


Review

A human-centered, health data-driven ecosystem

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Abstract

New forms of digital care are introducing new methods of communication, care delivery, data sharing, and access to health information. The internet of things, in which sensors continuously transmit data on all types of processes, hold great promise for the care industry. Medical sensors could for instance allow clinicians to remotely monitor their patients and to take immediate actions when required. Furthermore, healthy people can be monitored as well, so that potential health issues can be either prevented or detected much earlier on. While there is clear agreement on the potential of the so-called internet of medical things, the scattering of data among the different stakeholders in care remains a critical challenge to overcome in order for this new technology to prove its added value. A human-centered, health-data-driven ecosystem in order to tackle these problems is given. The model consists out of four data quadrants: administrative and financial, logistics and facility, medical, and paramedical generating data based on four different questions: 'who am I?', 'where am I?', 'Am I healthy?', and 'how do I recover?'. It frames how data from all these different sources needs to be integrated by technology surrounding the central client in different environments. The connection and integration of this generated data can come from different sources like devices, platforms, humans, etc. Three possible flows have been described on how this integration and connection can be achieved based on edge and fog computing, cloud computing and centralized computing.

Keywords Healthcare & Welfare ecosystem · Value-based care · Connected care · Integrated care · mHealth · eHealth · Medical devices · Healthcare management model

1 Introduction: a patchwork in continuous evolving ecosystems

1.1 Demarcate the playground: connected, integrated & value-based healthcare

Michael Porter [1] defined value-based care as "achieving the highest possible outcome, that matters for the patient, for the lowest possible cost over the whole trajectory of care.". Colorafi [2] concluded from her review about connected care systems that being connected to care actors can only benefit your health. Therefore connected care solutions, where patients are continuously connected to their caretakers, offers great prospects to improve patient outcomes. The World Health Organisation [3] defines integrated health services as "health services managed and delivered in a way that they ensure people are receiving a continuum of health promotion, disease prevention, diagnosis, treatment, disease management, rehabilitation and palliative care services, at the different levels and sites of care within care system, and

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according to their needs, throughout their whole life.” Therefore, a connected and integrated care offer the potential to greatly improve our care from a value-based perspective [4]. But how far is the daily practice from these value-based, connected and integrated care solutions?

1.2 A complex patchwork of digital health-data

Since 1990 care institutions and caretakers started to digitize their paper-based records [5]. What followed was a digital transformation leading to a more automated, distributed and mobile care [6]. Trends like the growing geriatric population (50% increase by 2050) [7], an increase of chronic diseases [8] and potential pandemics are pressurizing hospital capacity [9]. On the other hand, new health technology and healthcare innovation have the potential to reduce the amount of hospitalisations, costs and increase patients experience [10]. Two concepts are of major relevance for our discussion on digital health: eHealth and mHealth. eHealth can be described as “an emerging field in the intersection of medical informatics, public health and business, referring to health services” [11]. mHealth is a subdomain of eHealth focusing on the use of mobile devices. The WHO defines mHealth as “medical and public health practice supported by mobile devices, such as mobile phones, patient monitoring devices, personal digital assistants, and other wireless devices” [12]. Chan [13] mentions that both mHealth and eHealth are already introducing new methods of communication, care delivery, and health information accessibility and that the changing health care model is simultaneously adapting to and driving initiatives in digital health care. The rise of mHealth and eHealth is enabled by the surge of the internet of things (IoT) in which devices such as sensors are connected to each other and exchange data over a network [14]. In the context of medical data, the term internet of medical things (IoMT) is sometimes coined. IoMT has launched care into a new extramural care where traditional carepaths will need to adapt to those digital care innovations [15].

With the rise of IoMT, mHealth and eHealth applications, care has becoming increasingly virtual, digital and distributed [16]. This rapid digitization is generating health-data at an unprecedented pace, so if no measures are taken, health-data shredding is going to exponentially increase with the rise of IoMT, eHealth and mHealth [17]. The possibility to share data (e.g. e-prescription, medication files, electronic patient records, electronic resident records, insurance profiles, social cards, medical images, etc.) with other care stakeholders increases the patient experience, organisational efficiency and realised the possibility to share [18]. Currently, most data generated by IoMT devices are controlled by different service providers, device manufacturers, or scattered in different care organizations [19]. The problem is not only the lack of willingness to share data, which induces the creation of ‘information silos’ in bigger hospital networks and other care institutions, but also that there is no clear view on which variety of data is available and needed for future care [20, 21]. This often causes valuable health-data to lose a lot of its value as it is not integrated nor connected to a larger ecosystem. It is recognised by the WHO that data sharing is essential, the WHO states: “Such sharing is vital as it can contribute to the enhancement of quality of processes, the outcomes of health services and the continuity of care for patients (primary use of health-data). The secondary use of health-data is important to improve the quality of healthcare and research effectiveness.” [22]. Those digital initiatives also rise some challenges like legal aspects, financial aspects, technological aspects, security and privacy aspects, and ethical aspects (see the “Discussion” section) [13, 16].

2 Methods

Insights for the development of the described model in the next sections were gathered in a three stepwise approach: literature study, stakeholder dialogue and panel expert round tables. In each step, new information was added to the model by using an iterative approach and the previous concepts were reviewed, adapted and complemented. This paper describes a theoretical model that aims to frame the innovations, initiatives, and challenges described above. By this means a possible framework on where to place those concepts in a care ecosystem are given. Examples and ideas on a more practical approach will be given and the non- technological aspects will be discussed.

2.1 Literature

A literature study was performed. Sources of literature varied from scientific papers, newspaper & magazine articles, motivational speakers, healthcare futurists, clinical examples and example projects all over the world. This allowed to identify the different actors, environments, and technologies for the care ecosystem. Once these different elements were noted they were put on the correct place which resulted into a first concept of the framework.

2.2 Stakeholder dialogue

In a second step, stakeholders like care actors and representatives from different environments and technologies were invited for an open informal discussion. Intramural actors (social service workers, transmurale coordinator, medical information officer, healthcare professionals, etc.), extramural care organizations (general practitioner unions, care service organizations, elderly care, residential care, home nursing services, etc.), MedTech companies (in branches of wearables, patient suites, patient management platforms, care path software developers, etc.) and governmental departments and clusters (Governmental consultants, FOD Gezondheidszorg and FAGG) were consulted to get a better insight into their role within the entire ecosystem. This allowed to identify the different components in connections between the client and care institutions.

