle of the CMBES Code of Ethics are: 1) the term welfare is substituted by well-being to prevent misunderstandings (welfare can be understood as governmental income support and services), and 2) the list of explicit beneficiaries has been expanded to also include research participants and healthcare workers.

The specification of beneficiaries is intended to prevent oblivions. It is equally important the specification of the purposes ("safety, health, and well-being"). Although no prioritization is indicated for the purposes, it is by no coincidence that the first purpose is safety. This resonates with the Latin phrase "Primum non nocere" that means "Above all, do not harm" and which gives top priority to non-maleficence. This aphorism is commonly taught in medical schools, and it has an uncertain origin that is sometimes wrongly attributed to the "Hippocratic Oath" [24].

The principle of non-maleficence has been considered the fundamental principle of moral order [25].

In the last century, the principle of non-maleficence was endorsed (at least in part) by three influential philosophers: W.D. Ross, H.L.A. Hart, and John Rawls.

William David Ross discusses the principle of non-maleficence in two of his best known works: The Right and the Good (1930)[26] and Foundations of Ethics (1939)[27]. Even though his discussion of this principle is not extensive, Ross clearly holds that the duty of non-maleficence has priority to a duty of beneficence, or the duty to promote a maximum of aggregate good: "The recognition of this duty of non-maleficence is the first step on the way to the recognition of the duty of beneficence; and that accounts for the prominence of the commands 'thou shalt not kill', 'thou shalt not commit adultery', 'thou shalt not steal', 'thou shalt not bear false witness' in so early a code as the Decalogue. But even when we have come to recognize the duty of beneficence, it appears to me that the duty of non-maleficence is recognized as a distinct one, and as prima facie more binding. We should not in general consider it justifiable to kill one person in order to keep another alive, or to steal from one in order to give alms to another" [26].

H.L.A. Hart also looks at the principle of non-maleficence favorably, and although he never uses that term in The Concept of Law (1961) [28], his comments on forbearance, prohibitions, and the truism of human vulnerability point to the endorsement of this principle: "The common requirements of law and morality consist for the most part not of active services to be rendered but of forbearances,

which are usually formulated in negative form as prohibitions. Of these the most important for social life are those that restrict the use of violence in killing or inflicting bodily harm".

While Ross was working within a paradigm of deontological intuitionism, and Hart one of natural law utilitarianism, John Rawls finds space for the principle of non-maleficence within his account of justice as fairness. In A Theory of Justice (1971) [29], Rawls distinguishes between our obligations and our natural duties. Obligations are the contribution one is required to make towards a just society, either for the sake of justice, or because one has voluntarily accepted the benefits of the arrangements. Regarding natural duties, he tells us that these can be either positive or negative. Rawls goes on to say that something along the lines of non-maleficence captures the essence of our natural negative duties, and that these have priority over our positive natural duties: "The following are examples of natural duties: the duty of helping another when he is in need or jeopardy, provided that one can do so without excessive risk or loss to oneself; the duty not to harm or injure another; and the duty not to cause unnecessary suffering. The first of these duties, the duty of mutual aid, is a positive duty in that it is a duty to do something good for another; whereas the last two duties are negative in that they require us not to do something that is bad. The distinction between positive and negative duties is intuitively clear in many cases, but often gives way. I shall not put any stress upon it. The distinction is important only in connection with the priority problem, since it seems plausible to hold that, when the distinction is clear, negative duties have more weight than positive ones".

The fact that it was approved by Ross, Hart, and Rawls suggests that the principle of non-maleficence holds an appeal to moral philosophers of all persuasions, notwithstanding their specific take on moral philosophy.

It is worth noting that the term "patients" here is also intended to encompass veterinary patients as, occasionally, animals are the beneficiaries of biomedical engineering. However, it is important to note that the term "research participants" does not encompass animals. Animals can be research subjects, but they cannot be participants as they do not participate freely and consciously. More importantly, although the eighth promise promotes the replacement, reduction, and refinement of the use of animals in research, the use of animals in research is still required and, more frequently than not, implies that their health is compromised.

