



Towards an ethics for telehealth

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Abstract

Over the last two decades, a public rationale for the implementation of telehealth has emerged at the interplay of specialised literature and political orientations. Despite the lack of consistent findings on the magnitude of its benefits, telehealth is nowadays presented as a worthy solution both for patients and healthcare institutions. Far from denying the potential advantages of telehealth, the main objective of this work is to provide a critical assessment on the spread of the remote services as a vector of positive transformation of contemporary health systems. For pursuing this objective, the EU agenda for the promotion of telehealth will be retraced, and the main evidences alleged to sustain the implementation of remote care services will be assessed. Furthermore, it will be evaluated the attempt made by the European Commission to establish an ethical framework for guiding the use of telehealth in daily practice, and a roadmap of the most relevant legal and ethical issues posed by the spread of telehealth will be traced. In the conclusions, it will be argued that the radical transformations induced by this form of technological innovation call on to a new, ad hoc ethics through which critically evaluate benefits and implications of telehealth services, with a view to keep high the standard of healthcare against the economic interests of private stakeholders and ICTs' vendors.

Keywords

Conflict of interest, e-health, healthcare ethics, information and communication technologies, public policy, telehealth

Introduction

Over the last two decades, the implementation of Information and Communication Technologies (ICTs) in healthcare has been intended as a fundamental means to deal with some of the major problems affecting the organisation of contemporary health systems. Among these, there is the so-called 'age time bomb' which stands for the constant increase of elderly population in industrialised countries.¹ Political orientations and the specialised literature have associated the demographic impasse with the need to reshape conventional care-delivery process, conferring therefore a crucial role to the development of 'telehealth' services.^{2–4} Telehealth has been exhaustively described by the World Health Organisation as⁵

the delivery of health care services, where distance is a critical factor, by all health care professionals using information and communication technologies for the exchange of valid information for diagnosis, treatment and prevention of disease and injuries, research and evaluation, and for the continuing education of health care providers, all in the interest of advancing the health of individuals and their communities.

The origins of this innovative dimension are to be searched in the experimentations carried out by the US National and Aeronautic Space Agency in the 1960s, aimed at providing remote assistance to the personnel involved in orbital space missions.^{6,7} In the 1990s, thanks to a progressive reduction in the cost of the ICTs – as well as to an improved capacity of data transmission – telehealth begins to flourish, evocating a large spread of the remote services in contemporary health systems.⁸ In the last survey conducted by the World Health Organization on the spread of telehealth worldwide,⁹ it has been pointed out that this form of intervention can be considered as an already consolidated practice in several specialties: ‘telecardiology’, which includes all the applications for the electrocardiogram and the remote monitoring of patients affected by heart diseases; ‘teleneurology’, which provides a remote evaluation of patients’ cerebral functions immediately after a stroke event, so as to take timely decisions on the most suitable intervention (surgical or pharmacological); ‘telepsychiatry’, which encompasses a series of activities delivered through video-conference with purposes of education, diagnosis and treatment of psychiatric symptoms and pathologies; ‘telerehabilitation’, which encloses a range of activities delivered through videoconference for rehabilitation purposes; and ‘teleradiology’, which enables to transmit X-ray images from a peripheral site to a specialist centre that will further provide for a radiological report.

In a first phase, the innovative conception that accompanied the emergence of telehealth has leveraged to the need of territorial coverage – especially rural underserved areas – as a major argument for its development. Indeed, one of the most important pledges of telehealth has been to scale-down the distances, enabling timely and adequate access to healthcare for all the population. Nowadays, telehealth ‘promises’ to move the main focus of healthcare intervention from the hospital to the primary care centres and patients’ homes, reducing therefore the volume of unduly transfers and avoiding unnecessary hospitalisations. Consequently, telehealth is also credited to increase continuity of care and improve quality of life of chronic patients. Furthermore, over the last years, we have assisted to a significant mutation in the trajectory of development of telehealth. The rise of ‘Mobile-Health’ from telehealth’s quintessence shows that the main vector of promotion of the remote care intervention is no longer the need to overcome physical barriers and cover long distances, but the opportunity to access healthcare services anyplace and anytime, that is to say, ubiquitously. As it will be argued, the spread of telehealth seems to entail a profound reshape of the space–time relation that underlies the conventional care-delivery process, contributing therefore to trace a ‘new geography of healthcare’ whose implications are not yet fully evaluated. Nonetheless, considering that available evidences on convenience, effectiveness and acceptability of the remote care services are still scarce and inconsistent, it is possible to argue that an enthusiastic ‘public rationale’ for the implementation of telehealth has emerged at the interplay of specialised literature and political orientations. Far from denying the potential advantages of telehealth both for patients and healthcare professionals, the main objective of this work is to provide a critical assessment on the spread of the remote services as a vector of positive transformation of contemporary health systems. In section ‘The EU agenda for the promotion of telehealth’, the setting up of an EU agenda for the promotion of telehealth will be retraced in order to evaluate the objectives pursued by the European policy-makers in this field. In section ‘Overcoming the legal uncertainty: the Telehealth Services Code of Practice for Europe’, the attempt to establish an ethical framework for guiding the implementation of the remote services will be analysed by evaluating the provisions of the Telehealth Code Service Practice for Europe, issued in 2013 on behalf of the European Commission. In section ‘Looking for evidences on telehealth: the WSDP’, the findings emerged from the Whole System Demonstrator Programme (WSDP) – the greatest telehealth trial up to now conducted – will be examined. As it will be then exposed, though the trial has generated inconclusive results, it has been considered by the European Commission and by several national health agencies as an ‘indisputable proof’ of the benefits associated with telehealth practice. In section ‘The legal and ethical implications of telehealth’, a roadmap of the most relevant legal and ethical issues posed by the spread of telehealth will be traced. On the basis of the overview sketched-up, in the conclusions it will be argued that the radical

