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Testing Cost Containment of Future Health Care with Maintained or Improved Quality – The COST CARES project
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Cost Containment of Future Health Care

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Abstract:	Increasing healthcare costs need to be contained in order to maintain equality of access to care for all EU citizens. A cross-disciplinary consortium of experts was supported by the EU FP7 research programme, to produce a Roadmap on cost containment, while maintaining or improving the quality of healthcare. The Roadmap comprises two drivers: Person-Centred Care and Health Promotion; five critical enablers also need to be addressed: information technology, quality measures, infrastructure, incentive systems, and contracting strategies. In order to develop and test the Roadmap, a COST Action project was initiated: COST CARES, with 28 participating countries. This paper provides an overview of evidence about the effects of each of the identified enablers. Intersections between the drivers and the enablers are identified as critical for the success of future cost containment, in tandem with maintained or improved quality in healthcare. This will require further exploration through testing. Conclusion: Cost containment of future healthcare, with maintained or improved quality, needs to be addressed through a concerted approach of testing key factors. We propose a framework for test lab design based on these drivers and enablers in different European countries.

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Abstract

Increasing healthcare costs need to be contained in order to maintain equality of access to care for all EU citizens. A cross-disciplinary consortium of experts was supported by the EU FP7 research programme, to produce a Roadmap on cost containment, while maintaining or improving the quality of healthcare. The Roadmap comprises two drivers: Person-Centred Care and Health Promotion; five critical enablers also need to be addressed: information technology, quality measures, infrastructure, incentive systems, and contracting strategies. In order to develop and test the Roadmap, a COST Action project was initiated: COST CARES, with 28 participating countries.

This paper provides an overview of evidence about the effects of each of the identified enablers. Intersections between the drivers and the enablers are identified as critical for the success of future cost containment, in tandem with maintained or improved quality in healthcare. This will require further exploration through testing.

Conclusion: Cost containment of future healthcare, with maintained or improved quality, needs to be addressed through a concerted approach of testing key factors. We propose a framework for test lab design based on these drivers and enablers in different European countries.

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Background

The European Council has agreed on several values and principles regarding healthcare systems that are shared across the member states. These values include universality, access to good quality care, equity and solidarity (Council of the European Union, 2006).

At that time, costs or affordability were not explicitly addressed, although these are important issues in any system whose aim is to safeguard these common values.

The Council also stated that it is essential to make European healthcare systems financially sustainable in a way that protects future healthcare. However, expenditure for health in all European Union (EU) countries between 2000 and 2009 increased from 8.0% to 10.0% of the gross domestic product (GDP), and in the "old" EU-15 countries alone, from 8.7% to 10.6% (WHO Regional Office for Europe, 2014).

In order to address important challenges affecting the future of European Health Care, a project, WE CARE funded by the FP7 programme, was initiated in 2013 and was finished in 2015.

During the final conference in April 2015, the WE CARE consortium presented its summary report "Healthcare innovations and improvements in a financially constrained environment: Strategy Plan and R&D Roadmap" (WE CARE consortium, 2015, Ekman et al., 2016). This report included a Roadmap, which proposed a new strategic plan embedding seven interdependent themes, responsible for facilitation of a breakthrough in cost containment while, at the same time, improving the quality of care. These themes fell into two categories: 1) two drivers, which form the "backbone" of the strategic plan: Person-Centred Care (PCC) and Health Promotion, and 2) five critical enablers, which are aspects of the macro environment that influence the implementation of these drivers: information technology, quality measures, infrastructure, incentive systems and contracting strategies (Figure 1). In this paper we explicate both PCC and Health Promotion, with examples, before setting out a framework for the design of test labs to put the Roadmap into practice.

Person-Centred Care

The core component in PCC emphasizes the patient as a person in order to involve that person as a '*partner*' in his/her own care and treatment. PCC is a shift away from a model, in which the patient is the passive target of a medical intervention, to an approach characterised by a '*more mutual agreement'*, in which the patient is an active partner in their own care and in the decision-making process of the care and treatment plan. Co-creation of care in the form of partnership between the patient, their family and carer(s), and the team of health professionals caring for them, is the core component of PCC, a concept that is becoming widely used (Ekman et al., 2011, Ekman et al., 2015, Foundation).
PCC embodies and enacts the philosophy and ethics applied in the Capability Approach, which has been used as a theoretical frame of reference in several research disciplines, for example in economics by the Nobel laureate Amartya Sen (Sen, 1993).
PCC is the concept used in this project and is distinct from patient-centred care, because the word 'patient' tends to objectify and reduce the person to a mere recipient of medical services, or to 'one who is acted on' (Ekman et al., 2011). Today, patients often have to navigate through a fragmented health care system and adapt to the usual practices of health care organizations and professionals, rather than receiving care designed to focus on the individual patient's resources and needs, preferences and values (Horrell et al., 2018).

The World Health Organization (WHO) uses the term **"**People-centred health services" which is an approach to care that consciously adopts the perspectives of individuals, families and communities, and sees them as participants as well as beneficiaries of trusted health systems that respond to their needs and preferences in humane and holistic ways.

How can Person-Centred Care be applied?

In PCC, patients and health care professionals jointly develop a healthcare plan based on the patient´s illness history and future goals, which identify personal resources and opportunities as well as potential barriers and needs (Ekman et al., 2011, Ekman et al., 2015, Foundation).

One of the fundamentals of PCC is the formation of a partnership between the patient and professionals. However, there is an asymmetry between the professional and patient.

Professionals are usually in a more powerful position, as they possess greater knowledge of their specialization than the patients they serve (McKevitt, 1998). This implies that there cannot be a symmetrical exchange. However, a one-way exercise of power cannot be ethically justified and will not serve either the patient or the professional. To establish a partnership requires an involvement from both parties, but from different starting points and with different prerequisites. The health professional is an expert in medicine, rehabilitation, nursing etc. and the patient is an expert on their own life. A partnership thus demands that the patient is treated as a person, who is simultaneously and capable, vulnerable, dependent as well as independent.

In summary, PCC is operationally defined as co-creation of care between the patients, patient proxies if appropriate, and health professionals (Ekman et al., 2011, Foundation, Richards, 2014).
The fundamentals have been defined into three core components of PCC by Ekman et al: (Ekman et al., 2011)

1. Initiating the partnership through the patient narratives
2. Working the partnership by creating a health plan in agreement
3. Safeguarding the partnership by documenting the health plan

Effects from controlled trials

PCC represents a movement that has an explicit focus on humanising health services and ensuring that the patient is an equal partner in their own care and treatment above and beyond care according to evidence based medicine. In this context, the body of evidence supporting the processes and outcomes associated with person-centeredness in health and social care is constantly growing. In the cardiovascular field, PCC interventions with patients hospitalized for chronic heart failure are associated with reduced length of hospital stay, a better discharge process, and reduced patient uncertainty about their disease and treatment (Ekman et al., 2012, Ulin et al., 2015, Dudas et al., 2013). Other outcomes include reduced health care costs and maintained functional performance (Hansson et al., 2015). Furthermore, other studies involving patients with severe chronic heart failure and evaluating the core components of PCC described above, found fewer hospitalizations and

improved quality of life (QoL) (Brannstrom and Boman, 2014). For patients with acute coronary syndrome (ACS), a randomised controlled trial (RCT) indicated that a PCC approach was effective in increasing self-efficacy over the whole care chain (from hospital to primary care)(Fors et al., 2015, Fors et al., 2017, Fors et al., 2016b). In particular, patients with lower education increased their self-efficacy significantly more than patients with a higher level of education (Fors et al., 2016a). A follow-up randomised controlled trial showed lasting effects of PCC after an ACS event over the two-year study period (Fors et al., 2017).

Thus the evidence demonstrates that PCC has the potential to combine high-quality evidence based care with controlled costs, in alignment with the aims of WE CARE and COST CARES.

Health Promotion

The second key driver besides PCC is Health Promotion. Multiple definitions for Health Promotion have been proposed since the term was introduced in the 1970´s. One of the first definitions was given by Lalonde, the Canadian health minister in 1974 as "*a strategy aimed at informing, influencing and assisting both individuals and organizations so that they will accept more responsibility and be more active in matters affecting mental and physical health*" (Lalonde, 1974). The Ottawa Charter for Health promotion later defined Health Promotion as "*the process of enabling people to increase control over, and to improve their health*" (WHO, 1986).

Targets for Health Promotion are primarily non-communicable diseases (NCDs), which are identified as the leading causes of mortality and have several modifiable, behavioural risk factors including excessive alcohol use, physical inactivity, tobacco use, and poor diet. Biological risk factors include high blood pressure, diabetes, and obesity (WHO., 2013). Health Promotion should be carried out on different levels to be effective, both population-wide (for example taxes, mass media campaigns, school programs) and individual, but there is uncertainty which components are more effective. There is also a gap in research evidence from low- and middle-income countries (Mosdol et al., 2017, Jeet et al., 2017).

