Section Two

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The 'Background' section of the thesis embraces two major parts: a background on quality and quality-initiatives. The first part provides a deeper perspective and support for major the content we have placed into the 'Introduction & Objectives', and that defines the context or scenario for the further development of this thesis. The second part specifically refers to the approaches for reviewing the literature, mostly those that can provide support for the options we shall make and turn explicit in the further 'Methods' section. In synthesis, the following sub-sections might be able to serve as background and support to the definitions and the developmental process of our thesis.

A- BACKGROUND ON QUALITY AND QUALITY-INITIATIVES

This first part about the quality and quality-initiatives refers to the underlying history, frameworks, major paradigms, concepts, and developments regarding healthcare quality and quality-initiatives in most recent years, particularly as applied to the context of United States of America, and later specified for the US PAC Rehabilitation system.

1 – The Basis of Quality and the Quality-Movement in Healthcare

We begin to overview the basis of quality and the quality-movement applied to healthcare.

1.1 The quality-movement coming to Healthcare

Quality of products and services represent a major concern for those responsible producing/delivering products or services, as well as for those consuming products or receiving services. The quality-movement, as a management strategy, was initially developed and implemented in manufacturing industry ('Toyota' manufacturing is an example often evoked), and only then it gained importance as applied to healthcare [1; 2]. Although similarities exist and some models are imported and adapted from manufacturing or aviation industries, the scope of quality is not exactly the same for healthcare as for other industries. The quality-movement in healthcare shall be adapted to its unique socio-technical characteristics [3].

There is plenty of evidence that healthcare quality falls short and that healthcare systems can clearly do better. But simply knowing that has not been enough to address the current quality gaps [3; 4]. However, although being a problem for many years, only over the last decade the issue of quality and quality-initiatives gained political momentum for large-scale transformational reforms in healthcare systems, as we begin to introduce in this thesis.

Program developers, policy-makers, healthcare managers, and practitioners continually express a need for defining and measuring quality so that better services can be developed, better quality of care delivered, and quality-initiatives can be evaluated on its impact [5; 6]. But in terms of quality definition, although many different definitions could be found in the literature, they do not differ so much into their major scope [5]. Therefore, healthcare quality can be generally defined as the match between clinical practice and the criteria-standards highlighted by the state-of-the-science, or at least by consensual best-practices, responding to the needs, values and preferences of patients and families [5; 7].

1.2 Quality-conceptualization in healthcare: Structure-Process-Outcomes (SPO) as a widely recognized model

Avedis Donabedian was, for decades, the major active developer of the conceptualization of quality and quality-initiatives in healthcare. For instance, his seminal SPO model for quality-conceptualization had, and still has, multiple healthcare applications, being commonly recognized by a wide range of stakeholders working in the field [8].

Donabedian first described the triad of structure, process and outcome in 1966, and in 1988 he outlines the model as applied to quality-assessment [7; 9]. The 3 key components of the model, as defined by him-self, are the following [9].

- Structure of care: refers to "the attributes of the settings in which care occurs", including material resources, human resources, and organizational structure.
- Process of care: refers to "what is actually done in giving and receiving care", including the providers' and the patients' activities in delivering or receiving care, the content of care (i.e. types of treatments), and how the care is delivered (e.g. frequency/duration of visits and the nature of the patient-provider interaction).
- Outcomes of care: refer to "the effects of care on the health-status of patients and populations", including improvements in patients' knowledge, beneficial changes in the patient's behavior and their satisfaction with care, as finally the effects on healthcare utilization.

A critical feature of the SPO model remain in the acknowledgment that structural and process elements can only become considered as quality-indicators if directly or indirectly related with desired outcomes of care, otherwise these processes and structures cannot be considered as quality-indicators.

Despite organizing the quality of care into structural, process or outcomes indicators, the SPO model further acknowledges that the healthcare process accomplishes two different but inter-related dimensions: the technical and the interpersonal dimensions of care.

More recently, in an action-oriented perspective, the US Institute of Medicine (IOM) launched a framework for quality that has been widely used to support quality-conceptualizations and mostly defining targets for quality-improvement initiatives. The IOM highlights a six-component framework for quality, including the following elements: safeness, effectiveness, efficiency, patient-centeredness, timeliness and equity [3]. The landmark 'quality chasm' report in the origins of these six-components will be largely explored in a further independent section related with quality in the US. Indeed, beyond the framework such landmark 'quality chasm' report also focuses on making a set of recommendations for the improvement of the US healthcare system we will further reveal in this 'Background' section as well.

2 – The Nature of Healthcare Quality-Initiatives

Beyond quality-conceptualizations and within the quality-movement there are a set of initiatives (quality-initiatives) that try to stimulate the optimal quality of care can become operationalized into routine practice.

2.1 The nature and type of quality-initiatives

Quality-initiatives are those activities that are taken in order to establish, protect, promote, stimulate, or more directly improve the quality of services and care. There are different types of quality initiatives, labeled according to their underlying purpose [7; 10]:

- *Quality-assessment*: It refers to the evaluation of the quality of a system, services, or care, such as the evaluation of the quality of a national healthcare system, integrated healthcare systems, healthcare organizations, services or practitioners against an established criteria-standard or peer-benchmark for one, but mostly a set, of quality indicators or measures. This procedure could be generally divided into internal quality-assessment (e.g., made by the own organization) and external quality-assessment (e.g., made by an independent or external entity).
- *Quality-monitoring*: It is an equivalent to quality-assessment, but it is made over time, often in regular defined periods, tracking evolution along time, including interrupted and uninterrupted time-series analysis of quality-indicators.
- *Quality-report (public/feedback)*: It refers to the act of reveal data from quality-assessment and quality-monitoring activities. It could be made using gross data but mostly aggregated or synthesized data in multiple forms to facilitate meaningful benchmark and public consultation from the stakeholders. Indeed, quality-data could be exclusively sent-back to providers, but it has gaining an increasing importance the public-release of this kind of comparative quality-data as a way towards informing consumers' and purchasers' choices for systems, providers and practitioners - a critical step to the advancement of the quality-movement.

- *Quality-improvement*: It refers to a wide range of activities, cycles or journeys promoted to enhance actual performance in quality-measures or indicators as applied to systems, organizations or practitioners.

  Broadly defined, it can also incorporate those activities that aim to implement research findings into practice; as well as activities occurring at the macro-system level or at the external-environment that aims to stimulate or facilitate the optimal quality of systems, services, and care. Thus, it might include the implementation of interoperable electronic infrastructures, the external action of quality-improvement organizations, and the introduction of quality-aligned payment mechanisms.
- *Quality-assurance*: It generally refers to a whole system, cycle or spiral that included the above mentioned quality-initiatives. It is often labeled as continuous quality-improvement (CQI).

2.2 Quality Assessment/Monitoring and Public and Feedback-report

Quality-assessment is the initial and a crucial step for a system of quality-initiative because the ultimate effectiveness of the subsequent quality-initiatives is dependent on the validity, reliability, comprehensiveness, comparability and meaningfulness of the quality-assessment system and procedures, meaning the type and accuracy of data collected and underlying quality-indicators used. There are structural, process, and outcomes-based quality-indicators or measures.

The quality-indicators or measures that relate with the structure of care, or structural quality indicators, assure the optimized organizational requirements, procedures, and conditions for healthcare services and practices to be delivered with high quality at the healthcare frontlines. But, as theory and practice has been denoting, the structural quality-indicators are those less directly related with best outcomes achievement [(7)]. Thus, structural quality-indicators should be complemented by process and outcomes-based healthcare quality-indicators.

The field of quality assessment/monitoring has been evolving over the last years. Thus, the development of quality-measures and indicators received an enormous development, exponentially augmenting the portfolio of existing/available quality-measures for different areas, levels, or conditions addressed by healthcare activity. While such an expansion raises

the potential for a more comprehensive quality-assessment, it also creates obstacles for comparing quality-measures or indicators if they are not uniformly used into quality-assessment or monitoring procedures across practitioners, settings, or systems. Indeed, there is a current great interest for achieving uniformity in the field of quality-assessment/monitoring and public/feedback-report, facilitating comparability across system and providers that is only possible using the same indicators and measurement process [(11)].

Within the movement for uniformization of quality-indicators, a non-for-profit organization in the US – National Quality Forum (www.qualityforum.org) – was precisely created with the aims of developing a consensus-building process towards endorsing quality-measures/indicators for uniform appliance into the healthcare field.

2.3 Quality-Improvement (QI) Overview

Improving the healthcare quality remains as the ultimate aim of the quality movement. Indeed, it only makes sense to measure/monitor, or to make a public/feedback-report of quality information, if the identified quality gaps are then complemented by QI initiatives.

The simple act monitoring and public/feedback-reporting quality information can it-self represent a stimulus for QI, due the attentiveness and efforts organizations and providers automatically direct towards the aspects of services and care that are measured by quality-indicators. But if only few, narrow, indicators were used to measure the healthcare quality, it can lead to 'unintended consequences' or compensatory decrease – or at least non-improvement - in the quality for those qualitative and comprehensive aspects of healthcare quality that remain non-measured by quality-initiatives or non-covered by quality-aligned payment approaches [(12; 13; 14; 15)].

One of the most recognizable facets of QI is the one directed to close the 'gap' among solid evidence or research knowledge and what is actually done in the routine practice. Such QI issue is known as translation and implementation of research findings and innovations into practice. Indeed, the translational, improvement, and implementation field have been receiving great attention over the last years, being gradually supported by a body of knowledge broadly called as improvement science, or more specifically as implementation science, the latter specifically focusing on effectivelly putting evidence at the bedside [(16; 17)].

There are plenty of QI programs, projects, intervention, initiatives, and techniques available that were previously successfully applied in the healthcare field. Examples of it could be found for instance in the Institute for Healthcare Improvement website (www.ihi.com) under the label of "Improvement Map" – an organized portfolio of improvement initiatives.

However, the examples of QI activities do not represent solutions of the kind 'one size fits all', neither it results in all settings and all conditions in which they are implemented in the exact same way or using the exact same prescription or protocol [(18)]. They are initiatives targeting healthcare complex social systems [(19)], so iterative adaptations to these complex socio-technical systems are required for the success of any QI initiative that represents a change in the way care is delivered, thereby in underlying providers' habits and behaviors [(20)].

QI initiatives are often applied under the form of Plan-Do-Study-Act (PDSA) cycles that allow for the iterative adaptations and on-going adjustments accordingly to signs and data from early implementation efforts. The PDSA cycle assumes the actual form and label under the work of Deming after evolutionary changes [(21)]. Such a PDSA cycle is still today a major underlying process for the development of specific QI interventions [(10)].

2.4 Overview quality-assurance at the organization level: The Accreditation Process

Healthcare organizations shall promote their own quality-assurance or continuous quality-improvement (CQI) systems (later highlighted in total quality management section) as part of their management strategy, for instance operationalized in multiple PDSA cycles. Continuous improvement cycles are supported by performance/quality-measurement systems internally and externally promoted. Organizational quality-assurance is for instance externally promoted by the accreditation process of different accreditation entities.

The accreditation process generally contemplates the assessment of structural quality and performance indicators of organizations against evolving quality and safety standards established by the accreditation entity. The accreditation process also include recommendations for improvement that healthcare organizations should comply with in order to receive, maintain or enhance grades in the attributed status of accreditation [(22)].

In the United States, the most representative accreditation entity is The Joint Commission (TJC) which also has an international implementation with the label of The Joint Commission International, providing accreditation of many types of healthcare facilities and certification of specific programs (www.jointcommission.org).

Traditionally, accreditation was focused on structural and organizational indicators of quality and safety, but it was progressively felt the need to evolve to a more clinically-related performance measurement using process and outcomes as quality-indicators as well. Indeed, performance measurement, and the uniform use of quality-indicators and measures, are among the current major developments of the action of the TJC [(23)], in close collaboration with other external quality-measurement stakeholders, including the US National Quality Forum and the public US Center of Medicare and Medicaid Services (CMS), the latter being the major US single-payer and regulator.

In Europe, a major accreditation entity covering the aspects of organizational management for quality - applied to healthcare [(24; 25; 26)] among other industries - is the European Foundation for Quality Management, often recognized by the acronym EFQM (www.efqm.org).

The EQFM accreditation process is based in the 'Excellence Model' guided by the following fundamental concepts: achieving balanced results; adding value for customers; leading with vision, inspiration and integrity; managing by processes; succeeding through people; nurturing creativity and innovation; building partnerships; and taking responsibility for a sustainable future.

In the field of Rehabilitation, the process of accreditation by the Commission on the Accreditation of Rehabilitation Facilities (CARF; US and international) is the most common in the field. CARF (www.carf.org) accredits organizations and services in the field of health and human service such as: the rehabilitation for a disability, treatment for addiction and substance abuse, home and community services, retirement living, or other health and human services with a plenty of differentiated accreditation programs.

CARF uses its own-framework for quality-improvement called as the 'ASPIRE to excellence'. ASPIRE is the acronym to action-oriented steps for an organizational quality-roadmap. This is to: Assess the environment; Set strategy; Person's served and stakeholders – obtain input; Implement the plan; Review the results; and Effect change.

Obviously, despite the differences in the organizational approach, there are great similarities among the different accreditation processes, steps, underlying frameworks and managerial models for the organizational quality-management. In synthesis, all the presented accreditation frameworks present major guiding principles directing healthcare organizations to produce or bring the best-value for their stakeholders, mostly through a concerted set of planned processes, iterative and interactive, which should be tailored to the specific organizational context and involved stakeholders.

3- Quality-Improvement (QI) Approaches and Evolution of QI Paradigms

QI is a relatively new field in healthcare. Nonetheless, there is yet a history of paradigms evolution that may classified into four different paradigms [27]:

- Passive diffusion;
- Guidelines and systematic reviews;
- Industrial-style (business-imported) QI management;
- Systems re-engineering.

Despite the systems re-engineering is the more recent paradigm for QI - at least for healthcare systems – the paradigms can coexist since these different paradigms address different, complementary, levels for QI [27].

For instance the systematic review and clinical guidelines can be directed to enhance the quality of clinical care action at the micro-system level. The industrial-style QI approaches mostly address the quality from a managerial and organizational level or perspective. Finally, the system-reengineering can be applied to and across the micro; meso and macro/organizational and external-healthcare levels for QI [28; 29; 30].

