DIGITAL TECHNOLOGY AND HEALTHCARE
WHICH ETHICAL ISSUES
FOR WHICH REGULATIONS?

Report of the taskforce commissioned by the French National Ethical Consultative Committee for Life Sciences and Health (CCNE) with the support of the Committee for the Ethics of Research in Information Sciences and Technologies (CERNA).

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Contents

COMITÉ CONSULTATIF NATIONAL D'ÉTHIQUE
POUR LES SCIENCES DE LA VIE ET DE LA SANTÉ

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For the attention of Claude Kirchner and David Gruson

Dear colleagues,

Digital sciences, technologies, uses, and innovations are profoundly altering our society as a whole and in particular all of the life sciences, research, and medical practices from birth to the end of life. The report on Artificial Intelligence directed by Cédric Villani describes the consequences of this development for all aspects of our society. More generally, Artificial Intelligence obliges us to (re)-examine the relations between human beings and machines in society.

Recent advances have highlighted, in particular, the important role of machine learning techniques based on the availability of datasets of all kinds.

In order to help CCNE to address all the big questions raised by Artificial Intelligence in the life sciences and in healthcare — more specifically the multiple interactions between digital technology and health, — the ethical challenges they pose, as well as the potential consequences for their incorporation into legislative measures, I am asking you to lead a taskforce that will be open to contributors (CERNA, academics and professionals, relevant ministerial actors...) other than the members of CCNE (particularly members of the working group dedicated to big data). The aim of this taskforce is to provide a rapid briefing for the CCNE for the life sciences and health as part of the National Consultation on bioethics.

To this end, I would like to receive your first conclusions at the end of May (to be presented at the CCNE meeting of May 31), so that they can be debated in the plenary committee meeting on June 14, 2018.

4

Drawing on documentary and bibliographic research, and on a series of specialized hearings, the taskforce will produce a report on the current forms of interaction between digital technology and healthcare, also mentioning directions for research on this subject, will provide insight into the strengths and weaknesses of the current positions, and will present the potential conflicts of values it identifies, before identifying the underlying ethical issues. The taskforce will seek to propose ideas for substantive regulation on the spread of digital technology in healthcare in both the legal and operational domains, and more specifically on the spread of robotization and artificial intelligence.

The primary objective of this taskforce is to identify some of the questions and challenges associated with these developments. For this reason, its ideas will contribute to the position paper that CCNE will submit for the National Consultation on bioethics, but also — more globally — to the necessary investigation into a "governance of digital ethics" called for in the recommendations formulated by Cédric Villani's working group.

In full awareness of the importance of these deliberations, and in the confidence, Dear colleagues, that I can count on your expertise and commitment, I wish you all the best in this endeavor.

Pr. Jean-François Delfraissy

President, Comité Consultatif

National d'Ethique

A. Summary of the joint conclusions of the taskforce

In this summary, we present the joint conclusions of the taskforce, which readers will also find in the body of the report.

The very rapid spread of digital technology in healthcare

- **The rapid pace at which digital technology is spreading through our healthcare system is a major and irreversible reality, which needs to become an even greater priority in the future response to public health challenges.** The information we have shows how **digital technology can be a source of major advances in the quality and efficiency of our healthcare system**. The benefits it can bring in the areas of teaching and research are also considerable. **All this potential is only just beginning to be marshalled**. The likely scale of the spread of these technologies calls for a **parallel commitment to continuing analysis of the ethical challenges associated with them and with their future developments**.

- **The organization and governance of the entire healthcare system, from research to clinical practice, from individuals to health professionals, from the independent practitioner to the biggest health institutions, will be profoundly affected** by digital technology, with consequences at the national, European, and international levels that are multiple but at present hard to predict. **This transformation is a source of opportunity, but its implementation entails tensions** that analysis of the ethical issues can help to identify. Digital technology is transforming our healthcare system by enhancing the quality of patient care and organizational efficiency. It is also helping to break down traditional divides and to facilitate the emergence of a "learning healthcare system" that is favorable to medical, technical, or managerial innovations. Already, and to a greater extent in the future, **profound changes are underway in the practices, roles, functions, and responsibilities of people working in the healthcare system**. This will have multiple consequences for the training of everyone concerned. Finally, infrastructures from the individual to the global level will change profoundly.

Major ethical issues

- The insufficient use of digital technology in patient care, in research, or to support the development of data-based management, **are a source of situations of substantial unethical practice within our healthcare system**. Resolving these problems is a priority and entails the use of public policy instruments that lie outside the primary normative provisions of the forthcoming French Bioethics Act.

- **An ethical middle way needs to be found between the imperatives of protecting health data and the need for the sharing of health data in order to enhance the quality and efficiency of our healthcare system.** The President of the Republic's announcement of a plan for a "national hub" for health data represents an interesting move in this direction, provided that the principles governing data acquisition and security, and the operation of the instrument, are clearly defined.

- **The uptake of digital technology in healthcare can have potentially significant effects on health inequalities, both reducing and, in certain cases, exacerbating them.** It is therefore indispensable to monitor the implementation of digital technology in healthcare in order to ensure that its adoption contributes to reducing these inequalities.

- Two major ethical challenges associated with the spread of algorithmic medicine have been identified and require regulation:

    - **The risk of depriving patients** — in practice by the "delegation of consent" — **of a significant part of their capacity to participate in the construction of their healthcare pathways** as a result of the role of algorithms in decision-making;

    - **The danger of a loss of responsiveness to personal situations** as a consequence of the reliance on reasoning based on models that may be limited in their capacity to take individual patient characteristics and preferences into account.

- **Digital technology, as a means of avoiding the traditional channels** of access to information and care or of sharing evaluations of practitioner performance, **constitutes a source of freedom and transparency for citizens, but also of destabilization for our healthcare system and health professionals.** These phenomena need to be carefully monitored, in particular to maintain the imperative of healthcare quality and safety that citizens have a right to expect.

- **The sharing of research data according to 'FAIR'** (*findable, accessible, interoperable, reusable*) **principles is a crucial factor for the development of world-class scientific research in healthcare** and in helping to guarantee the reproducibility and validity of results. Moreover, in

the field of health research, access to data from healthcare itself, from healthcare systems, or from other personal databases, represents a major advance by avoiding the duplication of data collection, which can significantly increase the cost of intervention research (clinical trials, intervention trials) or observation research (cross-sectional studies, cohorts). It would therefore be good practice, as far as possible, to have a consent procedure that enables people to authorize the sharing of their data in the knowledge of how they will be shared (sharing plan), rather than why (by whom and for what research). **It is also important to acquire the scientific, technical, and regulatory resources to control the risks of people being re-identified from databases in which direct identifying information has been removed** and to support the development of ethical tools for the regulation of access to sensitive data.

What instruments of regulation?

- **The exercise of maximum restraint in the use of legislative and regulatory instruments to regulate the uptake of digital technology in the healthcare system should be considered a key priority.** This recommendation should be considered in the light of the forthcoming revision of the Bioethics Act and in the current legislative and regulatory context, including in particular the transposition of the GDPR (European General Data Protection Regulation) into French law.

- The *Comité Consultatif National d'Éthique pour les sciences de la vie et de la santé* (CCNE — National Ethical Consultative Committee for life sciences and health) should evolve into a **Comité National d'Éthique** (National Ethics Committee), a body with the capacity to work on ethical issues relating not just to life sciences and health, but also to digital sciences, technologies, practices and innovation. If necessary, it could be able to address the ethical problems associated with other scientific disciplines.

  A corollary of this development would be that the terms of reference of CCNE would be broadened in the next Bioethics Act.[1]

- The ethical issues of digital technology in healthcare are dealt very differently at European or international level, but there is a consensus on the need to take practical measures, which will be as responsive to change as possible, to **ensure the reliability of digital applications and control of their use.**

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[1] It should be noted that CCNE did not adopt this recommendation as such in its position paper 129, September 2018

- **The response to the ethical challenges associated with the spread of digital technology in healthcare will be enhanced by adopting an international — and initially European — perspective.** Nonetheless, there is still an essential role for the national level, since the implementation of a flexible normative system of regulation at European level will require a strong initiative on the part of governments to support the joint construction of regulatory tools appropriate to national needs.

- **With respect to the next Bioethics Act, it is desirable that the fundamental principle of a Human Warranty of digital technology in healthcare should be entrenched in law.**

  With regard to the equally fundamental principle of obtaining patient consent (for the collection of health data and for the care process itself), the substantive right — in all its stringency — remains appropriate. Nonetheless, **this substantive legislative right would gain from additional new or updated practical tools to guarantee that such consent is actually obtained** (sequential consent arrangements, revival of the trusted person concept, stronger procedures for vulnerable individuals...).

  The creation of a secure national hub for the collection and processing of health data represents a useful method of connecting together the different ethical issues relating to health data. The decision on how data would be fed to this hub would fall within the legislative arena if a political intention was expressed for the creation of a mechanism of presumed consent in the case of a public health interest, of the kind that exists for organ donation.

- **The establishment of a general framework of compensation for injury that may be caused by digital objects does not seem to be an immediate priority in the revision of the 2018 Bioethics Act.** This issue is worth examining in depth in a context where damage and injury, as things stand, remain relatively well covered by liability arrangements relating to damage or injury caused by things which are in one's custody and caused by defective products. **Given the potential scale of the issue in coming years, it would be desirable if a framework specifically designed to cover injury caused by digital objects were developed at least at European level.**

- **There needs to be a strong initiative within the next few months to trigger a dynamic for the practical creation of soft law type instruments of substantive regulation applicable to the spread of digital technology within our healthcare system.**

- **The effects that the adoption of a digital system will have on the conditions of professional practice in the health and medico-social**

sectors need to be anticipated with supportive measures. Public and private actors should be further encouraged to adapt the training — both initial training and continuing professional development — of healthcare workforce to the challenges of digital technology and to support the emergence of new professions associated with the spread of digital technology in the health and medico-social sectors. **The very large mismatch that currently exists between our system of initial training and continuing professional development** and the challenges associated with the spread of digital technology is a serious problem for our healthcare system. **Initiatives** — such as those of the *Conférence des Doyens de Faculté de médecine* and of UNESS — **are in preparation to remedy this situation and should be encouraged.**

B. Background to this report

The taskforce on digital technology in healthcare was set up in response to the engagement letter reproduced in the appendices to this report. Its objective was to provide additional briefing on a specific theme in order to support the *Comité Consultatif National d'Éthique pour les sciences de la vie et de la santé* (CCNE - National Ethical Consultative Committee for life sciences and health) in drafting its position paper following the National Consultation on bioethics in 2018 and, more broadly, to guide its future deliberations on these issues. "*The primary objective of this taskforce is to identify some of the issues and priorities. For this reason, its ideas will feed into the position paper that the CCNE will submit for the National Consultation on bioethics, but also — more globally — will contribute to the necessary investigation into a "governance of digital ethics" called for in the recommendations formulated by Cédric Villani's[2] working group.*"

This assignment was the basis of the composition of the taskforce and the different qualified individuals interviewed in order to marshal materials previously considered by CCNE, in particular:

The National Ethical Consultative Committee

The Comité consultatif national d'éthique (CCNE) is an independent French institution, created in 1983, whose mission stipulated by law is "to formulate opinions on ethical and social issues arising out of advances in biology, medicine, and health." Since 2011, the CCNE's remit has been to organize and stimulate public debate in the run-up to the revision of the bioethics law.

Currently chaired over by Professor Jean-François Delfraissy, the CCNE has 39 members from various disciplines that raise bioethical questions: medicine, philosophy, research, law, religion… It has produced nearly 130 opinions and reports since its creation, by a process of self or direct referral.

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[2] Cédric Villani is a mathematician (Field medal in 2012) and member of the French Parliament. He has been commissioned by the government to produce a report on artificial intelligence (March 2018)

- The report of the *Conseil national de l'Ordre des médecins* (CNOM — National Council of the Order of Physicians), *Médecins et patients dans le monde des data, des algorithmes et de l'intelligence artificielle*;[3]
- The work of the Commission de réflexion sur l'éthique de la recherche en sciences et technologies du numérique d'Allistene (CERNA — Allistene's Committee for the Ethics of Research in Information Sciences and Technologies);[4]
- The proposals and scoping papers established under the Ethik IA initiative;[5]
- The report *Intelligence artificielle et travail*,[6] published by France Stratégie.

The work was pursued in consultation with the "*Big Data*" working group otherwise established through the normal CCNE procedure.

The French bioethics law

A strong attachment to ethical questions and to democratic involvement in health policy has underpinned France's pioneering role in bioethics legislation. A specific so-called "bioethics" law has defined a set of legal rules governing medical and/or research practices relating to the human body and human embryos. The first law was approved in 1988 and is revised regularly.

The last revision of the bioethics law dates from 7 July 2011 and a new revision is scheduled for 2019. The law asserts, among other things, "any planned reform concerning ethical and social issues arising out of advances in biology, medicine, and health must be preceded by public debate in the form of consultations, organized on the initiative of the Comité consultatif national d'éthique."

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[3] "Doctors and patients in the world of data, algorithms and artificial intelligence", *Conseil national de l'Ordre des médecins* (CNOM), January 2018. Its 33 recommendations are reproduced in the appendices to this report.

[4] http://cerna-ethics-allistene.org/

[5] The Ethik IA initiative consists of a team of researchers in digital law, in the information and communication technologies, and in the humanities and social sciences (geopolitics, sociology, behavioral sciences, economics and the sociology of work), together with professionals from the health and medico-social sectors working on the regulation of artificial intelligence and robotics in healthcare. It draws in particular on the work already done through the Health Chair at Sciences-Po Paris and the Institut Droit-Santé de Paris Descartes (Paris Descartes Health Law Institute).

[6] S. Benhamou and L. Janin (2018). Intelligence artificielle et travail. Report to the Ministry of Labour and to the Secretary of State who reports to the prime minister on digital matters. France stratégie, 90 p.

The National Consultation on Bioethics, "les Etats généraux de la Bioéthique", was held in the first half of 2018 and all studies, arguments, and opinions were included in a synthesis report[7] published in June 2018.

The CCNE also formed an opinion[8] on all subjects that were debated, based on all the views voiced during consultations and on the principal conclusions of its previous studies.

The taskforce, whose final short form report was expected at the end of June 2018, drew on an already extensive body of research materials, studies and reports. Among them, several documents were seen as of specific interest in terms of the terms of reference of the engagement letter:

- The report by the *Office parlementaire d'évaluation des choix scientifiques et technologiques* (OPECST — Parliamentary office for the evaluation of scientific and technological choices);[9]

- The report published by the French Member of Parliament Cédric Villani on artificial intelligence;[10]

- The CERNA reports *Éthique de la recherche en robotique, Éthique de la recherche en apprentissage machine*, and *La souveraineté à l'ère du numérique;*[11]

- The report of the *Académie des Technologies* (Technologies Academy);[12]

- The report *Growing the Artificial Intelligence Industry in the UK* by Wendy Hall and Jérôme Pesenti,[13] whose recommendations are reproduced in the appendices;

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[7] A summary in English of the synthesis report is available at: http://www.ccne-ethique.fr/sites/default/files/synthese_anglaise_v1909.pdf

[8] Opinion 129 is available at: https://www.ccne-ethique.fr/en/publications/contribution-comite-consultatif-national-dethique-revision-bioethics-law

[9] C. De Ganay and D. Gillot (2017). Pour une intelligence artificielle maîtrisée, utile et démystifiée. The OPECST Reports, Assemblée nationale, Sénat, 273 p.

[10] C. Villani (2018). Donner un sens à l'intelligence artificielle: pour une stratégie nationale et européenne. Report on the assignment given by the Prime Minister, 242 p

[11] http://cerna-ethics-allistene.org/Publications+CERNA/

[12] *Académie des Technologies* (2018). Renouveau de l'Intelligence artificielle et de l'apprentissage automatique. Report established by the committee on information and communication technologies, 102 p.

[13] Dame W. Hall and J. Pesenti (2017). Growing the artificial intelligence industry in the UK. Independent report, 78 p.

- The Commission nationale de l'information et des libertés (CNIL — French data protection commission) report on the ethical challenges of algorithms and artificial intelligence.[14]

More comprehensive bibliographical information is provided in the appendices.

The taskforce was also involved in a number of hearings held by CCNE as part of the National Consultation on Bioethics, which for the first time included topics relating to digital technology in healthcare. At this stage, it would be useful to recall the aspects of the subject that are usually seen as the most technical and difficult for our fellow citizens to understand, and are therefore least often tackled.

Main lessons from the National Consultation On Bioethics concerning

*"**Health Data" and "Artificial Intelligence and Robotics"** [15]*

As the Comité consultatif national d'éthique noted in its short form report, the 2018 National Consultation on Bioethics highlighted certain key points relating to the recent spread of digital technology in healthcare, which reflect the opinions and concerns expressed by the participants. The human priority at the heart of the healthcare system was frequently stressed in the course of the consultation and strong emphasis was placed on the risk of dehumanizing the relationship between patient and caregiver. Fears were expressed concerning the fraudulent or abusive use of health data, as well as about inequalities (territorial, intergenerational) in access to healthcare in the digital age.

In addition, the public consultation showed that the subject of digital technology is not ancillary to bioethical deliberation, but an integral part of it: "implicitly revealed... [was] what might be described as a "transformation of the core of the bioethical debate" (...) [i.e.] a new objective view of the human body in which the genome and health data, for example, become integrated

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[14] CNIL (2017). Comment permettre à l'homme de garder la main ? Les enjeux éthiques des algorithmes et de l'intelligence artificielle. Summary of the public debate led by CNIL within the framework of the ethical assessment mission established by the Digital Republic Act, 80 p.