One very important principle of Health Promotion is empowerment, i.e. seeking to ensure that individuals have the power to affect their own health. This aligns closely with the

principles of PCC. Other important criteria include participation and having a broad perspective of health and inequality. Health Promotion has gained recognition in recent years because of the growing evidence on the importance of lifestyle behaviour for individual health (Lee et al., 2012, Swinburn et al., 2011). In addition, socioeconomic conditions, as well as social and structural support have been identified as important determinants of health. Thus, addressing public health in the modern era includes lifestyle behavioural changes based on a bio-psycho-social model (Engel, 1977).

There are clear similarities between Health Promotion and PCC, for instance the emphasis on identifying and supporting the individual's resources to influence their own health and the focus on the societal context affecting this process. A key component is tailoring the process to each person, exemplified by the identification of barriers and facilitators, unique to the individual, as well as the importance of the social environment for such changes to take place, e.g., positive/negative reinforcement by relatives or the surrounding community.

Health Promotion is included in the context of WE CARE and COST CARES because it represents high quality interventions that keep populations healthy and, at the same time, means that health care is less costly for society. Health Promotion and PCC are key drivers to cap health care costs, while simultaneously maintaining or improving the quality of care and resulting improved health for all.

Cost Action 15222 (COST CARES)

In order to carry forward the WE CARE Roadmap, Cost Action (CA) 15222 was initiated in 2017 with the project name COST CARES. The main aim of COST CARES is to establish processes for implementing PCC and a working framework for evaluation test labs of PCC and Health Promotion in different countries. These test labs are essential to the effort necessary to expand the evidence-base regarding how PCC and Health Promotion drive cost containment in healthcare while maintaining and improving quality of care in various settings and countries. The work in COST CARES is managed in four working groups (WGs) (See Supplementary Appendix 1). The overall aim of the work of WG2 is to define a logistic and organisational framework that is necessary for the design of large-scale testing of PCC systems that will contain costs while maintaining quality of care.

The WE CARE roadmap was developed by WG2 in reviewing the existing literature as well as practice. Examples of implementing PCC policy and practice in different settings in different countries were also identified and explored. Two successful examples/cases are outlined in Supplementary Appendix 2.

Framework for Test Lab Design:

The Test lab(s) in COST CARES are designed to guide and stimulate the integration and collaboration between academic disciplines, industry, healthcare professionals, policy makers and patient representatives in healthcare to achieve cost containment and quality research. COST CARES sets out to tackle these challenges by:

1. Working towards the development of care systems based on PCC and Health Promotion that can be tested on a macro level
2. Defining the parameters necessary to perform and evaluate large scale implementation
3. Executing studies that will provide an adequate evidence base for PCC and Health Promotion across various contexts in different countries

WE CARE posits the notion that cost containment and quality initiatives, although inextricably linked, should also be considered from a person-centred micro level including the elements of healthcare which support preventative/health promoting strategies (Ekman et al., 2016). It is important to consider the interdependent macro-level enabling factors including: *information technology, quality measures, infrastructure, incentive systems* and *contracting strategies* **(Figure 1**). (Insert Figure 1 here)

The precise design of each test lab requires a particular combination of enabling factors, underpinned by a rationale explaining how they would improve PCC and Health Promotion.

The hypothesized enablers in the WE CARE roadmap can be used to develop implementation strategies to overcome barriers for the effective implementation of PCC and

Health Promotion. Just as clinical interventions are studied in randomized controlled trials, research designs exist to study the effectiveness of implementation strategies in a real-life setting. Implementation strategies, which will likely involve one or more enablers can be implemented sequentially, concurrently, or in an isolated fashion (depending on the programme theories to be tested). As the test lab sites will be geographically, socially and economically disparate, the implementation strategies and role of specific enablers will differ. (TS et al., 2014, Sullivan et al., 2013, Alharbi et al., 2014) What will be common to all test labs, however, is the monitoring of the core components of the PCC or Health Promotion intervention. Existing evidence to support the WE CARE roadmap framework for implementation of PCC and Health Promotion as part of the COST CARES project is defined and discussed below.

The macro enablers: Each of these enablers are outlined in **Figure 2** on the vertical axis and are defined below in line with current evidence and discourse. In COST CARES it was realized that the intersections between the enablers and the two drivers identify the core challenges in implementing the roadmap from WE CARE. These intersections are highlighted in Figure 2.

(Insert Figure 2 here)

The performance in the intersections between drivers and enablers have not yet been tested. There are a number of reasons why it is difficult to develop, test, and scale-up innovative care models. First, care systems are very complex, and often highly fragmented. The model must appease the interests and diverse goals of key stakeholders underpinning the health system. Second, scientific siloes tend to result in limited interaction between vital disciplines that include medical and care services, health systems, health economics, health policy, implementation science, medical technology, information and communications technology (ICT), and communication science. Third, these care models are typically tested in smaller scale contexts with insufficient examination of the organizational, cultural, financial, technical and legal aspects necessary to implement the model on a large scale in a real-world setting. Thus, critical evidence to support larger scale implementation is not widely available (Lloyd et al.,

2017). Innovative care models require testing on a macro level to engage policy makers, funding institutions, and care providers who can collaborate with multidisciplinary researchers to drive the systematic evaluation and practical implementation of these innovative care models. In order to develop and test such a complex intervention further, a programme theory is needed. A programme theory is an explanation, or series of linked explanations, showing how the different components of an intervention work together to produce specific outcomes. Such a model would answer the question: "How and why might this intervention (test lab) produce intended outcomes?" In addition, "What are the likely mechanisms involved?" Other relevant questions at this stage include "what existing evidence is there that this intervention might work, and can this intervention be fully described?" The latter would facilitate replication, dissemination and implementation. These questions are answered by using a parallel process evaluation (Moore et al., 2015) along with implementation questions that cover intervention fidelity or adaptation (was the intervention delivered as intended?), dose (how much of the intervention was delivered?), and reach (how many of the intended recipients actually received the intervention?).

Information technology (IT) encompasses a variety of technologies that include simple charting, advanced decision support, integration with medical technology, and co-development with patients, such as mobile applications or patient-accessible electronic health records (EHR).

The use of information technology offers great potential for reducing clinical errors (e.g., prescribing errors, disease diagnostic errors), supporting healthcare professionals (e.g., timely availability of up-to-date patient information), and collecting patient key information (symptom diaries, sensor data, digital peer-to-peer networks). This has increased the efficiency of care (e.g. shorter patient waiting times) or even improve the quality of patient care (Yasser and Alotaibi, 2017).

However, in the field of healthcare, there are also risks associated with information technology: modern information systems are costly and their failure can have a negative impact on patients and workers (Sittig et al., 2018).

The most adequate description of healthcare IT tasks is provided by the World Health Organization: the health IT is the basis for decision-making and has four main functions (WHO, 2008):

- data generation,
- compilation,
- analysis and synthesis,
- communication and use.

In addition to the integrated role of IT in clinical and diagnostic equipment, it has a unique position to capture, store, process, and timely transmit information to better coordinate health care at both the individual and population levels. For example, data mining and decision-making capabilities can point to potential risk events for each patient, as well as contribute to the health of the population by providing insights into the causes of disease complications (Horvath et al., 2018).

Moreover, ensuring information security and privacy in the healthcare sector is becoming increasingly important. The adoption of digital patient records, tighter regulation, consolidation of providers and the growing need for information from patients, providers and payers point to the need for better information security. To this end, cyber security must become an integral part of patient security. Changing human behaviour, technologies and processes is part of a holistic solution (Coventry and Branley, 2018).

One of the most important factors in person-centred care (PCC) and health promotion is addressing new information technology solutions enhanced by artificial intelligence (AI) to support better, safer and more accessible health care.

The Information System technology vision in healthcare should highlight the changing definition of valuable care, which includes acute, chronic and preventive care and patient health wellness promotion (Fichman et al., 2011).

Quality Measures: In the past 5 years, many studies have been published in the area of quality measures within healthcare include the following five key dimensions aligned with COST CARES framework: safety, equality, appropriate, person-centred and

efficiency. Study designs are varied and include systematic reviews, cross sectional, prospective, and retrospective approaches with a paucity of literature regarding the methodology (Bilimoria and Barnard, 2016). Thus, future studies should consider taking into consideration specific patient safety culture measurement tools, the level of analysis, and selection of outcome measures (DiCuccio, 2015, Shekelle et al., 2016, Simmons et al., 2016, Penman-Aguilar et al., 2016, Brownlee et al., 2017, Fazio et al., 2018, Greene and Sacks, 2018). Current metrics suffer from low reliability and validity scores, (Podolsky et al., 2014, Gonçalves et al., 2014) for example the Adverse Outcome Index should be modified to more appropriately measure preventable adverse events (Foglia et al., 2015). Moreover, health professionals, patients, and relatives should be involved in the design and collection of data (Donaldson, 2015, Podolsky et al., 2014, Auerbach et al., 2012) which should include patient reported outcomes, morbidity, and cost (Cobb, 2015), for which more recent efforts, such as the Patient-Reported Outcomes Measurement Information System (PROMIS) measures, indicate important steps forward (Schalet et al., 2018).

