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Clinical Governance Framework for Chronic Diseases in Primary Care

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Clinical Governance Framework for Chronic Diseases in Primary Care

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Conflict of interest

The authors declare not to have any financial or other relationship that might lead to a conflict of interest.

Data sharing statement

No additional data available.

Keywords: primary health care; chronic disease; health care research; health system framework;

Abstract

Objectives: Our goal is to conceptualize a clinical governance framework for the effective management of chronic diseases in the primary care setting, which will facilitate an reorganization of healthcare services that systematically improves their performance.

Setting: Primary care.

Participants: Wagner's Chronic Care Model and Scally's Clinical Governance statement were taken for reference. Each was reviewed, including their various components. We then conceptualized a new framework, merging the relevant aspects of both

Interventions: We conducted an umbrella review of all systematic reviews published by the Cochrane Effective Practice and Organisation of Care (EPOC) Group to identify organizational interventions in primary care with demonstrated evidence of efficacy.

Results: All primary health care systems should be patient-centred. Interventions for patients and their families should focus on their values; on clinical, professional and institutional integration; and finally on accountability to patients, peers and society at large. These interventions should be shaped by an approach to their clinical management that achieves the best clinical governance, which includes quality assurance, risk management, technology assessment, management of patient satisfaction, and patient empowerment and engagement. This approach demands the implementation of a system of organizational, functional and professional management based on a population health needs assessment, resource management, evidence-based and patient-oriented research." It also demands professional education

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5 , team building, and information and communication technologies that support the delivery
6
7 system. All primary care should be embedded in and founded on an active partnership with
8
9 the society it serves.
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11
12 **Conclusions:** A framework for clinical governance will promote an integrated effort to bring
13
14 together all related activities, melding environmental, administrative, support and clinical
15
16 elements to ensure a coordinated and integrated approach that sustains the provision of
17
18 better care for patients with chronic conditions in primary care setting.
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Strengths and limitations of this study

The study give a new comprehensive framework to drive an effective management of chronic diseases in the primary care setting;

A systematic review was made showing all relevant studies in Cochrane Effective Practice and Organisation of Care Group alongside the dimensions of the framework

We do not report studies illustrating interventions for a specific unique disease even if chronic disease.

Introduction

The dramatic increase in the burden of chronic diseases in the last twenty years represents a primary concern for health services, and global health system sustainability demands a massive shift to primary care [1-3]. As a consequence, the organization and provision of primary care now faces new challenges (e.g. polypharmacy, multimorbidity, fragmentation of care, frequent transitions of care, a need for strong integration, and pressure from patients) [4]. There is currently a growing interest in developed countries to redesign health care organizations, focusing on practices that improve the quality of care and guarantee the equitable, timely and effective management of patients with chronic diseases [5, 6]. With these pressures, primary care systems may have difficulty ensuring a coordinated approach, and the lack of clarity concerning their goals has led to divergent approaches, and a slow and often disjointed adoption of changes and improvements. [7, 8]

Clinical governance is an umbrella for the systematic administration and coordination of different processes having a direct impact on healthcare delivery, including the management of patients with chronic conditions. It encompasses the tools, methods, and infrastructure devoted to assuring healthcare delivery, continuously improving the quality of the service, and striving towards clinical excellence for patients. Clinical governance was first established in the UK, [9] and has been implemented in many different countries [10-13]. Until now, it has focused largely on in-hospital care, and met with significant difficulties when transferred to primary care. [14] Clinical governance for primary care, focusing on the management of chronic diseases, has specific features and relies on a network of different health professionals working together for their patients' benefit [15].

Our paper aims to conceptualize a clinical governance framework and the tools it needs for

1
2 the effective management of chronic diseases in the primary care setting, allowing to drive an
3
4 effective change in healthcare services and thereby systematically improving their quality and
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6 safety.
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12 **Methods**

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14 For the purposes of our analysis, we used the Chronic Care Model [16] and Scally's Clinical
15
16 Governance statement [17] for reference, carefully reviewing each of them and their various
17
18 components. We then conceptualized a new framework, merging the relevant aspects of
19
20 both, and also defining and implementing new themes in a way that is relevant for primary
21
22 care. We ultimately selected five core elements from the original Chronic Care Model
23
24 (Delivery System Design, Decision Support, Clinical Information Systems, Self-Management
25
26 Support, The Community) and six approaches (Risk avoidance, Coherence, Infrastructure,
27
28 Culture, Quality Methods, Poor Performance) from the clinical governance framework
29
30 described by Scally based on their relevance to primary care and chronic disease
31
32 management.
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40 We then devised a framework arranged like a sunflower, where the *stem* and *leaves*
41
42 represent the *structural components* of the system needed to supply and support the *petals*.
43
44 The petals in turn represent the themes or topics that shape direct actions involving patients
45
46 or caregivers (the *bud* of the system). The sunflower is rooted in the *earth*, from where its
47
48 structural components receive inputs in the form of water and nutrients; in healthcare, inputs
49
50 from the "soil" enable the provision of primary care, collaboration between service providers,
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1
2 and resources from the outside world. The *atmosphere* in which the sunflower grows informs
3
4 the views and attitudes that guide the actions of both health professionals and patients.
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8
9 For each *petal* (i.e. theme or topic), we searched for relevant interventions in the Cochrane
10
11 Library from 2010 to the end of 2016, in the context of chronic care in the primary care
12
13 setting. The search strategy used in our umbrella review of the Cochrane Library was based
14
15 on the MeSH terms: (“general practice*” or “primary care”) and (“chronic disease*” or
16
17 “multimorbidity”), plus one of the following: 1) “clinical governance”; 2) “quality assurance” or “
18
19 “evidence-based healthcare”; 3) “satisfaction, patient”; 4) “risk management”; 5)
20
21 “empowerment” or “health literacy” or “engagement”; 6) “health technology assessment” or
22
23 “cost-effectiveness” or “cost-utility”. We also identified all systematic reviews published by the
24
25 Cochrane Effective Practice and Organisation of Care (EPOC) Group that met our criteria.
26
27 We included all relevant studies published in the Cochrane Review Database from 2010 to
28
29 06.2017, and excluded all studies illustrating interventions for a specific disease, or those not
30
31 involving patients with chronic disease.
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38 Results

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40 The resulting conceptual framework is shown in Figure 1. We define three targets where
41
42 management strategies could be acted:
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44

- 45 1) The petals consist of the management strategies that directly inform the interventions
46 and clinical practice that acts on and with the patient and their family;
- 47
48 2) The stem represents the underpinning management strategies that support the
49
50 delivery system, which is the personnel and structures that permit the organization to
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1 support the “life of the petals”;

2
3
4 3) The ground is the environment in which primary care delivery is located, which gives
5
6 “nourishment” and foundation.

7
8
9 4) Finally, there is the atmosphere, which represents the management strategies that
10
11 influence the first three targets.
12
13

14 15 *The bud is the center of the flower*

16
17 Placing personalized patient-centred care at the heart of the system is an important way to
18
19 create catalysts for change and encourage service re-organization, by focusing on patients’
20
21 health needs and motivating health system’s changes [18]. We define patient-centred care as
22
23 care that is based on continuous, healing relationships among health professionals, patients
24
25 and their families; care that is customized based on the patients’ needs and values; [19]
26
27 ensuring that the patient is the source of control; sharing knowledge and information freely;
28
29 and maintaining transparency.
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36 37 *The petals define what and how to act on and with the patients*

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39 The petals represent the management strategies that should shape directly the interventions
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41 on and with the patients. These dimensions include quality management, perceived quality
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43 management, empowerment strategies, risk management, and health technology
44
45 assessment. The IOM defines **quality management** as the degree to which health care
46
47 services for individuals and populations increase the likelihood of desired health outcomes
48
49 and are consistent with current professional knowledge [20]. It usually has two facets: quality
50
51 assurance and quality improvement. In chronic disease management, quality assurance
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1 concerns the activities and programs intended to assure or improve the quality of care in a
2 specified medical setting or program. The concept includes assessing (measuring)
3
4 the quality of care, identifying problems or shortcomings in the delivery of care, designing
5
6 activities to overcome these deficiencies, and follow-up monitoring to ensure the effectiveness
7
8 of any corrective action. [21] Quality improvement involves the process of attaining a new,
9
10 higher level of performance or quality [22]. Adopting the philosophy of evidence-based
11
12 medicine in planning the diagnosis, care and follow-up of chronic patients has resulted in a
13
14 more effective and consistent transfer of the lessons learned from research into routine
15
16 practice, helping to reach higher quality standards [23, 24]. However, while many measures of
17
18 quality of care in the primary care setting have been validated for specific diseases, little has
19
20 been done to examine the validity or usefulness of these measures in the context of
21
22 multimorbidity. Our scoping review found that interventions designed to target specific factors
23
24 (e.g. treatment for depression), or that focus on difficulties people experience with daily
25
26 functioning (e.g. physiotherapy to improve capacity for physical exercise) may be
27
28 effective.[25] Another review showed that, in 5 of 17 good-quality RCTs, several different
29
30 interventions were able to improve both adherence to prescribed medicines and clinical
31
32 outcomes. These interventions frequently included enhancing support from family, peers, or
33
34 allied health professionals such as pharmacists, who often delivered education, counseling, or
35
36 daily treatment support, even if no common features could be identified to explain their
37
38 success. [26] However, to guarantee quality assurance it is necessary to consider the
39
40 deliberate and systematic coordination of an organization's people, technology, processes,
41
42 and organizational structure in order to add value through innovation, using research to inform
43
44 practice [27] (see table1a).
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4 **Risk management** concerns the systematic identification, assessment and integrated
5
6 management of current and potential hazards relating to patient care. This is particularly
7
8 relevant for the care of complex patients with (“multimorbidity”). [39] The creation of a culture
9
10 that is free of blame and encourages an open examination of errors and failures is key to
11
12 improving quality and learning.
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18 Clinical incident reporting is a key feature of a risk management system that can improve
19
20 identification of errors and how we can learn from them. Leape suggests that successful
21
22 systems provide a safe non-punitive environment, and are simple, timely and inexpensive
23
24 [40]. However, the effectiveness of such systems in promoting adverse event recording is not
25
26 clear. To evaluate the effects of interventions designed to increase clinical incident reporting
27
28 in healthcare settings, Parmelli and colleagues in 2012 conducted a review of four trials with
29
30 several methodological shortcomings. Despite their limitations, two studies showed the
31
32 effectiveness of the system implementation: one reported an increase in incident reporting
33
34 rates, while the second showed a sustained improvement after nine months [41].
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38 One review on non-clinical health professional roles, found that older people were more likely
39
40 to receive appropriate medicines with the provision of a pharmacist led intervention. [42] This
41
42 service provided by pharmacists that involves identifying, preventing and solving medication-
43
44 related problems, as well as promoting the correct use of medicines and encouraging health
45
46 promotion and education. Another strategy found to be useful was computerized support for
47
48 decision-making. The review focused primarily on process outcomes, and provided only
49
50 limited evidence of whether these interventions resulted in clinical improvement. Another
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1
2 review found that self-monitoring of medicines and patient self-management programs were
3
4 generally effective in improving the use of medicines, adherence to prescriptions, reducing
5
6 adverse events, and improving clinical outcomes. It also found a lower mortality rate among
7
8 people self-managing their antithrombotic therapy. [41] The same review revealed numerous
9
10 other promising interventions to improve adherence and other key outcomes related to
11
12 medicine usage (see Table 1b).
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18 **Patient satisfaction** is fundamental in the case of patients with chronic disease who are
19
20 likely to be involved in a lasting relationship with healthcare services. It is linked to patients'
21
22 expectations of ideal care and their actual experience of care [48], and it is considered by
23
24 most as a multi-dimensional construct including multiple domains such as accessibility,
25
26 organizational characteristics of the system, clinical and communication skills, and the doctor-
27
28 patient relationship, among others. Long waiting lists for non-urgent health procedures are
29
30 quite common and may affect the health professional-patient relationship, causing distress for
31
32 patients and their caregivers and distrust of the health care system. Improving access by
33
34 implementing an open access or direct booking for some health problems or referrals has
35
36 been shown to improve patient satisfaction [49]. Home-based interventions for end-of-life care
37
38 have also been shown to improve both patient and caregivers satisfaction [50] (see table 1c).
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44 **Patient and caregiver engagement** refers to a patient- and family-centred collaborative
45
46 approach that is tailored to match the fundamental realities of chronic care. Patient and
47
48 caregiver engagement helps patients discover and develop their inherent capacity to take
49
50 responsibility for their own life. [52] Empowering patients by providing information and
51
52 increasing their contribution to the planning of services can greatly influence the development
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1 of clinical governance, not only on clinical processes, but also on organizational matters.
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4 Contributions from patients will affect not just the responsiveness and performance of
5
6 healthcare services, but also the process by means of which quality improvement initiatives
7
8 are identified and prioritized. [53]. Recent reviews highlighted that interventions promoting
9
10 sharing medical decision making with active involvement of both patients and health
11
12 professionals, has found moderate evidence of better patient involvement. In addition,
13
14 decision aids (pamphlets, videos or video-based tools) may improve patient's knowledge of
15
16 their care options, so they feel more informed and better able to participate in decision making
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18 [54, 55] (see Table 1d) .
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27 **Health Technology Assessment (HTA)** refers to the systematic assessment of the
28
29 properties and effects of a health technology, addressing the direct and intended effects of
30
31 the technology, as well as its indirect and unintended consequences. The main aims of HTA
32
33 are to inform decision-making regarding health technologies (bearing in mind the finite
34
35 resources available), to drive the introduction of innovations, and to identify ineffective or
36
37 harmful technologies. [57] Whether it involves introducing electro-stimulators for treating
38
39 incontinence, or disinvesting in old medical ventilators for long-term domiciliary respiratory
40
41 support, or a new clinical pathway for diabetes, HTA is a robust method for orienting decision-
42
43 makers and clinicians towards the best available choices (see Table 1e).
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50 *The atmosphere*

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52 The atmosphere dimensions defined at this level shape not only the interventions given to
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1 patients, as petal dimensions, but also describe activities inside the organisational between
2 professionals, as well as the relationship with the civil society. Dimensions of the atmosphere
3
4 include vision and values, integrated care, and accountability.
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11 A well-led organization will monitor whether the **vision and values** of clinical governance are
12 being clearly and effectively communicated to all members of the staff. This communication
13 gives staff a common and consistent purpose, and clear expectations. A clear, vision
14 engenders an open-minded and questioning culture, and ensures that both the ethos and the
15 day-to-day delivery of clinical governance remain an integral part of every clinical service.
16
17 Apart from health system issues, one of the major barriers to the successful transfer of
18 evidence into locally-accepted policies lies in ineffective and unaccountable leaders and
19 managers [61] (see table 1f).
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32 **Integrated care** is a concept that brings together the inputs, delivery, management and
33 organization of services related to patients' diagnosis, treatment, care, rehabilitation and
34 health promotion. As individuals move across healthcare settings and services, the model of
35 care requires integration and cooperation between a multiplicity of professionals. This
36 integration and cooperation demands a high degree of collaboration between healthcare
37 professionals involved in these services, as well as organizational support. This integration
38 should operate not only within a primary care system, but also through effective
39 communications between specialist and primary care providers, to guarantee better
40 transitions of care for patients with chronic disease. The latter has significant positive effects
41 in reducing hospital readmissions and mortality [65-67] (see table 1g).
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4 A robust, comprehensive, and transparent **accountability**, with measurement of performance
5
6 in healthcare activities can ensure that the system is accountable to society at large, to health
7
8 professionals and others involved in delivering care, and to patients. A fundamental shift is
9
10 needed from a demand-driven model valuing the volume of the production, to a new model
11
12 where the providers are accountable for the care outcomes and value that matter to patients
13
14 and the broader population. Driving accountability for outcomes and value leads to several
15
16 key benefits: it encourages innovation along entire care pathways, to raise quality and reduce
17
18 cost; it incentivizes collaboration between providers to co-ordinate care to deliver outcomes; it
19
20 clarifies for policy-makers what is being achieved by the money being spent; and it gives
21
22 people a stronger voice in their own care and in defining what matters.[70, 71] Such a system
23
24 can support effective auditing, which can improve care processes in health districts over the
25
26 long term. [71]
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36 *The stem define the means to reach the petals*

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38 It is also important to ensure that key underpinning strategies (such as information
39
40 technology, education and training, research and dissemination) support the delivery system
41
42 to reach the defined petals dimensions. For example, any service re-organization should
43
44 involve building better information communication and technology (ICT) systems, to enable a
45
46 better exchange of information throughout a newly rearranged organization. An effective
47
48 workforce also needs appropriate technical support, such as access to valid best evidence, to
49
50 support its clinical decisions. To be useful, the data in information systems must be valid, up-
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1 to-date, and presented in a way that offers insight. It should also be integrated with the
2 electronic health record, and not provide excessive alerts that lead to “alert fatigue”. Finally, it
3
4 should focus on research that provides evidence of improved patient-oriented outcomes,
5
6 rather than disease or surrogate markers of improvement. [72]
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13 Data to highlight differences in patient outcomes, shortfalls in standards, comparisons with
14 other services, and time trends are essential. Interconnected electronic health records
15 support clinicians’ efforts to improve outcomes across the full continuum of care, while
16 ensuring accountability, engaging patients in making decisions and managing their care,
17 improving safety and care coordination, and avoiding any waste of resources. [73] Data are
18 essential to managing performance, normally in relation to two subsets of activities:
19 performance evaluation, and performance improvement. Both make use of indicators for
20 assessment purposes, and the latter also to monitor a healthcare organization’s performance
21 during an improvement process [74]. For patients with multiple chronic conditions, it is also
22 necessary to devise team indicators and indicators that encompass all the care provided to a
23 given patient.
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41 Improving the training of health care professionals will be important in any effort to re-
42 organize a health care system. For example, if more nurses are going to take on the role of
43 case study managers, they will need additional training to build their skill base. [75] Ideally,
44 continuing professional education should not be limited to updating professionals’ technical
45 skills, knowledge of new research, and improved clinical decision-making. In addition, it
46 should enable all members of the staff to develop skills that allow them to practice to the
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1 maximum of their training, and to assure that their skills are aligned with the organization's
2 objectives.
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8 *The earth defines the ground where primary care is delivered*