[15] See the full report (in French) on https://www.ccne-ethique.fr/en/publications

into the traditional characteristics of the body and further complicate the bioethical question" notes the Committee in its summary.

Health data

1.   Generally speaking, the lack of information cited by many in the debates or hearings with regard to technical data (anonymization, pseudonymization, data security methods) or legal texts may explain why the participants did not tackle certain questions specific to this topic, including the sharing of data for research.

2.   The participants above all shared their perceptions, firstly, of what big data represents in the context of healthcare and, secondly, of the impact that they expected the use of these data to have on their lives.

Three recurrent points thus emerged from the consultation:

(i)   The first point, universally shared, was a demand for explanation and information regarding digital systems, and therefore about the use of the data collected. This demand, which the participants considered to be inadequately met at present, creates a certain sense of powerlessness and lack of control over the use of one's own data.
(ii)   The second point was a marked fear that the progress of these digital instruments (which people find easier to picture than data, which are more virtual) might lead to a loss of the human relationship between patient and doctor, and ultimately to medical decisions being dictated by computers rather than explained and shared between the patient and the physician. Moreover, there was a concern that telemedicine and connected objects might be the only solutions available to mitigate the inadequacies of the healthcare system and, in particular, the growing shortage of doctors.
(iii)   The third point was a widespread mistrust concerning the use of data and the risk of those data being diverted to malicious, coercive, or commercial ends, in particular in the case of vulnerable individuals, by insurance companies or medical platforms, or even by the national Health Insurance system itself.

3. In response to these concerns, beyond the primary imperative for citizens to be kept informed, two other main imperatives were expressed: (i) that each person's freedom of choice should be genuinely guaranteed, in particular through an overhaul of the consent system, (ii) that data systems should not replace human decision-makers in healthcare, and that safeguards should be

put in place to protect privacy. These demands were not translated into specific proposals for legislative change, but into general safeguarding principles with respect to confidentiality, data anonymization, medical confidentiality, a prohibition on the selling of data, and secure data hosting. The institution of trusted third parties to explain the purpose of the data and ensure traceability, or else the introduction of labels for telemedicine systems, are potential options. The public institutions are strongly encouraged to develop these monitoring measures.

Artificial intelligence and robotics

1. In the health sphere, applications of new technologies offer great promise, and in some cases are already being implemented. Putting brakes on their development, as has sometimes been proposed, could itself be considered unethical.

2. Nonetheless, these applications raise issues, even concerns, which lawmakers and system designers need to take seriously. Excessive reliance on these systems carries the risk of dehumanizing medicine. The relationship between the caregiver and the patient remains fundamental. Human beings "must stay in control", must remain the final decision-makers.

3. Following the consultation, a few themes could be identified as summarizing the fundamental ethical questions: (i) Given the complexity of the systems, how do we ensure that the patient gives informed consent for their use? (ii) Who is responsible if the machine makes a mistake or malfunctions? The chain of liabilities (designer, user?) therefore needs to be defined. (iii) The management of the huge volumes of data collected by these systems is a concern. What happens to them and what are the implications of this for medical confidentiality?

4. While these systems could offer solutions for geographic zones that are devoid of medical services, they would not be "the" solution and should not become a pretext for the elimination of positions or jobs in the caring professions. Instead, these services should be available everywhere and to everyone, and should not create new social or territorial inequalities. In this respect, it is important to take note of the risk of potential biases that could become built into algorithms in the machine learning process.

5. Education and information are crucial. The training of doctors and healthcare personnel needs to be based on an analysis of their specific roles

16

and their particular responsibility with respect to the use of these instruments; for their part, the designers who work on them need to be educated about the consequences of their choices. CNIL made three recommendations on this subject in its contribution: (i) all the links in the algorithmic chain (designers, professionals, citizens) should receive training in ethics; (ii) algorithmic systems should be made understandable by reinforcing the existing rights set out in France's Data Protection Act, and by organizing mediation with users; (iii) AI algorithmic systems should be designed and built to serve human freedom, in particular in their human/machine interfaces.

The taskforce also conducted some 30 additional, more targeted hearings on the question of digital technology in healthcare (see appendix 10). These hearings were held on the basis of proposals by the task force or at the request of certain actors.

This report is divided into three parts:

1. A progress report on the uptake of digital technology in the healthcare system;
2. A description of ethical issues associated with this uptake;
3. The formulation of a series of recommendations for the regulation of these existing or potential ethical conflicts.

It culminates with a series of appendices that provide more insight into the topics raised as necessary.

This report contributed to CCNE's collective deliberations about the ethical challenges of digital technology in health. While most of the main recommendations formulated were incorporated into CCNE's position paper 129, this paper in fact adopted a different formulation with regard to the recommendations on the future missions and scope of CCNE itself. Indeed, they call for consultation and reflection that is both larger in scope and longer in duration (http://www.ccne-ethique.fr/fr/actualites/lavis-129-contribution-du-ccne-larevision-de-la-loi-de-bioethique-est-en-ligne).

The publication of this report in November 2018 will allow everyone, citizens, healthcare system users, patients, health professionals, companies, and politicians, to draw on its analyses and proposals to instigate or pursue their own reflections.

C. The very rapid spread of digital technology in Healthcare

"Information is information, not matter or energy. No materialism which does not admit this can survive at the present day." N.Wiener (1948). Cybernetics: or control and communication in the animal and the machine. 2nd revised version in 1961. The MIT Press, Cambridge, MA, 231 p.

The digital revolution is profoundly transforming our societies on a worldwide scale. This impact is also apparent in the healthcare sector, which is now completely permeated with digital sciences, technologies, practices, and innovations. These technological inputs are often seen, experienced, or suffered as unnecessary but often unavoidable impositions, a reflection of the general digitization of our societies.

While this is true, the fundamental role of digital science and technology for the processing of information makes it a critical component in the handling of information in the fields of health and biology, a reality that is often poorly understood. Information as an elementary entity is fundamental to being human: we are information processing systems, though of course that is not all we are. From the level of DNA, through our cells, our organs, our bodies, our social structures, we store, communicate, and process information. Reading this text, the functioning of an organ, using reason to understand a situation, these are all forms of information processing, in many cases highly complex.

Digital processes are therefore fundamentally and increasingly a reality at the very heart of the whole healthcare system. Their spread is driving major upheavals in patient care, in research, in the organization of health services, and in the evolution of professions in the health and medico-social fields.

These major transformations are, to a large extent, already underway within our healthcare system. Nonetheless, they are far from always visible in all their dimensions to professionals who, working on the frontline, are frequently propelled by concerns that are more pressing and immediate.

1) Digital technology, artificial intelligence, and robotics

What are we talking about? We will begin by recalling the fundamental definitions of these three concepts, which are often used as buzzwords, fashionable notions rather than technical concepts.[16]

"To give a precise intentional definition of Artificial Intelligence is not easy, and if we take a broad approach, it covers much of information technology. The ambiguity begins with the word "intelligence". This term can be understood by reference to human intelligence, making AI the science of imitating human reasoning, or in a performative sense, to mean taking good decisions based on the effective understanding of an environment." This quotation from the report *Renouveau de l'Intelligence artificielle et de l'Apprentissage Automatique* [Renewal of artificial intelligence and machine learning] from the ICT Committee of the *Académie des Technologies* moves the term first introduced by John McCarthy in 1956 into the contemporary context.

Today, the term Artificial Intelligence (AI) is often used in the generic sense of "digital technology". Originally, in 1956, the aim of AI was to simulate human cognitive faculties on computers and the term encompassed scientific approaches relating to computer science and mathematics, at the leading-edge of cognitive sciences such as knowledge representation, machine reasoning, problem-solving with constraints, optimization, automatic language processing, machine vision, or machine learning. Today, the term AI tends to be employed in reference to machine learning, or even more specifically deep learning.

The first medical decision support systems were based on making expert knowledge explicit in the form of decision rules. With machine learning, the systems build up knowledge by different approaches. With *supervised learning*, predictions are made — for example diagnoses of clinical situations — on the basis of data previously labelled by experts. With *unsupervised learning*, the system groups data into homogeneous classes. And finally, in the case of *reinforcement learning*, the system learns by interacting with its environment, which then provides reinforcement in the form of positive or

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[16] Readers wishing to enter into the subject in greater depth can, for example, consult the book by Gérard Berry (G. Berry (2017). L'hyperpuissance de l'informatique : algorithmes, données, machines, réseaux. Éditions Odile Jacob, 512 p.), based in particular on his classes at the Collège de France, including his inaugural 2008 lesson, « Pourquoi et comment le monde devient numérique » [Why and how is the world becoming digital].

negative feedback. Learning systems are used, among other things, in predictive medicine and in genomic medicine.

The recent successes of learning methods (in particular so-called "deep learning") owe a great deal to the increase in the computing power and storage capacity of machines, as well as to an explosion in the volume of data available and the ability to process them on a large scale. A feature of this vastly increased performance is that it is currently difficult to explain the results obtained by these methods. The possibility that algorithms may behave unpredictably as a result of machine learning is also problematic in our current state of knowledge, especially as this could be exploited to malicious ends.

AI techniques can be used in the design of robots, in particular for environment recognition and interpretation, computation of the most relevant tasks to perform, and the planning of those tasks. As most commonly understood, a **robot** is a computer-controlled machine that moves in physical space. [17] The robot acquires data using its sensors, and makes an interpretation or interpretations of those data, in order to compute decisions relating to its actions in physical space. A robot can also be a software agent with no physical parts (also called a bot), which acquires data and performs tasks within the cyberspace. A robot can be programmed to interact with a user, either physically or via an interface. The generic term robotics refers to the science of designing and studying robots.

The term "**digital technology**" as used here refers to the sciences (in particular informatics and mathematics), technologies, uses, and innovations associated with the study, storage, processing, reception, or transmission of information. **Digital technology in healthcare** thus refers to all the computerized processes in the health field, whether on not these processes involve artificial intelligence or robotics.

2) Prospects of major advances associated with digital technology in health

The spread of technology in healthcare is currently well underway in France in an extremely active international context.. The year 2018 marked the sixtieth anniversary of the "ordonnances Debré", the ministerial orders that set up France's CHU (university hospitals), and these institutions in

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[17] J.-P. Laumond (2012). La robotique : une récidive d'Héphaïstos. Leçons inaugurales ; Collège de France, Fayard, 80 p.

particular are determinedly pursuing the potential for innovation that has opened up in the fields of healthcare, teaching, and research. This pursuit of innovation is increasingly widespread within our healthcare system, going beyond the traditional divides, notably between the independent health practioner and the hospital, prevention, treatment, and medico-social support, or between the public and private sectors.

So medical professionals in all sectors, whether working in independent practice, big health institutions, or medico-social structures, are directly involved in this movement towards technical innovation and digital democratization in the field of healthcare. More and more institutions are acquiring robots, for example in the context of strategies to improve cognitive functions.

With respect to the development of medicine itself, the "human component" in medical practice has been steadily diminishing in the last few decades, with significant developments in medico-technical robotics (especially in biology and pharmacy) and, more recently, in software to assist treatment prescription and decision-making. The use of such software is even covered by specific legal provisions, notably with the assignment of jurisdiction to the *Haute Autorité de Santé* (HAS — Central Health Authority). In the last 10 years or so, surgery itself has been on an accelerating path towards robotization.

As noted by the *Conseil national de l'Ordre des médecins* in its previously cited report, *"the medicine of the future is already here"*: *"the first computerized diagnostic support algorithms have been approved, surgeons manipulate robots, while their anesthetist colleagues test the impact of virtual reality on patient anxiety...."*

With respect to patients or future patients, people today are not the same as they were yesterday. Digital technology is an integral part of their lives, they have immediate access to information from numerous sources with no hierarchy of priority. This raises the question of the individual's ability to analyze this information, in particular its relevance and validity. The huge increase in access to information is altering the relations between individuals and healthcare professionals.

Cédric Villani's report identifies healthcare as a priority sector for the development of artificial intelligence. According to this report, *"artificial intelligence in healthcare offers very hopeful prospects for improvements in the quality of patient care and reductions in its cost — through more personalized and predictive care practices — but also for safety — thanks to greater input into medical decision-making and better traceability. It can also*

help to improve citizens' access to health, with pre-diagnosis systems or guidance through the treatment pathway."

The potential benefits of digital technology in healthcare apply equally to the areas of prevention, screening, care, support, training, and research, as well as to the governance or organization of healthcare systems.

These attainable advances in the quality of patient care and in the efficiency of the healthcare system have already been demonstrated in numerous studies.

As noted in the previously mentioned France Stratégie report, *"almost all areas of artificial intelligence — image and video recognition, natural language processing, machine learning, robotics, etc. — can have applications in the health sphere. It is true for diagnosis and care recommendations, for treatment, surgery, personalized monitoring, the medico-social field, and for rehabilitation, but also for prevention and clinical research. With artificial intelligence, it is possible to automate not only simple tasks such as measuring a patient's weight or blood pressure, but also complex tasks such as medical diagnosis and therapeutic care.* [...]

There are numerous AI tools on the healthcare market and the range of their current applications in medical diagnosis is substantial. They can be found in medical specialties like oncology — covering all the medical aspects of cancer care, tests, diagnoses, and treatment — cardiology, ophthalmology, radiology, the detection of specific physical conditions (diabetes, Alzheimer's, etc.) or mental health conditions (depression or other psychological problems). Whatever the field, the principle is always the same: algorithms fed and driven by big data (medical image recognition, medical research results, etc.) are programmed to detect pathologies using protocols predefined by the medical community."

3) Multiple examples in all areas of the life sciences and healthcare illustrate the progress that digital technology brings

- **Signal processing, machine learning, and healthcare**: major advances in digital image analysis, in sensor design, in processing and transmission speed, are now spreading into every field of medicine. Whatever the technology used — MRI (magnetic resonance imaging), scans, radiology, ultrasound, and their combination — the acquisition, visualization, and interpretation of data by means of algorithms have made and will continue

22

to make remarkable progress. Machine learning techniques are bringing results in the interpretation of images that can outdo the capacities of the top specialists. The role of the radiologist has been profoundly transformed, to the point that some see it as destined to disappear, though this is not a common view. However, the reality of the transformation is universally recognized, along with the current inadequacy of training in this field. A more recent development concerns the tools employed: the sensors used for these analyses can be highly sophisticated, as with very high-density MRI, but can alternatively be simple and widely available, like the cameras or microphones on smartphones. In the latter case, it is now possible to diagnose skin lesions by photographic analysis, or neurodegenerative diseases through voice and speech analysis.

- **Telemedicine**: the capacity to send data at speeds and with a degree of reliability never previously achieved, potentially anywhere in France, and even overseas, raises the possibility of applications of telemedicine ranging from prevention to monitoring. Here again, whether for citizens or for health professionals, the change is profound and is significantly altering the relationship between individuals and health professionals. Medical consultations can be conducted remotely with the patient at home, for example using specific devices, some of them cheap, to measure physiological parameters with the participation and direct help of the individual patient.

- **The digitization of operating rooms**: already a reality for some 15 years with, for example, the development of Da Vinci type robots initially designed at the international Stanford Research Institute at Menlo Park in California, digital technology in all its forms has arrived in operating theatres. Here too, the consequences are profound. Firstly in the use of these techniques to train healthcare professionals in highly realistic virtual environments for technical procedures such as cataract operations, brain surgery, or micro-invasive surgery. And secondly, to provide additional capacities within operating rooms, for example in anesthesia, to enable medical personnel to manipulate documents (images, texts) without touching them, to plan and record activities for purposes of traceability, teaching, or research.

- **Digital research for healthcare**: digital research is omnipresent in every field of healthcare. To cite just a few examples, bioinformatics research, including genomics, research on the modelling of cognitive capacities,

cardiac modelling, the modelling of cells, tissues, organs, organisms, the modelling of the propagation of infected cells or epidemics, affective robotics, etc. It is significant that in the 6 IHU (university-hospital institutes: LIRYC, Imagine, MIXsurg...) digital healthcare research plays a fundamental role.

- **Hospital management**: computerized handling of data, inventory, maintenance, energy, digital or physical networks, safety, human resource management... The use of artificial intelligence solutions in healthcare system funding is also significant, with solutions — like the one proposed by ALICANTE — for the automated coding of medical acts in hospital financial management systems.

- **Diagnostic support**: to take only one example, the possibilities of progress in the handling of cancer opened up by artificial intelligence are very considerable. For example, the French firm *Therapixel* distinguished itself in several international competitions, notably by winning the *Digital Mammography Challenge*. Its solution can identify early signs of tumor risk through the mass processing of medical images by AI.

- **Genomics**: the application of AI is a major objective of the sequencing platforms provided for in France's Genomic Medicine Plan 2025. However, artificial intelligence is already present in genomics, as illustrated by the example of the *Dr WareHouse* instrument developed by the Necker Hospital (AP-HP — Assistance publique — Hôpitaux de Paris) and the Imagine university hospital institute (IHU). Indeed, this institute has just been given labelling for a RHU (university-hospital health research) project in Machine Learning on genomics and renal ciliopathies.

- **Medical teaching**: the uptake of digital technology in medical teaching has accelerated considerably in the last 10 years or so, notably with the use of MOOCs (massive open online courses) and the development of training centers that use robot and digital simulation. The establishment of a Université du numérique en Santé et Sport (UNESS) — with the active involvement of the *Conférence des Doyens de Faculté de médecine, pharmacie et odotonlogie* — constitutes a very important step in the development of a full spectrum of digital training in France.

