



SHAPES

Smart and Healthy Ageing

through People Engaging in supportive Systems

D3.5 – Initial SHAPES Collaborative Governance Model

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Table of Acronyms and Abbreviations

Table 3 Acronyms and Abbreviations

Acronym	Full Term
AAATE	Association for the Advancement of Assistive Technology in Europe
ADL	Activities of Daily Life
AHA	Active and Healthy Ageing
AIDS	Acquired Immune Deficiency Syndrome
APO	Align, Plan and Organize
BAI	Build, Acquire and Implement
CC	Control of Corruption
CHAT	Cultural-Historical Activity Theory
CIMA	Chartered Institute of Management Accountants
CMMI	Capability Maturity Model Integration
CNSE	Spanish National Confederation of Deaf People
COBIT	Control Objectives for Information and Related Technologies
COM	European Commission
COTRAIN	Community Organization Training and Research Advocacy Institute
CRPD	Convention of Rights of Persons with Disabilities
CSO	Civil Society Organization
CSR	Corporate Social Responsibilities
DMA	Digital Markets Act
DoA	Description of Action
DPO	Disabled persons' organizations
DSS	Deliver, Service and Support
EDM	Evaluate, Direct and Monitor
EHDS	European Health Data Space
EHR	Electronic Health Record
EIPonAHA	European Innovation Partnership on Active and Healthy Ageing
EIT	European Institute of Innovation and Technology
FCTC	Framework Convention on Tobacco Control
GAATO	Global Alliance of Assistive Technology Organizations
GDPR	General Data Protection Regulation
GE	Government Effectiveness
GP	General Practitioner
GPG	Global Public Good
GWGIIAS	Governance Working Group of the International Institute of Administrative Sciences
HIV	Human immunodeficiency virus
HPU	Health Promoting University
IACO	Internal Alliance of Carer Organizations
ICT	Information and Communication Technology
IFAC	International Federation of Accountants IFAC
IHR	International Health Regulation
ISACA	Information Systems Audit and Control Association
IMF	International Monetary Fund

KPI	Key Performance Indicator
MDG	Millennium Development Goal
MEA	Monitor, Evaluate and Assess
MS	Member States
NPM	New Public Management
NGO	Non-governmental organization
NHS	National Health Service
OI2	Open Innovation 2.0
OECD	Organisation for Economic Co-operation and Development
PHR	Personal Health Record
PV	Political Stability and Absence of Violence/Terrorism
R&I	Research and Innovation
RACI	Responsible, Accountable, Consulted, Informed
RL	Rule of Law
RQ	Regulatory Quality
RWD	Real-World Data
SDG	Sustainable Development Goal
TSO	Third sector organisations
UHC	Universal Health Coverage
UNDP	United Nations Development Programme
UoA	Unit of Analysis
VA	Voice and Accountability
WGI	Worldwide Governance Indicators
WHA	World Health Assembly
WHO	World Health Organization
WB	World Bank

Keywords

CONSULTATION, GOVERNANCE, GOOD GOVERNANCE, HEALTH, PARTICIPATION, PLATFORM, STAKEHOLDER, USER, ACTIVITY SYSTEM.

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Executive summary

Deliverable D3.5 “Initial SHAPES Collaborative Governance Model” presents a review and analysis of relevant governance models as candidates for either adoption or adaptation to serve as a proposed SHAPES governance model. This document reports on the initial phase of this analysis, and synthesis work that will be subject to continued exploration and validation during the second phase of this task. For the purposes of this document, governance is defined in terms of strategic decision-making activity that determines the range of possible actions and decisions that can be performed at lower levels of management and operations. This definition though maintains the view that governance is a process that involves the broadest set of actors as governance participants requiring exploration of the range of participation modes and barriers/facilitators to engagement in governance.

Chapter 1 introduces the work and its rationale and outlines the objectives of the deliverables and its relation to other work packages and tasks in the project. It also offers a working definitions of health for SHAPES.

In Chapter 2 (**concept of governance**), we provide a summary of the concept and practice of governance including a definition of governance, values and processes of governance, and a brief overview of practical implementation.

Chapter 3 looks at **key stakeholders and domains of governance** as candidates for consideration. These selected stakeholders and models are subject to analysis with respect to their comparative relationship to the characteristics and ethos of the SHAPES platform and broader sociotechnical ecosystem.

Chapter 4 outlines the **current findings from the consultation and data collection** process aimed at 1) establishing the range of actors and stakeholders involved, directly or indirectly, in governance and decision-making more broadly, 2) delineating the range of participation modes across different levels of engagement and decision making activity, and 3) identifying the known and potential facilitators and barriers to participation in governance including structural, cultural, technological, and personal/psychological barriers.

Chapter 5 introduces the **activity-centred approach to governance** and COBIT 2019. These frameworks are the background for discussing the role of information and technology (I&T)

governance in terms of a broader enterprise governance framework. Also, the core **principles of enterprise governance of IT (EGIT)** provide an orientation towards looking at the notion of value creation relative to the stakeholder, as a holistic systems approach.

The final chapter (6) presents the **conclusions, next steps, and a roadmap** for the further development and validation of the SHAPES Governance Model and its relationship to the other key work packages going forward, particularly WP2, WP4, WP6, WP7, and WP8. This will culminate in D3.6 scheduled for delivery in M42.

1 Introduction

Task 3.4 sets out to establish the SHAPES Governance Model and guidelines, which will support active ageing and extend older people's ability to live independently, taking into consideration the participation of SHAPES end-users in the governance of the SHAPES sociotechnical system.

In deliverable D3.5, which is associated with the objectives of Task 3.4, we present here the initial outline SHAPES Governance Model. We are paying particular attention to the issue of user participation in health and social care systems as mediated or facilitated by the SHAPES platform towards the aim of fostering greater independence and enhanced quality of life for the ageing EU population. With this in mind, we are conscious that SHAPES as a platform and IT ecosystem intersects in a complementary way with existing healthcare infrastructures and does not stand as an alternative to them. On the other hand, SHAPES is to provide the means towards opening doors for users in terms of their taking more control of their own fate when it comes to the level and quality of care afforded to them in collaboration with care providers. SHAPES therefore adds value to the lives of individual end-users as well as to the systems on which they are reliant. The question of governance then for SHAPES is one of intersecting horizon. There is healthcare governance, clinical governance, IT governance, data governance, etc., and a key task for this deliverable as well as the final SHAPES governance model and guidelines, is to chart where SHAPES sits at the point of intersection with all of these horizons. Considering that IT infrastructures exist in order to facilitate the achievement of business objectives of an organisation, it is naturally the case that operational practices of organisations become restructured resulting from the combination of affordances and constraints provided by IT systems.

As per the SHAPES Description of Action (DoA), Task 3.4 – SHAPES Governance Model and Guidelines – sets out to do the following:

“This task will involve consultation between user representatives from individual, community, health and care system provision, industrial and commercial providers and policymakers to identify the optimal form of governance with older individuals’ participation in mind. Then different levels at which the Platform’s ownership is distributed will be examined and appropriate models identified and analysed for suitability in a collaborative manner. The legal and ethical aspects of governance will be an important aspect of this analysis. What governance is

and is not; governance as a strategic issue; evaluated at a point of service delivery.”

Understanding the purpose of this in relation to the larger project of the development, piloting, and future exploitation of the SHAPES platform and associated ecosystem, requires a closer look at three aspects of this:

- Consultation with key stakeholders involved in both the provision and receipt of care services and associated products and tools to establish an appropriate level of participation in governance for each category of stakeholder. This requires careful consideration of not only the opportunities for participation in governance as an activity, but the potential pitfalls, difficulties, and consequences of too narrow or too broad definition of governance actors;
- Resulting from this consultation process, it is necessary to analyse existing models of governance and map their characteristics with both the ethos of SHAPES as well as the requirements of the informants from the consultation process considering the question of ownership, but also rights and responsibilities towards the management and strategic decision making in relation to its operation and future development;
- Through a continuing collaborative process, the most appropriate model or family of models, capable of representing the diversity of SHAPES deployment contexts, is to be identified and validated, both in terms of fitness for purpose, consistency with the objectives of SHAPES, as well as compliance with legal and ethical frameworks.

The emphasis of this task is on the strategic context of governance, more so than the day-to-day decision-making process about the nature and level of care provided at the point of use. Nonetheless, strategic questions, relating to both the spatial distribution and the evolution of the system over time, along with the cost and resourcing aspects, must also consider seriously the potential impact at the point of use and ensure that optimal levels of care and satisfaction are maintained or improved upon in a sustainable manner.

This current deliverable focuses on the first two points while keeping an eye on the third to be addressed more thoroughly in the second iteration of this work. It will discuss the results from an initial consultation process with key experts during the 2nd SHAPES Dialogue Workshop held in September 2020 and also the establishment of a method and process for continuous data collection throughout the duration of the task. More substantially, this deliverable establishes a foundation based on review and analysis of the extant literature pertaining to governance models and best practice and provides the range of options to be considered

further as we proceed further into the project and towards the identification of the most appropriate model/s for SHAPES.

At this time, it is worth noting a number of key questions that T3.4 needs to address which will be considered carefully but may not be answered entirely at this point.

1.1 The meanings of governance

In the context of SHAPES, to what does the term “governance” refer? There are a number of conceptualisations of governance, but we will need to identify a workable definition that covers the reality of what SHAPES is and will be, as not only a technological platform but also a broader social and informational ecosystem; the Platform will be more than a single digital solution: beyond its interoperability features, it will gather all types of end-users, influencing the lives of multiple classes of user and stakeholder. Further, we will address who is involved in governance. While many models stratify the activity in terms of strategic, managerial, and operational levels, with corresponding boards of expert and representative voices and responsibilities, the purpose of the SHAPES governance task is to broaden the scope of participation to a larger set of people in a way that is appropriate – meaning achieving the right balance between consultatory functions and direct decision-making functions. The meanings of governance for SHAPES will be discussed in greater detail in Chapter 2 (Sections 2.1 “Defining” and 2.2 “Understanding” governance).

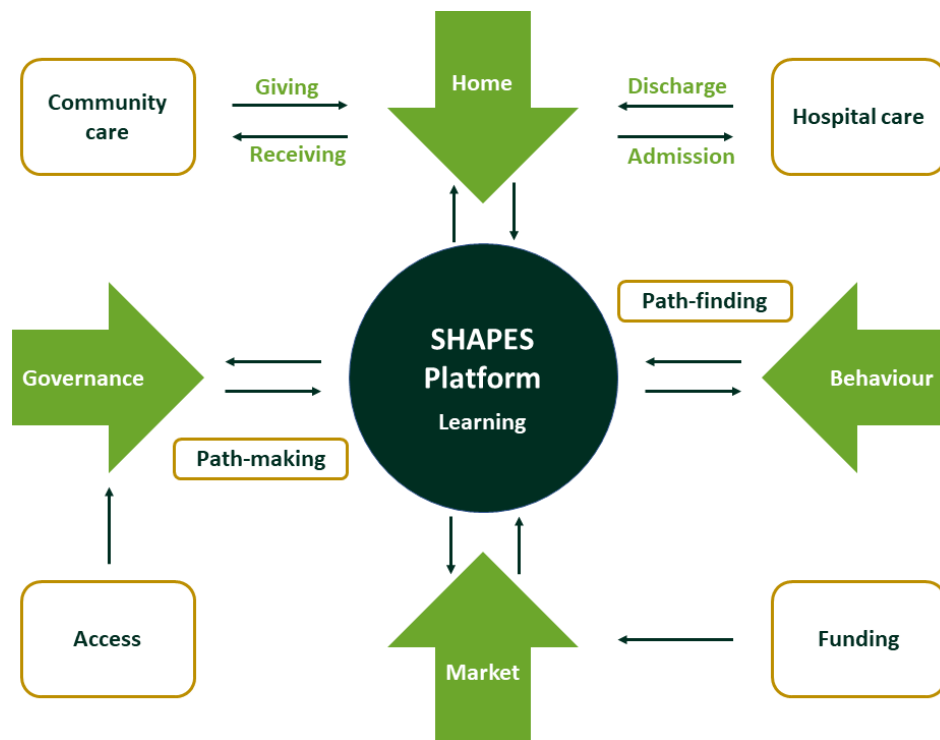


Figure 1: SHAPES Platform (Own figure)

1.2 The meanings of health

SHAPES, as a platform and ecosystem, aims to support and promote active and healthy ageing, health, wellbeing and quality of life, and promote efficiency in health and social care systems. Governance of the SHAPES Platform and ecosystem ought to be cognizant of these as overall aims for SHAPES.

1.2.1 Defining health

The most common understanding of health is the definition provided by the World Health Organization in the Preamble to its Constitution: “Health is a state of complete physical, mental and social well-being and not merely the absence of disease or infirmity.” (Official Records of WHO, no. 2, p. 100). It entered into force and has not been amended since 1948.

SHAPES adopts this understanding of health. It is intrinsically linked to acknowledging the different determinants of health and the inequities associated to health, as will be illustrated in the next section.

1.2.2 The social determinants and factors influencing health

There are myriad influences on health, wellbeing, and quality of life. Some factors, such as age, genotype and behaviour, are personal. Many other factors may be understood as social determinants of health (Dahlgren & Whitehead, 1991). These include: social and community networks and features thereof (for example, social support); the conditions in which a person lives or works (including, for example, working conditions, housing, and access to services), and; the wider social, economic, political, cultural, and physical environments.

This was first recognised at the International Conference on Primary Health Care in 1978 and the so-called “Alma-Ata” Declaration (WHO, 1978). WHO subsequently established its own Commission on Social Determinants of Health with the clear goals to reduce inequalities within and between the countries—and commissioned researchers to list the pointers of social determinants of health which are collected in the publication “Solid Facts” (Wilkinson & World Health Organization, 2003) (Marmot, 2005). Among the indicators named by Wilkinson and Marmot, one can find: social gradient; stress; early life; social exclusion; work and unemployment; social support; addiction; food; and transport.

Factors that influence active and healthy ageing may be modifiable or non-modifiable. Personal, or individual, factors such as chronological age and genotype are typically non-modifiable. Modifiable factors include individual factors, such as a person’s behaviour and lifestyle; and many of the social determinants, from the social and network factors; to living conditions, working conditions, and service access, and to even the wider social, economic, political, cultural, and physical environments. Modifications may take many forms, including the design and provision of technologies and technologically-enabled ecosystems for active and healthy ageing, and wellbeing.

1.2.3 Health as a public good

Understanding health as a public good builds upon the above definitions and is necessary for the comprehension of the SHAPES platform governance model at stake in Task 3.4. Indeed, while the term goods is being primarily used in the sense of physical commodities, it also includes services such as information. And while goods are mostly understood as private, i.e. being consumed exclusively by the individuals who purchased or own them, other goods are public, and “non-excludable”: they can be consumed by many, without the consumption of some individuals excluding the use of the goods for others: “goods in the public domain [are] available for all to enjoy. Examples include the lighthouse, peace and security, and law and order.” (Kaul & Faust, 2001). Another example was provided by Smith (R. D. Smith, 2003):

“no one in a population can be excluded from benefiting from a reduction in risk of infectious disease when its incidence is reduced, and one person benefiting from this reduction in risk does not prevent anyone else from benefiting from it as well.”

Finally, for the matter of SHAPES, it is important to follow that logic and classify health as not only a public good but also a *global* public good (R. Smith et al., 2003) (R. D. Smith, 2003), that the European Union recognised as such (Duten, 2014). That claim will also remain a priority in the “post-COVID” era (Abdalla et al., 2020). The assumption of health being a (global) public good is closely linked to calls for collective action.

1.2.4 Ethical and legal considerations of health

The ethical implications of globalisation have been addressed in terms of biomedical ethics and the ethics of care by Beauchamp and Childress (2001).

Table 4 Principles of Biomedical ethics and Ethics of Care (Beauchamp & Childress, 2001)

Biomedical ethics (Beauchamp & Childress, 2001)	Ethics of Care
Respect for Autonomy	Empathy
Non-maleficence	Relationships
Beneficence	Uniqueness of case
Justice	

The practice of global ethics supposes (moral) reasoning beyond borders. Part of the Global Ethics, the capability approach introduces a space in which judgements can be made on the quality of life, i.e. to health. The notion of capabilities will prove itself important for the definition of SHAPES Platform which is such a space within which, because whether of socio-determinants or biomedical reasons, two people suffering from ill health will still engage in different paths depending on their capabilities¹.

Table 5 Central Human Capabilities (Nussbaum, 2011)

Central Human Capabilities (Nussbaum, 2011)			
1	Life	6	Practical Reason
2	Bodily Health	7	Affiliation
3	Bodily Integrity	8	Other Species
4	Senses, Imagination and Thought	9	Play
5	Emotions	10	Control over one's environment

¹ Nussbaum's capability approach (2011) is grounded within the intuition of a dignified **human** life whereby people have the **capability** to pursue their conception of the good in cooperation with others.

Anchoring health as a human right originated in documents by international organisations:

- Constitution of the World Health Organization (1946)
- Article 25.1 of the Universal Declaration of Human Rights (1948): Article 25 1 (United Nations, 1948). “Everyone has the right to a standard of living adequate for the health and well-being of himself and of his family, including food, clothing, housing and medical care and necessary social services, and the right to security in the event of unemployment, sickness, disability, widowhood, old age or other lack of livelihood in circumstances beyond his control.”
- Article 12 of the International Covenant on Economic, Social and Cultural Rights (1966): “the right to the highest attainable standard of physical and mental health” (United Nations General Assembly 1966).
- Convention on the Rights of the Child (1989)
- United Nations World Conference on Human Rights, Vienna, (1993)

In 2002, a special rapporteur was appointed to the UN Commission on Human Rights in order to support a right to enjoy the highest attainable standard of physical and mental health.

At the European Union level, the Charter of Fundamental Rights states in its Preamble (2012):

“Conscious of its spiritual and moral heritage, the Union is founded on the indivisible, universal values of human dignity, freedom, equality and solidarity; it is based on the principles of democracy and the rule of law. It places the individual at the heart of its activities, by establishing the citizenship of the Union and by creating an area of freedom, security and justice.”

Enjoyment of these EU Fundamental Rights entails responsibilities and duties with regard to other persons, to the human community and to future generations (COM 2021, preamble).

Article 35 (under Title IV: Solidarity), of the *Charter of Fundamental Rights of the European Union* (European Union, 2012) recognises the right to health care:

Everyone has the right of access to preventive health care and the right to benefit from medical treatment under the conditions established by national laws and practices. A high level of human health protection shall be ensured in the definition and implementation of all the Union's policies and activities.

From the viewpoint of SHAPES Governance, the EU fundamental rights form a sound value basis for the design of SHAPES – and also its governance models. Alongside these rights,

the Convention of Rights of Persons with Disabilities (CRPD), Ethics of Care, Biomedical Ethics and Capabilities approach provide key input for the SHAPES value base. (SHAPES, 2020b).

Table 6 EU Fundamental Rights (European Union, 2012)

EU Fundamental Rights (most relevant for SHAPES written in black)		
	Fundamental Right	Most Relevant for SHAPES
	Dignity	
1	Human dignity	✓
2	Right to life	✓
3	Right to the integrity of the person	✓
4	Prohibition of torture and inhuman or degrading treatment or punishment	✓
5	Prohibition of slavery and forced labour	✓
	Freedom	
6	Right to liberty and security	✓
7	Respect for private and family life	✓
8	Protection of personal data	✓
9	Right to marry and right to found a family	
10	Freedom of thought, conscience and religion	✓
11	Freedom of expression and information	✓
12	Freedom of assembly and of association	✓
13	Freedom of the arts and sciences	✓
14	Right to education	✓
15	Freedom to choose an occupation and right to engage in work	✓
16	Freedom to conduct a business	✓
17	Right to property	✓
18	Right to asylum	
19	Protection in the event of removal, expulsion or extradition	
	Equality	
20	Equality before the law	
21	Non-discrimination	✓
22	Cultural, religious and linguistic diversity	✓
23	Equality between men and women	✓
24	The rights of the child	
25	The rights of the elderly	✓
26	Integration of persons with disabilities	✓
	Solidarity	
27	Workers' right to information and consultation within the undertaking	
28	Right of collective bargaining and action	
29	Right of access to placement services	
30	Protection in the event of unjustified dismissal	
31	Fair and just working conditions	✓
32	Prohibition of child labour and protection of young people at work	

33	Family and professional life	
34	Social security and social assistance	✓
35	Health care	✓
36	Access to services of general economic interest	
37	Environmental protection	✓
38	Consumer protection	✓
	Citizens' Rights	
39	Right to vote and to stand as a candidate at elections to the European Parliament	
40	Right to vote and to stand as a candidate at municipal elections	
41	Right to good administration	✓
42	Right of access to documents	✓
43	Ombudsman	
44	Right to petition	
45	Freedom of movement and of residence	
46	Diplomatic and consular protection	
	Justice	
47	Right to an effective remedy and to a fair trial	
48	Presumption of innocence and right of defence	
49	Principles of legality and proportionality of criminal offences and penalties	
50	Right not to be tried or punished twice in criminal proceedings for the same criminal offence	

Arguments in favour of considering health a human right include the notoriety and visibility it allocated to health issues, such as HIV/AIDS, and the correlated allocation of resources to specific diseases. However, health as a human right is also more difficult to actively protect (Evans, 2002).

Within SHAPES, health is understood as an ethically grounded human right, responding to imperatives of globalisation and global governance, determined by socio-economic gradients, guarded by European Rights, while at the same time being impacted by the interplay of human capabilities.

1.2.5 Summary

In line with extant evidence, SHAPES embraces the understanding of health as an outcome of wider social and economic determinants of health, as opposed to the simple expression of a biological or medical condition (see also D3.1). The relevance of social and economic determinants of health is central to SHAPES and the starting point of the governance of SHAPES Platform, since it considers the broader issues at stake for all SHAPES stakeholders.

Simple access (to water, medicine, points of care) is not sufficient for health and wellbeing but need to come in a setting (Chapter 5 and WP9).

Similarly, it is important to acknowledge that determinants of health are shifting from being exclusively national characteristics to being contingent upon globalisation and shifts regarding trade, the environment, and political stability. In the European context, this means that neither are the causes of ill health, poor health literacy or unequal access to care services solely linked to for instance birth or residence in one member state above the other, nor do the solutions engage single states or regions but should be designed as a common enterprise. This is what SHAPES aims to do.

1.3 Governance of and through SHAPES

On the one hand SHAPES represents an integrated IT system that gathers and processes health and lifestyle data as well as facilitating the connection to a wide range of current and future digital solutions. In this capacity, it is subject to IT governance processes, as any IT system would be, as well as to data governance and privacy regulations. On the other hand, it has the potential to facilitate active participation in the governance of health and social care systems more generally and thus can be seen as “participating” in the governance of those systems. This will be expanded on further below.

1.4 Ownership of SHAPES

This question relates to the fact that health and social care services are usually distributed between public and private sectors according to different models (see SHAPES D3.1 for further discussion). SHAPES is likewise envisioned to operate across both models and in fact facilitate the integration of public and private sector care provision. But the question of ownership, beyond the product and IP developed by the consortium, has to be addressed along with the potential business models for sustainably resourcing healthcare systems that may be supported or augmented with by the SHAPES platform capabilities, including the idea of Market Shaping in WP7. Finally, on this point there is the fact that SHAPES is a lot more than an IT platform and network of digital solutions, but it is also the ecosystem of SHAPES which includes the technological aspects, but more importantly the sociocultural, knowledge & informational, educational, economic, and lifestyle aspects of SHAPES in context. The details of the nature, composition and structure of this ecosystem are being explored within WP2 and

WP3 and will have a direct impact on how we approach the question of ownership and governance.

1.5 Governance domains

What are the domains of governance for SHAPES? On the one hand we can discuss SHAPES in the context of health and social care systems, with the presumption that SHAPES will be subsumed in one way or another within such a system. It is necessary therefore to consider the governance structures and processes of healthcare provision. However, SHAPES as an IT system is subject to the principles of IT governance models also which has its own set of unique considerations and standards pertaining to data protection, security. Rather than seeing this as competing structures for governance, we need to examine how one is nested within the other, which is a principle that will again be discussed further below.

When addressing these issues, it is useful to think of the SHAPES platform as instrumental with respect to the broader ecosystem of SHAPES as it is discussed in this project. By instrumental we mean that it is a key enabler of function and capacity. To put this another way, SHAPES as an IT system mediates the activities of actors within the ecosystem towards the collaborative achievement of their respective goals and needs while accommodating their diversity.

1.6 Rationale, purpose, and scope of the deliverable

This deliverable (D3.5 Initial SHAPES Collaborative Governance Model) seeks to outline initial steps towards the optimal governance structure with focus on participation of all users at all levels of service provision where it is understood that participation is mediated (facilitated by) the SHAPES Platform. It intends to identify the distributed ownership structure of the platform as well as the relevant structures of accountability and responsibility.

The document here is intended to be used by a wide range of partners within the project as well as members of society more broadly. For consortium members, the output can be used to steer the development of the platform and digital solutions towards representing the wide range of stakeholders and users concerned with SHAPES and facilitating their participation in the governance of issues of relevance to their lives. For the broader community this document will help to structure the dialogue and consultation process to ensure that the eventual final governance model is representative of the diverse needs and preferences of the European

population and also provides clear guidance on how their participation in governance can be supported through the platform.

1.6.1 Deliverable objectives

As per the DoA, this deliverable “...outlines the optimal governance structure considering the appropriate levels of participation by users at all levels of service provision, mediated by the SHAPES Platform.” As this is the first iteration of this task its purpose is to report on initial consultation activities and set out the agenda and method for broader consultation in phase 2 of the task. By outlining the conditions for an optimal governance structure, this will allow for a process of iterative evaluation and validation of an evolving governance model.

The deliverable is also intended to be used as a working guide to inform the development of the platform, the planning and running of the pilots and their evaluation, and the exploitation of SHAPES with the broadest range of end-users and stakeholders in mind.

1.6.2 Key inputs and outputs

This deliverable incorporates some of the preliminary results from D2.1, draws upon research undertaken in the T2.1 and T3.1, WP8. It is intended to support the further development of WP4, WP6, WP7, WP8, and Task 9.1.

1.7 Structure of the document

Chapter 1 introduces the rationale and purpose of D3.5 and outlines the objectives of the deliverables and its relation to other work packages and tasks in the project.

In Chapter 2 we provide a summary of the concept and practice of governance including a definition of governance, values and processes of governance, and an overview of actors of governance, both actors generally and actors specifically relevant to the SHAPES Platform.

In Chapter 3 (Stakeholders and domains of governance), we investigate the domains of governance that are relevant to the SHAPES Platform in greater depth. The first two sections (Sections 3.1 and 3.2) summarise the structures, processes and values that govern clinical care and home care. In so doing, we contextualise the wider environment in which the Platform is embedded. We then explore those domains of governance which are directly related to the business model of SHAPES (Section 3.2.4 Business and Corporate Governance), and to the Platform (Section 3.2.3 IT Governance and Section 3.2.5 Data Governance).

The SHAPES Governance Model is not created in a vacuum but in collaboration with experts. As outlined in Chapter 4 (Participation in health and social care governance), we will consult relevant key stakeholders for their expert insights into existing structures, processes and opportunities for participation in healthcare and social care governance. A combination of focus group conversations, interviews in with older adults and informal caregivers in Task 2.1 and lastly, a survey on governance participation is expected to facilitate some preliminary insights into the challenges and opportunities associated with health and social care governance.

In Chapter 5 (Outline of the SHAPES activity-centred governance model), we combine the theoretical and empirical knowledge about governance as a basis for the Initial SHAPES Governance Model. In addition, we take into consideration that the governance model must work at multiple levels corresponding to the different, interconnected elements of SHAPES. Based on these considerations, we will develop an outline of a SHAPES Governance Model which, in the second iteration of this deliverable, will be developed further incorporating the findings from the other work packages, as described in the following Chapter.

In Chapter 6 (Conclusions), we provide a summary of the deliverable. We visualise the interdependencies between the second iteration of the SHAPES Governance Model (D3.6) and other deliverables, tasks and work packages in SHAPES. This allows us to demonstrate the next steps towards developing a fully-fledged governance model. Furthermore, we outline the limitations of D3.5 and the activities undertaken to address these shortcomings in D3.6.

2 The concept of governance in the SHAPES context

This chapter provides the necessary background for our present understanding of governance. We begin by seeking to define the concept of governance, and we then proceed to expound upon our understanding of its models, address foundational values and principles, and finally consider issues of implementation to achieve functions. Agreeing on a common understanding is essential in order to understand the realm of possibilities for the governance of the SHAPES Platform itself.

2.1 Defining governance

“Governance is a very old concept, and an even older reality. Societies have always required some form of collective steering and management.” (Pierre & Peters, 2005, p. 49). The term governance draws its origins from the French word ‘gouvernance’, describing the manner of governing. Its current use is attributed to Ronald Coase (1937) and his description of an anomaly in the neoclassical market theory that seemed in need of a certain degree of steering. Since then, the concept was transferred to the economy of institutions and applied to micro, meso and macro levels (Benz et al., 2007, p. 11). Yet, it is safe to say that no consensus can be found on an exact definition of governance in general nor for health or other domains of governance in particular. Therefore, this deliverable will draw upon a variety of definitions. Considering the complexity of SHAPES ambitions, the many layers of governance will support the multifaceted aspects of the project itself.

A number of definitions of the term have been reviewed in order to illustrate the breadth and the depth of the discussions around governance. A framework drawing on the many definitions of governance was given by Kaufmann et al. (2010, p.4), including:

“the traditions and institutions by which authority in a country is exercised. This includes (a) the process by which governments are selected, monitored and replaced; (b) the capacity of the government to effectively formulate and implement sound policies; and (c) the respect of citizens and the state for the institutions that govern economic and social interactions among them.”