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10 Community participation should be part of healthcare service planning and evaluation. It is
11 also essential to mobilize community resources to meet the needs of people with long-term
12 conditions, creating a culture and mechanisms that promote safe, good-quality care. It has
13 been suggested that positive outcomes for people with long-term conditions are only achieved
14 when not only individuals and their families but also community partners are informed,
15 motivated, and work together. [76] Families and individuals are then supported by the broader
16 community, which in turn influences the broader policy environment, and vice versa. In this
17 model, integrated policies span different types of disease and prevention strategies,
18 consistent financing, the development of human resources, legislative frameworks, and
19 partnerships.
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38 **Discussion**

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40 A framework for clinical governance promotes an integrated effort to bring together all
41 relevant activities, melding environmental, administrative, support and clinical elements to
42 ensure a coordinated and integral approach, and thus sustain the provision of better care for
43 patients with chronic disease and multimorbidity.
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50 There are numerous challenges to providing coordinated and high-quality primary care to
51 patients with chronic disease. For instance, the quality of the management of patients with
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1 multiple chronic conditions should be examined, taking the completeness of care into
2 account. [77, 78] There is often a lengthy gap between the generation of new research-based
3 evidence and the application of this evidence in clinical practice. This is true not only for
4 clinical management, but also for organizational management of patients. Knowledge
5 management is achieved by creating, sharing, and applying knowledge, as well as through
6 feeding the valuable lessons learned and best practices into the “corporate memory” to foster
7 continued organizational learning. [77] This broad remit of knowledge management and the
8 sharing of knowledge amongst organizational fields includes developing values, structures
9 and information technology. It places emphasis on how value can be added: the petals should
10 be revitalized by the atmosphere and ground. Moreover, quality assurance in patients with
11 chronic illness implies using measures to assess the impact of interventions for chronic
12 conditions on a patient’s daily functioning and quality of life. A number of measures from the
13 Medical Outcomes Study have been used in studies of multi-morbidity in primary healthcare
14 [79]. An advantage of using such measures for patients with multimorbidity lies in that it does
15 not focus on the care provided for specific diseases. Overuse of healthcare has also been
16 assessed by examining hospitalization rates for ambulatory care sensitive conditions (ACSC),
17 i.e. conditions for which it is believed that well organized delivery of high quality primary care
18 services can prevent the need for hospitalization [80, 81]. Overuse of healthcare has also
19 been measured in terms of the frequency of hospitalization and emergency department
20 attendance for patients with multiple morbidities [82]. These measures are not disease-
21 specific, so they could be used to assess overall quality of care for patients with multiple
22 health problems. One of the main challenges, which takes a different form in each context, is
23 to develop appropriate incentives that promote and encourage a collective commitment to this
24

1
2 alternative paradigm of continuous performance improvement [83]. The organizational
3
4 leadership should maintain the organizations' focus on the use of information for improvement
5
6 rather than sanction or punishment. This involves being able to establish a trusting and
7
8 working relationship with the potential users, and to move away from a controlling or
9
10 paternalistic approach.
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14 An important consequence of how care of patients with chronic disease is managed relates to
15
16 perceived quality or satisfaction, which itself is associated with the health of the population as
17
18 a whole [48]. Patient satisfaction is associated with clinical outcomes, patient retention, and
19
20 medical malpractice claims, so it is a proxy, but nonetheless is a very effective indicator of the
21
22 success of a primary care system. Different tools have been developed to assess perceived
23
24 health quality for chronic diseases. A recent European project [84][focused on perceptions of
25
26 quality in primary health care in seven countries, highlighting the natural impact of waiting
27
28 time on patient satisfaction, and the more complex association between equity and access to
29
30 primary health care services. There is strong evidence that one of the most important
31
32 determinants affecting satisfaction with health services is the patient-practitioner relationship,
33
34 including the information the former receives from the latter. [85] This is a crucial issue in the
35
36 long-term management of chronic conditions. In the literature, increasing patient age has
37
38 also emerged as a less powerful, but consistent predictor of patient satisfaction. [48] The
39
40 Australian experience in improving and assessing satisfaction with primary care services
41
42 considered three aspects: 1) satisfaction with the primary care practice environment based on
43
44 client satisfaction with waiting times, information regarding appointments, waiting room
45
46 environment, provision of information about other services available, amount of time spent
47
48 with health professional, attitude of staff and cost of service; 2) satisfaction with service
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1 provision measuring client satisfaction with information provided, concern shown, skill,
2 assistance with health problem, and ability to self-manage as a result; and 3) satisfaction with
3 provision for special needs, measuring the client's perception of responsiveness to any
4 special needs, such as cultural/linguistic requirements and physical disabilities.
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11 The evidence linking patient activation, including person's beliefs, motivation, and actions for
12 self-care, with health outcomes, the patient experience, and cost has grown substantially over
13 the past decade. [86] Higher activation levels in chronically ill patients are associated with
14 higher levels of adherence to treatments, self-monitoring of conditions, and regular chronic
15 care. Patient activation to enhance patients' skills, knowledge and confidence in their ability to
16 take healthy action and manage their disease should therefore be one of the main goals of a
17 primary care health system. Patient activation can increase the motivation for self-
18 management for chronic diseases, such as creating durable healthy lifestyle changes and
19 improving adherence to treatment recommendations. In this respect, self-management
20 reaches beyond traditional disease management by incorporating the wider concept of
21 prevention, emphasizing the notion that people who are chronically ill still need preventive
22 services to promote their wellness and mitigate any further deterioration of their health. Self-
23 management is consequently an excellent way to address chronic conditions as a major
24 public health issue [87]. Researchers have also placed a strong emphasis on the crucial role
25 of family in patient self-management, recognizing that enhancing families' self-management
26 generates better health outcomes [88]. Despite its important beneficial effects, many factors
27 threaten effective empowerment, including individual patient characteristics, poor
28 technological or IT infrastructure, poor educational or communications strategies, and
29 communication and language barriers between healthcare providers and patients.
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4 Where performance monitoring systems are adopted as a management approach,
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6 performance tends to be better than when such systems are not in place, although reverse
7
8 causality could be argued higher quality primary care organizations may be more likely to
9
10 implement performance evaluation. Healthcare professionals are generally keen to measure,
11
12 know, and demonstrate that they are making an important difference for their patients.
13

14
15 Although there is little evidence of its effect on health outcomes or overall value for money
16
17 [89, 90], the emphasis on performance management in primary care is growing. A recent
18
19 report highlighted how performance management is influenced by its own understanding, the
20
21 systems used, and the evaluator- evaluated relationship. [74] Performance management
22
23 needs an appropriate set of valid of indicators relevant to primary care practice that recognize
24
25 the complexities of different clinical pathways, multimorbidity, educational and counselling
26
27 activities, goals, and other activities typical in primary care. [91]
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32 An example of such indicators was identified by the Australian Institute of Primary Care, [92]
33
34 which classified them as discipline-specific, disease-specific, or systemic; these indicators
35
36 could effectively inform primary care governance. Where instances of poor quality were not
37
38 assessed, the management was to be ineffective, staff concerns about standards of care
39
40 were marginalized or worse, adequate improvement systems were not in place, and the
41
42 service was not seen through the patients' eyes. Clinical pathways are quite popular as a
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44 format for translating guidelines into practice and facilitating an integrated approach to care
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46 that is supported by scientific evidence, but is also respectful of organizational issues. These
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48 pathways design an optimal pathway (or series of pathways) for managing clinical problems
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50 within a healthcare organization. Their development engages all of the professionals
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1 responsible for managing the disease or problem, and provides an opportunity to establish
2 clinical and organizational indicators, and to define information flows. Certainly, the
3
4 management of multiple conditions using clinical pathways requires a comprehensive
5
6 approach that should consider many aspects, such as establishing the patient's priorities,
7
8 evaluating the disease and treatment burdens, and having a discussion of the benefits and
9
10 risks of specific interventions. As part of the patient-health professional relationship, the
11
12 individualised management plan constitutes the foundation of a shared explicit decision-
13
14 making process. It is a written agreement that includes all relevant decisions, such as starting
15
16 or stopping a treatment, anticipating the possible disease evolution, and future healthcare
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18 appointments. It should assign responsibility for processes and interventions to specific health
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20 professionals, to ensure appropriate communication with the patient and caregivers, and with
21
22 other providers. [93, 94]
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30 In 2012, the WHO prioritized clinical risk management in primary care, forming its Safer
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32 Primary Care Expert Working Group that recently produced a technical series. [95, 96]
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34 International data suggest that safety incidents in primary care are mainly diagnostic and
35
36 prescribing errors, with a rate estimated between less than 1 and up to 24 safety incidents per
37
38 100 consultations reviewed. [97] Key elements influencing patient safety are related to
39
40 structural and technological prerequisites (e.g. electronic health records, decision support
41
42 systems), including organizational structure (e.g. leadership, governance structure,
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44 organization of work shifts, workload); human factors (e.g. individual perception, diligence,
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46 decision-making ability, professionalism, interpersonal and group dynamics); and community
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48 characteristics (e.g. epidemiological profile, resilience), and external influences (e.g. media
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50 and public opinion). At the international level, the commitment to improving safety in primary
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1 care has focused mainly on building and implementing incident-reporting systems, and on
2 proactive or reactive risk analysis systems (e.g. analysis of critical incidents and adverse
3 events, root cause analysis, failure mode effect analysis). Several interventions in primary
4 care at the local level have been suggested by national agencies, including improving incident
5 and adverse event reporting, integrating comprehensive risk management systems, and
6 continuous learning environments. Specifically, pharmacist-led medication review,
7 computerised physician order entry, computerised decision support systems, error alert
8 systems and education of professionals have all been shown to be effective interventions that
9 could potentially prevent up to half of all errors. [97]

10
11 A continuous, proactive learning environment in primary care enables health professionals to
12 deepen their knowledge and expand their skills, which even at the end of formal postgraduate
13 professional medical are insufficient to ensure competence and performance over a life-long
14 career. In addition, continuing professional development systems whose relevance has been
15 widely recognized [98],. Ways to keep clinicians updated with practice relevant information
16 have evolved since late 90's, in the form of useful criteria to identify patient-oriented,
17 evidence-based information. One example is the Information Mastery framework, which
18 emphasizes Patient-Oriented Evidence that Matters (POEMs) of Slawson and Shaughnessy.
19 [72] POEMs are studies that are relevant to primary care decision-making, have been
20 assessed for validity, and have the potential to change practice. Each year, only about 200 to
21 250 studies from the top 100 clinical journals meet these criteria. An evolution of this concept
22 has been translated into an online resource, Essential Evidence Plus, which is unique in
23 comparison to other point-of-care tools in that it provides daily emailed POEMs to
24 subscribers. [99]

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2 Regarding the telephone and email consultation skills of clinicians, which are important for
3
4 effective remote consulting, we do not yet have strong evidence regarding how health
5
6 professionals should be trained to make the best use of this communication challenge.[78]
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8 Educational gaming is potentially a way to improve health professionals' knowledge and skills,
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10 in particular for its motivating competitive nature. However, evidence of its effectiveness is
11
12 limited, with only two studies identified and no difference seen between the intervention and
13
14 control groups. [100]
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18 Interprofessional education is increasingly recommended as an approach that has the
19
20 potential to improve communication between different types of healthcare providers, as well
21
22 as an improved understanding of the skills and capabilities of different team members, and
23
24 better team functioning. However, the evidence regarding its effectiveness is limited. In one
25
26 study, improvements in diabetic health outcomes, greater attainment of healthcare quality
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28 goals, and improved patient satisfaction and team behaviour have been reported and
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30 sustained over time [101].
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34 35 *Conclusions*

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38 The number of patients with chronic diseases will continue to increase with the aging of the
39
40 population, and the ongoing existence of risk factors for chronic diseases. We offer this
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42 framework with the aim of shedding light on how to reorganize primary care health systems,
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44 identifying and implementing an organic approach to optimizing care for patients with chronic
45
46 disease. Implementing such a framework will be a responsibility shared by the public and
47
48 private health sectors, as well as by the communities where patients live and the primary
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50 health system operates. Strengthening partnerships with and between these sectors will be
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1 crucial to achieving the vision of a quality of care for multiple chronic conditions.
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5 **Contributorship Statement**

6
7 Alessandra Buja, Roberto Toffanin and Vincenzo Baldo: conceptualization, design of the
8 methodologies, wrote and approved the final manuscript as submitted.
9

10 Mirko Claus: review analysis, wrote and revised the manuscript, approved the final
11 manuscript as submitted.
12

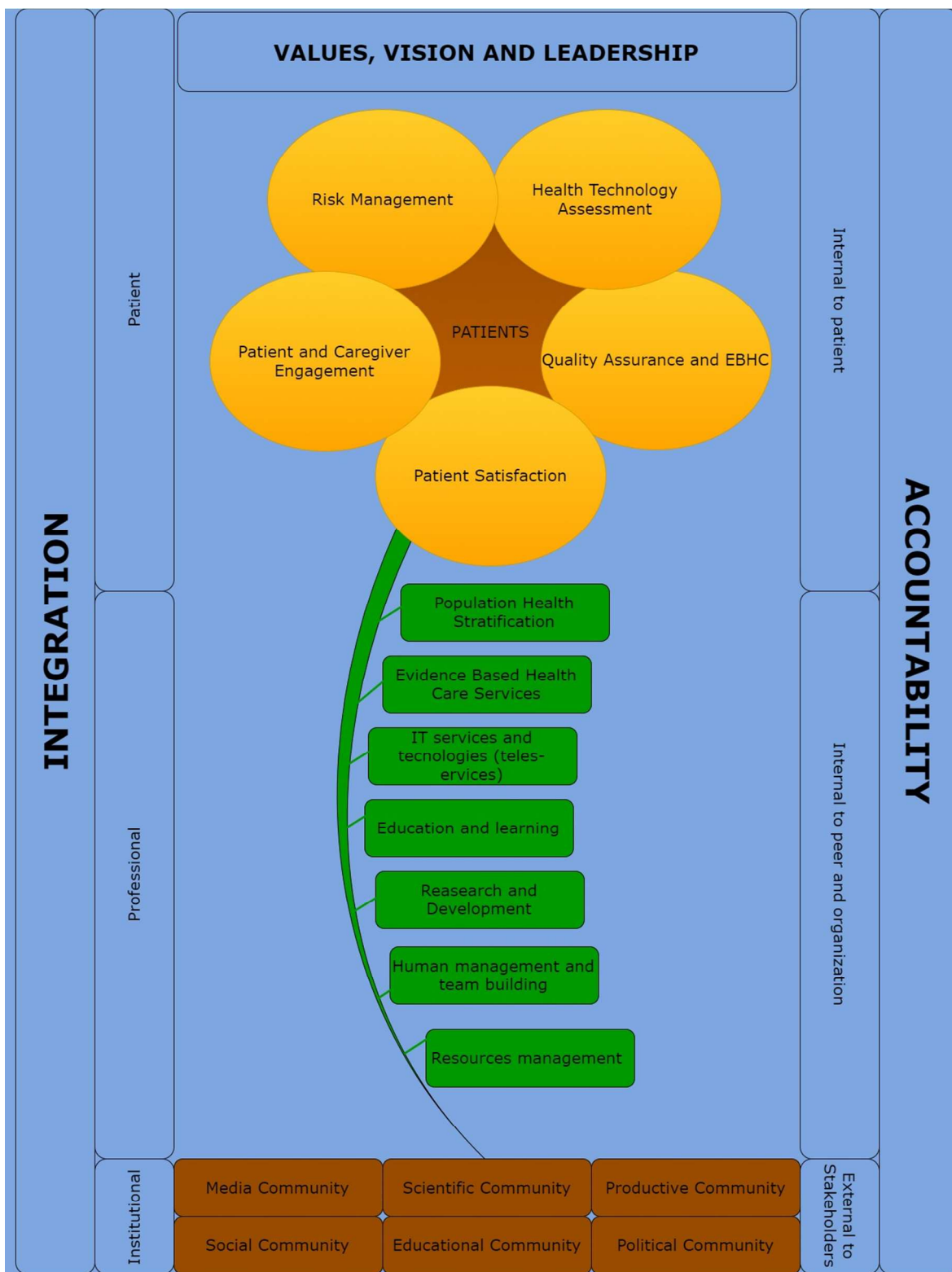
13 Gianfranco Damiani: conceptualization, supervision of the study, approved the final
14 manuscript as submitted.
15

16 Mark Ebell and Walter Ricciardi: supervision, critically reviewed the manuscript, approved the
17 final manuscript as submitted.
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Figure 1: Framework for primary care management of chronic disease