Finally, it is important to note that the explicit prioritization of this first promise implicitly requires to analyze and judge the potential consequences of the actions or omissions. In other words, it is implicit the need to carry out an analysis of the risks and the benefits. The risks of the actions or

omissions must be weighed against the benefits. This concept, the consideration of the benefit-risk ratio, is typically encoded in the guides or rules applied by ethics committees responsible for oversighting medical or human research studies. In fact, one of the precepts of the "Nuremberg Code", which set the principles to protect research participants after the cruel human experiments performed by Nazis in concentration camps, is "The degree of risk to be taken should never exceed that determined by the humanitarian importance of the problem to be solved by the experiment" [30]. More directly related to biomedical engineering: this concept is also encoded in medical devices regulations. In particular the European Union Medical Device Regulation (EU MDR) states that "[medical devices shall be safe and effective] … provided that any risks which may be associated with their use constitute acceptable risks when weighed against the benefits to the patient and are compatible with a high level of protection of health and safety, taking into account the generally acknowledged state of the art" and specifically requires that "Manufacturers shall establish, implement, document and maintain a risk management system" [31].

The practical application of this principle may not be straightforward in all scenarios. The analysis of the benefit-risk ratio implies an active effort. And, more importantly, this principle still leaves room for ethical dilemmas. For instance, would it be acceptable to implement a treatment device that is highly beneficial to patients but that is somewhat dangerous to its operator even when all risk mitigation measures are put in place? The subsequent promises are intended to narrow down the space for ethical dilemmas but to close such space is an impossible task. Regulations and laws, which can be understood to be the result of agreements reached by society, can frequently help in this regard. For instance, in the above hypothetical case, medical devices regulations tell us that to implement such treatment device may be acceptable, provided that a set of procedures are followed (e.g., technical analyses of risks, extensive documentation, rigorous testing, and implementation of quality assurance protocols). But, even in this case, there is room for inconclusiveness: similar to the situation faced by judges in handing down a sentence, the examiners in the regulatory body will have to interpret the benefit-risk ratio and make a decision on whether it is acceptable based on previous resolutions and on their own judgement. Furthermore, not always and not everywhere the regulations and laws are up-to-date and fair.

Second promise ("Upholding the above, I will exercise my profession with integrity and responsibility.")

In this promise, the phrase “Upholding the above” indicates that this promise has less priority than the first promise.

As pointed out above, the professional practice of biomedical engineering has consequences, some of them possibly severe and significant, that can affect the life and survival of people. These are not indifferent actions and, therefore, the biomedical engineers must take responsibility for them and their results; that is, the biomedical engineers are responsible for them and, therefore, biomedical engineering has an undeniable moral dimension. Responsibility, together with duty, is the basic concept of ethics insofar as we must “take care of” for our actions and omissions as well as for their results and consequences, for which we will have to be “accountable”.

Ethical responsibility involves recognizing the consequences of one’s actions and taking ownership of them, particularly when they impact others or the society as a whole.

Responsibility in ethics goes beyond mere compliance with laws and regulations. It involves a deeper understanding of the ethical implications of one’s actions and the willingness to be accountable for the outcomes. Ethical responsibility also encompasses the idea of “doing the right thing” even when there are no explicit rules or guidelines to follow. It encompasses both individual responsibility, where individuals are accountable for their own actions, and collective responsibility, where groups or organizations bear responsibility for their actions as a whole.

Integrity, on the other hand, is defined as a pattern of behavior that entails both the observation and promotion of the highest professional standards and moral principles in the exercise of the profession.

Integrity is linked to the notion of good practice (and thus the avoidance of bad practice). “Good practices” refer to those experiences, processes and activities that are desirable in a given field because they have yielded positive results and have proven to be successful and useful in a particular context, so that they are worth replicating and sharing with as many stakeholders as possible who can adopt them. Good practices include the following attributes:

- They develop positive solutions and improvements to an activity.

- They start from a careful, evidence-based assessment and analysis of the values and principles of the activity.

- They act as models and guidelines.

- They are systematised through their formulation in codes or other documents, leading to their institutionalisation and sustainability (being maintained over time and producing lasting effects).

- They generate shared knowledge that implies their dissemination and replication.