However, this is geographically limited. For SHAPES, the term needs to be opened to non-territorial understandings. Therefore, Rosenau’s understanding of governance is the basis of

this deliverable. Indeed, in his groundwork on "global governance", Rosenau argues that "global governance is conceived to include systems of rule at all levels of human activity--from the family to the international organization--in which the pursuit of goals through the exercise of control has transnational repercussion" (Rosenau, 1995, p. 13). **As such, governance includes all environments in which control is being exercised and relationships between actors are being observed.**

All in all, "Governance is a useful concept not least because it is sufficiently vague and inclusive that it can be thought to embrace a variety of different approaches and theories (...) This is the beginning, rather than the end, of the discussion." (Peters & Pierre, 2000, p. 37). Pierre and Peters (2000) distinguish two meanings of the notion: (i) 'governance' as the process or state of relations trying to be regulated; (ii) a more normative meaning of the word implying a concept of how social systems are being regulated.

At the same time, governance bears the idea of 'sound management' just as much as the 'government' dimension (Lamy, 2001). This normative concept brought along the term 'good governance', extensively used by the World Bank e.g., setting efficiency, constitutionality and closeness to the citizens as criteria for developing countries to obtain credits issued by the international organisation (Benz, 2004).

In the context of this deliverable and SHAPES in general, the understanding of 'governance' provided by Mayntz (2004) is useful. The inherent process-component of the term is being put forward, distinguishing between its use to describe interrogations about the pros and cons of hierarchical steering as opposed to market-oriented regulations and its use in international and national politics emphasising non-hierarchical and non-state regulations (Mayntz, 2004). The latter employment of the word governance and the related normative idea of 'good governance' in (global) governance opened the door to the involvement of civil society in policy making processes (Mayntz, 2004).

Finally, for the European Union, 'Governance' means "rules, processes and behaviour that affect the way in which powers are exercised at European level, particularly as regards openness, participation, accountability, effectiveness and coherence" (European Governance - A White Paper, 2001) So, although the Commission seems to adopt a 'process' understanding of the term governance according to Pierre and Peters (2000) analysis, it is also strongly normative in that it mentions 'participation', 'effectiveness' and 'openness'.

The topic of governance is very broad and is a multi-layered, nested issue. Governance is often characterised in structural terms that can be neatly depicted in organisational structural

models. However, governance is also an activity that can be characterised in terms of what people are doing within that structure. With this in mind, we distinguish between governance and management:

- *Governance – the creation of a setting in which others can manage effectively.*
- *Management – the making of operating decisions.*

SHAPES adheres to the normative understanding of the term governance in order to promote good health (see introduction); therefore it rests upon a set of values and principles described in the following sections.

2.2 Understanding governance

As discussed above, the necessity of governance arose together with the neoliberal aspirations of “New Public Management” and other ideologies aiming at taming and grooming governments towards more efficiency, eventually delineating a “Governance without government”, as the milestone paper by Peters and Pierre is entitled (1998).

The concept of governance may be and is applied in all aspects of society, education, politics, the environment, health, business and so on. The particularities of these different types of governance will be discussed below. Hence, before exploring the many dimensions of governance, the embedded tools and principles, it is necessary to understanding some overarching and theoretical underpinnings of models of governance.

2.2.1 Models and levels of governance

2.2.1.1 Control vs supervision models

Borrowed from the science of higher education, the distinction between rationally planning and controlling models of governance and supervising models is very useful. Those two concepts of governance can be described as follows: the model of rational planning and control assumes the power of the state (this is a state-centric approach) is limitless; the model of self-regulation believes in the self-regulation of smaller (decentralised) entities (van Vught & de Boer, 2015). The role of the “steerer” is largely different than in the first model: it becomes more that of a co-designer, interfering solely when the conditions are not optimal anymore or do no longer suit the aim of the relational interplay.

2.2.1.2 Top-down versus bottom-up models

Similarly, top-down models of governance can be distinguished from bottom-up models. Environmental governance scholars (see among others have widely debated on the advantages and downfalls of those approaches in terms of city planning e.g., or (global) environmental policies. Does collective will (bottom-up) trump unilateral decisions? Do prescriptive solutions (top-down) ensure more adherence? These models are helpful because they depict the variety of actors involve and consider the different levels and impact of "decision-making powers". They are however limited by their dichotomy and fail to take into account the many shades of multi-level governance that SHAPES acknowledges.

2.2.1.3 Global governance

Global governance recognises both the variety and multitude of stakeholders. The term was defined as "the sum of the world's formal and informal rules systems at all levels of community amount to what can properly be called global governance" (Rosenau, 2003). Whereas global governance classically belongs to international relations research and therefore of limited added value for SHAPES, it provides a crucial understanding to the term governance in general since it dissociates it from the state itself. Talking about global governance is acknowledging that governing can be done without being the "sovereign" (state) and a power exercised upon relationships of many actors, beyond national frontiers (Finkelstein, 1995). Finally, the so-called Commission on Global Governance, a group of international experts who received the full support of the then Secretary-General of the United Nations Boutros-Boutros Ghali, defined governance as "the sum of the many ways individuals and institutions, public and private, manage their common affairs. It is the continuing process through which conflicting or diverse interests may be accommodated and co-operative action may be taken" (Commission on Global Governance, 1995). As such, the global level of governance offered the term governance some legitimacy in order to describe, analyse and improve relations between all type of stakeholders.

These relationships have been further categorised and rated. Selecting criteria for an optimal model of governance for SHAPES will take this into consideration. Next we need to understand the dimensions of governance as well as their underlying principles as will be discussed in the following sections and later defining the nature of the optimal SHAPES Platform governance model. Further, the activity-centred approach introduced in Chapter 6 will offer a new framework to determine an innovative model of governance for the SHAPES Platform aligned with enterprise governance of IT.

2.2.1.4 The European Union governance model

Similarly to the necessity of understanding the notion of global governance and its impact on the conceptualisation of governance itself, it is essential to look at the governance model of the European Union in order to set the scene within which SHAPES will be operating. The European Union (EU), is a supranational organisation: “a unique economic and political union between 27 European countries” (European Commission & Directorate-General Communication, 2020, p. 7).² Decisions are taken through democratic processes involving the following four core institutions: The European Commission (EC), the European Parliament, the Council of the European Union (the Council), and the European Council.

There are also a range of other organs, including two advisory bodies (i.e. the European Economic and Social Committee and the European Committee of the Regions) whose role is to advise Parliament, Council and Commission. The 27 national parliaments of the EU MS function as national oversight bodies. They also hold the EC accountable with regards to draft legislation which may be in breach of the principle of subsidiarity³. The European Central Bank seeks to “maintain monetary stability” [and] “makes its decisions [independently] without seeking or taking instructions from governments or other EU institutions” (European Commission & Directorate-General Communication, 2020, p. 55). Lastly, the European Investment Bank lends money “for investments that support the EU’s objectives” (*ibid.*).

Finally, for the European Union, ‘Governance’ means “rules, processes and behaviour that affect the way in which powers are exercised at European level, particularly as regards openness, participation, accountability, effectiveness and coherence” (European Governance - A White Paper, 2001) So, although the Commission seems to adopt a ‘process’ understanding of the term governance according to Pierre and Peters (2000) analysis (see section 2.1 above), it is also strongly normative in that it mentions ‘participation’, ‘effectiveness’ and ‘openness’.

² The following sections, based on the recent publication “The European Union: What it is and what it does” (European Commission & Directorate-General Communication, 2020), briefly summarise the main functions of several key institutions of the EU.

³ Principle of Subsidiarity is “laid down in the Treaty on European Union, defines the circumstances in which it is preferable for action to be taken by the Union, rather than the Member States” (European Parliament, 2021).

2.2.2 Dimensions and functions of governance

The concept of governance has, as explained above, evolved at great pace throughout the twentieth century. The role of globalisation, the emergence of global governance and the impact of technologies impacted on the understanding of what governance is and what it could achieve. While in the 1990s, it was common to refer to three dimensions of governance: the economic, the political and the institutional (GWGIAS, 1996). All three dimensions regroup processes: the ones around election, monitoring and replacement of those in power (political dimension); the ones describing the management of resources and the implementation of sound policies (economic dimension); and finally the processes enforcing the respect of the state, the public institutions and the citizens themselves. SHAPES evolves in all three dimensions, and even differentiates between different type of processes involving the citizens, at the community and private level, as well as at the action level.

These dimensions were quickly enhanced by others, addressing the processes enshrined within those dimensions. This section and this deliverable in general do not claim to comprehensively catalogue all dimensions or processes. However a selection of dimensions and associated functions of governance will be discussed in this section

The use of the term governance picked up speed with the New Public Management (NPM) school of thought, as a “business-based” approach to the public sector. Governance becomes a set of normative functions, that serve goals (see e.g. Peters and Pierre (2000), who clustered those into four categories: i) “articulating collective goals and priorities”, ii) “ensuring coherence”, iii) “steering” and iv) “accountability”).

One of the most comprehensive methodological efforts to understand the interaction between governance dimensions and its processes, is building upon those categories. It was put together by the Worldwide Governance Indicators (WGI) Project, which reported aggregate and individual governance indicators for over 200 countries and territories for over ten years (1996–2019). The Project established a framework of six dimensions of governance at the country level, based on data gathered from a number of survey institutes, think tanks, non-governmental organisations, international organisations, and private sector firms:⁴

⁴ “The Worldwide Governance Indicators (WGI) are a research dataset summarizing the views on the quality of governance provided by a large number of enterprise, citizen and expert survey respondents in industrial and developing countries.” Cf. <http://info.worldbank.org/governance/wgi> (31.01.2021)

It is important to note that while the WGI do not reflect the official views of the World Bank, nor are being used by the World Bank Group to allocate resources, it is safe to assume that they align broadly with the WB’s understanding of governance.

- Voice and Accountability
- Political Stability and Absence of Violence
- Government Effectiveness
- Regulatory Quality
- Rule of Law
- Control of Corruption

Table 7 Six dimensions of governance (Kaufmann et al., 2010)

Six dimensions of governance		
(a) The process by which governments are selected, monitored, and replaced :	(b) The capacity of the government to effectively formulate and implement sound policies :	(c) The respect of citizens and the state for the institutions that govern economic and social interactions among them:
1. Voice and Accountability (VA) – capturing perceptions of the extent to which a country's citizens are able to participate in selecting their government, as well as freedom of expression, freedom of association, and a free media.	3. Government Effectiveness (GE) – capturing perceptions of the quality of public services, the quality of the civil service and the degree of its independence from political pressures, the quality of policy formulation and implementation, and the credibility of the government's commitment to such policies.	5. Rule of Law (RL) – capturing perceptions of the extent to which agents have confidence in and abide by the rules of society, and in particular the quality of contract enforcement, property rights, the police, and the courts, as well as the likelihood of crime and violence.
2. Political Stability and Absence of Violence/Terrorism (PV) – capturing perceptions of the likelihood that the government will be destabilized or overthrown by unconstitutional or violent means, including politically-motivated violence and terrorism	4. Regulatory Quality (RQ) – capturing perceptions of the ability of the government to formulate and implement sound policies and regulations that permit and promote private sector development.	6. Control of Corruption (CC) – capturing perceptions of the extent to which public power is exercised for private gain, including both petty and grand forms of corruption, as well as "capture" of the state by elites and private interests.

The WGI-authors underlined that the dimensions identified were in no way independent from each other Kaufmann et al. (2010). On the contrary, the high level of interdependencies means

that the task of assigning individual variables to each of the six dimensions is not clear-cut. What WGI is doing is providing a blunt tool for policy advice at the country level.

The model of governance of the SHAPES platform is of course different from governance at country level. Yet, the SHAPES model of governance remains an object of governance itself, not providing care, but (potentially) part of the health system infrastructure, and will therefore make use of the indicators identified by WGI in D3.6, once further consultations will have been carried out in T3.4.

2.3 Enabling governance

As described above, governance research in general, as well as for SHAPES in particular, aims above all at improving governance itself and encompasses a range of normative concepts. This section will examine the values, principles and functions of governance in general as well as in the specific context of health and care.

In certain disciplines, it is important to note the nuance between principles and values. This deliverable will interchangeably address both, even if we understand that **principles** are commonly understood as rules and **values** as standards or beliefs about what is right and wrong or beliefs about what is most important in life. Each could therefore imply or demand a different level of enforcement in different governance settings. The use of both terms paves the way for acting upon what is either determined by law or commonly understood as what is right and wrong. The optimal governance for the SHAPES Platform will be contingent upon and respect the principles and values deemed most appropriate and relevant following stakeholder consultation.

2.3.1 Values and principles of governance

The mention of governance is often preceded by a qualifying term: “good”, “democratic”, or “smart”. This relates to the concept’s normative power, impacting on the outcome to be expected of certain forms of governance above others: increased accountability, efficiency, quality or even sustainability. These section sets out to briefly describe the values and principles which will be key to the SHAPES Platform.

Barbazza and Tello (2014) review aspects of governance, including fundamental values, sub-functions contingent upon the values, and the outcomes of governance. Their approach provides a useful overview of the heterogeneity of health governance conceptualizations, functions, and even prospective outcomes. Indeed their quite comprehensive review was not a full, systematic review per se, but rather a restricted review that was specifically tailored to review the non-academic grey literature, where many extant frameworks reside. They uncovered a wide range of values and principles, functions, and outcomes of governance (Table 8). Many of the frameworks originated or were situated outside the domain of health, but were nonetheless influential.

Many approaches to governance take a principle or norm-based approach. This is exemplified by Siddiqi and colleagues' (2009) framework for assessing governance. The authors analysed four existing frameworks for assessing governance, from the World Health Organization, the Pan American Health Organization, the World Bank, and the United Nations Development Programme. Based on the analysis of these four frameworks, Siddiqi et. al (2009) outlined ten principles that are necessary for ensuring the good delivery of and access to health and care services. Principles included: strategic vision, participation and consensus orientation, rule of law, transparency, responsiveness, equity and inclusiveness, effectiveness and efficiency, accountability, intelligence and information, and ethics.

This principles-based approach aligns with the underlying values and aims of SHAPES, including, but not limited to inclusion, participation, active and health ageing, good quality of life and health and care system efficiency (SHAPES Grant Agreement). A principles- based approach to our understanding of governance offers a useful starting point and taking a principles-based approach will permit analysis, reflexive interpretation, and evaluation of such principles in future iterations of the SHAPES Governance model (D3.6). Below, we provide a brief overview of each of the principles enumerated by Siddiqi and colleagues (2009).

According to Siddiqi et al. (2009), strategic vision involves governance leaders maintaining a view of health and human development that is broad and long-term, and strategic. An awareness of foundational and contextual complexities of history, culture, and society is important. Strategic vision helps to ensure the sustainability of programmes, organisations, and systems.

Effectiveness, or even overall quality, is a typical principle or overarching aim, and a core principle of a range of existing health governance frameworks (Barbazzza & Tello, 2014; Garattini & Padula, 2017; Gray, 2005). Siddiqi and colleagues (2009) affirm that governance should meet the needs of stakeholders and the population, and advance health outcomes in a resource-efficient manner. In the arena of clinical governance or health and social care professions, effectiveness, and indeed the whole concept of clinical governance itself, has been concisely encapsulated as "doing the right things, for the right people, at the right time and doing them right first time" (Donaldson & Gray, 1998).

Siddiqi and colleagues (2009) affirm that all stakeholders – all people – should have the opportunity to participate in decision-making for health. A full realisation of participation in health and social care would mean that all stakeholders may participate in priority-setting, decision-making, feedback, review, and evaluation. Stakeholders include, but are not necessarily limited to care recipients, health and social care professionals, formal care

providers, family and informal caregivers, administrators at all levels, and policymakers. Such participation may occur directly, or indirectly, via representative institutions. The principle of participation, and ensuring opportunities to participate, does not mandate compulsory participation of stakeholders (beyond that which might be an occupational requirement), and therefore ought not necessarily be marshalled to justify undue responsabilisation of care recipients. Good governance, say Siddiqi and colleagues (2009) acts to mediate divergent interests in order to arrive at consensus.

Inclusion is frequently a core aspect of governance frameworks in health and social care (Barbazzza & Tello, 2014; Scally & Donaldson, 1998), meaning that governance should include all stakeholders; not merely those who work in the system, but also those who are the targets of the system. All people should have the opportunity to improve and/or maintain health and wellbeing (Siddiqi et al., 2009). Inclusion should be evident in both processes and outcomes (OECD, 2020). An inclusive and equitable governance system or process is particularly cognizant of and actively supports the needs of stakeholders who experience inequality or inequity, may be vulnerable, or may not typically have sufficient voice. Although complementary and mutually reinforcing of participation, inclusion is separable. A system or process may be participatory, but exclude various people or groups.

Responsiveness may be found in a number of health system governance models (Barbazzza & Trello, 2014). Responsiveness holds that processes and organisations or institutions should seek to serve all stakeholders and ensure that policies and programmes are responsive to their users' needs (Siddiqi et al., 2009). Local priorities and needs should be considered.

Rule of law, as a governance principle, holds that laws and regulations should be fair and enforced with impartiality (Siddiqi et al., 2009). Law on human rights, and especially those that relate to health, are of particular concern. This aligns with the principle of rule of law as specified in the Council of Europe's (n.d) framework, *12 Principles of Good Democratic Governance*, which additionally stipulates that authorities should comply with all applicable laws and regulations.

"True leadership is having the conviction to be accountable" (Halligan, 2013, p. 117). Accountability may be considered to be "a principle which requires public authorities to explain their actions and be subject to scrutiny. It may also entail sanctions, such as resignation from office or censure" (Cane & Conaghan, 2008). In health professions it may be considered "the obligation of being answerable for one's own judgments and actions to an appropriate person or authority recognized as having the right to demand information and explanation" (Martin & McFerran, 2017). Accountability is a multifaceted construct, with democratic, administrative,

management, and clinical/quality typologies, and with structural and procedural dimensions (Byrkjeflot et al., 2011). It is a core aspect – whether a principle or function – of a wide range of governance frameworks (Barbazza and Tello, 2014).

Transparency is a state in which the rules of operation and decision-making processes are clear, are easily observed, obtained, or are obvious, and, ideally, are based on demonstrable evidence. To facilitate transparency, information must flow freely and sufficient information should be provided to understand and monitor health and social care. Processes, institutions, and information should be directly accessible to stakeholders (Siddiqi et al., 2009). Transparency is a key element of governance in general and to SHAPES governance in particular, as it provides the data necessary to hold any actor accountable of his or her actions, inform about his or her rights.

Often subsumed under a principle such as transparency, Siddiqi et al. (2009) include intelligence and information as a separate principle. Intelligence and information are essential foundations of the accurate understanding of health and social care systems and informed decision-making.

Practical health or medical ethics have, at least typically, their foundation in four *prima facie* principles: respect for autonomy, beneficence, nonmaleficence, and justice (e.g., Beauchamp & Childress, 2019, Dawson & Garrard, 2006, Gillon, 1994, 2015). Respect for autonomy may be understood as making one's own decisions, and freedom from external control. Beneficence may be understood as the maximization of benefit to both the individual and to society. Nonmaleficence may be understood as not causing harm. Justice may be understood as acting on the basis of "fair adjudication between competing claims" (Gillon, 1994, p. 185). Ethics, as a principle, protect the interests and rights of stakeholders (Siddiqi et al., 2009).

In summary, a principles-based approach has a number of benefits. Firstly, it is founded upon an analysis of comprehensive and widely used frameworks of governance, b) being broad in scope, and c) aligning with the values and aims that underpin the SHAPES Platform, Ecosystem, and activities, such as inclusion, equity, participation, active and healthy ageing, and efficient health and social care systems. Additionally, and importantly, these principles offer a starting point for the construction of the SHAPES governance model. Taking a principles-based approach will permit analysis, reflexive interpretation, and evaluation of such principles in the future, final iteration of the SHAPES Governance model (D3.6: SHAPES Governance Model). The selected principles are drawn from analyses of extant frameworks for the governance of health systems. Although SHAPES is not a health system unto itself and does not provide care directly, it functions as a socio-cultural system and is envisioned

as a component of the health system infrastructure. Ultimately, these principles could assist in the development of a governance model that facilitates not only good governance, but also the ultimate realisation of active and healthy ageing, good quality of life, and more efficient health and social care systems in ways that are inclusive, equitable, and value and promote stakeholder participation, and that of older adults and caregivers in particular.

2.3.2 Implementing governance for health and care

Translating the theoretical and principled elements of governance into results and outcomes requires implementation tools and practical steps. Therefore, an integrated care platform, like SHAPES, must be developed with cognizance of the range and import of such factors tools for the implementation of good governance.

Barbazza and Tello (2014) specify a wide but non-exhaustive array of tools and practical steps that may be taken to facilitate or achieve good governance and the functions of governance, while adhering to fundamental values and principles. An exhaustive overview of the breadth of available tools is beyond the scope of this chapter. Nevertheless, it may be useful to take the tools and steps to implement accountability and transparency as exemplars.

For accountability, such tools may comprise: regular and appropriate audit (Phillips et al., 2010), sharing of information on performance (Botje et al., 2014), clear division of responsibilities and pre-defined lines of accountability (Botje et al., 2014; Davies & Mannion, 1999), establishing procedures (Botje et al., 2014), open disclosure, promotion and solicitation of feedback and the opportunity to provide same, opportunities to make complaints (Harris & White, 2018), continuous review, fair processes, and risk assessment. Practical tools to implement transparency include, but are not limited to watchdog committees (e.g., ombudsman), availability to stakeholders and the public of information in relation to performance and finances, inspectorates, stakeholder report cards, and conflict-of-interest boards (Barbazza & Tello, 2014).

Barbazza and Tello's (2014) framework offers a number of benefits for SHAPES itself, and health and care more broadly. Ever changing and evolving landscapes are a reality, whether in health, medicine, social care, technologies, empirical knowledge and methods, and, the wider social, physical, economic and fiscal, and political environments. Fundamental values may also change over time. Health and social care systems in general, and SHAPES, must be adaptable to such changes. A health system that takes cognizance of not merely principles, but also functions, i.e. the overall purpose of governing, and the outcomes of such governance can better measure, evaluate, adapt, iterate, and grow toward achieving its aims in adherence

to its fundamental values. Such as system must be capable of and implement the continuous generation of data to evaluate performance and outcomes, in order to facilitate iterative action for continuous improvement (Kruk et al., 2018). This permits the system to become a learning system, something that is essential to meet long-term goals.

Table 8 Common dimensions of governance across literature reviewed (Barbazza & Tello, 2014)

	Authors chronologically																		
Dimensions of governance	UNDP (1997) [18]	World Bank (1999) [20]	WHO (2000)* [3]	Travis et al. (2002)* [6]	Islam (2007)[21]	WHO (2007) [4]	WHO/EURO (2008)* [8]	Siddiqet al. (2009) [14]	Lewis & Pettersson (2009) [22]	Savedoff (2009) [23]	Mikkelsen-Lopez et al. (2011)[2]	HealthGovMonitor (2011) [37]	Baez-Camargo & Jacobs (2011) [12]	Kickbush & Gleicher (2012) [10]	Council of Europe (2012) [24]	Wendt (2012) [58]	Smith et al. (2012) [39]	Kaplan et al. (2013) [43]	MSH (2013)[45]
Fundamental values																			
Control of corruption																			
Democracy																			
Human rights																			
Ethics and integrity																			
Conflict prevention																			
Public good																			
Rule of law																			
Sub-functions																			
Accountability																			
Partnerships																			
Formulating policy/strategic direction																			
Generating information/intelligence																			
Organizational adequacy/system design																			
Participation and consensus																			
Regulation																			
Transparency																			
Outcomes																			
Effectiveness																			
Efficiency																			
Equity																			
Quality																			
Responsiveness																			
Sustainability																			
Financial and social risk protection																			
Improved health																			

2.4 Summary

This Chapter has provided a working definition of governance and an overview of what the use of the concept of governance implies at the global and European level. For this deliverable, the normative functions of governance and its principles, in particular when dealing with the health and care setting, are key to introducing a governance model for SHAPES itself.

Values and principles are important foundations for governance. Principles, including those of governance will operate as toolbox when confronted t

Governance is not a theoretical exercise, and therefore, no model can be developed without cognizance of the need for practical implementation, and the tools to achieve that. A wide range of tools exist to assist with implementation and the achievement of outcomes of interest while adhering to fundamental values and principles of governance.

The ensuing chapters will introduce stakeholders and domains of governance (Chapter 3), report on our consultation methods (Chapter 4), and introduce the SHAPES governance model (Chapter 5).

3 Stakeholders and domains of governance

Chapter 3 is divided into two sections. In Section 3.1, we introduce key governance stakeholders which we define in terms of the roles they play in three sectors: public, private and third sector. In Section 3.2, we provide a higher-level analysis of several of governance domains (clinical, home care, IT, data and business and corporate governance). Here, we summarise the characteristics, challenges and gaps of each domain, which are part of the SHAPES ecosystem. The descriptions of both governance stakeholders and domains allows us to situate the SHAPES Platform within systems of human activity as will be described in Chapter 5, including its wider socio-cultural, economic, technological and legal context. This existing ecosystem simultaneously shapes and is shaped by the Platform, which is expected to mediate the challenges posed by the complexities of health and care provision and moreover, support, enhance and sustain active and healthy ageing.

3.1 Key stakeholders in governance

No two models of governance are alike and thus, the governance stakeholders may differ in functions, motivations and approaches to governing as well. SHAPES does not intend to elevate one function or approach to governance over another but rather, to incorporate the different models that currently exist within the developing SHAPES Governance Model. Thus, the following sections on the roles of the public, private and third sectors in governance are

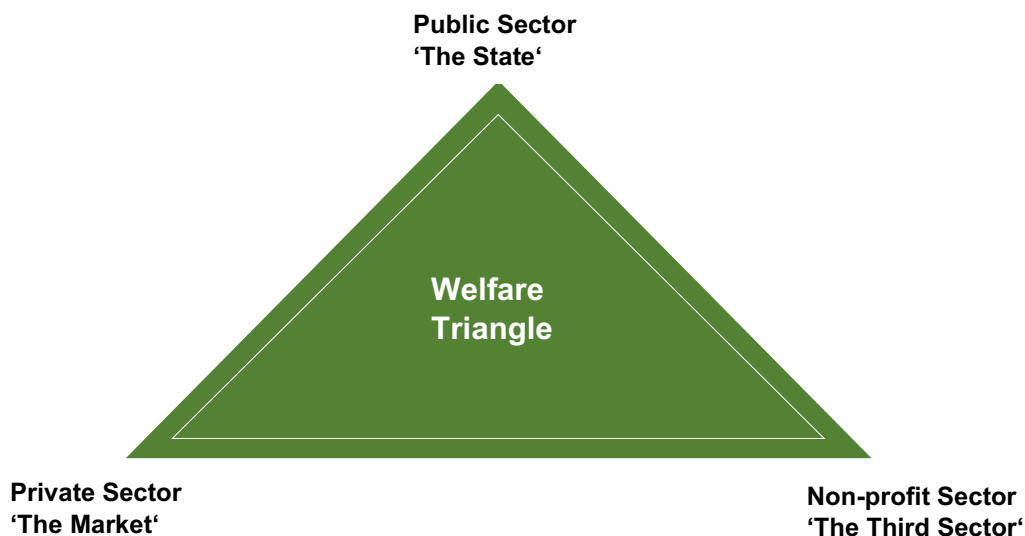


Figure 2 Welfare Diamond (Own figure, adapted from Leibetseder et al.'s, 2017)

intended to provide a deeper understanding of current models of governance. This, in tandem with Section 3.2, provides the contextual basis for the SHAPES Governance Model.

The clustering of stakeholders into three sectoral categories (public, private and third sector) leans on Leibetseder et al.'s (2017) 'welfare diamond' which includes four domains of health and social care governance. These are the public sector represented by the state, and the private sector which includes for-profit companies ('market'), the family or immediate community, and non-profit organisations also referred to as the 'third sector' (Daly & Lewis, 2000; Leibetseder et al., 2017). Yet, SHAPES takes into account a greater range of domains of governance including business and corporate governance, IT governance and data governance. Thus, for the purpose of the SHAPES Governance Model, the categorisation of stakeholders into the public, private and third sector was more appropriate (**Error! Reference source not found.**).

3.1.1 The role of the public sector

The public sector plays an important role in the governance of health and social care at multiple levels. The OECD defines the public sector as "the general government sector plus all public corporations including the central bank" (OECD, 2001). In the following sections, we unpack the roles of the public sector in care governance starting at the global level before focussing in on the national level. At the global level, we discuss the functions of the World Health Organization and other United Nations organisations, the World Bank and the European Union. At the national level, we break down the involvement of governments in the provision of care.

3.1.1.1 *Global actors of governance*

Global governance actors will not be users of the SHAPES Platform *per se*. nonetheless, this deliverable considers them in their role as stakeholders within the domains of governance described in this chapter. Among the many United Nations organisations, the World Health Organization was selected for its role in health governance; among other global actors the World Bank was selected for the impact its programmes had in steering good governance, and further light is shed onto the European Union's relationship to health governance. All are being considered here because of their normative role in governance.

The World Health Organisation

The World Health Organization (WHO), a United Nations (UN) agency established 1948, is a key player in fighting communicable and non-communicable diseases as well as promoting global public health. The provision of information on public health concerns, such as outbreaks of infectious diseases, as well as the organisation of health conferences are among the core missions of the WHO (Duten, 2014).

The WHO, which has its headquarters in Geneva, Switzerland, draws much of its own governance structure from the *Office International d'Hygiène Publique* (OIHP). Comprising of 194 Member States located in six regions the WHO is governed by the World Health Assembly (WHA) composed of representatives of all full members. The WHA meets once a year as opposed to WHO's Executive Board, composed of 34 representatives, who meet twice as frequently. Most decisions within WHA are adopted by consensus.

