C- 2ⁿᵈ REVIEW

State-of-the-science and -action of healthcare quality-initiatives – A systems-based stakeholders' perspective

1- Review Introduction

The field of quality-initiatives has been receiving tremendous input mostly in last decade after the landmark call for a transformational change in the way healthcare systems (US context) are organized and care is delivered [1].

Although yet in a beginning of a long-term (or never-ending) journey for such quality transformational change; the fields of quality-assessment, quality-improvement, quality-reporting and quality-aligned payment initiatives gained momentum and experiential learning mostly in later years. There are multiple initiatives in such field, as we cite some of the more representative: demonstration projects from the US Centers of Medicare and Medicaid Services (www.cms.gov.com) the public and largest US single-payer; institutions that have leading and leveraging the field of quality-measurement through a consensus-based processes (www.qualityforum.org); and the quality-improvement movement and structurally leveraged initiatives (www.ihi.com); periodic publications exclusively dedicated to such regards (e.g. BMJ quality & safety; Jt Comm J Qual Improv; Implementation Science), among many more illustrative examples we could cite within the advancement-journey of quality-initiatives in healthcare.

In summary, there is an increasing body of knowledge, experience, perspectives as well as a portfolio of big-scale and smaller-scale quality-initiatives that we could not neglect to support the achievement of our thesis goal. Therefore, we need to absorb the major trends, perspectives state-of-the-science and –action for quality and quality-initiatives among the general healthcare, supporting further proposed applications to the PAC Rehabilitation scope in the later "preliminary recommendations".

2- Review Objective

To synthesize the literature on the state-of-the-science and –action of quality-initiatives as applied the US whole health/healthcare system. The rationale of this objective is presented in Objectives section.

3- Synthesis of the Methods

We conducted a literature review and synthesis by integrating principles from the wide scope [2; 3], complex-based realist [4] and integrative [5] review approaches, with similarities with the approach followed in the 1st review, including the 1st review – part B. Such review process and similarities are outlined in-depth in Methods section.

Herein, as presented under the form of an organizing diagram (fig.5), we just overview the underlying ecological framework which guided all stages of the review process, including the synthesis stage, by generally guiding the construction of main headings for the narrative-based 'framework synthesis'. Broadly, the organization of the review was made around ecological levels of influence to the quality of the US health/healthcare system, as sub-divided by stakeholders' groups and different sub-systems, highlighting the roles, perspectives, trends, and data regarding their specific contribution to quality and quality-initiatives in the US health/healthcare/system.

The basis of such presented ecological framework was used as an underlying framework also for the construction of the landmark 'quality chasm' report, more than a decade ago [6]. Herein applied, it is updated to some evolving features in the organization of the US healthcare system. The more representative are the development of overarching entities above the macro-system level (Macro-Integrator) and subsequent systems at a regional level (Regional Health System) that are more recent features for the US health/healthcare system organization.

Results: 2nd review

Finally, in contrast to the 1st review and 1st review – part B, this 2nd review did not hold the parallel intent of a peer-review publication in an international periodic of the specialty, so it was not limited to word counting. It clearly presents as our most expanded review in terms of consuming space and information presented, but either way it still represents a synthetic review as compared to the so wider scope of possible applied information.

4- Review Results

We present the results of such review according to our underlying ecological framework. First of all, we outline the Consumers level in its centric position. The External Environment level which can influence the Macro- and also the Micro-system level are highlighted next. After the External Environment level, we present the Macro-system level. At such level we begin by the smaller macro-system units, then being macro-integrated and enlarged until conjointly forming Regional Health Systems. Then, we present the Micro-system level, which represent the frontline where quality of care is delivered to Consumers and with their active contribution, being broadly influenced by the External Environment and Macro-system levels. We should note the Public Policy-Makers remain outlined in the last section of this review due their overarching influential and integrating position to the all previously mentioned levels.

A) CONSUMERS LEVEL

The label consumers (or users) refer in first place to the patient under care, but also encompass their families or relatives, since the patient's health and healthcare is influenced by families attitudes and actions; as well as the own health and quality of life of family elements might be influenced by healthcare quality of care. Such rationale embraces a systems view of family functioning, which might be better understood as whole unit affected by disease or disabling process [7; 8; 9]. Herein, the consumers label can also broadly

encompass (sub)populations at a community, regional or national levels, covering the different levels of interest for quality [10; 11].

Consumers are placed right in the middle of our diagram (fig. 1) at this review, as it was in the 1st review. It happens because the quality of healthcare is made for consumers and with consumers' contribution. In other words, they are the target and center of quality of care (patient-centered quality dimensions); but simultaneously active stakeholders for optimizing healthcare and the quality-improvement effort. This section is made around these two perspectives.

1) Patient- and Family-Centered Dimension of Quality

According the 'quality chasm' report - besides safe, effective, efficient, with equity, and timely - a healthcare of quality needs to be patient-centered [12,] and broadly seen, family-centered. Care shall reflect meaning and value for the individual healthcare consumer - ultimately to whole population and society – and it might be a primary dimension of quality by its own right, even in cases when it is not a determinant of safer and more effective care [13].

Despite the definition offered by the 'quality chasm' landmark report, there are several definitions of patient-centeredness that try to better capture the widely complexity and comprehensiveness around the concept and it underlying meaning [13; 14; 15; 16]. But the lack of a uniform definition and operationalisation turns difficult the task of comparative research under the subject [17; 18]. Under the subject of patient- and family-centered care, there are two institutions specifically committed to create the conditions and develop this quality dimension and underlying research.

The 'Institute for Patient- and Family-Centered Care' develops a wide range of activities with the ultimate aim of promoting and empowering patients and families as critical stakeholders for healthcare definitions, as well as fostering the advancing, the understanding, and the practice of patient- and family-centered care. By its side, the 'Picker Institute', a world-wide spread institution, is committed with support initiatives and fund research with focus also in the enhancement of patient-centered care and practices.

Activities of both institutions are available for consultation in their respective websites (www.ipfcc.org/; http://pickerinstitute.org/).

One of the greatest threats to the quality of the American's patient experience and patient-centered care - particularly those with multi healthcare needs – is related with consumers having difficulties in navigation through multiple providers within a fragmented healthcare system, needing a system-based approach to solve such threat to patient-centered care along the continuum of healthcare [19; 20] and integration of services and care that will be later addressed at the macro- and micro-systems levels.

For improving patient-centered care, healthcare organizations (e.g. hospitals) should pro-actively design services and quality-improvement initiatives directly with such aims, for instance enhancing effective communication and cultural competent care for their consumers. This is for instance supported by guidance provided by the Joint Commission (accreditation agency) [21], by the American Medical Association [22], as well as exemplified by best-in-class hospitals [17; 23; 24].

2) Consumers Active Role for Quality

Traditionally, the concept of quality in healthcare embraced what is within the direct scope of action and responsibility of healthcare organizations and professionals. However, conceptually, we could enlarge the definition of quality in healthcare, by including patients and consumers' active role on it. It makes the quality concept going out of the exclusively/ direct responsibility of healthcare providers, on a broader vision of quality left opened several years ago by Donabedian, in a recognized quality-framing paper [25].

Indeed, consumers are the ultimate target for quality, but they also need to be critical active elements influencing and shaping the quality of care they experience. Rather than being passive healthcare receivers, consumers also have a shared responsibility for the quality of a health and healthcare system, yet they need to be activated and engaged in that sense [26; 27]. Nowadays, the enhancement of consumers' active engagement is a top priority for quality action [20].

The 'quality chasm' report [12], supports an idea of a consumers active role for quality, but it was criticized by did not operationalize so well the action that should be taken under this subject [28]. In a very helpful organizing paper, Hibbard [26] defines the active role of consumers to improve the quality of care as three major roles:

o   The co-producer role: consumers co-responsible for their health and quality of their healthcare (proxy of the wider Donabedian's quality delimitation [25];

o   The quality-informed choice for providers;

o   The evaluator role on the quality of care received, as well as helping defining the quality evaluation parameters.

We below illustrate and support these three roles with updated research support; as well as adding a fourth dimension:

o   Consumers' role in planning and (re-)designing health and healthcare system.

2.1 Co-producer role: Engaging consumers with their own health and healthcare

Before we could embrace the engagement of consumers with their own healthcare, we first need to mention consumers' engagement begins with a focus on health promotion.

2.1.1 Engaging consumers behaviors with a health promotion perspective

Consumers' active role for quality begins with an engagement on health promotion (e.g. healthy lifestyle or feeding patterns) and disease-preventive behaviors and activities, including seeking preventive healthcare. This is a major actual political trend for improving the quality and efficiency of healthcare systems, which requires collaborative efforts of a health system with different societal sectors, community resources, and population. This is a feature further addressed at the macro-system level.

Herein, we highlight that only a strong commitment and collaboration among consumers and health-related stakeholders – on a system perspective far beyond the limits of healthcare [29] - can change the determinants (e.g. sedentary lifestyles, high caloric alimentation) of American's poor health [30]: on population [31] and citizen perspective [32].

2.1.2 Engaging consumers with healthcare activities: self-management and adherence

Besides health promotion, consumers need to be engaged and adhere to healthcare activity such as preventive, primary, curative, chronic disease management, palliative, or rehabilitative care. One of the most relevant features - part of the national priorities [20] - is the enhancement of the self-management of chronic conditions - as a critical element of the chronic care model [33; 34; 35] - being pointed as relevant for the efficiency and sustainability of healthcare systems, while improving patients outcomes [36].

An understanding of self-management strategies can help patients avoid exacerbations or setbacks, which can lead to burdensome and preventable treatments and hospitalizations. Engaged patients are more likely to demonstrate self-management behaviors, which are vital to achieving better health outcomes, lower service utilization, and lower costs [37].

Therefore, engaging patients with self-management activities and adherence prescriptions is a critical task healthcare providers need to accomplish [20; 27]. Professionals should activate and sustain patients' compliance, motivation and engagement with self-management, but it does not exclusively relate with providing patient education for self-management, but also relate with specifically what and how it is done. For instance, providers need to enhance patient's perceived control and self-efficacy as critical determinants of patients' health behaviors: as health psychology have been heavily studying [38; 39].

Operationally, clinicians can achieve it through the use motivational interviewing [40], the development of effective communication, as well empathic, caring and emotionally supportive provider-patients relationships [22; 41]. Empirically, a recent meta-analysis reveals that effective communication presents highly correlated with better patient adherence, as well such communication can be enhanced by clinicians training [42].

2.1.3 Engaging patients in a informed shared-decision process

Another priority within the improvement of patient-centered care is the enhancement of patients' participation in their healthcare decision, instead of the decision remaining almost

exclusively based on providers: what is been called as the shared decision-making for health and healthcare [20].

Effective shared decision-making, besides patient-centered, can also be critical for the efficiency of care, for instance making savings of 23% in surgeries while providing better function and satisfaction [43]. It happens mostly on those elective or 'preference-sensitive' interventions, although the size-effects vary across related studies [44].

Despite highlighted relevance, multiple studies highlight significant practice gaps when it comes to engaging patients in shared decision-making, in both primary and specialty care [13; 45; 46; 47; 48]. Clinicians shall make use of shared-decision making process and existing tools to improve knowledge, adjust unrealistic expectations, and elicit desired outcomes, and finally achieve a degree of acceptable risks for individual patients [49; 50], as well as achieving understanding of detailed information needed beyond the gist [51].

Enhancing informed shared decision-making is eminently an adaptive task for the professional who need to individualize their action and mostly their communication strategies to different patients' values; as well as different patients' levels of health literacy and numeracy, particularly concerning consumers with lower levels of those competencies – those at high risk of poorer involvement and health outcomes [52; 53; 54].

In summary, enhanced approaches to shared-decision making shall become the practice norm, rather than the exception, for a high-value healthcare care [55].

2.1.4 Incentives and initiatives for activating the consumers' co-producer role

Activating consumers for being a co-producer of their own health received more attention and interest from the healthcare stakeholders in the last years. This is for instance explicit in a recent formulation of a theory precisely related with activation of consumers and patients [27], but also accounting for a growing set of initiatives for instance providing incentives (including financial) with the explicit aim of activating the co-producer role, and often also envisioning reducing global healthcare expenditures.

In terms of incentives, mostly financial, those could be: paying patients for smoke cessation behaviors [56]; as well the 'consumer-directed health plans' (CDHP), which aim to stimulate

consumers to become more actively involved in their own health and informed healthcare choices (also addressed at the macro-system level).

The major idea behind such CDHP plans is to 'activate' patients for their own care. However, empirical data does not prove the enrollment in such plans really activates a quality-based choice for providers: the activation occurred in enrollees previously with more readiness to be active agents of health/healthcare – taking financial advantages of the extra-incentives and information such health plans promote [57; 58].

In terms of patients' activation - despite those addressing consumers' life-styles and behaviors in a health promotion perspective [59; 60; 61] - there are also types of initiatives that aim to improve patients' communication with their doctors [62]; or even preparing patients to communicate what they need and want before consultation [63; 64].

An ultimate, integrative and larger-scale example is the program launched by the Robert Wood Johnson Foundation launched in fourteen communities to align forces and expanding the involvement of consumers in all facets of care. These multi-stakeholder organizations provide an early glimpse into the opportunities and challenges to integrate consumers completely in their chronic care strategies, as early experiences highlight [65].

As a corollary, it is advocated these approaches for activating/stimulating patients as co-producers of their own quality of care are under-valued and under-studied on its effects for quality and efficiency of care, thus it needs to be supported by more solid research [26], for instance a research agenda for the financial incentives directed to patients [66].

2.2 Engage Consumers with Quality-Information (quality-informed choices for providers/ health plans)

Quality-informed choice for care and providers is another way consumers can critically influence the quality of a healthcare system. That is critical for a proclaimed transformational change for quality in healthcare systems [12].

Operationally it should serve as a stimulus for providers pursue high quality of care. It is been argued that market pressure of a consumer's choice for quality-providers could represent a greater stimulus than the use of quality-reimbursement policies [67].

2.2.1 Consumers use of public-reported quality-information

Public reporting of quality-information shall have a central role on consumers' choice for providers. Consumers can have access to the so-called health report-cards, progressively more comprehensive, mostly on web-based comparative tools. They can be accessible on a public-accessible compendium created for such information becomes accessible from a single resource [68].

However, despite the efforts continually being applied to performance measurement and public-reporting (we address the subject at the external environment level), advances are still far from the desired levels of consumers' engagement with public quality-information for choosing providers. It happens due lack of consumers knowledge that such data exists; lack of motivation to search for it; lack understanding of such information (inadequate information for different levels health literacy and numeracy) or even lack of trust or meaning/value placed in such measures [28; 69; 70; 71; 72; 73; 74; 75; 76]. The subject applies to choice for providers, but also with consumers' choice for health plans with many consumers having difficulties in understanding comparative plan information and in making informed healthcare choices [77].

2.2.2 Adapting public-reported quality-information to the level of consumers' interest and understanding

Without patients knowing, consulting, understanding and ultimately valuing quality-information, a transformational change for quality supported in consumers' choice for quality-providers cannot occur [26]. Indeed, despite convenience and price might preserve at least some role in consumers' choice for health plan and providers [70]; quality-related information should 'conquer' preponderance on other determinats of consumers' choice such informal networks of information [28; 75].

Despite some ambiguity on data [69], if consumers get access to quality-information, it can represent an important determinant of consumers' choices, at least with the health-plans' choice [70], but it requires that population often seek and have access to that kind of

information. Therefore, enhancing access of more people to comparative quality-information remains a first step in an advancement roadmap [357].

A second feature is that consumers need to understand the comparative public quality-information available. Therefore, such sort of information needs to be 'democratized' to the full range of consumers' health literacy and numeracy [54]. Indeed, consumers' health literacy and numeric skills - besides influencing shared decision-making yet highlighted - can also interfere in the process of consumers' choice for different health plans and providers with basis on comparative quality-information [76; 77; 78]. Thus strategies directed to active the good-use of comparative quality-information among people with lower numeric and health literacy are required [76].

To enhance comprehension and use of comparative quality information, the way and format quality-reported information is presented and compared is far from being a neutral element. With this respect, there is a paucity of research directed to highlighting the formats for the best-presentation of quality-information – those that better engages consumers and facilitates understanding and the decision-making process. In a recent experimental study, authors concluded that when a framework was provided and plain language was used to describe quality indicators, consumers were better able to understand and to place greater value in the information [79].

Other format and presentation tips being outlined are: user-friendly and easy-to-read presentation formats and explanatory messages [70]; less information and easy presentation format lead to more engagement, particularly in consumers with low numeric skills [80], as readability and non-ambiguity of terms and quality concepts should be fostered for presenting comparative quality-information [81].

As a third aspect to be enhanced within quality-information (after accessibility and understanding), the consumers need to select and weight quality-data that respond to their concerns, what they want to know and value: in other words, what would be critical and meaningful for them as quality-informed choice for providers [73; 82]. Indeed, if we want consumers' use quality-information, such available information - besides valid, reliable, sensitive to differences, and feasible to ascertain - needs to be meaningful for consumers, becoming sensible to their particular choice process [82].

However, we must highlight that consumers do not value all quality-information available in the same way, with differences from consumer to consumer. Despite individual differences, there are some tendencies and patterns that should be mentioned. For example, the most valued element for choosing a physician is the experiences of other patients - interpersonal quality and patient recommendations (patient-centeredness). In such cases, consumers tend to choose accordingly such criteria [83].

As a corollary, performance measurement, reporting and aligned payment mechanisms must leave a provider-based narrow focus in order to public expose what is important to patients, which includes items corresponding to the provider-patient relationships, consumers previous experiences and broadly patient-centered measures [84; 85].

2.3 Evaluator role: Enhancing consumers' participation in evaluation of health and healthcare systems

Another way to engage consumers in an active role for quality relates with engagement in evaluating the quality of care. It can be operational through evaluation of their own health, function, health-related quality of life and outcomes of care; the evaluation of the experience or satisfaction with care; as well as evaluation of the meaningfulness of the quality parameters used for quality measurement and reporting.

A multidimensional concept often used as a metric for quality-evaluation from the consumers' perspectives is consumers' satisfaction. Due being often associated with a re-use, loyalty or recommendation for providers, it gained preponderance an increased interest among providers, as cited in the 1st review. Therefore, there is a huge number of satisfaction measures for different services, but used with a lack of uniformization, even within the same healthcare area. We cite only few examples [86; 87; 88].

Consumers' satisfaction is a subjective and multi-dimensional own judgment or processing about the overall experience of care, which is tied to individual preferences and values; as it's also influenced by baseline expectations [89]. Due such reasons, satisfaction measures were losing ground in consumers' quality-evaluation for another patient-centered concept: consumers' experience. Although it could have similarities on constitutive dimensions, the concept of consumers' experience generally goes beyond satisfaction towards a more

objective report of experience (rather than subjective rating, judgment or recommendation) on meaningful dimensions such: providers' communication; education; support; timeliness; responsiveness and access to care [90]. Despite differences or similarities in concepts, both concepts could be used in a same set of quality-indicators to ensure patient- and family-centeredness of healthcare [91].

The CAHPS' program (Consumer Assessment of Healthcare Providers and Systems) - developed under the activity of the US Agency for Healthcare Research and Quality (AHRQ) - is today the mainstream program to assess the patient-centeredness of care (using the concept of consumers' experience) across providers and health plans. That is made through the appliance of a wide range of CAHPS's instruments, which shall be used for benchmarking and ultimately to quality-improvement based on consumers' point of view [92].

Quality feedback based on consumers' experiences - as the CAHPS' family of tools provide - is a way to shape healthcare to become more patient-centered; to assure consumers' preferences are considered when care is provided; as well as to assure providers engage with those 'qualitative' aspects of care that are often neglected when quality-initiatives of narrow scope are applied [84]. For preventing low effectiveness or unintended consequences of quality-initiatives for the provider-patient relationship and the patient-centered perspective, consumers should be the fundamental source of definition of quality [13; 6].

Consumers should help to establish the parameters they want to be reflected in public reported quality-information, reflected in higher meaningfulness and higher consumers' use of quality-information they helped to shape and score [82]. In that sense the evaluator role feeds the consumer informed choice role for quality, with previous consumers' ratings serving as a source for other consumers' choice for providers or health plans [26].

The consumer evaluative role is also a critical source of information for peer-benchmark made by providers, highlighting targets for patient-centered care improvement with based on consumers' evaluations. But more recently it is been claimed a higher level of consumers influence in way care and services are planned, designed or delivered.

2.4 Enhance consumers' participation in planning and (re-)designing meaningful health and healthcare systems

An ultimate way of consumers' active role for quality - often through different forms of representativeness - relates with being actively involved in designing, planning, and implementing health and healthcare systems, organizations and practices. This is something healthcare leaders need to facilitate with a systematic approach and a meaningful concerted roadmap applied along the next years [93; 94; 95].