Contracting Strategies: Many healthcare systems use weighted capitation mechanisms for payment to general practitioners**.** In the ideal capitation model several measures such as age, gender, morbidity, additional health needs, local labour costs, rurality, patient turnover etc. can be included and comprehensively examined to predict patient expenditure and base capitation on the prediction (McElroy, 2017).. In Sweden, some argue that the current capitation function or service-purchasing model may contribute to or increase inequality (Petersson and Twetman, 2017).Health economics are increasingly interested to expand evaluation of cost-effectiveness in integrated care for chronic conditions (Tsiachristas et al., 2016). In the UK, the Quality and Outcomes Framework (QOF) pay for performance (P4P) scheme was explored as a potential model to reward primary care practitioners. Workers who relocate themselves on the basis of their ability may increase productivity and wages in organizations that use P4P scheme (Fichera and Pezzino, 2017). There is a lack of knowledge about the sorting and retention effects that P4P may produce.

Infrastructure, service delivery and organisational models: The fragmentation of services and providers together with shared delivery create potential risks to the management of health care (Chon, 2013, Kim et al., 2013, Scholz et al., 2015). In many national healthcare systems, the financing and operational control over different parts of the delivery of health care is managed by completely separate legal entities. This clearly impacts the utilisation of resources. In addition, a high quality healthcare system requires a safe environment with sufficient technical medical equipment (Scholz et al., 2015). From a fiscal perspective, the focus may be put on public-private partnerships, which can impact on quality, risk management, competition and diversity. In time this may provide service integration and an adequate welfare system (e.g. support economic growth, subordinate to economic policy) (Chon, 2013).

Incentive Systems: There are many types of incentive systems, typically described as financial vs. non-financial or direct vs. indirect. Good evidence regarding the effectiveness is lacking because of weak research designs. Financial incentives are most commonly applied and studied. QOF P4P showed some indication that efficient physicians may be rewarded by the system but the study did not investigate if the overall quality increased (Fichera and Pezzino, 2017). In addition, three Cochrane reviews concluded that there is insufficient evidence to accept or reject the use of financial incentives as a method to improve the quality of care (Giuffrida et al., 2000, Scott et al., 2011, Witter et al., 2012). Furthermore, the cost-effectiveness of a financial incentive model has been questioned (Scott et al., 2011). Regarding incentive systems for Health Promotion practices, Town et al (Town et al., 2005) conducted a systematic review of the impact of financial incentives (defined as direct payments or bonus as well as more diffuse incentives) to providers for preventive care delivery. They concluded that small rewards are likely not enough to motivate physicians to change their practice behaviours with respect to preventive care.

Furthermore, unintended consequences of introducing financial incentives into a healthcare system should be taken into account in research design. A checklist is available to determine if a financial incentive should be used and assist in its design (Glasziou et al., 2012). According to WHO Guidelines, non-financial incentives play an

equally crucial role in incentive systems (Weller, 2008). Design of an appropriate incentive system should address to whom incentives are targeted, ongoing evaluation at multiple levels, and potential unintended consequences. It is recommended that incentives systems adhere to the four principles below (Custers et al., 2008):

- fiscally prudent;
- simple to administer;
- culture of continuous improvement;
- equity in and access to quality care.

Next Steps

COST CARES continues to discuss the transfer and scaling up of PCC and Health Promotion to different contexts. Test labs will involve various alternatives to describe how the intervention and implementation of the intervention can be appropriately evaluated. In particular, COST CARES is examining system characteristics at the micro, meso, and macro levels, including:

1. Micro – the intervention itself, e.g., the types of care professionals engaged in carrying out the intervention and types of patient groups involved
2. Meso – type of centre, e.g., primary care vs. hospital setting
3. Macro – country and types of health care policy and funding mechanisms

Conclusions

The achievement of cost containment of future healthcare with maintained or improved quality can be addressed through a concerted approach involving several identified key factors. WE CARE identified that the fundamentals to this achievement are the drivers: PCC and Health Promotion. The key focus of COST CARES is the intersections between these drivers and five critical enablers. Sustainable and efficient implementation is dependent on the interplay across these identified factors.

COST CARES recognises that, in order to sustain the benefits of implementing PCC and Health Promotion, a focused approach that is cognisant of content, including geographical disparity, client care need(s) and the focus of care, is necessary. In order to deliver care in a test lab scenario it may not be feasible, or necessary, to change all

enablers at once and the decision to develop implementation strategies involving certain enablers should be taken together with the stakeholders, including healthcare professionals, policy makers and patient representatives themselves.

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Figure 1: Interdependencies of Macro and Micro enablers and the two central innovations close to the individual (modified from WE CARE (Ekman et al., 2016) (WE CARE consortium, 2015) with permission)

Figure 2 details the critical macro enablers and the intersections with the Person-Centred Care and Health Promotion on the horizontal axis

Testing Cost Containment of Future Health Care with Maintained or Improved Quality – The COST CARES project

Running title:

Cost Containment of Future Health Care ~~– The COST CARES project~~

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Abstract

Increasing healthcare costs need to be contained in order to maintain equality of access to care for all EU citizens. A cross-disciplinary consortium of experts was supported by the EU FP7 research programme, to produce a Roadmap on cost containment, while maintaining or improving the quality of healthcare. The Roadmap comprises two drivers: Person-Centred Care and Health Promotion; five critical enablers also need to be addressed: information technology, quality measures, infrastructure, incentive systems, and contracting strategies. In order to develop and test the Roadmap, a COST Action project was initiated: COST CARES, with 28 participating countries.

This paper provides an overview of evidence about the effects of each of the identified enablers. Intersections between the drivers and the enablers are identified as critical for the success of future cost containment, in tandem with maintained or improved quality in healthcare. This will require further exploration through testing.

Conclusion: Cost containment of future healthcare, with maintained or improved quality, needs to be addressed through a concerted approach of testing key factors. We propose a framework for test lab design based on these drivers and enablers in different European countries.

Word count 187

Keywords: cost containment; health promotion; person-centred care; person-centered care; quality of care;

Background

~~In 2006, t~~The European Council has agreed on several ~~common~~ values and ~~operating~~ principles regarding healthcare systems that are shared across ~~the healthcare systems of~~ the member states. These ~~common~~ values include universality, access to good quality care, equity and solidarity (Council of the European Union, 2006).

At that time, costs or affordability were not explicitly addressed, although these are important issues in any system whose aim is to safeguard these common values.

~~Nevertheless, the~~The ~~European~~ Council also stated that it is essential to make European healthcare systems financially sustainable in a way that protects ~~central values in the~~ future healthcare. However, ~~health~~ expenditure for health in all European Union (EU) countries between 2000 and 2009 increased from 8.0% to 10.0% of the gross domestic product (GDP), and in the "old" EU-15 countries alone, from 8.7% to 10.6% (WHO Regional Office for Europe, 2014).

In order to address important challenges affecting the future of European Health Care, a project, WE CARE funded by the FP7 programme, was initiated in 2013 and was finished in 2015.

During the final conference in April 2015, the WE CARE consortium presented its summary report "Healthcare innovations and improvements in a financially constrained environment: Strategy Plan and R&D Roadmap" (~~2015,~~ Ekman et al., 2016). This report included a Roadmap, which proposed a new strategic plan embedding seven interdependent themes, responsible for facilitation of a breakthrough in cost containment while, at the same time, improving the quality of care. These themes fell into two categories: 1) two drivers, which form the "backbone" of the strategic plan: Person-Centred Care (PCC) and Health Promotion, and 2) five critical enablers, which are aspects of ~~-~~the macro environment that influence the implementation of these drivers: information technology, quality measures, infrastructure, incentive systems and contracting strategies (Figure 1). In this paper we explicate both PCC and Health Promotion, with examples, before setting out a framework for the design of test labs to put the Roadmap into practice.

Person-Centred Care

The core component in PCC ~~acknowledges~~ emphasizes the patient as a person in order to ~~engage~~ involve that person as a '*partner*' in ~~their~~ his/her own care and treatment. PCC is a shift away from a model, in which the patient is the passive target of a medical intervention, to an approach characterised by a '*more mutual agreement'*, in which the patient is an active partner in their own care and in the decision-making process of the care and treatment plan. Co-creation of care in the form of partnership between the patient, their family and carer(s), and the team of health professionals caring for them, is the core component of PCC, a concept that is becoming widely used (Ekman et al., 2011, Ekman et al., 2015, Foundation). PCC embodies and enacts the philosophy and ethics applied in the Capability Approach, which has been used as a theoretical frame of reference in several research disciplines, for example in economics by the Nobel laureate Amartya Sen (Sen, 1993).
PCC is the concept used in this project and is distinct from patient-centred care, because the word 'patient' tends to objectify and reduce the person to a mere recipient of medical services, or to 'one who is acted on' (Ekman et al., 2011). Today, patients often have to navigate through a fragmented health care system and adapt to the usual practices of health care organizations and professionals, rather than receiving care designed to focus on the individual patient's resources and needs, preferences and values (Horrell et al., 2018).