The role of the WHO is threefold: to provide support to populations and countries in debt so they can access the market; to produce independent knowledge while working closely with policy-makers; and finally, to supply technical support to governments (Buse et al., 2002, p. 279). The WHO issues the international health regulations (IHR) which control information management of, for instance, disease outbreaks (Rushton, 2010).

The WHO's main constraint is the organisation's legal status of a technical agency that "mainly offers information and technical advice but cannot substantively influence how national governments allocate financial and human resources to strengthen health systems" (Reich & Takemi, 2009, p. 14). The challenges to its authority and reform attempts have been multiplying such threats of pledges cuts.

The WHO is relevant for SHAPES as the source of the definition of health but also as for setting the scene in which SHAPES Platform will operated and how health must be addressed: in a collaborative, cross-border manner, allowing participation by all stakeholders such as civil society and the private sector, drawing on every expertise and gathering it in its recommendations. The criticisms to WHO are also relevant since they address the issue of leadership (Drager & Sunderland, 2007), policy coherence (Kelley Lee, 2009) and ethical compliance (Ferriman, 2000).

In addition to the WHO, there are a great number of UN agencies (e.g. UNAIDS, UNFPA, UNICEF) and governance bodies (e.g. Security Council, General Assembly and Secretariat) established post Second World War, which shaped the discourse and understanding of health as it is employed in SHAPES. Yet, it is beyond the scope of this deliverable to describe them individually. Rather than the agencies themselves, the principles and values of governance

derived from this discourse (see Chapter 2) will play a role in the development of the SHAPES Governance Model.

The World Bank and the International Monetary Fund

Since the 1960s, the World Bank (the Bank) has been a powerful actor in health governance. Its influence grew both directly because of the co-financing programmes, and indirectly because of the socio-economic consequences of the Bank's structural adjustment programmes (Harman, 2010, p. 228). The Bank grew to become the largest 'financier' (as opposed to donor) for health in low-middle-income countries and a strong candidate for leadership in global health governance, not the least because of the financial power.

The 1993 World Development Report "Investing in Health" (World Bank, 1993) depicts a market driven approach to health. Together with the International Monetary Fund (IMF), the instrument through which the World Bank ensures surveillance and provides financial and technical assistance, these organisations are part of the so-called "Bretton Woods Institutions", that were set up on the idea that a virtuous cycle (i.e. 'more wealth - more health') rests upon free trade agreements and less public spending. One World Bank instrument widely implemented in the 1980s were the structural adjustment policies (SAPs). In terms of health goals these instruments have been largely criticised since the privatisation measures enshrined in the programmes led to austerity measures, sometimes even turning "freely" available health services into fee paying services therefore preventing large population groups from accessing essential medicines and/or quality care (Duten, 2014).

The European Union

The EU's role as a stakeholder of governance is limited. The EU as a supranational organisation (see Chapter 2) is not considered as a direct end-user of the SHAPES Platform. Yet, the EU's "ambition ... to ensure the accessibility, effectiveness and resilience of health systems in the EU" (European Commission & Directorate-General Communication, 2020, p. 37) corresponds with the values and principles of governance described in Chapter 2. As a matter of fact, "[t]he EU has an interest in promoting its model as a contribution to good governance - an essential prerequisite to effective regional cooperation and global governance" (Cameron, 2004, p. 10).

However, according to Duten (2014), the EU has been taking a cautious approach to pan-European health policy governance, seeking to avoid appearing as too powerful an actor of health governance, which is reflected in its recent publication "The European Union: What it is and what it does" (European Commission & Directorate-General Communication, 2020).

Here, the EU's limited role in health and care governance is described as complementary to national policies. While the EU provides a framework of “shared objectives” (p. 37), it is emphasised that the organisation of health and social care to achieve these objectives falls under the remit of each individual EU MS. Instead of zoning in on the activities of individual MS, the EU focusses on EU-wide promotion and support of public health, e.g. through financial support through the EU health programme. In addition, the EU seeks to tackle EU-wide threats where the principle of subsidiarity does not suffice. A recent and on-going example is the EU's involvement in the procurement and distribution of vaccine to combat the COVID-19 virus.

In the preceding sections, we have provided a summary of the roles that global actors play in health and social care governance. In the following sections, we will narrow our focus discussing the role of the public sector in the governance of health and social care systems at national level, acknowledging that national care policies are influenced by these higher-level organisations.

3.1.1.2 The role of the state health and social care governance

The core responsibilities of governments are the regulation and financing of care, provision of care, regulation of access to care, and quality control of care (Boerma & Genet, 2012; Genet, Kroneman, et al., 2012; Leibetseder et al., 2017; Spasova et al., 2018). Generally, several ministries are responsible for the regulation, provision, or financing of home care as explored in more detail in 3.2.2). In most countries, responsibilities for health and social care are shared horizontally between the health sector and social care sector. In addition, responsibilities are divided vertically at national, regional and local administrative levels. For example, funding and regulation of health care tends to fall within the remit of national or regional governments. By contrast, social care (including home care) is more commonly funded and regulated at municipal level (Genet, Kroneman, et al., 2012; Spasova et al., 2018). This division of responsibilities is further explored in 3.2.2). This fragmentation of responsibilities for home care has previously been highlighted as problematic as it hinders collaboration and integration of care services (e.g. Kröger & Bagnato, 2017; Leibetseder et al., 2017; Spasova et al., 2018; Zigante et al., 2019) as well as harmonisation (Sabatinelli & Sempredon, 2017).

Public health governance involves multiple processes and systems that ensure that health and care are created, provided and monitored at the local or national level. These include creation of policy and legislation, funding, organisation of institutions and participating entities that provide or monitor health and care provision, as well as control of quality and audit of such services and institutions. The provision of health and social care services and the governance of health systems are strongly linked to EU fundamental rights (Article 35 e.g.)

and people's rights to health and well-being. This makes the public sector responsible for establishing laws and practices to ensure access to prevention services and medical treatment. Therefore, key players in governance are those bearing political responsibility; they will however not be affected by the SHAPES governance model itself, unlike the selection of stakeholders below, that will be users and contributors to the SHAPES Platform.

3.1.2 The role of the private sector

The private, for-profit sector plays a crucial role in governance, not least in the governance of health and social care systems. The private sector represents a great variety of actors: private clinics and care services, privately-hired carers, pharmaceutical companies, private health insurance providers, logistic and mobility firms, medical technology firms, start-ups – some of these are explored in more detail in later sections in the present chapter (Chapter 4). Private organisations provide a mix of goods and services including the direct provision of health and care services, medicines and medical products, financial products, training for the health workforce, information technology, infrastructure and support services (e.g. health facility management).

With regards to private care providers, some of these companies receive public funding, and they typically supply professional care practitioners. By contrast, other care services are paid privately by care receivers and are delivered either through professional or non-professional caregivers (Leibetseder et al., 2017). Funding models of care services are discussed further in Section 3.2.2.5. According to Zigante et al. (2019), private provision of care for older people has increased considerably in recent years, and Aulenbacher et al. (2018) have suggested an acceleration of the marketisation of care services. The increase in private companies providing care services facilitates the availability of care services (Zigante et al., 2019).

Governance means collaborating with other sectors, which includes the private sector to promote and maintain population health in a participatory and inclusive manner. Therefore, the question is not *whether* the private sector is involved in the delivery of health and care services but *how* it is involved. Private actors participate in governance through various mechanisms:

- Self-regulation measures such as corporate social responsibility schemes.
- Measures influencing public regulations e.g. lobbying.
- Public-private-partnerships when for instance a usually public health service is delivered in partnership with the private sector.

In the following sections, we are describing the roles of payers and pharmacists as examples of private sector actors in more detail.

3.1.3 The role of payers

In this section, we describe the role of payers in health and care governance. First, we outline the three models of reimbursement which are typically operated in Europe. These have already been described in detail in D3.1 but are presented here again as context for the second section.

3.1.4 Models of Reimbursement

Payers differ in terms of the specific models of health systems operated within the EU. Depending on the organisation of the health and care system, a range of different payers can be identified, such as individuals, private or public insurance companies, or the government itself. Therefore, influences on health care-related decisions also vary.

As described in D3.1, the reimbursement models operated in Europe fall into one of three categories: the Beveridge Model, the Bismarck Model and the Out-of-Pocket Model. First, there is the national health model, (Beveridge Model), where health care coverage for all citizens is provided by the government (Chung, 2017; Cummiskey, 2008; Kulesher & Forrestal, 2014; Reid, 2010; Wren & Connolly, 2016). This model is financed through taxes (Kulesher & Forrestal, 2014). An example for this model is the UK (Cylus et al., 2015). Decisions about the amount of financing a health treatment are made for the whole population by governmental institutions with guidance from cost-utility studies (Cylus et al., 2015). The second type of health system is the social insurance model, also known as the Bismarck Model (Chung, 2017; Cummiskey, 2008; Kulesher & Forrestal, 2014; Reid, 2010; Wren & Connolly, 2016). This model is characterised by mandatory health insurance for every citizen (Busse et al., 2017). Health coverage is financed by the following parties: employer, individual, private insurance funds and partly by the government. This model has been adopted in Germany (Busse et al., 2017). Thirdly, there is the private insurance or out-of-pocket (OOP) model where every individual needs to finance health services on its own or through private health insurances which are funded by the individuals and/ or by the employer depending on the model in the specific country (Chung, 2017; Cummiskey, 2008; Kulesher & Forrestal, 2014; Reid, 2010; Wren & Connolly, 2016). In the EU, while general taxation or SHI are the predominant funding model, there are varying degrees of additional out-of-pocket payments.

Regardless of the type of model, most public health decisions are made by the government with advice based on scientific research by non-state or governmental institutions. So, in the case of the national health model, the decision maker is also the payer for health services (Mance et al., 2019). Therefore, decisions are partly based on the available budget. In countries that operate the social insurance model, the government also makes decisions regarding the services that will be funded by insurance companies. These decisions are commonly based on expert advice. In Germany, insurance companies (*Krankenkassen*) also attend those discussions in the Federal Joint Committee (FJC) where they can express concerns and ideas, and vote on proposals (Busse et al., 2017). However, the votes of the insurance providers carry the same weight as those of the other members of the FJC, and thus, the final decision is usually made by an impartial member (Etgeton, 2009), since all other votes cancel each other out. So, insurance companies have a moderate level of influence on decision-making processes.

The third party of payers identified are the individuals. When health services are not paid by the insurance provider, the individual must finance care services through out-of-pocket payments (Thomson et al., 2009). The influence on public health care decisions by individuals is even lower than the influence of insurances. In the case of Germany, the patient representatives can also attend the discussions but are not allowed to vote in the final decision (Etgeton, 2009).

3.1.4.1 Roles of payers in the health system

The roles of payers in health and care systems vary across the different European countries. Nonetheless, there are two core roles that can be identified. Multi-payer systems as utilised, for example, in Germany or Czechia, typically have high levels of engagement in the decision-making processes. In both countries insurance funds and health care providers are coming together to negotiate health care decisions (Alexa et al., 2015; Busse et al., 2017). The insurance funds are self-governed and because of the possibility of free choice of insurance fund by the population the different insurances funds are competing in an open market (Alexa et al., 2015; Busse et al., 2017). There are a few options in terms of what insurance funds can offer their members to differ from other insurance funds. Contribution rates, special health services and tariffs at a lower price are possibilities to conquer against other insurance funds (Busse et al., 2017). So, one can see in multi-payer systems, the health services offered are demand-driven by the consumers.

On the other hand, there are the national health models where the government oversees most of the payer's role. Decision-making lies in the hand of the government but in those systems

private insurers may offer more services than the government (Mossialos et al., 2004). Especially in health systems where only basis coverage is offered by the nation, private insurance funds are getting more important and compete against each other. Even though the private sector has no influence in decisions about financing and organisation of the health system (Economou et al., 2017), they play an important role in ensuring better health coverage for the population.

3.1.4.2 Data responsibility and data collection

In most of the countries different types of data are collected for quality, reimbursement, and research reasons (Alexa et al., 2015; Anell et al., 2012; Chevreul et al., 2015). The collected data comes from different actors such as providers, payers or from the g themselves (Alexa et al., 2015; Anell et al., 2012; Chevreul et al., 2015; Ferré et al., 2014; Keskimäki et al., 2019). In most countries, these data are not connected or compiled in one single platform but instead, split up into different forms of data, which makes it impossible to merge them (Alexa et al., 2015; Anell et al., 2012; Ferré et al., 2014). Some countries have already started to develop a system where all data can be merged but this is still a challenge (Alexa et al., 2015; Ferré et al., 2014). Only Finland and France managed to aggregate all existing data in one platform since 2015 (Chevreul et al., 2015; Keskimäki et al., 2019). There, the data are anonymized through ID-numbers (Keskimäki et al., 2019). All public and private providers are obligated to deliver their data to the system (Keskimäki et al., 2019).

In the previous sections, we have described the role of payers in health and care governance. In the following section, we provide an example of the role of pharmacists who are associated with the private sector as stakeholders in governance.

3.1.4.3 The role of pharmacists in health and care governance

Medicines are the most common interventions offered to patients to improve their health and wellbeing. A pharmacist is an expert in the safe and effective use of medications. Depending on national regulations, qualified pharmacists obtain key competencies through structured programmes and register with the appropriate authority. Registration is essential to work as a pharmacist. Pharmacists may go on to develop specialisms depending on their area of practice e.g. Masters in Clinical Pharmacy or independent prescribing status. In Europe, further training is required before achieving the protected legal title of a Hospital Pharmacist.

Pharmacists generally work in either hospital pharmacy where they provide pharmaceutical care to service users of the hospital, in community where pharmacists are based in health centres and retail pharmacies or there is a growing number of pharmacists working alongside

GPs in a multidisciplinary team as practice-based pharmacists in primary care. A smaller proportion of pharmacists are involved in the manufacture and development of medicines and are employed within the pharmaceutical industry.

The role of a pharmacist includes advising other healthcare professionals on the choice of medicines; ensuring that medicines are safe and appropriate for use; providing advice on the dosage and formulations of medicines; education of patients on the use of their medicines; helping to manage long term conditions; monitoring the effects of treatment; independent prescribers may prescribe medication.

Pharmacists provide a wide variety of services to the population and in Northern Ireland, these services are either commissioned directly by the Department of Health in the case of pharmacists working in hospitals or via a contract negotiated between the community pharmacy and the Commissioning Board.

Clinical governance (see Section 3.1 for more detail) is the system through which health organisations are accountable for continuously improving the quality of their services and safeguarding the high standards of care by creating an environment in which clinical excellence will flourish (DH (UK), 2010). Clinical governance underpins the provision of quality pharmacy services. The mainstay of pharmacists' involvement in clinical governance is typically at the individual patient level with the aim to achieve continuous improvement in the quality of pharmaceutical services, to safeguard high standards of care and promote the optimal use of medicines. This is achieved through many different mechanisms including annual Continuous Professional Development training requirement; completing clinical audits; driving evidence-based practice; implementing risk management programmes; supporting staff training and development; ensuring adequate staffing levels; and performing research and development. Within the hospital setting there is a Standard for Medicines Management and a requirement to maintain substantive compliance to this standard at a level of >75 percent in terms of safety, quality and efficacy.

At both strategic and policy levels, pharmacists can influence service provision by lobbying the government. This is usually carried out by bodies representing different cohorts of pharmacists. Changes to service provision would then be implemented in hospital by a change to the commissioning of services and in community pharmacy by a change to the community pharmacy contract. Additionally, there is active contract monitoring for pharmaceutical services provided by community pharmacists.

As a stakeholder group, pharmacists are held to professional and regulatory standards which are upheld by appropriate statutory bodies. This includes regular inspections of hospital and community pharmacies by an independent inspectorate.

Fundamentally, pharmacists are tasked with providing access to medicines. The main concern for pharmacists is the safe use of these medicines without harm. This is reflected by the current World Health Organisation Global Patient Safety Challenge: Medication without harm (WHO, 2021), which aims to reduce medicines related harm by 50 percent over the next five years. In order to achieve this aim, one of the key challenges is to identify the effectiveness of interventions pharmacists make on a daily basis. There are no consistent methods for reporting these interventions and without robust evidence for clinical effectiveness it is harder to justify investments being made in this area or widening the scope of pharmaceutical service provision.

To achieve medicines without harm it is essential to create a 'no blame' culture to promote the reporting and publishing of 'near misses' or incidents that occur during clinical practice. This can be challenging to achieve in a highly regulated environment but adopting a 'no blame' culture can promote staff learning, reduce the likelihood of the same error occurring in future and can result in changes to policy.

In community pharmacy, a key aim is to disseminate rapid public health advice which is achieved through local connections to the communities they serve and the fact that they are trusted as a reputable source of health advice.

Another motivator for pharmacists is maximising the use of their extensive training and understanding of medicines. A recent example was a call for community pharmacists to be included in the roll out of the COVID-19 vaccine in Northern Ireland. Upskilling the pharmacy workforce has been one of the key factors in improving clinical care and increasing capacity within the healthcare system which is under increasing pressure with people living longer with greater numbers of chronic diseases.

3.1.4.4 Public versus private sector debates

The preceding sections outlining the roles of the public and private sectors in health and care governance have also highlighted certain tensions between the two sectors. In this section, we present current discourses on the role of both sectors in the provision of health and care services, and the challenges this presents for SHAPES.

Cooperation with the private sector is often considered as encouraging an innovation-friendly environment. In times of accelerated globalization, corporations often have greater budgets and regional influence than single states themselves. This has pushed international organisations, such as the UN, to establish partnerships with the private sector to achieve several health goals, such as the Sustainable Development Goals (SDGs). However, observers have been criticising the implications of private companies as opposed to civil society's involvement on good governance (Dür & De Bièvre, 2007).

While the public sector bears political responsibility regarding health and care, academic discussions on the political Corporate Social Responsibility sparked over the last decade. This is linked to this topic of moral division of labour between public and private sector. Mäkinen and Kourula (2012) use the Rawlsian conceptualization of division of moral labour within political systems to describe background political theories of various CSR approaches. Classic CSR literature was more pluralistic in terms of background political theories. Instrumental CSR adopted classical liberalism and libertarian laissez-faire as its structural logic. New political CSR, based on a strong globalist transition of responsibilities and tasks from governments to companies, lacks a conceptualization of division of moral labour that is needed to fully depart from a classical liberalist position. Further, Mäkinen and Kasanen (2016) argues that the dominant framing of the political CSR challenges the traditional economic conception of the firm and aims to produce a paradigm shift in CSR studies wherein the traditional, apolitical view of corporations' roles in society is replaced by the political conception of CSR. According to the authors this framing of the political CSR discussion calls for a redirection to take international hard legal and moral regulations, as well as the need for the boundaries between business and politics into account (see also D8.14).

The future will inevitably give rise to a wide variety of 'blended' for-profit and non-profit, public/private sector solutions. The WHO has the potential to play a pivotal role in supporting universal health coverage (UHC) through the governance of private health sector service delivery. A resolution to engage the private sector in providing essential health services was adopted in the Sixty-third World Health Assembly (WHA). Since then, the WHO has made progress towards recognizing and engaging the private health sector, but a more system-wide shift is necessary to catalyse action for UHC. Leveraging on work to date, the WHO will support Member States to strengthen governance of mixed health systems and assure alignment of the private sector for UHC, to promote equity, access, quality and financial protection for ageing societies, consistent with the aims and aspirations of the UN Decade for Healthy Ageing. The Advisory Group on the Governance of the Private Sector for UHC recommends a strategy for WHO that will support a new way of doing business for health

system governance (WHO, 2020). While undoubtedly a global challenge, the convergence of game-changing assistive technologies and big data analytics constitutes a golden opportunity to rethink the provision of health and social care for ageing populations. What is missing is a common language and a widespread view of what good care looks like, and what it should cost, making it hard for central and local government, business and industry stakeholders, to plan with any degree of certainty.

In the present section (Section 4.1.2), we have discussed in detail the role of the private sector in health and care governance. In the following section, we will shift our focus on the third actor of the welfare triangle: The Third Sector.

3.1.5 The role of the Third Sector

3.1.5.1 *The role of Civil Society, Academia, and the Community in governance*

The term Third Sector has gained importance towards the end of 1990s under the perspective of “Bringing society back in” (Zimmer & Freise, 2008). For the purpose of this deliverable, we will consider Civil Society, whether organised in civil society organisations (CSOs), non-profit and/or charitable (sometimes faith-based) organisations, philanthropies, think tanks, academia and individuals all as Third Sector.

Civil society refers to all forms of social action carried out by individuals or groups who are neither connected to, nor managed by, the State. It is often seen as the “third sector” of society, along with government and business. “A civil society organisation is an organisational structure whose members serve the general interest through a democratic process, and which plays the role of mediator between public authorities and citizens” (EU, 2021).

According to the World Bank Group, civil society includes “the wide array of non-governmental and non-profit organizations that have a presence in public life, express the interests and values of their members and others, based on ethical, cultural, political, scientific, religious or philanthropic considerations. They can be community groups, labour unions, indigenous groups, charitable organizations, faith-based organizations, professional associations, and foundations” (World Bank, 2021). According to Salamon and Sokolowski (2016), third sector organisations occupy a peculiar

“social space beyond the state, the market and the [family] ... because, unlike the state, they are private; second, because, unlike market entities, they primarily serve some common good; and third, because, unlike families,

participation in them involves some meaningful element of free choice” (p. 2, emphasis in original).

Civil society includes organisations of older persons, as well as organisations of persons with disabilities. Unlike in other movements, the creation of organisations of persons with disabilities (DPOs), as well as organisations representing older persons have traditionally been created by families and representatives of persons with disabilities, and the issues advocated for were closely related to support, such as financial and medical, meaning these movements have largely remained in the private and family sphere. For instance, only recently, disability has been present in policy making, and in human rights advocacy discourses where the influence of national disability councils and DPOs has grown and so has the visibility of the rights of persons with disabilities. Moreover, there are more and more persons with disabilities, and older persons have become self-advocates who speak for themselves and their communities. Undeniably, disability has traditionally been explored through a medical and scientific approach, where people with disabilities have been treated as “patients” and “ill people”, often institutionalised and marginalised, and consequently, considered to be a burden to societies, which has often been the case for many elderly populations. However, there has been a transition from an individual, medical model to a structural, social model (WHO & World Bank, 2011, p. 4). For decades, the issue of disability has been considered first and foremost a part of traditional social policy instead of a topic related to questions of equality and citizenship (Maschke, 2004). There has therefore been a discourse and conceptive shift that has changed the approach to disability, by embracing a human rights perspective and to favour the equality, non-discrimination and integration. The creation of the CRPD in 2006 marked a before and after in the full recognition of the rights of women and men with disabilities around the globe.

Overall, Third sector organisations (TSOs) play an important societal role, not least in the provision of care (Pape et al., 2020). They are an important source of information for both citizens and government; they monitor government policies and actions; they engage in advocacy and policy making - to name a few. Another key aspect is the delivery of services for groups in need of assistance for instance, the elderly, as well as the representation of interests and rights, including the fight against human rights violations or discrimination due to ageism.

It is worth mentioning that intersectionality, although less than in the past, still remains largely unexplored by civil society organisations, often due to the limitation in resources and expertise. This means that for example, organisations of persons with disabilities often fail to acknowledge the experience of older persons and the barriers or discrimination they might

experience both due to age and disability, and in the other hand, organisations of older persons fail to encompass the experience of persons with disabilities.

Nevertheless, civil society is essential in the empowerment, visibility and representation of certain groups such as the elderly or disability and their fight for a human rights approach and self-advocacy. In the case of persons with disabilities, the work carried out by DPOs are key in the inclusion of persons with disabilities into mainstream society. In the disability rights movement, the slogan “nothing about us without us” comes to represent that people with disabilities should control their own lives and decisions regarding their lives (Ben-Moshe & Magaña, 2014, p. 108) . It is precisely for this reason that the demands of persons with disabilities all over the world are not, any longer, for improvements in existing services but control over them. It is therefore essential that civil society is included and actively involved in governance models and decision making.

Within civil society, and more specifically in the case of persons with disabilities, there are key players that also play a very important role in the integration and representation, like for example, sign language interpreters, guide-interpreters, assistants or support persons. For example, for deaf persons or persons with deafblindness, this service is essential for communication and participation, which means support services must be guaranteed for persons with disabilities and should be personalised according to needs or preferences. In the involvement of persons with disabilities in any process, accessibility and accommodations should be taken into consideration to ensure a meaningful participation.

Civil society is essential as it constitutes an important element in awareness raising and representation. In any process, it provides citizens or groups with an alternative way of channelling different views and securing a variety of interests in the decision-making process. In a recent report by the European Observatory on Health Systems and Policies and the WHO Regional Office for Europe the authors distinguish civil society organisations by type (Table 9) and action (Table 10).

Table 9 Main categories of civil society organisations (WHO, 2018)

Main category	Brief description	Sub-groups and examples relevant for health and social care and governance
Interest groups	A distinction should be made between Business groups and groups advocating for specific Causes.	Business groups are typically advocating for policies that benefit their members, for example organisations of companies selling

		<p>pharmaceutical products, medical devices or assistive technologies.</p> <p>Groups advocating for “causes” are advocating for policies whose benefits to donors and volunteers exceed the cost of advocacy. Examples are organisations that advocate against pollution and for a cleaner and healthier environment.</p>
Professions	Professions are the organizations representing and often self-regulating a set of professionals.	Examples of organisations relevant to the health and social care sector are organisations of occupational therapists, doctors, nurses, social workers, etc.
Community organisations	<p>Communities are social groups united by a shared attribute or identity that is not family, such as ethnicity, gender orientation, or a health condition, such as being patients or having a specific disability.</p> <p>The organisations that represent and serve them are diverse and can be evaluated for their combination of autonomy from state, market, and family, and for their representativeness of and service to that constituency.</p>	<p>Health condition-related community organisations (patient groups, support groups) (Baggott et al., 2005; Löfgren et al., 2011). Condition-related groups are united by a specific health attribute.</p> <p>Social community organisations are groups organized to enable some kind of social activity. Social groups do not have an obvious link with health in many cases, but they are a big part of civil society. It has been argued that even if social groups make no great claim to representation or service, the networks, connections, culture of joining and organizational skills that they produce strengthen the ability of civil society to carry out any function (Putnam, 1993). Most of the time their participation in health is indirect, improving health through empowerment, togetherness, sport, and friendship rather than through directly identifying and</p>

	addressing health needs. That does not mean a strong social component of civil society is not a boon to health.
International non-governmental organizations	International NGOs are a category by themselves. Their size, visibility, international reach and distinctive funding and accountability relationships mean that they are only rarely comparable to NGOs that operate exclusively in the context of a single state.

Table 10 Type of actions of civil society organisations (WHO, 2018)

Type	Short description	Sub activities relevant for governance
Policy	Policy means engagement in decision-making and public policy – representing interests, advocating for policies, pushing for implementation of decisions, challenging other decisions, and holding policy-makers to account in a watchdog capacity that enhances public sector accountability.	<ul style="list-style-type: none"> • Evidence and agenda setting • Policy development • Advocacy • Mobilisation • Consensus building • Watchdog
Service	Service means providing something directly, whether it is lottery tickets for casual buyers, subsidized hotel discounts for members, weekly football games for sporty locals, or a needle exchange for drug addicts.	<ul style="list-style-type: none"> • Services to members • Services to the public
Governance	Governance is when civil society organizations have important social functions such as wage-setting or standardization delegated to them by public organizations. There are three major areas in which we find civil society playing an explicit role: in technical standard-setting; in professional and other self-regulation; and in corporatist arrangements for governing the economy.	<ul style="list-style-type: none"> • Standards • Self-regulation • Social partnerships

Civil society organisations act at different level ranging from local to international. In the following Table 11 their typical contribution to governance of those relevant for SHAPES is fleshed out taking into account their level of operations.