transformations induced by this form of technological innovation call on to a new, ad hoc ethics through which critically evaluate benefits and implications of telehealth services with a view to keep high the standard of healthcare against the economic interests of private stakeholders and ICTs' vendors.

The EU agenda for the promotion of telehealth

Over the last decade, the European Commission has shown to increasingly rely on the implementation of the remote care services as a driver for the reorganisation of the Member States' health systems. In 2004, the Commission adopted its first 'e-Health Action Plan',¹⁰ illustrating the potential advantages associated with the spread of telehealth in daily practice. The Action Plan contained the strategic approach that EU institutions have consistently followed to promote the spread of telehealth services into the Member States' health systems. The approach encompassed three main objectives: to cope with the economic burden overwhelming public health systems because of ageing population and mounting incidence of chronic diseases, to encourage the mobility of EU patients across Member States and to take advantage of the opportunities led by technological innovation for stimulating the economic growth in the EU area. In order to pursue these objectives, the e-Health Action Plan has called on to the EU national governments for supporting the integration of telehealth in the respective national health services. As also stated by the European Commission, 'by end 2008, the majority of all European health organisations and health regions (communities, counties, districts) should be able to provide online services such as teleconsultation (second medical opinion), e-prescription, e-referral, telemonitoring and telecare' (p. 20).¹⁰

The strategic axis of the e-Health Action Plan was further reaffirmed through the Communication no. 630/2007, which explicitly linked telehealth to one of the fundamental principles of the European Union's treaty: the promotion of human health to a high level, in all its policies and activities (art. 9).¹¹ In this context, therefore, the Communication no. 630/2007 encouraged the spread of technologies capable of improving the effectiveness of healthcare-delivery process. This necessity acquired a renewed relevance also in the light of a substantive change in the patients' expectations. As stated by the Communication no. 630/2007, indeed, patients cannot be considered anymore as 'passive objects' of health interventions. Rather, they are ever more engaged in prevention activities and assume proactive behaviours in the management of their own health conditions (p. 10).¹²

Within the whole strategy for the promotion of ICT-mediated care services adopted by the European Commission,¹³ nevertheless, the most important act is certainly represented by the Communication no. 689/2008, which is exclusively focused on the implementation of telehealth into the Member States. Its main objective, indeed, has been to sustain the latter in the effort to integrate the innovative services in daily practice. In this context, a primary aim to fulfil was to 'reassure' patients about the efficacy and reliability of telehealth, promoting therefore its social acceptability among the final users.

Telehealth was again brought to the attention of the EU institutions in 2010, for the establishment of a 'European Digital Agenda'. For what concerns the healthcare sector, the main purpose of the Digital Agenda has been to promote financial sustainability, and safeguard autonomy and dignity of the patients affected by chronic-degenerative diseases (p. 32).¹⁴ Having regard to the implementation of telehealth, the Action no. 13 has reaffirmed the need to pursue a high spread of the remote care services into the Member States' health systems.

The EU strategy for the promotion of telehealth received a new significant input in 2012, with the issue of a second 'e-Health Action Plan'.¹⁵ Among its main objectives, the Plan has assumed to cope with the major obstacles that until then have inhibited the consolidation of telehealth in routine practice. Once more, in this circumstance, the European Commission has called on to the EU national governments for a joint effort aimed at promoting a wider awareness on the potential of telehealth among patients and professionals. Besides this, the new e-Health Action Plan has also encouraged the research and the international

cooperation, with the ultimate objective to achieve forms of interoperability among the different platforms and applications used across the Member States.