The World Health Organization (WHO) uses the term **"**People-centred health services" which is an approach to care that consciously adopts the perspectives of individuals, families and communities, and sees them as participants as well as beneficiaries of trusted health systems that respond to their needs and preferences in humane and holistic ways ~~((WHO), 2019)~~.

How can Person-Centred Care be applied?

In PCC, patients and health care professionals jointly develop a healthcare plan based on the patient´s illness history and future goals, which identify personal resources and opportunities as well as potential barriers and needs (Ekman et al., 2011, Ekman et al., 2015, Foundation).

One of the fundamentals of PCC is the formation of a partnership between the patient and professionals. However, there is an asymmetry between the professional and patient. Professionals are usually in a more powerful position, as they possess greater knowledge of their specialization than the patients they serve (McKevitt, 1998). This implies that there cannot be a symmetrical exchange. However, a one-way exercise of power cannot be ethically justified and will not serve either the patient or the professional. ~~Establishing~~ To establish a partnership requires an ~~active~~ involvement from both parties, but from different starting points and with different prerequisites. The health professional is an expert in medicine, rehabilitation, nursing etc. and the patient is an expert on their own life. A partnership thus demands that the patient is treated as a person, who is simultaneously ~~vulnerable~~ and capable, vulnerable, dependent ~~and~~ as well as independent. ~~While this meeting is personal, it does not exclude or diminish the professional dimension.~~

In summary, PCC is operationally defined as co-creation of care between the patients, patient proxies if appropriate, and health professionals (Ekman et al., 2011, Foundation, Richards, 2014).

~~There are three fundamentals of a PCC intervention, namely that PCC:~~

~~(1) Is guided by an ethics conceptualized in the PCC approach, whereby the patient is a person and an *active partner* in their own care~~

~~(2) Uses a non-reductionist approach. Patients are persons and should not be reduced to their disease alone. Their subjectivity and integration within a given environment, their resources and future plans combined with medical and health research evidence should be taken into account. This approach can be achieved by giving importance to and valuing patient narratives.~~

~~(3) Incorporates a health care professional – patient partnership. A more contractual arrangement is made involving the patient as an active partner in their care and in the decision-making process. This partnership can be manifested in a mutually-agreed plan for care and treatment.~~

The fundamentals have been defined into three core components of PCC by Ekman et al: (Ekman et al., 2011)

1. Initiating the partnership through the patient narratives
2. Working the partnership by creating a health plan in agreement
3. Safeguarding the partnership by documenting the health plan

Effects from controlled trials

PCC represents a movement that has an explicit focus on humanising health services and ensuring that the patient is an equal partner in their own care and treatment above and beyond care according to evidence based medicine. In this context, the body of evidence supporting the processes and outcomes associated with person-centeredness in health and social care is constantly growing. In the cardiovascular field, PCC interventions with patients hospitalized for chronic heart failure are associated with reduced length of hospital stay, a better discharge process, and reduced patient uncertainty about their disease and treatment (Ekman et al., 2012, Ulin et al., 2015, Dudas et al., 2013). Other outcomes include reduced health care costs and maintained functional performance (Hansson et al., 2015). Furthermore, other studies involving patients with severe chronic heart failure and evaluating the core components of PCC described above, found fewer hospitalizations and improved quality of life (QoL) (Brannstrom and Boman, 2014). For patients with acute coronary syndrome (ACS), a randomised controlled trial (RCT) indicated that a PCC approach was effective in increasing self-efficacy over the whole care chain (from hospital to primary care)(Fors et al., 2015, Fors et al., 2017, Fors et al., 2016b). In particular, patients with lower education increased their self-efficacy significantly more than patients with a higher level of education (Fors et al., 2016a). A follow-up randomised controlled trial showed lasting effects of PCC after an ACS event over the two-year study period (Fors et al., 2017).

Thus the evidence demonstrates that PCC has the potential to combine high-quality evidence based care with controlled costs, in alignment with the aims of WE CARE and COST CARES.

Health Promotion

The second key driver besides PCC is Health Promotion. Multiple definitions for Health Promotion have been proposed since the term was introduced in the 1970´s. One of the first definitions was given by Lalonde, the Canadian health minister in 1974 as "*a strategy aimed at informing, influencing and assisting both individuals and organizations so that they will*

accept more responsibility and be more active in matters affecting mental and physical health" (Lalonde, 1974). The Ottawa Charter for Health promotion ~~(1986)~~ later defined Health Promotion as "*the process of enabling people to increase control over, and to improve their health*" (WHO, 1986).

Targets for Health Promotion are primarily non-communicable diseases (NCDs), which are identified as the leading causes of mortality and have several modifiable, behavioural risk factors including excessive alcohol use, physical inactivity, tobacco use, and poor diet. Biological risk factors include high blood pressure, diabetes, and obesity (WHO., 2013). Health Promotion should be carried out on different levels to be effective, both population-wide (for example taxes, mass media campaigns, school programs) and individual, but there is uncertainty which components are more effective. There is also a gap in research evidence from low- and middle-income countries (Mosdol et al., 2017, Jeet et al., 2017).

One very important principle of Health Promotion is empowerment, i.e. seeking to ensure that individuals have the power to affect their own health. This aligns closely with the principles of PCC. Other important criteria include participation and having a broad perspective of health and inequality. Health Promotion has gained recognition in recent years because of the growing evidence on the importance of lifestyle behaviour for individual health (Lee et al., 2012, Swinburn et al., 2011). In addition, socioeconomic conditions, as well as social and structural support have been identified as important determinants of health. Thus, addressing public health in the modern era includes lifestyle behavioural changes based on a bio-psycho-social model (Engel, 1977).

There are clear similarities between Health Promotion and PCC, for instance the emphasis on identifying and supporting the individual's resources to influence their own health and the focus on the societal context affecting this process. A key component is tailoring the process to each person, exemplified by the identification of barriers and facilitators, unique to the individual, as well as the importance of the social environment for such changes to take place, e.g., positive/negative reinforcement by relatives or the surrounding community.

Health Promotion is included in the context of WE CARE and COST CARES because it represents high quality interventions that keep populations healthy and, at the same time, means that health care is less costly for society. Health Promotion and PCC are key drivers

to cap health care costs, while simultaneously maintaining or improving the quality of care and resulting improved health for all.

Cost Action 15222 (COST CARES)

In order to carry forward the WE CARE Roadmap, Cost Action (CA) 15222 was initiated in 2017 with the project name COST CARES. The main aim of COST CARES is to establish processes for implementing PCC and a working framework for evaluation test labs of PCC and Health Promotion in different countries. These test labs are essential to the effort necessary to expand the evidence-base regarding how PCC and Health Promotion drive cost containment in healthcare while maintaining and improving quality of care in various settings and countries. The work in COST CARES is managed in four working groups (WGs) (See Supplementary Appendix 1). The overall aim of the work of WG2 is to define a logistic and organisational framework that is necessary for the design of large-scale testing of PCC systems that will contain costs while maintaining quality of care.

The WE CARE roadmap was developed by WG2 in reviewing the existing literature as well as practice. Examples of implementing PCC policy and practice in different settings in different countries were also identified and explored. Two successful examples/cases are outlined ~~below~~in Supplementary Appendix 2.~~:~~

~~**Example 1: Gothenburg, Sweden: Implementation of an intervention based on Person-Centred Care across health care levels:**~~

~~The study was a two-armed randomised intervention study on three health care levels (hospital, outpatient and primary care). Eligible participants had an uncomplicated acute coronary syndrome (ACS) and were randomised to parallel groups, one control group receiving usual care and one intervention group receiving a PCC-intervention in addition to usual care (Fors et al., 2015).~~

~~The intervention was provided by staff specially prepared during a one-day introduction in the theory and practice of PCC. This was followed by four three-hour booster sessions during the study period to share experiences and maintain a continuous application of PCC. Five primary centres had designated PCC professionals [one primary care physician (PCP)~~

and one registered nurse (RN)] who worked with the patient as a team. Five centres geographically disseminated over the Gothenburg region (population 450 000) participated voluntarily to be intervention primary care centres. Patients in the intervention group participated in a PCC process emphasizing the patient as a partner through all three health care levels [hospital, outpatient and primary health care (PHC)].