Table 11 Civil society organizations relevant for SHAPES (Own table)

Type of organization	Local level	National level	International level
Business interest groups in the field of medical devices, digital health, assistive technologies, wearable sensors, ICT.	It is not very likely to find local business groups of companies organised in interest groups at local level where they are expected to be in competition. Individual companies might lobby with the local health authorities and or public and private care providers for the provision of certain types of products and services. They will try to impact with all legally permitted tools to advocate for policies (e.g. digital health) and influence public and private procurement (e.g. publicity, information, events, networking with other stakeholders, etc.).	National sector organisations might lobby with the government for the wider uptake of technology in the Health and Social Care sector, as well as for accreditation and certification of specific innovative products and services. A list of national organisations can be found on the website of the Medical Device Industry.com	Some business sectors might have international associations as well, such as Medtech Europe. They will typically work on Regulations, Research, Data collection, etc.
Cause related interest groups	There are many cause related interest groups at local level. Those relevant for SHAPES will typically advocate for better health care or care which is delivered in the community. They will also function as watchdogs for	National federations of local “cause”-related groups might express concern in the media or directly in the political arena. Some of their representatives might candidate as parliament members to promote legislation	At international level there are associations promoting specific causes relevant for SHAPES, such as the promotion of integrated care, digitalization in care, quality of care. They are typically formed by a membership that

	<p>patient's rights, for integrated care and against the dehumanization of healthcare by technology advancing in approaches traditionally characterized by human intervention (e.g. home care).</p>	<p>in line with their values.</p>	<p>consists of different stakeholders, such as academia, service providers, end users, etc. They will typically focus on gathering evidence, supporting policy development and building consensus or standards.</p> <p>Examples include Health First Europe, the International Foundation for Integrated Care, AAATE and GAATO.</p>
Organisations of professionals	<p>Many organisations of professionals have local or regional charters. In some countries specific professions, especially in the health sector are "protected" meaning that membership of a professional body is a requirement for being able to exercise the profession. Relevant professionals for SHAPES are doctors, nurses, occupational therapists, engineers, etc. They will be particular attentive to how SHAPES will change the way care is delivered. Their concerns are therefore extremely important as they are real gatekeepers to change.</p>	<p>At national level organisations of professionals have significant political influence and together with the trade unions can impact on standards and regulations.</p>	<p>Health and care policies are very much determined to the national, level, which makes that organisations of professionals have less political space at international level. Their role is typically related to the exchange of best practice, organizing conferences and the development of generic international standards.</p>
Community organisations	<p>At local and regional level the most</p>	<p>At national local and regional community</p>	<p>Community organisation might be</p>

	<p>relevant community organisations are patients organisations, very often organised on the basis of pathologies. Others are more focused on a specific area of activity, such as sports, healthy life styles, nutrition and food, etc.</p> <p>Some provide relevant services as well to their members in first place, but sometimes also to others. In these cases funding will come from public sources, private donations or out of pocket contributions.</p> <p>Based on whether these organisations deliver services as well their position in governance change. Their advocacy role can be compromised or strengthened in case of direct inclusion in public health schemes as economic actors providing services against payment.</p>	<p>organisation tend to be federated to have a stronger say also at national level where policies are defined.</p>	<p>federated as well at international level, basically for raising awareness on issues and to impact on European policies in the for them relevant domains. Clearly the broader the scope the more the distinction between them and cause related interest groups at international level becomes blurred.</p>
International civil society organisations			<p>the EU's good governance.</p> <p>"To date the literature also has not addressed civil society's role throughout all stages</p>

of the policymaking process within international health organizations. Furthermore, little effort has been made to engage existing policymaking theories, develop theoretical frameworks, provide clear and consistent definitions of civil society's roles and influence, provide methodological specificity and diversity, while emphasizing the importance of causal mechanisms.” (Gómez, 2018, p. 9)

3.1.5.2 Third sector organisations and health and care governance

The Third Sector as it relates to health and social care includes a diverse range of organisations, such as compulsory/ governmental health insurance providers that operate on a competitive, yet not-for-profit basis (Spasova et al., 2018), community, charity and voluntary associations which provide care services through unpaid volunteers, and welfare organisations which employ professional care practitioners as well as unpaid volunteers (Leibetseder et al., 2017; Pape et al., 2020). Aside from service delivery, TSOs are increasingly participating in localised social activism and advocacy work, e.g. in the shape of “patient organizations, as well as grassroots initiatives, community groups and social enterprises” (Pape et al., 2020, p. 7).

The importance of informal carers in health and care governance

Care can be formal and informal, paid and unpaid, and provided through services or cash benefits. Generally, healthcare tends to be more professionalised than social care. But in addition to social care practitioners, home care is also delivered by family members and informal, privately hired caregivers. As emphasised by Leibetseder et al. (2017), the family, as well as immediate community members, often act as primary, unpaid caregivers. In addition, families may hire private caregivers on an informal basis who are paid out of pocket.

In many countries, the family (spouses or adult children) or immediate community (e.g. neighbours, voluntary organisations) of the care receiver are the main providers of informal home care (Carrera et al., 2013; Leibetseder et al., 2017; Spasova et al., 2018; Vjenka Garms-Homolová et al., 2012). However, the degree of informal care delivery varies and depends, to some extent, on cultural attitudes towards caring responsibilities. According to Carrera et al. (2013), national preferences can be grouped as follows:

- Strong preference for care provided by adult children (Central-eastern countries and Greece).
- Preference for care provided by family members (Southern European countries e.g. Portugal, Spain, Malta, and Cyprus; , Germany and Austria).
- Equal preference for formal and informal care (Italy, Ireland and the UK).
- Strong preference for formal public or private care (Nordic countries, France and Belgium).

Informal carers, also known as family caregivers, unpaid carers or just carers, play a crucial role beyond what the term "informal" might presume. Indeed, who among us has never taken care of someone who has lost their autonomy due to old age, obstacles to accessibility or because of an illness or injury (COFACE Families Europe, 2016)? The role of the informal carer is essential in the health system in that they bear the responsibility for the provision of home care and long-term care services. They also fill in the gaps in the Health System in terms of lack of adequate community-based or individual services that support people in need of care, or that support certain needs.

The definition of "informal care" varies from country to country (Colombo et al., 2011). Despite the lack of standardization, we can refer to the definition used by the European Charter for Family Carers⁵. According to this Charter, a family carer is

"a non-professional person, who provides primary assistance with activities in daily life, either in part or in whole, to a person with care, or support needs in his/her immediate circle. This regular care, or support may be provided on a permanent or temporary basis and can take various forms, including nursing, care, assistance in education and social life, administrative formalities, travelling, coordination, vigilance, psychological support, communication, or domestic activities".

This definition resembles the one used by the International Alliance of Carer Organizations (IACO), which states that

⁵ <http://www.coface-eu.org/disability/european-charter-for-family-carers/>

“[a] caregiver, carer or family caregiver (as they referred to around the world) is an unpaid individual, such as a family member, neighbour, friend or other significant individual, who takes on a caring role to support someone with a diminishing physical ability, a debilitating cognitive condition or a chronic life-limiting illness” (IACO, 2021).

In other words, we generally understand that this is a category of people who are not considered professionals and/ or are not paid, and who have a bond with the person supported. However, the definition given by the Charter mainly assumes a dependency link between the patient and the informal carer. To capture the nuance, the French definition of informal carer is that of *“aidant informel”*, which implies the formulation of help and involves a functional contribution. However, the person being “helped” may not need any help (tasks or other assistance), but just a “presence”, having some company. This is why the community has a role to play. We will come back to this later on. The key point to attribute a person as informal carer with the term « unpaid » in opposition to professional carer tends to be fuzzy as the States recognize the importance to support them with incentives (Pavolini & Ranci, 2008).

The role of informal carers

Because of their “natural” role, informal carers have generally gone unnoticed by health systems. Originally, they were considered to be private/familial, although they are an “invisible” pillar of the health system. Without them, the system would collapse. Many of us mistakenly do not consider themselves as healthcare stakeholders. Available estimates of the number of informal carers range from 10% to 25%. 80% of long-term care in Europe is provided by informal carers (Hoffmann & Rodrigues, 2010). Informal care *“forms a cornerstone of all Long-Term Care systems in Europe and it is a key issue for future welfare policy”* (Zigante et al., 2018). Their role is therefore essential in supporting, helping and accompanying people who are losing their independence.

The particularity of carers is that they are a heterogeneous social group. There is a diversity of profiles, whether they are spouses, members of the family, neighbours, close friends or even a community. The nature of the tasks is also diverse when trying to identify them. The following, non-exhaustive list highlights the versatility of tasks performed by informal carers: personal care, medical and nursing care, recreational visits, home adaptation, preparing meals, support in education and social life, administrative procedures, coordination, psychological support, communication, domestic activities and advocacy. This list, which may

grow as the care receiver's condition worsens, combines the tasks performed by professional health and social care providers, as described in Section 4.2.2.

Moreover, the informal carer takes on a management role, i.e. a “care manager” (Da Roit & Le Bihan, 2009), due to the organisational work involved in providing stable and reassuring support for the care receiver. For instance, informal carers may need to act as a stand-in nurse to provide continuous care. It takes time and organisation to find and contact the right service. This type of delegation is necessary for a good distribution of tasks within the family, for example if one can count on the solidarity of all family members. Even if there is more delegation, it is a responsibility to ensure that proper instructions are given and followed up so that tasks are effectively carried out. Communication is also essential in this coordination work. This is why informal carers have a key role in the communication between the person/patient and the professionals. It is therefore necessary to take into account the relational and emotional work (Mallon & Bihan-Youinou, 2017) between the person being cared for, and the other members of the entourage and/or the professionals.

Communication between health and care professional and patient

Communication with professionals is the key for the provision of care, support, and participation in decision-making. Improving communication with the person who is being cared for is necessary to set up strategies for handling problematic behaviours. When caring for a person, informal caregivers are of vital importance to ensure good communication flows between professional caregivers and the patient.

As described in the previous section, informal carers often perform a multitude of tasks, which can take a heavy toll on their own health, as described in D3.1. Thus, it is important that health-care professionals support informal carers, e.g. by providing sufficient and easily accessible information on the prognosis of the patient, care-plan, information about self-care, how to prepare for an appointment, and so on (Tabootwong & Kiwannuka, 2020).

Raising awareness on the situation of informal carers is also very much needed. This way, professionals are more aware of what they can do for the carer and the patient in terms of information sharing and meeting their other needs (Denham et al., 2020). Better support from professionals allows for better feedback as informal carers are often better informed about the health status and/or needs of the care receiver. In this context, informal carers can also become advocates for the care receiver as there may be situations where patients' care needs might have been neglected without the informal carer's intervention, as illustrated in the case of John Skinner. Skinner, a deaf pensioner (Ardehali, 2019) was unable to communicate with

the residents and staff in a care home and felt desperate and lonely as a result. His son, Robert Skinner, posted a video of his father's despair on social media where was shared so many times that it went viral. This helped to remedy the situation as John Skinner was subsequently placed in a Deaf Care home, a service where British Sign Language is the main language.

Skinner's case also highlights the leverage of a person's community as members of the deaf community who shared the post helped to put pressure on the system which was then forced to take appropriate action.

Another example of community advocacy is the establishment of the VidAsor service (Confederación Estatal de Personas Sordas, 2021). The VidAsor service was created in 2017 with the pressure from the CNSE (Spanish national associations of the deaf). This is a service which acts as an assistant and companion for deaf elderly people, who are a particularly vulnerable group with their own particular needs and little or no technological skills. Thus, VidAsor offers its service through conventional television. Following installation, the user will have both conventional channels and a specific VidAsor channel, through which they receive video calls from the video assistants offering assistance and company. As they are deaf people, communication is also carried out in sign language and without intermediaries, which offers support and confidence to the user. VidAsor contributes to combat social isolation of people in general. Yet, there tends to be more social isolation among people who cannot easily communicate, such as the deaf and deafblind.

These examples illustrate how informal carers and community advocates can educate professionals about the unique care needs of minority groups, such as deaf people. This can foster a more inclusive approach respect for diversities (Navaie-Waliser et al., 2001). Ideally, professionals should either be from the same minority group or receive training that takes into account the particular needs of minority groups. The heterogeneity of societies and time constraints pose challenges which may be difficult to address.

This underlines the importance of good collaboration between the informal carer and professionals to respond to care in the best possible way. Otherwise, a "poor communication access and lack of cultural competence in service provision will adversely affect the kind and quality of assessment and service provision available to Deaf older people" (Young, 2014).

Importance of informal carers for the SHAPES Platform

As this section has demonstrated, informal carers are of vital importance for health and care governance. As stated earlier, their intimate knowledge of care receiver's needs will assist the

Platform in learning about its user experiences. Beyond, informal carers will also be users of the SHAPES Platform and their perspectives are crucial for both development and evolution of the Platform, which learns through interaction with its users. Thus, informal carers are key to understanding and overcoming additional barriers to healthy ageing.

Academic institutions as key players in governance

Academic institutions (e.g. universities and research and innovation (R&I) organisations) play an important role in European health and care governance through education, training, science, innovation, culture and policy. In this section, we first we discuss the role of academic institutions in the promotion health and care governance. Second, we identify key-challenges facing universities, and appropriate responses to strengthen their role in governance. We then outline how scientific expertise is integrated into the SHAPES Platform.

Academia's role in health and care governance

Academic institutions are key participants in health and care governance. One key area of participation in governance is through the promotion of health, which, according to Tsouros (1998), goes beyond the classical functions of education and awareness-raising. Instead, universities integrate factors such as culture, social processes and policies in their multidimensional understanding of health. Academic conceptualisations of health include factors such as empowerment, dialogue, choice, participation, equity, sustainability, and moreover, a healthy life, work and educational environment (Tsouros, 1998). Thus, the successful promotion of health requires two aspects: one, actors and organisations that possess the capacity for initiative, participation and creativity and two, a new understanding of health that goes beyond the “absence of disease”, “risk behaviour” or “safety standards”. Instead, Tsouros (1998) suggests a:

new public health movement inspired by the strategy for health for all and the experience with health-promoting settings such as the healthy city and the health-promoting school and hospital have generated a climate that is much more favourable to change than was the climate a few years ago (pp. 11-12)

Abercrombie et al. (1998, pp. 33–39) highlighted several characteristics that academic institutions in the 21st Century should possess to be recognised as a health-promoting university:

- To be an agency for “learning” and “development” through education, training and research;

- to aggregate creativity and innovation, with concrete expressions in teaching-learning processes, in the application of knowledge and in the interaction between disciplines;
- to provide a life context for students to develop independence, experiential learning, life skills;
- to be a teaching-learning context which makes students critical and reflective, that is, “in which mature students undertake learning”;
- to establish partnerships with local, regional, national and international organizations;
- to promotes its image, performance and production within the business and competitive markets.

In practice, academic institutions promote health and well-being internally through health regulations, health education, environmentally friendly buildings, volunteering and sports programmes.

Furthermore, universities deliver multidisciplinary, science-based health-and-care-related education and training, research, innovation and services to the community. Moreover, science-led health promotion is underpinned by a set of fundamental values including democracy, mutual empowerment, individual autonomy and community participation (Abercrombie et al., 1998, pp. 33–39).

The 2015 “Okanagan Charter: An International Charter for Health Promoting Universities and Colleges” (American College Health Association, 2015) suggested improvements to the academic environment through the incorporation of “health into the university culture, processes and policies, and promote an organizational culture and learning environment that enhances health, well-being and the sustainability of its community (Suárez-Reyes et al., 2019, p. 1015). The same publication identifies the key principles that should organise actions to promote health and well-being at the University, highlighting that these should be personalised according to the conditions of each academic context (Table 12).

Table 12 Calls to Action with key action areas of Health Promoting Universities and Colleges (American College Health Association, 2015)

Call to Action 1	Call to Action 2	Key Principles for Action
Embed health into all aspects of campus culture, across the administration, operations and academic mandates	Lead health promotion action and collaboration locally and globally	
1.1 Embed health in all campus policies. Policies and practices focus on health, well-being and sustainability	2.1 Integrate health, well-being and sustainability in multiple disciplines to develop change agents. Health, well-being and	1. Use settings and whole system approaches

	sustainability across all disciplines	
1.2 Create supportive campus environments. Campus as a living lab for studying and supporting health, well-being, sustainability and resilience	2.2 Advance research, teaching and training for health promotion knowledge and action. Training, learning, teaching and knowledge exchange for the communities and societies health & wellbeing	2. Ensure comprehensive and campus-wide approaches 3. Use participatory approaches and engage the voice of students and others 4. Develop trans-disciplinary collaborations and cross-sector partnerships 5. Promote research, innovation and evidence-informed action 6. Build on strengths 7. Value local and indigenous communities' contexts and priorities 8. Act on an existing universal responsibility
1.3 Generate thriving communities and a culture of well-being. Be proactive and intentional in creating empowered, connected and resilient campus communities	2.3 Lead and partner towards local and global action for health promotion. Mobilize knowledge and action for health promotion locally and globally	
1.4 Support personal development. Develop and create opportunities to empower the students and staff potential and participation		
1.5 Create or re-orient campus services. Coordinate and design services to support access, health, wellbeing and supportive organizational culture		

Source: Based in "Okanagan Charter: An International Charter for Health Promoting Universities and Colleges" (*American College Health Association, 2015*).

Challenges for academic institutions

However, academic institutions are facing a range of challenges as presented in the European Commission's (2020) policy report "Towards a 2030 Vision on the Future of Universities in Europe". Here, Commission identifies the expected acceleration of economic and societal changes as key challenges facing academic institutions within the next decade. Examples the key drivers of change include:

However, academic institutions are facing a range of challenges as presented in the European Commission's (2020) policy report "Towards a 2030 Vision on the Future of Universities in Europe". Here, Commission identifies the expected acceleration of economic and societal changes as key challenges facing academic institutions within the next decade. Examples the key drivers of change include:

- Globalization (and, conversely, pushback and deglobalization / increased localisation)

- Technological developments (e.g., digitalisation and the growing importance of artificial intelligence (AI));
- Demographic factors (brain drain, ageing populations, increased migration);
- Changes in the economy;
- Environmental and sustainability issues, e.g. climate change;
- The UN's Sustainable Development Goals (SDGs) (European Commission, 2020, p. 5).

The Commission suggested that universities responded to this “paradigmatic transition” by adopting the following recommendations:

- Retain a high degree of autonomy and will use this responsibly to provide visible value to, and for society through excellence in research and innovation activities;
- Continue to be recognised, trusted and valued by society as leading creators and imparters of knowledge;
- Develop talented academics and researchers for a rapidly-changing Europe and fast-evolving workplace;
- Provide lifelong learning opportunities for academics and researchers to maximise their individual employability opportunities;
- Foster structured collaboration with non-academic sectors (e.g. industry / business, government / public sector, the non-profit sector), organisations and citizens in their preferred domains;
- Be open and inclusive and ensure a high degree of integrity in all activities;
- Ensure excellent, rewarding, equal and inclusive opportunities to develop research careers for talented researchers from all backgrounds, in particular, those from marginalised or vulnerable groups;
- Have its knowledge, data security, research integrity protected against national and foreign interference;
- Operate in a level-playing field globally and internally for FAIR, open (but secure and reciprocity-based) exchange of knowledge, data, etc. (EU trade competency);
- Benefit from free movement of knowledge, knowledge workers (researchers) and learners (fifth freedom) and have access to (legal) tools to challenge and dismantle any existing or new barriers to this free movement (European Commission, 2020, p. 12).

Figure 3 below provides a legal framework which further illustrates how universities can both adapt to the changes and challenges outlined above and moreover, play a crucial role in

strengthening the scientific and technological bases of the European Union in a range of key areas including globalization and de-globalization, digital and green transition, socio-demographic trends towards increased immigration and ageing populations, economic recovery and geo-political and geo-economic changes in the world. The role of academia in health and care governance can be cemented further through participation in programmes such as Horizon Europe (2020-2027) and collaboration with partnerships like EIT-Health or EIPonAHA. Collaborative efforts like these can make effective use of academic excellence in science and technology. In the last section, we address the contributions of universities to the SHAPES Platform.

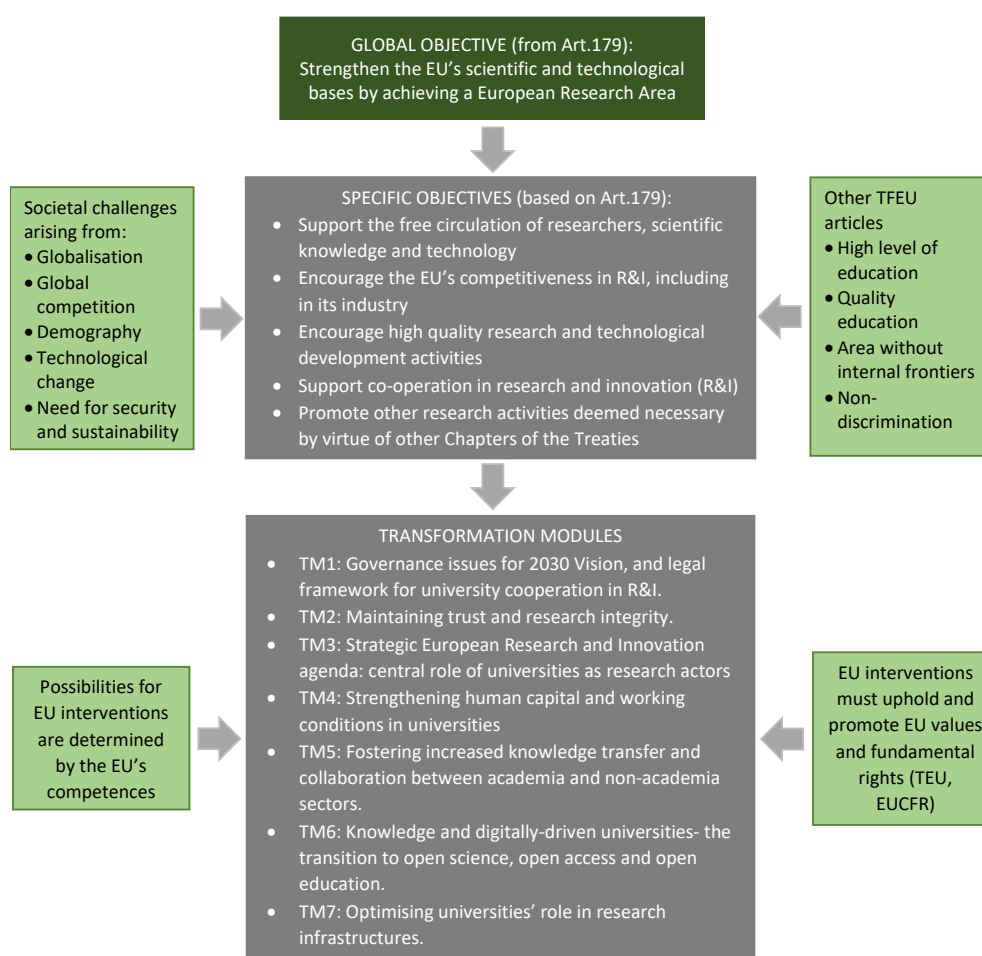


Figure 3 Legal basis for the 2030 Vision on Universities' Role in Research and Innovation (CSES, 2020).

Academia's role in health and care governance

The preceding sections illustrated both the role of academic institutions in governance, and the challenges that need to be addressed. In this section, we present ways in which academic expertise is integrated in the SHAPES Platform. Table 13 below links the proposals for

university participation in health and care governance (left column) with corresponding functions of the SHAPES Platform (right column).

Table 13 SHAPES Platform contributions for Health and Care Governance by Universities and R&I Organizations (SHAPES Proposal.)

Challenges and Issues for Governance	»»»	SHAPES Platform contributions (by SHAPES Proposal)
Promoting the Digital Transition (eHealth and eCare)	»»»	<p>The SHAPES Technological Platform brings a combination of devices, software, and accessible modes of interacting within the living environment that can adapt to the needs and priorities of older individuals.</p> <p>The SHAPES Technological Platform is a European open ecosystem enabling the large-scale deployment of a broad range of digital solutions and services for sustaining and extending healthy and independent living for older individuals.</p>
Enabling Health and Care systems by multilateral and common diplomatic agendas, and their prioritization	»»»	<p>The SHAPES Technological Platform delivers evidence-based results also support policy-makers to scale and design better integrated care policies; public and private care service providers to deliver high-quality integrated care services; and research institutions to elicit innovative (applied) research on the role played by digital platforms and solutions to foster effective pan-European integrated care models and pathways.</p>
Integrating governance clusters in Health and Care fields (Local, National, International)	»»»	<p>The SHAPES Technological Platform integrates the home, behaviour, market and governance vectors as part of smart digital solutions, capable to collect and analyse older individuals' health, environmental and lifestyle information, identify their needs and provide personalised solutions that uphold the individuals' data protection, safety, security and trust.</p>
Facilitating Health and Care strategies emanate from local needs and interests	»»»	<p>The SHAPES Technological Platform is continually learning from the needs and preferences expressed in the active behaviour of different users.</p> <p>The SHAPES Technological Platform increases social cohesion, by advertising social activities, crowdsourcing local initiatives, or creating a local audience for specialist training on health technologies. The Platform facilitates social interaction.</p>

Empowering leadership, influence and resources to Health and Care players	»»»	The SHAPES Technological Platform increases access to traditionally smaller niche markets, allowing for economies of scale, reduced pricing, the provision of product maintenance, or user training courses, virtual or physical.
Reducing negative impacts of governance patchwork (fragmentation, inefficiency)	»»»	The SHAPES Technological Platform facilitates pathfinding through the complexities of referral processes, clinical services, community supports, welfare entitlements and citizens' rights.
Increasing collaboration between academic and non-academic sectors	»»»	The SHAPES Technological Platform facilitates the cross-over of individual, community and clinical action-taking; integrating interaction.
Increasing global, FAIR, open, secure and reciprocity-based exchange	»»»	The SHAPES Technological Platform is secure and reliable; allowing users the degree of anonymity they choose, while also providing them with the benefits of a population level evidence-based resource.
Allowing free movement of knowledge by access to (legal) digital tools	»»»	The SHAPES Technological Platform integrates data from various devices, databases and reporting services that monitor health states and treatments, but also engage and empower individuals and healthcare providers in terms of preventative measures and quality of life indicators.
Promoting healthy and wellbeing lifestyles and values	»»»	The SHAPES Technological Platform cultivates cohesion, allowing for life course developments to be experienced as continuous, not interruptions or dislocations, but as a part of smart and healthy ageing, at home. The SHAPES Technological Platform promotes a positive proactive initiative by individuals and/or communities, regardless of health status.
Supporting education and training, research, innovation and services to the community	»»»	The SHAPES Technological Platform delivers European evidence-based results, conclusions and findings on the application of digital solutions to improve the implementation of integrated care models and their impact in older individuals' communities in what concerns healthy lifestyles, active ageing and extended independent living.

3.1.6 Summary

This section (Section 4.1) has provided a detailed overview of the three key stakeholders in governance – i.e., the public, private and Third Sector – including a discussion of their various roles in governance. These key elements to governance are non-exhaustive; they are based on literature reviews and may serve as references when considering optimal governance models for SHAPES. In the second version of this deliverable (due in M42), these preliminary

understandings will be triangulated with the findings from the pilot themes (WP6) and enhanced with further empirical research. The role of each stakeholder within SHAPES and for its Platform will follow the exemplary suggestions provided for academia. In the second part of Chapter 4, we put the spotlight on five distinctive domains of governance which were deemed relevant for the SHAPES Platform.

3.2 Governance domains

No two systems of governance are alike and thus, this section captures the diversity within the individual domains of governance. In the first two sections, we outline the principles, structures and processes that govern various aspects of both institutional (clinical) care and home care. We then explore the domain of corporate and business governance, which addresses how corporate structures and processes can facilitate an environment of trust, transparency and accountability. These are necessary prerequisites for long-term investment, financial stability, and business integrity, and ultimately, more inclusive societies. Lastly, IT and data governance deal with the technological aspects of the Platform. IT governance, a domain close to corporate governance, refers to a framework that facilitates the alignment IT and business strategies to achieve the organisation's goals, taking into account decision rights and accountability to encourage desirable behaviour in the use of IT. Lastly, data governance introduces the planned common European Health Data Space (EHDS), which seeks to improve the exchange of and access to different types of health data, and describes possible connections between the EHDS and SHAPES environment.

3.2.1 Clinical governance

3.2.1.1 Definition and scope of clinical governance

Within healthcare, governance may be defined as “the process of collective decision-making and policy implementation used to deliver public health, medical care, and other public goods” (Porta et al., 2018). A number of models and frameworks of health governance exist (Barbazzia & Tello, 2014). These include frameworks such as the World Health Organization's domains of stewardship (Travis et al. 2002), and UNDP's principles of good governance (Community Organization Training and Research Advocacy Institute (CO-TRAIN) and United Nations Development Programme (UNDP)-Philippines, 1997). Such frameworks focus primarily on meta-level systems and are limited by being substantially removed from the everyday experiences of governance, decision-making, and its consequences.

Clinical governance frameworks have been developed to govern care provision and clinical practice, and ensure, for example, quality and safety of care organisations, services, and programmes. Clinical governance has been defined as a system by which an organisation is “accountable for continuously improving the quality of their services and safeguarding high standards of care by creating an environment in which excellence in clinical care will flourish” (Scully & Donaldson, 1998). Clinical governance may be considered to be nested within overall health system governance. The UK’s NHS clinical governance framework, for example, forms part of an overall NHS governance framework and echoes corporate governance principles.

3.2.1.2 Clinical governance frameworks

Clinical governance frameworks have been developed by or for numerous national and regional health and social care systems. The United Kingdom’s National Health Service (NHS) is perhaps one of the earliest systems to adopt a clinical governance framework (Scully & Donaldson, 1998), and is thus particularly influential. The NHS is the UK’s publicly funded health system, incorporating health care and elements of social care. Clinical governance is the umbrella framework used by the NHS to continuously ensure service quality and ensure high standards of care by creating an environment in which excellence of care can flourish.

There are three overarching characteristics (which could be understood as values or principles):

- high standards of care;
- transparency and accountability;
- continuous improvement.

There are then seven constituent pillars of clinical governance (Gray, 2005):

- 1) patients and public: ensuring services are appropriate for the populations served, solicitation of feedback from patients and the public;
- 2) audit: continuous monitoring of clinical practice relative to extant standards;
- 3) risk management: use of robust risk management systems for the monitoring, minimisation, and reduction of the impact of adverse events; learning from adverse events, a blame-free culture and the reporting of mistakes without fear of consequences,

- 4) teaching and education: updating clinical knowledge and practical skills, regular assessment, annual appraisal;
- 5) information and technology: compliance with data protection regulation, data accuracy and secure data storage;
- 6) effectiveness and research: seeking the best outcomes possible for each individual, adoption of new practices in alignment with the extant evidence base, advancement of understanding with research, and prevention, detection, diagnosis, and treatment;
- 7) staff management: recruitment, encouragement and support to improve performance, linking role satisfaction to retention.

The UK's clinical governance framework been distilled down to “doing the right thing, at the right time, by the right person—the application of the best evidence to a patient's problem, in the way the patient wishes, by an appropriately trained and resourced individual or team ... that individual or team must work within an organisation that is accountable for the actions of its staff, values its staff (appraises and develops them), minimises risks, and learns from good practice, and indeed mistakes” (Gray, 2005).

Denmark has a long-established governance framework for ensuring quality and safety of health care. This has been described as a dialogue-based governance model and serves as an example of top-down and bottom-up governance processes working in concert (Mainz, Kristensen, & Bartels, 2015). Its governance has been described as being characterized by “flat bureaucratic structures, whereby top–down and bottom–up knowledge, opinions, decisions and actions originating from the political, administrative/bureaucratic and professional level of the healthcare system are integrated” (Mainz et al. 2015, *p.* 526). Like the UK, it is a unitary system, with values, strategic vision and planning, and financing decided at national, governmental level. Administrative and professional stakeholders undertake overall evaluation, and cyclical governance activities, such as audit and quality improvement initiatives. The focus of governance leans heavily toward hospital-based activity, but there are initiatives underway to include primary care under the governance umbrella.