3.1 Passive Diffusion

Few years ago, it was assumed that clinicians would naturally implement new clinical research published, which represents a passive diffusion view. In this paradigm, the only

acknowledged impediment to the flow of evidence from the pages of medical journals to the minds of practitioners could be the sheer volume of information and variation in its quality. Advocates of evidence-based medicine (EBM) promoted, therefore, the adoption of systematic reading habits and the acquisition of basic skills in appraising research articles.

It was a particularly optimistic phase with evident shortcomings (lack of providers' time and the far greater complexity of factors changing providers' behavior not considered) undermining the effectiveness of these strategies when applied alone. Indeed, these strategies can show low influence in positively shaping the behaviors of the great majority of practitioners in the field, if not supported by additional efforts [16; 20].

3.2 Guidelines and systematic reviews

In this second phase, it was realized that even with more judicious reading habits, evidence-based and critical appraisal skills, for instance developed through participation into journal-clubs, a variety of factors prevented clinicians from acquiring evidence into a reliable and timely fashion. Systematic reviews of the evidence and clinical practice guidelines would, therefore, identify and synthesize studies supporting important clinical decisions, accompanied by graded recommendations for practitioners [31].

The establishment of practice guidelines not always was able to change regular practice. This is due a combination of factors that involved the continued reliance on passive diffusion strategies and other factors receiving only limited study, such as: the professional's disagreement with the content of guidelines, which show wide variations in methodological quality and quickly become out-of-date; the personal characteristics of providers, for example the resistance to perceived infringements on physician autonomy; the low consideration of patients' preferences or other differences on their development; and finally some logistic or financial barriers to a feasible implementation of guidelines [32].

3.3 Industrial-style (business-imported) quality management

Industrial-style QI has appliance to the managerial activity of healthcare organizations and services. Those managerial QI approaches are business-imported (e.g., manufacturing,

aviation) and applied to the healthcare field, although not always considering the complex socio-technical characteristics of healthcare that differ from other industries [7].

Below, we describe the Total Quality Management (TQM) approach, as well as other more industrial-style management approaches - more specific than the generalist TQM - applied to healthcare QI. These more specific approaches are the lean thinking; six-sigma; and a combination of both called lean-six-sigma.

3.3.1 TQM/CQI:

A major overarching quality managerial approach is the Total Quality Management (TQM) approach, often operational through a Continuous Quality Improvement (CQI) approach, becoming a concept particularly popular in the 90s [27; 33], and the major focus of activity from quality management accreditation entities, such as the EFQM already outlined.

We refer to TQM/CQI as an overarching framework since it refers more to a set of overarching action-principles which can achieve a wide array of operationalizations under the same label, which brings great difficult to assess the effectiveness of something that assumes varied forms of application [34]. It also seems obvious that the success of implementation depends crucially on the interaction between the local context and the approach - one of the major conclusions of a systematic review made over this subject [35].

TQM has origins in manufacturing industry, but particularly in the 90s it was applied in the healthcare field as well. It represents a set of management principles that reflects practices geared to ensure the organization consistently meets, or exceeds, client-requirements and satisfaction. TQM seats strong focus on process dimension and controls as means of incessant improvement, integrating all quality-related functions and processes all the way through the organization levels of activity, as well as including all organizational levels and professionals - from management to front-line staff - into the process [36].

Core concepts for implementing TQM refer to set of management practices which are guided by the following principles [36; 37] :

- Executive Management – Top management should act as the main driver for TQM and create an environment ensuring its accomplishment.
- Training – Employees should accept regular training on the methods and concepts regarding quality.

- Customer Focus – Improvements in quality should be reflected into improvements into customer received services, experience and satisfaction.
- Decision Making – Quality decisions should be made based on capacity.
- Methodology and Tools – Use of suitable methodology and tools ensures that non-conformances are identified, deliberated, and addressed consistently.
- Continuous Improvement – Organization should incessantly work towards improving performance.
- Organizational Culture – The culture of the organization should aim at increasing employees' ability to work mutually to improve quality.
- Employee Involvement – Employees should be confident to be pro-active in identifying and addressing quality related problems.

Among the different practical approaches and tools which can be used within these overarching principles, the most recognizable is the yet highlighted PDSA cycle, still a 'gold-standard' for quality-improvement interventions; as well the 'root-cause analyses' that has been particularly applied to safety issues. This is in order to retrospectively identify the causes and the 'causes of causes' in the origin of the safety failure. These causes might be eliminated or at least mitigated to avoid similar failures [38; 39].

3.3.2 Lean Thinking

Lean thinking was pioneered by 'Toyota Corporation' with an emphasis on standardization with various tools to optimize process and productivity**.** Since its introduction, the understanding of lean has changed considerably. For instance, Hines and colleagues used the stages of organizational learning to demonstrate such evolution [40]. Evolution was speed up by the description of Womack & Jones' five (operational) principles [41]:

- Principle 1: Provide the value customers actually desire;
- Principle 2: Identify the value stream and eliminate waste;
- Principle 3: Line up the remaining steps to create continuous flow;
- Principle 4: Pull production based on customers' consumption;
- Principle 5: Start over in a pursuit of perfection, meaning 'the happy situation of perfect value provided with zero waste'.

The key concept in lean thinking is 'value'. Value is defined as the capability to deliver exactly the (tailored) product or service a customer wants, with minimal time between the

moment the customer asks for that product or service and the actual delivery, and finally making all that process at an appropriate price [41]. By defining 'what customers want', process-steps can be divided in value-adding and non-value adding. Value adding activities contribute directly to create a product or service a customer wants. Non-value adding activities can be seen as waste. Obviously, waste is to be removed or avoided.

Application of standard organizing tools seems reasonably straightforward and they are discussed in most papers specifically addressing the lean thinking approach [41]. By using these principles and tools, hospitals have for instance reduced waste in inventory, reduced waiting times, and improved productivity [1; 42].

At the operational level, improvements are mainly achieved by reducing unwanted variation into productive processes. Indeed, artificial variability (in contrast to natural variability) is related to controllable factors in the design and management of healthcare systems which, once adequately managed, increase productivity and reduce waste [1; 43].

Lean emphasizes a systemic, holistic view of process improvement. Application of lean thinking may initially focus on improving a single process (e.g., clinical department), but needs to be rapidly diffused into the total value system otherwise problems are not completely solved and will occur elsewhere in the system. This is congruent with a systems reengineering paradigm we will foster later.

One possible limitation being pointed to lean thinking, as applied to healthcare, is that standardization makes jobs more simple and repetitive. These jobs may no longer be challenging to highly trained, smart, and reasoning healthcare professionals. However, with critical socio-technical principles embedded into the lean thinking, this reduced complexity might turn some easier tasks executed by less skilled professionals, thus freeing-up physicians' time to deal with the more complicated and complex aspects for a highly individualized patient care. This simple example shows that, without taking into account these dynamics - and the redesign of responsibilities as well - lean interventions can easily have negative effects on job characteristics and satifaction [44].

Despite some practical considerations need to be resolved, it has been applied successfully in a wide variety of healthcare settings. But while lean theory emphasizes a holistic view, most cases report narrower technical applications with limited organizational reach, outlining the need for more fully engaged implementations [45]. Indeed, one of the

difficulties of applying lean thinking to healthcare is the wide difference in the underlying meaning of the healthcare 'value' term. It may justify much of the narrowly applied interventions seen in many healthcare settings [46].

3.3.3 Six Sigma

Six Sigma is a fact-based, data-driven, philosophy of quality-improvement that values defect prevention over defect detection. It drives customer satisfaction and bottom-line results by reducing variation and waste, thereby promoting a competitive advantage. It applies anywhere variation and waste exist, and every employee should be involved into the process. In numerical terms, Six Sigma quality performance means no more than 3.4 defects per million opportunities. Several different definitions have been proposed for Six Sigma, but they all share some common themes [2]:

- Use of teams that are assigned to well-defined projects that have direct impact on the bottom-line performance of the organization.
- Training in "statistical thinking" at all levels and providing key-people with extensive training in advanced statistics and project management. These key people are designated black belts, while there are more basic belts, levels and roles in applying Six Sigma as well.
- Emphasis on the DMAIC approach (define, measure, analyze, improve and control) to engage into problem-solving.
- A management environment that supports these initiatives as a business strategy.

Despite common themes, there are differing perspectives for the Six Sigma definition [47]:

- Six Sigma is a philosophy. This perspective views all work as processes that can be defined, measured, analyzed, improved and controlled. Processes require inputs (x) and produce outputs (y). If you control the inputs, you will control the outputs: This is generally expressed as $y = f(x)$.
- Six Sigma is a set of tools. The Six Sigma expert uses qualitative and quantitative techniques to drive the improvement process. These tools include statistical process control (SPC), control charts, failure mode, effects analysis and flowcharting.
- Six Sigma is a methodology. This view of Six Sigma recognizes the underlying and rigorous approach. For instance the DMAIC method defines the steps a Six

Sigma practitioner is expected to follow, starting with identifying the problem and ending with the implementation of long-lasting solutions. While DMAIC is not the only Six Sigma methodology in use, it is certainly the most widely adopted and recognized.

Being mostly a data-drive approach, the organizational culture should be considered as part of the decision about using Six Sigma. If the institution has a history of making data-driven decisions, or at least has openness to operate in that manner, Six Sigma could be a valid option. Six Sigma compares baseline or historical data with data obtained after implementation of Six Sigma-driven changes in order to determine if desired changes in performance have been achieved. A Six Sigma project requires a major expenditure of money and employees' time, and a willingness to make some hard decisions about jobs, employee retention, and relationships among stakeholders. Like any approach or method, the results of using it are highly dependent on whether it is used with competence, on the right problem, with the right context-framing [48].

3.3.4 Lean Six Sigma in healthcare

Principles of Lean Thinking and Six Sigma can be combined to provide an effective framework for producing systematic innovation. Indeed, these quality management approaches are more complementary than mutually exclusive, with practice examples of gains for quality, safety, timeliness, and efficiency in healthcare provision [49; 50; 51; 52]

3.4 Systems re-engineering

Systems re-engineering is the more recent paradigm applied to healthcare improvement. It is based on a 'systems thinking' perspective, applied to the (re-)design of healthcare delivery systems across ecological levels [27; 28; 30].

3.4.1 The systems thinking evolution in healthcare

The systems thinking is an approach to problem solving which views 'problems' as part of a wider dynamic system. The systems thinking involves much more than a reaction to present outcomes or events. It demands a deeper understanding of the linkages, relationships, interactions and behaviors among the elements that characterize the entire

system. Commonly used in other sectors where interventions and systems are complex, the systems thinking in the healthcare sector shifts the focus to:

- The nature of relationships among the building blocks;
- The spaces between the blocks and understanding what of happens there;
- The synergies emerging from interactions among blocks;

The application of systems thinking in the health sector is accelerating a more realistic understanding of what works, for whom, and under what circumstances [53; 54].

System thinking has its origins in the early 20th century in fields as diverse as engineering, economics, and ecology. With the increasing emergence of complexity perspectives, these and other non-health disciplines developed systems thinking to understand and appreciate the relationships within any given system, and in designing and evaluating system-level interventions [55; 56; 57; 58; 59].

In recent years, the health sector has started to adopt a systems thinking perspective to tackle complex sector problems such as tobacco control [53] and obesity [60]. However few have tried to implement these concepts beyond single issues within the health system itself, as well as few initiatives described how to move from theory to practice: perhaps due to the seemingly overwhelming complexity of health and healthcare systems [57].

Despite potential barriers to its implementation, systems thinking is for instance called as the major rationale for the great problems health systems needs to address, such as reflected in the landmark 'quality chasm' report [3].

3.4.2 Common characteristics of the systems

Particularly when taken together, the systems common characteristics (self-organizing, constantly changing, tightly linked, governed by feedback, non-linear, history dependent, counter-intuitive and resistant to change) influence how systems, including health systems, respond to external factors or to an intervention. Such definition of "system" is described in the literature as a "complex adaptive system" – one that self-organizes, adapts and evolves with time. "Complexity" arises from a system's interconnected parts, and "adaptability" from its ability to communicate and change based on experience and new context/information [53; 61].

We describe below each of the common characteristics of the systems [62, 63]:

Self-organizing. System dynamics arise spontaneously from internal structure. No individual agent or element determines the nature of the system – the organization of a system arises through the dynamic interaction among the system's agents, and through the system's interaction with other systems. Dynamics of health systems are shaped by the multiple and complex interactions among the blocks – and not by the behavior of any block alone.

Constantly changing. Systems adjust and readjust at many interactive time scales. Change is a constant in all sustainable systems. Indeed, systems that do not change ultimately collapse since they are part of wider systems that do change. As systems are adaptive rather than static, they have the ability to generate their own behavior; to react differently to the same inputs in unpredictable ways; and to evolve in varying ways through interconnections with other parts of the system (which in turn are constantly changing). This element of change and adaptation often poses particular and often hidden challenges in evaluating or understanding discrete health systems interventions. Given those constant interactions and the impossibility of freezing individual dynamics, interventions and their effects can hardly be fully understood or effectively measured in isolation from other building blocks.

Thickly linked. The high degree of connectivity means that change in one sub-system affects the others. Related to the characteristic of change and adaptation is the notion that any intervention targeting one building block will have certain effects (positive and negative) on other building blocks. Without a systematic framework to consider possible major synergies (or negative emergent behavior), the less obvious effects of an intervention may be missed, either at the design or evaluation phase.

Governed by feedback. A positive or negative response may alter the intervention or expected effects. Systems are controlled by "feedback loops" providing information flows on the state of the system, moderating behavior as elements react and "back-react" on each other, requiring design of mechanisms of monitoring effects over time.

Non-linearity. Relationships within a system cannot be arranged along a simple input-output line. System-level interventions are typically non-linear and unpredictable, with their effects often disproportional or distantly related to the original actions and intentions. For instance, interventions to increase quality of care are likely to succeed initially, but as skills

reach a certain level, or caseloads increase beyond what health workers will accept, the enhancing effects of the intervention may flatten or actually decrease over time [56; 63].