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| Table 1a: Systematic reviews about quality improvement | | | | |
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| Author, Year | Title | Objectives | Inclusion criteria | Main findings |
| Smith SM et al, 2016 (25) | Interventions for improving outcomes in patients with multimorbidity in primary care and community settings | To determine the effectiveness of health-service or patient-oriented interventions designed to improve outcomes in people with multimorbidity in primary care and community settings. Multimorbidity was defined as two or more chronic conditions in the same individual. | We considered randomised controlled trials (RCTs), non-randomised clinical trials (NRCTs), controlled before-after studies (CBAs), and interrupted time series analyses (ITS) evaluating interventions to improve outcomes for people with multimorbidity in primary care and community settings. This includes studies where participants can have combinations of any condition or have combinations of pre-specified common conditions. The comparison was usual care as delivered in that setting. | Overall the results regarding the effectiveness of interventions were mixed. There were no clear positive improvements in clinical outcomes, health service use, medication adherence, patient-related health behaviours, health professional behaviours or costs. There were modest improvements in mental health outcomes from seven studies that targeted people with depression, and in functional outcomes from two studies targeting functional difficulties in participants. Overall the results indicate that it is difficult to improve outcomes for people with multiple conditions. The review suggests that interventions that are designed to target specific risk factors (for example treatment for depression) or interventions that focus on difficulties that people experience with daily functioning (for example, physiotherapy treatment to improve capacity for physical activity) may be more effective. There is a need for further studies on this topic, particularly involving people with multimorbidity in general across the age ranges |
| Nieuwlaat R, et al 2014 (26) | Interventions for enhancing medication adherence | The primary objective of this review is to assess the effects of interventions intended to enhance patient adherence to prescribed medications for medical conditions, on both medication adherence and clinical outcomes. | We included unconfounded RCTs of interventions to improve adherence with prescribed medications, measuring both medication adherence and clinical outcome, with at least 80% follow-up of each group studied and, for long-term treatments, at least six months follow-up for studies with positive findings at earlier time points. | The present update included 109 new studies, bringing the total number to 182. In the 17 studies of the highest quality, interventions were generally complex with several different ways to try to improve medicine adherence. These frequently included enhanced support from family, peers, or allied health professionals such as pharmacists, who often delivered education, counseling, or daily treatment support. Only five of these RCTs improved both medicine adherence and clinical outcomes, and no common characteristics for their success could be identified. Overall, even the most effective interventions did not lead to large improvements. |
| Arditi C et al. 2012 (28) | Computer-generated reminders delivered on paper to healthcare professionals; effects on professional practice and health care outcomes | To evaluate the benefits and harms of rehabilitation interventions directed at maintaining, or improving, physical function for older people in long-term care through the review of randomized and cluster randomized controlled trials. | We included individual or cluster-randomized controlled trials (RCTs) and non-randomized controlled trials (NRCTs) that evaluated the impact of computer-generated reminders delivered on paper to healthcare professionals on processes and/or outcomes of care. | There is moderate quality evidence that computer-generated reminders delivered on paper to healthcare professionals achieve moderate improvement in process of care. Two characteristics emerged as significant predictors of improvement: providing space on the reminder for a response from the clinician and providing an explanation of the reminder's content or advice. The heterogeneity of the reminder interventions included in this review also suggests that reminders can improve care in various settings under various conditions |
| Thomas RE et al. 2014 (29) | Interventions to increase influenza vaccination rates of those 60 years and older in the community | To assess access, provider, system and societal interventions to increase the uptake of influenza vaccination in people aged 60 years and older in the community. | Randomised controlled trials (RCTs) of interventions to increase influenza vaccination uptake in people aged 60 and older. | There are interventions that are effective for increasing community demand for vaccination, enhancing access and improving provider/system response. In particular effective interventions in this comparison were a letter plus leaflet/postcard compared to a letter, nurses/pharmacists educating plus vaccinating patients, a phone call from a senior, a telephone invitation rather than clinic drop-in, free groceries lottery, and nurses educating and vaccinating patients. We were unable to pool trials of postcard/letter/pamphlets, communications tailored to patients, a customised letter/phone-call or client-based appraisals, but several trials of these interventions showed they were effective. |

QUALITY IMPROVEMENT

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| 1 2 3 4 5 6 7 8 9 10 11 12 13 14 15 16 17 18 19 | 1)Krogsbøll LT, et al 2012 (30) | General health checks in adults for reducing morbidity and mortality from disease | We aimed to quantify the benefits and harms of general health checks with an emphasis on patient-relevant outcomes such as morbidity and mortality rather than on surrogate outcomes such as blood pressure and serum cholesterol levels. | We included randomised trials comparing health checks with no health checks in adults unselected for disease or risk factors. We did not include geriatric trials. We defined health checks as screening general populations for more than one disease or risk factor in more than one organ system. | There was no effect on the risk of death, or on the risk of death due to cardiovascular diseases or cancer. We did not find an effect on the risk of illness but one trial found an increased number of people identified with high blood pressure and high cholesterol, and one trial found an increased number with chronic diseases. One trial reported the total number of new diagnoses per participant and found a 20% increase over six years compared to the control group. No trials compared the total number of new prescriptions but two out of four trials found an increased number of people using drugs for high blood pressure. Two out of four trials found that health checks made people feel somewhat healthier, but this result is not reliable. We did not find that health checks had an effect on the number of admissions to hospital, disability, worry, the number of referrals to specialists, additional visits to the physician, or absence from work, but most of these outcomes were poorly studied. None of the trials reported on the number of follow-up tests after positive screening results, or the amount of surgery used. With the large number of participants and deaths included, the long follow-up periods used in the trials, and considering that death from cardiovascular diseases and cancer were not reduced, general health checks are unlikely to be beneficial. |
| 20 21 22 23 24 25 26 27 28 29 30 31 32 33 34 35 | Archambault PM 2017 (31) | Collaborative writing applications in healthcare: effects on professional practice and healthcare outcomes | The objectives of this review were to (1) assess the effects of the use of CWAs on process (including the behaviour of healthcare professionals) and patient outcomes, (2) critically appraise and summarise current evidence on the use of resources, costs, and cost-effectiveness associated with CWAs to improve professional practices and patient outcomes, and (3) explore the effects of different CWA features (e.g. open versus closed) and different implementation factors (e.g. the presence of a moderator) on process and patient outcomes. | We included randomised controlled trials (RCTs), non-randomised controlled trials (NRCTs), controlled before-and-after (CBA) studies, interrupted time series (ITS) studies, and repeated measures studies (RMS), in which CWAs were used as an intervention to improve the process of care, patient outcomes, or healthcare costs. | We screened 11,993 studies identified from the electronic database searches and 346 studies from grey literature sources. We analysed the full text of 99 studies. None of the studies met the eligibility criteria; two potentially relevant studies are ongoing. We did not identify any studies that measured the effect of CWAs on how healthcare professionals care for their patients. |

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| <p>1 2 3 4 5 6 7 8 9 10 11 12 13 14 15 16 17 18 19 20 21 22 23</p> | <p>Fiander M, et al. 2015 (32)</p> | <p>Interventions to increase the use of electronic health information by healthcare practitioners to improve clinical practice and patient outcomes</p> | <p>To assess the effects of interventions aimed at improving or increasing healthcare practitioners' use of electronic health information (EHI) on professional practice and patient outcomes.</p> | <p>We included studies that evaluated the effects of interventions to improve or increase the use of EHI by healthcare practitioners on professional practice and patient outcomes. We defined EHI as information accessed on a computer. We defined 'use' as logging into EHI. We considered any healthcare practitioner involved in patient care. We included randomized, non-randomized, and cluster randomized controlled trials (RCTs, NRCTs, CRCTs), controlled clinical trials (CCTs), interrupted time series (ITS), and controlled before-and-after studies (CBAs).The comparisons were: electronic versus printed health information; EHI on different electronic devices (e.g. desktop, laptop or tablet computers, etc.; cell / mobile phones); EHI via different user interfaces; EHI provided with or without an educational or training component; and EHI compared to no other type or source of information.</p> | <p>The results of this review showed that when provided with a combination of EHI and training, practitioners used the information more often. Two studies measured doctors' use of electronic treatment guidelines, but showed that the electronic aspect of the guidelines did not mean that doctors followed the guidelines. This review provided no information on whether more frequent use of EHI translated into improved clinical practice or whether patients were better off when doctors or nurses used health information when treating them.</p> |
| <p>24 25 26 27 28 29 30 31 32 33</p> | <p>Flodgren G et al. 2016 (33)</p> | <p>Tools developed and disseminated by guideline producers to promote the uptake of their guidelines</p> | <p>To evaluate the effectiveness of implementation tools developed and disseminated by guideline producers, which accompany or follow the publication of a CPG, to promote uptake. A secondary objective is to determine which approaches to guideline implementation are most effective.</p> | <p>We included randomised controlled trials (RCTs) and cluster-RCTs, controlled before-and-after studies (CBAs) and interrupted time series (ITS) studies evaluating the effects of guideline implementation tools developed by recognised guideline producers to improve the uptake of their own guidelines. The guideline could target any clinical area.</p> | <p>Two of the four included studies reported on how well healthcare professionals stick to guideline recommendations when providing care to their patients, depending on whether they received a CPG with a tool aimed at improving the use of the CPG, or if they received the CPG only. The results of this review show that healthcare professionals who received a guideline tool together with the CPG on the management of non-specific low back pain or ordering thyroid-function tests probably stick more closely to the recommendations, compared with those who received the CPG only. A guideline tool aimed at improving the use of a guideline, may lead to little or no difference in cost to the health service.</p> |

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| Chen CE et al. 2017 (34) | Walk-in clinics versus physician offices and emergency rooms for urgent care and chronic disease management | To assess the quality of care and patient satisfaction of walk-in clinics compared to that of traditional physician offices and emergency rooms for people who present with basic medical complaints for either acute or chronic issues. | Study design: randomized trials, non-randomized trials, and controlled before-after studies. Population: standalone physical clinics not requiring advance appointments or registration, that provided basic medical care without expectation of follow-up. Comparisons: traditional primary care practices or emergency rooms. | Walk-in clinics are growing in popularity around the world, but it is unclear if the medical care provided by walk-in clinics is comparable to that of physicians' offices or emergency rooms. |
| Scott A. et al. 2011 (35) | The effect of financial incentives on the quality of health care provided by primary care physicians | <p>The aim of this review is to examine the effect of changes in the method and level of payment on the quality of care provided by primary care physicians (PCPs) and to identify:</p> <ul style="list-style-type: none"> i) the different types of financial incentives that have improved quality; ii) the characteristics of patient populations for whom quality of care has been improved by financial incentives; and iii) the characteristics of PCPs who have responded to financial incentives. | Randomised controlled trials (RCT), controlled before and after studies (CBA), and interrupted time series analyses (ITS) evaluating the impact of different financial interventions on the quality of care delivered by primary healthcare physicians (PCPs). Quality of care was defined as patient reported outcome measures, clinical behaviours, and intermediate clinical and physiological measures. | The use of financial incentives to reward PCPs for improving the quality of primary healthcare services is growing. However, there is insufficient evidence to support or not support the use of financial incentives to improve the quality of primary health care. Implementation should proceed with caution and incentive schemes should be more carefully designed before implementation. In addition to basing incentive design more on theory, there is a large literature discussing experiences with these schemes that can be used to draw out a number of lessons that can be learned and that could be used to influence or modify the design of incentive schemes. More rigorous study designs need to be used to account for the selection of physicians into incentive schemes. The use of instrumental variable techniques should be considered to assist with the identification of treatment effects in the presence of selection bias and other sources of unobserved heterogeneity. In randomised trials, care must be taken in using the correct unit of analysis and more attention should be paid to blinding. Studies should also examine the potential unintended consequences of incentive schemes by having a stronger theoretical basis, including a broader range of outcomes, and conducting more extensive subgroup analysis. Studies should more consistently describe i) the type of payment scheme at baseline or in the control group, ii) how payments to medical groups were used and distributed within the groups, and iii) the size of the new payments as a percentage of total revenue. Further research comparing the relative costs and effects of financial incentives with other behaviour change interventions is also required. |
| Young et al. 2017 (36) | Home or foster home care versus institutional long-term care for functionally dependent older people | To assess the effects of long-term home or foster home care versus institutional care for functionally dependent older people. | We included randomised and non-randomised trials, controlled before-after studies and interrupted time series studies complying with the EPOC study design criteria and comparing the effects of long-term home care versus institutional care for functionally dependent older people. | There are insufficient high-quality published data to support any particular model of care for functionally dependent older people. Community-based care was not consistently beneficial across all the included studies; there were some data suggesting that community-based care may be associated with improved quality of life and physical function compared to institutional care. However, community alternatives to institutional care may be associated with increased risk of hospitalisation. Future studies should assess healthcare utilisation, perform economic analysis, and consider caregiver burden. |

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| 1 2 3 4 5 6 7 8 9 10 11 12 | Nkansah N. et al. 2010 (37) | Effect of outpatient pharmacists' non-dispensing roles on patient outcomes and prescribing patterns | To examine the effect of outpatient pharmacists' non-dispensing roles on patient and health professional outcomes. | Randomized controlled trials comparing 1. Pharmacist services targeted at patients versus services delivered by other health professionals; 2. Pharmacist services targeted at patients versus the delivery of no comparable service; 3. Pharmacist services targeted at health professionals versus services delivered by other health professionals; 4. Pharmacist services targeted at health professionals versus the delivery of no comparable service. | Only one included study compared pharmacist services with other health professional services, hence we are unable to draw conclusions regarding comparisons 1 and 3. Most included studies supported the role of pharmacists in medication/therapeutic management, patient counseling, and providing health professional education with the goal of improving patient process of care and clinical outcomes, and of educational outreach visits on physician prescribing patterns. There was great heterogeneity in the types of outcomes measured across all studies. Therefore a standardized approach to measure and report clinical, humanistic, and process outcomes for future randomized controlled studies evaluating the impact of outpatient pharmacists is needed. Heterogeneity in study comparison groups, outcomes, and measures makes it challenging to make generalised statements regarding the impact of pharmacists in specific settings, disease states, and patient populations. |
| 13 14 15 16 17 18 19 | Gonçalves-Bradley DC, et al 2016 (38) | Discharge planning from hospital | To assess the effectiveness of planning the discharge of individual patients moving from hospital. | Randomised controlled trials (RCTs) that compared an individualised discharge plan with routine discharge care that was not tailored to individual participants. Participants were hospital inpatients. | A discharge plan tailored to the individual patient probably brings about a small reduction in hospital length of stay and reduces the risk of readmission to hospital at three months follow-up for older people with a medical condition. Discharge planning may lead to increased satisfaction with healthcare for patients and professionals. There is little evidence that discharge planning reduces costs to the health service. |

Table 1b: Systematic reviews about risk management

| | Author, Year | Title | Objectives | Inclusion criteria | Main findings |
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| | Parmelli et al. 2012 (41) | Interventions to increase clinical incident reporting in health care | To assess the effects of interventions designed to increase clinical incident reporting in healthcare settings. | Randomised controlled trials (RCT), controlled before-after studies (CBA) and interrupted time series (ITS) of interventions designed to increase clinical incident reporting in healthcare. | Because of the limitations of the studies it is not possible to draw conclusions for clinical practice. Anyone introducing a system into practice should give careful consideration to conducting an evaluation using a robust design. |
| RISK MANAGEMENT | Ryan R, et al 2014 (43) | Interventions to improve safe and effective medicines use by consumers: an overview of systematic reviews | To assess the effects of interventions which target healthcare consumers to promote safe and effective medicines use, by synthesising review-level evidence. | We included systematic reviews published on the Cochrane Database of Systematic Reviews and the Database of Abstracts of Reviews of Effects. We identified relevant reviews by hand searching databases from their start dates to March 2012. | <p>Looking across reviews, for most outcomes, medicines self-monitoring and self-management programmes appear generally effective to improve medicines use, adherence, adverse events and clinical outcomes; and to reduce mortality in people self-managing antithrombotic therapy. However, some participants were unable to complete these interventions, suggesting they may not be suitable for everyone.</p> <p>Other promising interventions to improve adherence and other key medicines-use outcomes, which require further investigation to be more certain of their effects, include:</p> <ul style="list-style-type: none"> · simplified dosing regimens: with positive effects on adherence; · interventions involving pharmacists in medicines management, such as medicines reviews (with positive effects on adherence and use, medicines problems and clinical outcomes) and pharmaceutical care services (consultation between pharmacist and patient to resolve medicines problems, develop a care plan and provide follow-up; with positive effects on adherence and knowledge). <p>Several other strategies showed some positive effects, particularly relating to adherence, and other outcomes, but their effects were less consistent overall and so need further study. These included:</p> <ul style="list-style-type: none"> · delayed antibiotic prescriptions: effective to decrease antibiotic use but with mixed effects on clinical outcomes, adverse effects and satisfaction; · practical strategies like reminders, cues and/or organisers, reminder packaging and material incentives: with positive, although somewhat mixed effects on adherence; · education delivered with self-management skills training, counselling, support, training or enhanced follow-up; information and counselling delivered together; or education/information as part of pharmacist-delivered packages of care: with positive effects on adherence, medicines use, clinical outcomes and knowledge, but with mixed effects in some studies; · financial incentives: with positive, but mixed, effects on adherence. <p>Several strategies also showed promise in promoting immunisation uptake, but require further study to be more certain of their effects. These included organisational interventions; reminders and recall; financial incentives; home visits; free vaccination; lay health worker interventions; and facilitators working with physicians to promote immunisation uptake. Education and/or information strategies also showed some positive but even less consistent effects on immunisation uptake, and need further assessment of effectiveness and investigation of heterogeneity.</p> |

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| Patterson SM, et al 2014 (44) | Interventions to improve the appropriate use of polypharmacy for older people | This review sought to determine which interventions, alone or in combination, are effective in improving the appropriate use of polypharmacy and reducing medication-related problems in older people. | A range of study designs were eligible. Eligible studies described interventions affecting prescribing aimed at improving appropriate polypharmacy in people 65 years of age and older in which a validated measure of appropriateness was used (e.g. Beers criteria, Medication Appropriateness Index (MAI)). | This review examines studies in which healthcare professionals have taken action to make sure that older people are receiving the most effective and safest medication for their illness. Actions taken included providing pharmaceutical care, a service provided by pharmacists that involves identifying, preventing and resolving medication-related problems, as well as promoting the correct use of medications and encouraging health promotion and education. Another strategy was computerised decision support, which involves a programme on the doctor's computer that helps him/her to select appropriate treatment. This review provides limited evidence that interventions, such as pharmaceutical care, may be successful in ensuring that older people are receiving the right medicines, but it is not clear whether this always results in clinical improvement. |
| Ivers N. et al 2012 (45) | Audit and feedback: effects on professional practice and healthcare outcomes | To assess the effects of audit and feedback on the practice of healthcare professionals and patient outcomes and to examine factors that may explain variation in the effectiveness of audit and feedback. | Randomised trials of audit and feedback (defined as a summary of clinical performance over a specified period of time) that reported objectively measured health professional practice or patient outcomes. In the case of multifaceted interventions, only trials in which audit and feedback was considered the core, essential aspect of at least one intervention arm were included. | Audit and feedback generally leads to small but potentially important improvements in professional practice. The effectiveness of audit and feedback seems to depend on baseline performance and how the feedback is provided. Future studies of audit and feedback should directly compare different ways of providing feedback. |
| Gillaizeau F. et al. 2013 (46) | Computerized advice on drug dosage to improve prescribing practice | To assess whether computerized advice on drug dosage has beneficial effects on patient outcomes compared with routine care (empiric dosing without computer assistance). | We included randomized controlled trials, non-randomized controlled trials, controlled before-and-after studies and interrupted time series analyses of computerized advice on drug dosage. The participants were healthcare professionals responsible for patient care. The outcomes were any objectively measured change in the health of patients resulting from computerized advice (such as therapeutic drug control, clinical improvement, adverse reactions). | Computerized advice for drug dosage can benefit people taking certain drugs compared with empiric dosing (where a dose is chosen based on a doctor's observations and experience) without computer assistance. When using the computer system, healthcare professionals prescribed appropriately higher doses of the drugs initially for aminoglycoside antibiotics and the correct drug dose was reached more quickly for oral anticoagulants. It significantly decreased thromboembolism (blood clotting) events for anticoagulants and tended to reduce unwanted effects for aminoglycoside antibiotics and anti-rejection drugs (although not an important difference). It tended to reduce the length of hospital stay compared with routine care with comparable or better cost-effectiveness. There was no evidence of effects on death or clinical side events for insulin (low blood sugar (hypoglycaemia)), anaesthetic agents, anti-rejection drugs (drugs taken to prevent rejection of a transplanted organ) and antidepressants. |