The UK's clinical governance framework is often used as a model for other clinical governance frameworks, for example in Ireland and Italy (Garattini & Padula, 2017). However, there are not merely differences in health and social care systems between states, but also *within* states. Garattini and Padula (2017) sound a note of caution on the wholesale importation of national clinical governance frameworks from the UK to a nation like Italy, where health and social care is decentralised, with policy determined at local, regional, and national level. National policy

is thus applied differentially across regions. Unlike the UK, Italian clinical governance legislation has been fragmented since its introduction. General practice is much more fragmented in Italy than in the UK, with care recipients being registered with a single general practitioner, rather than a practice. Consultant physicians also reportedly have much more power relative to the nursing profession within the Italian health system, and therefore clinical governance is implicitly associated with *medical* governance, or governance related to physicians' activities. By way of contrast, the authors note that approximately one third of clinical governance articles in the UK are published by nurses. In the Netherlands, hospitals are private, not-for-profit organisations and provision is largely decentralised (Botje et al., 2014). Since the 1990s, medical (physician) specialists and executive boards have assumed joint responsibility for strategic vision and planning, with medical specialists participating in system/service management.

National frameworks of clinical governance, such as the UK NHS's Clinical Governance framework (Scully & Donaldson, 1998) are tailored to national or regional conditions and contexts, and may not reflect interjurisdictional or cross cultural difference. Australia, as a federal state, with a unitary clinical governance framework, is a useful source of information for SHAPES, providing an example of both a national framework, and interjurisdictional implementation. Clinical governance in Australia is seen as an integrated component of corporate governance, alongside risk governance, financial governance, and other forms of governance, including, for example, human resources and legal. Similar to the UK, Australian clinical governance has the objective of ensuring that all policy, management, and care provider stakeholders are accountable to patients and the community for ensuring that care is safe, effective, integrated, of high quality, and continuously improving (Australian Commission on Safety and Quality in Health Care, 2017).

In Australia, implementation of clinical governance has presented challenges. Spigelman and Rendalls (2015) described inter-jurisdictional variation and fragmentation across Australia, despite a well-documented clinical governance framework. Such variance, particularly in the absence of a common framework and measurement method, is a barrier to comparability across regions and contexts. Spigelman and Rendalls (2015) identified organisational stability as a primary factor in ensuring and maintaining the cultural changes to deliver persistent quality. Organisational stability can be improved by clear objectives and meeting by the needs of the stakeholders within.

Veenstra et al. (2017) conducted a Delphi study to explore what elements of clinical governance were perceived as important by physicians and nurses in the Netherlands. A 24-person panel came to an agreement that clinical governance, understood in the same way as

the UK's system (an environment in which excellence in clinical care will flourish), is facilitated by the following factors: good relationships between healthcare professionals, managers, and care recipients; teamwork, and shared values in terms of care quality. The panel of physicians and nurses also felt that clinical governance should be embedded in organisational culture and that such a culture should understand that quality improvement is contingent upon shared values of openness and trust and of considering mistakes as learning opportunities. Importantly, the panel of physicians and nurses rejected managerial and top-down approaches to governance and quality improvement. This aligns with a clear statement made at the inception of clinical governance in the UK's NHS: "It requires an organisation-wide transformation; clinical leadership and positive organisational cultures are particularly important (Scally & Donaldson, 1998, p. 61).

Differences not only in the clinical governance frameworks, but also their implementation, the wider health system culture, and that aspects of clinical governance may be considered differentially important to different stakeholders, must be considered and accounted for by an integrated platform like SHAPES.

3.2.1.3 Clinical governance and quality initiatives as responses to risk events

Clinical governance has often been shaped by responses and reforms in the wake of transgression, malpractice, or scandal. The Francis Inquiry in the UK is a key milestone (Francis, 2013) in identifying and illuminating how a care provision organisation lost sight of its fundamental duties. Specific recommendations included seeing everything from the perspective of the patient, increased transparency, promoting a learning culture, and genuine accountability. Poor continuity and coordination of care across health and social care provision, disconnection between providers, and nonadherence to evidence-based guidelines, have been associated with avoidable harm in primary care settings (Avery et al., 2020). Modifying aspects of clinical governance is a likely intervention option in each of these scenarios. Thus, good clinical governance, does not merely support effectiveness, but reduces risk and prevents harm. In cases of harm, flawed or 'bad' clinical governance has often played a role in that harm. Cleary and Duke (2019) detail a number of Whistleblowing cases in the Australian system, wherein concerns that were reported via conventional channels were not addressed by management. Instead, whistleblowing nurses were subject to surveillance, examination of performance, and disciplinary action. The authors suggested that psychological factors may have played a role, such as the tendency to favour positive news and avoid conflict. Suggested remedies included increasing awareness of 'wilful

blindness' and competing emotions. This recalls the idea of creating an environment and culture that promotes learning from mistakes, as in the UK's NHS.

3.2.1.4 Considering governance participation from the standpoint of clinical governance

Participation and inclusion are not merely elements of specific programmes of governance, but much wider and overarching themes. SHAPES, as a platform and ecosystem, is designed to be inclusive, and therefore its governance model must consider and incorporate public and user participation.

While participation is a common element in clinical and health system governance, a number of the most commonplace, extant governance frameworks do not necessarily, fully account for participatory processes or inclusion, a relatively recent development in health and social care and governance. Inclusion, participation, and equity in health and social care processes and decisions not only align with human rights approaches (Charter of Fundamental Rights of the European Union), but have been shown to make care more effective and more satisfactory.

As expounded upon above in Section 3, the set of stakeholders includes, or ought to include, care recipients. A recent article by Bigdeli et al. (2020, p. PAGE) suggested that, even in best case scenarios "we have limited this stake-holder group to the 'Patients', the passive users of health services. And even in that role, consideration is often only given to the users who need curative care." It is quite clear that clinical governance framework must account for care recipients or service users other than those requiring acute health care, including, but not limited to: people with chronic, rehabilitative, or long-term care needs; people receiving social care; family and informal caregivers; care recipients who are considered vulnerable; people who typically experience health, social, or political inequities or inequalities, and; the wider public. Despite benefits of care recipients' and families' participation in decision making, including improved overall care quality and safety, specific barriers to such participation persist, including health system fragmentation, paternalistic professional cultures, poor process design and infrequent involvement of patients and families in co-design (Gandhi et al., 2018).

For professionals, West (2001) contended, based on a body of extant evidence in non-healthcare settings, that participation is likely most effective when it is integrated as a permanent and inclusive feature of the employment relation rather than a sporadic or exclusive feature. Such permanent and inclusive forms of participation in the professional context include: participation in work decisions via permanent programmes where workers assume

formal, direct roles in decisions about their work; consultative participation which comprises long term interventions like ‘quality circles’, wherein employees are consulted for decision making by managers, and; employee ownership.

3.2.1.5 Summary

Fundamental rights and accepted values or principles offer a foundation on which to set clinical governance. Different countries will have different specific clinical governance frameworks or arrangements, some being more unitary (e.g., UK, Denmark, Ireland), others more fragmented or with greater regional or local variation in control over, design of, or implementation of clinical governance (e.g., Australia, Italy, Netherlands). Clinical governance frameworks typically aim to promote and ensure quality and safety of services and accountability. Clinical governance and its related activities has trended toward wider stakeholder inclusion and participation over time. Initial inclusion of policymakers, administrators, and professionals with the advent of clinical governance initiatives, is yielding to a growing acknowledgement that all stakeholders are integral to the governance process, with parity of esteem, and a growing appreciation of the need to include care recipients and their families to ensure quality optimisation.

3.2.2 Home care governance

3.2.2.1 The meaning of care

Care is a complex concept with many facets and blurred boundaries (Anttonen & Zechner, 2011), which suffers from ‘role ambiguity’, i.e. it is unclear what the care role actually involves (McTaggart et al., 2017). Care, Daly (2002) suggested, quite simply means “looking after those who cannot take care of themselves” (p. 252), which includes people of all ages. Care for older people can be provided both in institutions (e.g. hospitals, nursing homes), in day care centres, and at home. Increasingly, European governments, seeking to promote independence, autonomy and an active life, have shifted their focus away from institutional care towards providing health and social care services to older adults in their own home (Genet, Kroneman, et al., 2012). Likewise, SHAPES is primarily concerned with enabling older people to live independently and autonomously, and ideally in their own homes. Hence, this section explores how home care is governed across Europe.

Based on Boerma and Genet (2012), home care is understood as any formal and informal care services provided at home on a short, medium or long-term basis, including both healthcare and social care services. As the meaning of care differs considerably across countries, this section is based on literature on varying related concepts, as well as the

previous deliverable *D3.1 Ecological Organisational Models of Health and Care Systems for Ageing* where we described European models of health and care provision. For example, it is common for home care to be discussed in the context of long-term care, i.e. “a set of medical, social, and personal care services provided on a regular basis for people who need help with ADLs [activities of daily life]” (Swartz, 2013, p. 400). In the literature, home care may also be associated with social welfare more generally.

In most countries, there is a vertical administrative division between healthcare and social care (Boerma & Genet, 2012; Kröger & Bagnato, 2017; Spasova et al., 2018) and hence, these concepts will be introduced separately in the following sections. This is followed by a brief description of the different instruments of home care governance, namely regulation, delivery, financing and regulation of access, and lastly, quality control.

3.2.2.2 Social home care

Usually, social care is the responsibility of the social services. Social care is a concept which is difficult to define (Anttonen et al., 2003; Lalor & Share, 2013) and thus, it is often – unhelpfully - defined in terms of what it is not (Anttonen et al., 2003). Care is related to, yet different from, the concepts of “housework, mothering and nursing” (Anttonen & Zechner, 2011, p. 15). The *Irish Association of Social Care Educators* suggesting that social care is “...a profession committed to the planning and delivery of quality care and other support services for individuals and groups with identified needs” (Cited in Lalor & Share, 2013, p. 4). Spasova et al. (2018) suggested that social care involves non-medical “care services that aim to help the care-dependent person to carry out activities of daily life (such as household tasks, eating etc.)” (p. 12). A more comprehensive description of social care⁶ emerged from a 2011

⁶ “Social care workers plan and provide professional individual or group care to clients with personal and social needs. Client groups are varied and include children and adolescents in residential care; young people in detention schools; people with intellectual or physical disabilities; people who are homeless; people with alcohol/drug dependency; families in the community; or older people.

Social care workers strive to support, protect, guide and advocate on behalf of clients. Social care work is based on interpersonal relationships which require empathy, strong communication skills, self-awareness and an ability to use critical reflection. Teamwork and interdisciplinary work are also important in social care practice. The core principles underpinning social care work are similar to those of other helping professions, and they include respect for the dignity of clients; social justice; and empowerment of clients to achieve their full potential. Social care practice differs from social work practice in that it uses shared life-space opportunities to meet the physical, social and emotional needs of clients. Social care work uses strengths-based, needs-led approaches to mediate clients’ presenting problems.

Social care workers are trained, inter alia, in life span development, parenting, attachment and loss, interpersonal communication and behaviour management. Their training equips them to optimise the personal and social development of those with whom they work. In Ireland, the recognized qualification is a 3-year Level 7 degree. In Europe, social care work is usually referred to as social pedagogy and social care workers as social pedagogues” (Cited in Lalor & Share, 2013, pp. 5–6).

consultation with a group of experts asked by the Irish Professional Regulation Unit of the Department of Health and Children. For the purpose of this deliverable, based on the definitions by Spasova et al. (2018) and Lalor and Share (2013), social care is defined as follows:

Social care involves professional, non-medical services, provided to a wide range of individuals or groups, including older people, aiming to help the care-dependent person to carry out activities of daily life (such as household tasks, eating etc.). Social care practitioners plan and provide care to a to meet their physical, social and emotional needs. Practitioners are professionals who support, protect, guide and advocate on behalf of service users. Social care practice is characterized by interpersonal relationships, teamwork and interdisciplinary work, and is underpinned by the following core principles: respect for the dignity of service users, social justice, and empowerment of service users to realise their full potential.

Non-medical home care varies from country to country and may include: “help with “activities of daily life (ADL) ... food services ... alert systems through which the elderly can connect to a help post in case of need ... nursing and technical aids and devices such as nursing beds ... support to adapt private houses ... social counselling ... tele-assistance ... and handyman services” (Spasova et al., 2018, pp. 13–14). In the following sections, we describe different aspects of home care governance including regulation, delivery, financing and regulation of access, and quality control.

3.2.2.3 Home healthcare

Generally, healthcare is part of the healthcare system and thus, regulated and funded at national level. Home health care services are provided by health professionals such as nurses, general practitioners (GP), physiotherapists and occupational therapists (Boerma & Genet, 2012; Spasova et al., 2018). Healthcare services include, but are not limited to, supportive nursing, technical nursing or rehabilitative nursing (Boerma & Genet, 2012). Table 14 provides an overview of the categories of nursing activities.

Table 14: Categories of nursing activities (Based on Boerma and Genet, 2012).

Categories of nursing activities			
Nursing activities	Supportive nursing	Technical nursing	Rehabilitative nursing

Details	Provision of health information and education	Assistance putting on prostheses or elastic stockings	occupational therapy
		Changing stomas and urinal bags	physiotherapy
		Help with bladder catheters	
		Skin care	
		Disinfection and prevention of bedsores	
		Oxygen administration	
		Catheterization	
		Giving intravenous injections	

Regulation of home care

European political systems are highly diversified and complex (Burau et al., 2007; Och, 2015) which entails “a unique combination of formal and informal structures” (Burau et al., 2007, p. 8). However, there are certain similarities between political systems which can be located on a continuum of centralisation and decentralisation which determines how decision-making powers and responsibilities are dispersed across various government levels (Burau et al., 2007; Genet, Kroneman, et al., 2012; Kuronen & Caillaud, 2015).

Broadly speaking, types of governments can be categorised as either centralised (unitary) or decentralised which, depending on country, may be described as federal, devolved, multi-level, framework political systems. In centralised systems, political powers and responsibilities are concentrated in the central government. In this system, the state takes on a dominant role for the formation of welfare policies, and for the distribution of funds for the municipalities. As local authorities generally lack decision-making powers, their role is limited to the implementation of national policies (Burau et al., 2007; Genet, Kroneman, et al., 2012; Kuronen & Caillaud, 2015). Although central governments can delegate administrative competences or responsibilities to the various subnational levels, it is the government at national level that has the final say (Burau et al., 2007, p. 9).

By contrast, in decentralised systems competences have been transferred “from an upper level of government to a lower level” (Och, 2015, p. 165), e.g. federal states, regions, provinces, municipalities, etc.). Depending on the organisation and level of division of

competences and responsibilities within countries, subnational governments are heavily involved in the formation of policies, organisation and delivery of services, and management of financial resources. In some countries, responsibility lies with regions, in others with municipalities or autonomous local authorities. Likewise, local authorities may receive funding through either national or regional governments (Kuronen & Caillaud, 2015).

Och (2015) suggests that the distinction between “three different dimensions of decentralisation” (p. 165) improves our understanding of the complexity of home care governance: regulative, administrative and financial decentralisation as described below:

- **Regulative decentralization** (also political decentralization or devolution) describes “the degree to which the power to decide on the rules for access and needs coverage of care benefits and services are located at subnational levels of government” (Och, 2015, p. 165).
- **Administrative decentralization** refers to “the degree to which the implementation of these rules and the actual provision (or its supervision) is delegated to subnational governments ... actual provision of benefits, how needs are met, and, if required, means tests, organisation of care services, planning, and so on” (Och, 2015, p. 166).
- **Financial decentralization** means “the degree to which the funding of benefits and services for eldercare needs is provided by subnational governments. In all countries, eldercare is funded by a combination of public and private resources” (Och, 2015, p. 165).

Decentralisation, which is the most common political system in Europe (Genet, Kroneman, et al., 2012), entails vast differences in care funding, delivery, rules and quality both between countries and within countries (Burau et al., 2007). Moreover, differences also exist within countries but between home care sectors. Healthcare policies are more commonly formed by national governments, whereas social care policies tend to be the responsibility of subnational governments (Genet, Kroneman, et al., 2012).

A national vision of care

Aside from levels of decentralisation, the presence a national vision of health and social care also plays an important role in the governance of care. National visions provide a framework for the nature of care and the place of care within society in both its current and future composition. Moreover, national visions describe current and potential future challenges facing care, and the changes necessary to achieve or maintain the desired quality of care. However, EU MS often either lack a fully formed vision of care or the existing vision only refers to one sector of care, i.e. either healthcare or social care, but not both (Genet, Kroneman, et al., 2012).

3.2.2.4 Delivery of home care

There are two main types of providers of home care: a) providers that are publicly owned and b) providers that are under private ownership. Private providers can be subdivided further into for-profit and non-profit organisations (Genet, Hutchinson, et al., 2012).

Home care services are often divided vertically along healthcare and social care lines: while healthcare services tends to be the responsibility of national or regional governments, social care is more commonly provided by local governments hindering the integration of both sectors (Genet, Kroneman, et al., 2012; Kröger & Bagnato, 2017). There are several ways in which governments are involved in the provision of home care. Governments may provide care directly through municipalities or government agencies. Governments can also commission private home care providers which are contracted through municipalities, government agencies, or private insurance companies. In this case, private providers must comply with the rules and regulations set by government (Zigante et al., 2019).

Private home care services, provided by for-profit, non-profit and family members, have been playing an increasingly prominent role while the involvement of governments in the provision of care has been decreasing (Leibetseder et al., 2017). However, the contraction of the public sector in the provision of services has negatively impacted financial resources for services (e.g. cash benefits), public service delivery and regulation and enforcement of care standards. Moreover, the decline of public involvement in home care provision entails the creation of informal markets, where mostly informal private caregivers (usually immigrants) deliver service provision” (Leibetseder et al., 2017, p. 145) evading public control and oversight.

Table 15 Governments' involvement in the provision of home care (Own table based on Genet et al., 2012)

Government as main provider of care	Government as partial provider of care	Private companies as main providers of care
Croatia, Cyprus, Denmark, Finland, Greece, Iceland, Ireland, Norway, Sweden	England, Estonia, Hungary, Latvia, Lithuania, Malta, Poland, Romania, Slovakia, Slovenia, Spain, Switzerland	Austria, Belgium, Bulgaria, Czechia, France, Germany, Italy, Luxembourg, Netherlands, Portugal

3.2.2.5 Financing and regulation of access to home care

Generally, home care services are paid for through a mix of public and private funding including taxation, insurance, service fees/ private payments as well as donations (Boerma & Genet, 2012; Genet, Kroneman, et al., 2012; Leibetseder et al., 2017). Care is funded publicly either through taxes or insurance (Genet, Kroneman, et al., 2012). However, the level of coverage varies according to country and type of care and may require private co-payments, which are determined either by national, regional or municipal government, or by national or regional social insurance (Genet, Kroneman, et al., 2012; Spasova et al., 2018). In some countries, co-payments are set by neither government nor insurance providers (Genet, Kroneman, et al., 2012).

Eligibility for publicly funded home social care is assessed by social services which carry out home visits to establish the level of care required, which increasingly involves a functional assessment (Spasova et al., 2018). This assessment is done through public organisations, private organisations or a mix of both (Genet, Kroneman, et al., 2012). Eligibility for publicly funded health and social care services depends on the dominant welfare model in place and on the care needs of the person, and the availability of familial caregivers. In Europe, countries either operationalise a model that grants universal coverage within a single programme, or a mixed welfare system. Under the universal coverage scheme, care users are granted access to formal, public care services regardless of income or assets. By contrast, mixed systems involve a mix of services and cash or in-kind benefits as well as universal and means-tested coverage (Gori et al., 2015; Spasova et al., 2018; Zigante et al., 2019). Cash benefits can be used to purchase services directly. However, if not covered by the public system, care receivers are required to fund care services privately (Zigante et al., 2019).

In most countries, home healthcare, such as nursing care, physiotherapy and rehabilitation is covered by the health system and provided either free of charge or in exchange for a nominal fee (Spasova et al., 2018). By contrast, publicly funded social home care services often require co-payments from the care receiver. Yet, people in need of care are often unsure about their entitlements (Ranci & Pavolini, 2013; Vjenka Garms-Homolová et al., 2012), for several reasons. One, the varying definitions of what care is as well as the numerous aspects of care makes it difficult to develop care protocols (as described in Section 3.2.2.6) (Ranci & Pavolini, 2013; Vjenka Garms-Homolová et al., 2012). Second, the often-vague descriptions of entitlements at national level, especially with regards to social home care, are inadequate to provide guidance for the objective interpretation of care needs (Genet, Kroneman, et al., 2012; Ranci & Pavolini, 2013). Third, cultural assumptions that care should be provided by family

members is sometimes reflected in welfare policies which creates confusion about the level of public care coverage (Ranci & Pavolini, 2013; Vjenka Garms-Homolová et al., 2012).

Often, there is a great deal of uncertainty about care entitlements. First, the multiple dimensions attached to providing “care” (personal help, social interaction, support for mobility or basic everyday life activity, and so on) have made it relatively difficult to develop specific technical protocols. The needs’ assessment of the dependent is complex in itself as it encompasses multiple aspects, some of which are subject to subjective interpretation. Second, care has been perceived as a relational activity implying a specific adaptation to the needs of the recipient (Ranci & Pavolini, 2013).

3.2.2.6 Quality control of home care services

Quality of care is an important criterion of good governance and takes into account the situation of both care receivers and caregivers. Governments, and in some cases social insurance providers or regional social insurance providers, usually seek to ensure the quality of care by defining minimum standards and requirements, through accreditation programmes and inspection or monitoring of services. Standards may be defined at national, regional or local level (Genet, Kroneman, et al., 2012; Spasova et al., 2018).

Yet, quality control is challenging due to a range of factors, such as lack of standardisation at intra- and inter-country level, lack of resources and sanctions and moreover, lack of evidence-based outcomes (Spasova et al., 2018). Well-defined quality criteria are more commonly available for the health care sector than for the social care sector, and rarely for home care services. While national quality criteria for healthcare are available in some countries, in others they are either only available in part (i.e. only basic criteria), only at regional level or else, quality criteria only apply to some home care programmes (Genet, Kroneman, et al., 2012). Moreover, existing quality criteria often only apply to institutional care but rarely to home care (Genet, Hutchinson, et al., 2012; Ranci & Pavolini, 2013; Spasova et al., 2018), which is partly due to the view of care as an informal activity provided primarily by family members (Ranci & Pavolini, 2013). In addition, lack of care practitioners and financial resources in the public sector poses challenges for care delivery, supervision and assessment of quality of care services (Marczak & Wistow, 2015; Spasova et al., 2018). Seeking to optimise the allocation of limited financial reserves (Marczak & Wistow, 2015), countries are increasingly commissioning private for-profit and non-profit providers including self-employed care practitioners (Marczak & Wistow, 2015; Ranci & Pavolini, 2013).

3.2.2.7 Summary

Section 4.5 has provided an overview of the governance of home healthcare and social home care in the EU paying particular attention to regulation, delivery, financing, regulation of access and lastly, quality control of home care. This section has outlined the complex interplay of home healthcare and social home care in the EU with particular attention to regulation, delivery, financing, regulation of access and lastly, quality control of home care. Section 4.5 has also highlighted the ongoing fragmentation of the home healthcare and social home care sectors in many European countries.

3.2.3 IT governance

3.2.3.1 Definitions

- IT governance is the responsibility of executives and the board of directors, and consists of the leadership, organisational structures and processes that ensure that the enterprise's IT sustains and extends the organisation's strategy and objectives (IT Governance Institute, 2005).
- IT governance is specifying the decision rights and accountability framework to encourage desirable behaviour in the use of IT (Weill & Woodham, 2002).
- IT governance is the organisational capacity exercised by the board, executive management and IT management to control the formulation and implementation of IT strategy and in this way ensure the fusion of business and IT (Van Grembergen, 2000).

The SHAPES platform, as an IT system, is a mediator between actors involved in the provision, and receipt of health and social care services and resources. It mediates the relationship between patients, carers, healthcare professionals, social services, healthcare administration, and so on. The opportunity for SHAPES now, is to explore how the SHAPES IT platform can and should facilitate the potential participation of all persons in governance health and social care governance. In this capacity, the SHAPES platform can be viewed as a participant in health and social care system governance, as well as facilitating the active participation of the widest number of people as possible, to the extent that they wish to, or need to, be involved.

Viewing the SHAPES platform as a participant in governance reflects the fact that it has structural characteristics that shape the nature of the interaction both with it and through it. These characteristics are not under the control of any one individual or at least cannot be readily changed by the user. The platform provides both new affordances and constraints for

each person. For our purposes here the term “*affordances*” refers to the opportunities for action available to the user through the platform. On the other hand, “*constraints*” refers to limitations or barriers to action built into the system. Both affordances and constraints need to be viewed together as mutually defining aspects of the environment and they are neither good nor bad in and of themselves. Affordances are opportunities for action, but these include potentially destructive acts that may occur deliberately or accidentally, such as the deletion of patient records, or sharing of personal information to an unauthorised recipient. Constraints are limitations on action, and good design involves getting the balance right between intended affordances, and intentional constraints. Whatever way we look at it, any designed system embodies the full range of choices that have gone into it through the process of requirements identification and selection, the definition of specifications, the prototypes developed and evaluated, and the criteria used to evaluate the system. Through this process the system acquires a certain degree of agency as it becomes an embodied synergy of numerous values originating in the concrete decisions made along the way about its form, function, priorities, aesthetics, ethics, and interaction style.

3.2.3.2 Enterprise governance of IT – EGIT

As described by CIMA and IFAC (2004), “*Enterprise governance constitutes the entire accountability framework of the organisation. There are two dimensions of enterprise governance – conformance and performance, that need to be in balance.*” (CIMA et al., 2004, p. 4)

SHAPES as an enterprise with its specific objectives linked to the grant agreement as well as the priorities of the European Commission as laid out in the original call, will be served by the development of a corporate structure and business exploitation plan in WP7. Corporate governance is concerned with the institutional integrity of SHAPES as an entity and its conformance to objectives, standards, and regulations. Business governance will be concerned with the business performance of SHAPES based on the principle of value creation and exploitation.

IT governance will have as its main focus the supporting of enterprise through enacting governance principles directly at corporate and business levels in line with the strategic objectives of the enterprise level.

According to de Haes and Van Grembergen (2020), Enterprise Governance of IT, or EGIT, is

...an integral part of corporate governance for which, as such, the board is accountable. It involves the definition and implementation of processes, structures, and relational mechanisms that enable both business and IT stakeholders to execute their responsibilities in support of business/IT alignment, and the creation and protection of IT value (Haes & Van Grembergen, 2020, p. 5561).

IT alignment is concerned with ensuring that the structures, principles, and processes of IT are aligned with the business and corporate goals and objectives of the enterprise.

3.2.4 Business & corporate governance

3.2.4.1 Definition

The term corporate governance has been incrementally used since the 1970s and 1980s (Tricker, 2015). Among the earlier attempts, the so-called Cadbury Report on the “The Financial Aspects of Corporate Governance” defined it as a “the system by which companies are directed and controlled” (Cadbury, 1992). The report describes a “set of relationships between a company’s management, its board, its shareholders and other stakeholders” (OECD, 2015, p. 7). As such, corporate governance refers to issues of conformance within the corporate structure.

At the same time, “[c]orporate governance also provides the structure through which the objectives of the company are set, and the means of attaining those objectives and monitoring performance are determined” (OECD, 2015, p. 9). Therefore, corporate governance can also refers to issues of performance. In order to better distinguish the two meanings, the latter will be referred to as “business governance”.

The normative power of corporate governance was made visible by the World Bank Report of 2000 that argued that “corporate governance matters- more than ever” (Iskander & Chamlou, 2000, p. 4). The report also distinguishes between internal and external factors of influence on corporations (2000, p. 4). “The purpose of corporate governance is to help build an environment of trust, transparency and accountability necessary for fostering long-term investment, financial stability and business integrity, thereby supporting stronger growth and more inclusive societies” (OECD, 2015, p. 7).

3.2.4.2 *Customer-centric approach*

Theoretical concepts of business have changed with the world and economic development. There has been a shift from a traditional production-centric approach to a service- and customer-centric mindset. We are currently living in a service society utilising the digital service economy. Most of this market change and increased dynamism is the result of technological evolution. However, the real challenge for companies and organisations does not stem from technological developments but from how customer behaviour has changed along with development (Heinonen & Strandvik, 2018).

The customer-centric way of thinking also places the customer in the role of an active actor (Mickelsson, 2013, p. 540). In customer-centric business logic, value is created through the customer's operations (Heinonen et al., 2013, p. 104). With digitalisation, the customer's own activities in creating value have become more important. Despite the fact that the service provider provides the service, the customer, supported by technology, controls the service process through his or her own operations. In this case, the customer is responsible for creating and producing value his- or herself (Mickelsson, 2017, pp. 24–25). The service provider acts as an enabler of value production, but it cannot itself generate value for the customer. The value the customer receives from the service becomes clear to the customer through experience. Customer-centric business logic combines value with what a person experiences, determines, and relates to emotions.

3.2.5 *Data governance*

3.2.5.1 *Definition*

Strengthening and extending the use and re-use of health and social care data of data is critical for innovations in the EU care sector. This enables healthcare authorities to make evidence-based decisions to improve the accessibility, effectiveness, and sustainability of healthcare-related activities. Thus far, several policies and legislation have been introduced to create a common *European Data Space*, including a common European Health Data Space (EHDS), which is one of the priorities of the European Commission 2019-2025. The EHDS seeks to improve the exchange of and access to different types of health data, such as electronic health records, genomics data, or data from patient registries. The EHDS endeavours to primarily support healthcare delivery, and moreover, health research and health policy making. This section describes possible connections between the EHDS and SHAPES environment in terms of facilitating discussion, guidance, regulation and causality

issues from the perspective of data governance of digital health and social care. The unit of analysis (UoA) used is a data flow.