History dependent. Short-term effects of interventions may differ from long-term effects. Time delays are under-appreciated forces affecting systems. For example, interventions designed to change people's behavior require measuring the intervention effects over a longer period to avoid making incorrect conclusions of no or limited intervention effects.

Counter-intuitive. Cause and effect are often distant in time and space, defining solutions that put causes close to the effects they seek to address. Some apparently simple and effective interventions may not work in some settings – while functioning perfectly well in others, mostly due the differences in complex interaction patterns among systems.

Resistant to change. Seemingly obvious solutions may fail or worsen the situation. Given system characteristics, and the complexity of their many interactions, it is sometimes difficult to develop an *a priori* effective policy without a highly astute understanding of the system. System characteristics can render the system "policy resistant," particularly when all of the actors within a system have their own, often competing, goals [63].

3.4.3 Systems thinking skills: a requisite for a paradigm shift

There is a need for a radical shift in the way interventions are designed and in the way health systems are evaluated, moving from a usually described linear input-output-outcome impact or chains of effect for a systems thinking approach [62]. This is along with a shift in mindset among designers, implementers, and funders of health-related initiatives.

Richmond [58], describes such kind of skills with a focus on the way of thinking: dynamic (instead of static), system-as-a-cause and understanding how behavior is generated (instead of system-as-effect or correlated factors), forest thinking (instead of tree-by-tree), and loop and on-going process thinking (instead of straight-line thinking and closed-time events).

3.4.4 Interventions design: system-wide effects and system-level interventions

All the health interventions have system-level effects to a greater or lesser degree in one or more of the system's building blocks. Many may be relatively simple interventions or incremental changes to existing interventions – e.g. adding vitamin A supplementation to routine vaccination – and not all interventions will benefit from, or need, a systems thinking

framing. However more complex interventions – e.g. the scaling-up of antiretroviral therapy – can be expected to have profound effects across the system especially in weaker health systems [64]. Thus, they require a systems thinking approach to illuminate the full range of effects, positive and negative, and the potential synergies to take benefit of in the development and implementation of the approach.

"Systems-level interventions" target one or multiple systems' building blocks directly or generically (e.g. human resources for health), rather than a health problem specifically. Given their effects on other building blocks, "system- level interventions" strongly benefit from a systems thinking approach. For instance, a financing instrument such as paying-for-performance is a "system-level intervention" as it will affect almost all other building blocks of the health system positively or negatively depending on the details, as well as different dimensions of healthcare quality.

A systems thinking perspective around payment schemas will for example present: governance challenges around the accountability and transparency concerning bonus payments dispensed to staff in health facilities; affect the information system in tracking and reconciling the conditions triggering payments; influence service delivery by stimulating behavior change, increasing utilization, or possibly crowding-out other services. It might potentially avoid conflict with other financing modalities, as well as shape organizational human resources policies.

A systems thinking approach will help to anticipate and mitigate such effects when developing interventions, as well as harnessing unexpected synergies by modifying the interventions. This, then, provides the basis for understanding how to measure them by better designed and more comprehensive evaluations [14; 65].

3.4.5 Intervening at high leverage points in the system

A health system, as with any adaptive system, is vulnerable to certain leverage or "tipping" points at which an apparently small intervention can result in substantial system-wide change in positive, but also negative spirals. From the positive side, interactions could be managed in a way that leads to synergies. However, it is often difficult to identify such leverage points, and there is no easy formula [66].

A summary of interventions in other (non-health) systems suggests that high leverage points are located in two sub-systems – governance and information [66]. These are two health system's building blocks receiving less attention from health system interventionists. Indeed, missing information flows are often identified as the most common cause of system malfunction [63], and incapable or overstretched governance structures can contribute to less than optimal performance and cohesion among the building blocks.

3.4.6 Evaluation design: systems-based planned evaluations

The conventional evaluation of inputs, outcomes and impacts often fails to illuminate the key determinants and contexts that explain overall success or create particular difficulties. Funders and programs seeking to understand and evaluate their investments and inputs tend to focus on disease and mortality impacts. As a result, they often neglect the wider health system synergies and emergent behavior that might, in the end, be more instructive in terms of the systems strengthening necessary to achieve health goals. These approaches to evaluation often inhibit the broader systems perspective and a fuller understanding of how interventions do or do not work, for whom, and under what conditions.

The systems thinking approach goes beyond this "input-blackbox-output" paradigm to one that considers inputs, outputs, initial, intermediate and eventual outcomes, and feedback, processes, flows, control and contexts [53]. Given that all evaluations are necessary simplifications of real-world complexity, systems thinking helps to determine how much and where to simplify these evaluations. A systems thinking approach can connect intervention design and evaluation more explicitly, both to each other and to the health system framework – though it should be added that not all interventions require evaluation or evaluation with a systems thinking lens [63].

3.4.7 Stakeholders networks

Stakeholders are at the centre of system, as mediators and beneficiaries, but also are active agents driving the system it-self influencing each of the building blocks, as health workers, managers, policymakers, as well as consumers. The function as a network is highlighted by how changes in one stakeholder of the system influence the others and the system overall. Inter-disciplinary expertise and multi-stakeholder involvement is central to this process and cannot be neglected, especially for health systems research [19].

4- United States (US) Healthcare System: A Quality Journey and underlying Frameworks

The context of application of our study is the US health/healthcare system, thus we felt the need to develop a background review among the American's healthcare quality context and status. We particularly put an emphasis into the two landmark quality and safety reports (safety is to be included into a broader quality definition) released by the Institute of Medicine about a decade ago. Finally, we will outline the current political priorities and strategic action being designed or taken for the whole nation with quality and quality-initiatives regards.

4.1 Quality falls short in the US Health and Healthcare System

America spends per capita in healthcare more than in any other industrialized country in the world. Despite that fact - and the leading position in biomedical research - we have data showing the America's health is far from the top in health-status and quality of healthcare. It happens fundamentally due [3; 67; 4; 68]:

- Service supply and care patterns illogically varying among providers and territory;
- Inequity in coverage and access to health services with high number of non- or low-insured people;
- Low emphasis on primary/ preventive care and health promotion for the mainstream of citizens;
- Americans' behavioral patterns: sedentary lifestyle and unhealthy feeding behaviors;
- The so-called American's fragmentation of the market-based healthcare delivering systems.
- The called "collective inattention" to quality in last decades, particularly at the systems levels.

These summarized factors are common societal concerns and current political priorities for the quality of healthcare, as well as the health of the communities. However, quality is a

major concern and opportunity for economic reasons as well. America per-capita healthcare costs are rising clearly above the economic growth and much more than other societal sectors. Healthcare spending accounts for 16 percent of the gross domestic product and it is increasing at an average annual rate around 7 percent [68; 69].

Therefore, improving the quality of the healthcare system - including prevention and enlarged coverage – are the America's top priorities reflected in the most recent US healthcare reform [70]. In a matter of efficiency, a high quality system can save an important amount of resources – it is estimated a waste of 30% of total healthcare costs [71] - that can help to ensure healthcare coverage for those patients underserved or non-insured [70; 72; 73].

In America, there is a quality-era before and after two landmark reports released by the Institute of Medicine (IOM). It does not mean there was no knowledge about safety and quality problems before, but that these reports triggered a new wave of public interest and sense of stakeholders' urgency to address these daunting issues. In synthesis, the reports putted quality in the US healthcare and overall societal agenda.

4.2 'To Err is Human' report on patient safety

In 1999, the American's Institute of Medicine (IOM) released the first of a series of two landmark reports. The first was entitled as *To Err is Human: Building a Safer Health System*. It concluded that tens of thousands of Americans die each year as a result of preventable mistakes in their care, the report lays out a comprehensive strategy by which government, healthcare providers, industry, and consumers can reduce medical errors and subsequent harm [38].

According to the report, safety flaws are unacceptably common, but the effective remedy is not to browbeat the healthcare workforce by asking them to try harder to give safer care. Members of the healthcare workforce are already trying hard to do their jobs well. In fact, the courage, hard work, and commitment of doctors, nurses, and other professional in healthcare were at that time the only real means for stemming the flood of errors that are latent in US healthcare.

The report advocates that safety should be a system property rather than exclusively relying on human factors. Poor designs set the workforce up to fail, regardless of how hard they

try. The report try not to blame worthy clinicians but rather the systemic factors such as unrealistic reliance on human memory, poor communication systems, unrealistic demands on human vigilance, too little respect for the consequences of fatigue, and reliance on handwriting in the computer age. Safer care will require redesigned systems of care, so safety becomes a systems property.

4.3 'Quality Chasm' report, recommendations and framework:

The second report, *Crossing the Quality Chasm: A New Health System for the 21st Century*, released in 2001, which builds over its precedent, also advocates that quality should be a system property, but widens the scope of definition from safeness to a broader perspective of quality in which safeness is just one of its components [(3)], which is the perspective of quality we were based on across this thesis. The report focuses more broadly on how the health-system can be reinvented to foster innovation and improve the delivery of care. Toward this goal, the IOM presents a comprehensive strategy and action plan to the following years.

Accordingly to the report, quality-advances must begin with all healthcare elements - health professionals, federal and state policy-makers, public and private purchasers of care, regulators, managers, governing boards, and consumers - committing to a national statement of purpose for the quality of the healthcare system as a whole.

4.3.1 Aims for quality and quality-improvement (the IOM quality framework)

The parties would adopt a shared vision around six specific aims for improvement, widely recognizable after the report was released. Thus, a health system should provide care that is:

- *Safe*: avoiding injuries and harm to patients from the care that is intended to help them.
- *Effective*: providing services based on scientific knowledge to all people who could benefit from it, and refraining from providing services to those not likely to benefit from it.

- *Patient-centered*: providing care that is respectful of, and responsive to, individual patient preferences, needs, and values, and ensuring that patient values guide all clinical decisions.
- *Timely*: reducing waits and sometimes harmful delays for both those who receive and those who give care.
- *Efficient*: avoiding and eliminating waste, including waste of equipment, supplies, intelligence, and energy.
- *Equitable*: providing care that does not vary in quality because of personal characteristics such as gender, ethnicity, geographic location, and socioeconomic status.

These different aims make part of a whole, indivisible, quality-concept. Indeed, a healthcare system that achieved major gains in these six dimensions would be far better at meeting patient needs. Patients would experience care that is safer, more reliable, more responsive, more integrated, and more available. Patients could count on receiving the full array of preventive, acute, post-acute and chronic services from which they are likely to benefit. Such a system would also be better for clinicians and others who would experience the satisfaction of providing care that is effective, more responsive to patients, and more coordinated. The entire enterprise of care would ideally be united across these aims by a single, overarching purpose for the American healthcare system as a whole.

4.3.2 Simple Rules for Systems Redesign

The IOM believes it would be neither useful nor possible to specify in detail the design of 21st-century healthcare delivery systems. Valuable pluralism abounds at the local level in the US healthcare enterprise. At the same time, a local pluralism would benefit from a common set of simple rules to guide the redesign of the healthcare system. These rules, substituting the prevailing ones, are the following [28]:

1. New: *Care is based on continuous healing relationships*. Replaced: *Care is primarily based on visits*.

   Patients should receive care whenever they need it and in many forms, being responsive to their needs, and not just constituted by face-to-face visits.

2. New: *Care is customized according to patient needs and values*. Replaced: *Professional autonomy drives variability*.

The system should be designed to meet the most common types of needs, but should have the capability to respond to individual patient choices, values, and preferences.

3. New: *The patient is the source of control*. Replaced: *Professionals control care*.

Patients should be given the necessary information and opportunity to exercise the degree of control they choose over healthcare decisions that affect them. The system should be able to accommodate differences in patient preferences and encouraging shared decision making.

4. New: *Knowledge is shared and information flows freely*. Replaced: *Information is a professional record*.

Patients should have unfettered access to their own medical information and to clinical knowledge. Clinicians and patients should communicate effectively and share information.

5. New: *Decision making is evidence-based*. Replaced: *Decision making is based on training and experience*.

Patients should receive care based on the best available scientific knowledge. Care should not vary illogically from clinician to clinician or from place to place.

6. New: *Safety is a system property*. Replaced: *Do not harm is an individual responsibility*.

Patients should be safe from injury caused by the care system. Reducing risk and ensuring safety require greater attention to systems that help prevent and mitigate errors.

7. New: *Transparency is necessary*. Replaced: *Secrecy is necessary*.

The system should make available to patients and their families information that enables them to make informed decisions when selecting a health plan, hospital, or clinical practice, or when choosing among alternative treatments. This should

include information describing the system's performance on safety, evidence-based practice, and patient satisfaction.

8. New: *Needs are anticipated*. Replaced: *The system reacts to needs*.

The system should anticipate patient needs, rather than simply react to events that could be prevented or anticipated.

9. New: *Waste is continuously decreased*. Replaced: *Cost reduction is sought*.

The system should not waste resources or patient time with unneeded, sub-optimal, non-effective, or even counter-productive procedures.

10. New: *Cooperation among clinicians is a priority*. Replaced: *Preference is given to professional roles over the system*.

Clinicians and institutions should actively collaborate and communicate to ensure an appropriate exchange of information and coordination of care.

4.3.3 An action-plan to activate the called transformational change for quality

The IOM report provides a series of recommendations as a part of an action-plan to follow:

Appropriate public funding on first steps to take:

To initiate a process of transformational healthcare change, public funding must be attributed to the development of foundational projects that will help to track and public-report the quality of care American's receive. Such information shall be able to be consulted by every interested stakeholder in order to drive quality-based choices for providers and quality-improvement action. Investment should be also made towards the development of projects culminating with a public-domain portfolio of programs, tools, and technologies of widespread applicability, and to help communicate the need for rapid and significant change throughout the health-system.