The latest noteworthy orientation adopted by the European Commission¹⁶ in this field is represented by the Background Paper ‘Growing the European Silver Economy’. Although it does not constitute a formal position, and has been intended just as a means to inform the discussion among stakeholders, the ‘Silver Economy’ paper provides a clear indication upon the future direction of the ‘EU Policy for Ageing Well with ICTs’. According to the European Commission, indeed, ageing population is not only a challenge to deal with, but a major opportunity to create employment and stimulate economic growth (p. 3).¹⁶ Admittedly, the spread of ICTs in healthcare is unfolding an impressive demand of new devices and applications: approximately 485 million wearable sensors estimated to be purchased in 2018;¹⁷ 97,000 smartphone applications already available for a market-value estimated in nearly 26 billion dollars for the 2017.¹⁸ Furthermore, it has been estimated that the whole services and products aimed to cover the needs of ageing population will generate a market of 7 trillion dollars per year.¹⁹

Overcoming the legal uncertainty: the Telehealth Services Code of Practice for Europe

The lack of international standards, together with the scarceness of legal provisions applicable to the remote services, has been identified as one of the major obstacles to the effective spread of telehealth in daily practice.^{9,13} For this reason, in 2008, the European Commission has set forth the ‘TeleSCoPE’ project, a supranational platform aimed to collect the best practices and share the most worthy experiences of remote care across Europe. The end of the project has been followed by the issue of the ‘Telehealth Services Code of Practice for Europe’ (briefly Telehealth Code), a soft-law instrument conceived to provide technical parameters for ensuring a high quality to remote care-delivery. According to the Telehealth Code, the correct management of the remote services requires an unequivocal repartition of tasks among the professionals involved in its management, namely physicians, nurses and private providers. The main objective of the Telehealth Code was to encourage the participation of users and healthcare professionals in the design, development and implementation of telehealth services. Besides this, by means of a dedicated glossary of the most relevant terms used in this field, the Telehealth Code intended to stimulate a kind of convergence, also considering the great heterogeneity in the features of the remote services (p. 11).²⁰

Among the provisions of the Telehealth Code, the ‘Ethical Principles’ included in Section B are ones of particular interest for the purposes of this work (pp. 23–26).²⁰ According to the latter, indeed, each telehealth service should allow their users to access the ‘Current Mission Statement’, which is also intended as a means to assess the compliance of the service with the fundamental principles of healthcare ethics (p. 23). The Telehealth Code also recommends to employ an adequate number of professionals for the management of the remote services (p. 34). Considering the peculiar nature of telehealth, it also establishes that involved professionals should receive a special training, so as to enable them to adequately act through the virtual setting and to establish positive relationships with the remote users (p. 34). Having regard to the quality of the virtual interaction, the Telehealth Code prescribes that the teleconsultation can be undertaken only by authorised professionals at work for the service and that the latter should be clearly identifiable by the patient from the beginning of the connection. In this context, the Telehealth Code also imposes to explicitly communicate and motivate to the patients the presence of third persons in the rooms of the service, allowing them to be aware and accept it (p. 39). For what concerns telemonitoring, it is recommended that all the professionals involved in the remote control of vital parameters ensure that timely actions will be undertaken in consequence of alarms or substantive variations of patients’ health conditions (p. 46). Furthermore, all the professionals involved in the service’s management and delivery, including volunteer and private contractors, are required to adopt transparent behaviours towards users and potential users. More in detail,

they are explicitly requested to deal with potential conflicts of interest arising from their eventual engagement in both the service and further external activities (p. 23).

Finally, the Telehealth Code also establishes that the staff at work for the service cannot provide misleading information on the quality or the magnitude of the benefits achievable by that means. In the same sense, they cannot overlook to inform the potential user of any circumstance that could be relevant for its consent. Signally, the Telehealth Code forbids to leverage the condition of psychological vulnerability usually faced by patients in order to promote the desirability of the remote services (p. 24). In this context, the main concern of the Telehealth Code is to ensure that potential users receive exhaustive information on the service's operation, maintaining freedom of choice between telehealth and the conventional services (pp. 19, 26).

Looking for evidences on telehealth: the WSDP

For a long time, the state of the art on telehealth has been characterised by scant evidences on the quality and effectiveness of the remote services.⁹ Most part of the specialised literature – especially from medical informatics and engineering^{21–24} – have unduly underestimated the human valences of the relationship between patients and healthcare professionals, suggesting an incautious equivalence between the technological feasibility of the remote services and the clinical acceptability of the treatments they convey.^{25–29} Another factor that has contributed to the paucity of the knowledge available in this field has been the scarce replicability of the results obtained through the randomised controlled trials. From an epistemic perspective, indeed, a significant gap between the ‘clinical experiment’ and the ‘experimental clinic’ has been reported, that is to say, a series of difficulties encountered when the ‘controlled setting’ of the trial ceases and the telehealth service has to ‘walk with their own legs’ (p. 600).²⁵ Another factor that has affected the reliability of the evidences is the methodological inadequacy of many experimentations conducted in this field. While several studies and reviews have concluded that the implementation of telehealth would bring benefits to both patients and healthcare professionals, they have largely failed to allege consistent evidences for justifying this kind of inference.^{30,31}