- **Personal empowerment**: digital technology is a key instrument for reinforcing individual autonomy with respect to health. The very positive role played by digital technology in the autonomy of people living with a

disability was highlighted by Pascal Jacob, president of *Handidactique*. Practical tools already exist in this domain: one example is the mobile phone app *Jase Up*, developed by the *Down-Up* voluntary sector organization, an easy and everyday tool for managing solidarity networks in support of individual autonomy.

- **Clinical research**: clinical research is embarking on a digital revolution driven by a combination of two factors:
    - the possibility of collecting large volumes of data generated by high-speed techniques (multiomic, imaging), which can feed algorithms capable of stratify patients independently of any knowledge of biological mechanisms, a contribution to the quest for "personalized" medicine;
    - the possibility of reusing, for research purposes, pre-existing data originating in research, in healthcare, or in healthcare systems, which potentially represents a major advance in avoiding the duplication of data collection.

- **Public health research**: similarly, the possibility of reusing pre-existing data from multiple sources, including sources outside the healthcare system (e.g. by reconstructing the lifelong exposure of individuals to pathogens in their working or living environment), and the exploitation of the new capacities for large-scale data processing, create the prospect of understanding the complex interactions that determine changes in the health of people and groups within the population, the real nature of their interactions with the healthcare system, and the effects of those interactions.

- **Risk detection and management**: algorithmic tools raise the possibility of early detection of epidemic risks and therefore early decision-making on how to handle such risks,[18] but also of detecting "weak signals" associated with environmental exposure, with medication, …

This is only a sample of the fields of application. Others might include: the training and monitoring of healthcare workers; the evaluation of doctors and health professionals in general, including those in the medico-social sector;

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[18] Tested in Brazil and in Malaysia, AIME — *Artificial Intelligence in Medical Epidemiology* — detected the start of an epidemic of Zika virus and of dengue with almost 90% accuracy within a radius of 400 meters. *HealthMap* also uses mapping. An online application, this system was designed by researchers at Boston Pediatric Hospital and Harvard University in 2006. It focuses on the early detection of risks of dengue fever, chikungunya, or malaria epidemics.

medical data from definition to use and persistence; the design, development, and use of drugs; digitization in reproductive health; brain-machine interfaces; prevention and personalized medicine; etc.

The applications of AI in healthcare are extensively covered in the book "Santé et intelligence artificielle",[19] a publication directed by Bernard Nordlinger and Cédric Villani. It looks in particular at applications for medical imaging, oncology, diagnostic support, genomics, emotions.

*The rapid pace at which digital technology is spreading through our healthcare system is a major and irreversible reality, which needs to become an even greater priority in the future response to public health challenges. The information we have shows how **digital technology can be a source of major advances in the quality and efficiency of our healthcare system**. The benefits it can bring in the areas of teaching and research are also considerable. **All this potential is only just beginning to be marshalled.** The likely scale of the spread of these technologies calls for a **parallel commitment to continuing analysis of the ethical challenges associated with them and with their future developments**.*

4) Major impact of digital technology on the governance and organization of healthcare systems at national and global scales

International research has shown that digital technology is a major source of change in healthcare systems. Firstly, these systems increasingly use digital tools to organize patient care and pathways, in particular, and also and increasingly in aspects of management associated with the collection and processing of health data. **Such "data-based management" is an absolutely crucial project for the future of the French healthcare system.**[20]

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[19] B. Nordlinger and C. Villani (2018). Santé et intelligence artificielle. CNRS Éditions, 416 p.
[20] Strictly speaking, this can be broken down into:
- The use of digital tools in individual patient care and procedures, with major impacts on the organization of the system;
- The use of digital tools (production of indicators, analytical models for the use or performance of healthcare services...) to support system management decisions, the aspect that might be referred to as "data-based management". In this report, the latter expression will be used in its broadest sense, encompassing these aspects of the use of digital technology in health.

This report is not the place to draw up a comprehensive inventory of the applications and impacts of digital technology in the operation, organization, and governance of the healthcare system. The contribution by Thomas London, Director of McKinsey Santé and President of the *Health data Institute,* reveals extensive documentation on the major positive effects — in terms of greater efficiency and increased quality of patient care — of more widespread use of data-based management and digital technology in our healthcare systems.

The taskforce was reminded of the major benefits of digital technology for the improvement of our healthcare system by Professor Guy Vallancien, whose work has demonstrated the prospects of achievable progress and the need to support it.[21] These advances apply equally to the healthcare system and to the social and medico-social sectors. Digital technology can thus be a major resource for responding to the challenges of ageing and failing health, as was shown by Dr Philippe Denormandie in his contribution to the taskforce.[22]

Professors Nathalie Salles and Thierry Moulin from SFT-ANTEL (Société française de télémédecine) showed the very significant impact of the spread of telemedicine on the organization of the system, with very positive results already observed for the use of telemedicine in areas with poor medical coverage, but also for the monitoring of patients at home or patients with reduced mobility.

Rémy Choquet, Innovation Director at *Orange Healthcare* gave specific examples of programs that show how digital technology can contribute to the emergence of genuine patient care improvements. This logic is at work, for example, in a post-operative face recognition project for pain management being conducted in collaboration with Nice University-Hospital, or in the development with Pitié-Salpêtrière Hospital (AP-HP) of an algorithm for monitoring patients suffering from rheumatoid polyarthritis.

The hearings and meetings with the heads of health institutions also showed the profound effects of the digital transformation on the management and organization of the healthcare system. At his hearing for the National Consultation on bioethics, Martin Hirsch, CEO of AP-HP described the establishment of a health data warehouse for the *Assistance publique*

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[21] See in particular G. Vallancien (2015). La Médecine sans Médecin ? Le numérique au service du malade. Le Débat, Gallimard, 243p., and G. Vallancien (2017). Homo Artificialis, plaidoyer pour un humanisme numérique, Michalon, 208 p.

[22] Director of health relations at MNH Group, Dr Philippe Denormandie, with Marianne Cornu-Pauchet, was charged by the Minister for Solidarity and Health to report on healthcare access for people with disabilities and vulnerable people.

(welfare system) and the development of very significant transformation programs underpinned by digital technology. The meetings with Professor Michel Claudon, President of the *Conférence des présidents de CME* (*commission médicale d'établissement*) *de CHU* (Conference of Presidents of University-Hospital Medical Committees) and Dr Thierry Godeau, President of the *Conférence des présidents de CME de Centres hospitaliers* (Conference of Presidents of Hospital Centre Medical Committees), highlighted the potential benefits and opportunities for medical practice of greater access to health data and more possibilities for the use of digital tools. For its part, *FEHAP* (*Fédération des Établissements Hospitaliers d'Aide à la personne —* Federation of Hospital Human Assistance Institutions) has been working with its member structures for many months around shared projects relating to artificial intelligence. UNICANCER is running the *Consor* (Continuum Soins Recherche) project — a common database for cancer treatment centers — and *OncoSnipe*, a machine learning project on biomarkers in breast, pancreatic, and lung cancers, funded by *BPI* (*Banque Publique d'Investissement —* Public Investment Bank) and headed by the firm *OncoDesign*.

Growing awareness of the major consequences associated with the speed of current and future changes linked to digital technology may challenge the traditional dividing lines within our healthcare system.

Thus, the announcement by the "G4"[23] in early June 2018 of the start of a plan to build a global French ecosystem for the development of image recognition algorithms in radiology, transcends the traditional oppositions between public and private or between institutions and independent medical practice.

From a managerial point of view, Etienne Grass, Director of Health at *CapGemini*, in his contribution to the work of the taskforce, explained the positive benefit of the simultaneous uptake of digital technology and design thinking within our healthcare system. Exploration around the design of the human/machine interaction contributes, in particular, to the development of ways to reinforce the quality and efficiency of human intervention or human use of digital tools, and thereby to transform our healthcare system in a positive direction.

The French government indicated the priority it places on this question by asking Dominique Pon and Annelore Coury to develop proposals on the digital transformation of our healthcare system. The conclusions of this

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[23] French professional radiology council.

mission, presented in September 2018,[24] specified in particular the methods envisaged for the implementation of a secure and personalized digital space, the promotion of a framework of values and a set of criteria for digital ethics, as well as the proposal for a package of services intended to simplify access to the different digital services for professionals and institutions.

The organization and governance of the entire healthcare system, from research to clinical practice, from individuals to health professionals, from the independent practitioner to the biggest health institutions, will be profoundly affected by digital technology, with consequences at the national, European, and international levels that are multiple but at present hard to predict. This transformation is a source of opportunity, but its implementation entails tensions that analysis of the ethical issues can help to identify. Digital technology is transforming our healthcare system by enhancing the quality of patient care and organizational efficiency. It is also helping to break down traditional divides and to facilitate the emergence of a "learning healthcare system" that is favorable to medical, technical, or managerial innovations. Already, and to a greater extent in the future, profound changes are underway in the practices, roles, functions, and responsibilities of people working in the healthcare system. This will have multiple consequences for the training of everyone concerned. Finally, infrastructures from the individual to the global level will change profoundly.

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[24] "Accélérer le virage numérique", report submitted on 18 September 2018 to the Solidarity and Health Ministry following the mission conducted under the Healthcare System Transformation Strategy;
https://solidarites-sante.gouv.fr/IMG/pdf/masante2022_rapport_virage_numerique.pdf

D. Major ethical issues

"[…] In my view, we have three challenges that are extremely typical when innovations of this kind appear or big revolutions occur: we have a choice in terms of conflicts between values and technology, we have an ethical tension in the geographical domain, and we have a tension in relation to time factors. We find ourselves in a system and a grammar that are, in this respect, familiar, and this is what we need to think about."

Speech by Emmanuel Macron President of the Republic — *"AI for Humanity"*
Paris, Collège de France — Thursday, 29 March 2018

Ethical thinking is about taking a position on hierarchies of values, as one goes along, on the basis of personal and collective experience and reflection. The aim of this reflection is to determine, in a reasoned way, what can be considered to be the most correct decision or action at a given moment and in a given context. Depending on the viewpoints considered, the hierarchies of values are not necessarily the same: it is the tensions between these values that define ethical issues. For example, the points of view of a patient with a particular health condition and of the citizen who does not have that condition are not necessarily the same and can themselves differ from society's collective viewpoint.

This attention to ethical issues is strongly present in the Villani report and in the speech given by the President of the Republic following the submission of that report.

Of course, ethical thinking about digital technology should not be separated from the application of more general ethical principles that date back at least to ancient times. In particular, in medicine, CNOM refers in its report to the applicability to digital technologies of the four principles of medical ethics: beneficence, non-maleficence, autonomy, and justice. Bearing these elements in mind, we will now explore the ethical issues associated with digital technology in healthcare, though we will stop short of considering points relating to trans-humanism and the "singularity", notions that are particularly well elucidated in Jean-Gabriel Ganascia's book.[25]

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[25] J.-G. Ganascia (2017). Le Mythe de la Singularité. Faut-il craindre l'intelligence artificielle ? Science Ouverte. Seuil, 144 p.

1) Multiple examples of ethical issues in digital technology and health

- **I have a rare disease** and making my personal data available for purposes of research and to improve treatment could add to the existing body of data. However, those data are sensitive. Should I do it and, if so, how?

  The values in conflict here are essentially respect for privacy versus contribution to knowledge. The decision is personal, but clearly has an impact on the community of people suffering from the same condition.

- **I am a doctor** and I use Gmail and DropBox to exchange information about the patients in my care. The convenience and speed of these methods make me more efficient.

  The values in conflict here are a degree of convenience versus medical confidentiality.

- **I am a patient and I have been asked to give my free and informed consent for the use of my personal data for purposes of research or healthcare system management**: free in what sense? Can I give my agreement for my data to be shared and reused for other purposes of public interest? If I refused, would I receive the same level of care? Can my data be shared then reused for other purposes, in particular commercial purposes? How can I give my consent, how long will it be maintained, who will have access to these data? Is there a risk that they could be used against me or against my children?

  The ethical issues here concern patient autonomy, the ability of patients to control what happens to the data they provide, the potential public interest of using those data, and collective responsibility in the protection and use of data.

- **I am an engineer working on the development of pollution monitoring software** (i.e. work that has an impact on public health). How should I respond if I am asked to develop programs that are intended to falsify measurements?

  This would create tensions between professional responsibility, the capacity to manage intracompany conflicts, and the values of beneficence.

- **I am a doctor and I use digital systems to help me make diagnoses or choose treatments.** What responsibility can I attribute to the digital system, and what confidence will the patient ultimately have in me? Can I be blamed if I take into account factors other than the recommendation generated by the digital system?

  The ethical issues here are multiple and there is a consensus, at least in France, about the importance of the final decision being taken by a human being, here in interaction between the patient and the physician. However, do doctors today, through their initial training and ongoing learning, possess the knowledge they need to understand how the digital instrument decides on its diagnosis or treatment plan and how to take this into account in their final decision?

- **I am the director of a medical institution and I am working with my teams to establish a health data warehouse.** This will allow me to support the development of research programs and implement data-based health management measures.

  The ethical issues here lie between the principle of obtaining patient consent and the need for flexibility in exploiting the benefits associated with digital technology. In addition, this issue raises the question of the security of the interface between these institutional data warehouses and the national health data hub currently under development.

- **I am a citizen and I could have myself "augmented" through the implantation of connected devices:** where is the boundary here between the person and the artificial device?

  The ethical issues here relate to the effects on the definition and protection of the human body associated with the spread of digital technology. What is the future of the current protected status of the human body in a context where the growing accumulation of connected objects will gradually alter the contexture of the human body itself?[26] Moreover, are all possible augmentations desirable? How

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[26] Act 94-653 of July 29, 1994 concerning the respect for the human body established the legal status of the human body by distinguishing, for purposes of protection, the person from his or her body in its physical contexture. The purpose of this Act was to remove the paradoxical difference that previously existed between the protection of the person in their environment and way of life (Article 9 of the Civil Code) but not in the sensory reality of the physical elements of their body. Arising from this Act, the terms of Article 16 of the Civil Code state that *"legislation ensures the primacy of the person, prohibits any infringement of the latter's dignity and safeguards the respect of the human being from the outset of life"*. Article 16-1, based on the same law, states that *"Everyone has the right to respect for his body. The human body is inviolable. The human body, its elements and its products may not form the subject of a patrimonial right.."*

much will they cost? Will they generate inequalities? How might they affect attitudes to people who are more fragile or who refuse to be augmented?

- **I work as a caregiver for elderly people who use a digital assistant to keep them company:** what is the psychological and emotional impact of such digital assistants? Could the use of these artificial aids generate a conflict of values for human caregivers?

    The ethical issues involved here are made explicit by Professor Laurence Devillers with her most recent work on human-machine interaction and on language.[27] The use of these technologies may generate a paradoxical development whereby an expanded digital presence goes hand-in-hand with greater isolation from other people.

- **I am a researcher in the field of public health,** and I have received public funding to produce a meta-analysis, based on patient data present in all existing published clinical trials, comparing the effectiveness and side-effects of treatments given for a specific condition, which will enable HAS (Central Health Authority) to improve its recommendations.

    Would it be possible to have access to these individual data, whether or not patient consent has been obtained for the use of their data? Will the consents have the effect of limiting the reuse of data to certain research studies? Were the patients able to withdraw their consent and their data after the end of the study, which might have the effect of distorting my analysis if patient dissatisfaction influences the decision to withdraw consent ("I am withdrawing my consent because I experienced a negative side-effect")?

- **I am a medical student,** and the training I am receiving includes the use of digital tools in my practice.

    If I have to take over from a digital device, will I know everything I need to know in order to do so? Will I also be taught how to enhance the human relationship in healthcare?

- **I am a specialist in genomics and am doing research in bioinformatics,** and I have multiple questions.

    What does it mean to obtain an individual's informed consent in the case of genome treatment, given that genome analysis generates

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[27] See in particular L. Devillers (2017). Des Robots et des Hommes : mythes, fantasmes et réalité. Plon, 240 p.

information not only about the individuals, but also about their family, and high-speed analysis techniques now allow us to analyze entire genomes, which may lead to incidental discoveries? What assurance of confidentiality can I give people when handling their anonymized data, given that the data could be reidentified by cross-referencing with other data sources? Can this information on the genome be shared and used for purposes other than those stated at the outset? Is there not a risk that my genome research could lead to genetic discrimination against individuals or groups, by revealing their predisposition to developing certain diseases?

The progress already made and the advances likely to be accomplished suggest that approaching these questions from a restrictive perspective would result in France missing out on unprecedented possibilities for innovation, with a major ethical component.

The ethical problems associated with the spread of digital technology itself appeared less immediately discriminatory. Nonetheless, those problems are real and need to be tackled at the highest level through preventive or regulatory initiatives.

2) CNIL's overview of the ethical issues raised globally by algorithms and AI

In its previously mentioned report, CNIL formulated a set of general recommendations for responses to the ethical issues raised by AI. It thus identified *"two seminal principles for an artificial intelligence that works for people"*:

- **A principle of loyalty** applied to all algorithms and that includes their public — and not just their personal — impacts. Any algorithm, whether or not it processes personal data, must be loyal to its users, not only as consumers, but also as citizens, and also loyal to communities or large public interests whose existence could be directly affected. **The interests of users must take priority.**

- **A principle of vigilance/reflexiveness**: a process of regular, methodical, and deliberative questioning should be established and maintained with regard to these evolving objects. This principle constitutes a direct response to the imperatives raised by these

technological instruments, because of the potential difficulty of predicting the results that they may produce (e.g. in machine learning), the highly compartmentalized nature of the algorithmic chains to which they belong and, finally, the excessive trust they can inspire.