Hospital stay:

Admission: The starting point for the intervention was a structured patient narrative at admission to hospital (within 24 hours after randomisation) to *initiate the partnership*, which served as the basis for the preparation of a PCC health plan. The PCC health plan was co-created by the patient and health care professionals in order to define opportunities and barriers during recovery after ACS. The focus was on each person's resources to achieve agreed goals during the recovery process, e.g. what activities the patient wanted to be confident enough to return to and even extend (work or leisure). The condensed narrative was compiled in the PCC health plan after the patient's approval.

Inpatient care: In order to *work with the partnership*, an appointment was set between the patient, physician, and RN to consider and sign the PCC health plan, discuss the patient's medical status, and propose a discharge date. This information was documented in the PCC health plan, which also included goals and the actions needed to accomplish them, personal resources, social network, assigned health care professionals, dates of appointments, and follow-up objectives. In addition, patients rated their symptoms, and the PCC health plan was reviewed every 48 hours and revised where necessary.

Discharge procedure: To *safeguard the partnership* the PCC health plan was accessible to both the patient and the health care professionals throughout the continuum of care. Medical and nursing referrals and discharge notes were shared with the patient to ensure transparency.

Outpatient visit:

About four weeks after discharge from the hospital, the patient met a cardiologist and a specialized RN in a team visit at the outpatient clinic. In order to *maintain the partnership*, the visit started by following up on the PCC health plan, which served as a basis for a

discussion of the overall condition. If the patient´s medical status was stable, the patient was referred to the primary care setting.

Implementation at visits to primary care centre:

After approximately eight weeks, the patient met the specialized PCC primary care professionals at the dedicated primary care centre. To *maintain the partnership,* the goals in the PCC health plan were assessed and modified when required (e.g. divided into several minor goals to achieve them stepwise or a new goal orientation was set). The patient´s resources and support within the patient´s network and/or among health care professionals were identified to help carry out agreed upon goals. Symptoms were also reviewed. For example, if sleep disorders and/or anxiety were reported during the hospital stay, they were re-assessed and management strategies were discussed during the visit. Additional visits were scheduled if suggested by either the patient or the health care professional.

Results: A composite score of changes in self-efficacy and morbidity showed that more patients (22.3%, n=21) improved in the intervention group at 6 months compared to the control group (9.5%, n=10) (odds ratio, 2.7; 95% confidence interval: 1.2-6.2; P=0.015). The effect was driven by improved self-efficacy ≥ 5 units in the intervention group. Overall general self-efficacy improved significantly more in the intervention group compared with the control group (P=0.026)

Example 2: Implementation of a Health Promotion in the Basque Health Care System in Spain:

The Primary Care Research Unit of Bizkaia (PCRUB), in Bilbao, Spain, has been working to systematically study the effectiveness of a Health Promotion intervention within the local healthcare system (Ozakidetza), and specifically within primary healthcare (PHC). The team began over fifteen years ago, collecting evidence on the effectiveness of PHC strategies to enhance smoking cessation (Grandes et al., 2003) and increase physical activity (Grandes et al., 2011, Grandes et al., 2009) using clustered randomized trials. However, the primary care physicians (PCPs) who participated in the studies did not continue to utilize the Health Promotion strategies, citing lack of time, organization, communication, and/or capacity building.

In January 2006, the Basque Country Health Department commissioned the PCRUB to undertake a literature review and formative qualitative study on Health Promotion in PHC (Grandes et al., 2008). The need for mutual adaptation – to adapt an implementation strategy to the organizational structure and create organizational change to accommodate a new focus on Health Promotion in PHC was recognized. The PCRUB then began a systematic action research programme to investigate the effective integration of healthy lifestyle promotion targeting multiple risk factors into the day-to-day PHC setting – specifically smoking cessation, exercise, and healthy diet. "Prescribe Vida Saludable" (PVS) translates into Prescribing Healthy Lifestyle and involves systematic study of the effectiveness of a clinical Health Promotion intervention combined with its implementation strategy to ensure sustained uptake of the intervention.

Intervention:

The intervention is composed of multiple active measures drawn from evidence-based theoretical models and intervention strategies for health behaviour modification such as the social learning and planned behaviour theories and the 5 A's (Ask, Advise, Agree, Assist, and Arrange follow-up) intervention framework (Goldstein et al., 1998, Whitlock et al., 2002). The intervention itself can be aligned with PCC in:

1. *Initiating the partnership*. The idea of focusing Health Promotion on primary care providers is based in the notion that the healthcare provider and patient already have an established relationship. The first "A" (ask) requires determining current levels of smoking, physical activity, and diet. For those individuals who do typically visit the healthcare centre, each participating centre determines how the partnership will be initiated. Some choose to have community agents (e.g., pharmacies, schools, parent associations, municipal sports centres) survey the individuals they have access to. Others engage the administrative assistants at the reception desk or RNs to make the first contact.

2. *Working within the partnership*. Information on current lifestyle behaviours is passed on to primary care providers in the health centre. Physicians and/or RNs (depending on the centre's unique needs) "Advise" the individual of the risks associated with his/her current lifestyle. Working together, they "Agree" on the healthy lifestyle behaviours that require modification, if now is the right time to act, and how. The patient/person and their narratives

are central to this process. If they do not feel that it is the right time to change their lifestyle, they are "advised" again at a later time and the "Agree" step is repeated as often as needed. Ownership of the lifestyle change is transferred to the person with support from healthcare professionals and the community. Agreeing on the change the individual will undertake and defining an appropriate plan and reasonable goals, consistent with the person's needs, is a core part of the intervention. A written health plan is documented in the person's electronic medical record by the RN or physician during the "Assist" stage.

3. *Maintaining the partnership*. The "Arrange" stage serves to maintain the partnership in a series of follow-up appointments with the RN and/or physician to review the prescribed lifestyle modification plan and its effectiveness, and determine adaptations needed to better fit the person's needs.

Implementation strategy: The implementation phases that are carried out are based on the Medical Research Council's evaluation framework (Craig et al., 2008, Moore et al., 2015). In the modelling phase, the PCPs, RN and administrative staff at four PHC centres followed an implementation strategy based on a collaborative and facilitated process, planned and designed intervention programs adapted to their specific contexts and resources, and identified strategies for change and mechanisms through which interventions should operate (Sanchez et al., 2009, Grandes et al., 2017). The RE-AIM (Reach Effectiveness Adoption Implementation Maintenance) Framework (Glasgow et al., 1999) process indicators were varied by centre, lifestyle habit, and patient characteristics.

The results of the Phase II quasi-experimental pilot trial indicated that more than half of the patients who visited a health centre (n=11,650; 51.9%) had lifestyle habits assessed; a third (33.7%; n=7,433) received advice; almost 10% (n=2,175) received a printed prescription for at least one lifestyle change (Sanchez et al., 2017). Focus groups were conducted with centre staff and 11 constructs from The Consolidated Framework for Implementation Research (CFIR) (Damschroder et al., 2009) were associated with the centre's level of implementation performance (defined as high, medium, or low (Martinez et al., 2017). The Phase III quasi-experimental hybrid effectiveness-implementation design trial to optimize the implementation strategy has concluded in seven centres. At the time of writing, data from the health care centres offered by participating professionals and patients is being analysed.

~~The implementation strategy itself exemplifies the core components of PCC. The ethics that form the foundation of PCC are applied to the healthcare professionals at the local PHCs who are supported by an external facilitator to set realistic goals regarding the reach of the intervention and involve community stakeholders to develop a community of practice. Regular feedback on progress and the integration of ICT to ensure adequate data capture is also part of the implementation plan, which is developed by each PHC according to their needs. The intervention implementation process illustrates basic PCC ethics because:~~

~~1. The specific implementation strategy is decided upon by each healthcare centre according to their own characteristics. The research team supports them through the collaborative modelling process, but the centre "owns" the final implementation strategy as it is built by their team bottom up.~~

~~2. The opinions of the healthcare professionals and administrative staff are heard during the collaborative modelling discussions. The implementation strategy is adapted to their needs and environment.~~

~~3. Decision making occurs collaboratively throughout the implementation process guided by an experienced facilitator who is part of the research team. Feedback about progress on centre-defined goals of reach of the target population for each stage of the five A's is reviewed so that the facilitator and centre implementation team can agree on action plans to improve outcomes.~~

~~Both the Gothenburg and Bilbao examples show how to implement and test PCC or a Health Promotion intervention. The emphasis in the Basque Health Care System example on the specification and study of implementation strategies adapted to the unique needs of the healthcare centres illustrates how a test lab must go beyond the study of intervention effectiveness and also examine context.~~

Framework for Test Lab Design:

The Test lab(s) in COST CARES are designed to guide and stimulate the integration and collaboration between academic disciplines, industry, healthcare professionals, policy

makers and patient representatives in healthcare to achieve cost containment and quality research. COST CARES sets out to tackle these challenges by:

1. Working towards the development of care systems based on PCC and Health Promotion that can be tested on a macro level
2. Defining the parameters necessary to perform and evaluate large scale implementation
3. Executing studies that will provide an adequate evidence base for PCC and Health Promotion across various contexts in different countries

WE CARE posits the notion that cost containment and quality initiatives, although inextricably linked, should also be considered from a person-centred micro level including the elements of healthcare which support preventative/health promoting strategies (Ekman et al., 2016). It is important to consider the interdependent macro-level enabling factors including: *information technology, quality measures, infrastructure, incentive systems* and *contracting strategies* **(Figure 1**). (Insert Figure 1 here)

The precise design of each test lab requires a particular combination of enabling factors, underpinned by a rationale explaining how they would improve PCC and Health Promotion.