Changing the environment and healthcare organizations supportive role:

A fundamental change for quality will occur most rapidly in an environment in which public policy and market forces are aligned, and in which the change process is supported by an appropriate information technology infrastructure. These changes in the environmental level should stimulate for similar changes at an organizational level in their supportive role for delivering quality of care at the frontline level. Indeed, there are four major areas supporting the desired changes at the healthcare environment or external level for quality:

1) Applying evidence to healthcare delivery, as supported by national comprehensive programs supporting the implementation and translation of solid research findings to routine practice;

2) Using health information technology (HIT). HIT holds enormous potential for transforming the healthcare delivery system, having a low use in healthcare in comparison to other societal sectors. It relates with automated patient and clinical information, which different professionals from different sites treating the same patient can access and update (interoperable electronic health records); the use of electronic forms for communication among patients and professionals (e.g. e-mail), and automated systems and software acting as reminder systems, supporting evidence-based decision-making, or preventing mistakes to happen. Widespread adoption will be needed to achieving its full benefits, requiring practitioners behavioral change, considering their habits and action and what variables might be addressed when planning and implementing information technology.

3) Aligning payment policies with quality-improvement. Payers and purchasers, both public and private, need to carefully reexamine their payment policies to remove barriers that impede best quality of care and build in stronger incentives for quality-improvement. It happens by aligning payment methodologies with higher quality of care for patients of different severities. Paying for the amount of services and not for the quality and value it brings undermines any systemic quality-improvement effort. Fragmented payments also favors fragmented care, thus integrative payment solutions must enhance coordination across sites of care.

4) Preparing the workforce. Stable, trusting relationships between a patient and people providing care can be critical to healing or managing illness. Therefore, the importance of adequately preparing the workforce to make a smooth transition into a thoroughly revamped healthcare system cannot be underestimated. Evidence-based practice, the use of supportive technologies and information, and interdisciplinary team-work effectiveness are major areas to be enhanced in the healthcare workforce, either for those in-training or for senior-practitioners as part of organizational programs for workforce development or continuous education programs from professional credentialing agencies.

4.3.4 Priorities definition and involvement of stakeholders

To facilitate the envisioned transformational change for quality, initial funding must be directed to priority target-conditions. The successes and failures of these initial steps directed to prioritized condition would serve as valuable background to initiate new improvement cycles addressing other quality-improvement targets. The criteria used to choose the priorities should be related to the susceptibility of major quality and efficient impacts that could be achievable.

Given the high prevalence of chronic conditions and the widely documented variations in the costs and effectiveness of interventions directed to prevent and treat them, the report advocates these conditions represent an excellent starting-point for efforts to better define optimum care or best practices, and to design care processes to meet patient needs. Nonetheless, the involvement of multiple representative stakeholders is crucial to establish a needed commitment to the process of defining priority conditions and priority action to be taken for quality. With such regards, a set of priorities was more recently developed by the National Priorities Partnership. These will be later exposed on an independent sub-section.

4.4 Behind the ‘Quality chasm’ report: Process & Rationale

The ‘quality chasm’ report is somewhat extensive and can be hard to read, but becomes simpler if one refers to its developmental process an underlying logical framework, which

did not appear explicitly in the final report, but which was the basis of its elaboration, as highlighted elsewhere by one of the report mentors [28].

4.4.1 Underlying process for report elaboration

The report elaboration started with a roundtable process working through a helpful nosology of quality-problems, primarily using the labels overuse, underuse, and misuse as classifications of quality-defects. Misuse was the term used for failures to execute clinical care plans and procedures properly, the domain of poor quality addressed most prominently by the 'To Err Is Human' report. Overuse was the term for the use of health care resources and procedures in the absence of evidence that they could help the patients subjected to them, such as prescribing advanced antibiotics for simple infections. Underuse denoted failures to employ healthcare practices of proven benefit, such as the failure to use beta-blockers in persons with acute myocardial infarction over age of sixty-five.

Building on extensive evidence collected by the IOM committee, and its predecessors, expressed in the report references list; the committee responsible for the final elaboration of the 'quality chasm' final report evolved for a more action-oriented perspective of improvement-goals, addressing the six major quality-aims we previously addressed. The committee went beyond the technical qualities of overuse, underuse, and misuse declared by the roundtable, by tying quality-issues more closely to patients' experiences, cost, and social justice, broadening the aims for quality.

4.4.2 Underlying rationale of the report

The 'quality chasm' report is foremost based in a systems thinking perspective, and rooted in the experience of patients as the fundamental source of control and definition of quality. The latter meaning that it advocates that definitions for quality of professional work, delivery systems, organizations, and policies are made by the cascade of effects it has back to patients and families. The underlying systems-ecological framework analyzes the needed changes in American healthcare, highlighting a chain of effects, at four different levels:

- *Patients' and families*' experiences and health/healthcare-related behaviors (Level A);

Patients and families should be the major source of quality-definition and for whom quality must be directed and centered. Changes in all other levels are only quality changes if reflected on patients and families.

The same mentor of the 'quality chasm' report later published an essay highlighting the critical importance of keeping patients and families in the center position in healthcare delivery [(74)]. As an additional note, we could reveal that such author was thereafter for directing the Center of Medicare and Medicaid Services: the public and larger US health program.

- *Microsystems* are the small units of healthcare delivery (Level B) which directly influence the Level A.

Achieving the six aims for quality-improvement will require redesigns of these small units of work, with three comprehensive redesign principles suggested: care should be knowledge-based, patient-centered, and systems-minded.

- *Macro-systems* are the healthcare organizations (Level C) which directly influence the Level B.

Organizations (hospitals, multispecialty group practices, integrated delivery systems, and so on) house and hold micro-systems, and might give them the suitable structural conditions they need to provide high-quality of services and care. The organizational quality - in the 'quality chasm' framework - represents the organizational ability to encourage and provide micro-systems capacity to achieve their best quality performance.

- *External environment*, including policy-makers, payers, regulators, accreditation agencies, quality improvement organizations, suppliers, the research community, the educational community, and other of these external stakeholders' groups (Level D) shaping the behavior, interests, and opportunities for the organizations at the Level C.

These external stakeholders' groups or systems, altogether, shape the context and stimulus in which healthcare organizations and practitioners develop their practices, thereby influencing the quality of care they provide by this mediating mechanism.

4.5 National Priorities Partnership – Establishing US National Priorities:

Following the recommendation of the 'quality chasm' report of getting action started with a set of priority issues for quality-improvement, and involving a wide range of stakeholders on their definition, the National Quality Forum (the American quality consensus-building organization) convened the National Priorities Partnership (NPP) towards consensually defining a set of major priorities to be addressed by the American's health/healthcare system [(71)].

The use of priorities shall help to focus improvement focus on high-leverage areas, those with most potential to result in substantial improvements in health and healthcare, accelerating the transformational change in the American's healthcare delivery system. As told, this fundamental change for quality requires aligned efforts among all relevant stakeholders which are actively-involved in defining quality priorities for the US healthcare system by the consensus-building process fostered by the NPP.

A set of six priorities were initially developed by the NPP to align US national efforts [(71)], being more recently updated with two additional priorities, further cited as number 7 and number 8 priorities [(75)]. We shall now expose them:

1. Empowering patients and families: *Engage patients and families in managing their health and making decisions about their care*.

The NPP envisions healthcare that honors each individual patient and family, offering voice, control, choice, skills in self-care, and total transparency. Additionally, healthcare must be able to be adaptable to the individual patient/family's circumstances. Operationally, the vision for this item consists on the following set of sub-items.

- Consumers' experience mattering: All patients will be asked for feedback on their experience of care. Thereafter, healthcare organizations and their staff will use this information to improve services and care practices that enhance consumers' experience.
- Navigation and self-management facilitated: All patients will have access to tools and support systems that enable them to effectively navigate in the systems and manage their care.

- Shared and informed decision-making: All patients will have access to information and assistance that enables them to make informed decisions about their treatment options.

2. Population focus*: Improve the health of the population*.

The NPP envisions communities that foster health and well-being at the local, regional, state, and broader national levels, promoting health and preventing disease, injury, and disability, rather than treat them.

- Enhancement of preventive services: All Americans will receive the most effective preventive services recommended by the US Preventive Services Task Force.
- Health promotion focus: All Americans will adopt the most important healthy lifestyle behaviors which are known to promote health.
- Community health focus: The health of American communities will be improved according to a national index of health.

3. Safety: *Improve the safety and reliability of America's healthcare system*.

The NPP envisions healthcare that is relentless in continually reduces the risks of injury from care, tending for "zero" harm wherever and whenever possible. Healthcare leaders and healthcare professionals shall be intolerant to defects or errors in care, and constantly seek to improve safety of the practices, regardless of their current levels of reliability.

- Culture of safeness: All healthcare organizations and their staff will strive to ensure a culture of safety. They will focus relentlessly on continually reducing and seeking to eliminate all healthcare-associated infections (e.g. catheter-associated blood stream infections, surgical sites infections, catheter-associated urinary tract infections, among others) and serious adverse events (e.g. pressure ulcers, falls, wrong-site surgeries among others safety errors reported).
- Reduced preventable mortality: All hospitals and their community partners will improve preventable and premature 30-day mortality rates following hospitalization for select conditions (acute myocardial infarction, heart failure, pneumonia) to the "best-in-class" levels.

4. Care Coordination: *Ensure patients receive well-coordinated care within and across all healthcare organizations, settings, and levels of care*.

The NPP envisions healthcare that guides patients and families through their healthcare journey and continuum of services and care; while respecting choice, offering physical and psychological support, and encouraging strong relationships between patients and the healthcare professionals and organizations - accountable for their quality of care.

- Patients' feedback on care coordination: soliciting and carefully considering feedback from all patients (and their families when appropriate) regarding coordination of care received.
- Communication with patients and other providers: Medication information shall be clearly communicated to patients, family members, and the next healthcare professional and/or organization of care, and medications shall be reconfirmed each time a patient experiences a transition in care.
- Coordinate efforts: All healthcare organizations and their staff will work collaboratively with patients to reduce 30-day readmission rates and reduce preventable emergency department visits.

5. Palliative and end-of-life care: *Guarantee appropriate and compassionate care for patients with life-limiting illnesses*.

The NPP envisions healthcare capable of promising dignity, comfort, companionship, and spiritual support to patients and families facing advanced illness or dying, fully in synchrony with community, friends, and family resources.

- Suffer releasing treatment: All patients with life-limiting illnesses will have access to effective treatment for relief of suffering from symptoms such as pain, shortness of breath, weight loss, weakness, nausea, serious bowel problems, delirium, and depression, including high-quality palliative and hospice care.
- Holistic approach: All patients with life-limiting illnesses and their families will have access to help with psychological, social, and spiritual needs.
- Effective communication and trustful relationship. All patients with life-limiting illnesses will receive effective communication from healthcare professionals about their options for treatment; realistic information about their prognosis; timely, clear,

and honest answers to their questions; advanced directives; and a commitment not to abandon them regardless of their choices over the course of their illness.

6. Elimination of overuse. *Eliminate overuse while ensuring the delivery of appropriate care*.

The NPP envisions healthcare promoting better health and more affordable care by continually and safely reducing the burden of unscientific, inappropriate, and excessive care.

- Overuse reduction will embrace areas such: inappropriate medication use (excessive use of antibiotics and poly-pharmacy); as well as unnecessary or unwarranted laboratory tests, diagnostic procedures, consultations, interventions, emergency department visits, and hospitalizations or even potentially harmful preventive services with no proven benefits.

7. Equitable access. *Assuring that all patients have access to affordable, timely, and high-quality care*.
   - Expanded coverage: decreasing the grade of uninsured population.
   - Culturally and linguistic appropriated: People shall receive communication and care tailored to their cultural background and in an understandable language.
   - Equitable to underserved areas: Creating infrastructure to provide high-quality of care in rural and underserved areas.

8. Infrastructure Supports. *Systems infrastructural solutions supporting care and quality-improvement initiatives*.

This priority has a different scope from others. It is not directed to any particular area of healthcare, but shall support the attainment of the whole of other priority areas, by supporting underlying systems changes. Investments in a national infrastructure and systems solutions will be needed to remove barriers to progress. Doing so, it includes major efforts such as building a national health information network (e.g. involving the introduction of health information technology), developing a strong and balanced workforce, establishing a solid evidence-base through research, and offering tools and technical assistance for the routine quality-improvement purposes.

4.6 The 'National Health Care Quality Strategy and Plan':

Following the recent and widely discussed Patient Protection and Affordable Care Act [(70)], the US Department of Human and Health Services (HHS) was able to release for public consultation. A preliminary 'National Health Care Quality Strategy and Plan' or abbreviated the National Quality Strategy serving as an overall guide for quality-initiatives for the next decades [(76)]. One of the inputs required for such national strategy it is the input from stakeholders' consensus - acknowledging the need for strong collaborations among stakeholders so the plan could be further well succeeded. This kind of input was concretely furnished by the NPP, with a content we describe after exposing the preliminary proposed strategy and plan [(71)].

Indeed, the US HHS National Quality Strategy builds and expands the existent public programs that assess and improve quality of care. Those are for instance the demonstration projects that could be consulted in the Center of Medicare and Medicaid Services' (CMS) website [(77)], and further programs linked to the public-reporting of selected quality-indicators [(78)]. Other CMS-based demonstration programs are related with the so-called 'medical homes'; value-based purchasing; and accountable care organizations, also fostered by the National Quality Strategy [(76)].

The National Quality Strategy outlines a core set of principles guiding the strategy, as well as a framework for establishing goals and priorities, while acknowledging the need for stakeholders' engagement and public commitment with a national strategy and plan for quality. The major aim is to provide a shared vision – aspirational, actionable and aligned across the nation - guiding every initiative made on larger and small scales for quality-improvement.

4.6.1 Principles guiding the National Quality Strategy

The initial set of potential core principles the National Quality Strategy guides the whole framework presented, including how goals, targets, and plans for quality should be established. These core principles include the following:

- Person-centeredness and family engagement shall guide all strategies, goals, and improvement efforts;

- The strategy and goals shall address all ages, populations, service locations, and sources of coverage;
- Eliminating disparities in care – including but not limited to those based on race, ethnicity, gender, age, disability, socioeconomic status and geography – shall be integral to all strategies and goals;
- The design and implementation of the strategy shall consistently seek to align the efforts of public and private sectors.