The concept of research integrity is of particular importance in biomedical engineering. In essence, research integrity means conducting research in such a way that allows others to have confidence and trust in the methods and the findings of the research. Promoting research integrity is essential for maintaining public trust in the scientific community and ensuring the credibility and impact of research outcomes. It is precisely the joint consideration of responsibility and integrity that has led to what is known as Responsible Research and Innovation (RRI). RRI is a model of science and research governance that aims to reduce the gap between the scientific community and society by encouraging different stakeholders (e.g., civil society organizations, the educational community, the scientific community, policy makers and the business and industry sector) to work together throughout the research and innovation process. Thus, through cooperation mechanisms between different actors, it is possible to better align the research process and its results with the values, needs, and expectations of today's society.

Although the term RRI was coined more than a decade ago [32], it has recently gained prominence in Europe because the research and innovation funding program “Horizon 2020”, of the European Commission, made RRI a main target [33].

RRI can be understood thus as an effort to justify innovation not on grounds of uncritical, or taken for granted macro-economic assumptions, but on the basis of societally beneficial objectives, or challenges, as openly defined and debated by a plurality of societal actors. As such, RRI-based EU policy aims to introduce “broader foresight and impact assessments for new technologies, beyond their anticipated market-benefits and risks” [34].
RRI’s radical rhetoric on openness and socialization regarding techno-industrial innovation processes has been claimed to ultimately reflect four fundamental principles of scientific governance: anticipation, reflexivity, deliberation, and responsiveness [35].

The subsequent promises should be understood as particularizations of what it means to act with integrity and responsibility. As a rule, if the first promise is not jeopardized, these subsequent promises should prevail over other moral considerations.

Third promise (“I will do my best to ensure the autonomy and dignity of patients and research participants.”)

This promise is an adaptation of the third promise in the “Physician’s Pledge” (“I WILL RESPECT the autonomy and dignity of my patient”).

Autonomy is a complex and very disputed term in ethics and law. Autonomy is generally understood as the possibility for self-governing, including the possibility and capability of understanding relevant information, elaborating a critical and personal reflection on it, and taking free decisions. Autonomy is the power to decide what decisions to make and to exercise freedom of choice when necessary. Biomedical engineers must respect the right of individuals to decide and exercise freedom of choice.

This principle of autonomy entails listening and paying attention to individuals not only as passive subjects in their relationship with technology (i.e., to respect), but also as collaborators and active participants, in a strategy to innovate and generate greater public value.

Although use of the concept of dignity is sometimes questioned because of its vagueness [36], it was decided to maintain its appearance in the “Biomedical Engineer Pledge” for consistency with the “Physician’s Pledge” and because it serves as a reminder that individuals should be treated as ends in themselves, never merely as means to an end; an element central to the concept of human dignity by Immanuel Kant.

Some biomedical engineering systems can monitor and adaptively modify the brain, affecting people's own sense of autonomy and identity, and ultimately how they see themselves and their relationships with others (neuro-emotional manipulation). Individuals must therefore be protected against the coercive use of these technologies and the possibility that technology can be used without their consent. People must always be an end and never a means. That is, the dignity of the individuals must be protected. Therefore, personal identity and continuity of personal behaviour must be preserved against non-consensual modifications by third parties. This fits within the framework of what have been called new “human neuro-rights” [37]. These rights are intended to protect cognitive freedom or mental self-determination: the right to mental privacy, the right to mental integrity, and the right to psychological continuity.

Fourth promise (“I will ensure the proper safeguarding of patient and research participant data.”)

In most settings of biomedical engineering research and practice, it is necessary to access, use, analyse, store, anonymise, or publish some patient and research participant data. Through the

fourth promise, the biomedical engineer acknowledges not only making good and responsible use of personal data, but also ensuring its safeguarding.

Within the health field, data security is not a new ethical issue. More than 25 centuries ago, the "Hippocratic Oath" already included confidentiality as a key aspect in the relationship between health professionals and patients. Today, main data protection regulatory frameworks consider data concerning health to represent a special category that deserves particular care.

Data management has been radically transformed by information and communication technologies, including artificial intelligence and big data sciences. These technologies are a double-edged sword: while there have been rapid advances in data use and data cybersecurity, intentional attacks that manage to defeat security systems and expose data to risks are becoming more frequent. New ethical challenges also have arisen with regards to privacy, integrity, and appropriateness of health-data use.