The hypothesized enablers in the WE CARE roadmap can be used to develop implementation strategies to overcome barriers for the effective implementation of PCC and Health Promotion. Just as clinical interventions are studied in randomized controlled trials, research designs exist to study the effectiveness of implementation strategies in a real-life setting. Implementation strategies, which will likely involve one or more enablers can be implemented sequentially, concurrently, or in an isolated fashion (depending on the programme theories to be tested). As the test lab sites will be geographically, socially and economically disparate, the implementation strategies and role of specific enablers will differ. (~~TS et al., 2014,~~ Sullivan et al., 2013, Alharbi et al., 2014) What will be common to all test labs, however, is the monitoring of the core components of the PCC or Health Promotion intervention. Existing evidence to support the WE CARE roadmap framework for implementation of PCC and Health Promotion as part of the COST CARES project is defined and discussed below.

The macro enablers: Each of these enablers are outlined in **Figure 2** on the vertical axis and are defined below in line with current evidence and discourse. In COST CARES it was realized that the intersections between the enablers and the two drivers identify the core challenges in implementing the roadmap from WE CARE. These intersections are highlighted in Figure 2.

(Insert Figure 2 here)

The performance in the intersections between drivers and enablers have not yet been tested. There are a number of reasons why it is difficult to develop, test, and scale-up innovative care models. First, care systems are very complex, and often highly fragmented. The model must appease the interests and diverse goals of key stakeholders underpinning the health system. Second, scientific siloes tend to result in limited interaction between vital disciplines that include medical and care services, health systems, health economics, health policy, implementation science, medical technology, information and communications technology (ICT), and communication science. Third, these care models are typically tested in smaller scale contexts with insufficient examination of the organizational, cultural, financial, technical and legal aspects necessary to implement the model on a large scale in a real-world setting. Thus, critical evidence to support larger scale implementation is not widely available (Lloyd et al., 2017). Innovative care models require testing on a macro level to engage policy makers, funding institutions, and care providers who can collaborate with multidisciplinary researchers to drive the systematic evaluation and practical implementation of these innovative care models. In order to develop and test such a complex intervention further, a programme theory is needed. A programme theory is an explanation, or series of linked explanations, showing how the different components of an intervention work together to produce specific outcomes. Such a model would answer the question: "How and why might this intervention (test lab) produce intended outcomes?" In addition, "What are the likely mechanisms involved?" Other relevant questions at this stage include "what existing evidence is there that this intervention might work, and can this intervention be fully described?" The latter would facilitate replication, dissemination and implementation. These questions are answered by using a parallel process

evaluation (Moore et al., 2015) along with implementation questions that cover intervention fidelity or adaptation (was the intervention delivered as intended?), dose (how much of the intervention was delivered?), and reach (how many of the intended recipients actually received the intervention?). Parallel process evaluations should also explore key uncertainties about the intervention and will require a combination of quantitative and qualitative data. Findings from process evaluations can shape the subsequent refinement and implementation of the intervention. Programme theories also help establish buy-in and understanding from key stakeholders required for the delivery and success of the intervention. Importantly, the programme theory will help focus key questions and methods for establishing if and how the intervention is working; the logic of the intervention will be tested using the most appropriate measures.

The Information Technology (IT) includes various technologies that span from simple charting, to more advanced decision support, integration with medical technology and co-creation with patients via, for example, mobile applications or patient-accessible electronic health records (EHR). The use of modern information technology offers tremendous opportunities to reduce clinical errors (e.g. medication errors, diagnostic errors), to support health care professionals (e.g. availability of timely, up-to-date patient information), to support patients and relatives (symptom diaries, sensor data, digital peer-to-peer networks), to increase the efficiency of care (e.g. less waiting times for patients), or even to improve the quality of patient care (Yasser and Alotaibi, 2017).

However, there are also hazards associated with information technology in health care: modern information systems are costly, and their failures may cause negative effects on patients and staff (Sittig et al., 2018).

The most adequate description of healthcare IT is provided by the World Health Organization (2008): The health IT provides the underpinnings for decision-making and has four key functions (2008):

- data generation,
- compilation,
- analysis and synthesis,

- communication and use.

In addition to the embedded role of IT in clinical and diagnostic equipment, it is uniquely positioned to capture, store, process and communicate timely information for better coordination of healthcare at both the individual and population levels. For example, data mining and decision support capabilities can identify potential adverse events for an individual patient, while also contributing to the population's health by providing insights into the causes of disease complications (Horvath et al., 2018).

Further, the importance of information security and privacy in the healthcare sector should be considered. The adoption of digital patient records, increased regulation, provider consolidation and the increasing need for information between patients, providers, and payers, all point towards the need for better information security. This requires cybersecurity to become an integral part of patient safety. Changes are required to human behaviour, technology and processes as part of a holistic solution (Coventry and Branley, 2018).

One of the Person-Centred Care (PCC) and Health Promotion critical enablers addresses information technology's new solutions that are enhanced by artificial intelligence (AI) so as to support better, safer, and more affordable health care. The Information System technology vision should support the evolving definition of high-value care, which includes the simultaneous provision of acute, chronic, and preventive care and promotion of patient wellness (Fichman et al., 2011).

Information technology (IT) encompasses a variety of technologies that include simple charting, advanced decision support, integration with medical technology, and co-development with patients, such as mobile applications or patient-accessible electronic health records (EHR).

The use of information technology offers great potential for reducing clinical errors (e.g., prescribing errors, disease diagnostic errors), supporting healthcare professionals (e.g., timely availability of up-to-date patient information), and collecting patient key information (symptom diaries, sensor data, digital peer-to-peer networks). This has increased the efficiency of care (e.g. shorter patient waiting times) or even improve the quality of patient care (Yasser and Alotaibi, 2017).

However, in the field of healthcare, there are also risks associated with information technology: modern information systems are costly and their failure can have a negative impact on patients and workers (Sittig et al., 2018).

The most adequate description of healthcare IT tasks is provided by the World Health Organization: the health IT is the basis for decision-making and has four main functions (WHO, 2008):

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- communication and use.

In addition to the integrated role of IT in clinical and diagnostic equipment, it has a unique position to capture, store, process, and timely transmit information to better coordinate health care at both the individual and population levels. For example, data mining and decision-making capabilities can point to potential risk events for each patient, as well as contribute to the health of the population by providing insights into the causes of disease complications (Horvath et al., 2018).

Moreover, ensuring information security and privacy in the healthcare sector is becoming increasingly important. The adoption of digital patient records, tighter regulation, consolidation of providers and the growing need for information from patients, providers and payers point to the need for better information security. To this end, cyber security must become an integral part of patient security. Changing human behaviour, technologies and processes is part of a holistic solution (Coventry and Branley, 2018).

One of the most important factors in person-centred care (PCC) and health promotion is addressing new information technology solutions enhanced by artificial intelligence (AI) to support better, safer and more accessible health care.

The Information System technology vision in healthcare should highlight the changing definition of valuable care, which includes acute, chronic and preventive care and patient health wellness promotion (Fichman et al., 2011).

Quality Measures: In the past 5 years, many studies have been published in the area of quality measures within healthcare include the following five key dimensions aligned with COST CARES framework: safety, equality, appropriate, person-centred and efficiency. Study designs are varied and include systematic reviews, cross sectional, prospective, and retrospective approaches with a paucity of literature regarding the methodology (Bilimoria and Barnard, 2016). Thus, future studies should consider taking into consideration specific patient safety culture measurement tools, the level of analysis, and selection of outcome measures (DiCuccio, 2015, Shekelle et al., 2016, Simmons et al., 2016, Penman-Aguilar et al., 2016, Brownlee et al., 2017, Fazio et al., 2018, Greene and Sacks, 2018). Current metrics suffer from low reliability and validity scores, (Podolsky et al., 2014, Gonçalves et al., 2014) for example the Adverse Outcome Index should be modified to more appropriately measure preventable adverse events (Foglia et al., 2015). Moreover, health professionals, patients, and relatives should be involved in the design and collection of data (Donaldson, 2015, Podolsky et al., 2014, Auerbach et al., 2012) which should include patient reported outcomes, morbidity, and cost (Cobb, 2015), for which more recent efforts, such as the Patient-Reported Outcomes Measurement Information System (PROMIS) measures, indicate important steps forward (Schalet et al., 2018).