CNIL also formulates six generic *"practical recommendations"* that may be equally applicable to digital technology in healthcare. They are reproduced in the appendices.

These general principles and these practical recommendations were considered with interest and attention by the taskforce. Nonetheless, in the different contributions from experts, there was another message often conveyed by figures within our health service, which concerned the scale of the current blockages and rigidities that hinder the effective spread of digital technology in health.

3) Insufficient use of digital technology, a source of immediate and already visible ethical problems

In comparison with the countries where data-based health management has made the most progress, France in 2018 is in a paradoxical situation. Although it possesses health databases with exceptional coverage, it is still relatively behind in the use of such data for management or research purposes. This situation is a source of ethical problems that are immediately visible.

In its contribution, *France Assos Santé* – a consortium of Patients associations - laid great emphasis on the need for more widespread data-based management in order for our healthcare system to progress.

In his submission to the taskforce, Pascal Jacob, Chairman of *Handidactique*, highlighted the *"lack of memory"* in our healthcare system, because of the social and health components of the system in different silos. There are major difficulties in trying to establish interfaces between them. These partitions also exist between the different operators within each sector, with a general problem arising from the existence of parallel information systems with no interoperability, and in the absence of a culture of data pooling and shared data processing to generate information of joint interest. Yet being able to access the stored information held by the different players is very important for providing effective care.

In the field of healthcare itself, the spread of data-based health management represents a major instrument for detecting cases of inappropriate care. In his contribution, Alexandre Vainchtock, Chairman of *Hevaweb*, showed the potential of data-based management to tackle this major challenge for the quality and efficiency of our healthcare system, an objective now recognized by the government as a priority for action.

The negative effects on the quality of patient care and on the efficiency of the healthcare system arising from the current model used in the funding of the treatment of chronic renal failure are another example of problems that could be more effectively identified and treated through an expansion of data-based management.

Identified by the Cour des comptes (Court of Accounts) in 2015, the deficiencies of this funding model act as a disincentive to effective measures to prevent and slow the progress of kidney disease, to the provision of home dialysis, to the maintenance of patient autonomy, but also to kidney transplants, by far the most efficient treatment for patients whose kidneys have ceased to function.

In its contribution to the taskforce, the *Renaloo* association reported that this funding system in particular is one of the factors that explains the obstacles and differences between regions in access to the transplant waiting list. It could also play a major role in the very limited use of palliative maintenance treatment rather than dialysis for very elderly or terminal phase patients by comparison with other countries. More widespread use of data-based management relating to chronic kidney failure would probably have facilitated earlier identification of these cases of inappropriate care, which is associated with significant reductions in patient life chances.

*The insufficient use of digital technology in patient care, in research, or to support the development of data-based management, **are a source of situations of substantial unethical practice within our healthcare system.** Resolving these problems is a priority and entails the use of public policy instruments that lie outside the primary normative provisions of the forthcoming Bioethics Act.*

4) Health data: between protection, medical confidentiality, portability, and communicability

While much still remains to be done on the introduction of data-based management, the ethical challenge of protecting these sensitive data is also particularly crucial. In fact, a first essential point is to determine which are the data of interest. While all the data arising from patient care, together with those relating to healthcare personnel, are obviously a subject of interest, there are many kinds of additional data, such as information from other big administrative databases, GPS data, or data supplied by digital personal assistants or smartwatches, and air quality or sleep quality sensors. Here we provide simply some initial guidelines, bearing in mind that CCNE's Big Data working group is also tasked with developing these points.

The transposition of the GDPR (European General Data Protection Regulation) [28] represents a significant positive step in strengthening the protection of such data. Since French legislation has been harmonized with this development through a specific legislative instrument, the taskforce did not feel it appropriate to open up this program immediately within the framework of a future discussion on the revision of the Bioethics Act..

Although they are not potential targets for legislative action in the near future, certain questions nevertheless deserve more in-depth exploration. This is the case, in particular, for the conditions governing access to data by insurance companies and mutual insurance companies.

In its previously mentioned report, CNOM moreover notes that *"medical confidentiality with regard to personal health data should be applied to the processing of big data and these data should not be used in such a way that a person may be identified, with a consequent risk of discrimination."*

In its contribution to the taskforce, *France Assos Santé* emphasized that *"one of the dangers often identified with the computerization of health data concerns the practice of risk selection by insurance companies. While the law prohibits discrimination on grounds of health, it excludes the domain of personal insurance, and therefore supplementary insurance. In a country where the patient's contribution to costs is 20% in hospitals and 30% for a doctor's visit, this is already a sensitive issue. It is even more sensitive in the*

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[28] Regulation (EU) 2016/679 of the European Parliament and of the Council of 27 April 2016 on the protection of natural persons with regard to the processing of personal data and on the free movement of such data, and repealing Directive 95/46/EC (General Data Protection Regulation).

case of standard care overall, where the patient's contribution is close to 45%. If insurers know what health conditions their policyholders have, the categorial solidarity of supplementary insurance might be adjusted to take account of the level of risk of the condition in question. This is what is called customer stratification on the basis of risk." [29] On this subject, it should be recalled that, since the 2002 Act, which created solidarity-based health insurance policies in order to make supplementary health cover affordable regardless of the policyholder's state of health, policies are said to be "solidarity-based" if there is no medical selection when they are taken out and the contribution rates do not change according to the individual's state of health. In return, these specific policies receive exemption from the tax on insurance contracts. A very large majority of the policies offered by insurers and health and pension insurance providers are therefore solidarity-based, as are all those offered by the mutual insurance companies. This is a legal obligation under the Mutuality Code.

A related question arises, in this respect, with regard to the update of the so-called "AERAS" system, which has failed to adequately reduce cases of adverse selection on health grounds in access to credit. The development of data-based management creates a risk that this adverse selection might be intensified if appropriate regulatory mechanisms are not implemented. *France Assos Santé* suggests that the Bioethics Act might be used as an instrument to tackle this situation. A device similar to quality certification could be another possible option, provided that the representatives of healthcare system users are involved in its governance.

The Villani Report also notes that *"the portability and ease of communication of "data relevant to health" need to be rethought in the age of AI. The challenge is to involve individuals, to empower them in the production of this information, while ensuring that the risks of intrusion into privacy and of escalation are limited."* The introduction of the "shared medical file" (DMP) provides a practical instrument for this.

Nonetheless, this imperative of protection needs to be balanced with the value added by the sharing of these data in improving the quality and efficiency of our healthcare system. Appropriate tools therefore need to be developed to facilitate such sharing.

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[29] The use of data obtain from the SNDS (national health data system) for this purpose is expressly forbidden by Article L1461-1 of the public health code, but the question may arise for health data from other sources, starting with data that may be held by the insurance companies themselves.

The announcement by the President of the Republic, following the submission of the Villani report, of the establishment of a future national health data "hub" administered by the Institut national des données de santé (INDS – National Institute of Health Data) is a clear and powerful initiative. The methods of connecting this future national hub with the data warehouses currently being established within healthcare institutions or across health regions will need to be defined.

As was explained by Yvanie Caillé, Director of INDS, the new procedures for access to health data that have come into force since the healthcare system modernization act have reduced the time taken to obtain regulatory approval: the mean delay between submitting an application for access to INDS and authorization by CNIL is now 70 working days, as compared with previous waiting times that could be as long as 18 to 24 months. Since the opening of the procedure in August 2017, some 300 applications have been submitted. Most of these are academic, but other types of applications for access are emerging. Nonetheless, there have so far been very few applications concerning development programs for Machine Learning solutions.

The establishment of this kind of national hub, with the appropriate level of security, would make it possible to advance further, to strengthen individual or collective digital sovereignties in particular at European level, to reassure the parties concerned, and to pursue artificial intelligence initiatives on a much larger scale. In this regard, the Health Data Hub project presented in October may constitute an appropriate pathway combining the need for data protection with the need for data sharing.[30] With respect to the methods of data supply, two approaches are theoretically possible:
- To obtain informed consent on a case-by-case basis for the secondary sharing of data on such a hub;
- A broader mechanism of consent, or even presumed consent, to the sharing of data for public interest purposes and within the framework of this secure national system.

The legitimate interest of processing data for public interest purposes, as Professors Anne Laude and Lydia Morlet of the Institut Droit Santé from Paris-Descartes University showed in their contribution, will undoubtedly be an essential consideration for the effective operation of this national hub. It would naturally need to be subject to specific mechanisms of regulation and

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[30] M. Cuggia, D. Polton and G. Wainrib (2018). Health data hub. Report on the feasibility study submitted to the Ministre des Solidarités et de la Santé, 110 p.

supervision involving professionals and representatives of healthcare system users.

Another possible proposal might be worth consideration in this domain: the recognition of "public interest data". The possibility could be explored of opening up certain datasets held by private actors for reasons of public interest, following on from the recognition of the notion of "*public interest data*" by the Digital Republic Act of 2016. In this respect, and in keeping with the conclusions of the Cytermann mission (Dec. 2015), the Villani report recommends consideration of the possibilities of access to private data for public interest purposes, ranging from access for public authorities alone, to access for other economic actors. In parallel, it would certainly be necessary, as also recommended by the Villani report, to strengthen public rights over data in order to adapt the protection of fundamental rights and freedoms to new practices, in particular with the aim of guaranteeing the protection of a right to nondiscrimination.

An ethical middle way needs to be found between the imperatives of protecting health data and the need for the sharing of these data in order to enhance the quality and efficiency of our healthcare system. The President of the Republic's announcement of a plan for a "national hub" for health data represents an interesting move in this direction, provided that the principles governing data acquisition and security, and the operation of the instrument, are clearly defined.

5) The risk of increasing inequalities within the healthcare system

In its aforementioned report, CNIL notes that *"algorithms and artificial intelligence can introduce bias, discrimination, even forms of exclusion."*

In its previously mentioned report, CNOM refers to the difficulties of accessing healthcare associated with the *"digital divide"*. It therefore recommends that efforts should be made, in particular investment in equipment, in order to bring access to high-speed Internet to the whole country. The purpose of this is to guarantee equality of rights in the uses of digital technology. According to CNOM, *"these efforts must be accelerated, in particular in vulnerable areas, in order not to introduce a further digital divide in access to health innovations and healthcare. Specific attention needs to be paid to the French overseas departments."*

The Ordre des médecins also takes the view that it is *"imperative that the anticipated progress in the technologies of artificial intelligence, big data, and robotics should benefit everyone and should not exacerbate social, socio-economic, or cultural divides. Our society, in its democratic and republican organization, must ensure in particular that the progress that these technologies may bring, in the screening and enhanced understanding of disease and disease risk, should not undermine our solidarity-based model of social protection, but should contribute to reducing inequalities and the risks of exclusion."*

The Conférence nationale de santé (CNS — National Health Conference) addressed this question in its position paper of February 8, 2018.[31] CNS called for *"the resolute pursuit of the digital transformation of our healthcare system, by employing the essential instruments capable of facilitating access for all: this means training users (and also providing help for those who need it), training professionals, guaranteeing digital coverage across the country and access for every individual to their DMP (personal medical file)."* CNS also recommends that connected applications and objects should be used as an instrument for combating health inequalities by *"developing information and evaluation by users, by supporting research in fields where the market would not spontaneously go."*

The uptake of digital technology in healthcare can have potentially significant effects on health inequalities, both reducing and, in certain cases, exacerbating them. It is therefore indispensable to monitor the implementation of digital technology in healthcare in order to ensure that its adoption contributes to reducing these inequalities.

6) The ethical issues more specifically linked with the spread of algorithmic medicine

Two major ethical issues associated with the spread of algorithmic medicine have been identified: the delegation of informed consent to an algorithm and a reduction in the responsiveness to personal situations.

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[31] Conférence nationale de santé (2018). Faire en sorte que les Applications et les Objets Connectés en santé bénéficient à tous. Avis établi à l'issue d'un processus de débat citoyen, élaboré en lien avec le CNCPH et le CNLE, 28 p [National Health Conference (2018). Ensuring that everyone benefits from Connected Applications and Objects in Healthcare. Position paper produced following a public debate initiative, undertaken in association with CNCPH and CNLE]

The delegation of informed consent to an algorithm

The spread of digital technology in healthcare may come with the risk of undermining the reality of patient consent. Indeed, since digital technology and algorithmic medicine rely on big data that can demonstrate its effectiveness in terms of care quality and efficiency, what will remain of the reality of patient choice when giving consent for treatment?[32]

These risks concerning the real involvement of patients in decisions concerning their care are highlighted in the contribution addressed to the taskforce by *France Assos Santé: "artificial intelligence is now about to burst into the relations between caregiver and patient, raising new ethical questions. The question is not whether we should fear or place excessive trust in Artificial Intelligence. While it without any doubt increases our capacities for medical analysis, the challenge is simply — but to the highest degree — to ensure that we work to readjust the relations between patients and health professionals. As things stand, we are afraid that the algorithms used take little or no account of the complexities of the dimensions of patient preferences and of the number of psychological factors involved, thereby introducing a new form of domination into the power balance between medicine and patience."*

More broadly, in its previously mentioned report, the Ordre des médecins recommends *"that the development of technical devices that employ artificial intelligence should be encouraged to move in the direction of an industrial market for decision support in medicine, rather than algorithms that dictate decisions to both doctor and patient, without the option of critique or contravention."*

Reduced responsiveness to personal situations

Digital technology highlights and headlines a question that has long been asked in the field of epidemiology, concerning the applicability to individuals of results obtained from population groups.

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[32] In a way, this is already true for decisions based on clinical practice recommendations or protocols; the principles applied were developed some 30 years ago by David Eddy, in particular, emphasizing the need to take into account both uncertainties and variability in the preferences of patients (Eddy, D. M. (1990). Designing a practice policy. Standards, Guidelines and Options. JAMA, 263 : 3077-3084. 10.1001/jama.1990.03440220105041.); these principles were taken up in approaches that promote "shared decisions": https://www.hassante.fr/portail/upload/docs/application/pdf/201310/12iex04_decision_medicale_partagee_mel_vd.pdf

This ethical issue is intertwined with the very nature of algorithms, which depend on computations of probabilities arrived at through the processing of mass data.

In the health sphere, therefore, there is a risk of the application of mechanisms — on an undoubtedly unprecedented scale — that reduce the responsiveness to specific personal circumstances and place reliance on an analysis that is perceived as universal in scope.

Two major ethical challenges associated with the spread of algorithmic medicine have been identified and require regulation:

*-   **The risk of depriving patients** — in practice by the "delegation of consent" — **of a significant part of their capacity to participate in the construction of their healthcare pathways** as a result of the role of algorithms in decision-making;*

*-   **The danger of a loss of responsiveness to personal situations** as a consequence of the reliance on reasoning based on models that may be limited in their capacity to take individual patient characteristics and preferences into account.*

7) Digital technology and avoidance of the healthcare system

Digital tools can be used by patients as a means of "bypassing" the traditional forms of access to the healthcare system.

There are now numerous ways in which people can access health information online. This increasing availability of information can be seen as contributing to an overall movement towards greater empowerment of citizens in the management of their health. However, it also exposes them to risks of disinformation or of mistakes in their approach to the healthcare system. In another respect, the broadening of access to remote consultation services not covered by Social Security increases the risk of deepening health inequalities with the *de facto* creation of a "two-speed system", where digital access to some healthcare is confined to those who can afford it.

As well as being an instrument for bypassing the traditional means of access to the healthcare system, digital technology has also led to the **development of forums or groups through which citizens can rate the performance of professionals in the health and medico-social sectors.**

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Online evaluation of health professionals is a source of transparency for citizens, but also a potential source of destabilization for professionals. In fact, CNOM has just addressed this topic with the publication of a guide to good practices.

*Digital technology, as a means of avoiding the traditional channels of access to information and healthcare or of sharing evaluations of practitioner performance, **constitutes a source of freedom and transparency for citizens, but also of destabilization for our healthcare system and health professionals**. These phenomena need to be carefully monitored, in particular to maintain the imperative of healthcare quality and safety that citizens have a right to expect.*

8) Digital technology and research in healthcare

The digital revolution in healthcare research relies in part on the possibility of reusing — for the purpose of interventional or observational studies — data from multiple sources: research data, treatment data, data from connected devices, from large administrative databases,…

- Sharing and reusing data from interventional research (clinical trials, therapeutic trials) or observational research (cohorts, registers) entails transposing the principle of access to research data into the healthcare field ("FAIR: findable, accessible, interoperable, reusable", Ohmann et al. 2017)[33] .
- Using data from treatment, from healthcare systems (electronic hospital files, data generated by connected objects, data from national databases) or from other big databases (in particular social or professional databases) raises technical problems (data formats and interoperability, traceability, quality, security, and need for an approved host for health data), but potentially represents a major advance by avoiding the duplication of data collection, which is one of the main factors that determines the cost of clinical trials, patient cohorts, or surveys (cross-sectional, cohort, intervention studies) conducted in the general population.

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[33] Ohmann *et al.* (2017). Sharing and reuse of individual participant data from clinical trials : principles and recommendations. BMJ Open ;7 : e018647. doi:10.1136/bmjopen-2017-01864

This nevertheless raises the question of consent, of withdrawal, and the risks of people being reidentified from reused data.