2.3 Panel expert round tables

At last, final discussions and brainstorming sessions were held between representatives (general managers, operating directors and clinical stakeholders) of innovative hospitals (AZ Maria Middelaere and AZ Sint-Vincentius Deinze) and industrial partners (EEG Group). Here the input from literature and the stakeholder meetings were discussed in order to come up with the final concepts on how to defy the practical structures of the total ecosystem.

3 A human-centered, health-data-driven ecosystem: humans, environments, technologies

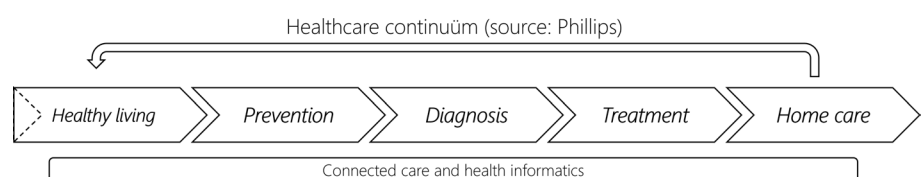
As a starting point we base ourself on the care continuum originally defined by Phillips [23]. Phillips defined the five phases of this continuum as healthy living, prevention, diagnosis, treatment and home-care (see Fig. 1). In all of these phases digital health initiatives can play a dominant role. Digital technologies can early diagnose different diseases by the use of health trackers and wearables, support rehabilitation and recovery by the use of specific devices or dedicated applications, provide better disease management for treatment of chronic diseases, support clinician in diagnoses based on real-world evidence and not to mention the tons of lifestyle applications helping people to improve their own habits [24]. But also applications like It's me to identify a client in those mHealth or eHealth applications play an important role [25]. The use of such applications results in large-scale data that is generated in all these five phases.

For the explanation of the human-centered, health-data-driven ecosystem we should mention care instead of healthcare as it can also involve well being & juvenile- or childcare. We will also refer to people enrolled in the ecosystem as "clients" instead of "patients" as they can also be in the phase of healthy living or prevention, where they are (not yet) a patient. The human-centered, health-data-driven ecosystem consists out of four different quadrants (Q). Each of these quadrants contain a specific data domain used in care. Each quadrant has a defining question that can be answered by the data generated within the quadrant itself. We defined the following quadrants (see Fig. 2).

3.1 Q1.'Who am I?': administrative and financial

Asking 'Who am I?' will generate **administrative and financial data** containing the client's personal info, historical medical data, medication schemes, social passports, etc. The data sources are the client himself, the government, voluntary caretakers and social workers. Typically administrative data is data collected at every encounter with the care system, through the entire lifetime of the client, going from birth over youth, adolescence, grown-up, elderly until passing away [26]. A first data source is the identification of a specific client as given by the population register. Examples of relevant data that is managed by the government is population and civil registry containing: ID numbers, data about dwelling place, birth place, etc. [27]. The data is to be supplemented with data from financial institutions, mutuality's, digital health data platforms, health insurances and care services [28]. More specifically, we identify the following sources:

Fig. 1 Care continuum originally defined by Phillips [23]



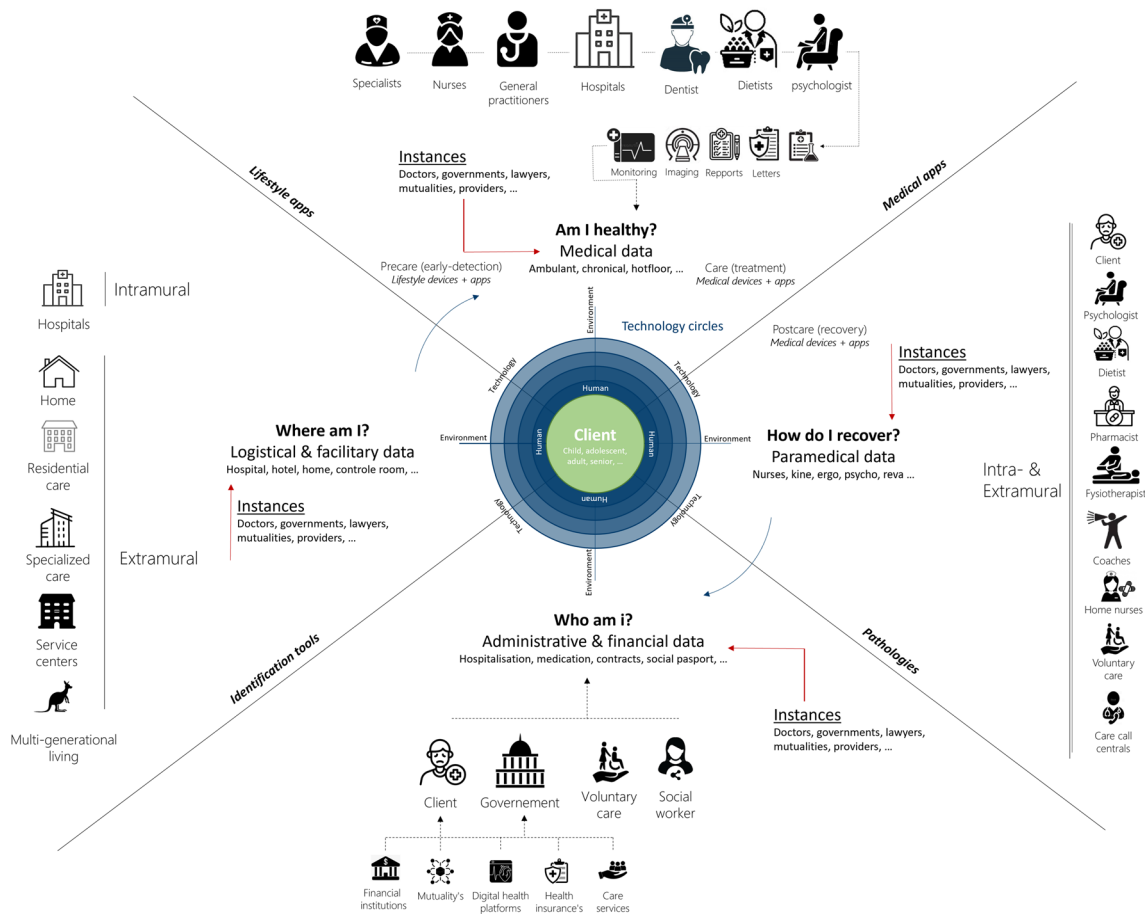


Fig. 2 Representation of the complete human-centered, health-data-drive ecosystem regarding its internal and external stakeholders and influences

- Financial institutions: financial status of the client e.g. the financial administration (bank account number), financial contracts, historical financial background like debt mediation, etc.
- Mutuality's: administrative information for reimbursement, the payer type [29], social status, etc.
- Digital health platforms: historical medical data, medication information, vaccinations, etc. This can be cataloged as medical data but is already available at the beginning and identifies a client.
- Health insurances: more specific additional insurances like hospitalization insurance, dental insurance, international insurance, etc.
- Care services: additional information about the client his/her actual well-being status and his/her self-dependency.