Aiming to cope with the discrepancy between the ‘promises’ of telehealth and the magnitude of the evidences until then available, in 2008, the UK Department of Health has financed the ‘WSDP’, the largest trial ever carried out before in this field, with a total duration of approximately 4 years and a total cost of nearly 29 million pounds. The WSDP has seen the participation of 230 general practitioners and more than 6000 patients affected by one of the following pathologies: chronic obstructive pulmonary disease, heart failure and diabetes. The trial has been divided in different sections, each assigned to an independent research institution. In 2011, before the end of the trial, the UK Department of Health released some notes from which results that the WSDP achieved ‘evidence of the benefits’ of remote care intervention.³² As stated by these notes, therefore, ‘if used correctly’, the implementation of telehealth in the UK National Health Service would be able to reduce up to 15% of the accidents occurred during the emergency visits, up to 20% of the emergency admissions, up to 14% of the elective admissions, up to 14% of the total length of the hospitalisations, up to 8% of the total expenditure in healthcare, and – strikingly – up to 45% of the mortality rate among telemonitored patients.³² Moreover, according to the former secretary of the Department of Health, the implementation of telehealth in the United Kingdom would have enabled to save up to 1.2 billion pounds in 5 years.³³ On the basis of this enthusiasm, the UK Department of Health announced the launching of a first initiative of implementation of telehealth in the National Health Service. In a first phase, the initiative was named ‘Three Million Live Campaign’, which evocated the number of patients that could have taken advantage from the adoption of this innovative form of intervention.

The estimates released by the Department of Health, nonetheless, did not find any correspondence within the official findings published at the end of the trial. More generally, they clashed with the prudent interpretation provided by the researchers at work for the WSDP. In a first section of the trial, indeed, it has been found that, if compared with the control group (patients treated traditionally), the intervention

group (patients treated with telehealth) registered a lower admission proportion (0.54 vs 0.68 days per patient) and a shorter total length of hospitalisation (4.87% vs 5.68%). Also the mortality rate resulted lower for the patients of the intervention group when compared with the control one (4.6% vs 8.3%). Moreover, within the 12-month experimentation, 42.9% of the telemonitored patients encountered a need for emergency admission, versus 48.2% of the patients conventionally treated. These differences can be seen as quite modest considering that the intervention patients were constantly ‘under control’. Commenting the findings,³⁰ indeed, the researchers of this first section have highlighted

this study has shown that a smaller proportion of telehealth users than controls were admitted to hospital during a 12-month follow-up. However, the magnitude of the group difference in admission proportion was relatively small [...] raising questions about the clinical relevance of the results. (p. 5)

Concerning other indicators, such as elective admissions, outpatient attendances and emergency visits, the difference between the intervention and the control group has been considered as ‘not significant in general’ (p. 5).³⁰ Having regard to the costs of remote care-delivery, a small decrease in the total expenditure of the intervention group has been observed in comparison with the control group (–£188 per head over 12 months). Nevertheless, this difference does not compensate the costs sustained for the implementation of the technological platforms, which were not taken into account in this section. Moreover, commenting the exiguity of that difference, the researchers have affirmed that it could have been the effect of a mere coincidence.³⁴

A further section of the WSDP assumed to evaluate the effects of telemonitoring on the quality of life of remote patients. Commenting the findings of this section, nonetheless, the researchers have observed a lack of positive effects on quality of life’s indicators:³¹

the current study’s conclusions therefore differ markedly from most extant studies and reviews examining the effect of telehealth on health related QoL, which are typically interpreted as showing benefits despite presenting equivocal evidence. The scope for inappropriate inferences is increased when small and methodologically weak studies generate inconclusive results. The current findings underline the importance of using data from adequately powered, high quality trials to make decisions about telehealth implementation and caution against reliance on meta-analyses based on small, poor quality studies. (p. 7)

The same tone has been adopted by the researchers at work on another section of the WSDP, directed to evaluate the effects of an integration between standard care and remote treatments. In this context, the researchers have found that while total expenditures for the intervention group – patients who enjoyed both telehealth and standard care – were higher than standard care alone, the integration did not generate a significant gain in terms of quality of life (p. 7),³⁵ suggesting therefore a limited impact of telehealth.

The evidence of the benefits: the public endorsement of a ‘misunderstanding’?

Paradoxically, on account of the declarations released by the UK Department of Health, the triumphalism for the benefits of telehealth has been ‘officially’ associated with the WSDP, which is currently the trial that most accurately rejects that rhetorical stance. Even more surprisingly, this rationale has been endorsed by other national and supranational political institutions with the purpose to sustain the implementation of telehealth services in public health systems. For instance, this has occurred with the Italian ‘Consiglio Superiore della Sanità’ (CSS), a national board enabled to issue orientations and normative integrations in the field of healthcare, on behalf of the Italian Ministry of Health. In 2014, the CSS issued a document containing guidelines for the development of telehealth in the Italian National Health Service.³⁶ In this document, the board finds out that the encouraging results achieved by the WSDP have induced the UK Department of Health to launch a first phase of implementation of telehealth (p. 6).³⁶ In some way, the CSS

seems to argue that the stance assumed by the UK Department of Health exempts from investigating furthermore the implications, convenience and acceptability of telehealth services. Indeed, the Italian guidelines not only disregard the official findings of the WSDP but also overlook the wider state of the art in this field, dismissing to quote any other trial, study or review on telehealth.