- With regard to the reuse of research data, it is important to be aware that the **unit here is not the patient, but the study.** If it is not possible to obtain the consent of all the patients who took part in a cohort or a clinical trial, subsequent analyses (reanalysis, meta-analysis, secondary analyses) will be exposed to a risk of distortion that would undermine their validity. For example, the withdrawal of consent for the reuse of data by patients who had experienced a negative side-effect would seriously skew results towards a better risk-benefit analysis. The same risk of distortion would arise if the investigator had to obtain individual consent for reuse from patients. It is therefore important that consent for the reuse of data should be obtained (on a separate consent form from that used for participation in the trial or cohort) **before the beginning of the study, with a limited possibility of withdrawal for legitimate reasons,** and in the form of a truly **broad consent, authorizing all reuses** for purposes of medical and health research, **following approval by the appropriate operational ethics committees.**

- In the case of treatment data, distortions can also arise from consent or non-consent, insofar as non-consent can affect the representativeness of the sample. Worse still, the possibility of retrospective withdrawal of consent opens the door to distortions if the withdrawal is related to satisfaction. It is therefore important that **consent should be obtained before treatment is given** so that the patient's satisfaction does not affect their decision to consent or maintain consent, which would otherwise be a major confounding factor.

- The patient's consent must be informed, and it is therefore important, in order to establish trust and empower patients, to tell them how the data will be shared, which implies that the data sharing plan should be an integral part of the research protocol, and that the conditions of sharing (identity removal, register, control of access, etc.) should be set out in detail in the information sheet provided before consent is obtained. The vast majority of patients understand the benefit of sharing data (93% in the survey by Mello et al., 2018).

- Identity removal can be reversible (pseudonymization) or irreversible (anonymization), and in the latter case the data are no longer

considered personal and therefore are not covered by the GDPR (i.e. do not require consent and can be freely accessed), provided however that there is no risk of re-identification, which in practice — given the possibilities of cross-referencing data — is difficult, if not impossible, to guarantee. If reducing this risk demands the removal of large quantities of data that could potentially be used for reidentification (e.g. an adverse side-effect in a clinical trial), the utility of these "anonymized" data would be greatly attenuated. It would therefore be desirable to provide the scientific community with **standard anonymization procedures that as far as possible safeguard the content of the data and are combined with the proscription of any attempt at reidentification. The continuing risk of reidentification means that the possibilities of access to these sensitive data must be monitored and managed.**

This analysis, which agrees closely with the findings of CCNE's *Big Data* working group, leads us to the following joint conclusions:

The sharing of research data according to 'FAIR' (findable, accessible, interoperable, reusable) ***principles is a crucial factor for the development of world-class scientific research in healthcare*** *and in helping to guarantee the reproducibility and validity of results. Moreover, in the field of health research, access to data from healthcare itself, from healthcare systems, or from other personal databases, represents a major advance by avoiding the duplication of data collection, which can significantly increase the cost of intervention research (clinical trials, therapeutic trials) or observation research (cross-sectional studies, cohorts). It would therefore be good practice, as far as possible, to have a consent procedure that enables people to authorize the sharing of their data in the knowledge of* <u>*how*</u> *they will be shared (sharing plan), rather than* <u>*why*</u> *(by whom and for what research).* ***It is also important to acquire the scientific, technical, and regulatory resources to control the risks of people being re-identified from databases in which direct identifying information has been removed*** *and to support the development of ethical tools for the regulation of access to sensitive data.*

One of the keystones of the ethical deliberation undertaken here is the strong tension between the values of protection and the values of sharing. It will be very usefully complemented by CCNE's forthcoming position paper on the subject of *Big Data*.

E. What instruments of regulation?

"The regulation of artificial intelligence in healthcare is an issue of national sovereignty within the context of an international technology race. Indeed, while an excessively restrictive regulatory environment would present the advantage of maintaining something of a short-term status quo, it would cede to states with a more flexible framework the capacity to develop their own philosophy on the uses of artificial intelligence in healthcare. It is therefore important that France should be contributing to the development of ideas at international level, and be fully involved in negotiations on future technological standards."

Villani Report: conclusion of the section *"AI for health policies"*

In accordance with the objectives of the engagement letter, the taskforce has a number of recommendations to put forward to CCNE intended to address at least some of the ethical issues identified.

The exercise of maximum restraint in the use of legislative and regulatory instruments to regulate the uptake of digital technology in the healthcare system should be considered a key priority. This recommendation should be considered in the light of the forthcoming revision of the Bioethics Act and in the current legislative and regulatory context, including in particular the transposition of the GDPR into French law.

There are two major reasons for this recommendation:

- **Firstly, the introduction of too many enforceable standards on digital technology in healthcare into our substantive law might further exacerbate the obstacles to the spread of innovation in France.** In fact, as was noted above, as things stand the main problem is the inadequate use of digital technology in healthcare services, research, and data-based management;

- Secondly, **there are practical limitations on the use of enforceable national law as an instrument in a context of accelerated globalization in access to healthcare services.** If we regulate too much in France with the collateral effect of slowing down innovation, there is a big risk that, in the very near future, patients and professionals may demand access to

digital solutions developed in and imported from other countries and under conditions that do not provide sufficient regulatory guarantees.

However, such moderation in the imposition of enforceable national standards does not mean that any attempt to regulate the spread of digital technology in healthcare will be ineffective in propagating an ethical vision commensurate with France's objectives in this domain.

1) Development of the missions and scope of CCNE

In the speech he made following the submission of Cédric Villani's report, the President of the French Republic strongly and repeatedly emphasized the need to consider the ethical issues associated with artificial intelligence.

In his report, the member of Parliament Cédric Villani recommended the creation of a specific ethics body to tackle the issues associated with artificial intelligence: *"The question of ethics in the debate on AI has now taken on such importance that it would seem that there is a need to establish, within an institutional framework, a National Ethical Consultative Committee for digital technologies and artificial intelligence. Such a body could follow the model of the Comité consultatif national d'éthique (CCNE), which has been in existence since 1983 in the fields of life sciences and health. Though separate, these two institutions could nevertheless explore and adopt a joint position on the problems that emerge at the interface between their fields of expertise, issues such as transhumanism, biohacking, or the use of AI for the processing of health data. Moreover, the two committees could have one or more common members, and it should also be understood that the rules of membership need not be excessively restrictive."*

The taskforce took the view that there might be a risk in this proposal of cutting this field off from others connected with digital technology in healthcare. Creating a separate body with a more specific focus on healthcare could potentially lead to a loss of expertise and depth of field for ethical regulation and reflection in this often complex and very fast changing domain. How, for example, could there be generic regulation of digital technology without capitalizing on experience acquired in robotization in healthcare or in the growing role of social networks in the sphere of preventative healthcare?

It may be noted that this change in the role of CCNE would be consistent with the op-ed published in *Le Monde numérique*,[34] but also that the important and acknowledged part played in France by CCNE for the life sciences and for health could be extended beyond digital sciences, technologies, and uses, to the ethical problems of the environmental sciences or of training, themselves closely linked with those relating to digital technology or healthcare.

From an operational perspective, this shift could be achieved by broadening the terms and references of CCNE in the next Bioethics Act. The establishment of an equal "digital" jurisdiction would be a first step. This would typically enable CCNE to handle referrals relating to digital technology in health, as discussed in this report, but also, for example, to address the ethical issues associated with autonomous vehicles, with digital technology in education, or with autonomous weapons with lethal capacity. The committee college could, where necessary and in accordance with the revised rules, set up ad hoc working groups to tackle different referrals, and thereby develop its positions with the input of appropriate experts.

Moreover, the taskforce took the view that the term "consultative" is redundant in the title, even with respect to the committee's current activities. It therefore reached the following joint conclusion:

*The **Comité Consultatif National d'Éthique pour les sciences de la vie et de la santé** (CCNE — National Ethical Consultative Committee for life sciences and health) should evolve into a **Comité National d'Éthique** (National Ethics Committee), a body with the capacity to work on ethical issues relating not just to life sciences and health, but also to digital sciences, technologies, practices and innovation. If necessary it should be able to address the ethical problems relating to other scientific disciplines.*

A corollary of this development would be that the terms of reference of CCNE would be broadened in the next Bioethics Act.

[34] https://www.lemonde.fr/idees/article/2017/12/14/il-faut-creer-un-comite-national-d-ethique-dunumerique_5229661_3232.html

2) Differing approaches to the ethical issues associated with digital technology in healthcare at international and European levels

The ethical issues associated with digital technology in healthcare, and the methods of regulating those issues, are understood and addressed differently at European and international levels. An analysis of this international diversity of approach is undertaken in an appendix to this report. This analysis concludes that, **with the implementation of the GDPR, the European Union is already one of the areas in the world where the spread of digital technology and data protection are subject to the greatest legal regulation.** By way of an example of this difference in the levels of regulation and risk associated with time differences in the spread of innovation, in April 2018 the US *Food and Drug Administration* (FDA) issued the first official license for a working digital solution applicable to image recognition for the diagnosis of diabetic retinopathy.[35]

The previously mentioned Hall-Pesenti report argues that the increased use of artificial intelligence could have very beneficial social and economic effects in the United Kingdom.

According to the guidelines formulated for the continuing development and application of AI, the report asserts that the UK will need to increase the ease of access to data in a wider range of sectors. The review recommends to:

- develop data trusts in order to increase confidence and ease around sharing data;
- make researches in machine learning more readable and accessible;
- support text and data mining as a standard and essential tool for research.

The ethical issues of digital technology in healthcare are dealt with very differently at European or international level, but there is a consensus on the need to take practical measures, which should be as evolutive as possible, to **ensure the reliability of digital applications and control of their use**.

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[35] This condition, which affects 50% of patients with type II diabetes, is caused by high blood glucose levels, which damage the blood vessels in the retina. In France, it is the primary cause of blindness in people under the age of 65, according to the FFD (French Diabetics Federation). The device approved by the US agency, named IDx-DR, is able to detect diabetic retinopathy (mild to advanced) using an algorithm that screens for ophthalmic disorder by analyzing photographs. It is authorized solely for adults over the age of 22 (W. Zirar (2018). La FDA autorise le premier dispositif médical utilisant l'IA pour dépister la rétinopathie diabétique, TICpharma.com, April 17)

3) A debate on regulation nevertheless needed at national and perhaps above all at European and international levels

France needs to develop appropriate instruments to support the establishment of vehicles for regulating the spread of digital technology in health. The matter can be divided into two layers.

Support for research on the regulation of digital technology in healthcare

As can be seen, the spread of digital technology in healthcare raises issues that are multiple and complex, and deciding on the right level and the right intensity of regulation demands input from a wide range of disciplines. **In order to ensure that digital innovation in healthcare spreads effectively and responsibly, sustained research is needed into the regulation of this process.**

As part of the public consultation undertaken by Cédric Villani, the Ethik-IA initiative put forward an initial proposal that one such vehicle could be a **Foundation to support applied research on the ethical, legal, and social regulation of the spread of robotization and AI in health.**

Engagement by France in the development of regulatory standards at European and international levels

France, which was a frontrunner in building the legal frameworks applicable to data protection or telemedicine, needs to take the initiative in the development of a system of adjustment to digital technology in healthcare that reflects the demands of a democratic society.

This initiative cannot be restricted to the national level. It would benefit from being taken up at European level.

Initiatives also need to be pursued at international level. In this respect, the project for a "COP for AI" proposed by Professor Guy Vallancien would certainly be worth pursuing. Such a "conference of the parties" would establish a multilateral framework for discussion of these questions. Nonetheless, the disparities in approach between countries with regard to the necessity and the nature of regulation on the spread of digital technology in healthcare suggests that progress is first likely to happen at the European level, where the example of the GRDP shows that a community dynamic on these digital issues is possible.

The response to the ethical challenges associated with the spread of digital technology in healthcare will be enhanced by adopting an international — and initially European — perspective. Nonetheless, there is still an essential role for the national level, since the implementation of a flexible normative system of regulation at European level will require a strong initiative on the part of government to support the joint construction of regulatory tools appropriate to national needs.

4) Possibilities of regulation for the future legislative process

So, while the taskforce took a strong position in favor of legislative moderation on digital questions at the time of the revision of the Bioethics Act, this preference should not rule out all legislative initiatives. Under the "Ethik IA" initiative mentioned previously, *"5 keys to regulation"* were proposed for the dissemination of artificial intelligence and robotization in health. This tool — set out in an appendix — identifies the normative elements already present in substantive law and those which, where appropriate, might be included in the revised Bioethics Act.

There needs to be better compliance with legislative principles or standards already in force in order to tackle the issues of digital technology

It should be possible for individuals to be informed in advance when a digital device will be used in their future healthcare program. In its ruling 2018-765 DC on *"Law relating to the protection of personal data"*, the Constitutional Council specified that **the person should receive advance information on the use of an algorithm as the basis for an individual administrative decision**. The principle of doctors giving their patients advanced warning about the use of an algorithm therefore seems consistent with this constitutional interpretation. A specific statement to this effect in the upcoming Bioethics Act would, however, emphasize the importance assigned to medical decision-making.[36]

The digital device should not undermine the importance ascribed to obtaining the patient's informed consent. Specific procedures — such as the

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[36] Alongside this, there should be an awareness of the practical necessity of not making the process of obtaining consent for these digital devices excessively specific and fragmented, whereas the principle of informing patients of all the factors entering into decisions about them is a major principle of informed consent for treatment.

use of a trusted person, or of arrangements for obtaining advance consent for a set of treatment options, or stronger protective measures for vulnerable people — should, where needed, be developed to guarantee that consent is genuinely obtained.

Several new legislative provisions could beneficially be introduced into the upcoming Bioethics Act

The inclusion of a "Human Warranty" principle on digital technology would place France in a positive position as an international pioneer.[37]

The principle of a Human Warranty of digital systems in healthcare must be followed. This guarantee could be upheld firstly by regular processes — both targeted and random — to verify the treatment options proposed by the digital system and, secondly, by arrangements for a second human medical opinion to be sought at the request of a patient or a health professional, and finally by the recognition of the need to maintain the ultimate prerogative of the health professional, in interaction with the patient, to take the decisions appropriate to each specific situation.

In the course of his contribution, Pascal Jacob, Chairman of *Handidactique*, placed great stress on the importance of human principles being applied when using digital technology in the case of people living with a disability. The goal must be that digital technology should assist people with disabilities in their quest for autonomy.

With respect to medical practice itself, Dr Jean-Paul Ortiz, Chairman of the Confédération des syndicats médicaux français (CSMF — Confederation of French Medical Federations), highlighted the fact that the spread of digital technology could facilitate a return to humanism in patient care, after a phase

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[37] In its previously mentioned ruling 2018-765 DC, the Constitutional Council argues that an algorithm cannot constitute an "exclusive" parameter in the taking of an individual decision. The Council noted that the person responsible for treatment must ensure that the algorithmic treatment and its developments are managed, so that it is possible to explain to the person concerned, in detail and in intelligible form, how their treatment was given. The result is that algorithms that are capable of revising the rules they apply — i.e. Machine Learning algorithms — cannot be used as the exclusive basis for an individual administrative decision, unless monitored and validated by the person responsible for treatment. This interpretation by the Council should probably not be seen as proscribing the use of any artificial intelligence process that entails a degree of autonomous decision-making. In fact, a whole series of processes of this type are already operating today in our healthcare system, especially in the case of medico-technical platforms. This ruling should probably be understood as a call for human supervision of the performance of an algorithmic decision-making system, but also as a reminder of the need to maintain a human intelligence in charge of decisions, in order to take into account specific factors that the algorithm would not have considered.

of relative blindness associated with the promotion of a "medical technician" culture.

This general principle should also be applied in practice to define a new phase in the progress of telemedicine, so-called "human warranteed" telemedicine, a notion developed by the Société française de télémédecine whose Chairs, Nathalie Salles and Thierry Moulin, were also interviewed. Its principle is simple: in the event that the patient or the treating physician should be in any doubt about a diagnosis reached by an algorithm, a new form of tele-expertise would be recognized, whereby a second medical opinion could be delivered by a human being.

In addition, it would be advantageous to introduce a legislative measure to provide a framework for a system of professional standardization. The taskforce took the view that specialist medical oversight by the *Haute Autorité de Santé* could be appropriate.

With respect to the next Bioethics Act, it is desirable that the fundamental principle of a Human Warranty of digital technology in healthcare should be entrenched in law.
With regard to the equally fundamental principle of obtaining patient consent (for the collection of health data and for the treatment process itself), the substantive right — in all its stringency — remains appropriate. Nonetheless, this substantive legislative right would benefit from additional new or updated practical tools to guarantee that such consent is actually obtained (sequential consent arrangements, revival of the trusted person concept, stronger procedures for vulnerable individuals...).
The creation of a secure national hub for the collection and processing of health data represents a useful method of connecting together the different ethical issues relating to health data. The decision on how data would be fed to this hub would fall within the legislative arena if a political intention was expressed for the creation of a mechanism of presumed consent in the case of a public health interest, of the kind that exists for organ donation.