Next to the client him/herself and the government also voluntary caretakers and social workers can be a source of information for the first quadrant. Voluntary caretakers can give information about home situations, societal background, human characteristics, lifestyle, etc. Social workers like for example debt mediators, probation officers or outreach workers poses information about the client regarding financial debt, behavior, societal influence, etc. As can be seen this data is located in many different institutions meaning different types of data structuring, ways of storage and possible communication protocols. So how can this (un)structured data be integrated into the described ecosystem? The technology that can facilitate this integration can be categorised under identification tools' e.g. digital identity applications, patient platforms, civilian databases and banking apps. They allow an identification of the person as a unique key to each of those databases, platforms and applications. These identification tools will transfer the generated data from the first quadrant to the different environments of the second one.

3.2 Q2: 'Where am I?': logistics and facility services data

The second question 'Where am I?' will generate the logistics and facility services data of the client. This data can be related to the centered client but also to the internal stakeholders. It describes where a client resides and from which environment the client originates. In order to facilitate the connection from the client to the caretaker and vice versa in order to organize remote monitoring [30], provide chronic disease management [31], supply elderly care [32], prevent readmission and provide personal care, the location and physical environment of the patient is, as Smeenk et al. [33] mentioned, an important aspect for the continuity of care. In the logistical and facility domain we define two different groups of environments: intramural and extramural.

- Intramural: If a client is hospitalized, it's important to know in which hospital, residency or rehabilitation center: is he/she already registered? Does the institution provide any e- or mhealth services? Which external care services is the preferential partner? etc.
- Extramural: Where does the client resides normally or temporarily: at home, elderly care, residencies, juvenile institutions, etc.? In order to receive, integrate and connect the data to these different locations, it is important to identify them.

On the border of the second quadrant and the third quadrant, the technology of prevention and healthy lifestyle applications or wearables can be found. Clients already generate a lot of relevant data in their home environment [34]. Hess et al. [35] mentioned that lifestyle applications contain relevant information that can help caretakers to actively contribute to the phases of healthy living, prevention and early detection. Lifestyle application provide the caretaker with a bunch of additional information that can give insights into the daily living of the client and support caretakers in future clinical decision making [23]. Mhealth and eHealth improve care by accelerating interactive communication between clients and care providers [36–38]. As a lot of these products are consumer based, they are already widely spread among the current population and can provide an enormous amount of valuable data [39]. In fact, Apple and Google have developed devoted platforms like Apple's ResearchKit [40] and Google Fit [41] for developing research applications for fitness and health statistics. These applications support seamless interaction with various consumer devices and embedded sensors for data integration. Many BigTech companies are launching 'consumer wearables' into the market. Many of these have already achieved FDA approval like apple, Samsung, Fitbit, etc. [42]. However, while the technology is in place, there remain challenges in terms of privacy, security and ethics. (see the "Discussion" section).

3.3 Q3. Am I healthy?: medical data

The third questions, 'Am I healthy?', generates the **medical data**. It finds its origin in exams (policlinic or technical), lab tests, imaging modalities, operations, etc. The content of the data is related to medicotechnical, ambulant, chronic and hot floor treatments [43]. Chronologically in the carepath of the client the third quadrant contains the early-detection of possible pathologies. In this part, data coming from lifestyle applications and devices of the second quadrant are processed, analysed and added to the digital environments of the care-actors of the third quadrant. This information provides early insight into the question 'is the client healthy?'. Detecting a deviation of the client current health status from an "ideal health status" is the main goal in this first part of the third quadrant. In the second part of the third quadrant the actual care taking takes place. During the diagnosis and treatment of the client a lot of data will be gathered. Written reports of care actors, lab results, data from static monitoring devices, information from imaging, referral letters, etc. [44] all need to be taken into account. Human actors involved in this quadrant can be located in many different environments ranging from a hospital, a general practitioners office, a juvenile care institution to a rehabilitation center, etc. A third part of information of medical data in this third quadrant will be the medical applications and wearable devices. The new booming business of medical application (according to GMI [45] the market is projected to grow at over 30% CAGR from 2021 to 2030) are able to generate a lot of data regarding the client's recovery, chronic disease management, therapy adherence, etc. These applications and wearables can be found on the transition of the third to the fourth quadrant. The devices and apps can be separated in two categories, those used in the internal care taking (located within the third quadrant) and those used for transmural monitoring

(located on the border between third and fourth quadrant). Devices or apps will capture, analyse and transmit the data from the client in recovery to the internal stakeholder of the third quadrant so that feedback and close follow-up can be provided to improve care [46]. This is what has been defined as patient remote monitoring [30].

3.4 How do I recover?: paramedical data

The fourth quadrant is where the **paramedical data** is being generated. Here all paramedic actors involved to the recovery and post-care of a client are localized. These will generate data that needs to be accessible for all internal stakeholders to close the loop of the ecosystem and lead to a full recovery. The main sources will be intra- and extramural care takers and the clients themselves who generates data through their wearables, medical applications or eHealth platforms used in their recovery process. A close feedback loop over the first and second quadrant to the actors of the third quadrant exists. The goal of this feedback loop is to closely connect as many caretakers with the follow-up of the recovery or post care of their clients. On the border between the fourth and first quadrant, new or recurrent pathology's are lurking. When they occur, the whole trajectory will restart (as we are in a continuous loop) and the client in the center will once again pass through the four quadrants of the ecosystem.