The complexity behind this problem is so high that national and international regulatory frameworks have been elaborated to protect data. A noteworthy example is the European General Data Protection Regulation (GDPR) [38]. But the effort to regulate and protect collectively is just as important as the need for all those professionals who work with data to assume their individual responsibility, to be informed on how they should protect data, especially data concerning health, and to be guided by high ethical and deontological principles [39].

Biomedical engineers should know local and international regulation frameworks related to health data protection, but they also need to be guided by ethics. Some broad deontological principles could be particularly helpful for responsible health data management and protection, such as the principle of parsimony that, within this context, implies not to ask for unnecessary information from patients, or the principle of transparency, by which patients and their families need to be well informed about the nature of stored data, their uses and any essential question related with their safeguarding.

Fifth promise ("I will not discriminate on the grounds of age, sex, sexual orientation, gender identity or expression, disease, functional diversity, origin, racial status, religious beliefs, political affiliation, social class, or any other identity factors.")

More than 70 years ago, the Universal Declaration of Human Rights established in its article 2 that "Everyone is entitled to all the rights and freedoms set forth in this Declaration, without distinction of any kind, such as race, colour, sex, language, religion, political or other opinion, national or social origin, property, birth or other status." In the same way, this fifth promise proclaims the need to prevent discrimination and emphasizes some reasons for discrimination.

The rationale for explicitly including some reasons for discrimination is that the evidence shows they are still very present in society, even if, in some regions, it may appear they are "things of the past". At an individual level, it could also be difficult to explicitly recognize that some of our attitudes could discriminate people for some reasons [40].

It is also necessary to recognise that many people suffer multiple discrimination reasons, making them even more vulnerable [41].

Technological advances can create new situations of discrimination and concerns for discrimination. For example, in studies that involve the collection of genetic information, the "fear factor" of being discriminated has been shown to be a significant barrier to patient participation [42].

Addressing discrimination in healthcare settings will contribute to the achievement of many of the Sustainable Development Goals, ensuring that no one is left behind [43]. This promise is a reminder that the discrimination problem is far from being solved.

Sixth promise ("I will not participate in patient deception or fraud against them.")

To the best of our knowledge, a principle similar to this one is not found explicitly in any pledge or oath related to biomedical engineering or medicine. And, in our view, it is particularly required in the case of biomedical engineering because there have been many instances of fraudulent medical technologies that, albeit did not imply a direct risk to the patients, caused economic distress and, in some cases, had an indirect negative impact on the health of patients. One of these cases is the Theranos case, which serves as illustration:

The TV series "The Dropout" is based on the events at Theranos, a Silicon Valley "unicorn" company valued at US$9 billion, that falsely claimed it had developed blood analyzers only requiring a drop of blood [44]. In its fifth episode, the characters Mark Roessler (whistleblower working at the company) and Richard Fuisz (who exposes Theranos's fraudulent blood testing system) have the following conversation:

— (RF): Out of curiosity, what made you decide to talk to me? Was it something I wrote on my LinkedIn message?

— (MR): It was your signature.

— (RF) Dr. Fuisz.

— (MR) We're both physicians.

— (RF) We took the Hippocratic Oath.

— (MR) Do no harm.

— (RF) Yeah.

— (MR) I'm ready for your questions now.

(Note: The "Hippocratic Oath" does not contain the "Do no harm" aphorism. As indicated above, the "Primum non nocere" aphorism, which is probably what Roessler meant, is commonly taught in medical schools and it is sometimes wrongly attributed to the Hippocratic Oath.)

In this case, Mark Roessler was infringing the rights of the company by revealing its trade secrets. In fact, he was infringing a non-disclosure agreement (NDA) he had signed when hired. This was clearly unlawful because he was revealing these secrets to somebody who was not a law enforcer. We are told he decided to reveal the fraudulent operations conducted at Theranos because he wanted to prevent damage to patients. And we must presume he decided to reveal these to Dr. Fuisz rather to a law enforcer either because of collegiality, because the opportunity was given, or because he considered the actions taken by Dr. Fuisz to stop Theranos fraudulent operations would be more effective than those carried out by law enforcers. The unanswered questions are: why did he have to resort to this desperate measure? and why he and his colleagues at Theranos did not act sooner to prevent the fraudulent operations? We wrote this sixth promise with the hope of helping to minimize similar situations in the future.