5) Instruments of regulation that do not fall primarily within the legislative and regulatory domain

Digital technology in health: approach to the issues of legal liability

The Villani report calls for a *"clarification"* of the liability of health professionals in the use of AI. However, as things stand, the question of the impact that the use of digital technology in healthcare might have on medical liability has received relatively little attention.[38]

From a global perspective, **this question is broadly and judiciously covered by existing law relating to liability for damage or injury caused by things in one's custody and for damage or injury caused by defective products.**

So while it has so far been possible for these major transformations in the foundations of medicine — both somatic and psychiatric — to be validly interpreted within the framework of liability law, by the system of liability for damage or injury caused by things in one's custody, the new generation of algorithms has upset the applecart. The current technological changes are creating conditions in which a change in the legal approach is needed.

The use of learning algorithms may result in the system of liability for damage or injury caused by defective products becoming partially inoperative. Indeed, the notion of development risk represents a reason for exemption from liability. This is a risk that arises from product defects that could not be anticipated at the time a product was designed in the then prevalent state of scientific and technical knowledge.[39] We could find ourselves in precisely this situation in the case of damage or injury caused by developments "self-generated" by an algorithm beyond its initial programming, on the basis of inferential reasoning. The first practical applications of machine learning techniques in the health sphere have shown that these possibilities of damage or injury are not at all theoretical and could be expected to increase significantly.

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[38] D. Gruson (2017). Les robots et l'intelligence artificielle vont-ils décider de l'avenir de nos corps ? La revue hebdo, Lexbase Privé, n° 723, 14 décembre ; J. Petrelluzzi et M. Miliotis (2017). L'intelligence artificielle : ses enjeux en droit civil européen, Editions universitaires européennes, 141 p.

[39] Pascal Oudot (2005). Le risque de développement : contribution au maintien du droit à la réparation, Editions universitaires de Dijon, 360 p.

This development should lead to general reflection on the organization of professional liability regimes, which in recent years has been characterized by the emergence of regimes that attribute an ever smaller role to the notion of fault on the part of medical and paramedical teams. The use of digital objects may therefore "slot" into this general organization, leading to the emergence of a new category of compensation regimes that is not directly based on the actions of the professionals themselves.

This raises the question of the potential basis of a possible system of compensation for injury caused to bodies by an algorithmic object. Given the possible scale of the issue, one might reasonably think that national solidarity alone would not be enough. Broader risk pooling schemes, at European and perhaps international level, may perhaps have to be considered. A consultation process on this is in fact currently underway, initiated by the European Union institutions.[40]

The establishment of a general framework of compensation for injury that may be caused by digital objects does not seem to be an immediate priority in the revision of the Bioethics Act. This issue is worth examining in depth in a context where damage and injury, as things stand, remain relatively well covered by liability arrangements relating to damage or injury caused by things which are in one's custody and caused by defective products. Given the potential scale of the issue in coming years, it would be desirable if a framework specifically designed to cover injury caused by digital objects was developed at least at European level.

Regulation and soft law (self-compliance and voluntary certification)

The ruling on December 7 last by the European Court of Justice notably circumscribed national capacity for regulation on digital innovation in the healthcare sphere.[41] This Community framework therefore opens the door to methods of regulation that do not entail enforceable law.

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[40] European Parliament (2017). Report with recommendations to the Commission on Civil Law Rules on Robotics (2015/2103(INL)). Committee on Legal Affairs.

[41] The Court of Justice of the European Union (CJEU) was called upon to rule on a prejudicial question regarding whether a software program for prescription support meets the definition of a medical device, if that program provides at least one function that can be used to process data specific to the patient for the purpose of helping the doctor to establish a prescription, in particular by detecting contraindications, drug interactions, and overdoses, although it does not of itself act in or upon the human body (CE, June 8, 2016, n° 387156). In a ruling of December 7, 2017, the CJEU answered that a software program that has a function that enables the processing of data specific to a patient, notably for the purpose of detecting

In its aforementioned report, CNOM takes the view *"that we should not try to make laws about everything, or seek to regulate everything by ministerial order. Instead, it recommends that qualified entities should produce flexible legal rules, modelled on the "soft law" of Anglo-Saxon countries."*

In the same way, the Villani report notes, more specifically with reference to AI, that the *"speed of change and democratization of the uses associated with artificial intelligence in healthcare demands that the authorities adapt quickly, or risk watching powerless as the issues of public health and medical practice are entirely reformulated. Indeed, overregulation would maintain the existing balances in the short-term, but would expose us to a loss of control over desirable changes in our health model."*

The work of the taskforce confirmed these risks of a disconnect between advances in research on digital technology in healthcare and their conversion into applications useful to patients. An early legislative or regulatory obstacle could stop potential progress in its tracks. Moreover, as was revealed in the hearing with Professor Olivier Amédée-Manesme, Director of *Paris BioTech*, it could increase the cost of innovation and lead to an international exodus of French digital innovators in health.

The Villani report also argues *"the systems that implement AI take decisions based on models constructed from data. This means that protocols must be developed, incorporating new metrics, that can be applied to data, to performances, to interoperability, to usability, to security, and to confidentiality."* A process of certification and of measurement, to assess the real utility of these applications, is particularly necessary in healthcare applications where the cost-benefit ratio needs to be evaluated.

Nonetheless, despite their utility, certification and standardization work in artificial intelligence for health and health robotics remains, for the moment, in a very fragmentary state.

The approach pursued by the *Imagine* University-Hospital Institute to produce a prototype standard for the good use of artificial intelligence applied

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contraindications, drug interactions, and overdoses, constitutes, by virtue of that function, a medical device under the terms of Directive 93/42/CE of June 14, 1993, even though the program does not act directly in or upon the human body. In this ruling, the CJEU also takes the view that CE marking constitutes a necessary and sufficient condition for the device to be put into service, thereby rendering superfluous the additional prior national licence that had been intended by the French legislature of (Sources: J. Peigne (2017). Un logiciel d'aide à la prescription est-il un dispositif médical ? Editions législatives, December 8; V. Granier (2017). La CJUE sonne le glas de la certification des logiciels d'aide à la prescription, TICpharma.com, December 19).

to genetic data, provides a concrete example of the value added by the possibility of standardization in this domain.

There needs to be a strong initiative within the next few months to trigger a dynamic for the practical creation of soft law type instruments of substantive regulation applicable to the spread of digital technology within our healthcare system.

Regulation and management (anticipation of the effects on health professions, digital corporate social responsibility)

The effects of the spread of digital technology in general and of artificial intelligence and robotics in particular may be particularly significant for jobs in the healthcare and medico-social sectors. These potentially major changes were clearly indicated in the previously cited *France Stratégie* report. As Salima Benhamou pointed out, digital corporate social responsibility also needs to be seen as an instrument of global performance, in other words organizational, economic, and social performance. According to a survey conducted by *France Stratégie* with more than 8,500 French companies,[42] the average economic gains (measured in particular by added value and net profit) arising from responsible practices in organizations were estimated at 13% on average for economic gains, and 20% specifically with regard to the "responsible" practices associated with the introduction of managerial practices (participation, collaborative management, teamwork...) and of management measures focusing on the anticipation of the skills needed to adjust in particular to technological and organizational changes.

Investment in regulating the implementation of digital technology will should therefore be recognized as a new form of corporate social responsibility (CSR). The decision to invest in a responsible framework for the use of digital technology is in fact an integral part of the broader trajectory of sustainable development as a whole.

In reality, nothing contradicts this recognition of the CSR perspective as defined in law. In its third report on CSR in 2011, the European Commission thus defines it as *"the responsibility of companies for the effects they have on society."* ISO 26000 guidance on CSR adopts the same position. The introduction of digital technology into a company or a given business sector undoubtedly produces major effects for society as a whole. Approaching this

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[42] S. Benhamou and M-A Diaye (2016). Responsabilité sociale des entreprises et compétitivité. Évaluation et approche stratégique, France stratégie, http://www.strategie.gouv.fr/publications/responsabilite-sociale-entreprises-competitivite

process ethically and responsibly can therefore be seen as an instrument in its own right through which a socio-economic entity exercises its social responsibility. From a practical point of view, this new form of CSR linked with responsible digital technology can take various forms: adaptation of initial and lifelong learning tools and forward management of jobs and skills; engagement in systems of self-compliance and voluntary self-certification; support for research on regulation...

More broadly, a strong initiative to better anticipate and manage the effects that the spread of digital technology has on the healthcare and medico-social professions should be a priority.

In its previously cited report, CNOM *"considers it essential to begin immediately to train doctors for the world in which they will practice, where technologies — alongside clinical practice — will play a big role."* It also recommends that *"in the initial training syllabus, as well as subsequently in continuing professional development, simulation using interactive digital methods should be more widely practiced, as a way of learning to respond to situations, to practice technical skills, or to conduct an investigation."* Finally, CNOM recommends that *"in making demographic decisions about the training of different medical specialists in university faculties, and about the content of those training paths, the foreseeable changes in professional disciplines should be taken into account."*

For its part, the Villani report suggests *"training health professionals in the uses of artificial intelligence, of the Internet of Things (IoT), and of big data in healthcare, as well as in the skills of coordination, empathy, and relations with patients."*

With regard to the possibility of a "disruption scenario", the previously cited report by *France Stratégie* notes that *"in the health sector, the arrival of newcomers to the healthcare "market" is controlled by the state (planning of hospital services, numerus clausus). However, there are other competitive players, international in scale. The drug and medical devices industry is a vehicle for the spread of AI into the health sector, notably through mobile applications incorporated into treatment protocols. Applications that can demonstrate high added value in terms of healthcare gains or quality of life could achieve dominance in patient treatment pathways."*

The effects of such a major change on professions in the health and medico-social sector should be considered closely and attentively, in particular with an eye to creating new monitoring and anticipation mechanisms.

The aim of these measures would be to assess the risks of substantial job losses or changes, but also the possibilities of creating new professional disciplines (for example in the different fields of Data Management or in the reinforcement of the human relationship between caregiver and patient).

These systems would benefit from the inclusion of **forms of shared governance between users of the healthcare system and health professionals**.

In his contribution to the taskforce, Professor Jean Sibilia, Chairman of the *Conférence des Doyens de Faculté de médecine*, placed great emphasis on the need for initial medical training programs to include modules that raise awareness about the ethical and practical issues associated with the use of algorithms in medicine. Simulation-based training techniques could be a very useful instrument for this purpose. As mentioned above, the establishment of a comprehensive French strategy on the use of digital technology in medical training, through the vehicle of UNESS, holds promise of significant progress in this respect.

Professor Jean-François Meder, Chairman of the *Société française de radiologie* (SFR — French Radiology Society) and Dr Jean-Philippe Masson, Chairman of the *Fédération nationale des médecins radiologues* (FNMR — National Federation of Medical Radiologists), told the taskforce about the ways radiologists were seeking to adapt their professional practices positively in order to incorporate the contributions of artificial intelligence.

The effects that the adoption of a digital system will have on the conditions of professional practice in the health and medico-social sectors need to be anticipated with supportive measures. Public and private actors should be further encouraged to adapt the training — both initial training and continuing professional development — of healthcare personnel to the challenges of digital technology and to support the emergence of new professions associated with the spread of digital technology in the health and medico-social sectors. The very large mismatch that currently exists between our system of initial training and continuing professional development and the challenges associated with the spread of digital technology is a serious problem for our healthcare system. Initiatives — such as those of the Conférence des Doyens de Faculté de médecine and of UNESS — are in preparation to remedy this situation and should be encouraged.

F. Glossary of certain terms relating to digital technology in healthcare

Artificial intelligence (AI): Originally, in 1956, the aim of AI was to simulate human cognitive faculties on computers it encompassed scientific approaches in computer science and mathematics, at the leading-edge of cognitive sciences such as knowledge representation, machine reasoning, problem-solving with constraints, optimization, automatic language processing, computer vision or machine learning. Today, the term AI is often used in the generic sense of "digital technology", but it also tends to be used to refer to machine learning, or even deep learning.

Weak artificial intelligence: Specialized AI, which concentrates on the performance of a specific task (e.g. image recognition, playing *go* or chess). This is the type of AI used particularly in medicine today.

Strong artificial intelligence: Artificial general intelligence (AGI), with capacity that is not limited to certain domains or tasks. Today, scientific and technological developments in this type of AI do not yet have real-world applications.

Algorithm: in the strict sense, description of a finite and unambiguous sequence of steps (or instructions) used to obtain a result based on initial input data. In today's digital world, computer algorithms can combine multiple kinds of data to produce a wide variety of results: simulating the propagation of influenza in winter, recommending books on the basis of choices made by other customers, comparing digital images of faces or fingerprints...

Big Data: extremely large datasets. These datasets have become so large that they are beyond the capacity of individual cognitive faculties alone, and require massive computing power. The term covers information originating from a multitude of sources, public or private, local or global.

Data anonymization: outcome of the processing of personal data in such a way as to irreversibly prevent any identification of individuals. It allows databases to be used while respecting individual rights to data protection.

Pseudonymization: outcome of the processing of personal data in such a way that these can no longer be linked to a specific person, without drawing on additional, separately stored, and protected information.

Health data (or personal health-related data): set of all available data (physical examinations, biological samples, data from medical imaging, genomic data) relating to the past, present, or future health, physical or mental, of a natural person. These data may be collected within a healthcare framework, but also by institutions associated with the healthcare chain (health insurance, hospitals...) and, more recently, by a range of online and connected tools that are unconnected with the health sector.

Consent: in the medical sphere, everyone must be presumed capable in principle of receiving information and giving "free and informed" consent to a proposed medical procedure, unless it has been established that the person lacks this capacity. The information must be "loyal, clear, and appropriate." The person giving consent must be able to comprehend (clarity of understanding or intellect) and to decide freely (self-determination).

Medical confidentiality: this is a requirement for all health professionals (medical and paramedical personnel), who must maintain the confidentiality of information regarding all individuals they may deal with in the exercise of their profession. Some information can be shared within a single care team.

Confidentiality: "To protect and preserve the confidentiality of information. means to ensure that it is not made available or disclosed to unauthorized entities" (International Standards Organization).

Shared medical file: digital medical file, which enables authorized health professionals to access information useful for the treatment of a patient and to share the medical information relating to a patient with other health professionals. The sharing of data with professionals who do not belong to the same care team requires the patient's consent.

Machine learning: capacity of algorithms to learn from datasets in order to improve the initial performances of computer programs. Recent developments in AI are linked with improvements in these new techniques. A distinction is made between *supervised machine learning* (where input data preprocessed by human beings are fed to the algorithm) and *unsupervised machine learning* (the algorithm processes raw data and develops its own classification).

Robot: a robot is a computer-controlled machine that moves in physical space. A robot acquires data using its sensors, develops an interpretation or interpretations of those data, in order to compute decisions relating to its actions in physical space. A robot can also be a software agent with no physical parts (also called a bot), which acquires data and performs tasks within a computational space. A robot can be programmed to interact with a user, either physically, or via an interface. The generic term robotics refers to the science of designing and studying robots.

Robotization: use of robots to carry out certain tasks.

National health data system: a system encompassing the main existing public health databases: Health Insurance data, health institution activities, causes of death, data on disability, and soon data originating from the supplementary health insurance companies.

APPENDICES

Appendix 1 Composition of the taskforce

The taskforce departed from the usual composition of the standing working groups of the Comité consultatif national d'éthique. It contained both members of CCNE and outside figures attached to independent institutions and ministries.

CCNE members
- Gilles Adda (CNRS)
- Cynthia Fleury (CNAM-Mines Paristech, GHT Paris Psychiatrie & Neurosciences)
- Claude Kirchner (Inria, CERNA)

CERNA members
- Gilles Dowek (Inria and ENS Paris-Saclay)
- Christine Froidevaux (Université Paris Sud / Paris-Saclay)
- Catherine Tessier (Onera)
- Célia Zolynski (UVSQ - Paris Saclay)

Other members
- Agnès Bocognano (France Stratégie)
- Christian-Claude Colas (Ministère des armées)
- Anastasia Colosimo (Fondation nationale des Sciences Politiques)
- Jacques Demotes-Mainard (DGRI/MESRI)
- Alain Fontaine (DGS/MSR)
- David Gruson (Cour des comptes)
- Clothilde Huyghe (DGOS)
- Benoit Le Blanc (DGRI/MESRI)
- François Lemoine (DGOS/DIRECTION/CONSEILLERS MED)
- Jacques Lucas (Vice Président de l'Ordre des Médecins)
- Marie Martin (DGS/SG/DDUAJE)
- Frédéric Séval (DGS/SG/DDUAJE)
- Stéphanie Seydoux (IGAS)

Associate members
- Julia Petreluzzi (PhD candidate in artificial intelligence law)
- Vincent Puybasset (CCNE Chargé de mission / Trainee student civil servant at ENS de Lyon)

Appendix 2 Some bibliographic resources

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Appendix 3 Recommendations of the Villani report for healthcare

AI as the servant of medicine

- A specific new project should be launched, connected with the Shared Medical File (DMP) for the production of health data and information that can be used for AI purposes in order to improve healthcare and healthcare coordination, but also to contribute to AI research and innovation projects in healthcare. Linked to the DMP, the latter would be expanded as a secure space where individuals could store their data, add further data, authorize their sharing with other parties (doctors, researchers, friends and family, etc.) and recover them for other purposes;
- Tools and technologies should be employed to automate the encoding of information produced by patients in forms that can be used for medical monitoring. This point would need to be combined with the task of standardizing medical information;
- Patients should be given education on managing their data (data literacy applied to health).