Typically, each civilian is located in one quadrant of the ecosystem depending on the health status. In each quadrant internal stakeholders will be present, influenced by several external stakeholders like governments, doctors, mutual-ity's, lawyers, care providers, etc. In our model all four quadrants are connected with one another by different types of technology. These technologies are represented by the blue circles in Fig. 2. The bigger the circles, the further away from the center, the larger the amount of data that will be generated. The collection, analysis, transmission and processing of personal data in the four quadrants will always be done in a symbiotic collaboration between humans, environments and technology. Furthermore each of the quadrant will be influenced by external stakeholders like doctors, governments, lawyers, mutuality's, care providers, etc. Besides technical challenges each quadrant, as well as the total model, will also contain its own specific legal, privacy and ethical aspects (see "Discussion" section).

4 Dataflow through the ecosystem: collect, transmit, process and interpret

Depending on the location and time of where and when the data analysis takes place, three possible bidirectional data flows between clients and end users are identified. Figure 3 gives three bidirectional data flows based on edge and fog computing, cloud computing and centralized computing [47].

4.1 Edge & fog computing

Shi et al. [48] defined "edge/fog computing as the enabling technologies allowing computation to be performed at the edge of the network, on downstream data on behalf of cloud services and on upstream data on behalf of IoT services." With the edge being the sensor itself, this flow can be used in healthcare in cases where large datasets are generated by different sensors (e.g. continuous ECG signal). It allows to send processed data instead of a continuous raw dataflow [49], this is beneficial for the battery of the used sensor [50]. Iorga et al. [51] describe a fog model that consists of fog nodes (physical or virtual), residing between smart end-devices and centralized (cloud) service, to build a connected lo(m)T network. The role of these mentioned fog nodes can be fulfilled by the device itself, a smartphone or an external BLE node, depending on the application.

4.2 Cloud computing

The National Institute of Standards and Technology (NIST) [52] defines cloud computing as "a model for enabling ubiquitous, convenient, on-demand network access to a shared pool of configurable computing resources (e.g., networks, servers, storage, applications, and services) that can be rapidly provisioned and released with minimal management effort or service provider interaction.". Cloud computing will analyse data captured from platforms, questionnaires, etc. in a more centralised cloud server. This allows the inclusion of other relevant data sources in the analysis [49]. It is providing virtually unlimited computing, scalability, storage, and communication resources as a utility [53]. Different types of cloud computing exists (public, private, hybrid, etc.) [54]. Due to the sensitivity of healthcare data a private cloud (where

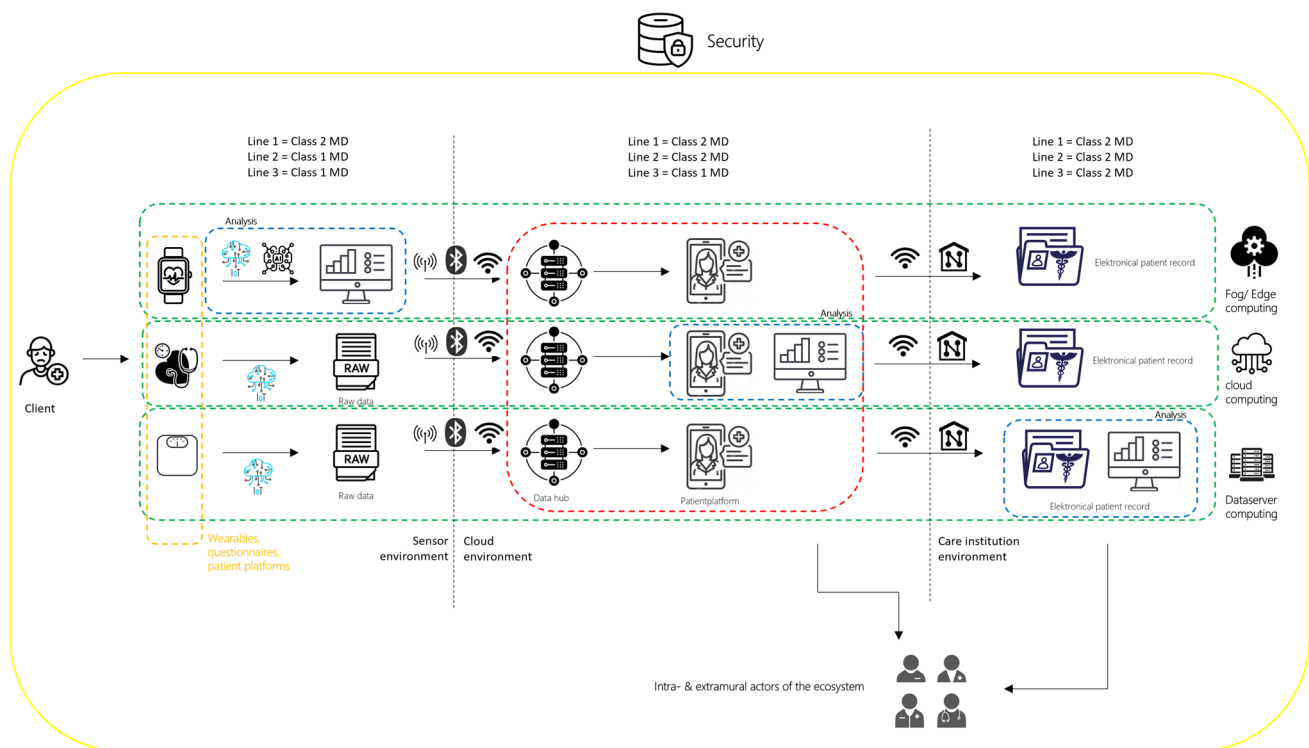


Fig. 3 Three possible data pathways to connect the client in a digital way to his/her clinical actors. First pathway including fog computing with on device edge analysis. Second pathway including cloud computing. Third pathway including computing on a centralised dataserver, typically of the care institution itself

the underlying infrastructure is not share with other parties [52]) is highly recommended. Ali et al. [55] described three major applications of cloud computing in healthcare: information processing, availability and cloud monitoring solutions.

4.3 Centralized computing

Centralized computing will perform the analysis and processing of the data on the centralised data servers of the care institutions, this allows incorporation of information from EHRs. Despite the evolving high-end security measurements of cloud and edge solutions, many care institutions remain faithful to on- premise computing out of the fear for data leakage and loss of control about their patients data [56]. However on-premise infrastructure can give scalability and configuration problems on longer terms [57].

