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METAMEDICA

Against the backdrop of key scientific and ICT developments (biobanks, predictive genetic research, precision medicine, health wearables, AI, big data, interoperability of IT systems, public use files, data mining, ...), related role-changes for patients and healthcare professionals, the proliferation of health-related data and new data protection and research data management frameworks, the Metamedica Platform conducts interdisciplinary, high-profile research in health privacy, health law and bioethics, involving and relevant for clinicians, lawyers, ethicists and ICT specialists. It also provides education and services to (future) clinicians and health care professionals.

Leading scientists: prof. Georges De Moor (Department of Medical Informatics and Statistics), Prof. Kristof Eeckloo (Department of Public Health), Prof. Guido Pennings (Ethics and Bioethics), Prof. Sigrid Sterckx (Ethics and Social & Political Philosophy), Prof. Gert Vermeulen (Criminal Law), Prof. Koenraad Vandewoude (Internal Medicine), Prof. Koen Van Herck (Preventive Medicine)

 # new professorships: 3

Project description

Ghent University Hospital and the faculty of Medicine and Health Sciences host top experts in medicine and health care. Yet a medical department should not only invest in clinical research and treatments, but also reflect on the issues that arise in the margin of the medical practice, the branch of the so-called meta-medica. A number of developments are occurring in healthcare that give rise to new legal and ethical questions which pose an urgent need of being clarified. At issue are, inter alia:

1. *The quickly increasing importance of the use of health related data, underpinning clinical decision-making, scientific research, the governance of insurance systems, and policymaking.* The growing importance of the use of health data gives rise to an exponential increase of the significance of 'health privacy'. This relates to, inter alia, the implementation of e-health policies, challenges regarding information security in the sharing of ICT data and the interoperability of systems, the uptake of 'health wearables', big data research, the increasing (transnational) processing by pharmaceutical companies of clinical and patient data, and the use of artificial intelligence in medicine. Data brokers collect personal information about individuals, and combine and analyze data about consumers to make inferences about them. This may infringe the privacy of individuals and expose them to significant risks. Therefore, adopting adequate legal safeguards for privacy, and addressing pertinent issues such as access by third parties, are of paramount importance. Data brokers are paying particular attention to the potential of health data. The current largest data holders, for example Google, and leading data brokers such as Axciom, would be able to connect an analysis of health data to an extraordinarily comprehensive set of behavioral and social information resulting from their pervasive services.

2.*The fast increasing importance of human biobanks (i.e. repositories of human body material and/or related data), for scientific research as well as product development.* Biobanks have become a mainstay of biomedical research, including genetic and (population) genomic research. The risk of physical harms resulting from biobanks (more specifically, physical harms to the sample providers) is usually regarded as minimal. However, biobanks may result in informational harm. Indeed, inappropriately disclosed personal health information that derives from biobank samples may expose sample providers to insurance or employment discrimination and hence to economic harm. Moreover, biobank research can also lead to severe 'dignitary' harms, which involve infringement upon the autonomy and moral integrity of the sample providers. Key legal and ethical questions pertaining to biobanks relate to: models of consent; access to and ownership of the material and data; and the reporting of incidental research findings.

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3. *The growing possibilities of predictive genetic research, including new possibilities for counselling and prevention aimed at individual patients as well as the potential use of research results in the context of non-curative decision-making (e.g. insurance, employment selection, and forensic purposes)*: Rapid advances in microarray and sequencing technologies are increasing the availability and affordability of genotyping and genome sequencing. The decreasing cost and time needed for sequencing has created the expectation that the use of next-generation sequencing technologies will hugely increase in various contexts. Key legal and ethical questions remain with regard to obtaining informed consent and the reporting of results (existing guidelines describing how to handle the return of results, including variants of unknown significance and incidental findings, require further elaboration). In order to enable scientific advances, various commentators advocate the identification and removal of practical, legal, institutional, and attitudinal 'obstacles' in order to achieve large scale creation, access and integration of data. As to facilitating downstream uses of data, it is important to ensure that the rights and interests of all parties involved are respected. Genomic data sharing triggers concerns that differ considerably from concerns regarding human subjects research, which tend to be traditionally associated with merely physical risks. Processing sensitive genomic data may raise informational risks for the data subjects, their family members or ethnic groups. The evolving potential of genomics and bioinformatics requires on-going monitoring of the field and assessment of the sufficiency of the legal, ethical and practical safeguards in place.