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| | Allred DP et al. 2016 (47) | Interventions to optimise prescribing for older people in care homes | The objective of the review was to determine the effect of interventions to optimise overall prescribing for older people living in care homes. | We included randomised controlled trials evaluating interventions aimed at optimising prescribing for older people (aged 65 years or older) living in institutionalised care facilities. Studies were included if they measured one or more of the following primary outcomes: adverse drug events; hospital admissions; mortality; or secondary outcomes, quality of life (using validated instrument); medication-related problems; medication appropriateness (using validated instrument); medicine costs. | We could not draw robust conclusions from the evidence due to variability in design, interventions, outcomes and results. The interventions implemented in the studies in this review led to the identification and resolution of medication-related problems and improvements in medication appropriateness, however evidence of a consistent effect on resident-related outcomes was not found. There is a need for high-quality cluster-randomised controlled trials testing clinical decision support systems and multidisciplinary interventions that measure well-defined, important resident-related outcomes. |
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Peer review only

Table 1c: Systematic reviews about patient satisfaction

| | Author, Year | Title | Objectives | Inclusion criteria | Main findings |
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| PATIENT SATISFACTION | Ballini L. et al. 2015 (49) | Interventions to reduce waiting times for elective procedures | To assess the effectiveness of interventions aimed at reducing waiting times for elective care, both diagnostic and therapeutic. | We considered randomised controlled trials (RCTs), controlled before-after studies (CBAs) and interrupted time series (ITS) designs that met EPOC minimum criteria and evaluated the effectiveness of any intervention aimed at reducing waiting times for any type of elective procedure. We considered studies reporting one or more of the following outcomes: number or proportion of participants whose waiting times were above or below a specific time threshold, or participants' mean or median waiting times. Comparators could include any type of active intervention or standard practice. | As only a handful of low-quality studies are presently available, we cannot draw any firm conclusions about the effectiveness of the evaluated interventions in reducing waiting times. However, interventions involving the provision of more accessible services (open access or direct booking/referral) show some promise. |
| | Shepeprd S. et al. 2016 (50) | Hospital at home: home-based end-of-life care | To determine if providing home-based end-of-life care reduces the likelihood of dying in hospital and what effect this has on patients' symptoms, quality of life, health service costs, and caregivers, compared with inpatient hospital or hospice care. | Randomised controlled trials, interrupted time series, or controlled before and after studies evaluating the effectiveness of home-based end-of-life care with inpatient hospital or hospice care for people aged 18 years and older. | The evidence included in this review supports the use of home-based end-of-life care programmes for increasing the number of people who will die at home, although the numbers of people admitted to hospital while receiving end-of-life care should be monitored. Future research should systematically assess the impact of home-based end-of-life care on caregivers. |
| | Dwamena F, et al 2012 (51) | Interventions for providers to promote a patient-centred approach in clinical consultations | To assess the effects of interventions for healthcare providers that aim to promote patient-centred care (PCC) approaches in clinical consultations. | In the original review, study designs included randomized controlled trials, controlled clinical trials, controlled before and after studies, and interrupted time series studies of interventions for healthcare providers that promote patient-centred care in clinical consultations. In the present update, we were able to limit the studies to randomized controlled trials, thus limiting the likelihood of sampling error. This is especially important because the providers who volunteer for studies of PCC methods are likely to be different from the general population of providers. | Interventions to promote patient-centred care within clinical consultations are effective across studies in transferring patient-centred skills to providers. However the effects on patient satisfaction, health behaviour and health status are mixed. There is some indication that complex interventions directed at providers and patients that include condition-specific educational materials have beneficial effects on health behaviour and health status, outcomes not assessed in studies reviewed previously. The latter conclusion is tentative at this time and requires more data. The heterogeneity of outcomes, and the use of single item consultation and health behaviour measures limit the strength of the conclusions. |

Table 1d: Systematic reviews about patient and caregiver engagement

| | Author, Year | Title | Objectives | Inclusion criteria | Main findings |
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| PATIENT AND CAREGIVER ENGAGEMENT | Légaré F. et al 2014 (54) | Interventions for improving the adoption of shared decision making by healthcare professionals | To determine the effectiveness of interventions to improve healthcare professionals' adoption of SDM. | Randomised and non-randomised controlled trials, controlled before-and-after studies and interrupted time series studies evaluating interventions to improve healthcare professionals' adoption of SDM where the primary outcomes were evaluated using observer-based outcome measures (OBOM) or patient-reported outcome measures (PROM). | It is uncertain whether interventions to improve adoption of SDM are effective given the low quality of the evidence. However, any intervention that actively targets patients, healthcare professionals, or both, is better than none. Also, interventions targeting patients and healthcare professionals together show more promise than those targeting only one or the other. |
| | Stacey et al. 2017 (55) | Decision Aids for People Facing Health Treatment or Screening Decisions | To assess the effects of decision aids in people facing treatment or screening decisions. | We included published randomized controlled trials comparing decision aids to usual care and/or alternative interventions. For this update, we excluded studies comparing detailed versus simple decision aids. | Compared to usual care across a wide variety of decision contexts, people exposed to decision aids feel more knowledgeable, better informed, and clearer about their values, and they probably have a more active role in decision making and more accurate risk perceptions. There is growing evidence that decision aids may improve values-congruent choices. There are no adverse effects on health outcomes or satisfaction. New for this updated is evidence indicating improved knowledge and accurate risk perceptions when decision aids are used either within or in preparation for the consultation. |

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| | Ciciriello S, et al 2013 (56) | Multimedia educational interventions for consumers about prescribed and over-the-counter medications | To assess the effects of multimedia education interventions about prescribed and over-the-counter medications in people of all ages, including children and carers. | Randomised controlled trials (RCTs) and quasi-RCTs of multimedia-based patient education about prescribed or over-the-counter medications in people of all ages, including children and carers, if the intervention had been targeted for their use. | <p>We found that multimedia education programs about medications are superior to no education or education provided as part of usual clinical care in improving patient knowledge. There was wide variability in the results from the six studies that compared multimedia education to usual care or no education. However, all but one of the six studies favoured multimedia education. We also found that multimedia education is superior to usual care or no education in improving skill levels. The review also suggested that multimedia was at least as effective as other forms of education, including written education or brief education from a health provider. However, these findings were based on a small number of studies, many of which were of low quality. Multimedia education did not improve compliance with medications (i.e. the degree to which a patient correctly follows advice about his or her medication) compared with usual care or no education. We could not determine the effect of multimedia education on other outcomes, such as patient satisfaction, self-efficacy (confidence in their ability to perform health-related tasks) and health outcomes.</p> <p>The review findings therefore suggests that multimedia education programs about medications could be used alongside usual care provided by health providers. There is not enough evidence to recommend it as a replacement for written education or education by a health professional. Multimedia education could be used instead of detailed education given by a health provider when it is not possible or practical for health professionals to provide this service.</p> <p>This review found that there were differences between the types of education provided to the control groups and what results were measured. This limited the ability to summarise results across studies, so most of the conclusions of this review were based on results from a small number of studies. More studies of multimedia educational programs are needed to make the results of this review more reliable.</p> |
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Table 1e: Systematic reviews about cost effectiveness

| | Author, Year | Title | Objectives | Inclusion criteria | Main findings |
|---------------------------------------|-----------------------------|--|---|---|---|
| HTA; COST-EFFECTIVENESS, COST-UTILITY | Atherton H et al, 2012 (58) | Email for clinical communication between patients/care givers and healthcare professionals | To assess the effects of healthcare professionals and patients using email to communicate with each other, on patient outcomes, health service performance, service efficiency and acceptability. | Randomised controlled trials, quasi-randomised trials, controlled before and after studies and interrupted time series studies examining interventions using email to allow patients to communicate clinical concerns to a healthcare professional and receive a reply, and taking the form of 1) unsecured email 2) secure email or 3) web messaging. All healthcare professionals, patients and caregivers in all settings were considered. | <p>Eight of the trials looked at email compared with standard methods of communication. Where email was compared to standard methods of communication we found that we could not properly determine what effect email was having on patient/caregiver outcomes, as there were missing data and the results of the different studies varied. For health service use outcomes the situation was the same, but some results seemed to show that an email intervention may lead to an increased number of emails and telephone calls being received by healthcare professionals.</p> <p>One of the trials looked at email counselling compared with telephone counselling. We found that it only looked at patient outcomes, and found few differences between groups. Where there were differences these showed that telephone counselling leads to greater changes in lifestyle than email counselling.</p> <p>None of the trials measured how email affects healthcare professionals and only one measured whether email can cause harm. All of the trials were biased in some way and when we measured the quality of all of the results we found them to be of low or very low quality.</p> <p>As a result the results of this review should be viewed with caution.</p> <p>The nature of the results means that we cannot make any recommendations for how email might best be used in clinical practice.</p> |
| | Flodgren G, et al 2016 (59) | Interactive telemedicine: effects on professional practice and health care outcomes | To assess the effectiveness, acceptability and costs of interactive TM as an alternative to, or in addition to, usual care (i.e. face-to-face care, or telephone consultation). | We considered randomised controlled trials of interactive TM that involved direct patient-provider interaction and was delivered in addition to, or substituting for, usual care compared with usual care alone, to participants with any clinical condition. We excluded telephone only interventions and wholly automatic self-management TM interventions. | <p>The findings in our review indicate that the use of TM in the management of heart failure appears to lead to similar health outcomes as face-to-face or telephone delivery of care; there is evidence that TM can improve the control of blood glucose in those with diabetes.</p> <p>The cost to a health service, and acceptability by patients and healthcare professionals, is not clear due to limited data reported for these outcomes. The effectiveness of TM may depend on a number of different factors, including those related to the study population e.g. the severity of the condition and the disease trajectory of the participants, the function of the intervention e.g., if it is used for monitoring a chronic condition, or to provide access to diagnostic services, as well as the healthcare provider and healthcare system involved in delivering the intervention.</p> |

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| | Weeks G, et al 2016 (60) | Non-medical prescribing versus medical prescribing for acute and chronic disease management in primary and secondary care | To assess clinical, patient-reported, and resource use outcomes of non-medical prescribing for managing acute and chronic health conditions in primary and secondary care settings compared with medical prescribing (usual care). | Randomised controlled trials (RCTs), cluster-RCTs, controlled before-and-after (CBA) studies (with at least two intervention and two control sites) and interrupted time series analysis (with at least three observations before and after the intervention) comparing: 1. Nonmedical prescribing versus medical prescribing in acute care; 2. non-medical prescribing versus medical prescribing in chronic care; 3. non-medical prescribing versus medical prescribing in secondary care; 4 non-medical prescribing versus medical prescribing in primary care; 5. comparisons between different non-medical prescriber groups; and 6. non-medical healthcare providers with formal prescribing training versus those without formal prescribing training. | The findings suggest that non-medical prescribers, practising with varying but high levels of prescribing autonomy, in a range of settings, were as effective as usual care medical prescribers. Non-medical prescribers can deliver comparable outcomes for systolic blood pressure, glycated haemoglobin, low-density lipoprotein, medication adherence, patient satisfaction, and health-related quality of life. It was difficult to determine the impact of non-medical prescribing compared to medical prescribing for adverse events and resource use outcomes due to the inconsistency and variability in reporting across studies. |
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| Table 1g: Systematic reviews about Leadership, values, vision | | | | | |
|---|-------------------------|--|---|---|---|
| LEADERSHIP, VALUES, VISION | Author, Year | Title | Objectives | Inclusion criteria | Main findings |
| | Flodgren G. et al. 2011 | Local opinion leaders: effects on professional practice and health care outcomes | To assess the effectiveness of the use of local opinion leaders in improving professional practice and patient outcomes. | Studies eligible for inclusion were randomised controlled trials investigating the effectiveness of using opinion leaders to disseminate evidence-based practice and reporting objective measures of professional performance and/or health outcomes | Opinion leaders alone or in combination with other interventions may successfully promote evidence-based practice, but effectiveness varies both within and between studies. These results are based on heterogeneous studies differing in terms of type of intervention, setting, and outcomes measured. In most of the studies the role of the opinion leader was not clearly described, and it is therefore not possible to say what the best way is to optimise the effectiveness of opinion leaders. |
| | Green C J et al. 2010 | Pharmaceutical policies: effects of restrictions on reimbursement | To determine the effects of a pharmaceutical policy restricting the reimbursement of selected medications on drug use, health care utilization, health outcomes and costs (expenditures). | Included were studies of pharmaceutical policies that restrict coverage and reimbursement of selected drugs or drug classes, often using additional patient specific information related to health status or need. We included randomised controlled trials, non-randomised controlled trials, interrupted time series (ITS) analyses, repeated measures studies and controlled before-after studies set in large care systems or jurisdictions. | Implementing restrictions to coverage and reimbursement of selected medications can decrease third-party drug spending without increasing the use of other health services (6 studies). Relaxing reimbursement rules for drugs used for secondary prevention can also remove barriers to access. Policy design, however, needs to be based on research quantifying the harm and benefit profiles of target and alternative drugs to avoid unwanted health system and health effects. Health impact evaluation should be conducted where drugs are not interchangeable. Impacts on health equity, relating to the fair and just distribution of health benefits in society (sustainable access to publically financed drug benefits for seniors and low income populations, for example), also require explicit measurement. |
| | Jia L. et al. 2014 | Strategies for expanding health insurance coverage in vulnerable populations | To assess the effectiveness of strategies for expanding health insurance coverage in vulnerable populations. | Randomised controlled trials (RCTs), non-randomised controlled trials (NRCTs), controlled before-after (CBA) studies and Interrupted time series (ITS) studies that evaluated the effects of strategies on increasing health insurance coverage for vulnerable populations. We defined strategies as measures to improve the enrolment of vulnerable populations into health insurance schemes. Two categories and six specified strategies were identified as the interventions. | Community-based case managers who provide health insurance information, application support, and negotiate with the insurer probably increase enrolment of children in health insurance schemes. However, the transferability of this intervention to other populations or other settings is uncertain. Handing out insurance application materials in hospital emergency departments may help increase the enrolment of children in health insurance schemes. Further studies evaluating the effectiveness of different strategies for expanding health insurance coverage in vulnerable population are needed in different settings, with careful attention given to study design. |

Table 1f: Systematic reviews about integration

| | Author, Year | Title | Objectives | Inclusion criteria | Main findings |
|--------------------|----------------------|---|---|--|---|
| INTEGRATION | Reeves S et al. 2017 | Interprofessional collaboration to improve professional practice and healthcare outcomes | To assess the impact of practice-based interventions designed to improve interprofessional collaboration (IPC) amongst health and social care professionals, compared to usual care or to an alternative intervention, on at least one of the following primary outcomes: patient health outcomes, clinical process or efficiency outcomes or secondary outcomes (collaborative behaviour). | We included randomised trials of practice-based IPC interventions involving health and social care professionals compared to usual care or to an alternative intervention. | Given that the certainty of evidence from the included studies was judged to be low to very low, there is not sufficient evidence to draw clear conclusions on the effects of IPC interventions. Nevertheless, due to the difficulties health professionals encounter when collaborating in clinical practice, it is encouraging that research on the number of interventions to improve IPC has increased since this review was last updated. While this field is developing, further rigorous, mixed-method studies are required. Future studies should focus on longer acclimatisation periods before evaluating newly implemented IPC interventions, and use longer follow-up to generate a more informed understanding of the effects of IPC on clinical practice. |
| | Smith SM et al. 2017 | Shared care across the interface between primary and specialty care in management of long term conditions | To determine the effectiveness of shared care health service interventions designed to improve the management of chronic disease across the primary/specialty care interface. | We considered randomised controlled trials (RCTs), non-randomised controlled trials (NRCTs), controlled before-after studies (CBAs) and interrupted time series analyses (ITS) evaluating the effectiveness of shared care interventions for people with chronic conditions in primary care and community settings. The intervention was compared with usual care in that setting. | This review suggests that shared care is effective for managing depression. Shared care interventions for other conditions should be developed within research settings, so that further evidence can be considered before they are introduced routinely into health systems. |

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| | Hayes SL, et al 2012 | Collaboration between local health and local government agencies for health improvement | To evaluate the effects of interagency collaboration between local health and local government agencies on health outcomes in any population or age group. | Randomized controlled trials (RCTs), controlled clinical trials (CCTs), controlled before-and-after studies (CBAs) and interrupted time series (ITS) where the study reported individual health outcomes arising from interagency collaboration between health and local government agencies compared to standard care. Studies were selected independently in duplicate, with no restriction on population subgroup or disease. | Collaboration between local health and local government is commonly considered best practice. However, the review did not identify any reliable evidence that interagency collaboration, compared to standard services, necessarily leads to health improvement. A few studies identified component benefits but these were not reflected in overall outcome scores and could have resulted from the use of significant additional resources. Although agencies appear enthusiastic about collaboration, difficulties in the primary studies and incomplete implementation of initiatives have prevented the development of a strong evidence base. If these weaknesses are addressed in future studies (for example by providing greater detail on the implementation of programmes; using more robust designs, integrated process evaluations to show how well the partners of the collaboration worked together, and measurement of health outcomes) it could provide a better understanding of what might work and why. It is possible that local collaborative partnerships delivering environmental interventions may result in health gain but the evidence base for this is very limited. Evaluations of interagency collaborative arrangements face many challenges. The results demonstrate that collaborative community partnerships can be established to deliver interventions but it is important to agree goals, methods of working, monitoring and evaluation before implementation to protect programme fidelity and increase the potential for effectiveness. |
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Clinical Governance Framework for Chronic Diseases in Primary Care

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2 1 Clinical Governance Framework for Chronic Diseases in Primary Care
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48 29 of interest.