3.2.5.2 Principles

According to the European strategy for data (COM, 2020a) the European Data Space will give businesses in the EU the possibility to build at scale for the Single market. Common European rules and efficient enforcement mechanisms should ensure that:

- Data can flow within the EU and across sectors;
- European rules and values, in particular personal data protection, consumer protection legislation and competition law, are fully respected;
- rules for access to and use of data are fair, practical and clear, and that there are clear and trustworthy data governance mechanisms in place; there is an open, but assertive approach to international data flows, based on European values (COM, 2020a).

These steps enable access to data but need to be complemented with a broader industrial strategy for the data-agile economy. Data spaces should foster an ecosystem (of companies, civil society and individuals) creating new products and services based on more accessible data. (COM, 2020a)

3.2.5.3 Regulations

The Commission will also support the establishment of the following nine common European data spaces, including health data space. A common EHDS is essential for improved prevention, detection and curing of diseases. Moreover, a common EHDS facilitates informed, evidence-based decision-making which will improve the accessibility, effectiveness and sustainability of the healthcare systems. (COM, 2020a)

The EHDS is a system for data exchange and access which is governed by common rules, procedures and technical standards to ensure that health data can be accessed within and between EU Member States (MS). Access to health data fully respects the fundamental rights of individuals in line with the General Data Protection Regulation (GDPR) and MS competences. The EHDS will be built on 3 main pillars:

1. A system of data governance and rules for data exchange.
2. Data quality.
3. Strong infrastructure and interoperability.

Proposal for the Data Governance Act

The Proposal for the Data Governance Act (European Commission (COM), 2020) aims to foster the availability of data in two ways: by increasing trust in data intermediaries, and by strengthening data-sharing mechanisms across the EU. The instrument would address the following conditions:

- Making public sector data available for re-use, in instances where such data is subject to rights of others.
- Sharing of data among businesses, against remuneration in any form.
- Allowing personal data to be used with the help of a 'personal data-sharing intermediary', designed to help individuals exercise their rights under the General Data Protection Regulation (GDPR).
- Allowing data use on altruistic grounds.

The instrument draws inspiration from the principles for data management and re-use developed for research data. The FAIR data principles stipulate that such data should, in principle, be **F**indable, **A**ccessible, **I**nteroperable and **R**e-usable.

According to the Proposal for Data Governance Act (European Commission (COM), 2020), the provision of data sharing services shall be subject to the following conditions:

- (1) the provider may not use the data for which it provides services for other purposes than to put them at the disposal of data users and data sharing services shall be placed in a separate legal entity;
- (2) the metadata collected from the provision of the data sharing service may be used only for the development of that service;
- (3) the provider shall ensure that the procedure for access to its service is fair, transparent and non-discriminatory for both data holders and data users, including as regards prices;
- (4) the provider shall facilitate the exchange of the data in the format in which it receives it from the data holder and shall convert the data into specific formats only to enhance interoperability within and across sectors or if requested by the data user or where mandated by Union law or to ensure harmonisation with international or European data standards;
- (5) the provider shall have procedures in place to prevent fraudulent or abusive practices in relation to access to data from parties seeking access through their services;

- (6) the provider shall ensure a reasonable continuity of provision of its services and, in the case of services which ensure storage of data, shall have sufficient guarantees in place that allow data holders and data users to obtain access to their data in case of insolvency;
- (7) the provider shall put in place adequate technical, legal and organisational measures in order to prevent transfer or access to non-personal data that is unlawful under Union law;
- (8) the provider shall take measures to ensure a high level of security for the storage and transmission of non-personal data;
- (9) the provider shall have procedures in place to ensure compliance with the Union and national rules on competition;
- (10) the provider offering services to data subjects shall act in the data subjects' best interest when facilitating the exercise of their rights, in particular by advising data subjects on potential data uses and standard terms and conditions attached to such uses;
- (11) where a provider provides tools for obtaining consent from data subjects or permissions to process data made available by legal persons, it shall specify the jurisdiction or jurisdictions in which the data use is intended to take place. (Proposal for Data Governance Act, Article 11).

Enabling the digital transformation of health and care in the Digital Single Market

Digital solutions for healthcare can increase the well-being of citizens and radically change the way services are delivered, if designed purposefully and implemented in a cost-effective way. Health data are a key enabler for digital transformations. Such data may be available in various forms and moreover, the data management varies both across EU Member States and within national health systems. It is often not even available to the patients themselves or to public authorities, medical professionals or researchers. Where health data exist, they often depend on technologies that are not interoperable, thus hindering its wide use (COM, 2018).

In its mid-term review on the implementation of the digital single market strategy, the Commission set out its intention to take further action in three areas:

- *citizens' secure access to and sharing of health data across borders;*

- *better data to advance research, disease prevention and personalised health and care;*
- *digital tools for citizen empowerment and person-centred care (COM, 2018).*

In the table below there are categories of ICT solution grouped according to these commission priorities (WE4AHA project, 2019).

Table 16 Categories of ICT solution according to COM priorities (WE4AHA project, 2019)

Table of categories of ICT solution according to COM priorities
<p>Priority 1: Citizen's secure access to and sharing of health data across borders.</p> <ul style="list-style-type: none"> • Citizens' secure access to their health data – e.g. via a secure online porta, citizen access to an Electronic Health Record (EHR), a Personal Health Record (PHR) including tele monitoring data and shared with health professionals • Interoperable EHRs deployed at national and/or regional levels enabling citizens' secure access to and sharing of health data; General Data Protection Regulation (GDPR) compliant, secure health data exchange • Citizen-enabled sharing of health data across borders: patient summary and/or ePrescription, discharge letter, medical images, lab results • Citizen-controlled data governance, health data cooperatives, health data donation
<p>Priority 2: Better data to promote research, disease prevention and personalized healthcare</p> <p>Digital infrastructure for personalized medicine, -omics databanks, biomedical infrastructures</p> <p>Good practice in digital genomics, including whole genome sequencing</p> <p>Use of real-word data (RWD), data quality assessment and improvement</p> <p>Health data analytics (Artificial Intelligences, algorithm development and calibration, machine learning, risk stratification tools, etc)</p> <p>Big data analysis, particularly for preventive medicine and treatment</p> <p>Interoperability of disease registries including for rare diseases, data aggregation and sharing across borders, including at EU level</p>

Digital tools for public health, epidemiology, pharmacovigilance, clinical research, including reuse of EHRs for clinical research

Priority 3: Digital tools for citizen empowerment and for person-centred care

Citizen/patient-focused solutions:

- Digital tools to support health education (health literacy), digital health literacy
- mHealth systems, wearables devices for monitoring and prevention, alerts, reminders
- Digital tools to support patient feedback and reporting of outcomes and experiences
- Digital tools to support proactive prevention, self-management, homecare, tele monitoring
- Tele-mentoring/coaching, virtual consultations, virtual coach, personal assistant
- ICT supporting adherence to medication and care plans
- Robotics (e.g. companion robots)
- Tools and services supporting independent living, ambient assisted living technologies, telecare

Care practitioners' solutions:

- Advanced digital tools for support Integrated Care, including integration of health and social care services
- Interoperable digital solutions to support person-centred and integrated care
- Regional and national EHPR systems and ePrescription solutions enabling person-centred care
- Regional, national and local electronic Integrated Care Record (eICR) systems, integration of EHR and social care records
- Digital share care plan (e.g. support to multi-disciplinary teams)
- Decision support for multi-morbidity and polypharmacy management
- ICT support for management of frailty
- ICT support for falls prevention
- eLearning to support workforce development for person-centred integrated care

Proposals for Digital Service Act and Digital Market Act

In December 2020, the EU unveiled proposals for a Digital Services Act (COM, 2020b) and a Digital Markets Act (COM, 2020c). The proposed Acts will prohibit illegal online content by placing increased responsibilities on online platform hosts to prevent the hosting of illegal content (SHAPES, 2020a).

From a SHAPES governance point of view, it is essential that the Digital Service Act will impose greater moderating and reporting obligations. Thus, it is advisable for SHAPES partners to adopt a robust governance structure for the maintenance and monitoring of the platform during the life cycle of the project and post the completion of the project. It is unclear as of now, the extent to which the obligations will apply to the SHAPES platform. The proposed rules lay down obligations to all providers of intermediary services to establish a single point of contact to allow for direct communication with national authorities (COM, 2020b, article 10). Platform controllers will be obliged to report to such bodies on incidents of the removal or disabling of information considered to be illegal content (COM, 2020b, articles 13 & 23). Project partners should also assess if the platform's operation protects the fundamental rights of all users of the digital services, including the right to an effective remedy, non-discrimination, and the protection of personal data and privacy online. These considerations are currently included in D8.4 ethics framework (SHAPES, 2020a).

Similarly to the DSA, the proposed Digital Markets Act (DMA) sets out new rules for gatekeeper platforms in the digital sector. The DMA focuses on imposing responsibilities on platforms that have 'a significant impact on the internal market.' New obligations relating to the use of data, interoperability and self-preferencing will be placed on gatekeepers. In particular, the gatekeepers will be required to allow third parties to inter-operate with the gatekeeper's services in specific circumstances (COM, 2020c).

3.3 Summary

In this chapter (Chapter 4), we have outlined the functions of key governance stakeholders (i.e. the public, private and third sector) and moreover, we have provided an overview of five domains of governance (clinical, home care, business and corporate, IT, data). This has facilitated the positioning of the SHAPES Platform within a wider ecosystem in which the Platform is embedded. As stated, the Platform, as a participant in governance, does not operate independent of the socio-cultural, economic, legal and technological structures and processes within which it is placed. Instead, the Platform both shapes and is shaped by the interactions and relationships between the various actors that are care providers and recipients.

In Chapter 5, we further contextualise existing governance structures and processes based on the perspectives and experiences of key stakeholders consulted during a dialogue workshop.

4 Governance participation: Consultation, empirical investigation and matrix development

4.1 Aims of the consultation

To enable the development of the SHAPES collaborative governance model, we effected broad consultation, using empirical methods. Consultation took three forms: a dialogue workshop with parallel workshops that functioned as a focus group discussion; drawing on data from interviews with integrated care service providers who had implemented person-centred technology, and a governance participation consultation survey. Each of these forms of consultation is reported on in turn in the following sections.

4.2 Dialogue workshops

4.2.1 Discussion

From the individual perspective, a key concern was the role of recipients in integrated care. There remains work to be undertaken to best understand how to facilitate person centredness and incorporating the needs of recipients in the governance of care systems. Particular attention must be paid to the consequences of shifting responsibilities, which could result in responsibilisation. Responsibilisation, or the transfer of all responsibility for decisions and their consequences into the hands of care recipients, presents as a risk. It is a risk which could present as a requirement for care recipients to assume a managerial role and accountability for their own *outcomes*. We obtained relatively little data in relation to the ethical and legal consequences of changes in practices or governance, or indeed of existing systems and processes.

Governance systems and processes, in facilitating person-centred integrated care and active and healthy ageing, ought to be cognizant of the full spectrum of health-related outcomes and quality of life, and ought to protect healthcare recipients from institutionalisation. The role of communication in the system is a particularly important consideration for governance, as is understanding how systems are interconnected, if at all. Systems with better communication and integration are likely to promote better outcomes, better overall quality.

The role of informal caregivers in integrated care was raised numerous times, and the integral role of informal caregivers in present HSC systems needs due consideration in any model. Of particular note was the perception that informal caregivers often assume the role of a mediator or translator within the care process, although a range of concerns emerged about potential – or likely – mismatch between the needs and priorities of recipients and informal caregivers, including whether informal caregivers accurately represent the needs and views of recipients. Perhaps of particular interest from a governance perspective was how frequently caregivers assume a role in the process of communication between recipients and providers, linking the health and social care systems, and making care arrangements. The highly prevalent gendering of informal caregiving is an important finding, particularly in light of the consideration that SHAPES will give to the gendered nature of “smart and healthy ageing at home” (SHAPES Grant Agreement).

A point made in relation to modes of communication is also particularly relevant to how services are structured in response to the SARS-Cov-2 pandemic and how technological innovations are implemented or may drive changes in practice. The pace of innovation in service providers and systems is problematically slow, and it was described as very difficult to introduce new systems or practices or technology or to implement innovations more generally.

There are some limitations to consider when interpreting the findings. While the 2nd SHAPES Dialogue Workshop sessions did facilitate the collection of individual perspectives on health and social care governance, a full appreciation of all the moving parts in the governance structures and processes in health and social care was not elicited. This is partly reflective of the care system related roles of the session participants. There were few, if any, participants who had a role in care system governance, particularly at the macro level. The sessions were also limited by the amount of time available for discussion; 20 minutes of discussion time in parallel, plus a further 20 minutes for collective discussion.

In uncovering some elements of the individual perspective on governance, these findings imprint the perspective of integrated care and person-centredness on the process of understanding governance structures and processes.

4.2.2 Aim of the workshops

We aimed to gain insight into existing governance structures and processes from the standpoint of individual actors, specifically care recipients, their families, and their informal caregivers. Our principal objective was to generate a descriptive understanding of existing systems and experiences across Europe. Systems change and evolve, and so any care

platform or ecosystem, such as SHAPES, must be responsive to change in both design and implementation. Designing health and social care systems in line with the principles of integrated care is desirable to improve quality, efficiency, and stakeholder experiences. Such redesign is also a present reality and increasingly likely in the future (Hughes et al., 2020). Therefore, we also wished to scope the injunctive, or how participation in decision making and governance might occur or might be facilitated in care systems that are integrated.

4.2.3 Workshop method

The 2nd SHAPES Dialogue Workshop was held online on October 29th, 2020. At the workshop, we facilitated group discussions with the aim of understanding existing governance structures and processes from the standpoint of the individual.

We facilitated a total of nine individual group discussion sessions in total across the day across the four interactive sessions scheduled on the day. The first four of these occurred in parallel, followed by the next two in parallel, the next two again in parallel, and one final group discussion. After each of the first three sets of parallel sessions, all of the parallel sessions convened for a summary discussion.

Participants were prompted to discuss various open questions about HSC governance across three broad categories: agency and responsibility, risks and implications, and sustainability.

- Agency and responsibility: Who are the decision makers? To what extent is decision making participatory? What are the channels of communication? How are decisions made? To what extent is informed consent sought and at what point in the health and care process?
- Risks and implications: What are the potential risks/implications if more responsibility is shifted to the individual? What does it mean for accountability? What are the ethical and legal implications?
- Sustainability: How can sustainability of the individual situation be ensured beyond the crisis situation?

Additionally, participants were provided with the following vignette to prompt discussion and ground the discussion in the consideration of the individual perspective:

Mary is an older adult healthcare recipient. Following a fall, she is admitted to hospital. The hospital has deemed Mary to be medically ready to leave acute care and the hospital 'needs the bed'. Mary would really like to go home. However, Mary faces health-related challenges. She has difficulty taking blood

sugar readings, needs to manage chronic illness, and experiences forgetfulness. As well as specialised clinical assessment, Mary may need tertiary or rehabilitative care and adaptations in the home environment. Mary lives alone, but has two adult children, one of whom lives near her home.

The responses of workshop participants were recorded by facilitators, with notetakers assigned to each parallel session. Responses were then subjected to a qualitative, thematic analysis; coded and categorised thematically.

4.2.4 Workshop findings

There were approximately 55 to 60 participants across the 9 separate sessions. Participants included physicians, engineers, healthcare recipients, and academics (including social scientists and economists). One parallel session included participants with hearing impairments and these sessions were facilitated with live signing and transcription.

The discussion topics were distilled into seven broad themes, which are:

- Actors and Inclusion in the Care Process and Decision Making
- Dis/Connection and Non/Communication Between Health and Social Care Systems and Components
- Funding Mechanisms and Equity of Access
- Non-Integration Engendering Worse Outcomes and Institutionalisation
- Informal Caregivers as Care Coordinators, Mediators, and Persons with Needs Divergent from Recipients
- Agents of Change: The Pandemic and Technology
- Risks and Ethical and Legal Implications

4.2.4.1 *Actors and Inclusion in the Care Process and Decision Making*

Discussion participants highlighted that involving health and social care recipients in the care process is main aim of integrated care and is a precondition for ensuring quality of care. The need to ensure the voice of the recipient. Participants spoke of the need to hear the person in need of care, to fully explain all alternatives in terms of care options, to involve recipients in care decision making, and to offer alternatives to the care recipient. Participants variously described care recipients, informal providers or family, formal providers (e.g., physicians, occupational therapists, physiotherapists, psychologists), administrators and managers, and engineers as decision makers.

Although, some participants cited professionals (e.g., physicians and engineers) as the appropriate decision makers as a function of their (professional) expertise participants generally agreed that the recipient should be the primary decision maker. Decision-making processes were described as asymmetric with participants, directly or indirectly, telling of the power imbalance between recipients and other actors within health and social care systems. Physicians and administrators in particular were held to possess much more power and influence in decision making than care recipients. In reference to this hierarchy, it was said that while the care recipient may be in a position to decide on care, they may feel too shy, or be reluctant to express opinions that differ from those of physicians.

Participants reported that currently recipients may not always be enabled or empowered to make informed decisions. For example, this partly related to recipients not having the requisite formal medical knowledge and training to fully evaluate alternative options and their consequences. Participants also cited insufficient communication and a lack of presentation and full explanation of alternatives to recipients. The need to communicate and explain to participants in ways that meet each recipient's accessibility needs was also highlighted. This also related to the point that recipients ought not be made accountable or legally responsible for decisions. This was especially so when recipients may not be in a position to make fully informed decisions.

4.2.4.2 Dis/Connection and Non/Communication Between Health and Social Care Systems and Components

Issues of connection and communication between systems were often linked. Participants generally reported disconnection between the health or 'medical' care and social care systems, with these systems being conceived as separate systems, and operating as such in most of the referenced countries and regions. Additionally, numerous participants reported a lack of communication between whole systems, between service providers, and between the system and the care recipient. This was also reported to be the case across several countries or regions. This separation of care systems, and the absence or insufficiency of communication was cited as a major barrier to integrated care. Participants identified the slow process of innovation in service providers and systems as problematic and that it was very difficult to update provision with new systems or technology or implement innovations.

One participant described discharge from hospital as a "done deal". Taking the example of discharge from acute care, there was general disconnection although there were some differences in the degree of integration across countries and regions. In Greece, there was

reportedly no structure to coordinate the health and social care systems; arrangement was dependent upon family. In Germany also, the system was dependent upon the availability of informal care. One participant mentioned that in Germany, many with the means to do so seek private home care provision, with these services often being provided by caregivers from Eastern Europe (implicitly: less wealthy countries). In Portugal, it was outlined that the only contact from the hospital was to arrange for collection from the hospital on discharge. In Spain, healthcare is the responsibility of regional authorities with variation in progress toward integration. In one region, there is reportedly a complete divide between health and social care, with no communications or sharing of information. In Ireland a community nurse was reported in one case to have made contact prior to discharge, although the extent of this contact was not reported. Recent and/or ongoing system developments in Northern Ireland involved development of a prototype system where health and social care systems “talk to each other” and stepdown care packages. These were aimed at improving integration and continuity of care, facilitated by improved interparty communication. Relating to Northern Ireland, there was a full evaluation by the social worker. This often meant that recipients had longer acute stays while this was completed. Participants were unsure to whom those evaluations were sent. Funding mechanisms, structures, and systems relate to this issue of dis/connection. The need to have a care package in place prior to discharge was highlighted.

4.2.4.3 Funding Mechanisms and Equity of Access

Participants discussed the funding sources of health and social care systems in partner countries. Relatedly, participants discussed access and equity of access to social care. While a wealth of specific detail on care funding mechanisms did not emerge, there were some points of note. Participants identified differences in whether certain elements of social care were publicly funded across different countries. In Spain, homecare is typically not means tested. For Nordic countries, and Finland specifically, it was reported that there is universal access to home care, but wealthier people might choose private services. Structures in Finland and Sweden were described as partially decentralised. Private, formal caregiving and informal caregiving may be filling a gap of care provision needs left by public services.

4.2.4.4 Non-Integration Engendering Worse Outcomes and Institutionalisation

Participants reported that non-integration of care leads to worse health and social care outcomes. It creates barriers to the sustainability of independent living and to HSC recipients’ ability to remain in their own home if that is their preference. This non-integration of systems engenders institutionalization, which is directly in contravention of the UN *Convention on the*

Rights of Persons with Disabilities. The need to recognise people with disabilities not as patients but as people with rights and freedoms was expressed.

4.2.4.5 Informal caregivers as care coordinators, mediators, and persons with needs divergent from recipients

Participants highlighted the integral role of informal caregivers (e.g., care recipients' family members) in existing health and social care systems, and the systems' reliance on informal caregivers. The importance of informal caregivers as care coordinators was highlighted. Informal care providers were reported to play a major role in connecting health and social care service providers, linking recipients to different parts of existing systems, and often arranging or organizing care or assisting recipients in doing so. In many cases informal care providers act ostensibly as mediators between the care recipients and formal care providers.

It was noted however, that informal providers may not accurately or fairly represent the wishes of care recipient with complete reliability; informal caregivers may have conflicting views, priorities, or objectives. It was also noted that informal caregivers were not always available to assist recipients. This could be due to the recipient not having family, or having difficult relationships, or with informal caregivers having limitations on what they can provide themselves. Indeed, informal caregivers' have their own needs (which, as noted above, may not match those of recipients), and may lack relevant supports.

The gender bias in informal caregiving was made clear, with women providing a disproportionately much higher share of informal care. In addition, psychosocial sequelae of informal care provision were outlined. This included psychological wellbeing and feelings of guilt in relation to providing, inability to provide, feeling obliged to provide, and being relied upon by formal systems to provide health and social care.

The family have been said to play a more central role in some parts of Europe – Spain and Portugal for example – than in other parts, such as Finland, where formal homecare meets the needs of care recipients.

4.2.4.6 Agents of Change: The Pandemic and Technology

In addition to the push of prevailing socioeconomic conditions and demographic changes, the ongoing coronavirus pandemic has reiterated and reinforced the need for integrated care to ensure continuity of care. It has highlighted problems of lack of coordination and gaps in care

provision; COVID was exposing silos. It was also reported that pathways of care had disappeared during lockdown, and that mortality had increased because of lack of monitoring.

Participants felt that the pandemic may catalyse the development of integrated care by way of necessity. However, participants also noted that the pandemic and associated public health lockdown measures may obscure a portion of true care needs. One contributor to this might be the different or additional capacities of informal caregivers to provide assistance or care under lockdown conditions that they otherwise might.

Technology was described as helpful, though not a substitute for informal care. Another participant described technology as very important to facilitate recipients' connectivity to family, support services, and emergency services. Technologies should be designed in such a way that even in situations where the recipient is experiencing panic or impairment, that they can use the device.

4.2.4.7 Risks and Ethical and Legal Implications

Participants identified risks in the event of changes in responsibilities or the allocation and distribution of responsibility. Participants identified ethical issues around the sharing of data between providers. They raised the question as to whether recipients would have the ability to (reliably) make the correct self-assessments of health status alone at home.

4.3 Stakeholder interviews

In autumn 2020, stakeholder interviews were held with managers and other key informants of integrated care service providers that had successfully adopted person-centred technology in their service delivery models and flows, or that were in the middle of the process of doing so. The interviews have been analysed and the outcomes have been reported in SHAPES D3.2. "Scaling-up Improved Integrated Care Service Delivery", while the full case reports are included in the annex to that deliverable.

The case reports focus on the process of technology adoption in integrated care processes, which very often leads to important changes in the existing relationships and practices within care ecosystems.

It was observed that technology adoption is very initiated by the authoritative 'governing' body (i.e., stewardship body) in health care, whether this is a government department, a health authority, or the management of a public or private care provider. In most cases they are in

the position to assess the need for change, to conceptualise innovative solutions, to implement and to evaluate these.

The decision to adopt technology in care pathways is very often driven by a mix of motivations related to improvements in overall systems performance in terms of health outcomes, but also to economic drivers such as efficiency gain, lower costs per unit, expected long term cost-benefits advantages, or just saving resources. The expectation of many decision makers is that technology and delivering care remotely can help to save money, while maintaining quality or even improving the services provided.

The introduction of technology in care ecosystems tends to change the relationships between the actors. This might pertain to division of responsibilities and tasks, as well as the decision-making processes. In some cases, we found that the care recipient became more active and effectively the protagonist of his or her own health care story. In other cases, the role of the case managing nurse was enhanced, or GPs and pharmacists were involved in additional tasks. However, although in medical and social care, responsibilities are rather well defined, technology in care is a game changer and those with the highest responsibilities and control over budgets and investments clearly govern these processes.

Patients or care recipients tend to see the added value of technology adoption in the care process but are not really involved in the decision-making process. Nevertheless, they might be consulted in the design phase or asked to evaluate the innovations. Most of the stakeholders interviewed considered the collaboration of care recipients as a key factor for success.

Health professionals are involved in innovation as facilitators or gatekeepers. There are differences between groups and within groups, ranging from innovators and early adopters to traditionalists and those who refuse to adopt the innovations. For the future it is to be expected that those professionals that have the highest adaptation skills will increase their impact and control over innovative systems that are the backbone of service delivery models and care organisational flows.

4.4 Governance participation survey

4.4.1 Survey aims

Different stakeholders in health and social care have differential levels of participation in governance, and different opportunities access points for participation. By virtue of the existence of different levels of participation, expectations, opportunity, resources, and

experiences, stakeholders may encounter a range of barriers to participation, or indeed a range of facilitators or enablers.

To explore how a range of stakeholders participate in health and social care governance and develop an inventory of related barriers and facilitators, we developed a survey for consultation with SHAPES partners.

To tap into both the specific and the general or universal, we aimed to gather information from respondents' own countries, regions, or settings that they knew best, but also examples of factors that may be considered more abstract, theoretical, or possible, that may be more universal, or that they may have heard about in another region. Additionally, we had the objective of expanding the list of known, relevant stakeholders for consideration in the SHAPES collaborative governance model. We also had the objective of piloting and validating the governance participation survey as a tool for data collection.

We aimed to conduct a provisional analysis of barriers and facilitators. Our range of possible respondents is limited by virtue of being within the SHAPES consortium, and itself contains a limited range of stakeholders. Similarly, our aims of piloting the governance participation survey itself and gathering an expanded list of stakeholders render analyses as provisional.

4.4.2 Survey design and method

We structured the governance participation consultation survey as a matrix, with rows and columns. Rows of the survey matrix represented stakeholders in health and social care governance. This included participants or stakeholders ranging from people not professionally engaged in the health care system, such as care recipients, family, and informal caregivers, to medical, social care, and administrative professionals and policymakers, to governance participants in the wider ecosystem, such as academics. Any of the stakeholders may participate in more than one level of governance category. In acknowledgement that our list of stakeholders is not exhaustive, we invited survey respondents to modify it as they saw fit, by either changing the categories of participant, or by adding new categories (rows).

Columns of the survey matrix represented levels of participation in health and social care governance, ordered by the degree of participation any individual may engage in within their own national or even regional setting, or in more abstract and universal terms. Arranged from left to right, this ranged from low levels of actual or perceived participation, to high levels of participation including activity or having a role in health and social care decision-making. Categories of governance participation specifically included: Low levels of participation; Low

levels of participation but interested or concerned; Moderate levels of participation; High levels of participation at the micro - individual – level; High levels of participation at the meso - management - level (hospital, clinic or care home management/administration); High levels of participation at the macro level through strategic decision-making in governance, and; Other category of involvement. An additional column was included in the matrix design to allow for qualitative comment.

Respondents were requested to choose categories of actor or stakeholder on which to provide information, and to provide input for the relevant row in the survey. We specified that we were not attempting to be prescriptive about who should or should not actively participate. Rather, we sought to establish the variety of ways people may participate, and to identify barriers to participation and enablers of more active engagement in health and care decision-making processes. Detailed explanatory notes were provided, containing instructions for how to complete the survey.

To analyse the response to the survey, responses were collated into a master file. Numerical codes could then be assigned to responses that explicated barriers or facilitators. Each barrier and facilitator in the response categories and or comment sections was coded. Barriers and facilitators were then grouped into manageable categorisations. Cross-cutting themes were also drawn from the data with a basic thematic analysis. As the range of possible respondents is somewhat limited (by virtue of being within the SHAPES consortium), and because our aims include piloting the governance participation survey itself and gathering an expanded list of stakeholders, our aims analyses should be considered provisional.

4.4.3 Preliminary survey results

We received eighteen (N=18) consultation survey responses from across the SHAPES consortium. Respondents largely completed the survey on behalf of whole organisations (n=16; AIAS, CH, EDGE, FhG, FNOL, gewi, KOM, Laurea, NHSCT, SciFy, UAVR, UCC, UCLM/SAL, UNRF, UP, UPORTO). The exceptions were consultations received from NUIM; these were completed on an individual respondent basis (n=3*), with one of these providing largely legal and ethical context, rather than specific barriers and facilitators.

In addition to the categories of stakeholder that we specified in our survey, numerous additional categories of stakeholder were provided by respondents. These included care recipients with specific health conditions (including, type II diabetes mellitus; cardiovascular disease risk; rare diseases; pre-obesity; asthma); healthy older adults as care giver to spouse or family member; neighbours of care recipient - living at home; crisis interventionists; medical

specialist (outpatient department); health homecare nurse; nurse ambulant; pharmacists working in various settings (hospital, community, GP practice); ambulance; nursing homes (private); professional (representative) organisations (including “doctors’ chambers” and “nurses’ chambers”); technical assistance and support (in cases of ICT used by patients); health technology providers; technology or technical services suppliers; higher education institutions (as distinct from individual academics); research governance stakeholders; information governance stakeholders; international networks (apolitical); and regional state administration agencies.