Operationally, consumers, patients and population needs, perspectives and priorities need to be considered for defining research agendas and ultimately provide responses for what they need and want in terms of their own health and healthcare (also highlighted in a later 'research community' sub-section).

Patients and populations need to be early involved in developing a national, regional, local and community health and healthcare priorities, actively influencing policy action that shall progressively emphasize patient-centeredness as a core quality dimension [96]. Consumers' values and preferences should be elicited and adequately reflected also in practice guidelines development [97; 98; 99], despite it is not actually the norm [100].

Within an organizational level, consumers, or their representatives, should be involved on support organizational quality management programs. It could happen for instance by inclusion and active involvement in quality committees, definition of quality objectives, participation in improvement initiatives, discussion of patient-based ratings, and discussion of effectiveness of improvement strategies or initiatives [17; 101].

As an example of a more operational perspective, patients and families can also be involved in development of patient information material based on their perceived needs, preferences and experiences for enhancing the use of these materials by consumers [102]. In this way, consumers (patients, relatives and their representatives) are not only helping designing systems of care, but tools that also enhance the quality of care, as it could be fostered by many other different forms of consumer engagement initiatives.

B) EXTERNAL ENVIRONMENT LEVEL

The external environment is composed by the amount of external entities and stakeholders groups that conjointly influence the macro-system level (and some cases directly the micro-level), in turn influencing the quality of care delivered at the micro-system level, thus experienced by patients and relatives.

We describe the action, roles and perspectives for quality of the different entities and stakeholders framed within the external environment level: payers & purchasers; external/ independent quality bodies; research community; suppliers; as finally the educational community (fig.1). Public policy-makers group also belong to an external environment level. However, it will be only exposed in an ultimate section, due the over-arching influential role over all the previously highlighted stakeholders' levels.

1) Payers & Purchasers

Payers (insurers, public programs, individuals) and purchasers (mostly employers, self-employed people and out-of-pocket consumers) both concern with the value of care they pay and receive for their own or for their beneficiaries. Such value account for the binomial among cost/price and the quality/outcomes it produces.

A main recommendation of the 'quality chasm' report is the need to align payment incentives for a transformational change for quality [12]. Instead of rewarding for quantity or intensity of services, payment systems must reward quality and efficient healthcare, eliminating waste and promoting the economical sustainability of healthcare provision.

There is a growing consensus the actual predominant payment model (fee-for-service) stimulates for unneeded and expensive services instead of quality, efficient, preventive, and coordinated care [67; 103]. Therefore, a payment reform is already in process, testing and implementing alternative or complementary methods herein compared.

1.1 Quality-aligned payment approaches compared

Capitation models, particularly popular in the 90s, are an option that stimulates for health promotion, prevention, efficiency and coordination of care, providing *ad hoc* payments to providers assure a range of population coverage [104]. However, it often presents too many financial risks for most providers; as well as needed care can be denied for some patients [105; 106; 107]. Partial capitation tries to attenuate the potential prejudices of full capitation, although preserves the same type of inconvenience. It can be additionally used as a complement of other ongoing payment methods under the actual payment reforms - Patient Centered Medical Home (PCMH) and Accountable Care Organizations (ACOs) - in order to enhance financial stimulus mostly for the effectiveness of health promotion and primary care activities, as well as promoting advanced capital for structural investments in higher quality and efficient care [105].

The PCMH, particularly acting from a primary care structure, is an innovative approach applied in the American context that synthetically consists in reward providers for those until now non-paid services such: coordination of services and care among providers, and the provision of an extended healing relationship which includes patient education on health, health services and self-management of their conditions under a proxy relationship of trust on a patient-centered basis [108; 109; 110].

However, as a payment method (it also serves as an organizational model for micro-integration, as later highlight), the PCMH model despite rewarding those activities until now non-paid, it does not promote for accountability of their actions and population, which lead purchasers to think in alternative, but mostly complementary, methods for incentivize short, medium and long-term efficiency of healthcare provision [105].

As told, partial capitation models can do it so, but it can put PCMH practices at financial risk, something most of them are not ready to assume. Thus, it is emerging a model that promotes a local accountability for the whole care provided to a range of population on a longitudinal per-capita basis. We are referring to the Accountable Care Organizations (ACOs) actually gaining momentum and political attention [111].

An ACO consists on a local functional agglomerate of providers, acting as a local integrated delivery system, but accountable for the quality and cost of healthcare, promoting value for those purchasing healthcare [112; 113]. When we mention value, we mean

the optimal balance between the best and meaningful outcomes achievable, at the lower global price the ACO can produce. On a typical ACO approach, ACOs should promote costs savings without, at least, diminishing the quality of care, although it also might be seek for improvement. Those costs savings are calculated with basis on estimations of per-capita costs for the range of population covered. Savings shall be shared among purchasers and the ACO, constituting a remuneration of their successful efforts for the quality and value of healthcare [114].

Unlike capitation models, it happens without necessarily put providers at higher financial risk, or even get patients 'locked in' in providers [105]. Despite the proposed adequacy of the ACO approach, and some preliminary results on a Medicare demonstration project [112; 113], the approach is far from getting consensus. As critics, it is been denoted that it can be difficult to fairly share financial gains [115] and to balance cooperation and competition among providers [116]; as well as that ACOs - as champion local organizations - might alter the equilibrium in market forces ultimately leading to higher prices for purchasers. Moreover, it can put the smallest providers, either those inside or outside the ACO - at a weakening positioning in the hierarchy of power/decision - actually getting prejudices rather than benefits. Savings, if existing, could be secured by providers in heading positions in the ACO. Either balancing potential threats, it seems prevailing the optimism about the approach [117]. Indeed, it was fostered to become a standard approach by Medicare as a result of the recent healthcare reform law [111].

Another payment approach that builds on efficiency advantages - possibly interoperable and complementary with ACOs - is the Bundled Payments for Episodes of Care [105]. The approach basically consists on prospective, but aggregated, payments given for all care needed within an entire 'episode' of care (in this aspect differing from actual prospective payments). Such 'episodes' can be either acute (e.g. until 30 days after the onset) or chronic episodes (e.g. one year of overall care required), previously defined by analyses of prototypal services needed for a care of quality.

The value of the bundled payment is the same despite the services providers use and despite providers' type. It should have flexibility for case managers and providers to make optimal choices for the quality and efficiency of care patterns (e.g. preventing avoidable re-hospitalizations actually happening) within the bundled [67].

But such stimulus only intervenes within the bundled services and not outside. Indeed, while the ACOs are stimulated for the diminishing incidence of 'episodes' per enrollee, the bundled payments method better rewards providers that have more episodes (in case of the acute) to treat, rather than stimulating for providers and systems to prevent them. This is one of the arguments used in favor of combining these two approaches [105].

The recent health reform legislation [111] determines bundled shall be widely tested and demonstrated on priority conditions to show its potential for systemic benefits on quality, efficiency and coordination of care. But important questions yet need answers.

A first is how to assure effectiveness of the method and preventing the so-called 'upcoding' fraud that may be difficult to control. A second question is the best way to assure a fair distribution of the bundled payment for the providers along the continuum of care, enabling and rewarding their quality efforts and contribution for patients' best care. A third is how to assure patients' ability to choice for providers remains unconstrained [67; 118]. A fourth important question (which may interfere with most of the others) is who's the entity receiving the bundle. The ACOs are one possibility; as well as the managed care organizations; the acute hospitals; or even the in-developing concept of Continuing Care Hospital [119]. This is a sensible question because it shapes the scope of accountability for care pathways management and the 'power' in providers' relationships. The respective US Secretary will assume such responsibility [111].

1.2 Pay-for-Performance (P4P):

An ultimate payment method gaining momentum and being widely used in last decade, not only in US, is the so-called Pay-for-Performance (P4P). It consists on a purchasing bonus for providers that comply with a set of quality or performance indicators. Different type of purchasers, including Managed Care Organizations [120], have been using this approach when contract with providers.

The major premise is that such financial incentive will improve compliance with the quality standards for target indicators, theoretically standing as a promising method to improve quality of care. Indeed, despite the evidence remains highly mixed and with lower ability for generalization, there is some of evidence supporting P4P ability to achieve its primary

focus: improved standards' compliance in pre-selected quality indicators: although high variation in approaches and effectiveness is reported [121].

However, there is also a movement arguing the systemic neutrality (or even prejudices) as a result of those P4P. Using a systems thinking rationale, it is argued that even if P4P achieves its primary focus, such gains might result from a system adaptation to score higher in those selected quality elements, lowering non-measured quality parameters. That is one of the often named 'unintended consequences' of P4P initiatives, at least in the way P4P has being applied.

In fact, literature highlights a series of common pitfalls of most actual P4P on the field. It does not mean P4P is an unviable approach to improve the quality of care - inclusively on a system perspective – but it means that such system of incentives needs to be very carefully designed and learning about the previous experiences either for effectively improve its directs targets, as to avoid the so-called 'unintended consequences' of pay-for-performance initiatives [121; 122].

In the box below we outline common pitfalls literature recommends to be addressed.

1. Relying on narrow sets of quality indicators, P4P does not reward comprehensive care [84]. The most prejudiced might be older patients; or patients with chronic, disability, or other complex conditions [35; 123]. Indeed, there is evidence suggesting that patient care not meeting standards may still be adequate [124]; as improved documentation may occur without any improvement in care [125]. Moreover, compliance with process standards can actually harm patients [123; 126], or limiting fruitful innovations [127].

2. Exclusive focus on quantitative (measurable) aspects of care leads to deflection on qualitative aspects (e.g. physician-patient-relationship), threatening patient-centered care as a critical quality component [84; 128]. Such qualitative dimension should be measured as complementary quality indicator [85].

3. P4P have been concentrated on short-term issues, excluding long-term criteria that may only show up in performance measures many years later to quality bonus reimbursement (myopia) [129].

4. If exclusively attached to standards, it could promote a 'satisfactory' league

ranking that disincentives innovation and excellence (complacency) [129].

5. With prevailing pay-for-performance calculation models, high-volume providers difficultly achieve top-ranking levels [130], calling for alternative pay-for-performance scoring methods [131].

6. Higher risk patients may be harmed by providers' negative attitudes [132] and even de-selection for attendance [133; 134]: in a way to 'gamble' the system for higher quality-scores; promoting inequity of services and care [135].

7. Misrepresentation of data, including creative accounting and fraud, may result in bonus for a 'fake' quality of care.

8. P4P may reward best those with high baseline score [136], allowing more resources for quality investments in those providers and less for those with lower baseline that in fact need quality-improvement. It inadvertently may increase disparities and inequity across providers [135; 137; 138].

As a final note, quality-payment methods can only be an effective if there is a good return of the investment and a positive business case for quality [139]. It requires a sufficient, instead of residual, amount of financial incentives to produce effects [121]; as well as concerted action among different payers with activity on a same local/community/region for a at least a certain period of time [108; 140; 141].

A local unified payment strategy gives important direction on providers working for multi-payers, as it allows the payment model (or mostly the combination of payment approaches) becomes adjusted/'costumized' to local circumstances and specificities of the healthcare delivering system and local stakeholders in a delimited location. Involvement of local stakeholders in a solution-development process may be critical for achieving a payment model, involving different method that fit their specific needs and community characteristics. Such 'costumization' on methods, or combination of those, should not threat the integrity of a national system of quality-initiatives made under unifying goals, strategies and common operational requisites [10].

2) External/Independent Quality Bodies

A major premise within the quality movement in healthcare is that improvement will be accelerated by adequate measurement. Quality-improving efforts will be actively made by providers and healthcare organizations accordingly the gaps exposed by external feedback reporting, peer benchmarking and public reporting of their quality data [142].

Effective quality-initiatives generally involve either internal as external quality-initiatives. Providers and mostly healthcare organizations are progressively more required to be responsible and accountable for the quality of care delivered in their practices. Their internal quality programs are the tool for assure, optimize and continuously improve the quality of their practices. However, for a valid and fair measurement across organizations and providers, quality assessment should also be promoted by external/ independent entities. From such external quality measurement/ monitoring shall result valuable comparative data for benchmarking and guidance on internal quality-improvement efforts, as well as stimulating for quality-improvement by the mechanism of public disclosure of quality-information [71; 143; 144].

Internal continuous quality-improvements improvement, by its turn, can also be guided and technically supported by different types of external entities, even in the sequence of an assessment process (for instance completing an accreditation process) or specifically facilitated by improvement expertise provided by external entities.

After such overview on the action of those different types of external/ independent quality-bodies, well outline their specific roles, actions and perspectives for the quality of healthcare systems.

2.1 Accreditation process

Accreditation entities have a long history as external bodies assessing and promoting the performance and quality at the level of healthcare organizations (macro-system). The accreditation process has evolved along the years, but synthetically it consists on a structured cycling process that aims to inform stakeholders - namely consumers and third-party purchasers on the conformity of healthcare delivering organizations - e.g. The Joint

Commission (TJC: www.jointcommission.org) - or health plans - e.g. National Committee Quality Assurance (NCQA: www.ncqa.org) - with regards to organizational performance, including quality and safety of their services [145].

Generally, this is made first by a structured assessment of organizational conformity with a set of pre-established criteria, which accrediting agencies define and continuously develop as standards for accreditation or certification on specific areas of healthcare activity. The accreditation process is not limited to an external assessment but it also encompasses feedback direction in how to achieve, maintain or - when differentiation of accreditation status exists - improve the grade of accomplishment with accreditation criteria and standards established by the external entity, and continuously improve their quality. As a cycling process, the defined accreditation status is hold by the healthcare organization for a period of time (the amount depends on the entity and program), followed by new assessment process for renew/ reclassification of the accreditation status.

Despite well-established implementation of the accreditation process in healthcare, a systematic review of the accreditation impacts reveals some inconsistency of benefits in the great majority of the multi-level domains of the accreditation process [146]. The benefits seem to appear relatively fast in first accreditation cycles, but their ability to help accredited providers diminishes along time, with the accreditation process being less challenging for providers after 10 years of implementation [147].

Additionally, it is been argued that - as part of their own evolving process on helping organizations advance their role for quality - the accreditation entities and their criteria shall be enhanced by a more solid supportive research-basis, as to provide more specific guide to healthcare managers on take decision that will drive to better front-line, clinical, quality of care [148].

Traditionally, accreditation bodies were focused on organizational attributes or structural aspects of service delivering as criteria for accreditation status. Although it may seem relevant to organizational quality-management; several recent analysis revealed that organizational accreditation status is not associated with higher levels quality performance measurement and reporting systems, as neither with patients' satisfaction scores [146; 149; 150].

In order to get a wider focus on integrating clinical effectiveness, the accreditation process was evolving for the development more clinically-related performance measurement

systems (i.e. ORYX for the Joint Commission and the HEDIS for the NCQA) to use as part of their accreditation processes. Incorporating information about clinical processes and outcomes it is included in the continuous pathway to achieve a comprehensive and clinically meaningful accreditation process [151; 152; 153].

Despite the value of the accreditation process - and the continuous development process accreditation bodies are making on their operations - the field of external quality-assessment has actual requirements that accreditation entities activity were not achieving only by them-self. Indeed, the unique scope and process of each accreditation entity led to unnecessary duplication of equivalent measures/ reporting system that contribute mostly to duplicate processes and confuse stakeholders [142; 154].

In sequence, as one measure to take worldwide, it is been suggested a greater coordination and horizontal collaboration among accreditation agencies and quality-measurement and -reporting systems. It should congruently inform stakeholders, thereby helping to enhance healthcare quality and safety [155]. With such regards, for achieving a valid, feasible and comparable system of external quality-assessment and assurance - also serving as a source of public reporting and benchmarking – it is needed a consensus in the selection and application of uniform core sets of quality-indicators for external quality-measurement [142].

2.2 Performance-Measurement and Public-Reporting of Quality-Information

Performance-measurement and public-reporting of quality-information are two critical, necessarily evidence-based, interdependent systems [156]. For instance a system of public-reporting of quality-information depends on the quality of performance-measurement system, since there will be prejudices of public-reporting inaccurate quality-data. Reporting non-uniform data also have low utility since it is non-comparable and it may only serve to confuse stakeholders.

2.2.1 Building uniformity of a Performance/Quality Measurement System

Performance measurement is fundamental to improve quality, engaging consumers through transparency, and supporting payment reforms. In this scenario for the US, a consensus-

building entity - namely the National Quality Forum (NQF: www.qualityforum.org) - has playing a critical role in achieving a critical collaboration among different quality stakeholders aiming to define common data-sets for quality-measurement and reporting, as endorsing evidence-based quality-indicators/measures.

The Hospital Quality Alliance (HQA) is major examples of such multi-stakeholders collaborative actions for uniformity of quality-measurement that set common measures for public quality-reporting of hospital quality/ performance (www.hospitalqualityalliance.org). Those for instance also received the contribution of representative accreditation entities and their performance-measurement systems such the ORYX of The Joint Commission.

More recently, the HQA joined force with other great multi-stakeholders colligation for the quality of care in other field of healthcare activity, namely the Ambulatory care Quality Alliance (AQA); as well involving other relevant healthcare stakeholders to build a new national Quality Alliance Steering Committee to better coordinate the promotion of quality measurement, transparency and improvement in care (http://www.healthqualityalliance.org/). In concrete, such steering committee will help coordinate and build the initial components of an infrastructure to collect healthcare quality and cost data nationwide.

Such nationwide infrastructure should use Electronic Health Record (EHR) systems - interoperable and planned for common data sets and coding systems – as well integration of clinical registries with claims data. It provides more accurate, valid and feasible data for subsequent use in quality measurement, (including risk-adjustment) public reporting, and quality-aligned reimbursement purposes [157; 158].

2.2.2 The state of public-reporting systems of performance/quality information

In a role to inform consumers and third-party purchasers, different type of quality-monitoring sponsors (accreditation, government departments or agencies and many other independent or colligated bodies) develop 'report cards' that public report the quality of different type of healthcare organization and individual providers. That is available on websites, often with comparable platforms, for instance the hospital compare

(www.hospitalcompare.hhs.gov), among other platforms for different healthcare areas. Such reporting systems are collected in a large compendium 'report cards', as an activity embedded in the 'talking quality' initiative – actually sponsored by the public Agency for Healthcare Research and Quality (AHRQ) – that globally aims to help sponsors of different reporting systems to turn their reporting initiatives more accessible, understandable and usable by consumers [68].

Stepping back, the public-reporting movement gained momentum as being considered as a critical element in the so-called transformational change for quality. Theoretically, it would promote great market pressures on providers and organizations to move forward on quality [12], although in practice inconsistency of the effects [72; 159], or even no significant impact [160] is reported. With such regards, we could denote that an inconsistency of effects might also be due an inconsistency of measures, methods and formats of public-reporting, clearly needing more uniformity [161]. Other reasons for suboptimal use of public-reported information are highlighted on consumers level.

2.3 Quality-Improvement Organizations

The ultimate goal of external or other form quality-monitoring or assessment is to highlight areas in need for quality-improvement. Despite the consultant role for improvement (meeting organizational or program accreditation standards) embedded in most accreditation processes, the improvement process ultimately depends on the effectiveness of organizational internal quality-improvement programs. As further outlined at the macro-system level, most healthcare organizations have a lack of infrastructural capacity to build up and fully deploy by them-self the optimal strategic and operational plans for internal quality-improvement processes, optimally addressing their specific quality-gaps.

With such regards, there are a group of external entities which aims to stimulate, support, give consulting expertise and facilitate the quality-improvement process within healthcare organizations, being seen progressively as more action-oriented supportive entities, for instance with regards to support the introduction of Health Information Technologies (HIT) [162].

Acting on wider national/ international basis for support different levels and processes associated with quality-improvement, we find the Institute of Healthcare Improvement (IHI) as a leading institution. Often acting in straight collaboration with the research community and leading providers [163], IHI develops, organizes, links and releases strategic white-papers, improvement frameworks, collaborative initiatives, educational actions, user-friendly applied tools among other initiatives (available at www.ihi.org) that help different type of healthcare organizations (managers and clinicians) to develop their maximum organizations potential for quality, and putting it into practice.

Among their different and on-going updated and new improvement-support initiatives, we might herein expose the 'improvement tracker' resource that allow to easily track and obtain graphic description of the quality/performance improvement along a series of measures, as activated by improvement initiatives (app.ihi.org/Workspace/tracker/); or the 'improvement map', which is a comprehensive, yet simple, free web-based tool that collects, organizes, exposes and links the needed critical start-up information for developing and deploying a wide range of quality-improvement initiatives available, being continuously updated (http://www.ihi.org/IHI/Programs/ImprovementMap/).