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50 30 Keywords: primary health care; chronic disease; health care research; health system
51 31 framework;
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Abstract

Objectives: Our goal is to conceptualize a clinical governance framework for the effective management of chronic diseases in the primary care setting, which will facilitate an reorganization of healthcare services that systematically improves their performance.

Setting: Primary care.

Participants: Wagner's Chronic Care Model and Scally's Clinical Governance statement were taken for reference. Each was reviewed, including their various components. We then conceptualized a new framework, merging the relevant aspects of both

Interventions: We conducted an umbrella review of all systematic reviews published by the Cochrane Effective Practice and Organisation of Care (EPOC) Group to identify organizational interventions in primary care with demonstrated evidence of efficacy.

Results: All primary health care systems should be patient-centred. Interventions for patients and their families should focus on their values; on clinical, professional and institutional integration; and finally on accountability to patients, peers and society at large. These interventions should be shaped by an approach to their clinical management that achieves the best clinical governance, which includes quality assurance, risk management, technology assessment, management of patient satisfaction, and patient empowerment and engagement. This approach demands the implementation of a system of organizational, functional and professional management based on a population health needs assessment, resource management, evidence-based and patient-oriented research, professional education, team building, and information and communication technologies that support the delivery system. All primary care should be embedded in and founded on an active

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1 partnership with the society it serves.

2 **Conclusions:** A framework for clinical governance will promote an integrated effort to bring
3 together all related activities, melding environmental, administrative, support and clinical
4 elements to ensure a coordinated and integrated approach that sustains the provision of
5 better care for chronic conditions in primary care setting.

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5 2 **Strengths and limitations of this study**6
7 3 The study give a new comprehensive framework to drive an effective management of chronic
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9 4 diseases in the primary care setting;10
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12 5 A systematic review was made showing all relevant studies in Cochrane Effective Practice
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14 6 and Organisation of Care Group alongside the dimensions of the framework15
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17 7 We do not report studies illustrating interventions for a specific unique disease even if chronic
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19 8 disease.
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1 Introduction

2 The dramatic increase in the burden of chronic diseases in the last twenty years represents a
3 primary concern for health services, and global health system sustainability demands a
4 massive shift to primary care [1-3]. As a consequence, the organization and provision of
5 primary care now faces new challenges (e.g. polypharmacy, multimorbidity, fragmentation of
6 care, frequent transitions of care, a need for strong integration, and pressure from patients)
7 [4]. There is currently a growing interest in developed countries to redesign health care
8 organizations, focusing on practices that improve the quality of care and guarantee the
9 equitable, timely and effective management of patients with chronic diseases [5, 6]. In fact It
10 is now widely recognized that the care and support needed to live with a long-term condition
11 requires a radical re-design of services, allowing patients to drive the care planning process
12 developing a new management of care for people proactive, holistic, preventive and patient-
13 centred as jet for example defined by “House of care” model [7]. With these pressures,
14 primary care systems may have difficulty ensuring a coordinated approach, and the lack of
15 clarity concerning their goals has led to divergent approaches, and a slow and often disjointed
16 adoption of changes and improvements. [8]

17 Clinical governance is an umbrella for the systematic administration and coordination of
18 different processes having a direct impact on healthcare delivery, including the management
19 of patients with chronic conditions. It encompasses the tools, methods, and infrastructure
20 devoted to assuring healthcare delivery, continuously improving the quality of the service, and
21 striving towards clinical excellence for patients. Clinical governance was first established in
22 the UK, [9] and has been implemented in many different countries [10-13]. Until now, it has
23 focused largely on in-hospital care, and met with significant difficulties when transferred to

1 primary care. [14] Clinical governance for primary care, focusing on the management of
2 chronic diseases, has specific features and relies on a network of different health
3 professionals working together for their patients' benefit [15] .

4 Our paper aims to conceptualize a clinical governance framework and the tools it needs for
5 the effective management of chronic diseases in the primary care setting, allowing to drive an
6 effective change in healthcare services and thereby systematically improving their quality and
7 safety.

8 9 **Methods**

10 For the purposes of our analysis, we used the Chronic Care Model [16] and Scally's Clinical
11 Governance statement [17] for reference, carefully reviewing each of them and their various
12 components. We then conceptualized a new framework, merging the relevant aspects of
13 both, and also defining and implementing new themes in a way that is relevant for primary
14 care. We ultimately selected five core elements from the original Chronic Care Model
15 (Delivery System Design, Decision Support, Clinical Information Systems, Self-Management
16 Support, The Community) and six approaches (Risk avoidance, Coherence, Infrastructure,
17 Culture, Quality Methods, Poor Performance) from the clinical governance framework
18 described by Scally based on their relevance to primary care and chronic disease
19 management.

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21 We then devised a framework arranged like a sunflower, where the *stem* and *leaves*
22 represent the *structural components* of the system needed to supply and support the *petals*.

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2 1 The petals in turn represent the themes or topics that shape direct actions involving patients
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4 2 or caregivers (the *bud* of the system). The sunflower is rooted in the *earth*, from where its
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6 3 structural components receive inputs in the form of water and nutrients; in healthcare, inputs
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8 4 from the “soil” enable the provision of primary care, collaboration between service providers,
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10 5 and resources from the outside world. The *atmosphere* in which the sunflower grows informs
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12 6 the views and attitudes that guide the actions of both health professionals and patients.
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18 8 For each *petal* (i.e. theme or topic), we searched for relevant interventions in the Cochrane
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20 9 Library from 2010 to the end of 2016, in the context of chronic care in the primary care
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22 10 setting. The search strategy used in our umbrella review of the Cochrane Library was based
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24 11 on the MeSH terms: (“general practice*” or “primary care”) and (“chronic disease*” or
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26 12 “multimorbidity”), plus one of the following: 1) “clinical governance”; 2) “quality assurance” or “
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28 13 “evidence-based healthcare”; 3) “satisfaction, patient”; 4) “risk management”; 5)
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30 14 “empowerment” or “health literacy” or “engagement”; 6) “health technology assessment” or
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32 15 “cost-effectiveness” or “cost-utility”. We also identified all systematic reviews published by the
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34 16 Cochrane Effective Practice and Organisation of Care (EPOC) Group that met our criteria.
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36 17 We included all relevant studies published in the Cochrane Review Database from 2010 to
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38 18 06.2017, and excluded all studies illustrating interventions for a specific disease, or those not
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40 19 involving patients with chronic disease.
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47 21 **Results**

48
49 22 The resulting conceptual framework is shown in Figure 1. We define three targets where
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51 23 management strategies could be acted:
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- 1) The petals consist of the management strategies that directly inform the interventions and clinical practice that acts on and with the patient and their family; primary care delivery happens at the level of the petals level, with the patient at the center.
- 2) The stem represents the underpinning management strategies that support the delivery system, which is the personnel and structures that permit the organization to support the “life of the petals”;
- 3) The ground is the environment in which primary care delivery is located, which gives “nourishment” and foundation.
- 4) Finally, there is the atmosphere, which represents the management strategies that influence the first three targets.

The bud is the center of the flower

Placing personalized patient-centred care at the heart of the system is an important way to create catalysts for change and encourage service re-organization, by focusing on patients’ health needs and motivating health system changes [18]. We define patient-centred care as care that is based on continuous, healing relationships among health professionals, patients and their families; care that is customized based on the patients’ needs and values; [19] ensuring that the patient is the source of control; sharing knowledge and information freely; and maintaining transparency.

The petals define what and how to act on and with the patients

The petals represent the management strategies that should shape directly the interventions on and with the patients. These dimensions include quality management, perceived quality

1 management, empowerment strategies, risk management, and health technology
2 assessment. The Institute of Medicine in the United States (IOM, now called National
3 Academy of Medicine) defines **quality management** as the degree to which health care
4 services for individuals and populations increase the likelihood of desired health outcomes
5 and are consistent with current professional knowledge [20]. It usually has two facets: quality
6 assurance and quality improvement. In chronic disease management, quality assurance
7 concerns the activities and programs intended to assure or improve the quality of care in a
8 specified medical setting or program. The concept includes assessing (measuring)
9 the quality of care, identifying problems or shortcomings in the delivery of care, designing
10 activities to overcome these deficiencies, and follow-up monitoring to ensure the effectiveness
11 of any corrective action. [21] Quality improvement involves the process of attaining a new,
12 higher level of performance or quality [22]. Adopting the philosophy of evidence-based
13 medicine in planning the diagnosis, care and follow-up of chronic patients has resulted in a
14 more effective and consistent transfer of the lessons learned from research into routine
15 practice, helping to reach higher quality standards [23, 24]. For example a review showed
16 that, in 5 of 17 good-quality RCTs, several different interventions were able to improve both
17 adherence to prescribed medicines and clinical outcomes. These interventions frequently
18 included enhancing support from family, peers, or allied health professionals such as
19 pharmacists, who often delivered education, counselling, or daily treatment support, even if
20 no common features could be identified to explain their success [25] (see table1a).

| Table 1a: Systematic reviews about quality improvement | | | | | |
|---|--|--|--|--|--|
| Author, Year | Title | Objectives | Inclusion criteria | Main findings | |
| Nieuwlaat R, et al 2014 (25) | Interventions for enhancing medication adherence | The primary objective of this review is to assess the effects of interventions intended to enhance patient adherence to prescribed medications for medical conditions, on both medication adherence and clinical outcomes. | We included unconfounded RCTs of interventions to improve adherence with prescribed medications, measuring both medication adherence and clinical outcome, with at least 80% follow-up of each group studied and, for long-term treatments, at least six months follow-up for studies with positive findings at earlier time points. | The present update included 109 new studies, bringing the total number to 182. In the 17 studies of the highest quality, interventions were generally complex with several different ways to try to improve medicine adherence. These frequently included enhanced support from family, peers, or allied health professionals such as pharmacists, who often delivered education, counseling, or daily treatment support. Only five of these RCTs improved both medicine adherence and clinical outcomes, and no common characteristics for their success could be identified. Overall, even the most effective interventions did not lead to large improvements. | |
| Smith SM et al, 2016 (26) | Interventions for improving outcomes in patients with multimorbidity in primary care and community settings | To determine the effectiveness of health-service or patient-oriented interventions designed to improve outcomes in people with multimorbidity in primary care and community settings. Multimorbidity was defined as two or more chronic conditions in the same individual. | We considered randomised controlled trials (RCTs), non-randomised clinical trials (NRCTs), controlled before-after studies (CBAs), and interrupted time series analyses (ITS) evaluating interventions to improve outcomes for people with multimorbidity in primary care and community settings. This includes studies where participants can have combinations of any condition or have combinations of pre-specified common conditions. The comparison was usual care as delivered in that setting. | Overall the results regarding the effectiveness of interventions were mixed. There were no clear positive improvements in clinical outcomes, health service use, medication adherence, patient-related health behaviours, health professional behaviours or costs. There were modest improvements in mental health outcomes from seven studies that targeted people with depression, and in functional outcomes from two studies targeting functional difficulties in participants. Overall the results indicate that it is difficult to improve outcomes for people with multiple conditions. The review suggests that interventions that are designed to target specific risk factors (for example treatment for depression) or interventions that focus on difficulties that people experience with daily functioning (for example, physiotherapy treatment to improve capacity for physical activity) may be more effective. There is a need for further studies on this topic, particularly involving people with multimorbidity in general across the age ranges | |
| Arditi C et al. 2012 (27) | Computer-generated reminders delivered on paper to healthcare professionals; effects on professional practice and health care outcomes | To evaluate the benefits and harms of rehabilitation interventions directed at maintaining, or improving, physical function for older people in long-term care through the review of randomized and cluster randomized controlled trials. | We included individual or cluster-randomized controlled trials (RCTs) and non-randomized controlled trials (NRCTs) that evaluated the impact of computer-generated reminders delivered on paper to healthcare professionals on processes and/or outcomes of care. | There is moderate quality evidence that computer-generated reminders delivered on paper to healthcare professionals achieve moderate improvement in process of care. Two characteristics emerged as significant predictors of improvement: providing space on the reminder for a response from the clinician and providing an explanation of the reminder's content or advice. The heterogeneity of the reminder interventions included in this review also suggests that reminders can improve care in various settings under various conditions | |

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| Thomas RE et al. 2014 (28) | Interventions to increase influenza vaccination rates of those 60 years and older in the community | To assess access, provider, system and societal interventions to increase the uptake of influenza vaccination in people aged 60 years and older in the community. | Randomised controlled trials (RCTs) of interventions to increase influenza vaccination uptake in people aged 60 and older. | There are interventions that are effective for increasing community demand for vaccination, enhancing access and improving provider/system response. In particular effective interventions in this comparison were a letter plus leaflet/postcard compared to a letter, nurses/pharmacists educating plus vaccinating patients, a phone call from a senior, a telephone invitation rather than clinic drop-in, free groceries lottery, and nurses educating and vaccinating patients. We were unable to pool trials of postcard/letter/pamphlets, communications tailored to patients, a customised letter/phone-call or client-based appraisals, but several trials of these interventions showed they were effective. |
| 1)Krogsbøll LT, et al 2012 (29) | General health checks in adults for reducing morbidity and mortality from disease | We aimed to quantify the benefits and harms of general health checks with an emphasis on patient-relevant outcomes such as morbidity and mortality rather than on surrogate outcomes such as blood pressure and serum cholesterol levels. | We included randomised trials comparing health checks with no health checks in adults unselected for disease or risk factors. We did not include geriatric trials. We defined health checks as screening general populations for more than one disease or risk factor in more than one organ system. | <p>There was no effect on the risk of death, or on the risk of death due to cardiovascular diseases or cancer.</p> <p>We did not find an effect on the risk of illness but one trial found an increased number of people identified with high blood pressure and high cholesterol, and one trial found an increased number with chronic diseases. One trial reported the total number of new diagnoses per participant and found a 20% increase over six years compared to the control group. No trials compared the total number of new prescriptions but two out of four trials found an increased number of people using drugs for high blood pressure. Two out of four trials found that health checks made people feel somewhat healthier, but this result is not reliable. We did not find that health checks had an effect on the number of admissions to hospital, disability, worry, the number of referrals to specialists, additional visits to the physician, or absence from work, but most of these outcomes were poorly studied. None of the trials reported on the number of follow-up tests after positive screening results, or the amount of surgery used.</p> <p>With the large number of participants and deaths included, the long follow-up periods used in the trials, and considering that death from cardiovascular diseases and cancer were not reduced, general health checks are unlikely to be beneficial.</p> |

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| 1 2 3 4 5 6 7 8 9 10 11 12 13 14 15 16 17 18 19 20 21 22 23 24 25 26 27 28 29 30 31 32 33 34 35 36 37 38 39 40 41 42 43 44 45 46 47 | Archambault PM 2017 (30) | Collaborative writing applications in healthcare: effects on professional practice and healthcare outcomes | The objectives of this review were to (1) assess the effects of the use of CWAs on process (including the behaviour of healthcare professionals) and patient outcomes, (2) critically appraise and summarise current evidence on the use of resources, costs, and cost-effectiveness associated with CWAs to improve professional practices and patient outcomes, and (3) explore the effects of different CWA features (e.g. open versus closed) and different implementation factors (e.g. the presence of a moderator) on process and patient outcomes. | We included randomised controlled trials (RCTs), non-randomised controlled trials (NRCTs), controlled before-and-after (CBA) studies, interrupted time series (ITS) studies, and repeated measures studies (RMS), in which CWAs were used as an intervention to improve the process of care, patient outcomes, or healthcare costs. | We screened 11,993 studies identified from the electronic database searches and 346 studies from grey literature sources. We analysed the full text of 99 studies. None of the studies met the eligibility criteria; two potentially relevant studies are ongoing. We did not identify any studies that measured the effect of CWAs on how healthcare professionals care for their patients. |
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| 1 2 3 4 5 6 7 8 9 10 11 12 13 14 15 16 17 18 19 20 21 22 23 24 | Fiander M, et al. 2015 (31) | Interventions to increase the use of electronic health information by healthcare practitioners to improve clinical practice and patient outcomes | To assess the effects of interventions aimed at improving or increasing healthcare practitioners' use of electronic health information (EHI) on professional practice and patient outcomes. | We included studies that evaluated the effects of interventions to improve or increase the use of EHI by healthcare practitioners on professional practice and patient outcomes. We defined EHI as information accessed on a computer. We defined 'use' as logging into EHI. We considered any healthcare practitioner involved in patient care. We included randomized, non-randomized, and cluster randomized controlled trials (RCTs, NRCTs, CRCTs), controlled clinical trials (CCTs), interrupted time series (ITS), and controlled before-and-after studies (CBAs). The comparisons were: electronic versus printed health information; EHI on different electronic devices (e.g. desktop, laptop or tablet computers, etc.; cell / mobile phones); EHI via different user interfaces; EHI provided with or without an educational or training component; and EHI compared to no other type or source of information. | The results of this review showed that when provided with a combination of EHI and training, practitioners used the information more often. Two studies measured doctors' use of electronic treatment guidelines, but showed that the electronic aspect of the guidelines did not mean that doctors followed the guidelines. This review provided no information on whether more frequent use of EHI translated into improved clinical practice or whether patients were better off when doctors or nurses used health information when treating them. |
| 25 26 27 28 29 30 31 32 33 34 35 | Flodgren G et al. 2016 (32) | Tools developed and disseminated by guideline producers to promote the uptake of their guidelines | To evaluate the effectiveness of implementation tools developed and disseminated by guideline producers, which accompany or follow the publication of a CPG, to promote uptake. A secondary objective is to determine which approaches to guideline implementation are most effective. | We included randomised controlled trials (RCTs) and cluster-RCTs, controlled before-and-after studies (CBAs) and interrupted time series (ITS) studies evaluating the effects of guideline implementation tools developed by recognised guideline producers to improve the uptake of their own guidelines. The guideline could target any clinical area. | Two of the four included studies reported on how well healthcare professionals stick to guideline recommendations when providing care to their patients, depending on whether they received a CPG with a tool aimed at improving the use of the CPG, or if they received the CPG only. The results of this review show that healthcare professionals who received a guideline tool together with the CPG on the management of non-specific low back pain or ordering thyroid-function tests probably stick more closely to the recommendations, compared with those who received the CPG only. A guideline tool aimed at improving the use of a guideline, may lead to little or no difference in cost to the health service. |