A similar situation occurred with the Portuguese ‘Grupo de Trabalho para a Informatização do Serviço Nacional de Saúde’ (Working Group for the Informatisation of the National Health Service), established on behalf of the Portuguese Ministry of Health.³⁷ Quoting the declaration of the UK Department of Health, in the final report, the compilers have called on to the ‘impressive results’ obtained by the WSDP (p. 44). Nonetheless, the Working Group has completely omitted any reference to the official findings of the trial, thus neglecting the discrepancy reported between the latter and the enthusiastic declarations released by the UK Department of Health.

Not least, the European Commission has defined the WSDP as ‘an example of successful experimentation’,⁴ contradicting therefore the interpretation provided by the researchers at work on the trial, especially for what concerns consistency and reliability of the achieved findings.^{30,38}

The legal and ethical implications of telehealth

Qualitative and organisational studies have already shown that the integration of telehealth does not provide a ‘technological fix’ for preexisting healthcare problems such as ageing, scarce resources and lack of coverage.²⁷ On the contrary, it has been proved that to be effective, remote services require a significant reshape of the conventional care-delivery process.^{39,40} First of all, the adoption of telehealth in daily practice affects the repartition of tasks among healthcare professionals – especially between physicians and nurses – leading to a new ‘labour division’ in healthcare. Moreover, it is worthy to remind that acting in the virtual setting entails a significant shift of the professionals’ practices and aptitudes. For this reason, as also stated by the Telehealth Code (p. 34), it is important to foresee an adequate training for those professionals involved in telehealth’s management and delivery. Indeed, most part of the remote services – and especially telemonitoring ones – enables healthcare professionals to have access to a greater portion of patients’ daily-life and consequently also to a bigger volume of sensitive data. Not only these (potential overwhelming) streams of data are to be protected against unauthorised access and misuse,^{25,41,42} but they also oblige healthcare professionals to take into account all of them, irrespective of its relevance to the patient’s conditions.²⁸ Hence, if not adequately addressed, the adoption of telehealth could easily exposes professionals to unforeseen liability issues and new cases of malpractice.

On a different standpoint, the redistribution of tasks does not only concern healthcare professionals. Telehealth requires a significant engagement of tele-patients, who are requested to contribute to the management of their own diseases through a proactive attitude, aimed at ensuring the effectiveness of remote intervention. This form of co-management, if positive in so far as it improves patients’ awareness upon their own health conditions, it could be also problematic since it blurs ever more the fine line that separates patient’s autonomy from the duties of healthcare professionals.²⁵ Together with privacy, confidentiality and liability, the ‘autonomy’ brought by telehealth to remote users is among the most discussed issues from an ethical viewpoint.^{28,43,44} Here, it is worthy to remind that this kind of discussion should be tailored on the peculiar features of the remote service considered – scope, features, pervasiveness, involvement of care professionals, length and so on. Nonetheless, for the purposes of this work, it is sufficient to consider that the adoption of telehealth services has been usually seen as a means to ensure a greater autonomy to elderly and chronic patients.⁴ In this context, it is undeniable that telehealth provides a valuable opportunity for these patients to avoid hospitalisation and stay at home. Nonetheless, this perspective seems to neglect that chronic patients are less likely to experience autonomy, and usually do not need to stay alone and live independently, but rather to enjoy of relations of closeness and intimacy with relatives and

caregivers.^{28,45} Hence, considering the therapeutic value of physical presence and touch in healthcare, telehealth services should be designed to supplement standard care more than substitute it.^{41,46,47}

Furthermore, in some cases, telehealth connects patients to automated or semi-automated care services, presented as ensuing from an authentic human expertise. Latest technological devices and applications integrate anthropomorphised and user-friendly interfaces, so as to give patients the impression of a human, warm interaction.⁴⁸ Patients themselves sometimes unconsciously contribute to the humanisation of artificial systems, charging them the responsibility for mistakes and malfunctioning.⁴⁹ For the purposes of this work, it is worthy to highlight that although patients are usually very prone to adopt new healthcare technologies, they rarely show to be fully aware of the ensuing implications.