On a state level, we outline the action of Quality Improvement Organizations (QIOs) under Medicare contract. Such organizations evolved from a focus on case, complains and appeals review (formerly named as Peer Review Organizations) to a more direct focus on facilitating and assisting organizations improving areas in which healthcare quality falls short [162; 164].

Major areas in which quality falls short in US territories are for instance highlighted by the national quality and disparities reports made by the Agency for Healthcare Research and Quality (AHRQ). Such reports are evolving for a more action-oriented perspective [165], which is also reflected on Medicare's Quality-Improvement Program on giving strategic directives on the contracts with the QIOs about themes in which quality must be improved: national healthcare system and regional gaps.

Indeed, one evolutional issue most recent QIO contracts now provide, it is a fundamental shift from a provider-based to a more patient-based quality perspective. Indeed, there is a wide focus on assure the quality delivered to different, often complex, patient along the continuum of care, despite providers type [164].

3) Suppliers

Suppliers furnish the equipment, material, drugs, software and communication/information technologies used in healthcare. Suppliers' continuous innovations contribute to elevate the standards of quality, particularly suppliers' industry working in close collaboration with the research community (e.g. pharmaceutics industry for producing new drugs).

In this section, we focus on major contributes of suppliers to cross the quality chasm (differential among what quality of care patients receive and the state-of-science), rather than elevating the state-of-science, as mostly the pharmaceutical activity tries to promote. Therefore, we build this section with a focus on suppliers of Health Information Technology (HIT), and their role in developing and helping implementing new technologies and communication/information infrastructure supporting a transformational change for quality in healthcare systems.

3.1 HIT supplying and healthcare quality

The need for a widely adoption of HIT is a current major theme within the quality movement. It is fairly recognizable that the healthcare sector - particularly when compared with other industries - historically took low advantage of the huge developments in information and communication technologies seen is last decades. The landmark 'quality chasm' report does not conceive a healthcare system of the highest quality without massive developments in the use of these technologies applied to the wider healthcare system quality challenges [12]. HIT technologies might help to avoid misuse, overuse and underuse of healthcare, potentially leading to more safe, effective and efficient care [166; 167].

3.1.1 Electronic interoperable communication and information systems

The widespread use of interoperable communication and information systems - including Electronic Health Records (EHR) systems – represent a major issue within the quality-movement [168]. It might provide an infrastructural communication and information platform

needed to coordinate care across multiple providers and avoid errors due miscommunication or lack of shared information [169; 170].

Widespread use of interoperable communication and information system besides promoting communication among providers and with patients, it might also facilitate a pro-active or real-time quality-improvement action, instead of only feed-back corrective action. It is for instance possible that QIOs can assist practitioners in real-time decisions for quality, efficiency and coordination of care [162].

Additionally, these interoperable electronic systems represent a requirement for an efficient performance/ quality monitoring system. Instead of traditional handwriting, HIT systems (e.g. software and electronic portable devices) allow for a more efficient and feasible clinical-data recording system. Such electronic clinical information is able to be uploaded (or web-registered) to be stored and analyzed into uniform large databases suitable for quality/ performance data analysis [171; 172; 173].

Such feasible performance/ quality-monitoring system is in turn critical as a source for other critical quality reforms, such payment policies that reimburse also indexed to quality/ performance data [67].

3.1.2 Electronic/Software supportive tools

Despite these interoperable electronic systems, there are also other HIT tools and software that can be used to enhance safeness and avoid errors with prescription (i.e. reminder systems and e-prescribing), as well as to avoid surgery errors and other safety risks that cannot be exclusively handled by human memory [174; 175]. There is also software supporting the process of evidence-based clinical decision-making, providing practitioners with guidance in standard proceeding according to patient's data-entry [172; 176; 177].

3.2 HIT development and implementation:

Despite critical importance and some strategic well-directed efforts to build a US national information infrastructure [168], the HIT implementation is still far way of being a norm [169].

The investment required and some uncertainty of the financial return hinders execution action to adopt it (we address this theme in macro-system level).

Additionally, clinical practitioners often have difficulty on perceive benefits of HIT introduction, often rising skepticism or even active behavioral resistance to its introduction [178; 179; 180]. It happens mainly because of the extra-effort and subsequent administrative burden caused in a busy practice, at least initially [181]. Besides, it is always difficult changing healthcare practice patterns, routines and habits by professional education and quality-improvement [182], as the psycho-sociological research highlights so well [183; 184; 185]. Therefore, target and ideally multi-faceted implementation initiatives are needed to enhance the effectiveness of interventions for HIT adoption [186; 187; 188].

The underlying factors of practitioners' resistance to HIT implementation should be early addressed by HIT suppliers in the process of developing/adapting those technologies that should become 'costumized' to their final users' needs, helping with healthcare process; as well as becoming adjusted to the workflow [181; 189]. It increases the likelihood of its practice adoption [190], as becoming fully embedded in routine practice as highlighted by the normalization process model [191; 192; 193].

HIT developers and vendors are already actively involvement practitioners in early definition of type, content, and organization of HIT products, and if it matches with their practice needs in a busy context [194]. They also need to define information and communication technologies' architectures capable of incorporating data relevant for practitioners, but also relevant for wider healthcare stakeholders such consumers, managers and policy makers [195].

3.3 Valuable versus non-valuable HIT innovations for healthcare

Despite the needed value that HIT must bring as requisite to cross the healthcare quality chasm; not all HIT should add the desired value for the quality and efficiency of healthcare. Indeed, suppliers in order to sell their products induce demands that not always correspond to an evident return to healthcare quality [196], or even present some unintended consequences [197]. Induced demand, with increasing costs and no added quality benefits,

can also occur with new medication and highly specialized equipment or resources. That is a source of unwanted variation in healthcare [198].

The contribution of suppliers' products (HIT and others) to quality-improvement should benefit of being independently evaluated by other external environment stakeholders, particularly the research community with comparative effectiveness research (CER, soon addressed). It would promote a more evidence-based decision about its adoption, and not only adopting an innovation based on anecdotal information, because it is new and impress by technology employed [199].

4) Research Community

Research community encompass people and institutions that produce, plan, fund, and communicate innovative knowledge; or even review, synthesize or integrate existing knowledge - grounding political, organizational and clinical decisions.

There is a great amount of money spend, with visible results, in the level of innovation in the basic biomedical and more recently focused on clinical science - raising the bar of the state-of-science. However, healthcare systems are not delivering the best quality of care to every patient/population. Such difference among what is known and what is the practice norm is higher for the United States – a quality chasm [12; 200]. Thus, holding an advanced scientific knowledge is far from being enough for every patient/population have access, at an affordable/sustainable cost, to best science and tailored care available. The research community has a role to play on supporting the crossing of such 'quality chasm' [12]. Despite fundamental/basic science, there is a sequence of research activities advancing translational blocks, in order to research advances become reflected in high-quality and efficiency at every system, service, and care for citizens [201; 202; 203].

At a first translational block, there is a need for clinical efficacy studies (e.g. trials). At a second translational block there is a need for clinical effectiveness studies, which should test who benefits in practice from innovations or alternative care pathways (health-services, outcomes, comparative effectiveness research) – ideally culminating with practice guidelines development. At a third translation block, there is a need for research to uncover

the 'how' of optimal healthcare systems delivering and quality-initiatives (broader field of systems re-designs and improvement science).

At the following sub-sections we highlight the different roles research community would play for support quality-initiatives and quality of care coming to the bedside, with a particular focus on those activities that relates with the less developed translational blocks (second and third translations blocks); as well as illustrating emerging perspectives and approaches the research community might follow in their role for underpinning quality, value and health for patient and populations.

4.1 Health-services research (HSR)

Health-services research (HSR), broadly defined, is the multidisciplinary field of scientific investigation that studies how social factors, financing systems, organizational structures, processes, health technologies, and personal behaviors affect access to health care, the quality and cost of health care, and ultimately health and well-being of people served. Therefore the research domains are individuals, families, organizations, institutions, communities, and populations [204].

Synthetically, health-services research generally aims to highlight the better ways to organize, manage, deliver and improve healthcare services, as well establish scientific support for health policy decision-making [205]. Their studies inform the way - including where, when or by whom - the most appropriated services are organized, managed and efficiently delivered to patients and sub-populations: for the right patient, by the right providers, in the right place, at the right time.

Health-services research should produce and synthesize knowledge to create, implement and evaluate effective and efficient healthcare delivering systems. These researchers use regression analysis as their major tool to highlighting the health-services determinants of valuable health/healthcare delivering systems [206] (http://www.hsrmethods.org/).

In comparison with the investments continuously made along years in innovative biomedical research, it was made a very low investment in health-services research with about 1% of total health research funding [207]. While innovative research is needed for continuously elevate the quality-standards, the investment in health services research is

absolutely needed as part of a wider effort to deploy the best quality of care for the great majority of persons and populations needing health-services [203].

4.2 Outcomes research

Outcomes research seeks to understand the end-results of particular healthcare practices and interventions, becoming more clinically-focused than for instance the broader field of health-services research. It is a research field advancing in the US, mostly with the support of public Agency for Healthcare Research and Quality (http://www.ahrq.gov/clinic/out2res/outcom1.htm).

The end-results of outcomes research include effects that people experience and concern about. For clinicians and patients, outcomes research provides evidence about benefits, risks, and results of treatments so they can make more care informed decisions for care [208; 209]. Such support for informed decisions would be made accordingly particular patients' characteristics and different care alternatives: in that sense it presents an intrinsic linkage with comparative effectiveness research further outlined.

Outcomes research changed the culture of clinical practice and research by changing how we assess the end-results of healthcare services. In doing so, it has provided the foundation for measuring the quality of care. Indeed, the results of outcomes research are becoming part of the quality-reporting schemes that purchasers and consumers can use to assess and turn public their quality of care through the use of outcomes as quality-indicators.

Advances in the outcomes research have been both received tremendous input from the outcomes measurement capability [210]. The feasible application of outcomes measurement into routine practice is an advent allowing for better use of large databases and allowing practice-based research - subjects further addressed in independent sub-sections.

4.3 Comparative effectiveness research (CER)

An in-developing research area informing practice guidelines and clinical decision-making is the field of comparative effectiveness research (CER).

Following the experience of agencies in other countries [211], and the input from the Institute of Medicine [212]; the recent US health reform legislation heralds the beginning of a national CER program as a step in a long-term journey for supporting the development of a high-value, cost-effective, healthcare delivering system [213]. In first instance, it might be reflected in developing and synthesizing comparative effectiveness evidence, as well improving the capacity to conduct CER along the following years [214].

CER should impartially highlight the most cost-effective policy strategies, programs, interventions, care pathways and procedures for the healthcare delivering [211; 215]. It can add important, neutral comparative support, for efficient policy and care decisions, but it requires integrating different stakeholders positioning, including consumers, in defining the best agenda, pathways and designs CER must follow [216].

In summary, CER can compare different treatments, health technologies impacts, medications, medical procedures, surgeries or even management strategies to better inform healthcare policy decisions and clinical decision-making on clinical effectiveness of alternative options – defining in specific who benefit from the different alternatives or biomedical innovations.

4.4 Quality-improvement science/research (improvement science)

Quality-improvement (QI) science/research, or simply improvement science, represent a broader emerging field supporting QI activities through evidence and an improvement body of knowledge. However, this is a field yet clarifying its epistemologies [217].

The improvement knowledge is context-specific and the knowledge and management of context and conditions that drive the improvement is also critical, if not most important, than the knowledge and management of the improvement intervention it-self [218]. Despite the mentioned, it is still possible to advance improvement theories and knowledge for generability, recurring to replications programs with allowed adaptations [219].

However, in contrast with multiple rigorously designed and conducted clinical trials, improvement studies and evidence typically were - and still are in some cases – made on the basis of intuition, anecdotal stories of success or studies that exhibited little methodological sophistication [220]. Therefore, developing and publishing such information

also needs clarifying, uniform, guide-lines. It emerged the need of doing and publishing evidence or best-practices with regards to quality and improvement journeys, requiring specific methods for development, writing and publication [221]. With such regards, it was developed a set of guidelines (SQUIRE - http://squire-statement.org/) for writing and publishing these matters in scientific journals, which also would help on getting improvement studies more homogenous [222; 223].

Concerning methodological approaches to advance improvement science, the simplest 'before-after' methodological approach needs to be replaced [220]. An option is the so-called 'interrupted times series designs', which can clearly provide more acute information. For instance, a study reported no differences in a QI intervention using a time-series analysis, in contrast to what suggested by a before-after design [224].

When multiple time points before and after interventions are not feasible, a reasonable alternative is a 'controlled before-after' design, in which before and after measures are used in two or ideally more equivalent, comparable, providers that did, and did not, implement the QI initiative. For instance, while a teaching hospital observed benefits (before and after) with a QI initiative, when compared with other hospitals in the same region, the same or greater size effect were also found. The benefits were therefore interpreted according to the changes in policy reimbursement applied at that time for all of them, rather than the specific QI initiative in the teaching hospital [225].

An alternative, more comprehensive approach, of advancing improvement science it is been to study common (quantitative and qualitative) case studies, which can offer unique insights into the improvement aspects that highlights why and how things work. However, these studies are particularly-demanding in data collection and analysis of data from diverse sources [226].

Within case-studies, there is a particular approach studying the factors behind outstanding quality performance of some exemplary organizations, in order to highlight improvement tips that others should follow. For instance the Pursuing Perfection (P2) Initiative was an eight-year demonstration program, funded by the Robert Wood Johnson Foundation, in which were assessed the effect of transformational changes for quality supported by expert staff. It highlighted that although the whole of interventions resulted in increased quality in different domains of healthcare organizations, more system-wide efforts on a health system, beyond healthcare organizations level, are needed to improve population health and health

system costs [227]. More recently the Commonwealth Fund that supports a series of case studies in improving population health and patients' experience of care, while reducing costs, on a 'triple aim' health system perspective [228].

4.4.1 Implementation Science

Within the broader scope of improvement science, it is often included the specific field of implementation science. Despite both terms often are used indistinguishably, there are other approaches such systems redesign and quality-management that are also embraced by the broader field of improvement science. When we specifically mention the term implementation science, it specifically addresses the effectiveness of development and the deployment of quality-improvement initiatives for applying evidence-based guidelines that did not achieved by them-self diffusion and penetration into practice.

Implementation science aims to highlight the best ways to improve the so-called process of Translating Research into Practice (TRIP) [229]. It includes for instance also to the implementation of results of comparative effectiveness research and solid practice guidelines to practice patterns [230]. As a recent in-development science, it should pass through continuous-improvement process also with basis on formative evaluation of the experience [231; 232; 233].

Implementation science ultimate effectiveness might be reflected on improvement of the quality of care delivered to patients through well designed and implemented quality-improvement with a focus on making solid evidence applied to routine care. That is a growing field that aims to highlight features about how to overcome the barriers that often impedes evidence being diffused and transferred to clinical practice patterns. Operationally, it scientifically supports the task of designing tailored quality-improvement interventions that ultimately enhance the suboptimal effectiveness of the last translational block for evidence becomes reflected on the bedside [234].

In synthesis, implementation science theoretically supports the decision-making process when it comes to define how to put evidence into the field in most effective way [235].

Although it is recognizable that there is no 'magic bullets', systemic reviews of implementation studies point out that multifaceted interventions combining elements and

strategies of different categories, as well as active strategies tend to produce better - modest yet consistent - size effects [182; 236; 237].

4.5 Matching the scope of Practice and Research: stakeholders' role in define a research agenda

If quality-improvement is exclusively focused in the task of Translating Research into Practice (TRIP), the practice problems not having a clear research answer are left out of the quality-improvement, and it may seem another paradox of the quality-improvement movement. Indeed, research is often made with, and for, typical cases; while in practice most patients have at least some untypical features. For instance, practice patterns and quality of care greatly varies across providers and locations exactly in the areas when solid evidence falls short - a critical matter for improving quality and efficiency of healthcare delivering [238], and an example that highlights that practice and research have a scope to match.

Some extreme positions argue there is an unsolvable unmatched scope of what science is, and what is practice [239]. While this rationale might represent an extreme bipolar positioning; in part it reveals what it is actually happening: an unmatched scope of action among these 'silos', ideally complementary fields for the quality of patient care. Indeed, there is some lack in the ideal match among practice and research scopes, and it happens due several reasons. For instance, the research agenda is defined with little apparent regard for clinical and population epidemiology [202]. Additionally, it has been observed that research is often driven by topics which are considered researchable, or even driven by the research methods, rather than by the needs of the end-user [205].

A roadmap to promote the research-practice match can also include using research methods that best meet a needed research agenda, instead of the research agenda being determined by the research methods; as finally, an active collaborative involvement of researchers and clinicians on define the research agenda, allocate resources and implement findings [240]. For instance when lead clinicians are early involved in defining the research questions, it increases the likelihood that research results will be translated in practice use [241]. Such process might start with a research question that represents a practice-problem the practitioners helped to define: a problem/solution-focus and an outcomes-oriented process

[240]. Such process begins with a complex, but clearly defined health problem, and works backwards from the problem to identify the multiple causal pathways and feedback loops that will lead to the development of the most powerful and efficient set of multi-level interventions to address the problem [242].

Finally, beyond researchers' perspectives and practitioners' perceived needs; the needs of the patients, and mostly of populations, should become collected and reflected in a research agenda that ultimately shall improve the value of healthcare [99; 203; 216; 240].

As a corollary, the research agendas can be *a priori* driven by feedback loops with origin in practice-improvement needs, as determined by healthcare stakeholders (such practitioners, but also managers, policy-makers, payers and mostly consumers) working in close collaboration and partnership to raise questions to be solved with the 'know how' of the research community. Rather than just following the TRIP sequence for quality-improvement: a narrow one-way implementation of research evidence; such stakeholders' collaborative input for defining a research agenda is a critical aspect for transform the health care system for quality, value and health [203; 240].

4.6. Doing research with routine practice-data:

One of the ways to promote a match among practice and research is through the use of practice-data as source for health-services and outcomes research analyses. The Practice-Based Research/Evidence (PBR/E) is actually seen as an important element of clinical research, which lives in the intersection of academics and practice [243], and inclusively in the interface between research and practice quality-improvement [194].

This type research approaches should complement, not much substitute, the information of traditional randomized controlled trials (RCTs) that is less generable and it is often difficult to apply to the heterogeneity and variability of conditions commonly found in practice. Thus, PBR/E also remains a useful methodology for the previously mentioned comparative effectiveness research [158; 244; 245].

Besides making the practice-testing of research evidence (effectiveness rather than efficacy); such planned PBR/E can also highlight important new intervention patterns that

produced the best results in routine practice, therefore could be later tested on the more controlled environment of RCTs [246].

Such PBR/E approach is particularly useful to understand what are the structures and processes that produces the best outcomes achievable for different sets of conditions (also considering costs); track experience with innovations as they are used in routine practice [247; 248] or more broadly having data to assess the effectiveness of quality-improvement actions [234; 249]. In synthesis, such routine practice-data driven research can reproduce highly valuable clinical knowledge of effectiveness of interventions.

4.6.1 Planning in-deep practice-data collection for Practice-Based Research/Evidence (PBE/R)

Within a broader field of PBR/E, it is possible to plan a practice in-deep level of routine data collection (using comprehensive uniform taxonomies, classifications, data-sets and collection systems) with a planned practice-based evidence (PBE) methodology.

It pro-actively seeks to respond to multiple research questions - prospectively hypothesized, to avoid 'fishing expeditions' - in order to find what are the specific structures and processes – and mostly the sequences of those - related with the best outcomes, as controlled for patient's differences [244]. This is a research approach particularly suitable for healthcare areas in which RCTs are particularly challenging and have demonstrated inability to produce answers for the most practice questions, mostly due great heterogeneity of populations served and the complex networks of outcomes determinants, as rehabilitation would be an illustrative example [250; 251].

4.6.2 Collaborative Practice-Based Research Networks (PBRNs)

Collaborative Practice-Based Research Networks (PBRNs) would have the double purpose of promoting a match among the practice-research field (a previous sub-section) and representing networks serving as collaborative platforms for the development of large-scale practice-based research/evidence (PBR/E).

In the US, there are actually more than 100 Practice Based Research Networks (PBRNs) in which researchers and clinicians actively collaborate to conduct improvement-driven studies, complementing the scope of TRIP sequence (in which research flows from the bench to the bedside) suggesting that is also as important to put practice into research as it is put research into practice [252].

PBRN are often seen as source of good ideas and effective solutions for quality-improvement, also proving grounds for developing and testing on the field of new methods, resources or tools that could enhance the quality of care delivered in practice. Only after adjustments promoted by this field testing, innovations would be widely available and disseminated for routine practice.