A shift to patient-centered medical practices

- The channels into medical studies should be transformed: firstly in order to attract a greater diversity of candidates and to include more students specializing in Informatics and AI (creation of a double curriculum, recognition of equivalents), and secondly to put an end to the system of competition throughout the university curriculum, which is counter-productive in developing transdisciplinary coordination and shapes the imbalance in authority relations between doctor and patient;
- Health professionals should be trained in the uses of artificial intelligence, of the IoT, and of big data in health, and should be taught skills in coordinating, empathizing, and relating to patients (e.g. virtual experience to help them better see and understand the lives of patients). This transformation in initial training could take place within the ongoing reform of the undergraduate and graduate programs in medicine being undertaken by the *Conférence des Doyens des Universités de médecine*. It could give rise to changes to the DPF;
- The medical liability of health professionals in the use of artificial intelligence technologies should be clarified: at present, a doctor may be held medically liable because of a mistake or because of an ethical violation (generally conceived as a violation of the obligation to inform patients and of the patient's right to give informed consent for a medical act). As long as the

algorithm or robot is not recognized as an autonomous legal entity, it would be possible to hold the doctor liable for the use of programs, algorithms, and artificial intelligence systems, unless there is a defect in the construction of the machine.

Establishment of a health system platform designed for AI-related uses

- A platform should be created where data relevant to health research and innovation can be accessed and shared (initially encompassing medico-administrative data, then genomic, clinical, hospital data, etc.), with the ultimate aim of replacing the Système National des Données de Santé (SNDS — National Health data System). As with the SNDS, the state would be responsible for organizing access to the system on the basis of a number of criteria, such as the nature of the entity, the purpose of the project, and its nature (research, marketing of a service, etc.). It should however be noted that a change of scale in terms of human and financial resources is needed to organize this access efficiently and to ensure that such a system is effectively used and contributes to innovation. The *Institut national de la santé et de la recherche médicale* (INSERM — National Institute of Health and Medical Research), which has particular responsibility for ensuring that data are made available to the research community, must be resourced to perform this gatekeeping role and to tackle demand that is certain to explode;
- Fluid procedures should be put in place for access to this platform in order to develop new AI-based approaches, while closely managing access to the information contained in the system for this purpose. A one-stop shop — in the form of a single online application form — could be created to handle requests to conduct experiments. There should be a guarantee that applications will be processed within three months, along with a "silence means consent" principle. In the event of a disagreement between the regulatory authorities and economic players on decisions concerning access to the sandbox, the possibility of appeal to an independent mediator could be guaranteed;
- A clear system should be developed for access to hospital databases (Hospital as a Platform): hospitals inherit, hold, or build their own databases of molecules and clinical notes. It would be beneficial to encourage hospitals to organize "data science bowls" or challenges around datasets (cf. National Cancer Institute), collaborative projects (e.g. the USA's "national patient-centered clinical research network" — PCORnet). Some services (such as training AI systems on hospital databases) could possibly be monetized;

- The data collected by the platform should extend beyond the medico-administrative domain: data from the *France Médecine Génomique* plan, data from the big national cohorts, clinical and hospital data. The data and systems will need to be interoperable (from hospitals through to the SNDS), a project that could be linked with the development of a technical architecture for the Shared Medical File that is compatible with research and innovation uses.

Regulation of healthcare innovation in the AI age

- New procedures should be tested for qualifying and certifying algorithms intended for use in a medical context, like the FDA Pre-cert program launched in July 2017 by the Food and Drug Administration in the US;
- The framework of ideas and debate on bioethics should be expanded to include issues linked with AI in healthcare and to develop citizen consultation methods that are more regular and more in sync with the pace of innovation.

Appendix 4 Recommendations of the Conseil national de l'Ordre des médecins

1. Technologies should be the servants of the individual and society. "*A person and a society that are free and not subjugated to the technology giants*": this fundamental ethical principle needs to be reasserted at a time when dystopia is and utopias of the most extreme kind are a subject of much media hype. The Order recommends that substantive legal rules be established to protect this fundamental ethical principle.

2. These protective legal rules should be international in scope. France and political Europe should make this one of their main objectives. Technologies exist to serve a societal purpose that reaffirms the essential features of our humanity.

3. It is imperative that the progress anticipated from artificial intelligence technologies, big data, and robotics, should be of benefit to all and should not exacerbate social, socio-economic, or cultural divisions. Our society, in its democratic and republican organization, must ensure in particular that the progress that these technologies bring in the identification and understanding of disease and disease risks, should not undermine our solidarity-based model of social protection, but should contribute to reducing inequalities and the risks of exclusion.

4. In healthcare, technologies should first be used to improve the capacities of doctors and care teams to understand and treat diseases and epidemics better, to support the principle of the autonomy of the individual, to *"heal sometimes, relieve often, console always"* those who are sick, fragile, dependent. [43] CNOM recommends that technologies should not be developed and used with the aim of replacing shared decision-making between doctor and patient, which remains a personal undertaking.

5. CNOM also recommends that the strengths of these technologies should be extensively exploited in all fields of prevention, both primary and secondary, to the benefit of the individual and for the preservation and maintenance of the individual's autonomy.

6. The changes to come are set to be as profound as those that followed the invention of writing, then of printing. This requires an effort of education

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[43] Louis Pasteur

and information, and a widening of the public debate. The debate on the impact of artificial intelligence technologies and big data is not a matter for experts, but concerns all of us. CNOM recommends that the government should organize this public debate, as this is the only way to guide parliamentary deliberations, whether at national or European level.

Ignorance is the first enemy to be fought, since it can leave the door open to the merchants of pseudo-techno-scientific illusions to dupe the over-credulous. The Order therefore recommends that the government should support the emergence of the free public health information service provided for by law, combining the outputs of scientific organizations and the free critical expression of "patient empowerment" and medical blogs, as an expression of healthcare democracy, within the framework of an editorial charter developed with all stakeholders.

7. The Order recommends that care should be taken that a sort of technological determinism does not lead to a state of apparent passivity in which society feels powerless to have its preoccupations heard. It stresses the fact that social or professional concerns that have gone unexpressed, unheard, or inadequately answered, could lead to violent opposition to changes that are too radical, too sudden, imposed, and poorly explained.

8. CNOM recommends that users, patients, doctors, and other health professionals should become involved in the world of data and algorithms, without paralyzing fear or dogmatic enthusiasm. It is by participating in and even contributing to the design and development of intelligent objects and devices with the capacity to meet their needs, that they will be able to give useful guidance to the industrial world rather than allowing market forces to dominate. To these ends, the professional medical and scientific organizations and representative bodies should support the aspiration for a digital healthcare economy in France.

9. Under the government backed National Health Strategy, CNOM recommends that the development of technical devices that employ artificial intelligence should be encouraged to move in the direction of an industrial market for decision support in medicine, rather than algorithms that dictate decisions to both doctor and patient, without the option of critique or contravention. CNOM recommends that the government should support these priorities for the development of the digital economy in healthcare, in particular by activating the potential for consultation represented by the recently established *Conseil stratégique du numérique en santé* (Strategic Council for Digital Technology in Healthcare).

10. Parliamentary studies and think tanks are proliferating,[44] for good reason, with the primary goal of contributing to government action. The Order is playing its part and stresses the importance of transparent information and a wide range of ethical analyses, focusing on the health of individuals, on the practical needs of users of the healthcare system and of professionals, in all their dimensions: medical, medico-social, but also human and social. This White Paper represents a first step in awareness raising that CNOM would like to see extended through public debate.

11. CNOM asks that the technological tools used by both health professionals and patients be reliable, intuitive, and regularly updated by their developers, and that the data they collect and process should be protected from any intrusion. It recommends that a public label be introduced to offer patients and doctors these guarantees.

12. CNOM recommends the promotion of text mining research so that observations and notes can be described simply, and Artificial Intelligence can be used for the purpose of evaluating, measuring, and producing indicators for practice. Similarly, this should be facilitated by devices able to interface with other information systems without the need for coding.

13. CNOM recommends that HAS and the scientific organizations should produce their recommendations in structured formats, and in French, so that software publishers can incorporate them directly into the intelligent tools that they develop as decision support systems. CNOM also recommends that the government should promote semantic interoperability, by providing standard reference terminologies in the health and social sector.

14. Initial training and continuing professional development play a crucial role in the anticipation of and progress towards a "medicine of the future". CNOM considers it essential to begin as of now to train doctors for the world in which they will practice, where technologies — alongside clinical practice — will play a big role.

15. CNOM also recommends that in the initial training syllabus, as well as subsequently in continuing professional development, simulation using interactive digital methods should be more widely adopted as a way of learning to deal with situations, to practice technical skills, or to conduct an investigation.

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[44] C. De Ganay and D. Gillot (2017). Pour une intelligence artificielle maîtrisée, utile et démystifiée.
Les Rapports de l'OPECST, Assemblée nationale, Sénat, 273 p.

16. Universities in general and medical faculties in particular should incorporate training in digital technology into their teaching programs, with extensive emphasis on a crosscutting syllabus covering mathematics, physics, computer sciences, medicine, and the humanities.

17. CNOM recommends that, in making demographic decisions about the training of different medical specialists in university faculties, and about the content of those training programs, the foreseeable changes in professional disciplines should be taken into account. This concerns not only new jobs, delegated practices, and advanced practices, but also the tasks that may — within the next 5 to 10 years — be performed by systems that incorporate Artificial Intelligence. This process of reflection needs to be undertaken quickly. CNOM also recommends that training for the health professions should include programs for "Data Scientists" and doctors trained in a dual syllabus of medicine and engineering.

18. Medical professions are likely to change, and knowledge and skills to become obsolete, at a much faster rate than in the past. This makes it essential to organize lifelong learning without a break between initial training and continuing professional development. It also demands better connection and the elimination of partitions between disciplines. In a world that is becoming increasingly technical and technological, greater educational emphasis is needed on ethical questions, on human relations, on professional ethics. This adaptation has already been undertaken in concert, in their respective fields of expertise, by the *Conférence des doyens de médecine* and the *Conseil national de l'Ordre des médecins*, with the inclusion of the professional national councils of the training specialties and organizations. The development of the *Université Numérique pour l'Enseignement de la Santé et du Sport* (UNESS) is one aspect of this process. Efforts need to be made by all the actors and the entire ecosystem to promote the emergence of a genuine community of digital literati. CNOM recommends that the government should support these orientations.

19. It should be emphasized that in the world of data, of robots, and of Artificial Intelligence, human intelligence and machine intelligence are complementary, not antagonistic. CNOM recommends the development of research that anticipates the potential impact of technologies in the ethical, social, and legal spheres, the promotion of "ethics by design", similar to the contemporary model of "privacy by design".

20. It also recommends encouraging research into and implementation of systems for evaluating, monitoring, and tracing algorithm-based methods

74

and models, and particularly machine learning systems, used in healthcare.

21. It undertakes to examine the system of legal liability: the liability of doctors in their use of decision support tools, and the liability of the algorithm designers with regard to the reliability of the data used and the methods of computer processing employed.

22. At the same time, CNOM recommends that the different healthcare actors (hospitals, doctors, researchers, etc.) should be educated in the value of data and in the advantage of maintaining a form of collective control over them. They should also be aware of the GIGO (garbage in garbage out) principle, i.e. that the results of data-processing depend on the quality of the initial input data.

23. The use of big data offers great potential, particular for public health. Most of the Western countries are moving towards a principle of "open data". France is following this course with the necessary caution, supported by CNOM through its contributions and its presence in the *Institut national des données de santé* (National Health data Institute). CNOM notes that the protection of medical confidentiality covering personal health data should be applied to the processing of big data and that these data should not be used in such a way that a person may be identified, with a consequent risk of discrimination. The law has established legal rules on permissions for access to public databases and on the handling of the data they contain. These rules must be consolidated through transposition into criminal law with penalties equivalent to those applicable in cases of invasion of privacy or unauthorized access to information systems.

24. Patients and health professionals whose data are hosted on servers must be given a guarantee that if the hosting is done outside French national territory, it will meet the same requirements, in terms of data security and availability.

25. Nonetheless, we think it essential that access to public health databases should be extended on the basis of a positive vision of their use, in terms of the cost-benefit outcomes for our healthcare system, to the advantage of all citizens. At the same time, CNOM recommends that access permissions for research purposes should be made public in the event that there could be a risk of the people whose data they contain being indirectly reidentified, and that the results of the research should be published.

26. However, we observe that citizens disseminate their personal health data, in even larger quantities, through the use of different online applications or objects. These personal data can be collected on private databases, without monitoring or regulation. They could be used for purposes, in particular commercial purposes, other than those for which the users intended them. It is possible that citizens are unaware of this, unless they are unconcerned by it because of the services they receive. The Order recommends that this subject should be one of the elements of the public debate called for above.

27. Applicable as of May 2018, the European General Data Protection Regulation imposes requirements and potentially places liability on the person responsible for data-processing .[45] This should help raise citizen awareness about the control of their personal data. The implementation of the European Regulation in France is an opportunity for the government, and CNIL, to organize the public debate that we wish to initiate. This debate should tell us, among other things, how much citizens wish to protect their health data, whether they consider these data to be a common good, notably with regard to research, and up to what limits and under what conditions. This is what CNOM recommends.

28. A large number of businesses in the digital world, including in healthcare, are developing powerful applications and introducing innovation that is sometimes disruptive. CNOM takes the view that one should not try to make laws about everything, or seek to regulate everything by ministerial order. Instead, it recommends that qualified bodies should produce flexible legal rules, on the model of the "soft law" of Anglo-Saxon countries. According to CNOM, this mode of regulation, which is much more agile in responding to digital disruption, maintains and supports capacity for agile innovations, while guaranteeing security and the respect for individual rights.

29. Since CNOM is one of the regulatory authorities to which the public and professionals turn to obtain answers and guarantees on these subjects, we are ready to co-construct the necessary recommendations in partnership, among others, with the *Haute Autorité de Santé*, the *Commission Nationale Informatique et Libertés*, the *Conseil National du Numérique*...

30. In order to steer future work on recommendations in the direction of "soft law", CNOM also recommends the establishment of a national observatory of artificial intelligence and robotics technologies in health, to record results and changes in practices.

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[45] As defined by France's data protection act.

31. The digital transformation in healthcare, healthcare organizations, jobs, and practices, will not take place without the necessary digital investments in all parts of the Republic, i.e. in infrastructures. The Order notes that there is still a digital divide, and that in territorial terms, the expression "medical deserts" coincides fairly spectacularly with other "rights deserts" — for example the lack of public services — but also with "digital deserts", areas with no access to the web or high-speed Internet. CNOM recommends that efforts — particularly investment in infrastructure — should be made to equip the entire country with access to high-speed Internet. The purpose of this is to guarantee equal rights in the uses of digital technology. These efforts must be accelerated, in particular in vulnerable areas, in order not to create a digital divide in access to health innovations and healthcare. Specific attention needs to be paid to the overseas departments.

32. Finally, CNOM draws attention to the fact that the data infrastructures, the collection and operating platforms, constitute a major priority on the economic and scientific fronts, and in the field of cybersecurity. The location of these infrastructures and platforms, their operation, their purposes, and their regulation represent a major issue of sovereignty, ensuring that France and Europe are not subjugated in the future to the supranational digital giants.

Attentive to the respect for the principles of medical and professional ethics on the part of all our members, as well as the need to contribute to answering the questions raised by these technological changes, the *Ordre national des médecins* undertakes to support the recommendations set out here with its sister organizations in the other EU member states and with the Standing Committee of European Doctors, as well as with the general assemblies of the World Medical Association, in order that the content of those recommendations should be widely disseminated and advocated.

Appendix 5 The principal recommendations of the report on *Growing the Artificial Intelligence Industry in the UK* by Wendy Hall and Jérôme Pesenti

Recommendations to improve access to data

1. To facilitate the sharing of data between organizations holding data and organizations looking to use data to develop AI, Government and industry should deliver a programme to develop Data Trusts — proven and trusted frameworks and agreements — to ensure exchanges are secure and mutually beneficial.

2. To improve the availability of data for developing AI systems, Government should ensure that public funding for research explicitly ensures publication of underlying data in machine-readable formats with clear rights information, and open wherever possible.

3. To support text and data mining as a standard and essential tool for research, the UK should move towards establishing by default that for published research the right to read is also the right to mine data.

Recommendations to improve supply of skills

4. Government, industry and academia must embrace the value and importance of a diverse workforce for AI, and should work together to break down stereotypes and broaden participation.

5. Industry should sponsor a major programme of students to pursue Masters level courses in AI, with an initial cohort of 300 students.

6. Universities should explore with employers and students the potential demand for one-year conversion Masters degrees in AI for graduates in subjects other than computing and data science.

7. Government and universities should create, at a minimum, an additional 200 PhD places dedicated to AI at leading universities. As the UK trains and attracts additional academic talent, this number should grow continually year on year.

8. An International fellowship programme for AI in the UK should be created in partnership with the Alan Turing Institute: the Turing AI Fellowships.

Recommendations to maximise UK AI research

9. The Alan Turing Institute should become the national institute for artificial intelligence and data science, becoming truly national and expanded beyond the current five universities, with a key stated aim that centers its mission on artificial intelligence.

10. Universities should use clear, accessible and where possible common policies and practices for licensing IP and forming spin-out companies.

11. The Alan Turing Institute, Engineering and Physical Sciences Research Council (EPSRC), Science and Technology Facilities Council (STFC) and Joint Information Systems Committee (JISC) should work together to coordinate demand for computing capacity for AI research, and negotiate for the UK research community.

Recommendations to support uptake of AI

12. Government should work with industry and experts to establish a UK AI Council to help coordinate and grow AI in the UK.