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| | Chen CE et al. 2017 (33) | Walk-in clinics versus physician offices and emergency rooms for urgent care and chronic disease management | To assess the quality of care and patient satisfaction of walk-in clinics compared to that of traditional physician offices and emergency rooms for people who present with basic medical complaints for either acute or chronic issues. | Study design: randomized trials, non-randomized trials, and controlled before-after studies. Population: standalone physical clinics not requiring advance appointments or registration, that provided basic medical care without expectation of follow-up. Comparisons: traditional primary care practices or emergency rooms. | Walk-in clinics are growing in popularity around the world, but it is unclear if the medical care provided by walk-in clinics is comparable to that of physicians' offices or emergency rooms. |
| | Scott A. et al. 2011 (34) | The effect of financial incentives on the quality of health care provided by primary care physicians | <p>The aim of this review is to examine the effect of changes in the method and level of payment on the quality of care provided by primary care physicians (PCPs) and to identify:</p> <ul style="list-style-type: none"> i) the different types of financial incentives that have improved quality; ii) the characteristics of patient populations for whom quality of care has been improved by financial incentives; and iii) the characteristics of PCPs who have responded to financial incentives. | Randomised controlled trials (RCT), controlled before and after studies (CBA), and interrupted time series analyses (ITS) evaluating the impact of different financial interventions on the quality of care delivered by primary healthcare physicians (PCPs). Quality of care was defined as patient reported outcome measures, clinical behaviours, and intermediate clinical and physiological measures. | The use of financial incentives to reward PCPs for improving the quality of primary healthcare services is growing. However, there is insufficient evidence to support or not support the use of financial incentives to improve the quality of primary health care. Implementation should proceed with caution and incentive schemes should be more carefully designed before implementation. In addition to basing incentive design more on theory, there is a large literature discussing experiences with these schemes that can be used to draw out a number of lessons that can be learned and that could be used to influence or modify the design of incentive schemes. More rigorous study designs need to be used to account for the selection of physicians into incentive schemes. The use of instrumental variable techniques should be considered to assist with the identification of treatment effects in the presence of selection bias and other sources of unobserved heterogeneity. In randomised trials, care must be taken in using the correct unit of analysis and more attention should be paid to blinding. Studies should also examine the potential unintended consequences of incentive schemes by having a stronger theoretical basis, including a broader range of outcomes, and conducting more extensive subgroup analysis. Studies should more consistently describe i) the type of payment scheme at baseline or in the control group, ii) how payments to medical groups were used and distributed within the groups, and iii) the size of the new payments as a percentage of total revenue. Further research comparing the relative costs and effects of financial incentives with other behaviour change interventions is also required. |

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| 2 | Young et al. 2017 (35) | Home or foster home care versus institutional long-term care for functionally dependent older people | To assess the effects of long-term home or foster home care versus institutional care for functionally dependent older people. | We included randomised and non-randomised trials, controlled before-after studies and interrupted time series studies complying with the EPOC study design criteria and comparing the effects of long-term home care versus institutional care for functionally dependent older people. | There are insufficient high-quality published data to support any particular model of care for functionally dependent older people. Community-based care was not consistently beneficial across all the included studies; there were some data suggesting that community-based care may be associated with improved quality of life and physical function compared to institutional care. However, community alternatives to institutional care may be associated with increased risk of hospitalisation. Future studies should assess healthcare utilisation, perform economic analysis, and consider caregiver burden. |
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| 13 | Nkansah N. et al. 2010 (36) | Effect of outpatient pharmacists' non-dispensing roles on patient outcomes and prescribing patterns | To examine the effect of outpatient pharmacists' non-dispensing roles on patient and health professional outcomes. | Randomized controlled trials comparing 1. Pharmacist services targeted at patients versus services delivered by other health professionals; 2. Pharmacist services targeted at patients versus the delivery of no comparable service; 3. Pharmacist services targeted at health professionals versus services delivered by other health professionals; 4. Pharmacist services targeted at health professionals versus the delivery of no comparable service. | Only one included study compared pharmacist services with other health professional services, hence we are unable to draw conclusions regarding comparisons 1 and 3. Most included studies supported the role of pharmacists in medication/therapeutic management, patient counseling, and providing health professional education with the goal of improving patient process of care and clinical outcomes, and of educational outreach visits on physician prescribing patterns. There was great heterogeneity in the types of outcomes measured across all studies. Therefore a standardized approach to measure and report clinical, humanistic, and process outcomes for future randomized controlled studies evaluating the impact of outpatient pharmacists is needed. Heterogeneity in study comparison groups, outcomes, and measures makes it challenging to make generalised statements regarding the impact of pharmacists in specific settings, disease states, and patient populations. |
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| 26 | Gonçalves-Bradley DC, et al 2016 (37) | Discharge planning from hospital | To assess the effectiveness of planning the discharge of individual patients moving from hospital. | Randomised controlled trials (RCTs) that compared an individualised discharge plan with routine discharge care that was not tailored to individual participants. Participants were hospital inpatients. | A discharge plan tailored to the individual patient probably brings about a small reduction in hospital length of stay and reduces the risk of readmission to hospital at three months follow-up for older people with a medical condition. Discharge planning may lead to increased satisfaction with healthcare for patients and professionals. There is little evidence that discharge planning reduces costs to the health service. |
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2 1 However, while many measures of quality of care in the primary care setting have been
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4 2 validated for specific diseases, little has been done to examine the validity or usefulness of
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6 3 these measures in the context of multimorbidity. However, to guarantee quality assurance it is
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8 4 necessary to consider the deliberate and systematic coordination of an organization's people,
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10 5 technology, processes, and organizational structure in order to add value through innovation,
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12 6 using research to inform practice [38] The systematic coordination and organization of
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14 7 primary health care team to develop proactive, holistic, preventive and patient-centred models
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16 8 of care mainly has primarily been developed for patients with chronic disease and
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18 9 multimorbidity. A review [26] concluded that health-service or patient-oriented interventions
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20 10 designed to improve outcomes in people with multimorbidity in primary care and community
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22 11 settings improved mainly mental health and functional outcomes. Another study [39]
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24 12 demonstrated the benefits of applying new technologies (telemonitoring) for community-
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26 13 dwelling patients care with chronic disease and multimorbidity, which significantly reduced
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28 14 health care costs, hospital ED admissions, hospital length of stay, and mortality.
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4 2 **Risk management** concerns the systematic identification, assessment and integrated
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6 3 management of current and potential hazards relating to patient care. This is particularly
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8 4 relevant for the care of complex patients with (“multimorbidity”). [39] The creation of a culture
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10 5 that is free of blame and encourages an open examination of errors and failures is key to
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12 6 improving quality and learning.
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17 8 Clinical incident reporting is a key feature of a risk management system that can improve
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19 9 identification of errors and how we can learn from them. Leape suggests that successful
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21 10 systems provide a safe non-punitive environment, and are simple, timely and inexpensive
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23 11 [40]. However, the effectiveness of such systems in promoting adverse event recording is not
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25 12 clear. To evaluate the effects of interventions designed to increase clinical incident reporting
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27 13 in healthcare settings, Parmelli and colleagues in 2012 conducted a review of four trials with
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29 14 several methodological shortcomings. Despite their limitations, two studies showed the
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31 15 effectiveness of the system implementation: one reported an increase in incident reporting
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33 16 rates, while the second showed a sustained improvement after nine months [41].
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38 17 One review on non-clinical health professional roles, found that older people were more likely
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40 18 to receive appropriate medicines with the provision of a pharmacist led intervention. [42] This
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42 19 service provided by pharmacists that involves identifying, preventing and solving medication-
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44 20 related problems, as well as promoting the correct use of medicines and encouraging health
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46 21 promotion and education. Another strategy found to be useful was computerized support for
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48 22 decision-making. The review focused primarily on process outcomes, and provided only
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50 23 limited evidence of whether these interventions resulted in clinical improvement. Another
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2 1 review found that self-monitoring of medicines and patient self-management programs were
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4 2 generally effective in improving the use of medicines, adherence to prescriptions, reducing
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6 3 adverse events, and improving clinical outcomes. It also found a lower mortality rate among
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8 4 people self-managing their antithrombotic therapy. [41] The same review revealed numerous
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10 5 other promising interventions to improve adherence and other key outcomes related to
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12 6 medicine usage (see Table 1b).
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Table 1b: Systematic reviews about risk management

| | Author, Year | Title | Objectives | Inclusion criteria | Main findings |
|------------------------|---------------------------|---|--|---|---|
| | Parmelli et al. 2012 (41) | Interventions to increase clinical incident reporting in health care | To assess the effects of interventions designed to increase clinical incident reporting in healthcare settings. | Randomised controlled trials (RCT), controlled before-after studies (CBA) and interrupted time series (ITS) of interventions designed to increase clinical incident reporting in healthcare. | Because of the limitations of the studies it is not possible to draw conclusions for clinical practice. Anyone introducing a system into practice should give careful consideration to conducting an evaluation using a robust design. |
| RISK MANAGEMENT | Ryan R, et al 2014 (43) | Interventions to improve safe and effective medicines use by consumers: an overview of systematic reviews | To assess the effects of interventions which target healthcare consumers to promote safe and effective medicines use, by synthesising review-level evidence. | We included systematic reviews published on the Cochrane Database of Systematic Reviews and the Database of Abstracts of Reviews of Effects. We identified relevant reviews by hand searching databases from their start dates to March 2012. | <p>Looking across reviews, for most outcomes, medicines self-monitoring and self-management programmes appear generally effective to improve medicines use, adherence, adverse events and clinical outcomes; and to reduce mortality in people self-managing antithrombotic therapy. However, some participants were unable to complete these interventions, suggesting they may not be suitable for everyone.</p> <p>Other promising interventions to improve adherence and other key medicines-use outcomes, which require further investigation to be more certain of their effects, include:</p> <ul style="list-style-type: none"> · simplified dosing regimens: with positive effects on adherence; · interventions involving pharmacists in medicines management, such as medicines reviews (with positive effects on adherence and use, medicines problems and clinical outcomes) and pharmaceutical care services (consultation between pharmacist and patient to resolve medicines problems, develop a care plan and provide follow-up; with positive effects on adherence and knowledge). <p>Several other strategies showed some positive effects, particularly relating to adherence, and other outcomes, but their effects were less consistent overall and so need further study. These included:</p> <ul style="list-style-type: none"> · delayed antibiotic prescriptions: effective to decrease antibiotic use but with mixed effects on clinical outcomes, adverse effects and satisfaction; · practical strategies like reminders, cues and/or organisers, reminder packaging and material incentives: with positive, although somewhat mixed effects on adherence; · education delivered with self-management skills training, counselling, support, training or enhanced follow-up; information and counselling delivered together; or education/information as part of pharmacist-delivered packages of care: with positive effects on adherence, medicines use, clinical outcomes and knowledge, but with mixed effects in some studies; · financial incentives: with positive, but mixed, effects on adherence. <p>Several strategies also showed promise in promoting immunisation uptake, but require further study to be more certain of their effects. These included organisational interventions; reminders and recall; financial incentives; home visits; free vaccination; lay health worker interventions; and facilitators working with physicians to promote immunisation uptake. Education and/or information strategies also showed some positive but even less consistent effects on immunisation uptake, and need further assessment of effectiveness and investigation of heterogeneity.</p> |

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| Patterson SM, et al 2014 (44) | Interventions to improve the appropriate use of polypharmacy for older people | This review sought to determine which interventions, alone or in combination, are effective in improving the appropriate use of polypharmacy and reducing medication-related problems in older people. | A range of study designs were eligible. Eligible studies described interventions affecting prescribing aimed at improving appropriate polypharmacy in people 65 years of age and older in which a validated measure of appropriateness was used (e.g. Beers criteria, Medication Appropriateness Index (MAI)). | This review examines studies in which healthcare professionals have taken action to make sure that older people are receiving the most effective and safest medication for their illness. Actions taken included providing pharmaceutical care, a service provided by pharmacists that involves identifying, preventing and resolving medication-related problems, as well as promoting the correct use of medications and encouraging health promotion and education. Another strategy was computerised decision support, which involves a programme on the doctor's computer that helps him/her to select appropriate treatment. This review provides limited evidence that interventions, such as pharmaceutical care, may be successful in ensuring that older people are receiving the right medicines, but it is not clear whether this always results in clinical improvement. |
| Ivers N. et al 2012 (45) | Audit and feedback: effects on professional practice and healthcare outcomes | To assess the effects of audit and feedback on the practice of healthcare professionals and patient outcomes and to examine factors that may explain variation in the effectiveness of audit and feedback. | Randomised trials of audit and feedback (defined as a summary of clinical performance over a specified period of time) that reported objectively measured health professional practice or patient outcomes. In the case of multifaceted interventions, only trials in which audit and feedback was considered the core, essential aspect of at least one intervention arm were included. | Audit and feedback generally leads to small but potentially important improvements in professional practice. The effectiveness of audit and feedback seems to depend on baseline performance and how the feedback is provided. Future studies of audit and feedback should directly compare different ways of providing feedback. |

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| | <p>Gillaizeau F. et al. 2013 (46)</p> | <p>Computerized advice on drug dosage to improve prescribing practice</p> | <p>To assess whether computerized advice on drug dosage has beneficial effects on patient outcomes compared with routine care (empiric dosing without computer assistance).</p> | <p>We included randomized controlled trials, non-randomized controlled trials, controlled before-and-after studies and interrupted time series analyses of computerized advice on drug dosage. The participants were healthcare professionals responsible for patient care. The outcomes were any objectively measured change in the health of patients resulting from computerized advice (such as therapeutic drug control, clinical improvement, adverse reactions).</p> | <p>Computerized advice for drug dosage can benefit people taking certain drugs compared with empiric dosing (where a dose is chosen based on a doctor's observations and experience) without computer assistance. When using the computer system, healthcare professionals prescribed appropriately higher doses of the drugs initially for aminoglycoside antibiotics and the correct drug dose was reached more quickly for oral anticoagulants. It significantly decreased thromboembolism (blood clotting) events for anticoagulants and tended to reduce unwanted effects for aminoglycoside antibiotics and anti-rejection drugs (although not an important difference). It tended to reduce the length of hospital stay compared with routine care with comparable or better cost-effectiveness. There was no evidence of effects on death or clinical side events for insulin (low blood sugar (hypoglycaemia)), anaesthetic agents, anti-rejection drugs (drugs taken to prevent rejection of a transplanted organ) and antidepressants.</p> |
| | <p>Allred DP et al. 2016 (47)</p> | <p>Interventions to optimise prescribing for older people in care homes</p> | <p>The objective of the review was to determine the effect of interventions to optimise overall prescribing for older people living in care homes.</p> | <p>We included randomised controlled trials evaluating interventions aimed at optimising prescribing for older people (aged 65 years or older) living in institutionalised care facilities. Studies were included if they measured one or more of the following primary outcomes: adverse drug events; hospital admissions; mortality; or secondary outcomes, quality of life (using validated instrument); medication-related problems; medication appropriateness (using validated instrument); medicine costs.</p> | <p>We could not draw robust conclusions from the evidence due to variability in design, interventions, outcomes and results. The interventions implemented in the studies in this review led to the identification and resolution of medication-related problems and improvements in medication appropriateness, however evidence of a consistent effect on resident-related outcomes was not found. There is a need for high-quality cluster-randomised controlled trials testing clinical decision support systems and multidisciplinary interventions that measure well-defined, important resident-related outcomes.</p> |