This sixth promise also forbids patient deception. Whereas it is obvious that committing fraud against patients is morally wrong, patient deception is seen as morally acceptable, or even morally required, in some specific situations: "When a distressed mother asks if her beloved daughter suffered in her dying moments, or when on the operating table a patient with a ruptured abdominal aneurysm asks the unhopeful anaesthetist whether he will be all right, the usually strict need for honesty gives way to compassion and humanity" [45]. Thus, although patient deception must be generally avoided because it, in most cases, if not all, threatens the autonomy of patients, the biomedical engineer might consider it morally acceptable and still in accordance with the "Biomedical Engineer's Pledge" in consideration of the first promise. However, if patient deception is

to be committed, as indicated in the argumentation of the first promise, the biomedical engineer must carefully analyze and judge the potential consequences of such patient deception. In other words, the biomedical engineer should "consider how he or she would articulate and defend their views and reasoning before a body of reasonable people, such as a professional association or a court of law" [45].

Seventh promise ("I will share my scientific and technical knowledge, and I will not use it to violate human rights.")

This promise is an adaptation and simplification of two promises in the "Physician's Pledge": the tenth promise, "I WILL SHARE my medical knowledge for the benefit of the patient and the advancement of healthcare;", and the twelfth promise, "I WILL NOT USE my medical knowledge to violate human rights and civil liberties, even under threat". The specific purpose of the tenth promise in the "Physician's Pledge" (i.e., "the benefit of the patient and the advancement of healthcare") is suppressed because its explicit indication would imply that only knowledge relevant for patients and the advancement of healthcare must be shared. We consider that all knowledge must be shared, regardless of whether it is immediately applicable to healthcare. Scientific and technical knowledge frequently crosses boundaries, and, in fact, it is probably most fruitful when it crosses disciplines. In the short or long term, all disciplines benefit from knowledge circulation. An anecdotical case is the invention of the voltaic pile: circa 1780, Luigi Galvani, a physician, discovered that when a dead frog was placed on an iron grating and a bronze hook touched the spinal cord then the frog's muscle twitched. His explanation to the phenomenon was based on what he called "animal electricity". Later, it was Alessandro Volta, an experimental physicist, who identified the correct explanation: the presence of two different metals in the same electrolyte (frog's body fluids) had created a DC current that stimulated the frog's muscles. That lead to the invention of the voltaic pile (Volta replaced the frog's fluids by brine-soaked paper), which was the first device able to produce steady electric current and that became a basic element for later discoveries in electromagnetism, which obviously have had a tremendous impact in medicine [46].

It must be noted that the obligation to share scientific and technical knowledge does not imply that such knowledge must be shared free of charge. Knowledge transfer and generation are activities that demand substantial effort and resources, and the professionals and organizations must be fairly remunerated. Furthermore, in accordance with the principle of integrity, the biomedical engineer must protect the rights of others to be fairly remunerated (e.g., must not disclose trade secrets).

It is obvious, from the first promise, that the biomedical engineer must refrain from violating human rights. Here it is explicitly expressed as a reminder, similarly to the case of the enumeration of discrimination reasons in the fifth promise. The phrase "even under threat" of the twelfth promise of the "Physician's Pledge" has been omitted because it is grandiloquent and because it implies a commitment to heroism that goes beyond professional duties.

Eighth promise ("I will promote the replacement, reduction, and refinement of the use of animals in research.")

Animal experimentation is required for the development of medical technologies and, as such, can be an important aspect in the professional practice of biomedical engineers. While no related promise is found in the "Physician's Pledge", the code of ethics of the IEEE Engineering in Medicine & Biology Society requires ensuring "a responsible and humane use of animals in research" and the code of ethics of the Biomedical Engineering Society (BMES) requires following laws and guidelines regarding rights of "animal subjects" [9], [12]. These are behaviors of professional integrity and responsibility and, therefore, the second promise mandates that biomedical engineers must comply with them. However, this eighth promise goes further: it compels the biomedical engineer to "promote" the minimal and humane use of animals in research.