13. TechUK should work with the Royal Academy of Engineering, the Digital Catapult, and key players in industry sectors, to develop practical guidance on the opportunities and challenges of successful adoption of AI across the UK economy.

14. Government, drawing on the expertise of the Government Digital Service, the Data Science Partnership and experts working with data in other Departments, should develop a programme of actions to prepare the public sector and spread best practice for applying AI to improve operations and services for citizens.

15. Government should ensure that challenges addressed by the Industrial Strategy Challenge Fund (ISCF) and Small Business Research Initiative (SBRI) are designed to attract and support applications of AI across the full range of challenge areas and set funded challenges which use public sector data for AI.

Appendix 6 The six practical recommendations by CNIL concerning the ethics of algorithms

1. *All the players-links in the "algorithmic chain" should receive training in ethics: designers, professionals, citizens.* Literacy training in digital technology should enable every individual to understand the workings of the machine.

2. *Algorithmic systems should be made comprehensible by reinforcing existing rights and by organizing mediation with users.*

3. *Algorithmic systems should be designed to serve human freedom.* In particular, to counter the "black box" effect.

4. *A national algorithm audit platform should be established.* This is essential to reinforce trust in the healthcare system among all parties.

5. *Research on technical solutions should be encouraged in order for France to become a leader in ethical AI.* Clearly, ethical considerations will need to be at the heart of initiatives such as the establishment of a future national health data hub.

6. *The ethical function within companies should be reinforced.* Ethics are also a factor of competitiveness, and should be based on the development of ethics committees, the dissemination of good practices within business sectors, and the construction or revision of codes of ethics.

Appendix 7 Some international comparisons of health data protection practices

Standardization by the United Nations

- Article 17 of the United Nations International Covenant on Civil and Political Rights protects only privacy, without mentioning data protection. However, on December 14, 1990, the General Assembly of the UN adopted a resolution setting out certain general principles regarding computerized personal files.

Specific standardization in Europe

- **Article 8 of the European Convention on Human Rights** states the necessity of protecting personal data and in particular health data.
- The 1981 Convention (called: <u>Convention 108</u>) protects the individual by obliging states that are party to the Convention to adopt certain minimum principles of protection in their legislation concerning the transmission of data to other states that are party to the Convention.
- The <u>Charter of Fundamental Rights of the European Union</u> specifically establishes the protection of personal data in its Article 8.
- **Directive 95/46/CE**, adopted before the Charter, deals with data protection and sets out the main principles applicable within the European Union.[46]

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[46] Switzerland has adopted these principles in its legislation. With regard to personal data, the drive for standardization comes from the EU. A Directive 95/46 CE concerning the protection of natural persons with respect to the handling of personal data and the free movement of these data was until recently the common foundation for the member states. It's aim was notably to produce a uniform definition for the notion of sensitive data.

"The transposition of Directive 95/46/CE has the effect of creating an almost entirely uniform legal framework for sensitive data.

*Directive 95/46/CE defines sensitive data and prohibits "the processing of personal data revealing racial or ethnic origin, political opinions, religious or philosophical beliefs, trade-union membership, and the processing of data concerning health or sex life." This prohibition on all processing contains a few exceptions, among which are the explicit consent of the interested party and authorisation by law, by regulation, or by the supervising authority. **With the exception of the German law of 1977, which ignores the notion of sensitive data, all legislation currently in force provides similar guarantees, very close to those contained in the Directive.***
*It should nevertheless be noted that the **Spanish law of 1992 distinguishes between two groups of sensitive data**: those that, under the **Constitution**, which states that "nobody may be obliged to declare their ideology, their religion, and their beliefs,", receive **maximum***

- The GDPR provides a new formulation of data protection principles: the processing of personal data must be fair and transparent in respect of the people concerned, which implies 5 principles: 1. Principle of purpose limitation; 2. Principle of data minimization; 3. Principle of accuracy; 4. Principle of storage limitations; 5. Principle of integrity and confidentiality.

Article 9 of the GDPR introduces two new categories of sensitive data:

- Biometric data;
- Genetic data.

The GDPR defines health data as data relating to the physical or mental health of a natural person, including the provision of healthcare services that reveal information on that person's health status.

Specific standardization in France

In legislative terms, the protection of health data in the form of privacy protection is governed equally by:

- Article 9 of the Civil Code: *"Everyone has the right to respect for his private life"*
- The Public Health Code: Article 1110-4 (act of March 22, 2004)
- The act of August 6, 2004, which transposes the 1995 Directive
- The Data Protection Act of January 6, 1978
- The bioethics acts

From a constitutional point of view, the Constitutional Council has recognized that health data must be protected under the principle of respect for private life: CC, July 23, 1999, *Loi portant création d'une couverture maladie universelle*, n° 99416 DC, pt. 45: it is not irrelevant to point out that the first constitutional decision that includes health data amongst data for which

protection, and those that receive intermediate protection. The processing of data in the first group requires the express and written consent of the interested party under all circumstances, whereas those in the second group follow the general rules of the Directive. The draft bill maintains this distinction.

The UK Data Protection Act of 1984 did not explicitly define the notion of sensitive data. It only stated that the Home Secretary could take regulatory measures concerning certain groups of data (racial origin, political opinions, health...), but this power was never exercised. It is therefore because of the transposition of Directive 95/46/CE that the notion of sensitive data was introduced into British law."

(https://www.senat.fr/lc/lc62/lc620.html)

Given the wide disparities between the legislations of the member states, the EU initiated a reinforcement of harmonisation through the GDPR, which therefore repeals Directive 95/46/CE.

disclosure may infringe privacy is also the first decision that links respect for privacy with Article 2 of the Declaration of the Rights of Man and of the Citizen.

The protection of personal data in the United States

The conception of personal data protection in the United States is very different. This difference arises first of all from the organization of the American legal system itself. Indeed, the Fourth Amendment of the US Constitution guarantees a right to privacy, but only from government.

This amendment gave rise to a first piece of legislation in 1973, the *Privacy Act*. This law established rules for the processing of personal data collected by the different branches of Government. It therefore only relates to infringements of the privacy of citizens by the Government. The other infringements of privacy and of personal data protection fall under the jurisdiction of each State and its Courts, on the basis of a 1965 ruling by the Supreme Court.[47]

The *Privacy Act* applies the "FIPs" (Fair Information Practices) developed by the US Health Department in 1973.[48] By contrast with European law, which encompasses European data protection rules within a single text, American legislation is applied per business sector or category of individuals. For example, for our purposes: the "*Health Insurance Portability and Accountability Act*"[49] relates to medical confidentiality, the "*Children's Online Privacy Protection Act*"[50] restricts the use of information collected by websites from children under the age of 13.

Finally, in addition to these Federal laws, each of the US States has adopted laws designed to protect certain aspects of the privacy of their citizens: that is the Common Law of each of the States.

There is therefore no general right to the protection of personal data in American law. Beyond the sectoral nature of the regulations and the variation in the level of protection from one State to another, it is the consumer rather than fundamental individual rights that American law seeks to protect.

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[47] *Griswold c/ Connecticut*, 381 U.S. 479 (1965)

[48] The FIPs subsequently formed the foundation of Convention 108 of the Council of Europe, the OECD 1980 recommendations, and European Directive 95/46/CE.

[49] Promulgated in 1996

[50] Promulgated in 1998 and amended in 2013 in order to clarify certain provisions, such as those relating to children's personal data.

Appendix 8 Five keys for substantive regulation of the spread of AI and robotics in healthcare / Ethik IA — March 2018

Key 1: Patient information and consent

Patients should be informed in advance when an artificial intelligence device is to be used in their healthcare program. The artificial intelligence device must not override the need to obtain patient consent. Specific procedures — such as the availability of a trusted person, or arrangements for obtaining advance consent for a set of treatment options, or stronger protective arrangements for vulnerable people — should, where needed, be developed to guarantee that consent is genuinely obtained.

Key 2: Human Warranty of AI

The principle of a Human Warranty of digital systems in healthcare must be followed. This guarantee should be provided firstly by regular procedures — both targeted and random — to verify the treatment options proposed by the digital system and, secondly, by arrangements for a second human medical opinion to be sought at the request of a patient or a health professional. This second opinion could, where appropriate, be obtained through telemedicine procedures.

Key 3: Gradations of regulation depending on the degree of sensitivity of the health data

There should be graduated regulation of the use of an artificial intelligence system for the mass processing of health data according to the degree of sensitivity of these data with respect to the principles of bioethics law. Standards of good practice can be developed for the application of this principle in specific healthcare contexts.

Key 4: Supporting adjustment in the healthcare professions

The implementation of an artificial intelligence or robotics system in healthcare should not result in a failure to apply ethical principles and rules in the practices of the health professions that use such systems. The effects of the use of an artificial intelligence or robotics system on the conditions of such practices should, as far as possible, be prepared for and anticipated. Part of the efficiency gains achieved by the implementation of artificial intelligence and robotics in healthcare should be used to finance this process of

preparation and anticipation, for the initial training and continuing professional development of professionals on the issues around artificial intelligence and robotics, and to support the emergence of new professions in the health and medico-social fields.

Key 5: Involvement of independent outside supervision

There should be independent outside supervision of the provisions made in order to ensure that these principles are followed. The authority responsible for ensuring that this outside supervision is effectively exercised should undertake regular evaluations to assess the effects of the implementation of artificial intelligence and robotics in healthcare. This authority should support research on the regulation of the use of artificial intelligence and robotics in healthcare.

Appendix 9 Summary of the meetings and hearings conducted by the taskforce

Date	Names of interviewees	Position and institution	Main topics
April 16, 2018	Professor Guy Vallancien	*Chairman CHAM*	Effects of transformations in the healthcare system associated with AI; diagnostic support; surgical robots, regulation of possible ethical failures; impact on the healthcare system and hospitals.
April 20, 2018	Rémy Choquet	*Director of innovation Orange Healthcare*	The fields of development of AI in health; regulation of AI in health; projects for the use of AI in public health
April 20, 2018	Thomas London	*Health Director McKinsey*	Effects of transformations in the healthcare system associated with AI; instruments for the improvement of AI in healthcare
May 3, 2018	Dr Philippe Denormandie	*Health Director MNH-Groupe*	The importance of data-based management; impact of AI on the patient/caregiver relationship; AI, ageing, and disability
May 3, 2018	Yann Mazens	*France Asso Santé*	Shared decision-making and consent; monitoring and citizen participation in algorithms; well-being data
May 14, 2018	Nathalie Salles and Thierry Moulin	*President and Past –President Société française de télémédecine*	Innovation in telemedicine; the patient's role in the healthcare system with the spread of AI; development of a telemedicine that gives a Human Warranty of artificial intelligence

May 14, 2018	Pascal Jacob	*Chairman of Handidactique*	Vulnerability in the context of new technologies; AI as an instrument for increasing autonomy for people living with disability
May 22, 2018	Professor Jean Sibilia	*Chairman of the Conférence des Doyens de Facultés de médecine, pharmacie et odontologie*	Training medical teams for AI; issues of data security; opportunities of the use of simulation for medical training; the need to transform initial education and continuing professional development
May 22, 2018	Dr Alexandre Vainchtock	*Chairman Hevaweb*	The opportunities offered by AI in healthcare to prevent inappropriate treatments; the advances made possible by data-based management in health.
May 22, 2018	Stéphanie Combes and Mylène Girard	*DREES (Research, surveys, evaluation, and statistics directorate)*	Digital technology as an instrument for supporting treatment and research; methods for the establishment of a future national health data hub; methods for obtaining consent
May 22, 2018	Etienne Grass	*Health Director Capgemini*	Effects of transformations of the healthcare system associated with AI; cases of the use of AI and robotics in healthcare
May 24, 2018	Jean-Philippe Masson	*Pres FNMR National Federation of medical radiologists*	Challenges of AI and robotics in radiology; pilot project undertaken by the G4
May 24, 2018	Matthias Dufour, Clara de Bort	*ThinkTank #Leplusimportant*	Challenges of adapting human resources to the spread of digital technology in society

May 25, 2018	Jean-Paul Ortiz	*President Confédération des Syndicats Médicaux de France (CSMF)*	Effects of transformations of the healthcare system associated with digital technology; transformations of private medical practice associated with the spread of digital technology; regulation of ethical issues
May 25, 2018	Antoine Perrin, Jean-François Goglin	*CEO and head of information systems, Fédération des Etablissements Hospitaliers d'Aide à la personne*	Effects of transformations of the healthcare system associated with digital technology; organization of FEHAP around plans for the implementation of AI solutions
May 30, 2018	Professor Michel Claudon	*President Conférence des Présidents de CME de CHU*	Effects of transformations of the healthcare system associated with digital technology; medical challenges of the spread of AI for teaching hospitals in healthcare, education, and research (working session organised with the Conference on June 11, 2018)
June 4, 2018	Dr Victor de Castro	*EthikIA Initiative; author of a dissertation for Sciences Po on the technical innovations associated with AI in healthcare*	The benefits of AI and health (aid in decision-making, virtual assistants, decompartmentalisation of decision-making, elimination of unnecessary spending); data ethics
June 4, 2018	Professor Wendy Mackay	*Research Director at Inria*	The research programs underway on AI and robotization in health; human-machine interactions in operating rooms

June 5, 2018	Yvanie Caillé	*CEO INDS*	The functioning of the SNDS; issues around the establishment of a future national health data hub
June 7, 2018	Professor Anne Laude; Lydia Morlet	*Institut Droit-Santé Paris Descartes*	Current provisions and principles that need to be altered in European or international legal documents; responsibility for health data; protection of personal data
June 12, 2018	Laurence Devilliers	*Professor at Université Paris-Sorbonne and researcher at LIMSI-CNRS*	Human-Machine Interactions; emotional and social dimensions in speech interactions; research program on the spread of robotization at EHPAD.
June 12, 2018	Pascal Flamant, Sandrine Boucher, Matthieu Robain	*CEO and heads of Data Management Programs Unicancer*	Challenges of the spread of digital technology for the Cancer Treatment Centres; databases and AI development programs supported by Unicancer
June 14, 2018	Professor Jean-François Meder	*Société française de radiologie*	Challenges of AI and robotics in radiology; pilot project undertaken by the G4
June 14, 2018	Dr Adnan El Bakri	President *InnovHealth*	Presentation of the PassCare Project: issues of the use of Blockchain in the spread of management based on health data
June 15, 2018	Professor Salima Benhamou	*France Stratégie*	HR issues of the spread of AI and robotization in healthcare
June 18, 2018	Magali Léo	*Director of Advocacy, Renaloo*	The issues around the spread of digital technology and management based on health data in the field of chronic renal failure

June 20, 2018	Professor Patrick Lévy, Professor Olivier Palombi	*Chairman and Scientific Director, UNESS*	Presentation of UNESS; issues around the use of digital technology to adapt the initial and continuing education of health professionals
June 27, 2018	Dr Thierry Godeau	*President Conférence des Présidents de CME de Centres hospitaliers*	The contributions of digital technology and AI to medical practice;
June 27, 2018	Dr Christian Muller	*President Conférence des Présidents de CME d'établissements spécialisés en psychiatrie*	The contributions of digital technology and AI for medical practice in psychiatry and mental health; the Conference's proposals on these questions

Appendix 10 Letter of acknowledgement

COMITÉ CONSULTATIF NATIONAL D'ÉTHIQUE

November 16, 2018

THE PRESIDENT

For the attention of Claude KIRCHNER and David GRUSON
Joint heads of the taskforce on digital ethics and health

Dear colleagues,

At the end of March 2018, within the framework of the National Consultation on Bioethics, we entrusted you with the mission of heading a taskforce on the theme of digital technology in healthcare in order to provide input to CCNE on this issue. You submitted a preliminary report to CCNE on July 5 and 10, then on November 8 to CCNE's technical section, which came back to you with a number of comments and ideas.

Following the final presentation of the report on digital ethics in health, I wanted — on behalf of the Committee — to thank you for the work you have done to fulfil the terms of reference of the engagement letter sent to you on March 22 last year. I would be grateful if you would pass on our thanks to all the members of the taskforce, as well as to the different experts you interviewed.

In its position paper published on September 25 last year (position paper 129), CCNE was able to incorporate most of the recommendations arising from your work. Your proposals provided valuable input into that position paper and opened new avenues for exploration, such as your observation that insufficient use of digital technology in our healthcare system would itself be unethical, or regarding the desirability of introducing the principle of a Human Warranty of artificial intelligence in the next Bioethics Act. However, CCNE also wished to pursue your initial observations further by reinforcing the notion of the risk faced by people who lack access to digital tools, further increasing the fragility of already vulnerable individuals as well as of older people.

One of your proposals concerned the possibility of a broader role for CCNE as a digital ethics committee. On this specific point, in its position paper 129, CCNE preferred to

propose that any intervention on its part should take place within the framework of assistance in the preparing the ground for an ethics committee specialising in digital matters. However, with regard to the ethical challenges of digital technology in health, it is essential that CCNE's competencies and organization should enable it to handle referrals on these topics, where necessary in partnership with specific ethics committees in this domain.

Your report also outlined further prospects, beyond the horizon of the upcoming revision of the Bioethics Act. That is one of the reasons why the Committee wished to see your contribution published in order to feed into the debate on these questions, fundamental as they are to the future of our healthcare system. The symposium being held on this theme, on November 19, 2018, in partnership with CERNA and the *Imagine* Institute, will be an opportunity to present the final version of this report.

Yours sincerely

Pr Jean-François DELFRAISSY
Chairman of the Comité consultatif national d'éthique

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