Each pathway will implicate different technical integration's, legal structures, security demands and data processing agreements.

4.4 Practical implementations

In the above section a theoretical model was described on which data is available and how it can be incorporated into the entire system. By giving some case-examples a possible practical approach will be added. In order to set up a data-framework, two different approaches can be found in practice: a centralized approach and a decentralized approach. Karon et al. [58] described centralisation as a requirement for data coordination in healthcare. In order to perform data-driven healthcare data, centralisation seemed a necessity to perform analysis and data processing. Therefore some regions are trying to centralize their populations health- data, e.g. European Health Space data [59], GAIA-X [60], E-Estonia [61]. Also in Denmark a hospital centralisation was performed by building a centralized health data platform (www.sundhed.dk [62]) on which citizens have access to their own health data [63]. Also with Directive 2011/24/EU on patients' rights in cross-border healthcare, a centralised European health record system would become a reality before 2020 [64]. However as centralised initiatives where being set-up, they gave rise to concerns about privacy and security aspects. The protective principles cause a defensive, data hiding attitude of the health system developers to avoid breaching the overall law

regulations [64–66]. This gave rise to the idea of decentralised data storage. Decentralized data storage offers a secure and at the same time publicly available storage in a regulated way [66]. In Belgium the government is investing in the decentralised Solid [67] solution, the UAE have built a Blockchain for healthcare [68] and also Europe is investing in a decentralised European health-data and Evidence Network [69].

5 Discussion: 'Is healthcare ready for a connected and integrated care?'

This paper introduces a theoretical model for connected and integrated care systems, still the question remains if the care industry is ready for this big data revolution [70]. Olaronke et al. [71] mentions five big limitation for the implementation of 'big data' in healthcare: resistance to change, healthcare fragmentation, ethical challenges, proliferation of healthcare standards and security and privacy aspects. Also Dimitrov et al. [72] mentioned that the challenges fall into two main categories: fiscal/policy and technology. Who will pay for it? Who is responsible to tackle fragmentation and implementation? Who will take the lead in organizing data into a consistent structure? Who will manage the data? [73]. In general, we find that five aspects are essential to consider. *Legal aspects*: With the new A.I. act [74] Europe has developed a legal framework to introduce A.I. into healthcare. Also the FDA [75] and MDR [76] have their regulations in place for software as a medical device, opening the way for future e- & mHealth initiatives. As Kostkova [77] mentions regulatory frameworks and evidence for the impact digital initiatives have on clinical care and quantifiable improvement of health outcomes, still remain limited. When generating data and using these applications in a care ecosystem, the integration requires a good governmental facilitated access tool for the different sources. Furthermore also the permission to access this data needs to be regulated in a correct way. It should grant the client and other involved actors the possibility to manage his/her data. The GDPR grants a client the possibility to withdraw their medical data from any database. This is not evident due to the complexity of data sharing and storage in different centralized or decentralized platforms [78]. This data storage can give rise to legal aspects like property and contract disputes, still the aspects around data security and privacy are the most prominent [79, 80].

5.1 Financial aspects

For the use of medical applications different countries are developing a legal framework. Belgium has its mHealth pyramid [81], Germany has the Digital Health Application (DiGA) [82] framework, France has DTx reimbursement route [83], Great-Britain has a test framework for devices and apps, the U.S. has reimbursement by Medicare, Australia offers reimbursements for telemedicine, etc. While Germany, Belgium, France and Great-Britain are very mature markets, Spain for example is still a market to tackle as it has many autonomous regional payers, which causes a lot of variation [84, 85]. This follows the typical range of leaders, fast followers, certifiers and lagers with regards to the development of financial and legal frameworks [86].

Because clinical data is becoming increasingly valuable for public and private health sectors in order to provide better, cheaper and more efficient care services, data-ownership is becoming an increasingly important topic [87]. It is generally assumed that clients own and control their data [88–90]. However, in healthcare systems like those of Great-Britain, Singapore, New-Zealand and Australia, doctors who add value to clinical data are (directly or indirectly) paid as public servants. The resources to store and manage data are provided by taxpayers. This implies that the state is co-owner and needs to maintain the data for public benefits [91].

5.2 Technological aspects

Health-data can have many different origins. The data can be subdivided into two major categories: unstructured and structured data. Gantz et al. [92] described that in healthcare 90% of digital data are unstructured of which 57% will be useful if properly tagged and analysed. Structuring standards exist, but still lack multi-stakeholder acceptance and large-scale implementation [93]. This is the reason it often tends to be unsaved and unused [94]. Open platform for integration and utilization of the unstructured clinical data should be developed while reflecting these concepts [95]. However state of the art deep learning models are able to extract useful insights with reasonable accuracy [96]. While the potential of e- & mHealth is enormous, integration into the IT clinical infrastructures with the successful resolution of privacy and security aspects remains an ongoing challenge [77].

5.3 Privacy and security aspects

Health Insurance Portability and Accountability Act (HIPAA) and European General Data Protection Regulation (GDPR) are in place to datawise, protect the consumer. Both tackle the notion of a primary data custodian and a third party that can process data on the custodian's behalf and give a list of permitted uses for sensitive data like health information or genetic markers [97]. Still as Bari et al. [97] mention, HIPAA could be modernized for the digital health era. The problem is that both regulations are installed to protect the client's identity. However if one wants to create added value from combining different data sources, identifying the client in some way is necessary [98]. Cross-context identity management in e-health systems rises the issue of different identifiers creating possible security problems [99]. Also by the use of IoMT identity management is an important requirement in order to assure the protection of clients data [100].

5.4 Ethical aspects

As mentioned the integration of lifestyle applications into the ecosystem can add a lot of value regarding healthy living, prevention and early diagnosis [35]. This is something that is reflected by the big interest of the BigTech companies in healthcare [101]. However where it is difficult to integrate medical platforms, the difficulty to integrate lifestyle applications might be even higher. Mostly the companies behind these applications tend to shield their data from the outside world. When those BigTech companies gather a lot of health-data, the effects of monopolistic data collection will be inevitable [102]. In particular, those Big Tech companies offer solutions for collecting, storing and analysing health data. This raises issues with regards to privacy, data protection and informed consent [103, 104]. Also the fact that client data can be used for further development of A.I. algorithms and improvement of the application itself, questions its ethical use.