On a different perspective, the spread of telehealth has been also proposed as a means to deal with the shortage of healthcare professionals,^{36,37} which nowadays is a persistent factor, also due to the sustainability problems faced by contemporary health systems. Indeed, the rhetorical stance that accompanies the promotion of telehealth services has leveraged to the 'optimisation of resources' in healthcare, resumed by the motto 'doing more, faster and cheaper'.^{4,50} Having clear that professionals are arguably the most important resource in healthcare, it is possible to affirm that here optimisation stands for dismissing a certain quote of them, meanwhile exacerbating the businesslike attitude of the others, that is to say, forcing them to act ever more in accordance to performance indicators. In this scenario, therefore, the emergence of telehealth as a means to deal with professionals' shortage endangers the frail equilibrium that underlies the relations of cooperation among different healthcare professionals. For what concerns nurses, the progressive emergence of registered nurse as care managers and nurse practitioners^{39,51} leads to think that nurses will be 'doomed' to replace the physical presence of remote or absent physicians, absorbing as well a remarkable portion of their responsibilities.

Finally, the new geography of healthcare traced by telehealth seems to overlook the relevance of cultural factors in healthcare organisation, especially for what concerns cross-border telehealth.²⁵ Connecting patients and professionals from different countries, or diverse professionals among them, could not be so easy as setting up a data transmission service. Indeed, beyond the potential linguistic barriers, it is worthy to point out that each healthcare profession and each service has a specific legacy of experience and a set of social practices that constitute its own 'culture'. This multifaceted, situated knowledge is fundamental in order to ensure meaningful interactions among the various professionals involved in the care-delivery process, as well as in the relationship with final users.

Conclusion: towards a new ethics for telehealth

Over the last two decades, a 'public rationale' for the promotion of telehealth has emerged at the interplay of specialised literature and political orientations. Despite the lack of consistent findings on the magnitude of its benefits, telehealth is nowadays presented as a worthy solution both for patients and healthcare institutions.^{14,15,52-54} In this context, it is possible to affirm that the strategy for the promotion of telehealth is going on under the aegis of a self-evident perspective in which technological innovation is used on a political level more for his evocative power than for the real extent of the benefits it could bring to healthcare. Nevertheless, considering that this implementation is to carry out in a context of scarce financial resources and with multiple alternative allocations for care purposes,⁵⁵ it is necessary to dispute this form of 'technological determinism', and restore a plan of analysis through which critically assess the implications of telehealth. This requires to consider not only the potential benefits – evaluating its effective extent – but also to explore the risks correlated to its spread in daily practice. Bringing into play the 'imperative of responsibility' of Hans Jonas,⁵⁶ it could be argued that the radical transformation induced by telehealth – or its 'qualitative novelty', to use the jargon of the philosopher – call on a new, ad hoc ethics, especially designed to address the operation of the remote services. An 'ethics of telehealth' should therefore offer criteria useful to take advantage of all the potential benefits it could ensure to patients and healthcare

professionals, meanwhile establish some limits in order to safeguard the quality of healthcare from the economic interests of private stakeholders. Up to now both EU and national institutions have disregarded the potential conflict of interest underlying the implementation of the remote care services into the Member States' health systems. As reported above (see section 'The EU agenda for the promotion of telehealth'), the promotion of telehealth is disclosing an immense demand of new services and products that will be mainly covered by ICTs' vendors, the only able to provide and guarantee the functioning of latest technological devices and applications. None of the orientations and policies adopted by the European Commission aligns on this aspect, except for the Telehealth Code (though briefly, in Section B2). Nonetheless, also due to the vagueness of its provisions, this instrument has largely failed to penetrate in daily practice. A different awareness has inspired the mentioned survey by the World Health Organization on the spread of telehealth,⁹ which explicitly stressed the importance of the rules presiding the relations between private providers and public healthcare institutions (p. 11). In such a scenario, it is fundamental to assess whether the innovative models are intended to cover real needs of the chronic patients or to induce new ones that match the economic interests of telehealth providers. By promoting an incremental logic according to which a 'good care' means to have access to as more care services as possible, the influence of private corporations in the definition of the public policies for technological innovation could have severe repercussions on the performance of the public health systems.

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References

1. European Commission. The 2015 ageing report economic and budgetary projections for the 28 EU member states, Available at: http://ec.europa.eu/economy_finance/publications/european_economy/2015/pdf/ee3_en.pdf (2015, accessed 1 September 2016).
2. Masino CA, Purdy B and Rossos P. The impact of telemedicine on greenhouse gas emissions at an academic health science center in Canada. *Telemed E-Health* 2010; 16(9): 973–976.
3. Hein MA. Telemedicine: an important force in the transformation of healthcare, http://ita.doc.gov/td/health/telemedicine_2009.pdf (2009, accessed 24 June 2016).
4. European Commission. EU digital agenda, Available at: <https://ec.europa.eu/digital-single-market/en/ehealth-and-ageing> (2016, accessed 12 September 2016).
5. World Health Organization. A health telematics policy in support of WHO's Health-For-All strategy for global health development. Report of the WHO group consultation on health telematics, Geneva, December 1997.
6. Bashshur LR. Telemedicine effects: cost, quality and access. *J Med Syst* 1995; 19(2): 81–91.
7. Perednia DA and Allen A. Telemedicine technology and clinical applications. *JAMA* 1995; 273(6): 483–488.
8. Wootton R. Telemedicine. Recent advances. Clinical review. *Brit Med J* 2001; 323: 557–560.
9. World Health Organization. Telemedicine. Opportunities and developments in member states. Report on the second global survey on e-Health, Geneva, 2010. Available at: http://www.who.int/goe/publications/goe_telemedicine_2010.pdf (accessed 20 March 2017)
10. European Commission. *e-Health: making healthcare better for European citizens: an action plan for a European e-Health area*. COM/2004/356, 30 April 2004. Brussels: European Commission.
11. Consolidated version of the treaty on the functioning of the European Union, <http://eur-lex.europa.eu/legal-content/EN/TXT/PDF/?uri=CELEX:12012E/TXT&from=IT> (2009, accessed 12 October 2016).