4.6.2 Framework for the National Quality Strategy

The initial thinking of the US Department of Health and Human Services is that the National Quality Strategy should be organized around a simple framework that should resonate broadly, be clear, be easily understood and be attainable with concerted efforts. The proposed framework consists of three components that shall be consistent over time, while allowing for both the initial identification of priorities and associated goals and measures, as well as allowing a regular updating towards accommodating new directions and emerging issues. The proposed components of the framework are, therefore, the three following ones:

- *Better Care:* Person-centered care that works for patients and providers. Better care should expressly address the quality, safety, access, and reliability of how care is delivered, as well as the experience of individuals in receiving that care. It includes the active engagement of patients and families for the best possible care at all stages of health and disease.
- *Affordable Care:* Care that inflects the tendency unsustainable costs for families, government, and the private sector, thus turning healthcare more affordable.
- *Healthy People/Healthy Communities:* Improving health and wellness at all levels through strong partnerships between healthcare providers, individuals, and community resources.

The framework components serve as the three pillars of the National Quality Strategy and it intends to frame its underlying priorities and goals.

4.6.3 Priorities and goals for the National Quality Strategy

According to criteria established to guide the selection of priorities, as exposed in the recent PPACA law, and generally related with the greatest potential for value improvements [(70)]; the priority interventions should be related at least with one of the main components of the framework. Attached to priorities, there should be established goals that the National Quality Strategy seeks to attain for each of the framework components. Thus, such goals need be actionable and attainable with planned concerted efforts.

Indeed, together, the priorities and goals should engage multiple stakeholders, inspire the nation, and provide a public and private roadmap for accelerating a common path towards better quality care, improved health outcomes for people and communities, and a more affordable healthcare system for all Americans.

Given the critical importance of the initiative, direct input from stakeholders was actively sought and gathered through multiple stakeholders' venues, including wide public electronic comments and a wide range of other forms of public forums to gather input and suggestions in the period following the release of the strategy.

One of the required inputs is to obtain a NPP position about the National Quality Strategy and the priorities to be pursued, which reinforced the use of the six initial priorities [(71)], supported by the two additional priorities already outlined [(75)]. The updated NPP framework aligns with many aspects of the new health reform legislation, thus it is able to provide an important starting-point for the development of the National Quality Strategy. The NPP establishes a matrix between the three National Quality Strategy pillars and the NPP priorities previously outlined. Out of the matrix stays the item "infrastructure support" (previously on number 8 for the NPP priorities), which rather underpins all the three pillars and seven priorities [(75)]. The matrix is among the outlined elements is depicted below.

- Better Care:
    - Patient and Family Engagement; Safety; Care Coordination; Palliative and End-of-Life Care; Equitable Access
- Affordable Care:
    - Elimination of overuse
- Healthy People/Healthy communities:
    - Population Health

It is additionally worth noting that each priority can have effects in more than one pillar. For instance coordination of care, patient and family engagement, and enhanced safety are all matters that despite contributing for better care can have also the potential to improve the health of communities and turn care more affordable [(71)].

5 – US PAC Rehabilitation Services, Quality and Quality-Initiatives

We shall now begin to approach the US context regarding the organization and delivering of PAC Rehabilitation services and care, which is the healthcare area specifically addressed by this thesis. We want to bring an overview of the current and future perspectives for quality and quality-initiatives, as specifically applied to this healthcare area. We shall denote that later on "Results" a more in-deep review on these issues will be independently outlined.

Herein, we first outline the actual context of the US PAC Rehabilitation system, followed by the US crucial political-input for a quality-based reform in the field. Thereafter, we highlight the few papers that conceptualize the PAC Rehabilitation specific quality of care, as well as we uncover other applications of the SPO quality framework in the rehabilitation field. Finally we outline the so-called "quality paradox" about the PAC Rehabilitation quality-improvement (QI) initiatives. This phenomenon seems to illustrate the need for advancing the 'quality' of PAC Rehabilitation quality-initiatives.

5.1 Current fragmentation in the US PAC Rehabilitation system

In the US, there is a fundamental distinction about two types of services in which rehabilitation care is provided, as it follows:

- In-patient and home-based post-acute rehabilitation care. This type of service is delivered after an acute episode of illness and disability and specifically refers to the PAC Rehabilitation label more directly addressed by this thesis.

- Outpatient/ambulatory rehabilitation services and specialized therapies. Those services could be provided after PAC Rehabilitation or as the primary type of intervention for less acute, complex, or disabling conditions.

This artificial differentiation is, most of all, administratively promoted, for instance fostered by public policy and payment-structures, particularly the differentiation among different Medicare programs (the great PAC Rehabilitation payer) and what they cover. Indeed, while PAC Rehabilitation services in the first item are totally covered by Medicare part A (public insurance every retired has access); outpatient rehabilitation is only covered by Medicare part B program, which is optional for Medicare enrollees (available by an extra fee). Furthermore, the latter services are subject to the financial limitations of the called 'therapy cap' of the Medicare Part B program (http://www.cms.gov/). By its turn, the Medicare part A reimburses all PAC care, with greater or less rehabilitation focus, into four different settings type, such as the following:

- Long-Term Care Hospitals (LTCHs)
- Inpatient Rehabilitation Facilities/Units (IRFs)
- Skilled Nursing Facilities (SNFs)
- Home Health Agencies (HHA)

Each of these settings-type has its own system for data gathering and claims, its own payment model (higher payment for more intensive settings) and their own norms and regulations providers might comply with [79; 80].

LTCHs and IRFs are hospital-based PAC settings. LTCHS hold, by far, the low percentage of attendances and the less active rehabilitative focus. It is mostly directed for medical stabilization of complex patients not expecting to exceed 25 days of length-of-stay (LOS). The IRF preserves a more direct and active rehabilitative focus. Compared to what happens in other countries, the IRF is often more acute (intensive and shorter LOS) than the generality of international rehabilitation centers [81; 82].

There are several regulations to determine admission-criteria for the IRFs, primarily driven by the Medicare reimbursement policy. For an IRF admission, Medicare have the 3-hour therapy rule, which requires that the patient is receiving - or is improving to the point of soon being able to receive - at least 3 hours of therapy per-day, 5 to 6 days per-week. In case of any missing therapy, the physician and treating therapist must provide a regulated

justification for that missing. The patient just refusing to do therapy is not accepted and may result in non-reimbursement for that day.

Moreover, for a patient to be suitable for an IRF admission the pre-admission assessment (made in the acute hospital) needs to conclude frequent physician visits and 24-hour rehabilitation nursing to remain medically stable and be able to tolerate the 3-hour therapy rule, and obviously having a degree of impairment and suitable conditions for benefiting of more than a small dose therapy as addressed by lower-intensive levels of rehabilitation services [(81)].

A SNF by its turn, in comparison with international centers, presents longer LOS and less intensity of care: exactly the opposite of the IRFs. The US SNFs receive the majority of patients requiring PAC care, with the ability to receive patients discharged from IRF, but mostly competing with IRFs for equivalent acute-discharges [(81; 82)]. Indeed, a research question that remains prevalent for years in the US PAC Rehabilitation health services research agendas remains about determining which of those two settings-types - alternative in many situations - represent the most cost-effective place for the provision of PAC Rehabilitation services [(83; 84)].

After in-patient rehabilitation, patients may be suitable for home-based PAC Rehabilitation, which is still covered by Medicare part A; as well patients may need no more therapy or rehabilitation, or still need outpatient rehabilitation or other type of care that is not reimbursed by Medicare part A. Home-based care can either be the upfront PAC Rehabilitation solution for patients after acute-discharge. This happens to an intermediate percentage of cases, standing between the percentages of SNFs and IRFs admissions after acute-discharges [(81; 82)].

5.2 US political input for quality in PAC Rehabilitation

Public policy in the US is demanding a PAC reform with a focus on quality in a patient-centered basis. This was made operational through a law approved some years ago [(85)].

The current status of differences in regulation, measures, and payments among different PAC settings (IRF; LTCH; SNF; HHA) are, according to that approved reform, a matter to be changed for a system that is designed and delivered towards optimally meet

patients/families' needs and preferences across the entire PAC Rehabilitation journey, rather than being based according to providers' needs, capacity, or interests, as it remains the standard today. Additionally, the current administrative differentiation among a continuum and/or alternative PAC settings turns difficult or impossible the task of making quality and efficiency comparisons among those settings, providers, or whole PAC Rehabilitation pathways; as well as it makes smooth transitions among settings become more challenging. In synthesis, the current administrative differences among PAC settings seminally undermined any structural advancement for quality in the US PAC Rehabilitation system.

Therefore, and underpinned by the mentioned political input/reform, it has been developed an assessment tool that is uniformly applied to all PAC Rehabilitation settings. This tool will be crucial for three major purposes. The first is to optimally define placement decisions after acute-discharges (it is first filled at the acute-care setting providing historical data in which to base further decisions regarding cost-effective post-acute placements for similar patients). Second, it aims to facilitate transitions and coordination among PAC settings because data-systems will be uniformly filled, accessed, and updated by all providers of different settings (not happening today). Third, but certainly not the least, the uniform tool will serve as common data-basis for underpinning a follow-up quality/outcomes monitoring and a fair case-mix adjustment procedure, which might be able to determine whether the final PAC Rehabilitation outcomes are optimal, adjusted to the specific and unique patients' characteristics and complexities [(79)].

According to the position expressed in the policy reform [(85)], payments or reimbursement mechanisms should reward for quality (e.g. pay-for-performance mechanisms). This quality-aligned reimbursement might be based on the data resulting from the uniform follow-up and case-mix adjusted outcomes-monitoring procedure made possible by the implementation of the new uniform toll we already mentioned. Yet, it might be complemented by the measurement/monitoring of quality-indicators regarding the process of care – both towards compensating eventual technical limitations in the case-mix adjustment procedure, but mostly towards uncovering care-process targets for quality improvement.

In synthesis, due the rising expenditures for PAC Rehabilitation services and inadequate distribution among payments [(86)], stimulus for quality and cost-effective practices will

continually to grow [87], with public policy representing a critical input [85]. The increasing importance attributed to the public-reporting of quality-information and quality-aligned reimbursements only place an additional value for the comprehensiveness and effectiveness of a quality-monitoring system, since the latter would represent the data-basis for all subsequent quality-initiatives in the field such as those mentioned.

5.3 Conceptual frameworks and 'organizing' papers applied to PAC Rehabilitation quality

Paradoxically to highlighted relevance on quality and quality-initiatives, there is still a paucity of PAC Rehabilitation-specific framing papers regarding the quality of care for this distinct or unique healthcare area, which is largely based on a byopsychosocial and functional-oriented paradigm [88; 89]. Eldar produced the unique public-available conceptual 'organizer' for the quality within the PAC Rehabilitation scope. However, it does not address the whole PAC Rehabilitation continuum, but more concretely it focuses on the narrower rehabilitation medicine level [90].

Eldar's framework for quality in rehabilitation medicine is based in the widely recognized Donabedian's SPO framework we already outlined at the beginning of this section. Despite valuable, we partly build on it for our further 'Results', it presents limitations as a conceptual framework for the quality PAC Rehabilitation. Indeed, beyond focusing on rehabilitation medicine (we broadly address the PAC continuum), the framework is dated from 1999, thus it is not able to account for the most recent conceptual, empirical, and socio-political developments in the PAC Rehabilitation and quality fields. Those are for example:

- The development of the World Health Organization's International Classification Functioning, Disability and Health (ICF) framework and constructs, which is widely recognizable among PAC Rehabilitation stakeholders [91].
- Features of rehabilitation studies applying the same underlying quality-framework (SPO model) [92; 93; 8].
- An array of advances in rehabilitation and quality-related research made over the last decade.

Nevertheless, the Eldar's framework [90] present valuable theoretical features. Perhaps the most relevant is the application of the Donabedian's conceptual distinction among immediate (micro); intermediate (mini) and delayed (macro) outcomes [94]. According to Eldar, theoretically supported in the Brook's 'time window' concept as well [95], these different types of outcomes adequately reflect the step-wised and integrative rehabilitation process, because it aims to achieve, progressively or stage-by-stage, more complex outcomes that are build over the accomplishment and integration of the smaller and earlier ones.

5.4 The SPO framework in the rehabilitation field: Other applications

Beyond Eldar, other authors applied the SPO framework to the PAC Rehabilitation filed. For instance, Hoenig and colleagues explored the utility of the SPO model for rehabilitation in a series of health services research-based studies, in case applied to the specific field of stroke rehabilitation.

First, they took a systematic approach, carrying out a systematic review of the literature using the Donabedian model, organizing the specialty-literature abstracted into sub-categories of structure, process and outcomes [92]. Then, the same group of researchers, in a second study, used a combination of expert panel and an empirical study to develop a Donabedian-based taxonomy of rehabilitation services [96]. This was followed by investigations showing that, for stroke rehabilitation, structure of care (facilities characteristics, types of personnel) predicted process of care (multi-disciplinary team meetings, care planning); and that, in turn, the process of care predicted outcomes, with the structure influencing outcomes mostly through a mediation process [93]. In addition, further studies showed that the process of care (as measured by compliance with process guidelines) can predict better functional outcomes [97], as well as the compliance with process guidelines can predict higher patient satisfaction [98].

Internationally (outside US), others also have used the Donabedian's model for the study the stroke rehabilitation. In the United Kingdom, Crawford and colleagues compared the process of care for acute stroke between 2 health systems that differed in the structure of care [99]. They found profound differences, for example with 45% fewer persons starting therapy within 72 hours and 75% fewer persons receiving discharge planning (process) in

the health system that lacked a full complement of rehabilitation providers, designated stroke units, formal policies and providers' incentives (structure). Another study compared 3 care settings for stroke patients in the same city and found that patients on units with rehabilitation nurses involved in the treatment-team (structure) were able to spend more time out of bed [100; 101].

For wider rehabilitation purposes, the S-P-O Donabedian's model has been used for a conceptual overview and organization of rehabilitation knowledge [8]; to discuss the state-of-science applied to quality measurement [102]; to highlight gaps in the literature [92]; as well as to make recommendations for the challenges and opportunities for PAC Rehabilitation quality and quality-initiatives, the latter characterized by the "quality paradox" [103], below detailed.

5.5 QuaIity-initatives in PAC Rehabilitation: The "quality paradox"

The term "quality paradox" was first applied to the PAC Rehabilitation field by Strasser to describe the PAC Rehabilitation practioners' sense about the worth of quality-initiatives, more often 'generalist' quality-improvement initiatives applied to PAC Rehabilitation [103].