As well as privacy and protection aspects, ethical concerns about data ownership need to be taken into account [77]. Ballantyne [105] mentions that the rise of eHealth, mHealth, A.I., etc. has only made the clinical data ecosystem more complex. She mentions that the ethical decision about ownership on medical data is not so straightforward as 'being property of the patient itself'. She concludes that health-data being the private property of the client creates some ethical problems. In particular, clinical data are co-constructed and therefore a broader relationship of ownership should be taken into account. This suggests more flexible models to 'reconnect' patients and communities with their clinical data are necessary. Also a social-economical aspect will need to be taken into account. How can this ecosystem be incorporated in the daily life and the current healthcare system. Are clients ready for these digital transformations? A lot of education, teaching, awareness raising, etc. will be necessary in order to reach those clients for whom our model can make the greatest impact: elderly, people in poverty, chronically ill patients, etc.

6 Conclusion

Care evolves in this digital era towards a connected, integrated and value-based care. However at this point the current way of implementing connected and integrated care is still a patchwork of different data platforms without coherent solutions. The fact that data is stored in different locations and requested upon from other location causes no general data overview, non-uniform data structures, a decrease in patient-value and legal issues. A human-centered, health-data-driven ecosystem in order to tackle these problems is given. It describes data sources in the form of technologies, humans and environments in four data quadrants (financial and administrative, logistical and facility, medical and paramedical). Collection, transmission, processing, interpretation and security are needed as elementary steps between the data source and end-user, to make data usable in the day-to-day practice. Edge and fog computing, cloud computing and centralized computing can be used to facilitate this data connection and integration from source to end user. Besides an overview on which data sources are available and should be included and how data transfer can be facilitated, other aspects about digital health systems are discussed. These include financial, legal, privacy and security, and ethical aspects.

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Author contributions GS drafted the initial version of the manuscript and prepared the figure. ML, LH and PV reviewed the manuscript and helped with the revisions. All authors read and approved the final manuscript.

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Declarations

Ethics approval and consent to participate We hereby declare that this is an original article, nor has it been published nor submitted for publishing anywhere else.

Competing interests The authors declare that there is no conflict of interest.

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References

1. Porter ME, Teisberg EO. How physicians can change the future of health care. *JAMA*. 2007;10(1001):1103–11.
2. Colorafi K. Connected health: a review of the literature. *Mhealth*. 2016;2:13.
3. WHO. Integrated care models: an overview working document. 2016.
4. Meinert E, Alturkistani A, Brindley D, Knight P, Wells G, Pennington ND. The technological imperative for value-based health care. *Br J Hosp Med*. 2018;79(6):328–32.
5. Wilson R, McLoughlin I, Garrety K, Yu P. The digitization of healthcare: electronic records and the disruption of moral orders. Oxford: University Press; 2017.
6. Kamoun F, Nicho M. Organizational factors of healthcare data breaches: the swiss cheese model of data breach causation and prevention. *Int J Healthc Eng*. 2014;9:42–60.
7. Department of Economic United Nations and Social Affairs. World population ageing 2017—highlights. Population Division, 2017:1.
8. He W, Goodkind D, Kowal PR. An aging world: 2015: international population report. U.S. Department of Health and Human Services, 2016.
9. Soria A, Galimberti S, Lapadula G, Visco F, Ardini A, Valsecchi MG, Bonfanti P. The high volume of patients admitted during the SARS-CoV-2 pandemic has an independent harmful impact on in-hospital mortality from COVID-19. *PLoS One*. 2021;16(1):e0246170. <https://doi.org/10.1371/journal.pone.0246170>.
10. Mathew J, Lail J, Chang AC, Jefferies JL. Outpatient monitoring and self-care. 2018;2018:755–772.
11. Eysenbach G. What is e-health? *J Med Internet Res* 2001;3(2):e20. <https://doi.org/10.2196/jmir.3.2.e20>.
12. World Health Assembly, 58. Fifty-eighth World Health Assembly, Geneva, 16–25 May 2005: resolutions and decisions: annex. World Health Organization. 2005. <https://apps.who.int/iris/handle/10665/20398>.
13. Chan J. Exploring digital health care: eHealth, mHealth, and librarian opportunities. *JMLA*. 2021;109(3):376.
14. Vishnu S, Ramson SJ, Jegan R. Internet of medical things (IOMT)—an overview. In: 2020 5th International Conference on Devices, Circuits and Systems (ICDCS), 2020, pp. 101–104.
15. Kumari A, Tanwar S, Tyagi S, Kumar N. Fog computing for healthcare 4.0 environment: opportunities and challenges R. *Comput Electr Eng*. 2018;72:1–13.
16. Wehde M. Healthcare 4.0. *IEEE Eng Manag Rev*. 2019;47(3):5.
17. Varshney U. Pervasive healthcare and wireless health monitoring. *Mobile Netw Appl*. 2007;12(12):113–27.
18. Kreps GL, Neuhauser L. New directions in ehealth communication: opportunities and challenges. *Patient Educ Couns*. 2010;1(78):3.
19. Zhang J, Xue N, Huang XA. Secure system for pervasive social network-based healthcare. *IEEE Access*. 2016;4:9239–50.
20. Miller AR, Tucker C. Health information exchange, system size and information silos. *J Health Econ*. 2014;1(33):1.
21. Manyika J, Chui M., McKinsey Global Institute, By 2025, internet of things applications could have \$11 trillion impact. 2025;11:1–2.
22. World Health Organization. Organization global strategy on digital health 2020–2025. Geneva: World Health Organization; 2021.
23. Phillips. Phillips onze aanpak. 2019, Jun 2021. <https://www.philips.nl/healthcare/over-ons/philips>
24. Khan ZF, Alotaibi SR. Applications of artificial intelligence and big data analytics in m-health: a healthcare system perspective. *J Healthc Eng*. 2020;2020:8894694. <https://doi.org/10.1155/2020/8894694>.
25. Itsme. Thanks to itsme®, patients are in charge of their own medical records, 2020.
26. Cadarette SM, Wong L. An introduction to health care administrative data. *Can J Hosp Pharm*. 2015;68(3):232.
27. City of Brussels. Population & civil registry—city of brussels.