PBRN are also seen as learning communities, in which different stakeholders can take benefit of the best practices - abstracted from different providers in the network - to produce the best tips and improved techniques; then combining those into a best method that would be tested as a whole, for instance in other network practices. This is a process that was labeled as 'best practices research' [253].

One important feature for adequately guiding the action of these PBRNs is the collaborative involvement of other community stakeholders despite researchers and lead practitioners. Representatives of patients, politicians and other community members might be involved in the different phases of the PBRNs activity in order important community-based outcomes could be achieved. Such process is labeled as Community-Based Participatory research (CBPR). For being accomplished, it requires funding agencies to consider, and fund, a step-by-step approach that includes a first stage of consultation with community members, ultimately resulting in alteration to the initial project design [254; 255].

4.6.2 Research using large administrative and quality-databases

Administrative databases – containing practice-data - were, and still are, valuable sources of data for healthcare services research, policy research; as well as they are used for quality purposes [256; 257; 258; 259; 260]. Multiple studies highlight the advantages of using such huge and 'real' samples for health-related research purposes [258; 261; 262].

If adequately planned and addressed the confidentiality concerns [263; 264; 265; 266], using data yet available on databases for research result in efficient meaningful research analyses, because its adds no great additional costs and burden for the research purposes, since data was already collected by administrative, quality measurement, reporting and pay-for-performance purposes.

As recommended in a wide variety of consulted papers of different scope [156; 158; 195; 240]; with progressively in-depth scope of quality-initiatives, performance measurement, and electronic technologies' use , there is a brand new world of opportunities to conduct research using more detailed clinical-information and quality/performance data stored in comprehensive and multi-use large databases. Indeed, once reached stakeholders' consensus on aspects such: approaches, standardized processes, and interoperable informatics systems; the research community should take advantage of such progressively more detailed information to link processes to the best outcomes – for instance linking large national clinical-registries with administrative data [158].

As elsewhere denoted, bridging the quality chasm required a continuous marriage between research and practice [28]. Actually, it seems evident that it requires a continuous marriage between research and practice, as well including quality-initiatives.

4.7 Advances in measurement capability applied to quality-initiatives and research

Nowadays it is possible to develop more easily large-scale research and routine performance/quality measurement initiatives. This is happening also due the advances in measurement capability, which allows for simultaneously comprehensive, but yet feasible - non-excessively burdensome - measurement capability.

A main advent behind such feasible revolution is the Computer Adaptive Testing (CAT). This is a method based on Item-Response Theory, allowing appliance of a tailored, short, instrument for each person being assessed - selected from a common graded pool - but scaling results on the same metric for the all persons within the same construct with adequate precision [267; 268; 269].

There are actually two US on-going landmark research projects building measurement capability using CAT methodologies (NIH Toolbox and the PROMIS). Those are first

designed to be applied in large-scale research projects (i.e. longitudinal epidemiologic studies, prevention or intervention trials across the lifespan), but some of their tools can be also applied to some specific outcomes measurement, as part of performance/quality measurement systems.

Specifying, the NIH Toolbox (http://www.nihtoolbox.org) provides assessment of neurological and behavioral function in four domains – cognitive, emotion, motor function and sensation – in their respective sub-domains. It not only assembles brief and comprehensive tools to uniform assessment, as it provides a new feasible way of doing it, requiring no more than 30 minutes to be completed on each domain [270].

By their turn, the Patient-Reported Outcomes Measurement System (PROMIS) is a group of complementary tools assessing self-report health status for a variety of populations, using a CAT methodology, thus also taking advantage of its feasible benefits. PROMIS provides decision makers with hard data on how healthcare affects what patients are able to do, and how they feel. It involves questions about different aspects of health-related quality of life (physical function, fatigue, pain, emotional distress, social health, quality of sleep etc.) grouped in physical, mental and social domains of self-rated health items [271; 272; 273].

4.8 Improving population health: Applying systems thinking and science into new research pathways

To produce higher population and community-level impact, thus improving quality of a whole health system, the research community must also actively engage a systems science perspective over an inter-disciplinary approach. It shall promote a meaningful integration of different scientific perspectives, fields, knowledge and tools into an integrated research agenda that addresses the multiple casual pathways of health, and healthcare, including a public health perspective [29; 242; 274; 275].

New research should support optimal health promotion and prevention, reduced disease burden and improved chronic disease management across the human lifespan and across generations, cutting across disciplines and across levels (from cells to society). System-level research might require inter- and trans-disciplinary research involving for instance

social sciences, psychology, economy, management and engineering research applied to the research on health and healthcare problems [276; 277; 278].

Actively integrating professionals of different scientific backgrounds into common scientific projects is recommended to advance in the state-of-the-evidence, thus the standards for quality of care [195; 278]. In synthesis, complexity science and systems thinking should be used to support the development of research networks producing integrative solutions answers to the actual complex challenges healthcare is facing [279].

5) Educational Community

The educational community is composed by universities and other healthcare educational entities and professionals working at the educational level. It also includes bodies assuring the credentialing and accreditation mechanisms directed to educational entities and programs, as well as entities responsible for professional credentialing and continuing education of healthcare providers. Such community is progressively more tuned with the improvement needs of a new quality healthcare era [280; 281].

5.1 Accrediting Quality of Healthcare Education Entities and Programs

Such as healthcare organizations and providers are subjects to performance/quality-assurance systems, the healthcare educational system must promote, for it-self, an equivalent process in order to meet their own performance goals, which is adequately developing and assessing if healthcare students have the competencies for the challenges of practicing in the performance/ quality era [282; 283]. In that sense, the development of competency-based objectives with an outcomes emphasis in healthcare higher-education (instead of a focus on structures and processes of educational programs) might be supported through a fundamental shift for an outcomes-based assessment in the process for accreditation of educational programs. An illustrative example is the Outcome Project promoted by the US Accreditation Council for Graduate Medical Education (ACGME)

addressing physicians' residency programs - aligned with certifying/credentialing entities such the American Board of Medical Specialties (ABMS) [284; 285].

In fact, the medical residency programs in the US have passed though a fundamental change that embrace quality aims. Indeed, the residency programs - to have/maintain and accreditation status - need to engage in a continuous improvement process guided by non-prescriptive cross-specialty training, clear aims, and simple rules. In terms of competencies, the residency programs must assure that the trainees' performance shows six core competencies - patient care; medical knowledge (such is specialty-defined); practice-based learning and improvement; interpersonal and communication skills, professionalism and system-based practice [285].

Despite the specific professional roles, disciplines or specialties; there are cross-specialty or cross-professional competencies heavily in need for advance care in a quality era. We mean for instance competencies for a [282; 286; 287; 288; 289]:

- evidence-base practice;
- patient-centered care;
- interdisciplinary teamwork;
- quality and safety improvement;
- micro-system leadership for quality and improvement;
- macro-system leadership for quality and improvement.

Underlying to these competencies there is also a need for informatics applied skills, which for instance would be a critical matter for enhance the evidence-based practice and quality- and safety-improvement (through better access and manage of evidence information, and supportive clinical decision-making and safety software systems); as well as enhancing the interdisciplinary teamwork (trough good use electronic interoperable communication system) [290].

Despite a new wave of educational initiatives around the above mentioned competencies [282; 291; 292; 293; 294], mostly following the input of the ACGME six-competencies [285], the norm is that these mentioned competencies were - and still are - traditionally undeveloped areas of healthcare professionals' education, being barely touched in the great majority of healthcare pre-graduated programs for long years [290].

Broadening the scope to overall healthcare education and improvement competencies for out of academic centers; there are initiatives for instance promoted by the Institute of Healthcare Improvement (IHI) - IHI Open School - trying to fill the gap most healthcare education still leave in these mentioned competencies for healthcare professionals (of all disciplines) and their leaders - as they need and often want to participate as active agents in the healthcare transformational change for quality [295].

In the sub-sections below presented we address the different competencies previously outlined as in need for being educated and trained in an effort to develop the workforce for a quality transformational change.

5.2 Educating frontline staff: evidence-based practice (EBP) competencies

Students and trainees might be able to continuously use and develop their competence in evidence-based practice (EBP) (knowledge, skills, attitudes and habits) as a scientific source of professional reasoning and decision-making process, becoming life-span learners, and scientifically-sound reflective practitioners [282; 296; 297].

Teaching the practice of EBP at undergraduate, graduate and practitioner level showed able to improve the knowledge, critical appraisal skills, use of original studies to answer clinical questions, attitudes about the role of the role of evidence, and clinical behavior. But such initiatives were more effective when it was interactive and integrated with 'bedside' clinical teaching, instead of didactic, classroom or standalone teaching [298; 299; 300], in more integrative approaches to evidence-based teaching-learning [301].

Indeed, providing just-in-time learning, through on-the-job-training, can have higher impact on students. However, clinical-teachers them-selves often do not have practice, knowledge and confidence for optimally teaching EBP at the workplace. Thus, first of all, there is a need to enhance the ability of clinical-teachers to enhance their EBP practices, then identify and make use of the best available opportunities in everyday practice to teach various steps of EBP and demonstrate their clinical applicability [302].

The use of EBP in real world clinical settings has many pragmatic obstacles. Besides lack of searching and appraising skills, or lack of confidence and habits of seeking information, there is fundamentally a lack of time to enter into the intimidating amount and complexity

of published evidence – one of the reasons originating gaps in translation of research into practice [303].

Educational strategies also might target competencies for search and use of practice guidelines and protocols (including algorithms, standard order sets, and flow sheets allowing individualization to patients' specific conditions). It enhances feasibility, because guidelines and protocols are an integrated summary of available research, based on exhaustive review, critical appraisal of literature, and practical considerations [282]. In addition, trainees should also learn how to use the assistance of clinical librarians, specialist 'informationists' and supportive software - increasingly important resources for EBP [304; 305]. This is an educational strategy for EBP yet insufficiently explored [306]. Finally, education should address information management techniques and skills to (pre-)filter, manage and organize valid and yet relevant scientific information, suitable to be applied to real, and just-in-time, patient care [307; 308].

5.3 Educating frontline staff: patient-centered competencies

Besides being able to continuously foster their scientific knowledge, practitioners also need to be competent on patient-centered aspects of care. Briefly, these patient-centered competencies ,might include: elicit, active listening, abstract and communicate critical care information (communication competencies); promotion of provider-user relationship that underpins care experience and subsequent engagement with care (relationship competencies); establish an effective partnership with users - making their values and preferences becomes reflected into care through a shared decision-making process (partnership competence); and finally the ability to facilitate or enhance the psychosocial determinants of consumer-centered outcomes, care engagement and health-related outcomes (influential competencies).

Such patient-centered competencies would represent foundations of individualized/ tailored healthcare process that is both: scientifically-sound, effective and evidence-based (previous sub-section); but also meaningful for the consumers, becoming sensitive to their values and preferences and working towards consumer-valued outcomes (patient-centeredness).

Indeed, the practice of a patient-centered and broadly family-centered care - a core dimension of quality [12] - might involve key smaller competencies and skills such: professionalism, ethics, humanism, communication, interpersonal and partnership skills [309; 310], as well as cultural competence gaining momentum in the field, particularly in the multi-cultural US [20; 311; 312]. As only one example, an approach being used for enhancing competencies for patient-centered care is to use patients and families, mostly in pediatrics, to advise medical curricula [313], and even teaching senior staff [314; 315].

Despite some visionary work [316], traditionally those competencies were not addressed by healthcare curricula. As an illustrative example, medical education could even decline students' baseline empathy [317; 318]. Such traditional educational gap becomes reflected in actual practice quality gaps [45; 319] for instance represent the major underlying reason for malpractice claims [320].

This is a trend actually starting a changing process [310; 321; 322], needing leverage mechanisms for the development and later use of patient-centered competencies in practice [93; 323]. But there are still many implanted cultural barriers that hinder the ultimate effectiveness of the different education pathways for an improved patient-centered care.

Such 'cultural' barriers exist either on universities (competencies development), as on practice contexts (transference of learned competencies to practice). In both contents these 'cultural' barriers generally happen due the underlying value attributed to provider-patient relationships and patient-centeredness. In fact, in many universities (even those in which the communication and humanistic skills are explicitly addressed by curriculum contents), the so-called 'hidden' and the 'informal' curriculum - hold by faculty leaders, teachers, clinical instructors and other staff - present as strong barriers for those competencies being valued by students, thus likely to be developed and further applied as foundations of patient-centered care [324; 325]. This is even more critical since the learning mechanism of these types of competencies heavily depend on role modeling by reference professionals [326; 327; 328].

Making the bridge for the practice-settings, the prevailing practice/ organizational culture often devalues time, resources and attention given to patient-centered practices or efforts, remaining mostly oriented for the scientific adequacy of the 'technical' aspects care. Such culture undermines any transference of learning foundational competencies for patient-centered care, as noted in many improvement studies [329; 330]. Furthermore, even some

quality-initiatives we previously highlighted - i.e. P4P narrowly-applied - can devalue provider-patient relationships and patient-centered care [84]. Such context reinforces the need to systemically coordinate actions across stakeholders in a systems-based approach to enhance patient-centered care [19].

In case of building on competencies for quality-improvement, there must be a match among what is expected from students and from senior practitioners. A brief but meaningful example of a initiative responding to such need is promoted by the American Board of Medical Specialties (ABMS) on its Maintenance of Certification (MOC) program that shall assess all physicians on their ability to communicate with patients and providers, as measured by the CAHPS tool [331]. It shapes also the attitudes students which see these aspects being measured also on senior professionals.

5.4 Front-line staff: interdisciplinary teamwork competencies

Despite the specialty-based competencies healthcare professionals must have, the quality of care delivered – particularly in a patient-perspective – is also dependent on the ability of the interdisciplinary teams (or widely the 'system' of treating healthcare providers) to articulate and coordinate their actions on a same patient or sub-population. We recall that there is a lack in care coordination among providers at different levels - within and across micro- and macro-systems - as a critical issue to improve US healthcare quality [12; 332].

Among many other external input, care coordination depends on improvement of healthcare professionals' ability to work effectively, efficiently and meaningfully together for the quality of patients care. Such needed care coordination - in this case particularly within the micro-system level - is dependent on the development of shared teamwork competency (knowledge skills and attitudes) [333].

The development of a teamwork competency is yet on the agenda of most healthcare high-education entities, although varying on focus given. There are often two categories of team-training: simulator-based programs and classroom-based programs, both with the final purpose of giving competencies for teamwork that support safety (e.g. in critical care and crisis situations), coordination, and efficiency of healthcare delivering. However, these

traditional methods still need incorporation of advances in: training technology, theory and processes being linked to a more effective training effectiveness [334; 335; 336].

In a systematic review, training interventions with medical under-graduated (mostly in clerkships or clinical rounds) and residency curricula generally appear to produce some effect sizes in competence, although yet evidencing room to be improved [293]. Teamwork competency is for instance fostered by educational strategies promoting common or shared tasks given to groups of students. For instance, problem-based learning (PBL) methods - gaining momentum in the field [337] - have one of its core definitions on group-work, often with differentiated roles and distribution of tasks among group elements, enhancing competencies for peer communication, self-directed continuing learning and more effective teamwork [338; 339; 340; 341]. However, despite some ground-breaking exceptions [342; 343], PBL methods and the underlying enhancement of team-work often happens only with students of a same professional discipline, while in practice coordination of care for a same patient mostly requires teamwork among professionals of different disciplines or specialties.

With such regards, interprofessional collaboration has been fostered by interprofessional education initiatives, mostly in last decade, being apparently well-received and having positive impacts in collaborative competencies (also applied to patient-centered care), holding a promising status for becoming a mainstream in the future of healthcare professionals education - although studies still need to be fostered, using more solid research designs [344; 345; 346; 347].

Among many interprofessional educational initiatives, we particularly outline the promise of inter-disciplinary training wards. It represents an extension of the classroom-based interprofessional learning, enlarged to the experiential learning of clinical settings. It is constituted by a group of different healthcare disciplines in a same clinical round. Students may act as a real team for a set of patients, sharing the responsibility (supervised) for their care. Common competencies (team-work and interpersonal dimension) are developed, trained and evaluated equally across disciplines, while allowing room for specific technical learning objectives of each discipline being trained and evaluated [347; 348; 349].

5.5 Educating Front-line staff: quality, safety and improvement education

Within the quality-improvement movement, it is increasingly acknowledged the need for developing specific educational initiatives for students of different healthcare professions develop their skills and competencies for improving the quality and safety of their practices. Indeed, it should represent a mainstream element of healthcare professionals' education [350].

Among healthcare educators it is increasingly consensual that these quality, safety and improvement competencies are acquired and optimally developed through experiential learning. We recall such experiential learning is reflected into a ACGME core competencies: practice-based learning and improvement [285]. Such experiential learning can become operational for quality, safety and improvement education goals through a four-element cycle (or spiral). In such four-element cycle, learners move from direct personal involvement in experiences to reflection on those experiences; integrate observations with sense-making concepts and mental models; and finally back to more experiences. It integrates learning the 'knowing that' with the 'knowing how' for best performance with real patients [282].

Optimally, quality, safety and improvement education would be embedded with interprofessional educational initiatives for achieving the best synergic effect on the front-line competencies required to students become – in a near future - educated active agents for safety- and quality-improvement process [351; 352].

An educational curriculum and content for these goals includes: continuous quality-improvement, root cause analysis, and systems thinking [353]. Furthermore, educational initiatives can address specific aspects of quality- or safety-improvement, for instance with some specific methods for their assessment being developed [354; 355]; or broadly the educational initiatives can address the quality, safety and improvement goals as a whole. Such broadly conceived educational initiatives can provide learners with the know-how across the entire scope of improvement-related knowledge while learners grapple with real-world quality and safety problems [282].

Recent systematic reviews highlight that many educational initiatives improved knowledge about quality- or safety-improvement; but simultaneously improved system-based learning, as well as achieved active participation and enthusiasm for quality-improvement initiatives

[294; 353]. Indeed, both quality-improvement and systems-based practice (including interprofessional collaboration competencies) are often concomitant targets of educational initiatives. It often consist on initiatives based on team-project model, where trainees have a team-responsibility to entirely develop and deploy and improvement initiatives, supported by in-time seminars and coaching [292; 356; 357].

Such type of initiatives recently received the development of methods to assess the competency in systems-based practice and quality-improvement concomitantly [358]; as well as received methods to evaluate trainees' quality-improvement proposals, embracing the underlying quality, safety and improvement competencies within a unique assessment [359].

The optimal place for such type multi-target quality, safety and improvement educational activities is the clinical education rounds and residency programs, ideally interprofessional training wards. This is the place where these initiatives can be made more closely to the practice requirements, as simultaneously fulfilling senior practitioners' quality-improvement goals if it embraces a trainees-practitioners team-project model [360; 361; 362].

Despite the multiple potential benefits the mentioned initiatives can bring, there is an agreement in the need for more research on the effectiveness of students'/trainees' participation and engagement in practice quality-improvement efforts, particularly studying it affects patients' clinical or health outcomes [294; 363]. This is a nascent researchable matter, yet with positive associations with outcomes [292] or at least with gains in clinical process guidelines [353].

5.6 Educating the Micro-system leadership: competencies for quality-improvement

The quality of care and its improvement, at the micro-system level, heavily depends on the ability of micro-system leaders to facilitate that different people - often of different disciplines and different care philosophies - effectively use the best of their talent, credentials and own skills to work together for a unit of purpose: do and improve the care the best they can for the great benefit of patients they conjointly serve.

Clinical and micro-systems leadership shapes the scope of providers interactions, either represented by a unique person (i.e. a head department physician being simultaneously a micro-system leader), or also embracing two or more different people (i.e. a middle

manager plus a physician and nurse leader). These leaders serve as reference and often have influential role model for other professionals, giving the example and facilitating (or otherwise) hindering the establishment of a quality- and safety-improvement culture, formal and informal communication processes, as well as fostering inter-group collaboration.

Leading a clinical micro-system for quality is a complex competency that among other things requires an applied knowledge of systems science and thinking, knowledge of quality and safety processes and standards, and knowledge of improvement processes and science. These features shall help leaders to guide micro-system practitioners in the task of continuously 'improving' care beyond just 'doing' care [364].

Indeed, professionals reaching clinical leadership positions might benefit of receiving (extra-)education for the applied leadership competencies needed to facilitate clinical micro-systems and their professionals to continuously reach/improve their highest level of quality. Educational programs are promoted by large healthcare organizations [365]; healthcare high-education graduate programs such healthcare leadership program of the 'The Dartmouth Institute for Health Policy and Clinical Practice' (http://tdi.dartmouth.edu/centers/education/degrees/ms/course-listings/); as well as by quality-external organizations such the Institute for Healthcare Improvement [366; 367].