Building in the notion of "unintented consequences" of quality-initiaives in general healthcare [12; 13], Strasser exposes a mismatch between the scope of quality-initiatives (mostly those promoted in a top-down fashion by hosptital/macro-system admnistrations in which rehabilitation facilities are embedded on), and the clinicians' perceived needs for improving the quality of PAC Rehabilitation. Indeed, rehabilitation quality deals which much more than biomedical variables typically adressed by hospital-based quality and safety improvement initiatives. Strasser gives the example of quality-improvement initiatives as "hands hygiene" and "order procedures" that, although needed and absolutely justified in the field, represent a very narrow hospital-based vision for what is the quality of rehabilitation care, and how it could be improved.

Thus, although these norms and interventions are also applicable to the PAC Rehabilitation units, it would be expectable that quality-improvement initatives, in a more comprehensive meaning, could bring more specific added-value for the complex and unique scope of PAC Rehabilitation quality. The pointed narrowness and over-simplification of quality-

improvement applied to the field can only contribute for clinicians could begin to devalue and creating 'anti-corps' to any initiative coming with the label of 'quality-improvement'. Furthermore, it is easy to assume that if clinicians perceive quality-improvement initatives has something of low value and effectiveness for a comprehensie quality-improvement, they can easily mitigate any improvement efforts or attemps [104].

In the same line of reasoning, practitioners are also concerned with the time- and mind-consuming colateral effects of these sub-optimal improvement initatives which, in a current busy practice, can rahter contribute to defocus practitioners from a highly-valued individualized rehabilitation care, without the ultimate ability to improve the quality of PAC Rehabilitation care, at least in the way clinicians perceive what it means to be the comprehensiveness and specificity of PAC Rehabilitation quality.

Indeed, Strasser points out that one of the major sources of the "quality paradox" phenomenon, or this sub-optimal effectiveness of PAC Reahabilitation quality-improvement initatives, has its origins on stakeholders' misconceptions regarding what PAC Rehabilitation quality specifically means. These stakeholders' miscoceptions seem to seminally undermine progress in the field. Lately, this rationale will support the need for the 1st review we later present on 'Results'.

B- BACKGROUND ON LITERATURE REVIEW APPROACHES

Our specific objectives depend on literature review approaches as the methodological mean to be accomplished herein. Therefore, as a crucial way of supporting the methodological approach to be used in this thesis, we felt the need for seeking and searching for literature about literature review approaches.

Indeed, it is increasingly acknowledged in the literature [105; 106] that any literature review must begin with a background about the review of methods and techniques suitable to be

employed, as well as looking at the ways other researchers have approached similar topics, and finally evaluating the suitability and effectiveness of methods for the intended purposes. Therefore, after presenting the general scope and approach of the mainstream Cochrane-style systematic reviews (which does not fit our review purposes); we further present alternative review approaches, which could better match our wide, integrative and complex review purposes. Lately, we outline applicable methods of qualitative analyses and synthesis, as well as approaches to combine different types of information and sources towards building a framework or an integrative synthesis.

1 - Literature Review Approaches

We begin to provide a box composed by a glossary of basic terms and approaches that constitutes the core of the review approaches. The glossary will include systematic reviews (Cochrane-style) as the 'gold standard' review approach used to abstract and synthesize the scientific knowledge at a clearly defined level of analysis. After the glossary, we distinguish the two major underlying aims for conducting research reviews.

Review - the process of bringing together a body of evidence from different sources [(107)].

Synthesis - Review stage in which evidence extracted from different sources is *juxtaposed* to identify patterns and direction in the findings, or *integrated* to produce an overarching, new explanation/theory attempting to account for the range of findings [(107)].

Systematic review**:** Systematic reviews are research reviews that combine the evidence of multiple studies regarding a specific clinical problem to inform clinical practice. It is the method of choice for evidence-based practice initiatives (e.g., Cochrane Collaboration). Systematic reviews require a well-specified clinical question, explicit methods, and a comprehensive search for relevant primary studies [(108)].

A systematic review tries to adhere to a set o "scientific" methods to limit error (bias) mainly by attempting to locate, appraise and synthesize (attempt to reconcile) all relevant evidence (from research or more widely) to answer particular questions.

Systematic reviews often include the statistical methods of meta-analysis if primary studies meet the assumptions required for meta-analyses. If primary studies cannot be combined statistically, a narrative analysis is undertaken in conjunction with vote counting or other quasi-statistical approaches [107].

Meta-analysis – method of analyses and synthesis that combines the evidence of multiple primary studies by employing statistical methods, thus enhancing the objectivity and validity of findings. The research design and hypotheses of primary studies need to be very similar [107].

Within a meta-analysis approach, each primary study is abstracted, coded, and entered into a quantitative database. Findings are subsequently transformed into a common metric to calculate an overall "effect size". A significant advantage of the meta-analysis method is that adjustment for sample size and study quality can be included in the analysis.

Narrative synthesis – the process of synthesising primary studies to explore heterogeneity descriptively rather than statistically. It is employed mostly when data and primary sources do not fit for a statistical analyses or when the results could be better presented in a descriptive form instead of an "effect size".

It might be the better solution for complex matters when there is not one dominant theoretical perspective. In such case, a meta-narrative synthesis telling the different storylines of research could be the appropriated because the synthesis follows each storyline of each paradigm/theoretical perspective, including its subsequent studies and findings that are finally brought together for a comprehensive understanding (under different perspectives) of a complex phenomena that cannot be totally translated into numbers [109; 110]. Narrative methods have been advocated as suitable for synthesis in quality improvement research [111].

A review of the literature can generally have two different categories of purposes. It could aim to support knowledge, or it could aim to support decisions [112].

Indeed, review for "*knowledge support*" tends:

- to focus on research evidence;

- not to make recommendations;
- to attend less to local context – has a global appliance.

Review for "*decision support*":

- includes more than just research, especially values and priorities;
- includes tasks which are part of the decision-making process;
- includes tailored recommendations for action;
- remains as context-specific;
- are directed to specific set of commissioners or decision-makers (may involve them directly in the process);

The kind of goals of this thesis fit in the scope of a "decision support" review, which represents a more suitable method for informing policy in compare with a single study or experts-opinion alone.

Although "decision support" reviews could be made operational through a Cochrane-style systematic review approach, none of our specific reviews purposes fit the major assumptions and requirement of that approach. Indeed, we do not want to summarize an exhaustive and detailed catalogue of the literature applied to a very narrow and clearly delimited subject under review. Rather, our review purposes relate with 'organize' different types of literature applied to very wide, complex, context-dependent subjects under review, producing an integrative 'big picture' of the complex forces, knowledge, actions, and perspectives that shape the scope of quality and quality initiatives applied to healthcare or specifically to Post-Acute Rehabilitation and finally accounting for the current and unique US context.

2- Review Approaches suitable for integrative, complex, and wide subject matters: Integrative Review, Realist Review, and Scoping Review

As already mentioned, we felt the need to look for alternative review approaches (other than traditional Cochrane-style systematic reviews) that could better match the wider, integrative, and complex scope of our review purposes and subject matter.

Therefore, we outline the scope, approach, stages, and methodological tips furnished by three review approaches we found as filling the above mentioned criteria, namely the "integrative review", the "realist review", and the "scoping review" approaches. We shall now expose each of these approaches in a detailed way.

2.1 Integrative review

Integrative review is a review approach allowing for the simultaneous inclusion of experimental and non-experimental research in order to more fully understand a phenomenon of concern. Integrative reviews may also combine data from the theoretical as well as empirical literature [113]. In addition, integrative reviews incorporate a wide range of purposes: to define concepts, to review theories, to review evidence, and to analyze methodological issues of a topic. The varied sampling frame of integrative reviews in conjunction with the multiplicity of purposes has the potential to result in a comprehensive portrayal of complex concepts, theories, or healthcare problems, enhancing a holistic understanding of the topic. Well-done integrative reviews reflect the state-of-the-science, contribute to theory development, and have direct applicability to practice or policy.

2.1.1 Integrative reviews: Potential benefits

Compared to other review approaches, integrative reviews can have potential benefits. Those are for instance [114]:

- Identifying gaps in current research, evaluating areas of research strength and weaknesses.
- Generating new research questions, bridging between areas of related work.
- Identifying or developing theoretical or conceptual frameworks of relevance.
- It is also claimed to be an efficient methodological approach [115].

2.1.2 Potential disadvantages or limitations

The complexity inherent to combine diverse methodologies, however, can contribute to lack of rigor, inaccuracy, and bias. This is a considerable issue, since the data extracted from primary articles of diverse methodologies generally consist of a large repertoire of

data of many types. Without explicit and systematic methods specific to undertake an integrative review, the risk of error increases exponentially.

Errors can occur at any stage. For example, the literature search stage may be incomplete without consideration of important primary sources. Data from primary sources can be incorrectly extracted and interpreted. Most important, data analysis may be incomplete or may not be an accurate synthesis of all data from primary sources. Analyzing and synthesizing varied primary sources is a major challenge to undertake an integrative review.

2.1.3 The integrative review process

To address these main concerns, Whittemore and Knaff [113] - based in Cooper stages of a research review [107] - highlight critical strategies to enhance the rigor of the process, thus of the outcomes of the integrative reviews.

Problem Identification stage

Having a well-specified review purpose and variables of interest will facilitate all other stages of the review, particularly the ability to differentiate between pertinent and extraneous information in the data extraction stage. Any integrative review can encompass an infinite number of variables, issues, or populations. Therefore, the clarity of the review purpose remains essential to provide focus and boundaries in the task of extracting appropriate data from primary sources. Integrative reviews should be carried out from an explicit philosophical or theoretical perspective, focusing a review within a broad and diverse sampling frame, in contrast to reviews that are solely descriptive of existing research.

Literature Search stage

A comprehensive search within an integrative review approach requires the use of more than a single strategy (databases search, reference lists search, network, journals hand search) in order to gather a starting sample with a breadth of comprehensive and diverse information. Purposive sampling can be combined with comprehensive search if appropriated to the review purpose, as well as it can be used differently for different sub-themes under review. However, any sampling decision must be justified and made explicit.

Data evaluation stage

Systematic reviews and meta-analyses can have more strictly defined guidelines because the sampling frame remains narrow and the research designs included are similar. In contrast, evaluating quality of primary sources in the integrative review method - where diverse primary sources are included - increases the review complexity. Broader quality criteria can enhance the sample of the integrative review, but can lose rigor and the ability to be reproduced. Additionally, very specific criteria for evaluation turn later analysis less feasible. A possible solution, in case of diverse empirical sources, is to evaluate quality in sources that represent outliers, because methodological quality can be a viable reason for discrepant findings eventually found.

In addition, how the quality of non-empirical primary sources is defined always represent a complex subject for quality-appraisal criteria. In an integrative review, such decisions should be made according to the review purposes. In other words, the authenticity, methodological quality, informational value, and representativeness of the available primary sources should be considered in balance for evaluation decisions.

Addressing conflicting evidence is a considerable challenge, particularly when results are equally compelling and from high quality reports. However, conflicting evidence in general demonstrates the need for further research with the subsequent research question possibly resolving the conflict [(107)].

Data analysis stage

A thorough and unbiased interpretation of primary sources along with an innovative synthesis of evidence, represent two main goals of the data analysis stage. This stage requires that the data from primary sources become ordered, coded, categorized, and summarized into a unified and integrated conclusion about the research problem [(107)].

The strategies for data analysis within integrative reviews are one of the least developed aspects of the process, yet represent one of the aspects suitable to fraught with error. Therefore, a systematic analytic method should be explicitly identified before undertaking the review. Research methods of analysis, primarily developed for mixed-methods and qualitative designs, are particularly suitable to be used within the integrative review method, allowing for iterative comparisons across primary data sources [(116; 117; 118)]. We will

analyze mixed-methods for qualitative analyses in a later independent section. They are also applicable to other review approaches as later seen as well.

According to Whittemore and Knaff [113], such qualitative analyses methods would be applied to the following sub-stages of the data analysis.

> *Data reduction* involves the determination of a classification system for managing data, as well as subsequent techniques for extracting and coding data from primary sources to simplify, abstract, focus and organize data into a manageable framework compiled into a matrix or spreadsheet [105; 119].
>
> *Data display* involves converting the extracted data from individual sources into a display that assembles the data from multiple primary sources around particular variables, themes or subgroups. Different data displays are likely to be required for each sub-group classification of the integrative review.
>
> *Data comparison* comes next, involving an iterative process of examining data displays of primary source data in order to identify patterns, themes, or relationships. Once patterns begin to be discerned, a conceptual map can be drawn that includes a majority of the variables or identified themes. Relationships can also be depicted between variables or themes. This process of data visualization and comparison can provide some clarity to the empirical and/or theoretical support emerging from the early interpretive efforts. Creativity, critical appraisal and analysis are key elements in data comparison and the identification of accurate patterns or emerging themes [117; 119].

Conclusions

Conclusions drawing and verification represent the final phase of data analysis that moves the interpretive effort from the description of patterns and relationships to higher levels of abstraction, subsuming the particulars into the general. There is a gradual elaboration from a small set of generalizations that encompass each sub-theme to one of the integrative review in its entirety.

Conclusions or conceptual models that are developed are continually revised in order to be inclusive of as much data as possible. Explicit caution needs to be undertaken during this

process to avoid premature analytic closure (being locked into a particular pattern) or exclusion of pertinent evidence [119].

Ultimate integrative synthesis and presentation: after completing analysis of each subgroup, a final step of the data analysis in an integrative review is the synthesis of important elements or conclusions of each subgroup into an integrative summary of the topic or phenomenon: the integrative synthesis linking to the presentation sub-stage.

Indeed, the *presentation* ideally captures the depth and breadth of the topic and contributes to a new understanding of the phenomenon of concern. Implications for practice are emphasized in addition to implications for research and policy initiatives; while at the same time the review limitations should be specified.