The consultation survey permitted both the extraction of specific barriers and facilitators and the compilation of emergent themes which are common, if not universal, across stakeholder categories or modes of participation. These are reported below in turn.

4.4.3.1 Barriers and facilitators

A large number of unique barriers and facilitators (circa 150) were reported by respondents to the consultation survey. With the application of qualitative, thematic analysis, barriers and facilitators were categorised into 19 superordinate categories. Categories included knowledge and awareness, capacity (personal), motivation and choice (personal), communication, inclusion, social role, resources – personal or professional, resources – organisational or systemic, power and its distribution, collective voice and action or solidarity, organisations and institutions, systems and services, access, legal & ethical contexts, social supports, technologies and tools, social, economic, and political environments, biases, inequalities, and inequities, and time. See Table 17 for a listing of categories with a non-exhaustive list of selected examples of barriers and facilitators pertaining to each category.

Table 17 Categories of Barrier and Facilitator (Own table)

No.	Category	Selected Barriers	Selected Facilitators
1	Knowledge and Awareness	Strong but unstructured knowledge, lack of instruction (or knowledge) available to recipients on how to raise concerns in the correct, official pathway, lack of information on relative performance of health system	Access to information, knowledge, education, training, evidence-based practice, caregiver having requisite experience and knowledge, experience of how the system works
3	Capacity	Cognitive impairment	Physical capacity, cognitive capacity, decision making capacity
4	Motivation and Choice	The influence of the socio-political environment, professionals' choice of enhanced services from an approved list only	Free choice of one's personal physician, ability to seek a second opinion, healthcare systems allowing care recipients to decide
5	Communication	Lack of clarity or communication about what (academic/research) recommendations actually influence policy, speed of the doctor's speech, conflict between stakeholders	Two-way communication with HC providers, conflict may also function as a facilitator, allowing for leverage over decision making
6	Inclusion	Perceived or actual tokenism	Person-centredness, encouragement to be active decision maker, patient and public involvement (PPI), involving decision makers in technological R&D
7	Social Role	Care recipient	Being and administrator, policymaker, or health and social care professional

8	Resources – personal or professional		Financial resources, social network
9	Resources – organisational or systemic	Staff turnover due to grant-linked employment (research/academia)	Availability of trained personnel, specialised personnel
10	Power and its distribution	Unequal distribution of power across social roles (for example, physicians having more power at micro level than nurses), feeling disempowered	Empowerment to implement change (which lies mostly with government and insurance companies),
11	Collective voice & action / Solidarity		Labour union membership, professional organisations
12	Organisations & Institutions		International organisations
13	Systems and Services	Specialists operating in silos, insurer's control over pricing of healthcare procedures, linking reimbursement to frequency of activity (e.g. number of patients seen, rather than quality), restricted appointment times	Well organised health and social care systems, integrated care partnerships, integrated care itself, emphasis on prevention, correct navigation of care recipients through system, uploading of outpatient specialists of non-specialised visits; transparency regarding service quality
14	Access (to services)	Physical barriers to service access, cost-related barriers (e.g., out of pocket costs), time-related barriers to access (e.g., waiting lists)	
15	Legal & Ethical Contexts and Tools	Restrictive regulations (for example, on reimbursement, or choice of services)	Regulations, guidelines (for technology use), advance care directive, developed policy

16	Social Supports	Caregivers not being supportive	Access to online communities, caregiver support, spiritual support
17	Technologies and Tools		Connected health technology. Availability of ICT tools such as health portals, symptom checkers, telemedicine, mHealth apps, synchronous and asynchronous communication with healthcare professionals, tools supporting integrated care, especially sharing information with social care and coordination of care of several kinds of professionals, electronic health care record (eHCR)
18	Social, economic, and political environments	Geographic inequalities	Small size of a geographic or administrative region
19	Biases, Inequalities, and Inequities	Age, gender, health status, disability status, citizenship or migrant status	
20	Time	Palliative care scenario dictating that limited time is available, length of time required to design, complete and report on trials	Availability of time for participation. Protected time (if governance is part of a professional function)

4.4.3.2 Emergent Themes and Contexts

A set of themes were assembled from the data. These themes were common, if not universal, across different respondents, different stakeholder categories, or different modes of participation. Themes are distinct from specific barriers and facilitators, but contextualise barriers and facilitators, or further our understanding of common and cross-cutting issues. Themes included: dimensionality and flux; power and imbalances thereof; opportunity and environments (incorporating structures, supports, inclusion and equity); interest, motivation, and choice; valuing governance participation, and duality of barriers and facilitators. Each of these themes is expanded upon and illustrated with selected examples from respondents' data.

Dimensionality and Flux

Dimensionality and flux (e.g., of a recipients' 'dependency') are often key aspects of governance participation. Care recipients' capacity, for example, may not fit a binary classification. Rather, capacity may operate on a spectrum, and may vary over time, either upward or downward. Additionally, capacity may be delineated across its different forms, with different forms of capacity also fluctuating over time. Additionally, the implementation of participation or decision making facilitators (such as assistive technology, or an advance care directive) may allow for change in terms of what forms of participation are available to people.

it may not always be clear to draw a line between a patient that is "dependent" vs one that is "independent". I appreciate this lies on a continuum, but it also may fluctuate from time-to-time within the patient (also patients may be dependent for some care needs, but not for others). [MU – RM]

Power and Imbalances Thereof

Power emerged as a prominent determinant, mediator, and moderator of participation in governance. Wide imbalances of power are evident between different stakeholder groups. Care recipients, their families, and informal caregivers typically have little power to make decisions or effect changes. At the micro level, health professionals have power over decisions in the care environment. Power is not distributed evenly across the professions; physicians typically have the most power as decision makers, both in care environments at a more meso/administrative and strategic levels. Government bodies and legislatures, administrative bodies, and insurers typically have much more power than individual care recipients or professionals, particularly at strategic levels. This also influences activity at micro

level in the care environment; professionals may be curtailed by what services they may provide by funding constraints or policy, for example. Individual actors, from care recipients to professionals may be empowered in various ways, whether through the formation of or participation in professional bodies, labour unions, recipient representative organisations, inclusion in decision making, initiatives such as advance care directives, or (perhaps indirectly) through improved knowledge, access to and availability of services.

Patients who stay in hospital usually do not have much power in the decision-making process as they are depending on the doctor's treatment; especially older adults are highly dependent and unwilling to challenge doctor's opinions [UP].

Nurses are very often the ones that take care of the patient the most, who know their needs, struggles and monitor their well-being, they have quite respected position in a dialogue with the patient and the doctor, they can make minor changes in the care plan, however major decisions are still in the hands of the doctor [UP].

The system is adjusted to allow nurses to educate and otherwise empower the patients. Nurse is compliant with possible standards. Nurse uses some ICT tools to access information or communicate with distant patients [FNOL].

Private health providers offer a lot of health care and usually they are big companies. In Finland public healthcare has enjoyed respect traditionally, but this position has already changed, in the quality of public health care services there are big differences between municipalities, anyway private companies have taken more and more power and affect also in macro level of governance. Private sector has power in many level of governance, they offer lot of workplaces and are thus significant employers, in national, regional and personal level even it needs to follow the same legislation as the local and NGO-level [Laurea].

[GPs have] different vehicles to engage with government to determine service provision and commissioning via Royal College of GP, GP Federations, local medical committees and regional medical committees, integrated care partnerships [NHSC].

[For health service administrators] Participation in the design of national and regional health policies [UAVR].

[Insurers are] the key player in the decision making processes as they are the ones splitting the funds and creating the charts for pricing each healthcare procedure; many doctors blame their full agendas on the insurance companies as they give them more money for more patients, not for a higher quality of their work [UP].

Informal caregivers participation in assessment of level of care dependency: Example: Asking for assessment of care dependency for financial and medical support for [her husband with dementia], Signe kept a diary for 4 weeks noting everything about his behaviour and needs. When the evaluation team came, they did not care for the diary but made their assessment on the spot within an hour. The assessment did not reflect the real needs. The diary would have done so. The process was therefore much prolonged and the needed support for the care dependency level came too late. Including informal carers into such evaluation processes is key for quick and correct assessment in long term care [NUIM - KS].

[With an advance care directive, the] subject is now empowered to manage his own health care. Has discussed with family doctor and partner and has decided what he would want in the future if he developed cardiac arrest, life threatening illness or needed a tube for feeding [UCC].

[For nurses] He/she is a member of a labour union in order to be able to enforce the legally regulated working hours [FhG].

In some nursing homes such as El Salvador (Pedroche, Córdoba), there are councils of elders, in which they themselves are the members, are in charge of collecting complaints and suggestions and then transferring them to the management of the centre. Also, they have a suggestion box. [UCLM/SAL].

Opportunity and Environments (incorporating structures, systems, inclusion and support)

Opportunity relates to environmental factors, such as health and social care environments, the contexts in which governance participation might occur, social, economic, physical, and situational factors, inclusion and supports. Naturally, features of existing structures and situations often operate as barriers or facilitators to governance participation, and are very common and prominent as factors that influence governance participation in responses across a range of stakeholders and levels of participation. Often, features of the environment are intertwined with the theme of power and imbalances thereof, such as hierarchies and

distributions of power. Opportunity may be expanded and bolstered by increasing stakeholder inclusion in decision making processes, and providing supports to stakeholders that enable participation in decision making, governance, or care more generally. Such supports could take the form of social support, wider and more equitable access to care, provision of assistive or eHealth technology, environmental adaptations (e.g., of the home), legal means, advanced care planning, and supports that target financial factors, from affordability of care and services, to supports or fiscal/economic change (non-exhaustive list). Interventions or facilitators that rebalance power relationships or empower stakeholders may also be considered as modifications of opportunity or environmental factors.

This case is applicable for younger patients (till 40yo) who are used to looking for the second opinion or approaching private doctors who can dedicate more time in treating patients; limiting factor in general are finances and awareness - those who do want to participate are usually those with higher education, or/and those who can afford extra care - as most procedures are funded by insurance so extra care needs to be paid [UP].

Enablers may include good levels of health literacy, good access to health services, access to appropriate aids (e.g., mobility aids, compliance aids), good relationships with healthcare professionals (HCPs), discussing decisions with friends/family and adaptations to living space. Barriers may include low levels of health literacy, poor access to health services, poor/untrusting relationship with HCPs, social isolation [NHSC].

Family members are interested but busy enough to work, care for themselves and their dependents (kids) and care recipients - there is no time to think about governance [FhG].

[The] financial model and overall concept of specialized (outpatient) care is not in favour of patients' empowerment and involvement. Specialist performs only necessary actions in care as required by the care procedures and guidelines. No specific activity is developed to collaborate with other professionals on the given case and to seek additional information about the patient [FNOL].

Care recipient sues in court for permission of assisted suicide [FhG].

[Name] sees the need for involvement on a political and systematic level, but she feels is robbing her too [of] much energy as it feels like a struggle against windmills in a system governed by strict hierarchies. [NUIM - KS].

Public health nurses are the core component of the national public healthcare systems. However, rarely are they asked to participate in the decision-making process. They are usually highly skilled professionals with many years of experience, even with difficult and stressed patients. They usually voice their opinions in the micro level (for example about a strategy they and their colleagues should follow) [SciFy].

National, regional (as appropriate) concept and implemented measures and systems that effectively empower the patients. Healthcare systems allowing patients to decide e.g. on the bases of second opinion [FNOL].

[Administrative body] Promotes the participation of citizens/care recipients in the quality assessment of health providers and health system [UAVR].

Personal Interest, Choice, and Motivation

Issues relating to personal interest, choice, and motivation to participate, were evident across data and how it relates to involvement. Stakeholders naturally have the choice to participate where opportunities are available to them. They also have the choice to not participate, even where opportunities are available, with the only exception being those whose social or occupational role requires or mandates particular forms of participation; for example a policymaker making macro-level decisions, or consultant physician's involvement in daily, micro-level governance activities. Choice is mediated by motivation, and motivation is in turn determined not merely by personal factors, but also by features of the actor's environment. Motivation or choice to participate may be influenced by structural, systemic, social and other barriers or facilitators, or indeed the information upon which choices are made. Thus, issues of choice are intertwined with a range of personal and environmental features, including but not limited to service access, availability of participation opportunities, inclusion and equality, technological supports, knowledge, and social supports.

[Caregivers] lack capacity and motivation to be involved in decision making as their time and energy must be dedicated to immediate demands of caring [NUIM - RM].

Patient is not interested in governance matters, sees it as too abstract and removed from their reality, or feels such questions are burdensome or stressful [FNOL].

Older people express their needs to their caregivers, but sometimes the process of taking actions is delayed in time, one of the reasons could be; due

to administrative complexity or because they did not know how to contact the correct people/department to solve it or to find more information. So that the motivation to participate in the process decreases [UCLM/SAL].

Family members may wish to take an active role in health and care of a care recipient but perhaps find themselves unable to participate as they would choose to. Barriers; geographic proximity to care recipient, inability to access information about services available, low levels of health literacy, strained personal relationship with care recipient. Enablers; access to informed HCPs e.g. social workers, GP with good knowledge of local services available, close proximity to care recipient, close relationship between family member and care recipient. Family members may also have a low level of involvement in health and care governance due to the high competency and empowerment of the care recipient. Alternatively, family members may act to allow a care receiver to participate in governance by facilitating attendance at appointments but do not have any involvement in the care decisions themselves [NHSC].

Valuing Participation in Governance

Respondents often took the perspective of considering participation or the opportunity for participation as valuable. This could be implicitly or explicitly, and at various levels and in various aspects of the health and social care systems. Similarly, respondents, at least implicitly, appeared to be interested in enabling participation and empowering stakeholders for participation. The overall tone and thrust of responses, and the wide range of barriers evidences that respondents value participation in governance.

Duality

Duality emerged as an explanatory theme; a single factor may function as *both* a barrier and facilitator. Taking education as a particular example; education indeed may function as a facilitator of governance participation. However, education may also operate as a barrier, contingent upon its accuracy, format, delivery, or ideological framework, boundaries, or content. Recipients of education that did not place emphasis or value on participation, inclusion, voice, or empowerment, may experience explicit or implicit barriers to participation. Education may, even implicitly, also have wrongly modelled governance participation as being suitable for a particular demographic or cohort (for example, males, White people, or those with certain formal education, professional expertise, resources), and not for others (for example, women, Black people, people without professional expertise, people with a disability, or people who cannot afford particular services). Conflict between stakeholders serves as an

example. As well as being a clear barrier, it may in certain situations also function as a facilitator, by allowing for or generating leverage over decision making.

4.4.4 Discussion

Our governance participation survey aimed to explore how a range of stakeholders participate in health and social care governance and develop an inventory of related barriers and facilitators. Responses to our survey generated circa 150 unique barriers and facilitators of governance participation. Application of qualitative analysis enabled the rationalisation of these into a manageable number of nineteen categories.

Our consultation provided a much-expanded list of relevant stakeholders for consideration in the SHAPES collaborative governance model. In piloting our governance survey matrix, we have found that it is a useful and pragmatic tool to expedite data collection in relation to governance participation. Our consultation permitted the collection of very specific barriers and facilitators (such as provision of specific forms of ICT) and more general or universal factors like integrated care. Responses were gathered from a broad range of countries and regions. Generation of cross cutting themes allows us to contextualise barriers and facilitators and to understand universalities.

4.5 Summary

We have, in Chapter 5, detailed our consultation process and developed an understanding of individual's experiences, of the role of technology in supporting participation, and of the factors that shape participation in governance, whether as barriers, facilitators, or factors that contextualise or moderate participation and experiences. Our consultation process involved conducting dialogue workshops that functioned as focus group discussions; drawing on data from interviews with integrated care service providers who had implemented person-centred technology, and a governance participation consultation survey.

This consultation process has allowed us to uncover detailed information about the actors and stakeholders in governance and the ways in which they currently, could possibly, may wish to, and should be enabled to participate. Individuals differ in terms of their capacity to participate, and their interest, desire, motivation, or choices around whether, how, and when to participate in governance. Capacity, however, should be considered not as fixed, but as modifiable and extendable with appropriate intervention. Intervention to promote opportunities to participate, or enablement, may take widely varying forms. Some examples include: providing access to information; raising health literacy; raising digital literacy; improving actual

and perceived empowerment; genuine and meaningful inclusion of stakeholders such as care recipients, informal caregivers, and their families in governance and decision making, including at the design phase; technology provision; reducing financial barriers to governance or even care itself; increasing equity within systems and services; creating integrated care systems; facilitating collective action; social support; promoting accessibility (*à la* universal design); and legal instruments.

Earlier chapters (2-4) the grounds for understanding governance, its dimensions, values, principles, and stakeholders, and outlined the high-level contextual dimensions of health and care governance. Chapter 5 has provided the context of existing governance structures and processes based on the experiences and perspectives of key stakeholders and shed light on factors that influence participation. In order to realise or provide opportunity for governance participation, SHAPES must consider not merely the person, but also features of their environment, the health and social care systems in which they move, and their lived contexts. The ensuing chapter, Chapter 6, will outline a governance model for SHAPES that considers SHAPES as an IT platform for health and social care, as an IT ecosystem, and as a sociocultural ecosystem.

5 Towards an activity-centred SHAPES governance model

So far in this deliverable we have discussed the range of issues shaping the content of a collaborative governance model for SHAPES, acknowledging that SHAPES exists as an IT platform, as a fluid IT ecosystem, as a consortium, and as a sociocultural ecosystem with a broader ownership linked to its participation. Resulting from this is the view that the ultimate SHAPES governance model must work at multiple levels corresponding to these interconnected realities of SHAPES.

In this section we present the outline of a governance model that will represent these different facets of SHAPES but will require further and continuous development and iteration when we integrate findings from the rest of the project, particularly WP2, WP4, WP6, WP7, and WP9.

5.1 *Governance as structure and activity*

Discussions around governance structures can lead towards thinking about governance as a relatively static phenomenon, suggesting that it is the structure itself that enacts the governance. However, governance can also be conceived of as a set of intersecting activities not only taking place within structures but actively constituting, maintaining, repairing, and changing those structures over time.

As Chapter 4 has demonstrated, distributed and participatory governance does not conform easily to a unitary hierarchical structure but instead represents a more fluid and dynamic confluence of diverse goals, objectives, concerns, and priorities. As this is part of the reality that the SHAPES platform must not only navigate but actively support by design. Under the Activity System framework (Engeström, 1987) derived from Cultural-Historical Activity Theory, emphasis is placed on the dynamic spatiotemporal relationship between actors, roles and dependencies, objectives and motives, tools and technologies, rules and constraints, and the social ecosystem where governance and all other associated activities are carried out.

Within this framework, all actors in a governance structure are understood as existing in relation to the tasks or “objects” that correspond to what they are trying to achieve at a given moment. This will be different for each actor, depending on their own particular needs, interests, concerns, priorities, and values, although they may be similar. From a governance point of view, we see the task or object as linked to a broader motivational context related to

the enterprise objectives of the organisation or community, or perhaps society more broadly. In other words the broader ...

5.1.1 Application of governance principles in SHAPES

An example of how these values will have an impact on SHAPES is the Open Innovation 2.0 paradigm and Citizen Science.

The Open Innovation 2.0 (OI2) paradigm addresses multistakeholder co-creation and citizen involvement in innovation ecosystems. It underlines the harnessing of creativity of many instead of a selected few, and foregrounds fostered collaboration in innovation ecosystems “enabled by and fuelled by” (Curley & Salmelin, 2018, p. 1) digital technologies and geared towards shared value creation (Curley & Salmelin, 2018, p. 1). Citizens can have a crucial role as users of public services in identifying problems, ideating solutions and adopting innovations (Curley & Salmelin, 2018, p. 72).

In Citizen Science, a closely related concept to Open Innovation 2.0, the potential provided by digitalization and online collaboration platforms is utilised for organized collective action in citizen engagement (EC Directorate General Connect 2020a) in scientific knowledge production and increasingly in initiatives of sustainability and social innovation (EC Directorate General Connect 2020b). User panels, both online and in real-life, is an approach well-suited for the systematic and sustained involvement of stakeholders with diverse interests in different phases of co-creation (Schuurman et al., 2012) .

In line with this, we propose a potential framework for participatory governance based on cultural-historical activity theory (CHAT) as a background for discussing the role of information and technology (I&T) governance in terms of a broader enterprise governance framework. CHAT is a framework for understanding human activity mediated by technology within complex sociocultural and historical systems including sociotechnical organisational systems. Applying CHAT to the topic of governance emphasises the practical aspects of governance vis-à-vis activity and sees the governance structure itself as an outcome of collaborative governance processes. Given the inclusive and participatory ethos of SHAPES as a social ecosystem the application of a framework that underscores this aspect is therefore critical.

CHAT is not in itself a governance framework per se but it allows us to read through existing structural governance frameworks with a process orientation. In this context we will also look in outline at COBIT 2019 as a framework for IT governance to the extent that it aligns with the broad principles of CHAT and we can then identify what needs to be done to

One of the key features of CHAT is concerned with the role of conflict and contradiction in any formal or informal organisational system, which is a natural consequence of diversity. One of the main objectives of this current deliverable is to explore the question of participation and inclusion with respect to governance, which is expected to highlight the diversity of the SHAPES social ecosystem and therefore the need for an approach to governance structures that accommodates potential conflict and contradiction in a constructive way.

As we will discuss further below, the core principles of enterprise governance of IT (EGIT) are consistent with an orientation towards looking at the notion of value creation relative to the stakeholder, a holistic systems approach

5.2 Cultural historical activity theory (CHAT)

Cultural-Historical Activity Theory (CHAT) is a framework for analysing the collaborative activities of people, groups, organisations and communities in terms of their interaction with their material, historical and sociocultural worlds. It has its origins in the socio-historical work of the psychologist Lev Vygotsky (1962, 1987, 1998), and continued by Alexei Leont'ev (1974), among others, who emphasised the need to understand human activity in terms of socially-meaningful object (goal) orientated behaviour as opposed to attempting to analyse the actions of individuals in isolation from others and divorced from their material, historical and cultural circumstances. As SHAPES is fundamentally concerned with connecting people in a more meaningful to their local and global networks with an emphasis on better quality of life and health outcomes, with health seen as a public good, this allows is to continuously examine the elements of SHAPES against the backdrop of these intended outcomes . Without the social (societal) motive it would not exist. This is a factor that relates directly to the policy context of governance.

The activity system is a version of activity theory developed by Yrjo Engeström (1987) that broadens the discussion of motivated, object-orientated, mediated activity towards emphasising the relationship between a person (subject) and their community. **Error! Reference source not found.** below illustrates the relation between the various nodes that constitute the activity system.

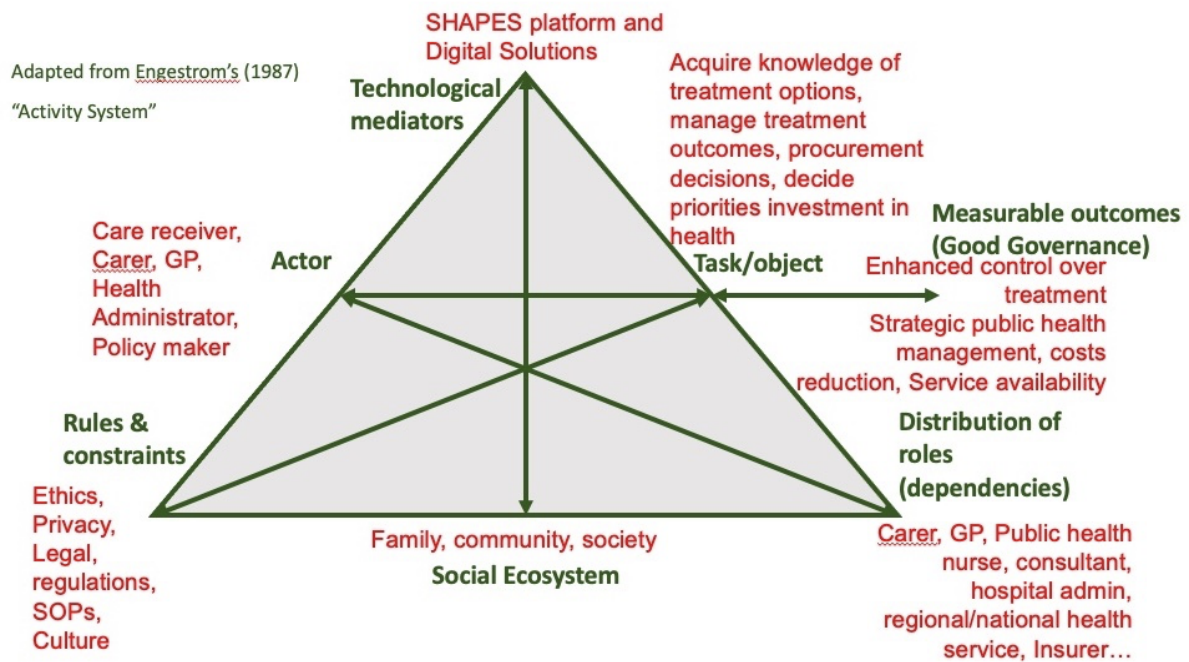


Figure 4 Activities of Governance framed in terms of the Activity System

These nodes are:

- **Subject:** the person who is acting towards an object (goal). In this case it can be the ageing individual, carers, healthcare providers, GP, consultant, policy maker, etc.;
- **Object:** the goal or product to which the activity is directed – e.g. symptoms of a patient, or engaging in exercise, healthcare policy;
- **Instruments:** the tools or artefacts that mediate the subject's achievement of the goal – the SHAPES integrated system of platform, digital solutions, clinical assessment methods, etc.;
- **Community:** the social and cultural context that makes a subject's object-orientated activity meaningful, whether the person is acting for or against the community – for SHAPES this is the socio-organisational structure or social ecosystem of the different actors and agencies involved in healthcare provision and governance, and the range of individuals (subjects) that comprise them;
- **Division of labour:** recognising that a person's activity is usually dependent on the activities of others and others are dependent on yours. There are different roles which interact with each other – this is particularly important in terms of anticipating and mitigating cascading effects by looking at the spatiotemporal interconnectedness of peoples' activities;

- **Rules:** these are the constraints that limit activity including the legal constraints, ethics, procedures as well as informal social or cultural norms – this links to policy consideration as well as operational rules within the health system;
- **Outcome:** the meaningfulness of activity is ultimately judged in terms of the outcome – whether or not your goals have been achieved (KPIs). A modification or change in any one of the nodes can affect the outcome as they are all essentially interdependent. For SHAPES this should be understood with reference to the view that health is both a personal outcome and also a socially meaningful and socially valued outcome. It is simultaneously a personal and public good.

Collectively, all of these nodes and their relation to each other constitute the activity framework. None of these nodes are meaningful by themselves but must be considered in relation to all the others. Therefore, when analysing human activity we can use this framework to generate a series of appropriate and integrated questions or **heuristics** (see below on governance activities) in order to gather data about **what** a person is doing, **why** they are doing it, with **whom** are they acting, **what** tools or resources do they use or require, what are their **constraints** and what is the overall **motivation** for their collective activity.

Activity Theory is highly contextual, meaning that while this high-level framework can be applied to any human activity context, and any health and social care situation, the resulting answers do not set out to provide generalisations but rather a richer understanding of the concreteness of a particular activity. However, as we are attempting with this deliverable, it can support the identification of **common themes** through a dialectical process/ system of analysis which will ultimately facilitate the process of design and implementation as well as evaluation of the SHAPES system.

5.2.1 Basic principles

Activity theory is not a theory in the conventional sense in that it does not “explain” human action or behaviour, nor does it generate hypotheses. Rather, Activity Theory should be thought of as a **heuristic framework** for asking practically useful and meaningful questions about what people are doing when engaging in their activities, particularly where technology is involved. It is therefore a general conceptual system for analysing and understanding human activity in a given context, particularly with reference to its social and cultural significance.

The basic principles and assumptions of Activity Theory, as adapted from Kaptelinin and Nardi (2006) include:

- *“The hierarchical structure of activity,*
- *Object-orientedness,*
- *Internalization/externalization,*
- *Symbol & Tool mediation*
- *Development over time*
- *Contradictions*
- *Functional organs”*

Hierarchical structure of activity

In Activity Theory the basic of unit of analysis is socially-meaningful activity. Figure 4 above represents a model of activity in terms of Engeström’s (1987) activity system, which is his approach to formalising the framework. All of the nodes within the triangle collectively and dynamically represent the activity, which is composed of subjects orientated towards objects (goals), mediated by tools, and situated within a social and cultural milieu. An activity is defined in terms of its object, that which provides the motivation for the activity in the first place. Actors can be said to be performing the same activity when they share the same object, although they may have different roles or tasks. The activity however also has a hierarchical structure. Performing an activity involves performing a series of more specific actions, which are directed towards specific goals. Each of these actions in turn involves the performance of operations which are low-level acts that are often automated or highly routinised to the extent that they do not require conscious attention or control.

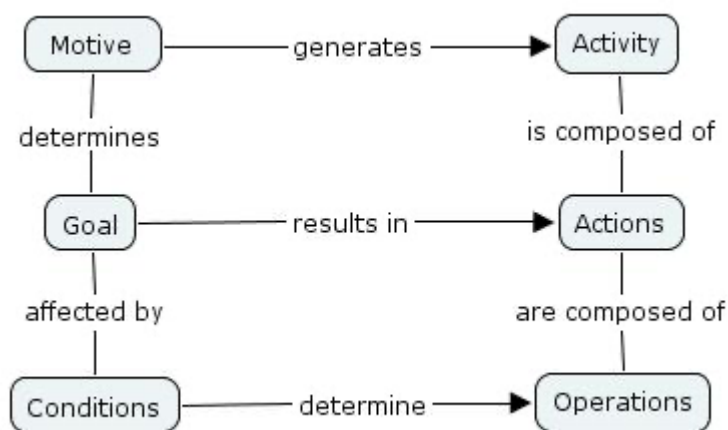


Figure 5 Hierarchical structure of activity from Wilson (2006).