28. Washington University. Examples of administrative data—center for administrative data research (CADR)—division of infectious diseases center for administrative data research. 2020.
29. Slaybaugh. The US versus the world—axene health partners, LLC. 2019.
30. Farias FA, Dagostini CM, Bicca YD, Falavigna VF, Falavigna A. Remote patient monitoring: a systematic review. *Telemed E-Health*. 2020;26(5):576–83.
31. Norris SL, Glasgow RE, Engelgau MM, Os'Connor PJ, McCulloch D. Chronic disease management. *Manag Health Outcomes*. 2003;11(8):477–88.
32. Lindesay J, Thompson C. Housebound elderly people: definition prevalence and characteristics. *Int J Geriatr Psychiatry*. 2022;8(3):231–7.
33. Smeenk FW, de Witte LP, Nooyen IW, Crebolder HF. Effects of transmural care on coordination and continuity of care. *Patient Educ Couns*. 2021;41:73.
34. Gay V, Leijdekkers P. Bringing health and fitness data together for connected health care: mobile apps as enablers of interoperability. *J Med Internet Res*. 2015;17(11):e5094.
35. Hess B, Davies N, Jacobs L, Borofsky H, Amunugama N, Sigmond S. How can big data power the future of healthcare. *Hosp Healthc Manag*. 2017:1.
36. Choi A, Lovett AW, Kang J, Lee K, Choi L. Mobile applications to improve medication adherence: existing apps, quality of life and future directions. *J Adv Pharmacol*. 2015;3:64–74.
37. Kelli HM, Witbrodt B, Shah A. The future of mobile health applications and devices in cardiovascular health. *Euro Med J Innov*. 2017;2017:92–7.
38. Ristau RA, Yang J, White JR. Evaluation and evolution of diabetes mobile applications: key factors for health care professionals seeking to guide patients. *Diabetes journals*. 2013;26:211–5.
39. Vogels E. About one-in-five of Americans use a smart watch or fitness tracker. PEW Research Center. 2017.
40. Apple. Researchkit en carekit—apple (be).
41. Google. Google fit help.
42. Saneesh. *11 Best ECG Smartwatch Approved By FDA March 2022*. Available from, 2022.
43. Ambigavathi M, Sridharan D. A survey on big data in healthcare applications. *Adv Intell Syst Comput*. 2020. https://doi.org/10.1007/978-981-13-8618-3_77.
44. MedData. Data resources in the health sciences. 2022.
45. Ugalmugle S. mHealth - Market Growth Statistics 2021–2030, Global Projections Report.
46. Charlson M, Abelson S, Symer M, Yeo H. Mobile health apps and recovery after surgery: What are patients willing to do? *Am J Surg*. 2017;1:616–22.
47. The European health-data Space. An opportunity for the public health community. 2021:17.
48. Federal Ministry for Economic Affairs and Energy (BMWi). Gaia-x: the european project kicks off the next phase. 2020;6:1–13.
49. EAS. Home page - e-estonia. <https://e-estonia.com/>.
50. E-health in Denmark. Danish ministry of Health, ISBN: 978-87-7601-332-5. <https://sum.dk/Media/637643563459491419/eHealth%20in%20Denmark.pdf>.
51. Christiansen T, Vrangbæk K. Hospital centralization and performance in Denmark—Ten years on. *Health Policy*. 2018;122(4):321–8.
52. Kierkegaard P. Electronic health record: Wiring Europe's healthcare. *Comput Law Secur Rev*. 2011;27(5):503–15.
53. Welten S, Mou Y, Neumann L, Jaberansary M, Ucer YY, Kirsten T, Decker S, Beyan O. A privacy-preserving distributed analytics platform for health care data. *Methods Inf Med*. 2022.
54. Stevens G et al. "Is healthcare ready for a digital future?" HiPEAC vision 2021: high performance embedded architecture and compilation. Marc Duranton et al. (eds) HiPEAC; 2021. pp. 198–205. <https://doi.org/10.5281/zenodo.4719708>.
55. Shi W, Cao J, Zhang Q, Li Y, Xu L. Edge computing: vision and challenges. *Internet Things J*. 2016;3(5):637–46.
56. Yousefpour A, Fung C, Nguyen T, Kadiyala K, Jalali F, Niakanlahiji A, et al. All one needs to know about fog computing and related edge computing paradigms: a complete survey. *J Syst Arch*. 2019;1(98):289–330.
57. Chun BG, Ihm S, Maniatis P, Naik M, Patti A. Clonecloud: elastic execution between mobile device and cloud. In: *Proceedings of the sixth conference on Computer systems* 2011; pp. 301–314.
58. Iorga M, Feldman L, Barton R, Martin M, Goren N, Mahmoudi C. Fog computing conceptual model, special publication (NIST SP), National Institute of Standards and Technology, Gaithersburg, MD [online]. 2018. <https://doi.org/10.6028/NIST.SP.500-325>. Accessed 7 Dec 2022.
59. Mell P, Grance T. The NIST definition of cloud computing, special publication (NIST SP), National Institute of Standards and Technology, Gaithersburg, MD [online]. 2011. <https://doi.org/10.6028/NIST.SP.800-145>. Accessed 7 Dec 2022.
60. Aceto G, Persico V, Pescapé A. Industry 4.0 and health: Internet of things, big data, and cloud computing for healthcare 4.0. *J Indust Inf Integr*. 2020;18:100129.
61. Qureshi A, Sharma A. Cloud computing: the new world of technology. In: Goyal D, Chaturvedi P, Nagar AK, Purohit S (eds) *Proceedings of second international conference on smart energy and communication. Algorithms for Intelligent Systems*. Springer, Singapore. https://doi.org/10.1007/978-981-15-6707-0_5.
62. Ali O, Shrestha A, Soar J, Wamba SF. Cloud computing-enabled healthcare opportunities, issues, and applications: a systematic review. *J Inf Manag*. 2018;43:146–58.
63. Reddy GN, Reddy GJ (2014) Study of cloud computing in healthcare industry. *ArXiv*, [arXiv:1402.1841](https://arxiv.org/abs/1402.1841). 2014:8.
64. Fisher C. Cloud versus on-premise computing. *AJIBM*. 2018;8(09):1991.
65. Karon R, Shaanika I, Mokhatu M, Tjiwemu J. Centralisation of healthcare systems in Namibia using information technology. *Int Assoc Dev Inf Soc*. 2015;294:294–8.
66. Magyar G. Blockchain: solving the privacy and research availability tradeoff for ehr data: s new disruptive technology in health data management. In: 2017 IEEE 30th Neumann Colloquium (NC), pp. 000135–000140, 2017.
67. T-VRT NWS: Nieuws Verheyden. Het Vlaamse 'SolidLab' wil mensen weer baas maken over het internet. 2022.
68. Dynaquest. The UAE and its blockchain built for healthcare. *Blockchain, Blockchain in Healthcare*, 2020. <https://dqtsi.com/2020/02/12/the-uae-and-its-blockchain-built-for-healthcare/>.