2.2 Realist reviews

The realist review is a relatively new literature review approach, holding review-stages based on a systematic review approach, but that in contrast to the Cochrane-style literature reviews, brings a more flexible approach that shall fit and embrace the complexity of factors and contexts when they play an important role to the subject under review. The review approach might be additionally theory-driven on the hypothesis and explications generated. However, the approach can still remain systematically developed, might apply an already standardized protocol developed for its accomplishment, and is subject to a set of guidelines for the evaluation of its quality for publication [120].

2.2.1 The scope of the realist review

Compared with clinical treatments, which are conceptually simple and have been evaluated mostly by randomized controlled trials (RCTs), the literature on healthcare management and policy interventions is epistemologically complex and methodologically diverse. Better than the Cochrane-style systematic reviews, another type of systematic review approach, called realist review, can be suitable to synthesize this kind of information for these complex purposes [121].

Realism is a methodological orientation that has its roots in philosophy and applications in fields so diverse as sociology, psychology, economics and evaluation, but still remains

largely untried as an approach to the review of evidence in healthcare until a recent, insightful, essay of Pawson and colleagues [121], which is the source for the great majority of content in the following paragraphs.

Few years after this essay publication, we could find the emerging of a new wave of publications in healthcare field using this approach towards supporting policy and management decision [122; 123; 124], including the contents related with quality-initiatives [45].

2.2.2 The differential value of realist reviews

The realist review seeks to unpack *how* complex interventions apply (or *why* they fail) in particular contexts and settings. Thus, the realist reviewer must contextualize any differences found between primary studies in terms of for example: policy timing, organizational culture and leadership, resource allocation, staffing levels and capabilities, interpersonal relationships, and competing local priorities and influences. The goal is to provide understanding of *what* is about this kind of complex intervention that works, for *whom*, in what *circumstances*, in *what respects* and *why*.

The hallmark of realist inquiry is in its distinctive understanding of causality. The generative model of causality (underpinning the realistic enquiry) posits that to infer a causal outcome one needs to understand the underlying mechanisms and the context in which the relationship occurs. This is in contrast with the determinist model (e.g., underpinning clinical trials) holding that causality is established when the cause X (experiment) is switched on, and the effect Y follows it as a consequence of the experiment.

The realist approach both considers quantitative or qualitative methods. Indeed, it sees merit in multiple methods, marrying the quantitative and qualitative so that both the processes and impacts of interventions can be investigated, so that policy and management decisions can be optimally informed [125]. With the mentioned regards, the realist review presents a similarity with the integrative review approach [113].

The realist review, in the spirit of scientific enquiry, seeks to explore complex areas of reality by tailoring its methods eclectically to its highly complex subject matter. It is not much about a method or formula, but rather logic of enquiry that is inherently pluralist and flexible. It is more about principles that guide the rules than exactly regularize.

Realist reviews are designed to address the multi-determined, systems (systems thinking based) and complex nature of healthcare projects or interventions, exploring and understanding the chain of effects and intermediate variables that leads to a final result, which is achieved by applying multiple theories towards hypothesis that, hopefully, are better understood at the end of the review.

2.2.3 Realist review: possible shortcomings

Being directed preferably to study complex service-interventions or the implementation of projects, a major limitation of the realist review approach, despite its intrinsic systems perspective, is that it limits the territory the reviewer will cover, for instance with a narrower focus than the larger subjects of quality and quality-initiatives addressed by our thesis. Other possible limitations are that it is not standardized and reproducible in the same way the Cochrane-style systematic reviews.

This is not to say for instance that quality assurance within the realistic review process is not an equally important consideration within realist methods. However, the quality assurance process is more dependent on the reflexivity, and also creativity, on the part of the authors undertaking the review. Another consideration is that realist review leads, at best, to tentative or preliminary recommendations (e.g. our intents in this paper). It will never produce generalizable effect sizes since all conclusions are contextual. Whether this is a drawback or a virtue depends, of course, on the underlying intents of the research enquiry [(121)].

2.2.4 Template for the realist review process

The realist review steps, as systematic based, use as point of departure the same Cochrane-headings (sequence of headings below). However, sub-stages are featured in a realist mode. Undoubtedly, there is added complexity that largely accounts for the need to deconstruct interventions into component theories and underlying chains of effects [(121)].

Although the methodological steps are presented in a sequence, they are actually overlapping and interactive in execution. For example, the search stage influences question refinement and vice versa, as well as the quality appraisal exercise occurs in parallel with, or remains as an integral part of, the synthesis stage. Realist review is about refining theories and second thoughts can, and should, occur at any stage as new evidence or

perspectives emerge from the literature, or even if a peer-review process raises questions about the emerging explanations. It is, indeed, a back-and-forth process going from exploration to refinement. Now, step-by-step, we outline the realist review methodological stages.

Clarify the scope

Within a realist review, clarify the scope means three sub-stages: identifying the review question, refine the purpose of the review, and articulate key theories to be explored under different hypothesis.

Identifying the review question it is an exercise in conceptual sharpening, attempting to define and refine precisely the question to be pursued for research synthesis. It happens due the different nature of the interventions studied (complex and systems-embedded rather than simple and discrete) and the different purpose of the review (explanation or tentative recommendations, rather than final judgment). Indeed, these differences in the scope of the realist review are highly reflected at this stage one of realist review template.

When it comes to redefining the purpose of the review, there are generally four possible purposes: reviewing program theory integrity; reviewing to adjudicate rival program theories; reviewing the same theory in comparative settings, and reviewing official expectations against actual practice.

Articulating key theories to be explored might consist on develop an initial *theory map* of possible explanatory paths for the intervention/program that will be tested and explained separately by the review process. Those key theories are possible explanations, which are not to be exhaustive, but mostly many and varied at this stage. In this formulation of theoretical aspects, the realist review follows the meta-narrative synthesis method about telling story-lines of research, which is method primarily developed by one of the authors, namely Greenhalgh, responsible for the development of the realist review approach [(109)].

Search for evidence

The search process consists of a progressive procedure operational through the following sequence: a background search to get a feel of the literature; progressive focusing to identify putative program theories; a search for empirical evidence to test a subset of these theories; and a final search when the synthesis is almost complete. This last stage seeks out

additional studies that might further refine the program theories or could have escaped to the first search wave.

The search stage of realist review differs in two key aspects from that of a conventional systematic review. First, there is not a finite set of relevant papers which can be found, rather there are many more potentially relevant sources of information, thus some kind of *purposive sampling* strategy needs to be designed and followed. Second, primary studies contribute with different elements to the rich picture of the synthesis.

A realist review will use multiple search strategies that make deliberate use of *purposive sampling* – aiming to retrieve materials purposively to answer specific questions or test particular theories. A decision has to be made also about when to stop-looking – when sufficient evidence has been assembled to satisfy the review purposes. It can only be applied iteratively, by asking after each stage or cycle of searching whether the literature retrieved adds anything new to the understanding or explanation of the intervention, and whether further searching is likely to add new knowledge.

Searching in realist review is both iterative and interactive (involving tracking back and forth from the literature retrieved to the research questions and program theories), and the search strategies and terms used are likely to evolve as the understanding grows.

Searching makes as much use of snowballing (pursuing references of references by hand or by means of citation-tracking databases). In a recent systematic review conducted along realist lines, it was found that 52% of the empirical studies referenced in the final report were identified through snowballing, compared with 35% through keywords database searching, and 6% through hand searching in scientific journals [(126)].

Searching mechanisms are similar to other systematic review methods, however with some differences in the emphasis. Within a realist review, it is more likely the use of the grey literature, the empirical studies could be actively drawn from different bodies of literature, a tight restriction to databases is inappropriate (e.g. considering web-site resources), and snowballing process is likely to be more fruitful than putting specific words into "PubMed" or other databases.

Appraising the quality of evidence and extracting data

Appraisal checklists are usually the method used for this review stage. But these checklists are not the answer to the complex challenge of realist review for three reasons. First, the synthesis calls not merely to conventional qualitative and quantitative research designs, but also on impact evaluations, process evaluations, action research, documentary analysis, administrative records, surveys, legislative analysis, conceptual critique, personal testimony, thought pieces and so on, as well as an infinite number of hybrids and adaptations of these.

A checklist for qualitative research can still address the clarity and coherence of the report [(117)]. In such cases, the checklist assigns structure and credibility to what are subjective judgments in true spirit. The realist solution is to cut directly to the judgment, which is made by balancing relevance and rigor as dimensions of fitness to the particular review purpose. In summary, the basic realist principle on quality assessment is that the *worth* of the studies is established in the later synthesis stage and not as a pre-qualification exercise.

Data extraction can be achieved by marking the relevance sentences with a highlighter pen. Realist review thus assimilates information more by note-taking and annotation than by exactly extracting data. Although a matrix can be used, grid entries might take the form of free text and usually consist of short verbal descriptions of key features of the studies, papers, or interventions. It is experienced a shift from divergent to convergent thinking as ideas begin to take shape and the theories underpinning the intervention gain clarity.

Synthesizing the evidence, drawing conclusions, framing recommendations and disseminating findings

Realist review perceives the task of synthesis as one that is related with the refinement of a preliminary theory and assumptions. It starts with a preliminary understanding of the phenomenon and theories of interest, which are then refined through empirical evidence shaping the highways and byways of an initial *theory map*. Thus, the review process begins with theory or theories and ends, hopefully, with a more refined theory or theories.

The findings and conclusions of a realist review must be expressed not as universal scientific truths but in the cautious and contextualized grammar of policy discourse. One of the goals could be alerting the policy community to the caveats and considerations that

should inform their decisions prior its taking. Citing the illustrative words of Pawson and colleagues [121], the conclusions of a realist review could be of the following type: "remember A, beware of B, take care C, D can result in both E and F, Gs and Hs are likely to be interpreted quite differently, if you try J make sure that K, L and M have also been considered, N effect tends to be short lived, O really has quite different components –P, Q and R, and S works perfectly well in T but poorly for U". The review will, inevitably, also reflect that "little is known about V, W, X, Y and Z".

Conclusions section of a realist review is not a final judgment on what works with a quantifiable size effect that is generalizable to all contexts. The progress made in a review is not one from ignorance to answer, but from some knowledge to some more knowledge. Therefore, there is room for debate about the precise scope of the policy implications of a realist review. It is not a question of everyone stopping doing A and starting to do B. It is about individuals, teams, and organizations taking account of all the complex and inter-related elements of the program theory that have been exposed by the review and applying these to their particular local contexts. In synthesis, the realist review is fundamentally a pragmatic literature review approach, enlightening a context-sensitive evidence-base for complex-based problems or decisions such as those of the healthcare management and policy making.

2.3 Scoping Review

The scoping review is an emerging review approach that is able to identify, map, summarize, and overview the available evidence or information, or gaps on it, on relatively wide topics of interest. Our review purposes for this thesis are a step further than only mapping and summarizing the existent literature on a wide topic, involving a more integration, complexity, and context-sensitiveness than what is typically provided by the scope of scoping reviews. These latter characteristics are better addressed by integrative and realist review approaches we previously outlined. However, due the characteristics of addressing wider subjects such as ours, this approach might provide some useful methodological tips we can abstract for our review processes.

2.3.1 The scope of scoping reviews

Scoping reviews are yet somewhat imprecisely defined but usually consist on non-Cochrane-style systematic reviews, with its typical goals being related to literature mapping, conceptual mapping, or policy-information mapping. It contextualizes knowledge in terms of identifying the current state of developments, this is the sorts of things we do know, and do not know about a wide subject or topic. Thus, it represents a crucial element in a portfolio of approaches to literature review and synthesis, particularly as a mechanism for helping or supporting research commissioners and policy-makers to indentify topics deserving more research (supporting the establishment research agendas within the review scope), and supporting the ability to ask the right questions for future research [(127)].

A scoping review refers to a process of mapping and summarizing a range of evidence in order to convey the breadth and depth of information about a field [(128)]. Cochrane-style systematic reviews and empirical research can be triggered, on a narrower subject, by the performance of preliminary scoping reviews [(129)].

The scoping reviews usually involve the synthesis and analysis of a wide range of research and non-research material to provide greater conceptual clarity about a specific topic or field of evidence [(130)]. Researchers can undertake a scoping review to examine the extent, range, and nature of research activity, determine the value of undertaking a full systematic review, summarize and disseminate research findings, or to identify gaps in the existing literature [(129)]. Therefore researchers can use a scoping review to clarify the state-of-the-science within a wide subject and refine subsequent research inquiries [(130)].

Scoping reviews may be particularly relevant for disciplines with emerging evidence, such as rehabilitation science (the field addressed by this thesis), in which the paucity of randomized controlled trials makes difficult for researchers to undertake Cochrane-style systematic reviews. In these situations, a scoping review enable researchers to incorporate a range of study designs in both published and grey literature, addressing questions beyond those related to intervention effectiveness, and generating findings complementing the findings of clinical trials [(128)].

2.3.2 The process of scoping reviews

In an effort to provide guidance to authors undertaking scoping studies, Arksey and O'Malley [129] developed a six-stage methodological framework. We expose the Arksey and O'Malley's stages of the scoping review process, receiving ulterior complementary recommendations on each stage made by Levac and colleagues [128], which aim to advance the rigor of each stage, uniformity, as well as overall the usefulness of scoping reviews as a literature review approach, with distinctive value, in the healthcare researchers' toolkit.

Identifying the research question

Similar to the other review approach we were describing, in the scoping review the task of identifying the research question provides a roadmap for subsequent stages. However, the research questions are typically broader in nature, once they seek to provide breadth of coverage under a wider review topic [129].

In order to clarify directions, a broad and ill-defined scope of interest can be combined with a clearly articulated scope of inquiry. Linking a clear purpose for undertaking a scoping review to a well-defined research question will help to provide a clear rationale for completing the study and facilitating decision making about study selection and data extraction lately to be made into the review execution.

A helpful strategy may be to envision the content and format of the intended outcome that may assist researchers to clearly determine the purpose at the beginning of the review, considering the rationale for why they should summarize the activity in a field, and the implications that this will have on research, practice, or policy. Therefore, authors might have an overall study purpose with multiple and specific objectives articulated [128]. To some extent, this is similar to the process we have followed to defined the goals of this thesis.