12. European Commission. *Together for health: a strategic approach for the EU 2008-2013*. COM/2007/630, 23 October 2007. Brussels: European Commission.
13. European Commission. *On telemedicine for the benefit of patients, healthcare systems and society*. COM/2008/689, 4 November 2008. Brussels: European Commission.
14. European Commission. *A digital agenda for Europe*. COM/2010/245, 26 August 2010. Brussels: European Commission.
15. European Commission. *Innovative healthcare for the 21st century*. COM/2012/736, 6 December 2012. Brussels: European Commission.
16. European Commission. Growing the European silver economy. Available at: <http://ec.europa.eu/research/innovation-union/pdf/active-healthy-ageing/silvereco.pdf> (2015, accessed 12 October 2016).
17. Merryll Lynch. The silver dollar – longevity revolution primer, <http://ec.europa.eu/research/innovation-union/pdf/active-healthy-ageing/merrill.pdf#view=fit&pagemode=none> (2014, accessed 19 September 2016).
18. Abir. Wearable computing technologies analysis report, <https://www.abiresearch.com/market-research/product/1015644-wearable-computing-technologies> (2013, accessed 11 September 2016).
19. Research2Guidance. The mobile health global market report 2013-2017: the commercialisation of mHealth apps – preview, <http://research2guidance.com/wp-content/uploads/2015/08/Mobile-Health-Market-Report-2013-2017-Preview.pdf> (2013, accessed 11 September 2016).
20. Telehealth services code of practice for Europe, <http://telehealthcode.eu> (2013, accessed 22 June 2016).
21. Ferrer-Roca O. Telepathology and optical biopsy. *Int J Telemed Appl* 2009, <http://www.hindawi.com/journals/ijta/2009/740712/> (accessed 28 June 2016).
22. Mulvaney D, Woodward B, Datta S, et al. Monitoring heart disease and diabetes with mobile internet communication. *Int J Telemed Appl* 2012, <http://www.hindawi.com/journals/ijta/2012/195970/> (accessed 21 June 2016).
23. Kailasam S, Kumar S and Dharanipragada J. Arogyasree: an enhanced grid-based approach to mobile telemedicine. *Int J Telemed Appl* 2010, <http://www.hindawi.com/journals/ijta/2010/536237/> (accessed 13 June 2016).
24. Bergrath S, Rörtgen D, Rossaint R, et al. Technical and organisational feasibility of a multifunctional telemedicine system in an emergency medical service: an observational study. *J Telemed Telecare* 2011; 17: 371–377.
25. Kluge EW. Ethical and legal challenges for health telematics in a global world: telehealth and the technological imperative. *Int J Med Inform* 2011; 80: e1–e5.
26. Zwijssen AS, Niemeijer AR and Hertogh MPM. Ethics of using assistive technologies in the care for community-dwelling elderly people: an overview of the literature. *Aging Ment Health* 2011; 15(4): 419–427.
27. Mort M, Roberts C, Pols J, et al. Ethical implications of home telecare for older people: a framework derived from a multisited participative study. *Health Expect* 2013; 18: 438–439.
28. Kaplan B and Litewka S. Ethical challenges of telemedicine and telehealth. *Camb Q Healthc Ethics* 2008; 17: 401–416.
29. May C, Harrison R, Finch T, et al. Understanding the normalization of telemedicine services through qualitative evaluation. *J Am Med Inform Assoc* 2003; 10(6): 596–604.
30. Steventon A, Bardsley M, Billings J, et al. Effect of telehealth on use of secondary care and mortality: findings from the whole system demonstrator cluster randomized trial. *Brit Med J* 2012; 344: e3874.
31. Cartwright M, Hirani SP, Rixon L, et al. Effect of telehealth on quality of life and psychological outcomes over 12 months (whole systems demonstrator telehealth questionnaire study): nested study of patient reported outcomes in a pragmatic, cluster randomised controlled trial. *Brit Med J* 2013; 346: f653.
32. UK Department of Health. WSDP headline findings, <https://www.gov.uk/government/publications/whole-system-demonstrator-programme-headline-findings-december-2011> (2011, accessed 16 June 2016).
33. UK Department of Health. Telehealth and telecare could save NHS £1.2 billion, *Press Release*, 7 March 2012, <https://www.gov.uk/government/news/telehealth-and-telecare-could-save-nhs-1-2-billion> (accessed 16 June 2016).
34. Steventon A and Bardsley M. The impact of telehealth on use of hospital care and mortality. Nuffield Trust report, http://www.nuffieldtrust.org.uk/sites/files/nuffield/publication/120622_impact_of_telehealth_on_use_of_hospital_care_and_mortality.pdf (2012, accessed 24 June 2016).