The promise is formulated following the Three Rs (3Rs) defined by W. M. S. Russell and R. L. Burch as guiding principles for ethical use of animals in product testing and scientific research [47], [48]. Namely:

"Replacement means the substitution for conscious living higher animals of insentient material". This includes total replacements to animal experimentation (e.g., replacing animals by *in vitro* models or by computer models) but also relative replacements (e.g., replacing vertebrates with invertebrates).

"Reduction means reduction in the numbers of animals used to obtain information of a given amount and precision". This refers to the use of strategies that will result in fewer animals being used to obtain sufficient data to answer the research questions.

"Refinement means any decrease in the incidence or severity of inhumane procedures applied to those animals which still have to be used". This refers to the use of husbandry and experimental

procedures that minimize pain and distress, for enhancing the welfare of the animals in research from the time they are born until their death.

This eighth promise not only compels the biomedical engineer to follow these guiding principles, which nowadays are encoded in most animal research guidelines of mandatory compliance, but it also compels the biomedical engineer to further their development. As an engineer, an essential task of the biomedical engineer is to ideate systems and methods. The biomedical engineer can and should contribute to the 3Rs by designing alternatives to animal models, by designing novel analysis methods to optimize the use of animal data, or by designing experimental procedures and devices that minimize pain and distress.

It is important to note that this promise is intended to foster minimal and humane use of animals in research, but it is not intended to hamper it. Animal experimentation is required for the development of medical technologies. In particular, it is required to demonstrate their safety before their use in humans. Currently, to renounce the use of animals in research would collide with the first promise.

Ninth promise ("I will contribute to the environmental and economic sustainability of healthcare and to universal health coverage.")

In the last decades, medicine has vastly progressed, driven mainly by advances in the fields of biology, physics, and technology. This has increased life expectancy and the quality of life of patients. However, the healthcare system lacks environmental and economic strategies to make it sustainable. Nowadays, it is estimated that the healthcare sector contributes with almost 5% of global carbon emissions [49] mainly due to healthcare waste, including hazardous chemicals, single-use equipment, and pre-made packs with items that are not used during interventions, but that must be discarded. For this reason, environmental sustainability is paramount, especially as, according to the WHO, environmental sustainability can help reduce costs of the healthcare system and increase its resilience [50]. Furthermore, medical advances should benefit the entire world population. However, the 2019 Global Monitoring report on the universal health coverage highlighted that less than 50% of the world's population is covered by essential health services [51]. Yet a study in 11 countries made by the World Bank and the Government of Japan showed that universal health coverage is feasible and achievable, and requires a long-term policy that combines political know-how and technical knowledge [52].

Biomedical engineering not only contributes to the advances in medicine but also to the environmental and economic sustainability of healthcare and may enrich public policy with the technical knowledge required to increase health coverage worldwide.

The IEEE EMBS Code of ethics has a section devoted only to sustainability and the environment, in which it explicitly states the need to "promote a culture of cost-effectiveness", and to "support the preservation of a healthy environment". The CMBS Code of Ethics statement 2 says "manage public resources with prudence and responsibility". This ninth promise not only compels the biomedical engineer to manage and preserve the environment and economic resources wisely, but also to accomplish a sustainable healthcare system with worldwide impact. We believe that the biomedical engineer should have an active role in this task, therefore the engineer must "contribute" to accomplish these sustainable development goals.

Tenth promise ("I will demonstrate to my teachers, colleagues of any discipline, students, and to the society at large, the respect and gratitude that is their due.")

A very similar promise is found in the "Physician's Pledge" (ninth promise: "I WILL GIVE to my teachers, colleagues, and students the respect and gratitude that is their due"), which derives from grandiloquent statements of gratitude towards teachers in the ancient versions of the "Hippocratic Oath" ("To hold him who has taught me this art as equal to my parents and to live my life in partnership with him, and if he is in need of money to give him a share of mine, and to regard his offspring as equal to my brothers in male lineage…" [53]). Here, in the "Biomedical Engineer Pledge", the respect and gratitude beneficiaries are expanded to include colleagues "of any discipline" and the "society at large". In contrast to the "Physician's Pledge", here this promise occupies the last position because it is of lower importance than the other ones and it was perceived by the team members it serves as agreeable conclusion to the list.