Contracting Strategies: Many healthcare systems use weighted capitation mechanisms for payment to general practitioners**.** In the ideal capitation model several measures such as age, gender, morbidity, additional health needs, local labour costs, rurality, patient turnover etc. can be included and comprehensively examined to predict patient expenditure and base capitation on the prediction (McElroy, 2017). ~~x~~. In Sweden, some argue that the current capitation function or service-purchasing model may contribute to or increase inequality (Petersson and Twetman, 2017).Health economics are increasingly interested to expand evaluation of cost-effectiveness in integrated care for chronic conditions (Tsiachristas et al., 2016). In the UK, the Quality and Outcomes Framework (QOF) pay for performance (P4P) scheme was explored as a potential model to reward primary care practitioners. Workers who relocate themselves on the basis of their ability may increase productivity and wages in organizations that use P4P

scheme (Fichera and Pezzino, 2017). There is a lack of knowledge about the sorting and retention effects that P4P may produce.

Infrastructure, service delivery and organisational models: The fragmentation of services and providers together with shared delivery create potential risks to the management of health care (Chon, 2013, Kim et al., 2013, Scholz et al., 2015). In many national healthcare systems, the financing and operational control over different parts of the delivery of health care is managed by completely separate legal entities. This clearly impacts the utilisation of resources. In addition, a high quality healthcare system requires a safe environment with sufficient technical medical equipment (Scholz et al., 2015). From a fiscal perspective, the focus may be put on public-private partnerships, which can impact on quality, risk management, competition and diversity. In time this may provide service integration and an adequate welfare system (e.g. support economic growth, subordinate to economic policy) (Chon, 2013).

Incentive Systems: There are many types of incentive systems, typically described as financial vs. non-financial or direct vs. indirect. Good evidence regarding the effectiveness is lacking because of weak research designs. Financial incentives are most commonly applied and studied. QOF P4P showed some indication that efficient physicians may be rewarded by the system but the study did not investigate if the overall quality increased (Fichera and Pezzino, 2017). In addition, three Cochrane reviews concluded that there is insufficient evidence to accept or reject the use of financial incentives as a method to improve the quality of care (Giuffrida et al., 2000, Scott et al., 2011, Witter et al., 2012). Furthermore, the cost-effectiveness of a financial incentive model has been questioned (Scott et al., 2011). Regarding incentive systems for Health Promotion practices, Town et al (Town et al., 2005) conducted a systematic review of the impact of financial incentives (defined as direct payments or bonus as well as more diffuse incentives) to providers for preventive care delivery. They concluded that small rewards are likely not enough to motivate physicians to change their practice behaviours with respect to preventive care.

Furthermore, unintended consequences of introducing financial incentives into a healthcare system should be taken into account in research design. A checklist is available to determine if a financial incentive should be used and assist in its design (Glasziou et al., 2012). According to WHO Guidelines, non-financial incentives play an equally crucial role in incentive systems (Weller, 2008). Design of an appropriate incentive system should address to whom incentives are targeted, ongoing evaluation at multiple levels, and potential unintended consequences. It is recommended that incentives systems adhere to the four principles below (Custers et al., 2008):

- fiscally prudent;
- simple to administer;
- culture of continuous improvement;
- equity in and access to quality care.

Next Steps

COST CARES continues to discuss the transfer and scaling up of PCC and Health Promotion to different contexts. Test labs will involve various alternatives to describe how the intervention and implementation of the intervention can be appropriately evaluated. In particular, COST CARES is examining system characteristics at the micro, meso, and macro levels, including:

1. Micro – the intervention itself, e.g., the types of care professionals engaged in carrying out the intervention and types of patient groups involved
2. Meso – type of centre, e.g., primary care vs. hospital setting
3. Macro – country and types of health care policy and funding mechanisms

Conclusions

The achievement of cost containment of future healthcare with maintained or improved quality can be addressed through a concerted approach involving several identified key factors. WE CARE identified that the fundamentals to this achievement are the drivers: PCC and Health Promotion. The key focus of COST CARES is the intersections between these drivers and five critical enablers. Sustainable and efficient implementation is dependent on the interplay across these identified factors.

COST CARES recognises that, in order to sustain the benefits of implementing PCC and Health Promotion, a focused approach that is cognisant of content, including geographical disparity, client care need(s) and the focus of care, is necessary. In order to deliver care in a test lab scenario it may not be feasible, or necessary, to change all enablers at once and the decision to develop implementation strategies involving certain enablers should be taken together with the stakeholders, including healthcare professionals, policy makers and patient representatives themselves.

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Figure 1: Interdependencies of Macro and Micro enablers and the two central innovations close to the individual (modified from WE CARE (Ekman et al., 2016) (2015) with permission)

Figure 2 details the critical macro enablers and the intersections with the Person-Centred Care and Health Promotion on the horizontal axis

Supplementary Appendices

Appendix 1

Working Groups (WG) in COST CARES and respective tasks

WG 1 : Secure funding of Labs

1. Establish background information for creating of a convincing package for stakeholders
2. Create influencing toolbox (slides, elevator pitch etc)
3. Stakeholder mapping
4. Stakeholder interactions

WG 2: Clarify design, content and localizations of Lab

1. Prioritization of Intersection Points
2. How to design a study (Lab) changing the enablers simultaneously in a large scale experimental setting?
3. Who needs to be involved in a Lab?
4. Where can a Lab geographically be located?

WG 3: How to assess output from labs

1. How to assess changes in Intersection Points (process change)
2. How to assess cost (output of change)?
3. How to assess all relevant aspects of quality (output change)?
4. What national and international resources/registers can be used?

WG 4: Communication and Dissemination

1. Facilitate Communication internal in CostCares

~~2. Facilitate communication of conclusions (ongoing and final) to stakeholders~~

Supplementary Appendix 2

Examples of implementing PCC policy and practice

Example 1: Gothenburg, Sweden: Implementation of an intervention based on Person-Centred Care across health care levels:

The study was a two-armed randomised intervention study on three health care levels (hospital, outpatient and primary care). Eligible participants had an uncomplicated acute coronary syndrome (ACS) and were randomised to parallel groups, one control group receiving usual care and one intervention group receiving a PCC-intervention in addition to usual care (Fors et al., 2015).

The intervention was provided by staff specially prepared during a one-day introduction in the theory and practice of PCC. This was followed by four three-hour booster sessions during the study period to share experiences and maintain a continuous application of PCC. Five primary centres had designated PCC professionals [one primary care physician (PCP) and one registered nurse (RN)] who worked with the patient as a team. Five centres geographically disseminated over the Gothenburg region (population 450 000) participated voluntarily to be intervention-primary-care-centres. Patients in the intervention group participated in a PCC process emphasizing the patient as a partner through all three health care levels [hospital, outpatient and primary health care (PHC)]:

Hospital stay:

Admission: The starting point for the intervention was a structured patient narrative at admission to hospital (within 24 hours after randomisation) to *initiate the partnership*, which served as the basis for the preparation of a PCC health plan. The PCC health plan was co-created by the patient and health care professionals in order to define opportunities and barriers during recovery after ACS. The focus was on each person's resources to achieve agreed goals during the recovery process, e.g. what activities the patient wanted to be confident enough to return to and even extend (work or leisure).

The condensed narrative was compiled in the PCC health plan after the patient's approval.

Inpatient care: In order to *work with the partnership,* an appointment was set between the patient, physician, and RN to consider and sign the PCC health plan, discuss the patient's medical status, and propose a discharge date. This information was documented in the PCC health plan, which also included goals and the actions needed to accomplish them, personal resources, social network, assigned health care professionals, dates of appointments, and follow-up objectives. In addition, patients rated their symptoms, and the PCC health plan was reviewed every 48 hours and revised where necessary.

Discharge procedure: To *safeguard the partnership* the PCC health plan was accessible to both the patient and the health care professionals throughout the continuum of care. Medical and nursing referrals and discharge notes were shared with the patient to ensure transparency.

Outpatient visit:

About four weeks after discharge from the hospital, the patient met a cardiologist and a specialized RN in a team visit at the outpatient clinic. In order to *maintain the partnership,* the visit started by following up on the PCC health plan, which served as a basis for a discussion of the overall condition. If the patient´s medical status was stable, the patient was referred to the primary care setting.

Implementation at visits to primary care centre:

After approximately eight weeks, the patient met the specialized PCC primary care professionals at the dedicated primary care centre. To *maintain the partnership,* the goals in the PCC health plan were assessed and modified when required (e.g. divided into several minor goals to achieve them stepwise or a new goal orientation was set). The patient´s resources and support within the patient´s network and/or among health care professionals were identified to help carry out agreed upon goals. Symptoms were also reviewed. For example, if sleep disorders and/or anxiety were reported during the hospital stay, they were re-assessed and management strategies were discussed during

the visit. Additional visits were scheduled if suggested by either the patient or the health care professional.