69. The European Health Data & Evidence Network. European health data evidence network, www.ehden.eu.
70. Dash S, Shakyawar SK, Sharma M, Kaushik S. Big data in healthcare: management, analysis and future prospects. *J Big Data*. 2019;6:1–25.
71. Olaronke I, Oluwaseun O. big data in healthcare: prospects, challenges and resolutions. *FTC*. 2016;1152–1157:2016.
72. Dimitrov DV. Medical internet of things and big data in healthcare. *Healthcare Inf*. 2016;22(3):156–63.
73. Hackl WO. Intelligent re-use of nursing routine data: opportunities and challenges. *Stud Health Technol Inform*. 2016;225:727.
74. European Commission. Laying down harmonised rules on artificial intelligence (Artificial Intelligence Act) and amending certain union legislative acts. Technical Report, European Commission, Brussels, 2021.
75. FDA. Software as a Medical Device (SaMD)—FDA.
76. Medical Device Coordination Group. Medical Device Medical Device Coordination Group Document. Technical Report, Medical Device Coordination Group, 2019.
77. Kostkova P. Grand challenges in digital health. *Front Public Health*. 2015;3:134.
78. Shabani M, Borry P. Challenges of web-based personal genomic data sharing. *Life Sci Soc Policy*. 2015;11:3.
79. Ward BT, Sipior JC. The internet jurisdiction risk of cloud computing. *Inf Syst Manag*. 2010;27(4):334–9. <https://doi.org/10.1080/10580530.2010.514248>.
80. Currie WL, Seddon JJM. A cross-country study of cloud computing policy and regulation in healthcare. *European Conference on Information Systems*, 2014.
81. World Health Organization. mhealth use of appropriate digital technologies for public health. 2018;28:1–5.
82. Federal Institute for Drugs Devices and Medical. BfArM—Digital Health Applications (DiGA), 2021.
83. Vibhindika C. How to get your digital health app reimbursed in Europe? Start with Germany, Belgium and France. 2020. <https://research2guidance.com/how-to-get-your-digital-health-app-reimbursed-in-europe-start-with-germany-belgium-and-france/>
84. Reinhard T, Devred T, Rio L, Mobmer L, Vass M, Downes S. Telemedicine in Europe. Technical Report, Osborn Clark.
85. Brinkmann-Sass C, Richter L, Silberzahn T, Somauroo A. The European path to reimbursement for digital health solutions. Technical Report, McKinsey, 2020.
86. Chawla V. Where is the money in digital health? The roadmap to digital health app reimbursement in Europe. *research2guidance* 2022. <https://research2guidance.com/where-is-the-money-in-digital-health-the-roadmap-to-digital-health-app-reimbursement-in-europe/>
87. Collins B. Big data and health economics: strengths, weaknesses, opportunities and threats. *Pharmacoeconomics*. 2022;2016(1):101–6.
88. Kaye J, Whitley EA, Kanellopoulou N, Creese S, Hughes KJ, Lund D. Dynamic consent: a solution to a perennial problem? *BMC*. 2011. <https://doi.org/10.1186/s12910-016-0162-9>.
89. Solove D. Privacy self-management and the consent dilemma. *Harvard Law Rev*. 2013;126(7):1880–903.
90. S. Sterckx, V. Rakic, J. Cockbain, and P. Borry. Data scheme and their wider relevance for biomedical research, medicine, health care and philosophy you hoped we would sleep walk into accepting the collection of our data: Controversies surrounding the uk care. 2015:1–14.
91. Cook-Deegan R, Heaney C. Patents in genomics and human genetics. *Annu Rev Genomics Hum Genet*. 2010;11:383–425.
92. Gantz J, Reinsel D. The digital universe in 2020: big data, bigger digital shadows, and biggest growth in the far east. IDC iView: IDC Analyze the future 2007.2012 2012;1–16.
93. Stamm T, Bott N, Thwaites R. Building a value- based care infrastructure in europe: the health outcomes observatory. *NEJM Catal*. 2021. <https://doi.org/10.1056/CAT.21.0146>.
94. Pak. Unstructured data in healthcare. *Healthcare Tech Outlook* 2018:2019.
95. Kong HJ. Managing unstructured big data in healthcare system. *Healthc Inform Res*. 2019;25(1):1–2.
96. Mathew A, Amudha P, Sivakumari S. Deep learning techniques: an overview. *Adv Intell Syst Comput Edition*. 2021;1141:599–608.
97. Bari L, O'Neill DP. Rethinking patient data privacy in the era of digital health. *Health Affairs*; 2019
98. El Emam K, Rodgers S, Malin B. Anonymising and sharing individual patient data. *BMJ*. 2015. <https://doi.org/10.1136/bmj.h1139>.
99. Deng M, De Cock D, Preneel B. Towards a cross-context identity management framework in e-health. *Online Inf Rev*. 2009;33(3):422–42.
100. Domenech MC, Comunello E, Wingham MS. Identity management in e- Health: A case study of web of things application using OpenID connect. In: 2014 IEEE 16th International Conference on e-Health Networking, Applications and Services, Healthcom 2014, pp. 219–224, 2014.
101. Insights CB. The big tech in healthcare report: How facebook apple, microsoft, google, & amazon are battling for the healthcare market. 2021;8:3.
102. Thomason J. Big tech, big data and the new world of digital health. *Glob Health J*. 2021;5(4):165–8.
103. Sharon T. The Googlization of health research: from disruptive innovation to disruptive ethics. *Per Med*. 2016;13(6):563–74. <https://doi.org/10.2217/pme-2016-0057>.
104. Schmietow B, Marckmann G. Mobile health ethics and the expanding role of autonomy. *Med Health Care Philos*. 2019;22(4):623–30.
105. Ballantyne A. How should we think about clinical data ownership? *J Med Ethics*. 2020;46:289–94.

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