During the preparation of the pledge, it was discussed the change from "that is their due" to "that they deserve". Although the expression "that they deserve" is more common and intelligible, the expression "that is their due" was considered more accurate and it was agreed to maintain it.

Concluding sentence ("I commit myself freely and publicly to these principles")

The concluding sentence is intended at closing the pledge, complementing it with the conditions at which it is taken. This sentence is also inspired by the concluding sentence of the "Physician's Pledge" ("I make these promises solemnly, freely and upon my honour"). The omissions ("solemnly" and "upon my honour") are intended to avoid a grandiloquent statement, framing the pledge strictly within the boundaries of what are the professional behavior duties.

In particular, the term "honor" is consciously avoided because it implies that the person stating "with honor" has to consider themself a "person of honor". "Honor" is a quality related to the person. Therefore, stating publicly to commit to the pledge with "honor" would imply a personal behavior directed to be considered themself "honorable", which goes beyond the duties of professional behavior.

The verb "commit" was carefully chosen because it refers to the firm decision to conduct actions in order to fulfill the promises. It should be noted that this commitment does not depend on the kind of professional activities carried out as a biomedical engineer. For instance, sales engineers, regardless of their position within their company, must still contribute, to the extent of their capabilities, "to the environmental and economic sustainability of healthcare and to universal health coverage".

While the pledge is already intended to be read in a public event, the concluding sentence explicitly states that the commitment is made "publicly" as an acknowledgment by the reader that the commitment (i.e., the adherence to the pledge) is made not only in front of the audience of the event but in front of the society at large.

(Note: the term bioengineering is frequently used as a synonym for biomedical engineering. However, this term is more precisely applied to the engineering of biological entities (e.g., bacteria and viruses) to produce a wide range of products. These products may be of medical use (e.g., engineered tissue grafts) but can also be non-related to medicine (e.g., biofuels or bioweapons). In consequence, bioengineering may involve ethical issues different from, or additional to, those found in biomedical engineering and in medicine. Although training in bioengineering is frequently found in biomedical engineering programs (e.g., in courses on synthetic biology), for the sake of simplicity and alignment with the "Physicians Pledge", it was decided not to try to cover the ethical issues that bioengineering may distinctively imply. However, this can be considered a matter to be debated and it is likely these distinctive ethical issues will be addressed in future versions of the "Biomedical Engineer's Pledge".)

4. Conclusions

It has been presented and argued a pledge of ethical principles applicable to biomedical engineering. In contrast to ethical codes by biomedical engineering societies, which are addressed to researchers or affiliated professionals, the pledge is primarily intended to be taken as a rite of passage by biomedical engineering students around their graduation. The pledge has been collectively drafted and revised by a diverse team of students and professionals, and it is formally and conceptually derived from the "Physicians Pledge", which is considered the modern adaptation of the "Hippocratic Oath". However, the drafted pledge is substantially different from the "Physicians Pledge" because it had to be adapted to the biomedical engineering field, because grandiloquent statements and expressions have been intentionally avoided and because novel aspects, corresponding to modern concerns, have been explicitly introduced such as sustainability, avoidance of fraud against patients and minimization of animal experimentation. The drafted pledge consists of a preamble sentence, ten promises, and a concluding sentence. Top priority is given to the first promise, which combines the fundamental principles of beneficence and non-maleficence.

The "Biomedical Engineer's Pledge" can be accessed at https://www.upf.edu/web/biomedical-engineers-pledge and is licensed under a Creative Commons Attribution-NoDerivatives 4.0 International License.