These educational initiatives play an important role mostly on provide post-graduate and professional development courses aiming to develop competencies for those professionals reaching micro-system leading positions. It will help leaders to obtain the needed competencies for facilitate quality-improvement at the frontlines of care.

5.7 Educating Macro-system leaders (including quality-officers)

Micro-systems and their leaders are, by their turn, embedded within larger healthcare organizations (macro-system level). Thus, the quality of care and quality-improvement initiatives might be activated, supported or otherwise hindered by the action or inaction of macro-system leaders, including the managers (e.g. chief quality officers) responsible to lead, manage, or at least support healthcare quality-initiatives at a healthcare organizational level.

There are a corpus of integrated knowledge and transformational change competencies to be learned in order to help macro-leaders on how to strategically envision, plan, build capacity, coordinate programs and spread quality-improvement that simultaneously add value for each of the different micro-systems of care (reflected in the consumers), as also bring value for the whole healthcare organizations, improving their global performance and also meeting the interests of their shareholders [175; 368; 369; 370].

C) MACRO-SYSTEM LEVEL

The macro-system level refers to the healthcare organizations and its management structures that hold, sustain, house or support the healthcare delivering process. They are not the responsible to directly provide healthcare to patients - as it happens with practitioners at the micro-system level - however their activities, as convincing evidence highlights [371; 372; 373], might influence the quality of care actually delivered by healthcare professionals.

Hospitals; primary care offices; multispecialty physician practices; outpatient clinics; home health agencies; as free-standing in-patient rehabilitation facilities and skilled nursing facilities are examples of settings, practices, providers, or healthcare organizations covering the wide range of population healthcare needs. Such different type of organizations might build and manage the most suitable infrastructures and structural conditions that best activate, support, hold, or sustain quality-improvement journeys or initiatives, achieving optimal clinical and front-line care delivered to patients and families [6].

With such regards, organization might first seek for, or renewing, an external and independent accreditation status (highlighted in the external/ independent bodies section) which might assure they are meeting healthcare organizational quality-standards. Accreditation (as exposed in external level) shall assure that a certain healthcare organization or program has the needed basis - mostly structural, management and operational conditions - for deliver high-quality and safe care.

1) **Healthcare Providers/ Organizations**

At this macro-system level, we first approach the healthcare organizations at the settings or providers level, such as hospitals, free-standing facilities or practices. Later, we approach organizations that represent integrated delivery systems providing services along a continuum of care.

1.1 Business-case for quality-journeys and structural investments

There are many potential barriers which can undermine a organization become engaged in quality-journeys. The first great barrier might be the lack of a strong and committed senior and board leadership for quality and quality-improvement (such aspect will be later better addressed). One of the reasons for a lack of a board leadership commitment might be due some doubts about the financial viability and the business case for quality-journeys within the specific organization context.

1.1.1 Engaging a organization for quality: the perspective of a positive return of the investment

From a business-case and financial return perspective, it is suggested that an organization might benefit from investing time and resources in continuously building capacity and an infrastructure that systematically support quality-improvements [167; 374]. The financial return can come for two different ways.

The first way is by the reducing the operational costs due increased organizational efficiency: eliminating services waste like: unneeded, double, redundant, unsafe, ineffective, less valuable proceedings; as well as a reduced variation that contributes to achieve a better match among demand and capacity [167; 169; 375; 376; 377].

The other is the market force operational in the patient's choice for providers delivering greater quality. It can happen by satisfied consumers' return; quality-reputation constructed

over time; by previous professionals or consumers recommendations, or even by consulting quality report-cards [144].

A major infrastructural quality-investment is the Health Information Technology (HIT). In such subject, the major amount of literature also appears to be clearly favoring the return of the investment over the costs: many organizations paid the investments in few years and then making subsequent on-going saving year by year [378; 379; 380]. But such conclusion is not generalizable, as such return also depends on what types of HIT, the organizational context, and the effectiveness of implementation methods [381].

Additionally, in a context of an adequate external payment system, organization could reflect their own quality-received payment into their own quality-rewarding policies to their micro-systems (middle managers, practitioners and other staff) - accordingly to their contributions and accountability for quality of care and quality-improvement. It might result in a positive chain of effects of financial quality-stimulus beginning at the external level [148].

1.1.2 Reasons for macro-leadership remain skeptical about quality-investments

The idealized scenario of getting macro-system leadership engaged and committed to invest in quality is not easily accomplished. There are different reasons for macro-leaders remain skeptical to commit organizations with quality-investments needed for a transformational change for quality. There are still factors that drive macro-leaders to become - rationally justified according organizational stakes - resistant or renitent to commit organizations with quality journeys [31].

Prevalent payment mechanisms like fee-for-service do not reward the potential efficiency that quality investments might achieve. Indeed, it better reimburses for providing high-quantity, high-complex, high-paid, services readmissions and overuse. Without a payment reform widely well-succeeded in reverting the rewarding for quality (as discussed in payers and purchasers section), macro-leaders may rationally defocus on quality [12; 31].

Also disfavoring the a macro-leaders engagement with quality-investments is the fact that the great potential benefits and return of the investment should only come with time, and it might come spread on medium and long-term range. In turn, the investments for building

capacity on quality-improvement – for instance HIT – have immediate negative budget-impact, creating skepticism among macro-leaders [382]. Indeed, in most organizations, budget-impact analyses might determine if there is room for structural and activation investments for quality, because it could threat immediate organization financial stability and survival [383].

1.1.3 Healthcare organizations size: advantages/disadvantages for quality-investments and improvement

Healthcare practices and organizations can widely vary among other things in size and scope. Therefore, administration and management systems also widely vary in organization and mostly in complexity. Using the extreme examples, it is expectable to achieve a great and more complex management structure in general hospital than in a small independent physician office.

In small independent practices, the roles of the macro- and micro-system levels of care are often embedded or closely connected with each other, being developed by just one person or few proximal elements. By contrast, in general hospitals, there are a great degree of roles differentiation: leadership boards and other managers only account for macro-issues of the healthcare organization, while the frontline staff focus on deliver the best quality care at the micro-level with their patients and families.

Both structures' type has potential, as well opposite, advantages and disadvantages (opposite to each other) for the development and deployment of quality-initiatives.

Potential disadvantages of the more complex organizational structure like general hospitals (in opposite with potential advantages of small practices), generally come from having more room for disconnected and unmatched aims, values, goals and approaches between the macro (strategic) and micro (operational) level of decisions for the quality of care and quality journeys/initiatives. In some cases, quality of care and services are better managed in less complex structures, with simple actions closely linked to operational activity and patients' needs [384].

Additionally, frontline staff may see denied, hindered, delayed or non-supported most of their efforts for an effective quality-improvement at a ground-level [385]; as well as in the

opposite chain of effects, quality-programs engendered at the macro-level often do not reach full engagement, implementation or compliance at frontline level, unless adequately involving frontline staff for implementation [386]. Finally, great and complex macro-system structures might consume a great degree of resources with overhead expenses, constraining resources and attention that should be directed patients' care and the practitioner-patient relationship [387].

As potential advantages, the more complex organizational structures (in opposite of potential disadvantages of small practices) have greater opportunities to build on economies of scale for creating supportive communication and information infrastructures and specialized resources for engage practitioners in continuous quality-improvement activities [388; 389]. They can more easily afford their own specialized resources, services or personnel directly assigned (or sub-contracted) to be accountable, plan, design, lead, guide, coach or technically support the quality-journeys and improvement processes within the healthcare organization [390].

In addition of taking advantage of scales of economy for sharing overhead, structural and some costs and investments of quality-programs, healthcare organizations on gaining dimension (or for instance being colligated or cooperating as integrated delivering systems, later highlighted) can spread the upfront investment costs, thus the distributing the associated risks among collaborative providers. It can critically attenuate some of the actual resistance to advance in quality-investments as we become to outline in this sub-section.

This is particularly true for concerted infrastructural investments in comprehensive Health Information Technologies (HIT), such common platforms for interoperable electronic health records (EHR), recording systems, computerized order entry software (e-prescribing), or software supporting reliability and decision-making that have not the same synergic benefit if used only by a small percentage of local provider, as might be costly to implement and maintain by isolated initiatives of small providers [378; 391; 392]. The same rationale is also applied to specialized supportive personnel resources (quality-experts) for implementing internal quality-programs that small providers, alone, often cannot afford nor build own capacity to optimally perform [393].

1.1.4 Know how of the leadership for quality: an upfront investment

The type of investments needed to transform organizational quality relate with: engaging the organization in accreditation process; implementing improvement actions with all costs associated; building a quality-infrastructure capacity, nowadays with great emphasis on health information technology (HIT); and sub-contracting, building or maintaining quality and implementation expertise resources.

However, we should denote that effective quality journeys do not only relate with put money for quality. It also requires other kind of substantial transformation. Indeed, it requires a cultural transformation for quality. This is a long-term commitment, constancy of purpose, and sustained efforts that shape a quality an improvement culture (addressed in a later independent section). Therefore, it is not a subject for massive infusion of monetary resources and expecting immediate success and return [166; 190].

Specifically in a matter of creating solid basis for quality to flourish, macro-leaders need to sustainably commit with quality and improvement. Operationally, it might require build an adequate *know how* for senior macro-leaders to lead and support quality-improvement journeys, and mostly build a strong organizational culture for quality [390].

Therefore, organizational quality journeys should become with senior-leaders developing their own *know how* for quality, for instance receiving education for quality that is adequate to their level of action (highlighted in educational community section). Rather than enabling macro-leaders to start a quality culture change on a single top-down direction, such enhanced *know how* might be directed to actively engage all organization members in such long-term process – starting at the actual organizational context and positioning for quality, then following a continuous, sustained, roadmap on a way towards advancing the organizational quality journey [227; 390].

1.2 Organizational design for quality: shaping the way services are managed, planned and delivered

Find a 'perfect' organizational structure and design that promotes quality, value and efficiency of both organizational performance and the quality of services delivered are continuous challenges healthcare macro-system leadership face [148; 166; 394].

Historically, most practices adopted a functional model of discipline-based units as their organizational design for healthcare delivery. Although it promotes a great degree of specialization, and it can promote savings due some economies of scale; by other side such organizational design can pose limits to quality-improvement actions, as well as it can hinder dimensions of a whole organizational efficiency. The historical specialty-based organizational design creates 'silos' undermining potential synergies, integration, cooperation and creative innovation across boundaries of specialty-units – particularly those which serve the complementary needs of the same patients [395].

1.2.1 Healthcare Service-lines: an organizational design around sub-populations' needs

With the aims of improving organizational efficiency and promoting coordination for quality of care and quality-improvement, there is nowadays a tendency for macro-leaders to consider - instead of specialized-based units or functional departments - the benefits of developing and deploying service-line/ product-oriented organizational designs in healthcare [396; 397], concept emanating from other industries.

Such service-lines represent a planned continuum of services, organized to deliver a meaningful and articulated sequence of services required to produce integrated answers to sub-populations' multiple and sequential needs. The formal establishment of such service-lines has been supported by the emergence of new organizational structures - based in the prevailing quality-improvement paradigm of systems re-design [220].

Indeed, to establish clinical service-lines, managers can use the notion of 'clinical micro-systems' as building blocks units (small units of service, later highlighted at micro-system level). A set or mostly a planned sequence of aligned micro-systems representing the continuum of care for a same sub-population would correspond to a healthcare or clinical service-line.

1.2.2 Meso-system structures accountable for quality/performance-improvement of service-lines

The emergence of organizational designs made by service-lines creates the need to develop a correspondent new intermediate organizational structures and respective leadership (between macro and micro-system). Such new intermediate structure - called as meso-system - would become accountable by the performance/quality-improvement of the emerging service-lines within the organization.

The meso-system structure, often represented by a leader/coordinator, remains accountable for the performance and quality-improvement in each respective service-line, which includes being responsible to coordinate the actions of the integrated building blocks (different clinical micro-systems). The meso-system leader uses their accountability to directly reporting the performance of the service-line to the board leadership (macro-system) structure [398; 399].

An illustrative example of a completely new clinical meso-system (yet emerging field) is the one created for patients requiring percutaneous cardiac intervention, as highlighted elsewhere [400]. In such case a new meso-system leadership was created for the sub-population attended, becoming accountable by a created inpatient/outpatient integrated clinical service-line, including ancillary services and ending with cardiac rehabilitation and scheduled follow-up appointments.

1.2.3 Decentralizing performance/quality-improvement accountability to the levels of micro- and meso-systems

Such service-line, product-oriented, organizational designs – as managed at the micro- and meso-system levels - brings a less centralized performance/quality management approach, giving more autonomy, empowerment and performance/quality accountability to the level of micro- and meso-systems structures – ultimately benefiting the quality of care delivered at the frontlines [373].

Such accountability, autonomy and empowered decision-making might allow for self-definition of specific goals, strategies and operational plans for performance/quality-improvement. Despite an enhanced autonomy, the micro- and mostly the meso-system

specific goals, strategies, plans and activities cannot be disruptive of the whole organizational goals, strategies and planning. Indeed, a link must be established to simultaneously attain specific micro- and meso-system goals (for instance in local peer-providers or services competition) and organizational performance as whole, with the different service-lines contributing and developing active partnerships to generate synergic effects and organizational value beyond their specific 'silos' [148; 401].

Either an organizational design by service-lines or a traditional organizational design by discipline-based departments, a ´silos' is still a 'silos'. Therefore a major executive management challenge is to put all employees working for their own specific level of objectives, but also for organizational goals - developing mechanisms for them to assume a 'dual citizenship' within the organization [148]. With this regards, successful businesses have been using 'balanced scorecards' as a management approach that promotes goals, strategies become aligned among different organizational 'silos' and structural levels [401; 402].

Such alignment of goals and strategies would promote cooperation among macro-, meso- and micro-systems at different hierarchic levels of accountability. For instance, as here applied, using such 'balanced scorecards' may turn possible the micro-system structures becomes both evaluated by their own quality/performance-improvement, as well as by the contribution to the quality/performance of meso-system structures: the 'dual citizenship' of the micro-system elements.

By their turn, meso-systems can be evaluated both by their own service-line quality/performance, but also by their contribution to the maro-organizational attainments: the dual citizenship of the meso-systems structures.

In summary the 'balanced scorecards', when adequately employed, can help to solve the conflict between central managerial control and specific units autonomy and accountability for the design and planning of services and their performance/quality-improvement initiatives - meeting organizational, staff and patients needs.

1.3 Design of Internal Quality-Improvement Journeys and Initiatives

An adequate organizational design can set some structural conditions for optimal quality-improvement journeys and initiatives (e.g. fostering organizational cooperation for a

continuum of services addressing the whole of sub-population needs); however, *per se*, it does not mean the optimal organizational quality programs are optimally taking place within the organization. For instance, it also depends on the design of internal quality-improvement journeys and initiatives.

1.3.1 Macro-system quality-management

At a macro-system management level, someone (quality/safety officer or quality manager) or more often a management structure (quality committee or QI management team) should carry out the task of managing the organizational quality/safety programs or journeys as a whole. It can represent functional tasks such ensuring adherence to accreditation standards and recommendations; building structural conditions and infra-structural capacity for organizational quality-improvement; and leveraging organizational culture and requirements for optimal quality-improvement initiatives can take place [175; 368]. A macro-system quality-management structure should also help to develop and design the systems of accountability for quality and quality-initiatives among the different meso- and micro-organizational structures [166].

However, there are yet today many interrogations about the impact of different systems, policies, management and strategies for quality (macro-level of quality-management) on the clinical effectiveness, patient safety and patient-centered outcomes (micro-level of quality delivered at frontlines of care) [403]. Hospitals might implement policies at a strategic level to meet legislative and accreditation requirements; however the implementation of such policies might not be achieve strong resonance at a frontline level. Indeed there is not rare to see a great dissonance among what is done for quality at macro- and micro-system levels [404].

In an attempt to induce more clinical integration in the organization quality-management programs, it is a trend to directly engage and involve more clinical staff in management and specifically in the quality-management roles [148; 405]. Although *per se* it could not achieve an optimal integration of macro- and micro-levels of quality-improvement; involving lead clinicians at least in defining and deploying a shared quality-improvement agenda for the whole organization would be of great value for a better match among quality-management

programs planned at macro-level and the quality-improvement needs and activities at the frontlines [406].

Intermediate structures with accountability for performance/quality-improvement, for instance the previously mentioned meso-system structures, can turn more easily the task of mitigating dissonance among the macro- and micro-levels of quality-improvement.

1.3.2 Quality-Improvement (QI) experts

Across the healthcare field there is a growing body of quality strategies (improvement science highlighted in the research community section), and an increasing portfolio of quality-initiatives designed for each of the six improvement aims for quality, reducing the gap among the state-of-science and the state-of-practice: see for instance the IHI 'improvement map' website [407]; as well as a constant renewal of research innovations that if effectively translated, disseminated and implemented into practice (not an easy or simple task [408]) would advance quality and efficiency of healthcare delivering - although not all innovations are exactly beneficial [199].

This type of improvement knowledge, *know how*, and overall quality-improvement competences and expertise is not yet part of the mainstream of healthcare professionals' education (although primary steps are being made, as exposed in the educational community section). Additionally, quality-improvement competencies and knowledge requires a constant updating effort, being informed of the constantly evolving solutions, innovations and technologies (e.g. HIT) available for quality-improvement. Thus, it is often required that such processes become facilitated by professional quality-improvement experts.

Practitioners and managers often do not have the time or inclination to read the large body of supportive improvement literature, which undermines ultimate effectiveness of quality-improvement or implementation initiatives [409]. In a way towards responding to such need there is progressively available facilitative software and toolkits designed and developed to overcome the challenge of putting quality-improvement and new technologies into practice [188; 410]. Either way, it is overwhelming for practitioners and managers to carry out the

challenge of quality-improvement and implementation alone and it might become sub-optimally made without help of specialized knowledge and improvement *know-how*.

With such regards, organizations committed to quality journeys are further investing in hire, sub-contract, or stimulate existent personnel to get a graduation and specialized education to becoming part of QI specialist staff/department. Within such staff, there is room for personnel specialized in specific improvement areas such safety-improvement or adoption of health information/communication technologies.

As guided by the macro-organization internal quality-strategy, such quality-specialized personnel should work conjointly with other organizational departments and structures (health-services research; health information technology; human resources; meso-system leaders; micro-system leaders, clinical leaders and front-line healthcare staff), supporting them in a common task of developing the organizational, meso- and micro-system maximum potential for quality and quality-improvement [101; 390].

Such specialized resources, internal staff or externally consulted or sub-contracted, can use their specific quality and improvement expertise towards supporting, advising, or coaching other staff in the tasks of studying, selecting, planning, adapting an organizational quality journey, and/or implementing specific quality-initiatives at any level of the healthcare organization.

1.3.3 Top-down vs bottom-up approaches for quality-improvement (QI)

Herein, we come to an important feature when it comes to define the scope of QI journeys and initiatives within an organization. It relates with the roles, emphasis, process and mostly the direction of the chain of the decisions for QI journeys and initiatives between the different organizational levels, hierarchies and structures.

With such regards there are two major perspectives a top-down perspective: emphasis on macro- and quality-expertise level of decision for QI, then flowing to the front-line level; and a bottom-up perspective: emphasis in micro-system activation and accountability for quality-improvement decision-making and action, despite the activation might be facilitated by the macro level and supported by quality expertise.

Some theoretical discussion can be found about what of these approaches is the best for the organizational QI process. But what achieves some consensus is that both perspectives are required, concomitant, and mostly can function as a complement to each other [411]. The great challenge for each organization is to find its own suitable balance between those top-down and bottom-up approaches to QI [390; 399].

In a top-down perspective, the organizational leadership, expertise input, and infra-structural support represent the main source of activation and decision for QI. Indeed, even it does not necessarily represent a top-down approach, the macro-leaders active involvement and assumed commitment with organizational quality journeys represent a critical way to promote effectiveness of QI and the ability to produce clinical adoption and improvements - as some evidence [412; 413; 414] and notable examples of visionary leadership highlight [390; 405; 415].

But the clinical micro-systems are the places where the quality of care is delivered to patients and families. Additionally, the strategies and interventions defined by other organizational structures are more effective when 'costumized' and 'contextualized' to the local, complex micro-system, or unit-specific characteristics [386]. Indeed, the use of frontline staff perspectives to define targets for QI enhances effectiveness and sustainability of the initiatives [416], particularly if the goal of the initiative is to become clinically meaningful and locally acceptable [232]; driving practice improvement [240].

In addition, QI made at least with the contribution of the micro-system level can also help to shape or define most of organizational strategies for their quality-journeys. It means that successful strategies and results developed at some micro-levels can inform macro-leaders and enhance their ability to facilitate and spread QI to other micro-systems, service-lines and levels of organizational activity [101; 417; 418].