35. Henderson C, Knapp M, Fernández J, et al. Cost effectiveness of telehealth for patients with long term conditions (whole systems demonstrator telehealth questionnaire study): nested economic evaluation in a pragmatic, cluster randomised controlled trial. *Brit Med J* 2013; 346: f1035.
36. National Health Board (Consiglio Superiore della Sanità), Guidelines for the development of telemedicine (Linea guida per lo sviluppo della telemedicina). Available at: http://www.salute.gov.it/imgs/C_17_pubblicazioni_2129_allegato.pdf (2014, accessed 19 June 2016).
37. Ministry of Health of Portugal. Report: Better Information, Better Knowledge. Final report of the working group for the informatisation of the National Health System, http://www.portaldasaude.pt/NR/rdonlyres/A5AC67FD-CC3A-4A53-B858-81F5BF61D706/0/RelatorioFinalGrupoTécnicoInformaçãonaSaúde_20150216_1300.pdf (2015, accessed 23 June 2016).
38. Hendy J, Chrysanthaki T, Barlow J, et al. An organisational analysis of the implementation of telecare and telehealth: the whole systems demonstrator. *BMC Health Serv Res* 2012; 12: 403.
39. Rajani R and Perry M. The reality of medical work: the case for a new perspective on telemedicine. *Virtual Real* 1999; 4(4): 243–429.
40. Whitten P, Sypher BD and Patterson JD. Transcending the technology of telemedicine: an analysis of telemedicine in North Carolina. *Health Commun* 2000; 12(2): 109–135.
41. Demiris G, Doorenbos AZ and Towle C. Ethical considerations regarding the use of technologies for older adults. The case of telehealth. *Res Gerontol Nurs* 2009; 2(2): 128–136.
42. Lateef F. The practice of telemedicine: medico-legal and ethical issues. *Ethics Med* 2011; 27(1): 17–24.
43. Sorell T and Drapper H. Telecare, surveillance and the welfare state. *Am J Bioethics* 2012; 12(9): 36–44.
44. LeBlanc T, Shulman LN, Yu PP, et al. The ethics of health information technology in oncology: emerging issues from both local and global perspectives. *Am Soc Clin Oncol Educ Book* 2013; 136–142. Available at: <https://www.ncbi.nlm.nih.gov/pubmed/23714480>
45. Chiapparino L, Annoni M, Maugeri P, et al. What autonomy for telecare? An externalist approach. *Am J Bioethics* 2011; 12(9): 55–57.
46. Mehta SJ. Telemedicine’s potential ethical pitfalls. *Virtual Mentor* 2014; 16(12): 1014–1017.
47. Irvin R. Mediating telemedicine: ethics at a distance. *Intern Med J* 2005; 35: 56–58.
48. Lahtiranta J and Kimppa KK. The use of extremely anthropomorphized artefacts in medicine. *Int Rev Inform Ethics* 2006; 5(9): 13–24.
49. Collste G, Duquenoy P, George C, et al. ICT in Medicine and Health Care: Assessing Social, Ethical and Legal Issues. In: Berleur J, Nurminen MI and Impagliazzo J (eds) *Social Informatics: An Information Society for all? In Remembrance of Rob Kling*. HCC 2006. IFIP International Federation for Information Processing, vol 223. Boston, MA: Springer, 2006, pp. 297–308.
50. Nordgren A. The web-rhetoric of companies offering home-based personal health monitoring. *Health Care Anal* 2012; 20: 103–118.
51. Bodenheimer T and Bauer L. Rethinking the primary care workforce – an expanded role for nurses. *N Engl J Med* 2016; 375(11): 1015–1017.
52. Zissman K, Lejbkowitz I and Miller A. Telemedicine for multiple sclerosis patients: assessment using health value compass. *Mult Scler J* 2012; 18: 472–479.
53. The telemedicine centre of the INRCA in Ancona (Italy). 2011; 13: 46–49.
54. Bartoli S and Cirilli F. *ICTs in healthcare: meaning and role* 2000; 3: 54–61.
55. Fraga MJG and Rodriguez ONH. Bioethics and New Technologies: telemedicine. *Rev Cubana Enfermer* 2007; 23(1): 1–12.
56. Jonas H. *The imperative of responsibility: in search of an ethics for the technological age*. Chicago, IL: University of Chicago Press, 1985.