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Annex A: Spanish and Catalan versions

“Compromiso de la ingeniera biomédica y del ingeniero biomédico”

Declaro solemnemente que como profesional de la ingeniería biomédica:

1. Tendré como prioridad la seguridad, la salud y el bienestar de pacientes, participantes en estudios de investigación, colegas de trabajo, personal sanitario y el público.
2. Respetando lo anterior, ejerceré mi profesión con integridad y responsabilidad.
3. Haré todo lo posible para garantizar la autonomía y la dignidad de pacientes y participantes en estudios de investigación.
4. Garantizaré la adecuada salvaguarda de los datos de pacientes y participantes en estudios de investigación.
5. No discriminaré por motivos de edad, sexo, orientación sexual, identidad o expresión de género, enfermedad, diversidad funcional, origen, condición racial, creencias religiosas, filiación política, clase social o cualquier otro factor de identidad.
6. No participaré en engaño o fraude a pacientes.
7. Compartiré mis conocimientos científicos y técnicos, y no los utilizaré para violar los derechos humanos.
8. Promoveré el reemplazo, la reducción y el refinamiento en el uso de animales en la investigación.
9. Contribuiré a la sostenibilidad medioambiental y económica de la asistencia sanitaria y a la cobertura sanitaria universal.
10. Demostraré a mi profesorado, colegas de cualquier disciplina, estudiantes y a la sociedad en general, el respeto y la gratitud que les corresponde.

Entiendo y me comprometo libre y públicamente con estos principios.

“Compromís de l’enginyera biomèdica i de l’enginyer biomèdic”

Declaro solemnement que com a professional de l’enginyeria biomèdica:

1. Tindré com a prioritat la seguretat, la salut i el benestar de pacients, participants en estudis de recerca, col·legues de feina, treballadors sanitaris i el públic.
2. Respectant això, exerciré la meva professió amb integritat i responsabilitat.
3. Faré tot el possible per garantir l’autonomia i la dignitat de pacients i participants en estudis de recerca.

4. Garantiré la salvaguarda adequada de les dades de pacients i participants en estudis de recerca.
5. No discriminaré per motius d'edat, sexe, orientació sexual, identitat o expressió de gènere, malaltia, diversitat funcional, origen, condició racial, creences religioses, filiació política, classe social o qualsevol altre factor d'identitat.
6. No participaré en engany o frau a pacients.
7. Compartiré els meus coneixements científics i tècnics, i no els faré servir per violar els drets humans.
8. Promouré el reemplaçament, la reducció i el refinament en l'ús d'animals en la recerca.
9. Contribuiré a la sostenibilitat ambiental i econòmica de l'assistència sanitària i a la cobertura sanitària universal.
10. Demostraré al meu professorat, col·legues de qualsevol disciplina, estudiants i a la societat en general, el respecte i la gratitud que els correspon.

Entenc aquests principis i m'hi comprometo lliurement i públicament.

Annex B: the logo

A logo was commissioned to represent the "Biomedical Engineer's Pledge".

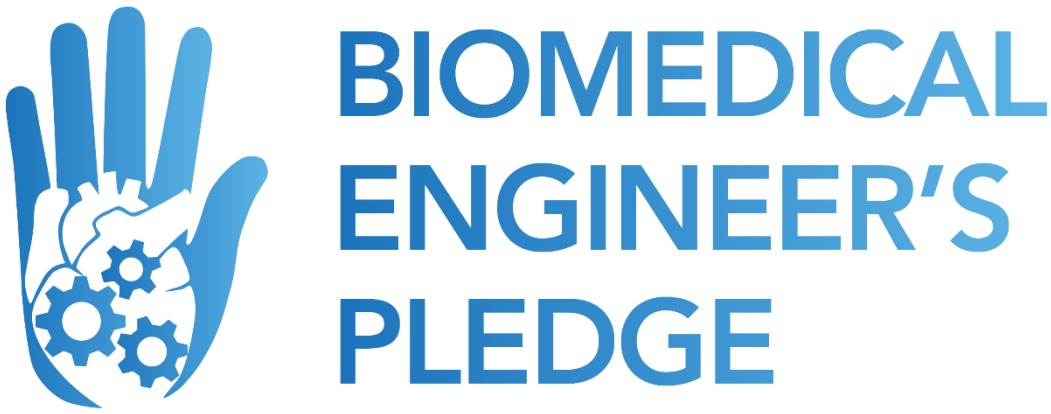

Figure B1. Logo of the "Biomedical Engineer's Pledge". The heart and the set of gears are intended to represent biomedical engineering. The raised hand is intended to represent both the concepts of pledge and of stopping and reflecting on the consequences before acting.

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