The key for achieving the right balance between these two approaches might be on achieving a great degree of trust and mutual collaboration among the macro- and micro/meso-system levels for QI [397]. Indeed, micro-system and service-line leaders and frontline staff can help macro-leaders at higher-levels of quality-management roles on the task of the design, plan, coordinative and implement equivalent advances in other organizational services, or even of wider organizational quality-programs that better supports their frontline QI initiatives. But also the macro-system and QI expertise structures can also help the micro-system and service-line leaders as well as other staff on tasks

related with define and plan the improvement process (e.g. scope, size, budget, targets, methods and content) of meso- and micro-level QI initiatives. Some organizational examples highlight the value of a strait collaboration among different organizational levels [390; 399; 400], as well as the physicians-managers active partnership for planning services, care and improvements [405].

In summary, active collaboration among the clinicians, managers and QI experts (as well as consumers for patient-centeredness) might result in higher effectiveness, involvement, engagement, coordination and commitment to continuously and effectively improving organizational services and care. It shall become reflected in optimized QI initiatives and optimized quality-journeys: adding value for patient care, staff satisfaction and overall organizational performance.

1.4 Internal Information Systems: Managing internal quality/performance information

Managing the information is a critical management task within any organization. Without adequate, valid and reliable information, the management decisions are not much better than arbitrary. In a matter of healthcare performance/quality-improvement the picture is not much different.

The organization only advances towards further performance and quality-improvement if they know exactly where they stand in the present. Such knowledge depends on externally-provided information (from accreditation, audits, and external performance/quality-monitoring, reporting and benchmark systems), but also from internal information the organization plan to produce and collect by it-self. In this sub-section we embrace such critical topic for performance/quality-improvement.

1.4.1 Overview of the role of HIT: an infrastructure for an efficient organizational information system

First we make an overview of the role of Health Information Technologies (HIT) as an infrastructure supporting the development of an efficient organizational information system. HIT are often called as one main infrastructural investment needed to create an

infrastructural platform activating and enhancing a spiral of benefits for quality, cooperation, safety and efficiency improvement [166; 167].

HIT can become a suitable infrastructural platform facilitating real-time communication among staff, as well as becoming a common platform for registering, storing, accessing, transforming, and reporting data about clinical processes, administrative and patient status. Such data should flow, become synthesized and used in the most efficient way for the different levels of clinical and organizational interest, including the management structure for planning and quality management purposes [169; 170; 172].

Inter-operable electronic health records (EHR), electronic registering/recording systems for care activities, or portable registering/access devices for frontline practitioners and ancillary staff are those HIT that better match internal organizational data systems. Yet HIT adoption in the US has wide variation [169; 389]. It relates to a series of constrains already mentioned in suppliers section.

1.4.2 Building an organizational information system

Building an effective organizational information system is far from being just determined by the infrastructural platform used, either electronic or paper-based. Indeed, having an electronic-based infrastructural platform is clearly not enough for having an optimized organizational performance/quality information system that shall feed planning and the design of services and care, including system-redesign and the planning of specific quality-improvement initiatives.

Indeed, the use of an electronic-platform can facilitate the processes of collection, storage, access and analyses of the information, making the system more efficient. But the usefulness of the data system mostly depends on the planned process and content. Meaning what kind of information, in what time, what for, for whom, and in what aggregated or synthesized levels it should be collected and available to different organizational elements [173].

Indeed, it could be a case of the organization collecting information not useful, inaccurate, or with no influence in organizational decisions and care activities. By the other side, there are management decisions to be taken that would be undermined by lack of meaningful and

timely data. Despite mandatory, billing and other externally required data and data-flow; the organization has the power manage the content and flow of their internal information systems, including data-types, registries forms, flow channels and synthesis criteria. These choices determine what kind of information supports organizational decisions for their own and tailored quality-journeys [166]

In fact, the effectiveness of such journeys first depend on having meaningful, valid and accurate information of actual performance and actual organization quality-gaps, so QI can be tailored to the right targets. The externally-monitored and benchmark information represent an important source of information with such regards. But beyond such information, the organization can plan to collect different type and more in-depth data and information to find out what are the granular determinants of optimal and sub-optimal performance/ quality, then reflected in target-precise improvement action [173].

In synthesis, the organization needs to plan the process and content of their performance/ quality data system. Such data might be used to perform retrospective and prospective analyses informing management decisions on how to strategically plan and operationally design organizational services, practices and quality-improvement [419; 420].

1.5 Developing and managing human resources for quality-improvement

The organizational human resources policy must be (re-)designed to address the needs of an organization and staff that is in need for constant change, in order to continuously improve quality of care delivered - an integrated part of staff duties [421].

In an integrative 'review of reviews', it was found that human resources management is linked to outcomes such mortality, but there is yet little research exploring such type of relations, and mostly the way through which human resources management affects practitioners performance [422]. In a QI perspective, the organizational human resources policy might activate a valuable chain of quality-effects by fomenting the staff capacity for continuous QI. It might happen through re-directing the human resources policy for quality and improvement, as reflected in human resources steps such: attraction, recruitment, selection, orientation, ongoing support and growth, retention, as well as performance management and evaluation [190].

For instance, in a matter of recruitment one of the most distinguishing features of a recognized high-quality healthcare institution is to invest a significant amount of time and money in a long-term process of contracting personnel that fit with their core cultural values of a collaborative organization. The idea is to recruit team players, with good communication skills and readiness to work in a collaborative environment for life, in which everyone openly consult, teach and learn with other for the patient benefit. The human resources policy of this widely recognized organization actively refuses to hire personnel that do not fit this core values, even if they are great 'technical', renamed or experienced doctors or nurses [405].

Internal ongoing training and education for QI would benefit of concerted actions between the human resources departments, QI experts, and broadly also those outside the organization responsible for promoting and developing healthcare professional education/development activities or continuum medical education (CME). For instance, recent examples have demonstrated room for fruitful results of enhanced collaboration between CME, practice-base learning and organizational QI initiatives as complementary activities [423; 424; 425].

Organizational human resources policies and activities can also incentivize, facilitate, legitimate and valorize workforce (middle managers, technical support staff, front-line healthcare professionals and other staff) to seek and frequenting external extra-education in areas related with quality and improvement (e.g. in educational community section). Such practices might empower professionals from all levels of organizational activity to become active agents for QI in their micro-systems or supportive departments, bringing value to organization as a whole.

1.6 Developing the Organizational Culture for Quality

An organizational culture represent a broadly defined concept that sets the background scenario for every organizational action, initiatives and *modus operandi*, as well as it becomes dynamically shaped by those everyday actions [129].

1.6.1 A culture for quality being constructed and improved

The scope of organizational and quality actions (investments and financial perspective; organizational design; quality-improvement designs; internal information systems; and human resources policies) reveals if an organization is committed to quality and improvement.

An organizational culture for quality and improvement is constructed by the history, mission, values, organizational strategies, but also shaped by the sum of all organizational programs, statements and actions that, on a daily basis, let transparent what really matters for such healthcare organizations and what the organization really want to be with quality regards. For example, organizations that emphasize group affiliation, teamwork and coordination have been associated with greater implementation of quality improvement [426], mostly by fostering a culture for mutual consulting and collaboration as the normative rather than the exception [405]; as well as creating a facilitative environment for exposing and discussion about potential and real-happened adverse effects for a culture of QI and safety improvement [174; 175].

By contrast, organizational structures that emphasize formal structures, regulations, and reporting relationships appear to be negatively associated with quality and safety improvement activity [427].

Shaping the organizational culture for quality is major strategy for quality transformational - rather than transactional - change. It needs to be fostered by a committed leadership that shall represent more than just few, isolated, transactional approaches to QI [129]. For a transformational cultural change for quality to occur, a renewed and radically redefined interpretation and experience of healthcare quality represents a requirement [129; 428]. In addition, planning a culture development for a quality transformational change should consider the unintended consequences and unexpected outcomes of such culture interventions, mostly those initiatives narrowly defined [84; 248; 429; 430].

1.6.2 The role of a committed leadership for a quality culture

Developing or changing a whole organizational culture for quality heavily depends on leadership. As Juran (a quality guru outside healthcare) says "a management commitment

is pertinent to every successful quality revolution, no exceptions are known" [431]. A quality journey begins with a strong quality commitment of the higher levels of the organization, reflected in an organizational culture that is supportive of the quality and improvement [383; 428]. In the opposite direction, leadership is also influenced by the organizational culture, which brings us to a dynamic integration of those two critical components of the organizations [432].

Quality recognized organizations put a great emphasis in all aspects that contribute to a culture o quality and improvement in every action they take and plan: with major culture and values for quality being fostered by leadership [390; 405]. By contrast, inadequate leadership has been identified as a key factor limiting the development of a culture of quality [129; 432].

Frontline staff - individually and collectively - can have their professional and micro-system 'culture' as active agents for quality and improvement. But it is clearly more difficult made in 'solo' and against an eventual non-supportive predominant organizational culture. Indeed, a non-supportive organizational culture for quality constrain time, resources and attention to the task of 'improving' work, in favor of the task of just 'doing' the work. It might be operational through a leadership demand for high-volume of acts, high-tech/expensive interventions, and lowering operational costs for the organization regardless the quality of care and the patient/population benefit.

Such behavior is promoted by actual payment models already addressed. Therefore, organizational leadership and subsequent culture would have rational reasons to have a culture of high-volume and expensive care unless the external system of incentives becomes aligned with quality of care and health promotion as fruitful alternatives [10; 31].

2) Integrated Delivering Systems

Integrated Delivering Systems remains as a label that could represent a different scope, size and models of organizations or functional agglomerate of providers. It might represent an integrated system of practices of a same owner, or representing a formal colligation of providers or organizations covering a continuum of services.

On the large definition, it could embrace networks of providers which can be composed of small or independent providers delivering complementary services or specialties; as well as larger networks that - formally or informally - involve individual providers, practices and organizations. For instance, it is frequent that US hospitals have well-established networks with primary-care practices; multi-disciplinary physician offices; tertiary services or post-acute facilities - loosely or more structured acting as functional integrated delivery systems [113].

We present the perspectives for quality from the point of view and action of integrated delivering systems of two types.

1. Health plans: an insurance plan with an active care management and/or their own integrated delivering system (for example the Kaiser Permanente);
2. Integrated delivering systems of a same owned or colligated healthcare organization, but not including health plans: therefore exclusively dedicated to healthcare delivering (for example within the Genesys Health System).

The major different between those two is that the first besides healthcare delivering holds financial risk and accountability for a population covered, while the second focus exclusively in healthcare delivering.

2.1 Health Plans

Different kinds of healthcare organizations commercialize and manage an array of health plans for general public. Some health plans are owned and managed by an employer subsidiary. Health plan are competitive for instance with indemnity health insurances (Payers & Purchasers section), but the idea behind creation of health plans was another, particularly those called as Health Maintaining Organizations (HMOs).

2.1.1 Health Maintaining Organizations (HMOs)

Indeed, decades ago, the initial aim of HMOs was to produce better health at lower costs for enrollees by an active management of enrollees' health and healthcare [433]. Despite it seems an adequate baseline idea - and few good exceptions in practice denotes it - the idea evolved to a disappointment solution for an healthcare of quality and affordable, with

consumers often felting needed specialty care is denied, and health plans competing just or mostly on price basis. It seem the majority of the institutions running health plans were just focusing on negotiating better prices with relatively open network of providers [113].

Indeed, due the wide proliferation and the aggressive market competition, healthcare providers which hold a remarkable quality and market position are refusing to work in the HMOs scheme, conditions and prices, which can make these plans a network of lower-quality and lower-price providers, at least at the eyes of consumers. In addition, there was lack of adequate tools to effectively manage care, as well as an over-estimation of the ability to contain costs with adequate care management, among other conditionings that led to the suboptimal panorama for the HMOs.

Indeed, many health plans limit their action almost only on negotiating lower prices for services, or using administrative-based management strategies for utilization review, or even for pressuring low-cost care decisions, by administratively profiling providers with comparative data on decision-making patterns with the underlying intention to lower the levels of specialty referrals [434]. Indeed, most HMOs have been focusing on managing prices, rather than actually managing care [127]. Thus, their action for quality is more closely related to those of the healthcare purchasers, than actually representing macro-system healthcare organizations.

But there are exceptions to such broader suboptimal picture. Some health plans are less focused on reduce utilization costs or competing exclusively on basis of prices, thus more engaged in actively manage the care their enrollees in a clinical quality basis, adding value for the care and health results [127]. Besides requiring providers hold an accreditation status - a standard for a health plan contract with providers [435] - health plans can perform a more active role for quality in many other concrete ways.

Using the leading example of Kaiser Permanente (www.kaiserpermanente.org), health plans can for instance: foster or support internal quality-programs of their owned providers or their providers networks; owning health services and other research staff for guidelines development on care management; develop referral patterns and support local or micro quality-improvement-initiatives; requiring, supporting or paying for the use of information and communication technologies implementation for enhanced safety and coordination of care; develop initiatives for an integrative, coordinated and timely care on the management of chronic conditions; investing in actively engaging enrollees in effective health

promotion, preventive and primary care activities (which should be the major emphasis of the HMOs health plans); among other different active roles for quality of care some health plan engage with their providers' networks [434].

2.1.2 Consumer-Directed Healthcare Plans (CDHPs)

One initiative gained some momentum in recent years in the health plan sector is Consumer-Directed Healthcare Plans (CDHPs), already approached in the Consumers level. CDHPs use different methods of patient-directed incentives (mostly financial/premium incentives) to reduce overuse of healthcare services of marginal or no value, or even to stimulate the choice for lower-cost providers.

Although it could generate some savings at an individual and payer level, it might not have the same level of effects for quality and system-level efficiency, with some noted unintended prejudices [436]. Indeed, it has been told that underuse of adequate services can be a higher problem than overuse [437]. In addition most of the overuse are related with providers action, not consumers; as finally it might be seen as a source to increase disparities in quality of care [438].

The prejudices for quality can be higher in CDHP as applied by high-deductible models, while low-deductible CDHP models (less aggressive approach) can comparatively have more positive impacts [439]. Due potential benefit impacts, and also potential prejudices, research is needed in the following years for more solid evidence on long-term impacts and for providing the yet unanswered questions for the CDHP health plans [440].

2.1.3 Regional variation in the Health Plan's implementation

Another feature we retain from health plans for the quality of care is that it varies a lot from different entities and implantation regions. There are regions in which the activity of health plans achieves considerable implementation and active influence in health and healthcare quality, while in other regions the market position is weaker and/or the activity more related with managing prices and administrative case management. It happens due the

different success of different players and their regions of activity. The later Regional Health System section addresses this subject.

2.2 Integrated delivering systems within a healthcare organization (without health plans)

The existence or formation of functional integrated delivering systems or integrated service-lines (within a same healthcare organization, colligation or overhead managed network of providers) has potential disadvantages and advantages for quality and efficiency of care.

In terms of efficiency, a potential advantage is the enhanced dimension and the creation of scales of economy for quality/efficiency-initiatives, with potential advantage of turning the business-case for quality more favorable - although there are also disadvantages of great size/complex structures, as previously outlined. For instance, it is a more recent finding that in most markets, integrated delivering systems can provide comparative higher quality of care with annual cost-savings of 272$ per patient [441]. In addition, integrated delivering systems might obtain negotiation leverage with payers, which gives competitive advantage to the organization. However if an organization gained excessive market power, it could represent a disadvantage for the efficiency of the healthcare system due the ability to establish higher prices in the market [442].

In terms of quality and QI initiatives, having an overhead macro-system structure able to manage a set complementary and inter-connected services for sub-populations needs (extended clinical service-lines) can represent a critical advantage for the value of QI initiatives within the organization. Indeed, overhead, unified or shared management structures stand in an optimal position to create and manage these extended clinical service-lines, and respective meso-systems accountable structures, through a overarching collaborative planning and cooperation among integrated micro-systems. For instance, it is much easier to harmonize clinical approaches, foster micro-systems collaboration and integrate information systems: critical infrastructural support for active clinical collaboration, proactive planning and quality-improvement [392; 443].

Although there are good examples of functionally integrated delivering systems owned or managed by a unique/shared macro-system structure, the existence of these is far from

being the mainstream is the US healthcare fragmented system [228; 390; 444]. Therefore, an important option for higher integration of services in the US healthcare system might be placed on foster the establishment of multiple inter-organizational service-lines (outlined in a next sub-section) that gives response to inter-related needs of well-delimited sub-populations. It might improve quality of care as reflected in a whole system of measures applied to integrated delivering systems [91].

However, it requires substantial changes in the way healthcare delivering systems are organized in the US. With such statement we enter to the subject of next section, which in the center of the US health/healthcare agenda, helping to solve fragmented scope of American's healthcare delivering system.

3) Regional Health System (macro-integration)

It is widely recognized that the US can do much better in a matter of population health and healthcare quality, and simultaneously containing the escalating costs. One great pointed cause of the suboptimal performance is a loose connection, coordination and cooperation among providers: the US fragmented healthcare delivering system. The other great pointed cause is the demand - mostly providers-driven [445] - for high-complex and expensive curative care, rather than investing in the promotion of health and preventing disease and disabilities to happen [30; 111; 200]. These two major issues underpin a reframing and reforms in the US health/healthcare delivery system [111].

3.1 Defragmenting (macro-integrating) the healthcare delivery system(s)

A defragmentation of the US healthcare delivering system is a very complex subject, originating amounts of public debate. Despite some divergent solutions and perspectives on ideal way to get through such wide and fundamental reform, there is progressively more consensus that the 'new' healthcare system needs to foster coordination in planning services for populations, including creating the suitable conditions for the emergence of integrated delivery systems or extended service-lines; as well as creating or empowering overarching structures to become accountable for macro-integration and driving

allocation/management of health/healthcare investments for quality and efficiency of the US healthcare system(s).

3.1.1 The need for coordinated US health/healthcare system

Coordination of care among different providers, composing a particular healthcare system for each individual patient and specific sub-population, represent a cross-cutting theme for improving the quality and efficiency of a broader healthcare system [332]; particularly in the advocated US fragmented healthcare system.

This is true for the generally of population and patients, but it gains particular emphasis for some particular population groups. For instance, we can give the example of chronic ills, persons with disabilities, and the elderly. These for instance correspond to the great proportion of care and resources spent in public programs such Medicare and Medicaid due the characteristics of their enrollees, requiring substantial redesign for these public-led programs [35; 141] – outlined in the Public Policy-Makers later section.

Indeed, in the chronic care model [33; 34], care coordination among a set of providers is one of the most important features, actually with a great room for improvement, improving a patient-based quality and overall system efficiency. For instance, patients requiring multi-specialty practitioners' interventions are at higher risk of do not fully receive a care complying with standards even receiving the quality-standards from some of the attending providers [35; 123; 142].

In acute and subsequent care, care coordination is reflected in efficient and seamless transitions from one site to another. Coordinate the care in that way - supported by adequate payment mechanisms and adequate electronic infrastructure - might avoid double use, misuse and even underuse of needed services that both damages the patient health and healthcare systems' efficiency: for instance the case of seamless transitions and preventable readmissions to acute care [20; 111; 446].

Coordination of care among providers (in chronic care or after an acute episode care) is also reflected in timeliness of care, meaning when care is delivered. Indeed, when care happen remains at least as important as what care patient receives. Optimal care can only be delivered to a patient when the right patient is in the right place, with the right provider, and

the right information, at the right time, with critical issues note becoming lost in transitions [12; 447; 448]. This is not easy to achieve, but it represents the optimal conditions for patients' health, quality of care as well as the system's efficiency.

3.1.2 Balance among providers' competition and collaboration for quality

In a provider-based perspective for quality-improvement, it was mostly promoted a peer competition among healthcare organizations and providers delivering the same specific type of service, care or intervention. Although such type of competition is - and still will be - needed as a peer benchmark tool to improve specific areas or aspects of care delivering, it does not necessarily assure patients receive coordinated care from the continuum of care; as well as the quality and efficiency of a whole healthcare system is damaged by a narrow focus on provider peer-competition for quality [142].

Indeed, by focusing attentions and efforts on peers' competition for market share, counter-productive effects could occur for the needed collaborative efforts to enhance the quality of patients care and experience across sites in a patient/populations' longitudinal quality perspective [116; 449]. Although both competition and collaboration is needed for high-quality healthcare systems, an optimal balance between them might be achieved. This in order to assure best quality from the three perspectives: provider; patient; and (sub-)populations [116; 142].

A possible way to achieve the right balance among providers must reflect the principles of a value-based competition - within and across elements and geography boundaries - with a major focus on health and system-level results. It clearly contrasts with the peer competition for market share, mostly based on peer benchmark for quality or, worst, mostly based in peer price benchmarking [127].