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2 1 **Patient satisfaction** is fundamental in the case of patients with chronic disease who are
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4 2 likely to be involved in a lasting relationship with healthcare services. It is linked to patients'
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6 3 expectations of ideal care and their actual experience of care [48], and it is considered by
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8 4 most as a multi-dimensional construct including multiple domains such as accessibility,
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10 5 organizational characteristics of the system, clinical and communication skills, and the doctor-
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12 6 patient relationship, among others. Long waiting lists for non-urgent health procedures are
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14 7 quite common and may affect the health professional-patient relationship, causing distress for
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16 8 patients and their caregivers and distrust of the health care system. Improving access by
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18 9 implementing an open access or direct booking for some health problems or referrals has
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20 10 been shown to improve patient satisfaction [49]. Home-based interventions for end-of-life care
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23 11 have also been shown to improve both patient and caregivers satisfaction [50] (see table 1c).
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Table 1c: Systematic reviews about patient satisfaction

| | Author, Year | Title | Objectives | Inclusion criteria | Main findings |
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| PATIENT SATISFACTION | Ballini L. et al. 2015 (49) | Interventions to reduce waiting times for elective procedures | To assess the effectiveness of interventions aimed at reducing waiting times for elective care, both diagnostic and therapeutic. | We considered randomised controlled trials (RCTs), controlled before-after studies (CBAs) and interrupted time series (ITS) designs that met EPOC minimum criteria and evaluated the effectiveness of any intervention aimed at reducing waiting times for any type of elective procedure. We considered studies reporting one or more of the following outcomes: number or proportion of participants whose waiting times were above or below a specific time threshold, or participants' mean or median waiting times. Comparators could include any type of active intervention or standard practice. | As only a handful of low-quality studies are presently available, we cannot draw any firm conclusions about the effectiveness of the evaluated interventions in reducing waiting times. However, interventions involving the provision of more accessible services (open access or direct booking/referral) show some promise. |
| | Shepeprd S. et al. 2016 (50) | Hospital at home: home-based end-of-life care | To determine if providing home-based end-of-life care reduces the likelihood of dying in hospital and what effect this has on patients' symptoms, quality of life, health service costs, and caregivers, compared with inpatient hospital or hospice care. | Randomised controlled trials, interrupted time series, or controlled before and after studies evaluating the effectiveness of home-based end-of-life care with inpatient hospital or hospice care for people aged 18 years and older. | The evidence included in this review supports the use of home-based end-of-life care programmes for increasing the number of people who will die at home, although the numbers of people admitted to hospital while receiving end-of-life care should be monitored. Future research should systematically assess the impact of home-based end-of-life care on caregivers. |
| | Dwamena F, et al 2012 (51) | Interventions for providers to promote a patient-centred approach in clinical consultations | To assess the effects of interventions for healthcare providers that aim to promote patient-centred care (PCC) approaches in clinical consultations. | In the original review, study designs included randomized controlled trials, controlled clinical trials, controlled before and after studies, and interrupted time series studies of interventions for healthcare providers that promote patient-centred care in clinical consultations. In the present update, we were able to limit the studies to randomized controlled trials, thus limiting the likelihood of sampling error. This is especially important because the providers who volunteer for studies of PCC methods are likely to be different from the general population of providers. | Interventions to promote patient-centred care within clinical consultations are effective across studies in transferring patient-centred skills to providers. However the effects on patient satisfaction, health behaviour and health status are mixed. There is some indication that complex interventions directed at providers and patients that include condition-specific educational materials have beneficial effects on health behaviour and health status, outcomes not assessed in studies reviewed previously. The latter conclusion is tentative at this time and requires more data. The heterogeneity of outcomes, and the use of single item consultation and health behaviour measures limit the strength of the conclusions. |

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2 1 **Patient and caregiver engagement** refers to a patient- and family-centred collaborative
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4 2 approach that is tailored to match the fundamental realities of chronic care. Patient and
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6 3 caregiver engagement helps patients discover and develop their inherent capacity to take
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8 4 responsibility for their own life. [52] Empowering patients by providing information and
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10 5 increasing their contribution to the planning of services can greatly influence the development
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12 6 of clinical governance, not only on clinical processes, but also on organizational matters.
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14 7 Contributions from patients will affect not just the responsiveness and performance of
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16 8 healthcare services, but also the process by means of which quality improvement initiatives
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18 9 are identified and prioritized. [53]. Recent reviews highlighted that interventions promoting,
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20 10 sharing medical decision making with active involvement of both patients and health
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22 11 professionals, have found moderate evidence of better patient involvement. In addition,
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24 12 decision aids (pamphlets, videos or video-based tools) may improve patient's knowledge of
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26 13 their care options, so they feel more informed and better able to participate in decision making
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28 14 [54, 55] (see Table1d) .
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Table 1d: Systematic reviews about patient and caregiver engagement

| | Author, Year | Title | Objectives | Inclusion criteria | Main findings |
|---|---------------------------|--|---|--|--|
| PATIENT AND CAREGIVER ENGAGEMENT | Légaré F. et al 2014 (54) | Interventions for improving the adoption of shared decision making by healthcare professionals | To determine the effectiveness of interventions to improve healthcare professionals' adoption of SDM. | Randomised and non-randomised controlled trials, controlled before-and-after studies and interrupted time series studies evaluating interventions to improve healthcare professionals' adoption of SDM where the primary outcomes were evaluated using observer-based outcome measures (OBOM) or patient-reported outcome measures (PROM). | It is uncertain whether interventions to improve adoption of SDM are effective given the low quality of the evidence. However, any intervention that actively targets patients, healthcare professionals, or both, is better than none. Also, interventions targeting patients and healthcare professionals together show more promise than those targeting only one or the other. |
| | Stacey et al. 2017 (55) | Decision Aids for People Facing Health Treatment or Screening Decisions | To assess the effects of decision aids in people facing treatment or screening decisions. | We included published randomized controlled trials comparing decision aids to usual care and/or alternative interventions. For this update, we excluded studies comparing detailed versus simple decision aids. | Compared to usual care across a wide variety of decision contexts, people exposed to decision aids feel more knowledgeable, better informed, and clearer about their values, and they probably have a more active role in decision making and more accurate risk perceptions. There is growing evidence that decision aids may improve values-congruent choices. There are no adverse effects on health outcomes or satisfaction. New for this updated is evidence indicating improved knowledge and accurate risk perceptions when decision aids are used either within or in preparation for the consultation. |

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| | Ciciriello S, et al 2013 (56) | Multimedia educational interventions for consumers about prescribed and over-the-counter medications | To assess the effects of multimedia patient education interventions about prescribed and over-the-counter medications in people of all ages, including children and carers. | Randomised controlled trials (RCTs) and quasi-RCTs of multimedia-based patient education about prescribed or over-the-counter medications in people of all ages, including children and carers, if the intervention had been targeted for their use. | <p>We found that multimedia education programs about medications are superior to no education or education provided as part of usual clinical care in improving patient knowledge. There was wide variability in the results from the six studies that compared multimedia education to usual care or no education. However, all but one of the six studies favoured multimedia education. We also found that multimedia education is superior to usual care or no education in improving skill levels. The review also suggested that multimedia was at least as effective as other forms of education, including written education or brief education from a health provider. However, these findings were based on a small number of studies, many of which were of low quality.</p> <p>Multimedia education did not improve compliance with medications (i.e. the degree to which a patient correctly follows advice about his or her medication) compared with usual care or no education. We could not determine the effect of multimedia education on other outcomes, such as patient satisfaction, self-efficacy (confidence in their ability to perform health-related tasks) and health outcomes.</p> <p>The review findings therefore suggests that multimedia education programs about medications could be used alongside usual care provided by health providers. There is not enough evidence to recommend it as a replacement for written education or education by a health professional. Multimedia education could be used instead of detailed education given by a health provider when it is not possible or practical for health professionals to provide this service.</p> <p>This review found that there were differences between the types of education provided to the control groups and what results were measured. This limited the ability to summarise results across studies, so most of the conclusions of this review were based on results from a small number of studies. More studies of multimedia educational programs are needed to make the results of this review more reliable.</p> |
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6 3 **Health Technology Assessment (HTA)** refers to the systematic assessment of the
7
8 4 properties and effects of a health technology, addressing the direct and intended effects of
9
10 5 the technology, as well as its indirect and unintended consequences. The main aims of HTA
11
12 6 are to inform decision-making regarding health technologies (bearing in mind the finite
13
14 7 resources available), to drive the introduction of innovations, and to identify ineffective or
15
16 8 harmful technologies. [57] Whether it involves introducing electro-stimulators for treating
17
18 9 incontinence, or disinvesting in old medical ventilators for long-term domiciliary respiratory
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20 10 support, or a new clinical pathway for diabetes, HTA is a robust method for orienting decision-
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22 11 makers and clinicians towards the best available choices (see Table 1e).
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Table 1e: Systematic reviews about cost effectiveness

| | Author, Year | Title | Objectives | Inclusion criteria | Main findings |
|--|-----------------------------|--|---|---|---|
| HTA; COST-EFFECTIVENESS, COST-UTILITY | Atherton H et al, 2012 (58) | Email for clinical communication between patients/care givers and healthcare professionals | To assess the effects of healthcare professionals and patients using email to communicate with each other, on patient outcomes, health service performance, service efficiency and acceptability. | Randomised controlled trials, quasi-randomised trials, controlled before and after studies and interrupted time series studies examining interventions using email to allow patients to communicate clinical concerns to a healthcare professional and receive a reply, and taking the form of 1) unsecured email 2) secure email or 3) web messaging. All healthcare professionals, patients and caregivers in all settings were considered. | <p>Eight of the trials looked at email compared with standard methods of communication. Where email was compared to standard methods of communication we found that we could not properly determine what effect email was having on patient/caregiver outcomes, as there were missing data and the results of the different studies varied. For health service use outcomes the situation was the same, but some results seemed to show that an email intervention may lead to an increased number of emails and telephone calls being received by healthcare professionals.</p> <p>One of the trials looked at email counselling compared with telephone counselling. We found that it only looked at patient outcomes, and found few differences between groups. Where there were differences these showed that telephone counselling leads to greater changes in lifestyle than email counselling.</p> <p>None of the trials measured how email affects healthcare professionals and only one measured whether email can cause harm. All of the trials were biased in some way and when we measured the quality of all of the results we found them to be of low or very low quality.</p> <p>As a result the results of this review should be viewed with caution.</p> <p>The nature of the results means that we cannot make any recommendations for how email might best be used in clinical practice.</p> |
| | Flodgren G, et al 2016 (59) | Interactive telemedicine: effects on professional practice and health care outcomes | To assess the effectiveness, acceptability and costs of interactive TM as an alternative to, or in addition to, usual care (i.e. face-to-face care, or telephone consultation). | We considered randomised controlled trials of interactive TM that involved direct patient-provider interaction and was delivered in addition to, or substituting for, usual care compared with usual care alone, to participants with any clinical condition. We excluded telephone only interventions and wholly automatic self-management TM interventions. | <p>The findings in our review indicate that the use of TM in the management of heart failure appears to lead to similar health outcomes as face-to-face or telephone delivery of care; there is evidence that TM can improve the control of blood glucose in those with diabetes.</p> <p>The cost to a health service, and acceptability by patients and healthcare professionals, is not clear due to limited data reported for these outcomes. The effectiveness of TM may depend on a number of different factors, including those related to the study population e.g. the severity of the condition and the disease trajectory of the participants, the function of the intervention e.g., if it is used for monitoring a chronic condition, or to provide access to diagnostic services, as well as the healthcare provider and healthcare system involved in delivering the intervention.</p> |

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| | Weeks G, et al 2016 (60) | Non-medical prescribing versus medical prescribing for acute and chronic disease management in primary and secondary care | To assess clinical, patient-reported, and resource use outcomes of non-medical prescribing for managing acute and chronic health conditions in primary and secondary care settings compared with medical prescribing (usual care). | Randomised controlled trials (RCTs), cluster-RCTs, controlled before-and-after (CBA) studies (with at least two intervention and two control sites) and interrupted time series analysis (with at least three observations before and after the intervention) comparing: 1. Nonmedical prescribing versus medical prescribing in acute care; 2. non-medical prescribing versus medical prescribing in chronic care; 3. non-medical prescribing versus medical prescribing in secondary care; 4 non-medical prescribing versus medical prescribing in primary care; 5. comparisons between different non-medical prescriber groups; and 6. non-medical healthcare providers with formal prescribing training versus those without formal prescribing training. | The findings suggest that non-medical prescribers, practising with varying but high levels of prescribing autonomy, in a range of settings, were as effective as usual care medical prescribers. Non-medical prescribers can deliver comparable outcomes for systolic blood pressure, glycated haemoglobin, low-density lipoprotein, medication adherence, patient satisfaction, and health-related quality of life. It was difficult to determine the impact of non-medical prescribing compared to medical prescribing for adverse events and resource use outcomes due to the inconsistency and variability in reporting across studies. |
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2 1 *The atmosphere*

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4 2 The atmosphere dimensions defined at this level shape not only the interventions given to
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6 3 patients, as petal dimensions, but also describe activities between professionals inside the
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8 4 organization, as well as the relationship with the civil society. Dimensions of the atmosphere
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10 5 include vision and values, integrated care, and accountability.
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15 7 A well-led organization will monitor whether the **vision and values** of clinical governance are
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17 8 being clearly and effectively communicated to all members of the staff. This communication
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19 9 gives staff a common and consistent purpose, and clear expectations. A clear vision
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21 10 engenders an open-minded and questioning culture, and ensures that both the ethos and the
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23 11 day-to-day delivery of clinical governance remain an integral part of every clinical service.
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27 12 Apart from health system issues, one of the major barriers to the successful transfer of
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29 13 evidence into locally-accepted policies lies in ineffective and unaccountable leaders and
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31 14 managers [61] (see table 1f).
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Table 1f: Systematic reviews about Leadership, values, vision

| LEADERSHIP, VALUES, VISION | Author, Year | Title | Objectives | Inclusion criteria | Main findings |
|----------------------------|-------------------------|--|---|---|---|
| | Flodgren G. et al. 2011 | Local opinion leaders: effects on professional practice and health care outcomes | To assess the effectiveness of the use of local opinion leaders in improving professional practice and patient outcomes. | Studies eligible for inclusion were randomised controlled trials investigating the effectiveness of using opinion leaders to disseminate evidence-based practice and reporting objective measures of professional performance and/or health outcomes | Opinion leaders alone or in combination with other interventions may successfully promote evidence-based practice, but effectiveness varies both within and between studies. These results are based on heterogeneous studies differing in terms of type of intervention, setting, and outcomes measured. In most of the studies the role of the opinion leader was not clearly described, and it is therefore not possible to say what the best way is to optimise the effectiveness of opinion leaders. |
| | Green C J et al. 2010 | Pharmaceutical policies: effects of restrictions on reimbursement | To determine the effects of a pharmaceutical policy restricting the reimbursement of selected medications on drug use, health care utilization, health outcomes and costs (expenditures). | Included were studies of pharmaceutical policies that restrict coverage and reimbursement of selected drugs or drug classes, often using additional patient specific information related to health status or need. We included randomised controlled trials, non-randomised controlled trials, interrupted time series (ITS) analyses, repeated measures studies and controlled before-after studies set in large care systems or jurisdictions. | Implementing restrictions to coverage and reimbursement of selected medications can decrease third-party drug spending without increasing the use of other health services (6 studies). Relaxing reimbursement rules for drugs used for secondary prevention can also remove barriers to access. Policy design, however, needs to be based on research quantifying the harm and benefit profiles of target and alternative drugs to avoid unwanted health system and health effects. Health impact evaluation should be conducted where drugs are not interchangeable. Impacts on health equity, relating to the fair and just distribution of health benefits in society (sustainable access to publically financed drug benefits for seniors and low income populations, for example), also require explicit measurement. |
| | Jia L. et al. 2014 | Strategies for expanding health insurance coverage in vulnerable populations | To assess the effectiveness of strategies for expanding health insurance coverage in vulnerable populations. | Randomised controlled trials (RCTs), non-randomised controlled trials (NRCTs), controlled before-after (CBA) studies and Interrupted time series (ITS) studies that evaluated the effects of strategies on increasing health insurance coverage for vulnerable populations. We defined strategies as measures to improve the enrolment of vulnerable populations into health insurance schemes. Two categories and six specified strategies were identified as the interventions. | Community-based case managers who provide health insurance information, application support, and negotiate with the insurer probably increase enrolment of children in health insurance schemes. However, the transferability of this intervention to other populations or other settings is uncertain. Handing out insurance application materials in hospital emergency departments may help increase the enrolment of children in health insurance schemes. Further studies evaluating the effectiveness of different strategies for expanding health insurance coverage in vulnerable population are needed in different settings, with careful attention given to study design. |

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2 1 **Integrated care** is a concept that brings together the inputs, delivery, management and
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4 2 organization of services related to patients' diagnosis, treatment, care, rehabilitation and
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6 3 health promotion. As individuals move across healthcare settings and services, the model of
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8 4 care requires integration and cooperation between a multiplicity of professionals. This
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10 5 integration and cooperation demands a high degree of collaboration between healthcare
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12 6 professionals involved in these services, as well as organizational support. This integration
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14 7 should operate not only within a primary care system, but also through effective
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16 8 communications between specialist and primary care providers, to guarantee better
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18 9 transitions of care for patients with chronic disease. The latter has significant positive effects
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20 10 in reducing hospital readmissions and mortality [65-67] (see table 1g).
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Table 1g: Systematic reviews about integration

| | Author, Year | Title | Objectives | Inclusion criteria | Main findings |
|--------------------|----------------------|---|---|--|---|
| INTEGRATION | Reeves S et al. 2017 | Interprofessional collaboration to improve professional practice and healthcare outcomes | To assess the impact of practice-based interventions designed to improve interprofessional collaboration (IPC) amongst health and social care professionals, compared to usual care or to an alternative intervention, on at least one of the following primary outcomes: patient health outcomes, clinical process or efficiency outcomes or secondary outcomes (collaborative behaviour). | We included randomised trials of practice-based IPC interventions involving health and social care professionals compared to usual care or to an alternative intervention. | Given that the certainty of evidence from the included studies was judged to be low to very low, there is not sufficient evidence to draw clear conclusions on the effects of IPC interventions. Nevertheless, due to the difficulties health professionals encounter when collaborating in clinical practice, it is encouraging that research on the number of interventions to improve IPC has increased since this review was last updated. While this field is developing, further rigorous, mixed-method studies are required. Future studies should focus on longer acclimatisation periods before evaluating newly implemented IPC interventions, and use longer follow-up to generate a more informed understanding of the effects of IPC on clinical practice. |
| | Smith SM et al. 2017 | Shared care across the interface between primary and specialty care in management of long term conditions | To determine the effectiveness of shared care health service interventions designed to improve the management of chronic disease across the primary/specialty care interface. | We considered randomised controlled trials (RCTs), non-randomised controlled trials (NRCTs), controlled before-after studies (CBAs) and interrupted time series analyses (ITS) evaluating the effectiveness of shared care interventions for people with chronic conditions in primary care and community settings. The intervention was compared with usual care in that setting. | This review suggests that shared care is effective for managing depression. Shared care interventions for other conditions should be developed within research settings, so that further evidence can be considered before they are introduced routinely into health systems. |