4. *The emergence of 'precision medicine', whereby tailored therapeutics and treatments are being developed for specific patient groups*: While the EU "recognises the challenges associated with [personalized medicine's] successful entry in healthcare systems", since 2007, it has allocated over €1 billion of health research funding underpinning the development of personalized medicine through its Seventh Framework Program and continues to support this field through Horizon 2020. Outside Europe, this trend is fueled by national research initiatives. For example, in the US the 'Precision Medicine Initiative' (PMI) was announced by then President Barack Obama in January 2015 and reinforced by Francis Collins, Director of the US National Institutes of Health. The purpose of the PMI is to pursue the paradigm shift that the Human Genome Project promised for healthcare. The promise of emerging scientific possibilities to distil valuable knowledge from big data is leading the scientific community to seek out more efficient ways to gather large numbers of empirical observations for analysis. For human health research, this means gathering more data about more humans. These trends give rise to legal and ethical questions about the role of government in managing the interests of patients and the interests of others who would benefit from access to patient data. In thinking about patient participation, patient engagement, and new models of governance of biomedical research, research is required into what bearing each 'precision medicine' initiative relying on the inclusion of huge numbers of citizens has on citizens' rights and duties, on definitions of 'societal good', and on the role of public authorities in the healthcare sector.

5. *Profound shifts in the division and distribution of tasks and responsibilities within the healthcare sector, implying a retreat of the 'hierarchical model', involving the primacy of physicians, in favour of a 'collaborative model'*: There are two aspects to this trend. First, we are witnessing an increasing collaboration between diverse types of 'health professionals' (including recently recognised professions such as clinical psychologists and clinical remedial educationalists) (see http://www.kb78.be). This raises a host of issues regarding the protection of professional secrecy. Second, the role of the patient in the healthcare process is clearly increasing. Patients are obtaining more possibilities to steer the delivery of their healthcare. For instance, various innovations in the field of 'wearable health technologies' are increasing the role of the patient in the diagnostic process. To provide but one example: previously, individuals had a specific pathway for accessing health (e.g. genetic) information through the traditional health care setting (e.g. via a clinical geneticist or counsellor) on the basis of specific clinical concerns. In contrast, individuals now have the opportunity to choose genetic testing without the intermediate of a professional assessment and can engage in testing for a variety of purposes. For about a decade now, genetic testing companies have been marketing genetic tests direct-to-consumer via the internet, as well as allowing consumers to receive an analysis of their raw genomic data. More generally, the role of individual patients and research participants in healthcare, research and data sharing is rapidly evolving. Some commentators argue that by using the potential of various online platforms, patients' interactions with researchers, research institutions and other patients can be

facilitated. Moreover, several patient organizations have identified gaps in the research agenda and have sought to fill these themselves. There is increasing talk of 'partnerships' between clinicians and patients and between research participants and researchers and even 'patient-driven' research. These developments pose huge potential legal and ethical challenges, which require interdisciplinary research.

6. *Significant changes in the nature of the collaborations between hospitals and other healthcare institutions*: The number of collaborations between Belgian hospitals has vastly increased during the last decade. The reasons for collaboration vary and include financial pressure (e.g. the joint exploitation of shared services such as an HRM department), governmental regulations (e.g. cardiac care programmes), sharing scarce human resources (e.g. interventional radiology) and providing patient-centered integrated care. Moreover, as a result of *inter alia* the decrease of the duration of hospital stays in acute hospitals, greater collaboration is required between various types of intra-, trans-, and extra-mural care. The collaborations and governance structures provided by the current Belgian Hospital Act are insufficient to guide these new developments. New governance models and legal frameworks are needed to support hospital collaborations that facilitate task distribution and the coordination of care across institutional boundaries. The overall goal is to provide better quality of care in an efficient way.

All these developments necessitate thorough interdisciplinary research. As outlined above, cross-cutting themes concern the legal and moral rights, obligations and responsibilities of healthcare providers (physicians and other care professions as well as institutions) and patients. Key concepts such as privacy, autonomy, consent, and patient empowerment are subject to increasingly shifting interpretations, and need to be reassessed and possibly rethought and strengthened to take account of the new realities of clinical care and biomedical research. In addition to the necessity of research, it is of the utmost importance for the faculties of Medicine and Health Sciences, Law, and Arts and Philosophy, to be able to provide research based, up to date and multidisciplinary teaching on all these topics. Hence we will create a Metamedica Centre for research and teaching concerning the various legal and ethical implications of current developments in healthcare. Thematically, this translates into three main themes and areas of specialisation: health privacy; health law; and medical ethics.

Proposed impact

Healthcare is a crucial sector of our society and our economy. Indeed, 11% of the Belgian GDP (40 billion Euros per year) is spent on healthcare, which affects the life of each citizen at some stage. Excellent interdisciplinary research and teaching on the abovementioned issues will contribute to more sound and evidence based health policies, improved decision-making in healthcare institutions, and a deepening of healthcare professionals' understanding of crucial legal and ethical issues confronting their profession.