Identifying relevant studies

This stage involves identifying the relevant studies and developing a decision plan about where to search, which terms to use, which sources are to be searched, time span, and languages accepted. Comprehensiveness and breadth is important in the search, while sources for searching include electronic databases, reference lists, hand searching of key journals, and conferences. Breadth is important, however, practicalities within the search

process such as time, budget, and personnel resources can limit the process. Therefore, decisions need to be made, at the outset, about how these practicalities will impact upon the search process and how to handle it [129]. Nevertheless, decisions to turn the process feasible/doable cannot compromise the study ability to answer the research questions. When limiting scope of the search process is unavoidable, researchers should justify their decisions and acknowledge the potential limitations of the study [128].

Study selection

Study selection involves *post hoc* inclusion and exclusion criteria. These criteria are based on the specificities of the research question and based on the new familiarity with the subject matter, achieved through the deeper knowledge of the subject under study [129].

Charting the data

A data-charting form is developed and used to extract data from each study. A "narrative review" or "descriptive analytical" method is used to extract contextual or process oriented information from each study, since scoping reviews are not simply a short summary of many articles [129]. Synthesizing information may benefit from utilization of qualitative content analysis approaches towards making new sense of extracted data, in a partial overlap with the next stage [128].

Collating, summarizing, and reporting results

Stage five is the most extensive in a scoping review. An analytic framework or thematic construction is used to provide an overview of the breadth of the literature. A numerical analysis of the extent and nature of studies, using charts and tables (e.g., of strengths and gaps in the evidence), is often presented. A thematic analysis can be also presented, with clarity and consistency being required for reporting the results [129]. The process could be sub-divided into three distinct steps: analyzing the data (use of qualitative analyses techniques), reporting results, and applying meaning to the results. This last step is crucial and it should be tied to the purpose of the scope review as defined into stage one [128].

Consultation (optional)

Consultation provides opportunities for experts, commissioners, consumers and broadly stakeholders to become involved in the process, for instance suggesting additional

references and analysis, as well as providing insights beyond those in the literature [129]. The consultation purpose might be clearly established. It may include sharing preliminary findings for feedback, further validation and refinement, providing meaning, expertise or perspective over the preliminary findings [128].

3- Analyzing and Synthesizing Qualitative Data

Analysis and synthesis is a crucial part of any review approach, including the review approaches before mentioned, which recommended the use of approaches and methods typically used for the analysis and synthesis of qualitative information. Therefore, after the outlining of the major designs that can be used to analyze and synthesize a mixed type of information (qualitative and quantitative data); we will outline in greater detail the major features of the methods (including the underlying epistemological positioning of these) which can be used for the analysis and synthesis of qualitative information.

3.1 Designs for analyzing and synthesizing mixed type of information

Analyzing and synthesizing different types of information (e.g. qualitative and quantitative data) in a mixed or combined way, represents a current major need and challenges for healthcare review studies. Indeed, combining different type of information (theory, frameworks, empirical, policy, legal perspectives, proposals, and others) might be a major current requirement for informing complex policy and management decisions [125].

The emphasis for a synthesis that mixes different types of information remains on data comparison and integration. The result "sum up" what is known about a target phenomenon from a variety of sources and evidence and, thereby, is able to direct practice, policy and future research. The way to combine different type of information has been for instance a target for methodological essays [118; 131]. These essays provide guidance for the analysis and synthesis of a mixed type of information. The process of analyzing and synthesizing mixed information can, according to those essays, follow one of the following designs, which might be selected according to the purposes of the review and the characteristics of the information available over the topic.

3.1.1 Segregated design

The 'segregated design' maintains the conventional binary distinction between qualitative and quantitative data, which means that the qualitative and quantitative data is analyzed and synthesized separately from each other, and possibly through different methods. Only after, each set of qualitative and quantitative findings (separated by synthesized products), could be themselves merged and mixed with each other towards being reflecting into a set of conclusions, a theoretical framework, or a path analysis over the subject.

3.1.2 Integrated design

In the 'integrated' design, the methodological differences between qualitative and quantitative studies are minimized. Both kinds of studies are viewed as producing findings that can readily be transformed into each other. A major assumption for the selection of this design is that the research synthesis of mixed information is defined as the assimilation, as opposed to configuration, of the research findings.

In integrated designs, the studies in a targeted domain are grouped for synthesis not exactly by the type of underlying sources (i.e., qualitative and quantitative data), but rather by findings/content that can answer to the same research questions, or addressing the same aspects of a target phenomenon. Therefore, qualitative and quantitative findings addressing the same aspects may extend each other, be a form of confirmation or contradiction. For instance, this integrated design can be accomplished by a mixed analysis in which the analytic emphasis is on transforming findings to enable them to be combined. Transformation can include *qualitizing*, or converting quantitative findings into a qualitative form so they can be combined with other qualitative data; and *quantitizing*, or converting qualitative findings into quantitative form so they can be combined with other quantitative data or information.

3.1.3 Contingent design

In the 'contingent' design, the analysis and synthesis of findings that answer to a first research question determines the next group of studies that will be retrieved and analyzed to answer a second research question which, in turn, may lead to the analysis of a third group of studies that answer to a third research question raised, and so on. The cycle continues until a comprehensive research synthesis can be presented.

Contingent designs may, or may not, depend on hard-lines drawn between qualitative and quantitative studies. Contingent designs may be operational through segregated designs by posing a series of research questions conceived to be amenable only to qualitative or quantitative studies. In this scenario, each type of information is analyzed with qualitative or quantitative methods respectively to produce the qualitative and quantitative research syntheses that will be ultimately configured into a theoretical or narrative rendering of the findings. Alternatively, contingent designs may be more like integrated designs in posing a series of research questions deemed answerable through both qualitative and quantitative studies in a targeted domain of research. The findings of these studies can, thereafter, be assimilated into an integrated research synthesis.

In short, the defining feature of contingent designs is the cycle of research synthesis conducted to answer questions raised by a previous syntheses; not exactly the segregation or integration of qualitative and quantitative data.

3.2 Methods of analysis and synthesis of qualitative information

Beyond designs, we can frame different methods primarily designed to analyze and synthesize qualitative information, but that can be secondarily applied to a qualitative-based synthesis of the literature material under review. We outline a broad array of these methods according to their epistemological perspectives.

3.2.1 Commonalities and differences among methods

The approaches for analyses and syntheses of quantitative research are few and very well-defined, such as narrative-based systematic reviews and meta-analyses. But in contrast, much more terms and methodological approaches exist to analyze and synthesize qualitative information. Such a proliferation of methods can lead to some confusion regarding which method is deemed as the most appropriate for each research question or situation. Nonetheless, the mentioned proliferation of methods does not mask some of the basic similarities in the approach beyond the differences they have, and that should lead a researcher to choose one, or another, accordingly to the research purposes.

To some extent, these differences can be explained by the epistemological assumptions underpinning each method. This is whether the approach tends to the idealist/constructivist

side, or to the opposite realist side of the same epistemological spectrum. Among the methods on the same side of the epistemological spectrum, the differences tend to be smaller [132].

In the following sub-sections we outline the two opposite sides of the aforementioned epistemological spectrum, describing the methodologies that predominantly follow one or another epistemological perspective.

Approaches tending to the idealist/constructivist perspective

Meta-ethnography [133; 134] and the *grounded theory* approach [135; 136] are two widely recognized approaches for analysis and synthesis of qualitative-based information that, despite their specificities, have in common a trend for interpretation, comparison, integration, and finally transformation of data into new theories or conceptions, rather than simple aggregation or summary of information. Therefore, these methods tend to an idealist/constructivist epistemological perspective. Indeed, these approaches reflect a focus on a more inductive and interactive approach (instead of a deductive and linear) to organize and present qualitative information. They seek to provide the synthesis of the *whole*, which has a greater explanatory value than the sum of parts or sources.

Specifically, the *meta-ethnography* approach for qualitative synthesis builds on a comparative understanding of a phenomenon of interest, highlighting how to put together written interpretative accounts beyond a mere aggregation or summary of information. The three following types of synthesis are used within a meta-ethnographic label [133; 134]. One involves the translation of concepts from individual studies into one another, constituting a process called "reciprocal translational analyses". "Refutational synthesis" involves exploring and explaining contradictions between individual studies; while "lines-of-argument synthesis" refers to building up a picture of the whole from studies of its parts.

By its turn, the *grounded theory* approach [135; 136] refers to an inductive approach to qualitative analysis and synthesis allowing the theory to emerge from the data, envisioning the generation of a 'new' understanding or theory about a phenomenon. It is an approach mostly based on a "constant comparison method".

Furthermore, other proliferating approaches can put emphasis in the interpretative, translational, inductive, and transformational processes for analysis and synthesis of

qualitative information. One of these approaches is for instance the *meta-study*, which involves a secondary formulation of constructions that were primarily formulated into primary studies, including the scrutiny of their underpinning philosophical and theoretical assumptions [(137)]. Other approach is the *meta-narrative* method in which a multi-paradigm of analyses and synthesis is developed towards addressing a complex subject matter. This is an approach particularly suitable towards informing complex policy and management decisions [(109)]. A *critical interpretative synthesis* can be used to synthesize a substantial amount of data with relevance being the main criteria for inclusion [(138)]. Finally, the *thematic synthesis* shares *meta-ethnography* influences, with the analytical themes being comparable to third-order interpretations, however, the approach also uses *grounded theory* methods such as the "constant comparison method" [(139)], thereby a mix-method approach.

Approaches tending to realist and positivist epistemological perspective

On the opposite side of the epistemological spectrum, there are methods of qualitative synthesis placing more emphasis into a realist and positivist epistemological perspective. These methods provide a more objective, aggregative, and cumulative synthesis, or summaries, of primary content under review.

Beyond the realist review approach, previously outlined, which can bring a methodological solution for a literature review process [(121)]; we can find methods specifically for qualitative-data analysis and synthesis, which tend for a realist or positivist side of an epistemological spectrum. Those are for instance: the *ecological triangulation*, which have commonalities with the realist review process, but placing more emphasis on the inter-dependent relationships between the behavior, the persons, and the environments [(140)]; the *content analyses*, in which the common content are condensed and mostly enumerated into fewer content-related categories [(141)]; and finally the *qualitative meta-summary* in which findings are accumulated and summarized rather than translated or transformed, further reflecting a quantitative logic for instance by determining "qualitative size-effects" [(117)].

Differentiating constructivist and realist approaches: a synthesis

Barret-Page and Thomas [(132)] provide a useful framework to outline the aspects in which methods for qualitative-data analysis and synthesis, as applied to literature reviews, mostly vary among each other. These differences are set as based on six major dimensions (searching, quality assessment, problematizing the literature, question, heterogeneity and

synthetic product) we below describe as tied to the epistemological perspectives we have been outlining.

Therefore, the methods tending to an idealist/constructivist perspective hold the following features: a more interactive *searching* process; a less clear *quality assessment*, meaning with a focus more in relevancy than on methodological issues; the *problematizing* or critique of the literature is actively present; the *questions* broadly relate with exploration of a phenomenon; the *heterogeneity* is actively fostered; and the final *synthetic product* is more complex, conceptual, sometimes operating at a symbolic or metaphorical level, requiring further operationalization for practice or policy-making.

Methods falling in the realist/positivist perspective hold the following features: they present a more linear approach towards *searching*; they hold a clear *quality assessment* procedure which is previously defined; they avoid a *problematization* of the literature; they aim to provide answers to a *question* rather than exploring a question or phenomenon; they avoid *heterogeneity* through a well-defined and narrow focus; and the final *synthetic product* can provide more clear directions for practitioners and policy-makers to be followed.

3.2.2 Framework syntheses

In this later sub-section of our 'Background', we independently outline an approach for analysis and synthesis of qualitative-based information that stays in a middle point between the two epistemological perspectives, combining features of the methods coming from the two sides of the epistemological spectrum. We refer to the *framework synthesis* approach.

Framework synthesis is, therefore, characterized by utilizing an *a priori* framework – informed by background material to extract, analyze, and synthesize information. Primarily developed to synthesize qualitative data, the *framework synthesis* reflects the original accounts and observations of the people studied (*grounded* and *inductive*); but it starts from a pre-established set of aims, objectives, and frameworks. In that sense it is, at the outset, a *deductive* approach although, in addition to topics identified by the framework, new topics may be developed and incorporated as they are *inductively* emerging from the data.

The synthetic product of a *framework synthesis* can be expressed in the form of a chart, which may be used to map the nature and range of the concept under study, find associations between themes, as well as exceptions to these. The *framework synthesis*

approach was applied, explicitly, in only few studies [142; 143], as based into the following five stages developed by Pope and colleagues [116]:

- Familiarization - immersion in the raw data (or typically a pragmatic selection from the data) by listening to tapes, reading transcripts, studying notes or broadly information under review (in case of a review), in order to list key ideas and recurrent themes.
- Identifying a thematic framework - identifying all the key issues, concepts, and themes by which the data can be examined and referenced. This is carried out by drawing on *a priori* issues and questions raised from the aims and objectives of the study or review.
- Indexing - applying the thematic framework or index systematically to all data in textual form by annotating the transcripts, or literature notes, with numerical codes from the index, usually supported by short text descriptors to elaborate the index heading. Single passages of text can often encompass a large number of different themes, each of which has to be recorded, usually in the margin of the paper.
- Charting - rearranging the data according to the appropriate part of the thematic framework to which they relate towards forming charts. For example, there is likely to be a chart for each key subject area or theme with entries for several respondents. Unlike simple cut and paste methods that group *verbatim* text, the charts contain distilled summaries of views and experiences. Thus the charting process involves a considerable amount of abstraction and synthesis.
- Mapping and interpretation - using the charts to define concepts, map the range and nature of phenomenon, create typologies and find associations between themes, in order to provide explanations about the findings. The process of mapping and interpretation is influenced by the original research objectives, as well as by the themes emerging from the data themselves.

These stages of the *framework synthesis* approach present frequent overlaps. Indeed, in many qualitative researches, the analytical process begins during data collection, with the data already gathered shaping further data collection. This sequential analysis or interim analysis has the advantage to allow the researcher to go back-and-forth to refine questions, develop hypotheses, and pursue emerging avenues of inquiry in further depth [119]. This is a feature that is common to the integrative, realist, and scoping review approaches, and which is reflected in the overall process of reasoning, development, and execution of this thesis.

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