3.1.3 Inter-organizational extended service-lines

A way towards achieving the optimal coordination of care along a continuum of care is by fostering the design of extended service-lines representing functional integrated delivering

systems for specific subpopulations (the same presented within a healthcare organization): but in this case cutting across organizational boundaries and ownership.

Indeed, in the US, the great majority of providers are small healthcare organizations or free-standing providers with focus at one specific level of care (general hospital for acute care, specialty hospitals; diagnostic test facilities; primary care offices, etc) that do not manage all the micro-system structures needed to form an extended service-lines for the continuum of services required to most sub-populations: mostly for those people with chronic, or complex healthcare needs or risk factors. It requires coming out of the existing borders among healthcare organizational management structures to build such needed service-lines extended across providers and organizations.

The actual US external system of incentives do not stimulate or even can undermine efforts to establish and develop inter-organizational extended service-lines, collaboratively planning and delivering comprehensive and coordinated care for a continuum of sub-populations' needs. Pervasive stimulus can be reinforced by narrow focus on provider-based quality-initiatives that only stimulate for more peer-competition, rather than also for a needed collaboration and cooperation underpinning quality and efficiency of a whole system.

For the establishment of inter-organizational service-lines, re-structuring and reforming the US healthcare delivering system(s) is required: promoting integration of macro-system structures.

3.1.4 'Macro-Integrator' in the US healthcare delivering reform

The concept of 'macro-integrator' - introduced by Berwick (recently nominated as the Center of Medicare and Medicaid Services' administrator by the Obama administration) and colleagues - does not necessarily represent the creation of a new entity or organization, but rather the establishment of an accountable overarching structure (as legitimated and supported by public and payment policy) that provides macro-integration and strategic leading for allocating resources, planning services, and promoting the optimization of healthcare delivering to pre-delimited sub-populations within a delimited geography [31]. In simpler terms, it refers to an overarching macro-structure that is accountable for quality and

healthcare expenditures (health value) for sub-populations within the limits of a specific community, local or region.

While accountable for allocating resources, such structure can re-distribute the focus and investment for the most timely and cost-effective services or operations (e.g. investments in primary care, instead of high-technology and acute care resources), but also by coordinating the planning and action among health/healthcare organizations.

Accountable Care Organizations (ACOs), highlighted in the purchasers section, is an example of a potential entity assuming the accountability of the 'macro-integrator' structure and its roles. An ACO could assume multiple forms, but it is generally formed by a colligation of local providers that over-manage regional care and becomes accountable for system efficiency with delimited area and sub-population: longitudinal per-capita costs, but also accountable for quality against regional benchmarks [105]. That is a model already functioning well in some US regions and states, although it does not necessarily mean it might function well in all different regions – it is argued in a next sub-section the need for 'costumized' solutions for the different regional contexts.

Indeed, the type of entities that could perform the 'macro-integrator' role could vary across a state and across the nation, as clearly left open in the original concept paper [31]. As alternative to the establishment of an ACO, the 'macro-integrator' role can be performed by entities such: established integrated delivering systems; local delivering champions; bundled receivers; a local health plan champion or other regional stakeholders well-positioned to perform their subsequent roles. The criteria would be that such organization holding a strong local good positioning and values centered on healthcare quality and value; yet with enough local influence to perform the overarching, activation and aggregative role expected from a 'macro-integrator'.

3.1.5 Regions as the units for health/healthcare design and accountability:

Healthcare organizations, integrated delivering systems and health plans have different representativeness and market-force in different US regions with varying influence for the way care is planned, delivered, and influence for resources allocation - mostly depending on regional champions [31; 450].

Indeed, although some external environmental factors, stimulated by federal policy, should be managed at a wider national federal level, there is a growing consensus that a national 'one size fits all' solution or approach for organizing health and healthcare delivering systems are not the optimal solution for every US local, community, region or state, with their varying contexts and conditions. There is a need for flexibility on way to organize totally different health and healthcare delivering systems existent across the United States, as well as there is a growing recognized need to enhance shared accountability, and empowerment of local providers for the quality, value and efficiency of care delivered [105; 112].

National definitions should left open room for locally tailored solutions in a way to organize a health and healthcare system for quality, adapting to the specific and complex intricacies of local influences, context and circumstances that characterize the US health/healthcare system in different regions [10].

Systems of different locations function quite differently from each other, with high divergences in quality and expenditures by regions [445], with no resultant benefit to quality, health indicators, or perceived quality by patients [451] and physicians [450].

Each region or state has their own particular quality gaps to solve. For instance the actual federal strategy for the Quality Improvement Organizations' program is reflecting state differences [162]. Additionally any location might have a particularly different amount of conditions, market forces, influential stakeholders and their own specific resources to improve the quality of their own regional health system. It first requires defining and seeing locations as a whole system unit, then actively involving and empowering the different local agents, sectors and stakeholders (including state and local politicians, community-stakeholders, local consumers and their representatives) into the tasks of planning, redesigning and implementing their own locally tailored health and healthcare system: best matching with local circumstances and resources [10].

But the question might be on how to delimitate such locations that constitute different health systems. Although not absolutely independent systems, the Dartmouth Atlas Project has identified - statistically by referral patterns - 306 relatively separate and geographically confined Hospitals Referral Regions (HRR) in the United States. Such regions are where resident population receives more than 85% of their care [452]. Indeed, despite existing

quality ranking in which consumers can nationally compare providers, the fact is that the great majority of consumers will receive care from a local provider.

The healthcare in these regions is, in great extant, directly and indirectly paid by resident population. Therefore, unlike the health insurance reform that might bring a national solution, it has been argued those 306 regions should constitute the less complex and less contentious population unit for the healthcare delivering reform [10].

3.2 Addressing the triple aim/three pillars for quality (better care; better population health; affordable costs)

A whole regional health/healthcare system might be accountable for the quality and efficiency of health and healthcare activities delivered to, and paid by, the living population. At this level of analyses, quality and efficiency goes much beyond the sum of performance of individual healthcare providers or organizations, for being framed for the whole regional health/healthcare system. Such quality and efficiency (value) must be framed in three complementary terms: quality of care; longitudinal per-capita costs; health of population/ communities: this is the triple aim for quality [31] - corroborated by the pillars for quality, recently released as a national quality strategy [453].

3.2.1 Better quality of care for individuals: Micro-integration for enhanced coordination

Delivering better care to individuals, among other things, depends on being available, disseminated and implemented, clear and more specific information or guidelines about the best clinical pathways to follow to specific sets of individual patients' conditions. It shall be supported by the advances in outcomes research, comparative effectiveness research, and improvement science, yet addressed in the research community section.

But delivering best care to each patient is also a matter for systems design and enhanced care coordination among treating providers. Indeed, such as happening in the level of healthcare system and services planning, a major threat for better care at the individual patient level is the lack of coordination in the navigation for different providers. Therefore,

besides being needed a macro-integrative role, there is also a need for a micro-integrative role assuring coordination of care to each unique individual patient.

The 'micro-integrator' is the healthcare structure that makes sure that the best and most appropriate care is delivered to individuals [31]. In a latter independent section at the micro-system level, the specific roles of the micro-integrator will be outlined.

3.2.2 The population/communities health

In a public health and health promotion perspective, local/regional systems should also work to the health of population. The North Karelia Project, in Finland, is perhaps the long-term example of what works for health promotion and disease prevention and how efficiently it could be maintained along years within a delimited population [454]. It is often used as study case for the scope of improving population and communities health, although some caution needs to be taken in the analysis due varying contexts [455].

In the US, despite many focal improvement initiatives, there are also whole-scale initiatives already in place facilitating the health of populations, for instance in the recent development of the measurement of a healthy bottom-line indicator as an outcome measure for health improvements [456]. Envisioning a health benchmark among communities, a recent web-comparable tool - funded by the Robert Wood Johnson Foundation - compares parameters such health behaviors, clinical care, social and economic factors, and the physical environment with counties (communities) as unit of analyzes [457]. The following headings address the perspectives of health promotion in populations and communities.

Integrated societal planning and cooperation for population health

Healthcare represent only slice of the population health's pie. Indeed, there are a series of health determinant factors that can be effectively promoted by community and societal sectors as a whole, not exclusively promoted by healthcare delivering stakeholders. Factors such smoking, violence, physical inactivity, poor nutrition and unsafe behavioral choices are the great threats to a healthy American population – far more than the quality gaps in the healthcare delivering system [11; 30; 458].

Indeed, a health system needs to be framed as embraced in an yet broader systems perspective with other economic and societal systems (policy, public health, social security, education, economic and productive sectors, etc) to act on health determinants and originating the best population health, societal production and quality of life an emergent property of an integrated societal planning and cooperation. Such inter-societal sectors cooperation might help on planning integrated societal programs within a broader system view, which includes a health perspective both determining and being determined by other societal sectors [29; 274].

Operationally, a shared strategic deliberation platform might be able to implement wider system approaches that would enhance population health on a citizen-perspective [32], by including other important societal sectors at a single overarching strategic framework – broadly what should consists the work in progress of policymaking.

In summary, the whole society can take the best value of enhanced population health, instead of spending high amounts of resources treating complex diseases preventable by integrated societal planning. It might be achieved by integrated strategic planning and action among whole societal inter-dependent sectors – particularly at a regional level.

The focus on health promotion

Health promotion is the major focus for the inter-sector societal initiatives with focus on population health and interventions based on system thinking perspectives [274; 275].

Health promotion becomes operational for instance in activities towards the development and change of life-styles, physical activity, healthy feeding patterns and wellness of the community. For instance it is showed that lifestyle changes (i.e. alterations in dietary intake and physical activity) were nearly twice as affective in compare to common medication in reducing the risk of developing type 2 diabetes [459].

Indeed, in literature we can find a number of different preventive and public health activities using other societal sectors to take place, or as means for being applied disseminated, and reaching great proportion of population. This is mostly the case of workplace interventions [460; 461; 462]; school-based interventions [463; 464; 465], and mass media interventions [466; 467; 468], all examples with great potential for efficient population-based

health results, most of them also requiring support of policy and public health structures for integration.

Inter-sectors planning and arrangements for disability prevention

Despite a health promotion and preventive focus, also the rehabilitation and social re-integration of population with disabilities relates to a broader social, vocational and community perspective; rather than being confined to the clinical services: a broader framework for quality regarding people with disabilities [469].

The community-based rehabilitation principles and approach are a major example in this area [470]. In the US, the National Institute on Disability and Rehabilitation Research (NIDRR) is in charge to act on a system level to promote the optimal societal integration of people with disabilities, as exposed in their Long Range Plan [471].

The release of a National Prevention Strategy

A US National Prevention Strategy is being prepared to be public released in a near future, following an equivalent process of the National Quality Strategy (highlighted in Background). However, there is an important concern raised by stakeholders' concerted opinion. Indeed, while the parallel development of a National Prevention Strategy offers great promise to address further the needs of the US population, concerns arise about concurrent strategies that may inadvertently foster the continuation of an action in different 'silos' between the healthcare delivery and public health systems. Therefore the National Priorities Partnership recommends deliberate efforts to harmonize these two strategies to ensure a coordinated and mutually reinforcing approach [472].

3.2.3 Affordable costs (system-level)

Spending more in healthcare does not exactly mean it is produced the better care to individuals and mostly produced the better health for the populations [445]. The very poor global US scorecard compared to other industrialized countries can be the best example for it. The US healthcare pulls about the double of resources (percentage of the GDP – gross domestic product), scoring much lower in quality and health indicators [30].

Therefore, lowering national costs with healthcare shall be in first instance a consequence of better individual care and better population healthcare. It is easier to understand that is more efficient for the healthcare expenditures - and the society is more productive - to promote health and preventing diseases to happen in population, rather than treat them costly later, however this has not been much the case of US, as something being addressed by the new healthcare reform [111].

Indeed, a regional health system that optimally promotes population and communities' health must spend a greater proportion of regional pool of resources in prevention and primary care activities, as well as in health promotion activities [473].

What actually often happens, in less efficient regions in the United States, is that the majority of resources is pulled by healthcare delivering in highly complex and expensive resources for treating advanced conditions, rather than prevent them to happen [10]. To advance in that way, prevailing payments systems (previously highlighted in external payers section) must be changed to compensate maintain patients healthy, rather than treat them costly later.

The high specialty resources are naturally needed in regional health system, but their use illogically varies among regions, induced by suppliers-driven demand [445], not much by patients' preferences [474]. Among other things, regional health system efficiency is dependent on an adequate use (avoiding overuse, misuse, and also underuse of needed services treated costly later) of those specialty resources – this is actually a major target for systemic quality-improvement actions [238].

D) MICRO-SYSTEM LEVEL

Despite the influence of the macro-system and the external environment, a healthcare of quality essentially takes place in the micro-system of care, or in other words, in the dynamic of the providers-patient-relatives relationship and subsequent health-related activities. The micro-system is the small unit of work that actually gives the quality of care patients' experience. Thus, as broadly defined, it is composed by [6; 444]:

1. The collective of healthcare practitioners that directly meet and intervene with consumers, happening within and across units. It may also involve inter-linked units, within and across settings and healthcare organizations;

2. Community of health-related resources/ services locally or web-based available;

3. Patient and their relatives as active elements of their own health and as healthcare consumers;

4. Set of processes occurring within the interfaces of such constitutive elements.

The consumers (patients and family) and the community services or resources – quality-stakeholders entering in the broader definition of micro-system – were highlighted initially at their own independent section, meaning at consumers level. Herein, we begin to focus our attention in the system constituted by clinical practitioners and their processes, which can be labeled as the clinical micro-system (444).

1) Clinical Micro-Systems

Clinical micro-systems represent the place, work-ground level, where the quality of healthcare is delivered. These are small, functional, front-line units of healthcare delivering, being the 'building blocks' of larger healthcare organizations and systems, constituted by small groups of front-line professionals (healthcare practitioners and support staff) working together or interacting under linked processes, for achieving common goals: the specific needs of patients' sub-populations [475].

We already mentioned the concept of micro-systems and further service-lines (and their meso-systems structures) in the macro-system section. But, while in the previous section we approached the principles of micro- and meso-systems as a managerial approach - organizational design - for decentralized accountability for the quality and quality-improvement; herein we will approach the clinical micro-systems inner-principles and specifically understand how the quality delivered can be planned, redesigned and improved at the frontlines [444].

Theoretically, the micro-systems are framed in a complex adaptive systems perspective. It means a collection of individual agents with freedom to act in ways that are not always

totally predictable and whose actions are interconnected. It is a non-reductionist paradigm focused on understanding relationships and applying a flexible problem-solving [476; 477; 478]. In a clinical micro-systems perspective, frontline healthcare services and care are understood, planned or redesigned not only in the basis of healthcare evidence, but also on the basis of applied systems thinking and improvement science for attaining goals of high-quality of care and services. Such a way (complex adaptive micro-systems) of conceiving, framing and designing front-line healthcare is pointed at the basis of a fundamental change in the way care is delivered [6].

1.1 Coordination within clinical micro-systems

A micro-system, besides micro, is still a system. Therefore, as any other system, their effectiveness heavily depends on the synergic action of healthcare practitioners and support staff - taken collectively – for achieving common micro-system purposes; rather than the simple sum of their individual actions or individual professional roles with strictly separated purposes.

A high-performing clinical micro-system takes the best benefit of the inter-dependency of their elements. The team-work and staff interaction is characterized by trust, collaboration, willingness to help each other, appreciation of complementary roles, and recognition that all contribute to a shared purpose, with respectful patterns of professional and interpersonal relationships [475].

The first needed element for an effective coordination among elements is the self-awareness as a micro-system and the notion of inter-dependency of services and care, something practitioners often have difficulties to recognize. Only with micro-system self-awareness, different staff can together engage in the development process of improving their whole services and care for sub-populations and individual patients they serve [444]. It could be made for instance by organizing multi-purpose micro-system meetings involving all staff, instead of multiple smaller department meetings [417].

We can generally differentiate what enhances coordination within micro-system as three different, yet complementary, aspects:

- o Planning micro-system services and care with data-support;

- o Coordinating care on time: timely sharing/exchanging relevant data;
- o Improving the teamwork process: team actions and supportive team relations.

1.1.1 Planning micro-system services and care with data-support

Planning services and care is the first, pro-active, way of enhancing micro-system coordination by making working processes and workflow fit well together; as well as pro-actively promoting patients go for the right professionals, with the right information, at the right time: avoiding overuse, misuse or underuse of structures and procedures (479).

Planning micro-systems services and care shall begin with analyses of aggregated and synthesized information of sub-populations attended (external and internal systems feed-back data). It might be used by all micro-system staff and their operational leaders for systematic studying targets for services re-design. Then, the planning and re-design of services and care should be made accordingly such data.

We note that within a rich information environment (about micro-system activity and results), staff can fairly develop analyses of what goes/went wrong or could get better in their practice: for instance, transparent root-cause analyses for safety concerns [480].

Indeed, data-based planning (feed-back data) is depend it-self of a previous planning of what kind of data the organizations and micro-systems want to collect in their own internal information systems outlined at the macro-system level.

Finally, with a good informational support, it is also more likely that all micro-system staff continually engages in the task of planning and redesigning care for micro-systems' improvement as a whole [166; 481]. Such process would be fostered by the micro-system leadership (as better highlighted in a further independent sub-section).

1.1.2 Coordinating care on-time: timely sharing/exchange relevant data

Coordinating care on time is a second level of coordination at the micro-system level. This is not much directed for coordinating services, but more for coordinating on-going care for

individual patients [482]. Indeed, for micro-system coordinated care and actions, on-time patients-related information (feed-forward data) shall be timely available to every micro-system element for prospective care. It has been noted particularly in critical care coordination, in which timely information and timely urgent action is a great determinant of care effectiveness and safety [481; 483].

Registering/recording feed-forward data:

But ever before it is available for being timely sharing and exchanged, such critical data needs to be collected, registered, communicated or simply become easily/timely accessible for consultation in a valid, timely and feasible way. When it happens, individual care procedures and decisions can be shaped and concerted accordingly a common and updated knowledge of patient-status, and other professional orders, activities or relevant registries about a same patient [481].

A valid yet feasible process to collect, register, and consult care data can be nowadays facilitated by the use of the yet mentioned HIT, composing integrated electronic data supported by the macro-organization. Indeed the processes of collect, register and consult needed information should fit with the work-flow, and should be *a priori* included as a design element when micro-system services and processes are planned by flow-charts [420; 479].

For instance the empowerment of non-clinical staff or other healthcare professionals for collecting standard information - or even patients performing these tasks with electronic devices - can free up time for clinicians to concentrate their focus on building a patient-provider relationship, enhancing patient-centeredness and individualized care [19].

Also the existence of a clinical 'informationist' embedded with care team, can save attending physicians' time directed for patient-centered and individualized care, while at the same time enhancing an evidence-based informed practice [305; 306].

Until now we focused on data collection process, but the meaningful use of data also depends on content, aggregation and data presentation. Indeed, in order to be used, updated or understood by all micro-system elements, an information system that enhances care coordination should be build on common data-sets with underlying, inter-disciplinary,

meaningful shared classification, terminologies and taxonomies (instead of professional-specific ones). Only in that way, information collected, communicated and easily accessible remains useful for all micro-system elements, coordinating their intra- and inter-disciplinary activity for the best patient quality and safety care [6].

Registries used as feed-back data for re-planning and re-designing services and care

Finally, in the perspective of complementary aspects contributing to micro-system coordination, we need to refer that all this data registered for feed-forward use - assuring on time coordination of care for an individual patient - is also useful to a later time as feed-back data, envisioning ulterior planning of services.

For instance, data systematically registered can be also used in retrospective analyses (e.g. root cause analyses) of what went wrong (e.g. safety problem), enabling planning a re-designing for addressing the underlying system deficits (e.g. that allowed a safety problem to happens), enabling a systematic addressing of an aspect able to be improved by a quality or safety initiative [480].

1.1.3 Improving the teamwork process

The third highlighted element for enhancing micro-system care coordination is improving the teamwork process it-self, supporting coordination of care. It may represent the teamwork proceeding; and underlying teamwork relationships among micro-system personnel; or ideally a mix of those two.

Teamwork operational proceeding

The teamwork operational proceeding represents actually a major field for quality and safety improvement in healthcare, importing and adapting teamwork strategies and communication structures, models and techniques derived from other industries.

For instance, teamwork and communication process, methods and structures – mostly derived from aviation - are being applied in training of healthcare teams in areas such critical and intensive care, due the equivalent requirements of time-pressure and the need

for complex teamwork that is highly reliable [484; 485]. For instance, it could be deployed and trained a shared mental model providing standardized communication structure, which appeals to share concise factual information under a SBAR (structure, background, assessment and recommendations) approach [486].