Results: A composite score of changes in self-efficacy and morbidity showed that more patients (22.3%, n=21) improved in the intervention group at 6 months compared to the control group (9.5%, n=10) (odds ratio, 2.7; 95% confidence interval: 1.2-6.2; P=0.015). The effect was driven by improved self-efficacy > 5 units in the intervention group. Overall general self-efficacy improved significantly more in the intervention group compared with the control group (P=0.026)

Example 2: Implementation of a Health Promotion in the Basque Health Care System in Spain:

The Primary Care Research Unit of Bizkaia (PCRUB), in Bilbao, Spain, has been working to systematically study the effectiveness of a Health Promotion intervention within the local healthcare system (Ozakidetza), and specifically within primary healthcare (PHC). The team began over fifteen years ago, collecting evidence on the effectiveness of PHC strategies to enhance smoking cessation (Grandes et al., 2003) and increase physical activity (Grandes et al., 2011, Grandes et al., 2009) using clustered randomized trials. However, the primary care physicians (PCPs) who participated in the studies did not continue to utilize the Health Promotion strategies, citing lack of time, organization, communication, and/or capacity building.

In January 2006, the Basque Country Health Department commissioned the PCRUB to undertake a literature review and formative qualitative study on Health Promotion in PHC (Grandes et al., 2008). The need for mutual adaptation – to adapt an implementation strategy to the organizational structure and create organizational change to accommodate a new focus on Health Promotion in PHC was recognized. The PCRUB then began a systematic action research programme to investigate the effective integration of healthy lifestyle promotion targeting multiple risk factors into the day-to-day PHC setting – specifically smoking cessation, exercise, and healthy diet. “Prescribe Vida Saludable” (PVS) translates into Prescribing Healthy Lifestyle and involves systematic study of the effectiveness of a clinical Health Promotion intervention

combined with its implementation strategy to ensure sustained uptake of the intervention.

Intervention:

The intervention is composed of multiple active measures drawn from evidence-based theoretical models and intervention strategies for health behaviour modification such as the social learning and planned behaviour theories and the 5 A's (Ask, Advise, Agree, Assist, and Arrange follow-up) intervention framework (Goldstein et al., 1998, Whitlock et al., 2002). The intervention itself can be aligned with PCC in:

1. *Initiating the partnership.* The idea of focusing Health Promotion on primary care providers is based in the notion that the healthcare provider and patient already have an established relationship. The first "A" (ask) requires determining current levels of smoking, physical activity, and diet. For those individuals who do typically visit the healthcare centre, each participating centre determines how the partnership will be initiated. Some choose to have community agents (e.g., pharmacies, schools, parent associations, municipal sports centres) survey the individuals they have access to. Others engage the administrative assistants at the reception desk or RNs to make the first contact.

2. *Working within the partnership.* Information on current lifestyle behaviours is passed on to primary care providers in the health centre. Physicians and/or RNs (depending on the centre's unique needs) "Advise" the individual of the risks associated with his/her current lifestyle. Working together, they "Agree" on the healthy lifestyle behaviours that require modification, if now is the right time to act, and how. The patient/person and their narratives are central to this process. If they do not feel that it is the right time to change their lifestyle, they are "advised" again at a later time and the "Agree" step is repeated as often as needed. Ownership of the lifestyle change is transferred to the person with support from healthcare professionals and the community. Agreeing on the change the individual will undertake and defining an appropriate plan and reasonable goals, consistent with the person's needs, is a core part of the intervention. A written health plan is documented in the person's electronic medical record by the RN or physician during the "Assist" stage.

3. *Maintaining the partnership.* The "Arrange" stage serves to maintain the partnership in a series of follow-up appointments with the RN and/or physician to review the prescribed lifestyle modification plan and its effectiveness, and determine adaptations needed to better fit the person's needs.

Implementation strategy: The implementation phases that are carried out are based on the Medical Research Council's evaluation framework (Craig et al., 2008, Moore et al., 2015). In the modelling phase, the PCPs, RN and administrative staff at four PHC centres followed an implementation strategy based on a collaborative and facilitated process, planned and designed intervention programs adapted to their specific contexts and resources, and identified strategies for change and mechanisms through which interventions should operate (Sanchez et al., 2009, Grandes et al., 2017). The RE-AIM (Reach Effectiveness Adoption Implementation Maintenance) Framework (Glasgow et al., 1999) process indicators were varied by centre, lifestyle habit, and patient characteristics.

The results of the Phase II quasi-experimental pilot trial indicated that more than half of the patients who visited a health centre (n=11,650; 51.9%) had lifestyle habits assessed; a third (33.7%; n=7,433) received advice; almost 10% (n=2,175) received a printed prescription for at least one lifestyle change (Sanchez et al., 2017). Focus groups were conducted with centre staff and 11 constructs from The Consolidated Framework for Implementation Research (CFIR) (Damschroder et al., 2009) were associated with the centre's level of implementation performance (defined as high, medium, or low (Martinez et al., 2017). The Phase III quasi-experimental hybrid effectiveness-implementation design trial to optimize the implementation strategy has concluded in seven centres. At the time of writing, data from the health care centres offered by participating professionals and patients is being analysed.

The implementation strategy itself exemplifies the core components of PCC. The ethics that form the foundation of PCC are applied to the healthcare professionals at the local PHCs who are supported by an external facilitator to set realistic goals regarding the reach of the intervention and involve community stakeholders to develop a community of practice. Regular feedback on progress and the integration of ICT to ensure adequate

data capture is also part of the implementation plan, which is developed by each PHC according to their needs. The intervention implementation process illustrates basic PCC ethics because:

1. The specific implementation strategy is decided upon by each healthcare centre according to their own characteristics. The research team supports them through the collaborative modelling process, but the centre "owns" the final implementation strategy as it is built by their team bottom up.

2. The opinions of the healthcare professionals and administrative staff are heard during the collaborative modelling discussions. The implementation strategy is adapted to their needs and environment.

3. Decision making occurs collaboratively throughout the implementation process guided by an experienced facilitator who is part of the research team. Feedback about progress on centre-defined goals of reach of the target population for each stage of the five A's is reviewed so that the facilitator and centre implementation team can agree on action plans to improve outcomes.

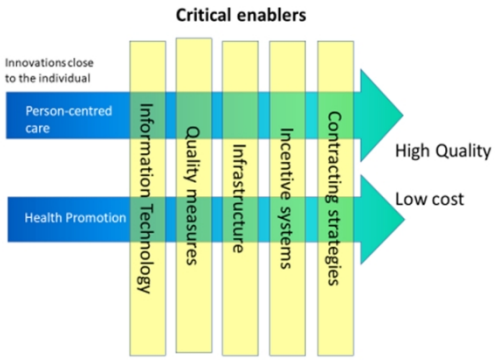
Both the Gothenburg and Bilbao examples show how to implement and test PCC or a Health Promotion intervention. The emphasis in the Basque Health Care System example on the specification and study of implementation strategies adapted to the unique needs of the healthcare centres illustrates how a test lab must go beyond the study of intervention effectiveness and also examine context.

Appendix 2

Subsequent figures/schematics in the Supplementary Appendix 2 provide hypothesized interactions between these enablers and PCC and/or health promotion. A qualitative/theory building perspective and an empirical/metrics-based quantitative evaluation can be informative in the design of test labs to examine how these contextual factors and the intervention influence one another.

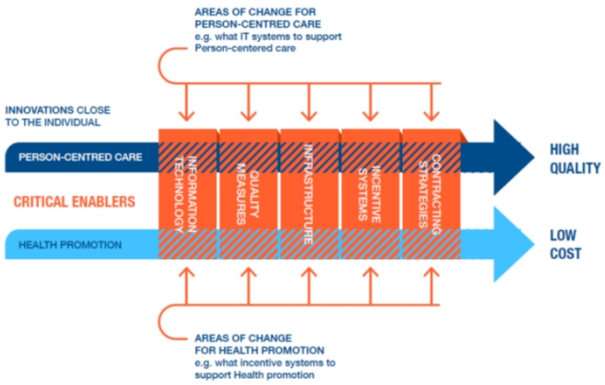
It should be noted that all five enablers are not only interrelated but to some extent, they overlap with each other. This means that it is difficult to set clear boundaries between the enablers with overlap e.g. quality measures and incentives since the process of measurement itself is an incentive when it is combined with effective feedback to actors who can influence the results being tracked. Similarly, incentives and contracting strategies also overlap with each other. Although, emphasising individual enablers is important as they can indicate critical areas with the highest potential to support PCC and Health Promotion implementation.

Figure 1



338x190mm (96 x 96 DPI)

Figure 2



338x190mm (96 x 96 DPI)