Different personnel of different levels of experience, skill and ability may approach an activity at a different point in the hierarchy. A novice will spend more time and focused attention on

mental and physical operations whereas an experienced operator will commit their resources to higher-level executive tasks. It is important to note that the introduction of new tools and systems can have a disrupting effect. It can make the novice perform at an expert level through automation and decision support, etc. It may potentially make the expert operator redundant. These are some of the considerations that we should entertain when evaluating the SHAPES system from a social and societal point of view. The basic principle here is that we should be watchful for all performance implications technology brings to operations and how we interpret their significance.

The hierarchical structure of activity will be important when considering the fluidity of participation in health and social care governance as illustrated in Chapter 3 recognising the possibility of occupying more than one level in a governance structure – e.g., being both a governance participant as well as a care recipient.

The human-centred activity framework, below, based on Engeström's (1987) adaptation of Activity Theory will complement this analysis by focusing on the perspective of the individual and teams within the process/ system but without losing sight of the relationship between parts and wholes within a sociotechnical system:

- The human actor in any system (subject) is goal oriented (towards an object) - a care recipient is orientated towards having their healthcare needs met; a care provider, such as a GP is orientated towards the treatment of illnesses.
- There is an inseparable relationship between the person and their role and the object of their activity
- The extent to which they are successful at achieving their goal results in a measurable outcome through the application of appropriate KPIs;
- The relationship between the subject and the object (and therefore the outcome), is mediated by technological and other artefacts (instruments or tools such as the SHAPES platform and digital solutions);
- Change, addition or removal of any technological artefacts will have an impact on the outcome, such as change in the processes, structure, culture and the introduction of new tools.

The **actor** is part of a larger organisational system with a division of labour meaning that the activities of the individuals are linked with those of others. Understanding health and social care provision therefore requires the understanding of the social and cultural (community)

aspects of the organisational system such as the care recipients, carers, healthcare providers, managers, procurers, suppliers, etc.

Activities are governed by rules, including ethical and privacy regulations which are essentially a set of constraints which set the boundaries for activity. This may be a changing field as policy changes will impact how border crossings are managed.

The main components of this framework allow for a reading of the diagram in **Error! Reference source not found.** in the following manner. The “subject” refers to a person (or in certain cases an agency) who is guided by a certain motivation linked to the achievement of an “object” or goal. This relationship between the subject and object is a tight one in the sense that they both co-define each other. An individual’s professional identity is closely tied to the object that they are attempting to achieve in their activity. The subject-object relationship is also mediated by “instruments” or tools which for some may be risk analysis or visualisation tools or databases and repositories of documents. The mediating tools depend on the individual and their task/object. The nature of the tool, in terms of its design and quality can mediate the activity in terms of affecting the outcome.

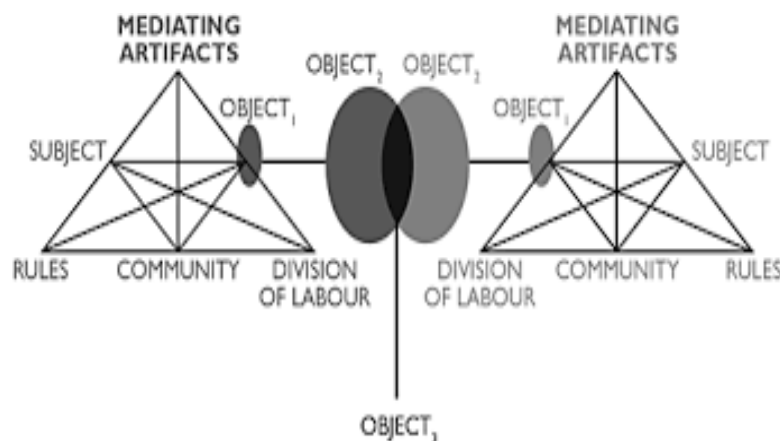


Figure 6: Activities and their Boundary Objects (Engeström, 1987)

The subject is also part of a larger organisational context (community) with a division of labour or responsibility, and is governed by rules or constraints. Awareness of the contradictions between actors and their interests and concerns.

A boundary object represents a situation where the object of one person’s activity coincides with that of another person or agency. This can be as a result of direct collaborative activity where multiple parties are working on the same object, but it can also represent situations where subjects are working towards the same or closely related goal but coming from different perspectives with diverging concerns and motives. A boundary object therefore can be a point

of harmonisation or conflict depending on the values, motives agendas and constraints of the people and agencies involved.

The SHAPES platform can therefore be considered as a boundary object where the activities of many different actors and stakeholders, with their diversity of interests and priorities, converge. The management of this diversity is one of the key drivers for the design of the SHAPES platform and therefore aspect concerning its governance, as well as its participation in other aligned governance structures.

5.2.2 Contradictions

Governance involves the representation and reconciliation of different needs, interests, and points of view. Engeström (1987) discussed the notion of contradictions within and between activities. What this refers to is the fact that often there is a conflict between two or more nodes within the activity system. For example, the goals of an individual may be at odds with those of the organisation as a whole, or the goal of an individual may be thwarted by the poor quality or inappropriate design of the tools used to achieve it. Contradictions are particularly relevant when considering the interaction between people and organisations as well as the suitability of innovations.

According to Engeström, there are four categories of contradiction:

1. Primary contradictions. These are contradictions that occur within a node. For example, a person needs to call emergency services but is mute and therefore does not have the vocal ability; a novice firefighter has not been trained in the use of a particular type of equipment thus lacking the knowledge or skill; a piece of equipment that is appropriate for the task but is broken or of poor manufacture.
2. Secondary contradictions. These are contradictions that occur between nodes. For example, a person trying to achieve a goal that is in conflict with the goals of others in the community with whom they share a division of labour, or a well-designed and manufactured piece of equipment is simply the wrong tool for the job intended, or the rules or procedures prevent the person from attempting to achieve their objectives.
3. Tertiary contradictions are those that exist between a current activity state and a future state. This is directly related to the notion of development and the changing of relationships between people, goals and tools, etc., over time. This is particularly relevant for contexts that involve change-management such as the introduction of new risk based approach.

The introduction of new technology to meet expected future needs may fail due to the over-rigidity of organisational structure as an example, if the two fail to evolve together.

4. Quaternary contradictions are those that exist between two different activity systems, usually understood in terms of differences in the motives and objectives or different stakeholder at organisational level or between organisations. An example may be the difference in agendas between operational staff who are concerned with having all the resources necessary to optimise effectiveness in times of risk and threat on the one hand, and the agenda of management who need to maintain cost efficiencies, throughput, to ensure a more sustainable availability of resources. Such contradictions may be real or perceived, either way they require careful consideration from the point of view of tool and operational process/system design.

In chapter 4 we presented a range of barriers and facilitators to governance. These can be re-examined in terms of contradictions to activity relative to actors and their objectives with respect to governance.

5.3 Enterprise Governance if IT (EGIT)

Enterprise Governance of IT (EGIT) is the approach to I&T governance that seeks to position information *and* technology in its proper context in the service of enterprise objectives and not only in the so-called IT department. It encapsulates all aspects of technology and data processing within and outside of the direct remit of IT departments themselves. It recognises that I&T are integral to the business operations and the means by which business is done. In effect this means that IT governance is not treated as a separate governance concern but one that is integrated with the enterprise objectives of an organisation, its corporate structure, and its whole range of business processes. With this way of thinking, IT strategy is not to be thought of as separate from the strategy of the enterprise as a whole because I&T stands in the service of that strategy. De Hayes et al. (2020) refer to EGIT as a mind shift, or paradigm shift a from the notion of IT governance. A key object of EGIT is therefore the alignment of business and I&T goals.

5.3.1 EGIT principles

ISACA (2018) have described the six core principles of EGIT as follows:

1. Provide stakeholder value
2. Adopt a holistic approach

3. Introduce a dynamic governance system
4. Distinguish governance from management
5. Tailor governance to enterprise needs
6. Employ and end-to-end governance system.

5.3.1.1 Providing Stakeholder value.

As with CHAT, the starting point for EGIT is a focus on needs and values. These are both the key explanatory factor in activity, and the core driver for enterprise. ISACA (2018) proffer a cascading relationship between stakeholder needs on the one end, and the definition of governance and management objectives on the on the other (**Error! Reference source not found.**). Stakeholder needs can be read as the varied needs and values the SHAPES end-user community, which is quite diverse as Chapter 4 illustrates. The specific management and governance objectives need to be always tailored and adjusted to the stakeholder needs with the goals of the enterprise and the alignment goals of I&T designed to mediate (enable) and achieve these objectives in a circular manner, that is through a feedback loop.

Ultimately the success or failure of an enterprise including its governance structure can be determined by assessing the extent to which stakeholder needs and values are satisfied.

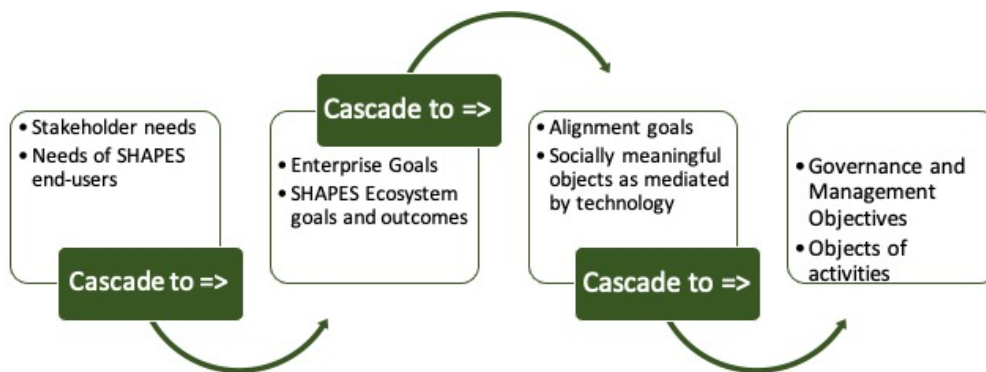


Figure 7 The COBIT goals cascade (ISACA, 2018)

5.3.1.2 Adopting a holistic approach

The second principle is concerned with ensuring that I&T is viewed in terms of organisational systems involving processes, structures, information flows, people & competencies, policies, culture & ethics, and services infrastructures. See **Error! Reference source not found.** below. These are the components of any organisational system. Note that I&T are not listed as a separate component but is part of the fabric that links all of these together.



Figure 8 Components of an EGIT system

For CHAT, activity is always understood in the context of rules, resources, environment, division of labour & dependencies, and rules (including procedures, policies and norms). The emphasis though is placed on these nodes in relationship to each other. So while they are discreet elements of any organisational system, they are meaningful only in terms of their relationship to each other.

5.3.1.3 Viewing the governance system dynamically

The dynamic principle is about acknowledging the point made previously in relation to CHAT about the dynamic interaction between nodes in the activity system, meaning they co-construct each other in a web of relationships. This means that change in one of the above components resonates throughout the system and impacts all other components to varying degrees. However, this is particularly the case for I&T given that it is woven into the fabric of the whole organisational system. Therefore, the governance of I&T should consider the potential impact of change in technology and data processing capabilities on the whole system, while also considering the impact of change in any one or more of the system components on the I&T structure.

5.3.1.4 Distinguishing between Governance and Management

For ISACA there is an important distinction to be made between governance activities and their processes and objectives, on the one hand, and management activities, processes and objectives on the other.

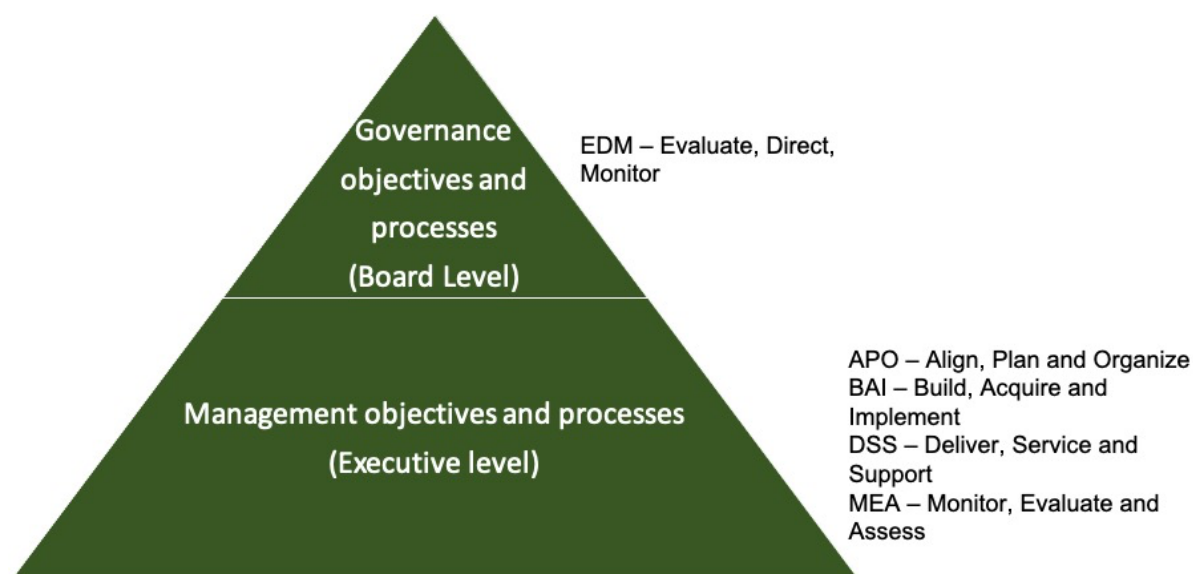


Figure 9 Distinction between Governance and Management Objectives in COBIT 2019

5.3.1.4.1 Control objectives for information and related technologies (COBIT)

COBIT 2019 identifies forty governance and management objectives comprising its COBIT 2019 core model which are listed in the following tables and summarised above in Fig7. While management is concerned with the operational execution, governance is about the creation of a setting in which others can manage effectively.

Table 18 COBIT Governance Objectives and Processes - Evaluation, Direct, and Monitor

Objective Code	Objective Description
EDM01	Ensured Governance Framework Setting and Maintenance
EDM02	Ensured Benefits Delivery
EDM03	Ensured Risk Optimization
EDM04	Ensured Resource Optimization
EDM05	Ensured Stakeholder Engagement

Table 19 Management Objectives and Processes - Align, Plan, and Organise

Objective Code	Objective Description
APO01	Managed I&T Management Framework
APO02	Managed Strategy
APO03	Managed Enterprise Architecture

AP004	Managed Innovation
AP005	Managed Portfolio
AP006	Managed Budget and Costs
AP007	Managed Human Resources
AP008	Managed Relationships
AP009	Managed Service Agreements
AP010	Managed Vendors
AP011	Managed Quality
AP012	Managed Risk
AP013	Managed Security
AP014	Managed Data

Table 20 Management Objectives and Processes - Build, Acquire, and Implement

Objective Code	Objective Description
BAI01	Managed Programs
BAI02	Managed Requirements Definition
BAI03	Managed Solutions Identification and Build
BAI04	Managed Availability and Capacity
BAI05	Managed Organizational Change
BAI06	Managed IT Changes
BAI07	Managed IT Change Acceptance and Transitioning
BAI08	Managed Knowledge
BAI09	Managed Assets
BAI10	Managed Configuration
BAI11	Managed Projects

Table 21 Management Objectives - Deliver, Service, and Support

Objective Code	Objective Description
DSS01	Managed Operations
DSS02	Managed Service Requests and Incidents
DSS03	Managed Problems
DSS04	Managed Continuity
DSS05	Managed Security Services
DSS06	Managed Business Process Controls

Table 22 Management Objectives - Monitor, Evaluate, and Assess

Objective Code	Objective Description
MEA01	Managed Performance and Conformance Monitoring
MEA02	Managed System of Internal Control
MEA03	Managed Compliance With External Requirements
MEA04	Managed Assurance

COBIT 2019 consists of five components which include the following

- COBIT 2019 Framework: Organises the IT governance objectives and activities by IT domains and processes linking them to business requirements.
- Process descriptions: This provides a reference process model and consistent set of terminology for all actors in an organisation. These processes are linked to the the four responsibility areas of plan, build, run, and monitor.
- Control objectives: This is a comprehensive list of objectives and high-level requirements for managers to consider in order to achieve efficient and effective control of information technology processes.
- Management guidelines: there are a resources assisting management on the assignment of responsibility, the articulation and agreement of objectives, performance measurement, and highlighting the interrelationships between processes.
- Maturity models: These are a set of tools for determining the maturity, capacity, and capability of each process assisting in the identification and completion of gaps.

For CHAT, the identification of stakeholder objectives needs to be aligned with the objectives of the organisational system, which may have a high degree of variability. This can make harmonious activity difficult, hence the role of contradictions as an analytical component. Heterogeneity of objectives may seem consistent in the macros scale of analysis but may be conflictual at the local or micro scale. It is important therefore to approach the governance of I&T with such diversity of values and objectives in mind.

5.3.1.5 Tailoring to Enterprise Needs

I&T governance needs to recognise and adapt to the range of internal and external contextual factors that shape the enterprise depending on the specific particularities. These include factors such as regulatory requirements, marketplace characteristics, threat landscape, economic variability, etc. Therefore, just as for CHAT, the broader context within which the

enterprise operates including the social, cultural, economic, legal & regulatory, and potentially even the political climate as comprising this context. There is a range of design factors that come into place for each specific enterprise which are covered within the COBIT 2019 design guide.

The range of design factors includes the following:

- Enterprise strategy
- Enterprise goals
- Risk profile
- I&T related issues
- Threat landscape
- Compliance requirements
- Role of IT
- Sourcing model for IT
- IT implementation methods
- Technology adoption strategy
- Enterprise size
- Future design factors.

5.3.1.6 End-to-End governance

End-to-end governance refers to the fundamental principle with EGIT of the need for I&T governance to extend far beyond the limits of the IT department and reflect the full range of activities within which technology and data processing capabilities extend. This means in essence that IT governance needs to be closely aligned with not only the high-level objectives and strategy of the enterprise but also the activities of the range of actors within it, looking at how they use IT, for what purpose, under what conditions, and to what effect.

This is close in spirit to the notion in CHAT that all activities are mediated by technology, whether it be high-tech or low-tech, but there is a clear dependency between the actor and their objective, and the tools used to achieve it.

5.4 Summary

In this section we have outlined the CHAT framework as a means of describing and analysing the interrelationship between people and their social community as well as the role of technology and other resources in mediating or facilitating the achievement of their goals. CHAT also directs attention to the role of contradictions or conflicts within activity as potential barriers to achieving desired outcomes. This is also important for the design of systems.

We have also argued the basic principles of EGIT and COBIT 2019 can be read through as consistent and complementary with CHAT to the extent that they can enrich each other. This is what we present at this point in time as the foundation for the SHAPES collaborative governance model which will be further detailed and validated throughout the remainder of this task.

6 Conclusions

6.1 Summary

This deliverable (D3.5: Initial SHAPES Governance Model) as well as its second iteration (D3.6 SHAPES Governance Model), plays an important role in the implementation of SHAPES and expansion of SHAPES.

In the current version of the SHAPES Governance Model (D3.5), we have provided a summary of the concept and practice of governance (Chapter 2 Background to Governance) including a definition of governance, values and mechanisms of governance, and an overview of actors of governance, both actors generally and actors specifically relevant to the SHAPES Platform.

In Chapter 3, we have investigated the stakeholders (3.1) and domains of governance that are relevant to the SHAPES Platform more deeply. These are twofold; Sections 3.2.1 and 3.2.2 summarise the structures, processes and values that govern clinical care and home care. In so doing, we have contextualised the wider environment in which the Platform is embedded. We then explored domains of governance which are directly related to the business model of SHAPES (Section 3.3.4 Business and Corporate Governance), and to the Platform (Section 3.2.3 IT Governance and Section 3.2.5 Data Governance).

The SHAPES Governance Model is not created in a vacuum but in collaboration with experts. As outlined in Chapter 4 (Participation in health and social care governance), we consulted relevant key stakeholders for their expert insights into existing structures, processes and opportunities for participation in healthcare and social care governance. A combination of focus group conversations, interviews in with older adults and informal caregivers in Task 2.1 and lastly, a survey on governance participation facilitated some preliminary insights on the challenges and opportunities associated with health and social care governance.

In Chapter 5 we combined the theoretical and empirical knowledge about governance as a basis for the Initial SHAPES Governance Model and enhanced those with activity-centred approach, to be specified going forward. We established that the governance model must work at multiple levels corresponding to the different, interconnected elements of SHAPES. Based on these insights and criteria, we have developed an outline of a SHAPES Governance

Model which, in the second iteration of this deliverable, will be developed further incorporating the findings from the other work packages, as described in the following section.

6.2 *Next steps*

6.2.1 EGIT and COBIT

In the following phase of the task we will proceed with elaborating SHAPES as an enterprise composed of a diverse community of actors with a variety of needs and expectations. The SHAPES platform will be examined with respect to the principles and philosophy of EGIT: that is, not as a stand-alone system but as an integrals feature of a sociotechnical ecosystem on which it depends, and which it depends on.

The process of guiding the application of EGIT and COBIT will be informed by using CHAT in order to emphasise the perspective of specific users, mapping the diversity, and identifying the key contradictions which stand as design challenges for the development and integration of the SHAPE IT platform. This will mean utilising the parts of COBIT that add most value to SHAPES but also reflecting on how COBIT can be potentially improved given the particular characteristics of SHAPES as an open platform.

Among the key tasks looking forward is the identification of the ownership model for SHAPES and delineating the relative roles of the various actors at all levels.

6.3 Interdependencies of the evolving SHAPES Governance Model with other work packages

The second version of the Governance Model (D3.6) will build on D3.5. As demonstrated in **Figure 10**, there are multiple interdependencies between deliverables, tasks and work packages, namely WPs 2, 4, 6 and 7, which will ultimately feed into Task 9.1 (Co-creation Think-tank for European Integrated Care).

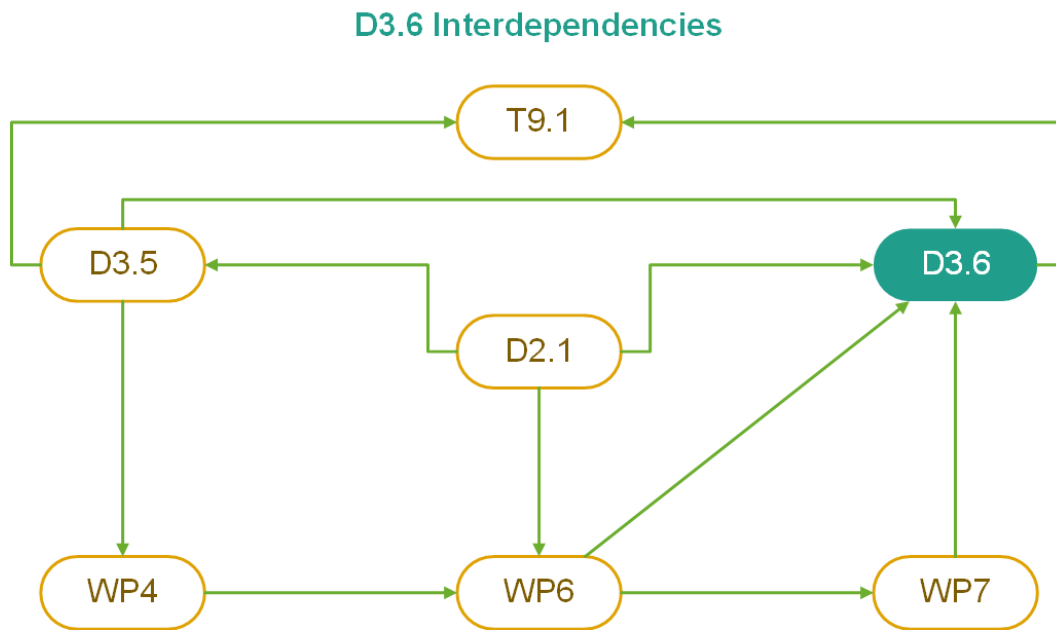


Figure 10 D3.6 interdependencies (Own figure)

The present deliverable (D3.5) plays an important role in shaping various tasks in WP4, most notably the tasks in relation to IT governance (Task 4.3: Implementation of the Mediation Framework and Interoperability Services and Task 4.7: SHAPES Gateway Reference Implementation) and data governance (Task 4.4: Implementation and Deployment of the Secure Cloud and Big Data Platform and Task 4.6: SHAPES Authentication, Security and Privacy Assurance). The activities in WP4 shape the pilots in WP6.

The second iteration of the deliverable (D3.6) will also receive input from WP6, namely the findings from the individual pilots of the SHAPES Pan-European Pilot Campaign. Although the results from the evaluation of the findings will inform the Governance Model directly, they will also be filtered through WP7, which will formulate the SHAPES Business Model.

As suggested in Chapter 2 (background to governance), sustainability is an important principle of governance, alongside effectiveness and fairness. WP7, based on the findings in WPs 2, 3, 6 and 9, will formulate the SHAPES Business Model which aims to successfully

commercialise the Platform on a global scale. WP7 factors in market needs, socio-economic sustainability including forecasts for the next 5 to 10 years and competitiveness of the Platform. The outcomes from WP7 will inform the business aspect of governance for the SHAPES Platform. The stakeholders and domains of governance (Chapter 3), especially relating to health and care, gave the necessary insights of roles and responsibilities that the SHAPES model of governance would have to address.

As discussed in Chapter 4, we have consulted key stakeholders for their expert views on existing governance structures and processes in care provision. In D3.6, we will further refine the evolving governance model based on the perspectives of individuals, such as care receivers, professional care providers and informal caregivers. We are interested in, for the example, the extent to which existing care systems facilitate patients' participation in decision-making processes regarding the care they receive. In order to do so, we will draw upon relevant findings of the ethnographic study in D2.1 (Understanding Older People: Lives, Communities and Contexts). The personal experiences of older people and their caregivers of the care system will facilitate insights into real-world examples of care governance including both barriers and facilitators. The amalgamation of insights from the key stakeholder consultations and the voices of patients and informal caregivers grounds the evolving SHAPES Governance Model in the reality of care governance.

6.4 Validation process

D3.6 will evolve in tandem with Task 9.1 (Co-creation Think-tank for European Integrated Care) which will establish the applicability and sustainability of the SHAPES Governance Model to the SHAPES ecosystem and moreover, disseminate the findings from D3.6 beyond the SHAPES Consortium to older individuals, care service providers, health and care industry, policy-makers and public authorities and researchers. This will facilitate the validation of the SHAPES Governance Model. In addition, we will be creating a range of high-level use cases which will allow us to explore and validate different elements of the Governance Model.

6.5 Consolidating SHAPES governance model

The results of expanded consultation with the public throughout the EU will involve a more comprehensive view on the ways in which people view themselves as participating within health and social care structures, and therefore will allow us to situate the governance of the SHAPES platform and ecosystem within the broader context of enterprise and corporate governance within which SHAPES intersects.

6.6 Limitations

This deliverable (D3.5) outlines the structure of the Initial SHAPES Governance Model based on theories of governance and empirical research into key stakeholders' perspectives on the existing structure and processes that govern healthcare and social care systems. Moreover, we have explored the barriers to and facilitators of participation in governance from the perspectives of professionals, patients and informal caregivers.

However, the current iteration has several limitations. In Chapter 1, we asked a number of key questions regarding the meanings of governance, the role of the SHAPES Platform in governance, the ownership of SHAPES and lastly, the domains of governance. We cautioned that answering these questions fully would be beyond the scope of D3.6.

In Chapter 3, we introduced a range of key stakeholders in governance. However, we have focussed primarily on those stakeholders who participate in healthcare and social care governance. In D3.6, we will broaden the scope by adding examples of stakeholders in other domains of governance, as also outlined in Chapter 3.

Another open question relates to the ownership of SHAPES beyond the product and IP developed by the consortium. As suggested above, a vital aspect of SHAPES is the question of marketability and sustainability after the project has ended. We will be exploring this question in tandem with WP7 (Business Model) and Task 9.1 in D3.6.

Yet, the extent to which the optimal governance of SHAPES will impact the delivery of health and care services, and ultimately on the health and care situation of older individuals remains to be seen. Although it may be assumed that optimal governance for SHAPES will also have a positive impact on the lives of older individuals, more research will need to be conducted in order to differentiate what can already be evaluated once the SHAPES ecosystem is being built and what may need further scaling up.

7 Ethical requirements check

The focus of this compliance check is on the ethical requirements defined in D8.4 and having impact on the SHAPES solution (technology and related digital services, user processes and support, governance-, business- and ecosystem models). In the left column there are ethical issues identified and discussed in D8.4.(corresponding D8.4 subsection in parenthesis). For each deliverable, report on how these requirements have been taken into account. If the requirement is not relevant for the deliverable, enter N / A in the right-hand column.

Table 23 Ethical requirements check (own table)

Ethical issue (corresponding number of D8.4 subsection in parenthesis)	How we have taken this into account in this deliverable (if relevant)
Fundamental Rights (3.1)	N/A
Biomedical Ethics and Ethics of Care (3.2)	N/A
CRPD and supported decision-making (3.3)	N/A
Capabilities approach (3.4)	N/A
Sustainable Development and CSR (4.1)	N/A
Customer logic approach (4.2)	N/A
Artificial intelligence (4.3)	N/A
Digital transformation (4.4)	N/A
Privacy and data protection (5)	N/A
Cyber security and resilience (6)	N/A
Digital inclusion (7.1)	N/A
The moral division of labor (7.2)	N/A
Care givers and welfare technology (7.3)	N/A
Movement of caregivers across Europe (7.4)	N/A

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