Interprofessional relationships

For supporting the effectiveness of teamwork structure and operations there is an underlying need for holding - or otherwise improving - teamwork relationships among micro-system personnel, adding the supportive interpersonal dimension to the teamwork operational proceeding [278; 487]. The team relations need to be shaped, built, fostered, or improved within the same disciplines, but mostly among different disciplines with their intergroup tensions or conflicts [488], and among micro-system personnel as a whole, including non-clinical staff, and promoting integrated interpersonal relationships among clinical and non-clinical staff [479].

Finally, we denote that a critical element shaping the scope of the teamwork process and team relations is the clinical-team leadership [489; 490] and broadly the micro-system leadership [364]. The micro-system leadership, as accountable for micro-system performance and their planning, has a critical role also for shaping the scope of the performance/quality-improvement process at the micro-system level.

1.2 Micro-system leadership and staff engagement for a collaborative quality-improvement (QI) process

As we begin to expose, a micro-systems action is much more than the sum of the actions of their individual practitioners. Thus, someone should carry out the task of planning and promoting the best synergic effect among individual elements' actions, thereby improving quality and efficiency of the whole micro-system.

The micro-system leader is the organizational element that is most accountable for the tasks of planning, (re-)designing and coordinating micro-systems' services, and patterns of care for quality, safeness and efficiency. The micro-system leader is a role that can be performed by an operations-manager or for a clinical head/leader accountable for it, or more often, by a team composed of an administrative, physician and nurse leader [364].

However, independently of the composition, the success of a micro-system leadership happens mostly when all micro-system staff is effectively engaged and actively involved, by micro-system leadership, in a shared mission of 'improving' the way care is designed, coordinated and delivered, instead of staff only concern with carrying out the task of 'doing' the work [444]. Indeed, micro-system staff, as facilitated by micro-system leadership - and supported by macro-leaders and improvement experts - might be actively engaged on re-designing services for improving performance/quality.

Frontline practitioners' participation on these tasks should be based on: field knowledge of typical patients, site patterns, and the contextual or local micro-politics and environmental variables [491]; as well as based on staff own competencies, creativity and individual talents - all contributing to shape and improve the way services and care are redesigned, planned and delivered to their subpopulations and patients [492].

In fact, the micro-systems leader's role on the improvement process mostly rely on activate, analyze, summarize, and integrate the contribution of those different micro-system elements - taking the best of their elements talent, training and skills - for designing, planning and support the deployment of a whole and unique micro-system's improvement pathway [364]. Such pathway needs to be adaptive to the specific patterns of interest, values and power relationships within the micro-system [491], but also adaptive to organizational core values, proceedings and quality-programs. Indeed, the micro-system leadership might balance what comes from above (macro-system level) with what comes from the bottom (frontline staff) in order to build the goals, strategy, priorities and actions for an optimal quality-improvement process-flow and success.

The micro-system leadership (and the yet highlighted meso-system at a second level) can be viewed as a 'gate-control' for diffuse information through a top-down and bottom-up ways with performance/quality-improvement regards [232; 386]. For instance, while the macro-system management structure - through the micro-system leadership - can diffuse the organizational guidance, or facilitate access to tools or resources that enable the front-line staff to achieve optimal levels of quality and efficiency; in the bottom-up direction, fruitful innovations and suggestions can emerge from the frontline practitioners and reach the executive level - through micro-system leadership - for a continuous and bi-directional cycle of organizational and micro-system quality-improvement.

For the task of redesign micro-system services, procedures and care; the leadership develops an operational process of guidance, oversight, and accountability for micro-systems action. More than a specific leadership style or traits, it relates with daily actions characterized by building knowledge, taking action, reviewing and reflecting. As exemplified elsewhere [364], there are several different ways of proceeding to fairly accomplishing such micro-system leading roles and activating the all system elements to improve their job and the micro-system results as a whole.

Finally, we should denote that are different, formal and informal, ways of leading others' actions. Reference practitioners' patterns are widely known to informally influence the practice patterns of those working close to them, creating unique micro-systems' practice cultures [493]. Such patterns can be very similar among practitioners within a same micro-system; and very different from others in different locations, being a factor that accounts for the wide, non-evidence based and undesirable variability in care patterns across sites and regions [445]. Reference practitioners play a critical role for micro-system performance. Therefore leaders should integrate reference practitioners (or clinical champions) early in any quality-improvement initiative [231].

1.3 Developing micro-system's human force for quality

Healthcare professionals and support staff are those professionals that face and meet individual patients' and relatives' needs. Much of the quality of care patients and relatives experience is deployed by front-line staff.

As we mentioned, in the previous sub-section, it is critical to motivate and engage all staff in the task of collaborating for re-designing a set of core processes and patterns of care they conjointly deliver, thereby improving the performance and quality of care as a whole micro-system. But besides such critical role, there is other roles staff can perform to improve performance and quality of care.

A workforce professional development and growth is needed not only to improve individual performance, but also to develop micro-system workforce performance as a whole. One way of promoting such professional development within the micro-system level

is to promote an environment that stimulates collaborative mutual learning through productive staff interactions and relationships [405].

Another way of promoting productive and learning staff interactions is involving all micro-system staff in the process of evaluating each other, and all staff involvement in orientation and cross-training of new members into micro-system values and proceeding, fostering a climate of mutual respect between clinical and administrative staff: active elements of the quality the micro-system deliver and improve [421].

Being active elements for quality require each micro-system element (of both healthcare professionals and support staff) continuously develop their knowledge, skills and competencies to apply into the task of improve their own contribution for the micro-system quality of services and care. With regards to formal frontline professional growth, traditional forms of continuum medical education (CME) has showed limited impact in improve the quality of care. Indeed, numerous studies highlight the fact that traditional models of continuing medical education - attending seminars and conferences – little improve the quality of services, although they may improve physicians' job satisfaction [494]. More recently, continuing education strategies can show some effectiveness but the effects are at the best low to moderate [495].

Within the quality-movement, comprehensive quality-monitoring and assessment data shall highlight what are the actual major performance/quality gaps in practice that practitioners should be able to improve. Quality-improvement initiatives can explicitly develop personnel competencies that are underlying to performance/quality identified gaps. Therefore it makes sense to frame and plan together the scope of what is 'quality-improvement' (QI) and what is 'continuum medical education' (CME) - or broadly healthcare professionals continuum education - to develop integrated programs, projects and initiatives with common ultimate goals of contributing the best quality and safety of patients care with an evidence-basis [423; 496].

A continuously evolving micro-system requires continuous development of their workforce and the development of competencies particularly in need for quality and quality-improvement in actual healthcare systems. These competencies were individually addressed in the Educational Community section.

A first competency staff might commonly develop is the ability to act together as a micro-system beyond professional boundaries, instead of being exclusively focused in their discipline-based job [6]. It is also required the development team-work, inter-professional, inter-agency and collaborative competencies of each professional. Despite improved in educational settings, it can also be fostered or developed in practice settings [497; 498].

Other competencies in need for development relate with interpersonal communication and patient-centered competencies [96] and others benefiting of being developed simultaneously by students and professionals, such practice applied evidence-based competencies and use of healthcare information and communication technologies [186], or specifically the quality-improvement process [361].

However, the first catalyst for change, and underlying professional growth, is the acknowledgement that practice needs to be constantly changed to continuously reaching their full individual and micro-system potential [390; 444]. Additionally, an acknowledgement of failures and need for professional growth should be promoted through a transparent, although non-judgmental, environment [174]. It involves collaboratively surfacing on the underlying assumptions of actual practice patterns, and choosing the right opportunities - attached to the local circumstances - to identify possible causes and intervene accordingly to build professional capacity, thereby reaching the best personnel contribution for the micro-system quality [444].

Finally, the micro-system human force shall have their own active part on define a self-directed (yet organizational- and systems-mentored) path towards a professional development [499]: facilitated by organizational human resources programs, and articulated with continuous professional educational systems. When professional and organizational development fit well together, it generally produces both: the enhanced organizational performance and practitioners' job satisfaction [421].

2) Micro-Integration: Integrating care and community resources at a patient level

In the macro-system section, we highlighted the 'macro-integrator' role, establishing inter-sector platforms of cooperation and coordination, serving as a macro-coordination basis for

better care for sub-populations and better population/communities health. But better care for individuals – patient level - depends also on micro-integration.

Micro-integration is facilitated by macro-platforms of cooperation and coordination among health and non-healthcare sectors and services, yet it still requires the action of a 'micro-integrator' responsible to articulate care and community resources for an individual patient.

2.1 Patient-Centered Medical Home: A model for performing a 'micro-integrator' role

The 'micro-integrator' role is mostly designed around a whole spectrum of individual patients' and respective families' needs [31]. The 'micro-integrator' shall represent a privileged, easy accessible, and integrative source of communication and support for patients and relatives in matters related with their health; healthcare; navigation through the system, and facilitating users take best benefit of community services and resources.

One of the greatest threats to the quality of the American's patient experience and patient-centered care - particularly those with multi needs – is the difficulty in navigation through multiple providers within a fragmented healthcare system, needing a systems-based approach for enhanced patient experience and care coordination [19; 20].

Particularly considering the actual fragmentation of the US healthcare system and poor connections with other community services and resources, the micro-integrator role is critical to enhance the navigation through the system. Operationally, the micro-integrator should also foster the patients and families (self-)management, understanding and compliance with health information, as tailored to individual patient needs, preferences, interaction patterns or health literacy [31].

A structure gaining momentum in the field to perform the role of the 'micro-integrator', enhancing care coordination from a primary care structure, is the Patient-Centered Medical Home (PCMH). The PCMH build on a customized, mutually trustful and continuous healing relationship, facilitating a proactive individualized care planning and the (self-)management of patients' conditions; as well as assuring the coordination for a comprehensive care along the healthcare continuum for all covered patients [110; 447].

The PCMH should help consumers to obtain, broadly integrate, coordinate care, and give/ translate technical information – from variety of providers - to a patient level of understanding, under an established trusting and healing relationship [110].

The relationship of patients/families and their 'medical home' should not only happens on a face-to-face basis, but often using e-mail and online methods for easy access and timeliness of the answer, in that way contributing to the achievement of better quality-indicators and both (providers and consumers) experience [500; 501].

2.2 Micro-integration of community services/resources: an sub-explored path

Performing a micro-integrator role - for instance a PCMH structure - can facilitate patient and relatives take the best achievable benefit of health-related community resources available or potentially available to patients and families [502].

The community services and resources to be integrated at a micro-level can embrace practical aspects related for instance with logistic assistance, like facilitating the access and use of transportation services [502]. But beyond such and other pragmatic aspects of assistance, it could also consist on helping patients and relatives using (or making a good use) of community services/resources that can potentially act as active-elements for their health and healthcare [32].

These health-related community services/resources (agencies, centers, consumers-led organizations or associations) can provide to patients and families health-related: information, education, social assistance, legal advice, social support, emotional support, counseling and self-help groups for patients and relatives. It could also be made on a face-to-face basis or in a web/electronic-basis. Indeed, in the web era, there are a great amount of health-related resources in virtual communities that consumers can make use. However, there is a paucity of well-designed studies and evidence demonstrating the grade and type of effects - intended and unintended - of such virtual communities and web-based resources in great development in the last years [503; 504].

The micro-integrators, and broadly the all frontline staff, might foster their field knowledge of the local, national and web health-related community services and resources potentially available at least for their typical patients' needs. This is in order to help their patients to

get access, select, and take the best achievable benefit of these services and resources [32; 502]. However, what we can broadly tell is that enhancing the contribution of those community resources/services available and mostly helping patients to take a good use and benefit – instead of nonuse or prejudice - is a path yet to be adequately explored by the health sector [6].

D- PUBLIC POLICY-MAKERS

At this last stakeholders' group level we outline the role for quality of the public policy-makers. Those are at an overarching external level, with their action able to influence and, at some level, foster integration of the action of other stakeholders' groups for quality, therefore outlined in this last section, and focusing on the US context.

1) Public Policy Leadership for Quality

A strong national policy leadership for quality is often called for a needed cultural change in national healthcare systems. This happens in America [6], but also in other countries, like the UK [428].

Focusing in the America's specific context – and despite healthcare is focused on the private-sector - the federal government still stands in a natural unique position for influencing the quality of care that no other US stakeholder could produce [154]. In synthesis, the US federal government can directly influence the way and quality care is delivered to all American population in two different ways:

1. Assuming a leadership/influential role in the alignment of a whole 'system' of influences, strategies, programs and actions among all stakeholders' groups and levels, nurturing the quality of health system(s) nationwide.

2. Take benefit of the administration position in public-led healthcare programs, directly influencing the quality of their beneficiaries, but indirectly to all Americans by example, or by setting the 'gold standard'.

1.1 Leadership/influential role to align a whole 'system' of initiatives for quality

Policy leadership is an essential element to transform healthcare, by critically supporting and coordinating different programs, strategies and actions, fomenting a national culture for quality of care [432].

It is widely recognized that transforming a health/healthcare system for quality requires multiple concerted actions among stakeholders levels supported in a global alignment of a system of incentives, priorities, strategies and quality-initiatives [12; 20].

Public policy-makers, in particular those at federal level (e.g. those at state level in a second level of influence), should take benefit of the unique, privileged, over-arching leadership/influential position to lead, stimulate, foster and guide a systems thinking and system-based solutions with nation-wide impact in quality and health of populations.

The very recent Patient Protection and Affordable Care (PPAC) law [111] - which introduces substantial reforms in the US healthcare field - gives important catalyzing steps towards the pointed direction. In the sequence of the law, it emerged a federal government 'national quality strategy' [453], which should be followed by a 'national prevention strategy' released for open discussion and foster refinement.

Both strategic papers, seeking wide-consensus, might serve as national guide for action in the years to come about these two directions.

In conjunct with enlarged access/insuring reform these two strategies are the three major pillars of US healthcare reform (PPAC) very recently approved. Soon before such landmark healthcare law, the American recovery and reinvestment act of 2009 [505], also gave an important budget input - for the creation of the Patient-Centered Outcomes Research Institute (www.pcori.org) - that determined the beginning of a long-term journey of federal funded Comparative Effectiveness Research (CER: highlighted in Research Community) which would provide more clear evidence of what works better, to whom, in what

circumstances, at the most affordable price: for the efficiency and quality healthcare delivering, thus the sustainability of the health/healthcare system.

Finally, there are also multiple synergies for quality and efficiency that can only achieve their maximum level if full applied at a national level. It might be the case of a full national adoption of HIT (Health Information Technologies), particularly interoperable Electronic Health Records (EHR) which can origin great system synergies, efficiency and national system savings estimated in several millions of dollars, which are not saved with the actual low-percentage of national HIT adoption [170].

Therefore, the public policy-makers, mostly the federal ones, should provide stimulus for high-leverage national improvement-related programs. In the example of national adoption of HIT, a planned program with a ten year duration started yet in the previous administration [168] can be a example, although excessively ambitious in the schedule [169].

1.2- The roles for quality: Using the public-administered healthcare programs to raise the 'gold-standard' for quality

Federal government should harmonize the approach of their different roles and health programs among their different departments towards a quality-focused healthcare delivering directly for their beneficiaries, as well as indirectly to all Americans [154].

In concrete, the federal government needs to coordinate their different healthcare-related departments, structures, agencies or programs on a same strategy for quality. This is also enhanced for instance by the recent 'national strategy for quality' [453]. American's public policy can shape the quality of the overall health/healthcare system into four different domains: direct provider; funder of health services and quality-related research; healthcare regulator, largest single purchaser [154].

1.2.1 Direct Provider

First, as direct provider to veterans, militaries and their families, and native Americans, the federal government can serve as a model for all aspects of healthcare organization and

delivery, taking benefit of being a direct provider, by using their own administration, structures, organizational and clinical processes and outcomes as an open national laboratory for innovation and implementation of quality-initiatives.

The best example of what said, and a study-case for quality, is the work being done in the Veterans Health Administration (VHA). For decades, fairly or unfairly, this healthcare system preserved a suboptimal image about quality. However, in the 90's, the VHA leadership began a committed process for a remarkable transformation with a series of strategic coordinated action and programs.

Such a journey led to sustainably, system-wide, quality improvements, with this public system scoring best in several process quality indicators than non-VHA settings, although the existent comparison of risk-adjusted outcomes generally show similar results [506]. Due its unique scope (largest delivering system, with a nationwide implementation, managed by a single administration with a very specific target population), it is not valid to absolutely copy or translate the VHA quality approach for the private delivering sector [507]. Despite that fact, VHA experience with quality-action, provide lessons private organizations are retaining and using for their own quality-improvement efforts. A set of such principles are synthesized in a following box, yet supported by additional theory and evidence.

- It is possible to achieve remarkable and wide deployed improvements in quality of a delivering system. Such transformational changes require a sustainable change for a so-called culture of quality [508], from management and design to implementation and practice [411].

- Transformational and cultural change for quality begins with a strongly committed leadership [509]. It provides coordination of programs and investments for a systemic goal [249]. It also prevents the well-described resistance to behavior in organizations [510] and by practitioners [183].

- Structural investments - as communication/information infrastructures – support transformational changes. Although scale/dimension diminishes implementation costs for the VHA system, integrated delivering systems might accomplish that requirement for the private sector [511].

- Internal health services researchers support managers' and clinicians' decision-making process within the large healthcare organizations [206]; as well as it specifically supports the quality-improvement process within the organization

on an evidence-basis. The VA QUERI (Quality Enhancement Research Initiatives) experience highlights a particular successful approach for the evidence-based implementation process, mostly characterized by active researchers-practitioners partnerships.

1.2.2 Funder of Health-services and Quality-related research

Through their own delivering structures - or through the Agency for Healthcare Research and Quality (AHRQ) - the federal government has another role for the quality of care all Americans receive, which is funding health-services and quality-related research, for instance through a strategy that supports the crossing of the 3 translational block to put evidence into practice [203]. As funder of health-services and quality-related research, federal government can support evidence-based decision making for the quality of healthcare in their own-run systems, as well as indirectly shaping the scope of private practice, for instance providing them with tools, techniques and supportive research for the most effective healthcare organization and practice.

Despite the importance of health-services and quality-related research, the governmental funding for such activity is very low in compare to other health research spending, and it experienced a comparative decrease in funding few years ago [207].

1.2.3 Healthcare regulator

Third, as a regulator, the government establishes the legal minimum standards and requirements for an authorized practice. Either by federal government, or by states governments in their jurisdiction. There are a series of rules and administrative controls that shape the scope of healthcare practice. Regulation exists to assure that different type of practices are complying with the minimum acceptable standards, enabling them to provide legal and responsible healthcare to the population.

Within a quality perspective, regulation might focus on assure that major structural requirements for the quality are accomplished. But the quality of care delivered to

population might be far beyond the spectrum of regulation. Indeed, regulation tends to become strengthened, inflexible and excessively focused on administrative and structural requirements, when there is a lack of fundamental information about the more clinical aspects of quality. As being noted, excessive regulation is burdensome; produces a lot of administrative data not always useful; de-focus on clinical aspects of quality; as additionally often hampers innovation, evolution, the appliance of system tools a for quality transformational changes on a system-level [195; 385].

The barrier of excessive administrative regulation can only become crossed in a secure way for the quality population receives, if there is in practice an effective 'quality system', focused on valid clinical quality/ performance data - sufficiently comprehensive to be meaningful, yet feasible to apply in routine practice.

A form of regulation is the mandatory data collection for the claims of the public programs (i.e. Medicare). This is a way public policy determines the scope and type of data required in practice, taking advantage of the role of most representative payer.

1.2.4 Largest Single Payer

As the largest single payer, the federal government (Medicare) also followed by states government (Medicaid), can lead the process of definition of payment policies and model of rewarding and incentivizing for quality and efficiency.

Indeed, as the largest single payer (Medicare), the federal government can model the trends of the market under their payment policies which, according the IOM's 'quality chasm' report [12], should become aligned with quality of care. In fact, new developed approaches, globally framed within a payment reform for quality, are being field tested under Medicare program through demonstration projects in current and past years [512]. The most recent 'national quality strategy' highlights that a new "Center for Medicare and Medicaid innovations" will assure that promising innovations in care delivering and payment are well-tested, expanded and implemented into future policies [453].

The payment approaches are exposed in the Payer & Purchasers section. Herein, it is important to retain the influential and testing role that public policy-makers might assume, taking advantage of the referential position within healthcare payers to shape the payment

policy trends, and giving the initial input for the establishment of local or regional arrangements with other payers - towards concerted payment policies applied in the different 'regional' healthcare systems in the country [23].

The States governments can also have active role through Medicaid payment policies. However, it is been recognized that if Medicaid wants to become effective in assuming such leading and referential role for a quality-aligned payment policy, the program needs a wider transformational change in actual policies and practices [141].

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