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| | Hayes SL, et al 2012 | Collaboration between local health and local government agencies for health improvement | To evaluate the effects of interagency collaboration between local health and local government agencies on health outcomes in any population or age group. | Randomized controlled trials (RCTs), controlled clinical trials (CCTs), controlled before-and-after studies (CBAs) and interrupted time series (ITS) where the study reported individual health outcomes arising from interagency collaboration between health and local government agencies compared to standard care. Studies were selected independently in duplicate, with no restriction on population subgroup or disease. | Collaboration between local health and local government is commonly considered best practice. However, the review did not identify any reliable evidence that interagency collaboration, compared to standard services, necessarily leads to health improvement. A few studies identified component benefits but these were not reflected in overall outcome scores and could have resulted from the use of significant additional resources. Although agencies appear enthusiastic about collaboration, difficulties in the primary studies and incomplete implementation of initiatives have prevented the development of a strong evidence base. If these weaknesses are addressed in future studies (for example by providing greater detail on the implementation of programmes; using more robust designs, integrated process evaluations to show how well the partners of the collaboration worked together, and measurement of health outcomes) it could provide a better understanding of what might work and why. It is possible that local collaborative partnerships delivering environmental interventions may result in health gain but the evidence base for this is very limited. Evaluations of interagency collaborative arrangements face many challenges. The results demonstrate that collaborative community partnerships can be established to deliver interventions but it is important to agree goals, methods of working, monitoring and evaluation before implementation to protect programme fidelity and increase the potential for effectiveness. |
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For peer review only

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2 1 A robust, comprehensive, and transparent **accountability**, with measurement of performance
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4 2 in healthcare activities can ensure that the system is accountable to society at large, to health
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6 3 professionals and others involved in delivering care, and to patients. A fundamental shift is
7
8 4 needed from a demand-driven model valuing the volume of the production, to a new model
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10 5 where the providers are accountable for the care outcomes and value that matter to patients
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12 6 and the broader population. Driving accountability for outcomes and value leads to several
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14 7 key benefits: it encourages innovation along entire care pathways, to raise quality and reduce
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16 8 cost; it incentivizes collaboration between providers to co-ordinate care to deliver outcomes; it
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18 9 clarifies for policy-makers what is being achieved by the money being spent; and it gives
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20 10 people a stronger voice in their own care and in defining what matters.[70, 71] Such a system
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22 11 can support effective auditing, which can improve care processes in health districts over the
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24 12 long term. [71]
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34 15 *The stem defines the means to reach the petals*

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36 16 It is also important to ensure that key underpinning strategies (such as information
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38 17 technology, education and training, research and dissemination) support the delivery system
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40 18 to reach the defined petals dimensions. For example, any service re-organization should
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42 19 involve building better information communication and technology (ICT) systems, to enable a
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44 20 better exchange of information throughout a newly rearranged organization. An effective
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46 21 workforce also needs appropriate technical support, such as access to valid best evidence, to
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48 22 support its clinical decisions. To be useful, the data in information systems must be valid, up-
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50 23 to-date, and presented in a way that offers insight. It should also be integrated with the
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2 1 electronic health record, and not provide excessive alerts that lead to “alert fatigue”. Finally, it
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4 2 should focus on research that provides evidence of improved patient-oriented outcomes,
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6 3 rather than disease or surrogate markers of improvement. [72]
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11 5 Data to highlight differences in patient outcomes, shortfalls in standards, comparisons with
12
13 6 other services, and time trends are essential. Interconnected electronic health records
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15 7 support clinicians’ efforts to improve outcomes across the full continuum of care, while
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17 8 ensuring accountability, engaging patients in making decisions and managing their care,
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19 9 improving safety and care coordination, and avoiding any waste of resources. [73] Data are
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21 10 essential to managing performance, normally in relation to two subsets of activities:
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23 11 performance evaluation, and performance improvement. Both make use of indicators for
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25 12 assessment purposes, and the latter also to monitor a healthcare organization’s performance
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27 13 during an improvement process [74]. For patients with multiple chronic conditions, it is also
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29 14 necessary to devise team indicators and indicators that encompass all the care provided to a
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31 15 given patient.
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39 17 Improving the training of health care professionals will be important in any effort to re-
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41 18 organize a health care system. For example, if more nurses are going to take on the role of
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43 19 case study managers, they will need additional training to build their skill base. [75] Ideally,
44
45 20 continuing professional education should not be limited to updating professionals’ technical
46
47 21 skills, knowledge of new research, and improved clinical decision-making. In addition, it
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49 22 should enable all members of the staff to develop skills that allow them to practice to the
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51 23 maximum of their training, and to assure that their skills are aligned with the organization's
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1 objectives.

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7 3 *The earth defines the ground where primary care is delivered*

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9 4 Community participation should be part of healthcare service planning and evaluation. It is
10
11 5 also essential to mobilize community resources to meet the needs of people with long-term
12
13 6 conditions, creating a culture and mechanisms that promote safe, good-quality care. It has
14
15 7 been suggested that positive outcomes for people with long-term conditions are only achieved
16
17 8 when not only individuals and their families but also community partners are informed,
18
19 9 motivated, and work together. [76] Families and individuals are then supported by the broader
20
21 10 community, which in turn influences the broader policy environment, and vice versa. In this
22
23 11 model, integrated policies span different types of disease and prevention strategies,
24
25 12 consistent financing, the development of human resources, legislative frameworks, and
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27 13 partnerships.
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33 14 **Discussion**

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36 16 A framework for clinical governance promotes an integrated effort to bring together all
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38 17 relevant activities, melding environmental, administrative, support and clinical elements to
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40 18 ensure a coordinated and integrated approach, and thus sustain the provision of better care
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42 19 for patients with chronic disease and multimorbidity.
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46 20 *Quality assurance*

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49 21 There are numerous challenges to providing coordinated and high-quality primary care to
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51 22 patients with chronic disease. For instance, the quality of the management of patients with
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53 23 multiple chronic conditions should be examined, taking the completeness of care into

1 account. [77, 78] There is often a lengthy gap between the generation of new research-based
2 evidence and the application of this evidence in clinical practice. This is true not only for
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4 2 evidence and the application of this evidence in clinical practice. This is true not only for
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6 3 clinical management, but also for organizational management of patients. Knowledge
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8 4 management is achieved by creating, sharing, and applying knowledge, as well as through
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10 5 feeding the valuable lessons learned and best practices into the “corporate memory” to foster
11
12 6 continued organizational learning. [77] This broad remit of knowledge management and the
13
14 7 sharing of knowledge amongst organizational fields includes developing values, structures
15
16 8 and information technology. It places emphasis on how value can be added: the petals should
17
18 9 be revitalized by the atmosphere and ground. Moreover, quality assurance in patients with
19
20 10 chronic illness implies using measures to assess the impact of interventions for chronic
21
22 11 conditions on a patient’s daily functioning and quality of life. A number of measures from the
23
24 12 Medical Outcomes Study have been used in studies of multi-morbidity in primary healthcare
25
26 13 [79]. An advantage of using such measures for patients with multimorbidity lies in that it does
27
28 14 not focus on the care provided for specific diseases. Overuse of healthcare has also been
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30 15 assessed by examining hospitalization rates for ambulatory care sensitive conditions (ACSC),
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32 16 i.e. conditions for which it is believed that well organized delivery of high quality primary care
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34 17 services can prevent the need for hospitalization [80, 81]. Overuse of healthcare has also
35
36 18 been measured in terms of the frequency of hospitalization and emergency department
37
38 19 attendance for patients with multiple morbidities [82]. These measures are not disease-
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40 20 specific, so they could be used to assess overall quality of care for patients with multiple
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42 21 health problems. One of the main challenges, which takes a different form in each context, is
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44 22 to develop appropriate incentives that promote and encourage a collective commitment to this
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46 23 alternative paradigm of continuous performance improvement [83]. The organizational
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1 leadership should maintain the organization's focus on the use of information for improvement
2 rather than sanction or punishment. This involves being able to establish a trusting and
3 working relationship with the potential users, and to move away from a controlling or
4 paternalistic approach.

5 *Client Satisfaction*

6 An important consequence of how care of patients with chronic disease is managed relates to
7 perceived quality or satisfaction, which itself is associated with the health of the population as
8 a whole [48]. Patient satisfaction is associated with clinical outcomes, patient retention, and
9 medical malpractice claims, so it is a proxy, but nonetheless is a very effective indicator of the
10 success of a primary care system. Different tools have been developed to assess perceived
11 health quality for chronic diseases. A recent European project [84][focused on perceptions of
12 quality in primary health care in seven countries, highlighting the natural impact of waiting
13 time on patient satisfaction, and the more complex association between equity and access to
14 primary health care services. There is strong evidence that one of the most important
15 determinants affecting satisfaction with health services is the patient-practitioner relationship,
16 including the information the former receives from the latter. [85] This is a crucial issue in the
17 long-term management of chronic conditions. Different conceptual frameworks were created
18 to understand patient's satisfaction, recognised as critical issue to developing service
19 improvement strategies. For example Dagger et al. [48] have proposed service quality as a
20 multidimensional, higher order construct, with four overarching dimensions (interpersonal
21 quality, technical quality, environment quality and administrative quality) and nine sub-
22 dimensions. They suggest that consumers assess service quality at a global level, a
23 dimensional level and at a sub-dimensional level, with each level influencing perceptions at

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2 1 the level above.
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5 2 *Patient Activation and Self Management*
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8 3 The evidence linking patient activation, including person's beliefs, motivation, and actions for
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10 4 self-care, with health outcomes, the patient experience, and cost has grown substantially over
11
12 5 the past decade. [86] Higher activation levels in chronically ill patients are associated with
13
14 6 higher levels of adherence to treatments, self-monitoring of conditions, and regular chronic
15
16 7 care. Patient activation to enhance patients' skills, knowledge and confidence in their ability to
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18 8 take healthy action and manage their disease should therefore be one of the main goals of a
19
20 9 primary care health system. Patient activation can increase the motivation for self-
21
22 10 management for chronic diseases, such as creating durable healthy lifestyle changes and
23
24 11 improving adherence to treatment recommendations. In this respect, self-management
25
26 12 reaches beyond traditional disease management by incorporating the wider concept of
27
28 13 prevention, emphasizing the notion that people who are chronically ill still need preventive
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30 14 services to promote their wellness and mitigate any further deterioration of their health. Self-
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32 15 management is consequently an excellent way to address chronic conditions as a major
33
34 16 public health issue [87]. Researchers have also placed a strong emphasis on the crucial role
35
36 17 of family in patient self-management, recognizing that enhancing families' self-management
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38 18 generates better health outcomes [88]. Despite its important beneficial effects, many factors
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40 19 threaten effective empowerment, including individual patient characteristics, poor
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42 20 technological or IT infrastructure, poor educational or communications strategies, and
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44 21 communication and language barriers between healthcare providers and patients.
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51 22 *Performance Monitoring*
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54 23 Where performance monitoring systems are adopted as a management approach,
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1 performance tends to be better than when such systems are not in place, although reverse
2 causality could be argued higher quality primary care organizations may be more likely to
3 implement performance evaluation. Healthcare professionals are generally keen to measure,
4 know, and demonstrate that they are making an important difference for their patients.
5 Although there is little evidence of its effect on health outcomes or overall value for money
6 [89, 90], the emphasis on performance management in primary care is growing. A recent
7 report highlighted how performance management is influenced by its own understanding, the
8 systems used, and the evaluator- evaluated relationship. [74] Performance management
9 needs an appropriate set of valid of indicators relevant to primary care practice that recognize
10 the complexities of different clinical pathways, multimorbidity, educational and counselling
11 activities, goals, and other activities typical in primary care. [91]

12 An example of such indicators was identified by the Australian Institute of Primary Care, [92]
13 which classified them as discipline-specific, disease-specific, or systemic; these indicators
14 could effectively inform primary care governance. Where instances of poor quality were not
15 assessed, the management was to be ineffective, staff concerns about standards of care
16 were marginalized or worse, adequate improvement systems were not in place, and the
17 service was not seen through the patients' eyes. Clinical pathways are quite popular as a
18 format for translating guidelines into practice and facilitating an integrated approach to care
19 that is supported by scientific evidence, but is also respectful of organizational issues. These
20 pathways design an optimal pathway (or series of pathways) for managing clinical problems
21 within a healthcare organization. Their development engages all of the professionals
22 responsible for managing the disease or problem, and provides an opportunity to establish
23 clinical and organizational indicators, and to define information flows. Certainly, the

1 management of multiple conditions using clinical pathways requires a comprehensive
2 approach that should consider many aspects, such as establishing the patient's priorities,
3
4 evaluating the disease and treatment burdens, and having a discussion of the benefits and
5
6 risks of specific interventions. As part of the patient-health professional relationship, the
7
8 individualised management plan constitutes the foundation of a shared explicit decision-
9
10 making process. It is a written agreement that includes all relevant decisions, such as starting
11
12 or stopping a treatment, anticipating the possible disease evolution, and future healthcare
13
14 appointments. It should assign responsibility for processes and interventions to specific health
15
16 professionals, to ensure appropriate communication with the patient and caregivers, and with
17
18 other providers. [93, 94]
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24 25 26 *Clinical Risk Management* 27

28 In 2012, the WHO prioritized clinical risk management in primary care, forming its Safer
29
30 Primary Care Expert Working Group that recently produced a technical series. [95, 96]
31
32 International data suggest that safety incidents in primary care are mainly diagnostic and
33
34 prescribing errors, with a rate estimated between less than 1 and up to 24 safety incidents per
35
36 100 consultations reviewed. [97] Key elements influencing patient safety are related to
37
38 structural and technological prerequisites (e.g. electronic health records, decision support
39
40 systems), including organizational structure (e.g. leadership, governance structure,
41
42 organization of work shifts, workload); human factors (e.g. individual perception, diligence,
43
44 decision-making ability, professionalism, interpersonal and group dynamics); and community
45
46 characteristics (e.g. epidemiological profile, resilience), and external influences (e.g. media
47
48 and public opinion). At the international level, the commitment to improving safety in primary
49
50 care has focused mainly on building and implementing incident-reporting systems, and on
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1
2 1 proactive or reactive risk analysis systems (e.g. analysis of critical incidents and adverse
3
4 2 events, root cause analysis, failure mode effect analysis). Several interventions in primary
5
6 3 care at the local level have been suggested by national agencies, including improving incident
7
8 4 and adverse event reporting, integrating comprehensive risk management systems, and
9
10 5 continuous learning environments. Specifically, pharmacist-led medication review,
11
12 6 computerised physician order entry, computerised decision support systems, error alert
13
14 7 systems and education of professionals have all been shown to be effective interventions that
15
16 8 could potentially prevent up to half of all errors. [97]
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21 9 *Education and Learning*

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23
24 10 A continuous, proactive learning environment in primary care enables health professionals to
25
26 11 deepen their knowledge and expand their skills, which even at the end of formal postgraduate
27
28 12 professional medical are insufficient to ensure competence and performance over a life-long
29
30 13 career. In addition, continuing professional development systems whose relevance has been
31
32 14 widely recognized [98],. Ways to keep clinicians updated with practice relevant information
33
34 15 have evolved since the late 1990's, in the form of useful criteria to identify patient-oriented,
35
36 16 evidence-based information. One example is the Information Mastery framework, which
37
38 17 emphasizes Patient-Oriented Evidence that Matters (POEMs) of Slawson and Shaughnessy.
39
40 18 [72] POEMs are studies that are relevant to primary care decision-making, have been
41
42 19 assessed for validity, and have the potential to change practice. Each year, only about 200 to
43
44 20 250 studies from the top 100 clinical journals meet these criteria. An evolution of this concept
45
46 21 has been translated into an online resource, Essential Evidence Plus, which is unique in
47
48 22 comparison to other point-of-care tools in that it provides daily emailed POEMs to
49
50 23 subscribers. [99]
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2 1 Regarding the telephone and email consultation skills of clinicians, which are important for
3
4 2 effective remote consulting, we do not yet have strong evidence regarding how health
5
6 3 professionals should be trained to make the best use of this communication challenge.[78]
7
8
9 4 Educational gaming is potentially a way to improve health professionals' knowledge and skills,
10
11 5 in particular for its motivating competitive nature. However, evidence of its effectiveness is
12
13 6 limited, with only two studies identified and no difference seen between the intervention and
14
15 7 control groups. [100]
16
17
18 8 Interprofessional education is increasingly recommended as an approach that has the
19
20 9 potential to improve communication between different types of healthcare providers, as well
21
22 10 as an improved understanding of the skills and capabilities of different team members, and
23
24 11 better team functioning. However, the evidence regarding its effectiveness is limited. In one
25
26 12 study, improvements in diabetic health outcomes, greater attainment of healthcare quality
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28 13 goals, and improved patient satisfaction and team behaviour have been reported and
29
30 14 sustained over time [101].
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34 35 *Conclusions* 36

37
38 16 The number of patients with chronic diseases will continue to increase with the aging of the
39
40 17 population, and the ongoing existence of risk factors for chronic diseases. We offer this
41
42 18 framework with the aim of shedding light on how to reorganize primary care health systems,
43
44 19 identifying and implementing an organic approach to optimizing care for patients with chronic
45
46 20 disease. Implementing such a framework will be a responsibility shared by the public and
47
48 21 private health sectors, as well as by the communities where patients live and the primary
49
50 22 health system operates. Strengthening partnerships with and between these sectors will be
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1 crucial to achieving the vision of a quality of care for multiple chronic conditions.

2 **Contributorship Statement**

3 Alessandra Buja, Roberto Toffanin and Vincenzo Baldo: conceptualization, design of the
4 methodologies, wrote and approved the final manuscript as submitted.

5 Mirko Claus: review analysis, wrote and revised the manuscript, approved the final
6 manuscript as submitted.

7 Gianfranco Damiani: conceptualization, supervision of the study, approved the final
8 manuscript as submitted.

9 Mark Ebell and Walter Ricciardi: supervision, critically reviewed the manuscript, approved the
10 final manuscript as submitted.

11
12 **Data sharing statement:** not pertinent

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Figure 1: Framework for primary care management of chronic disease

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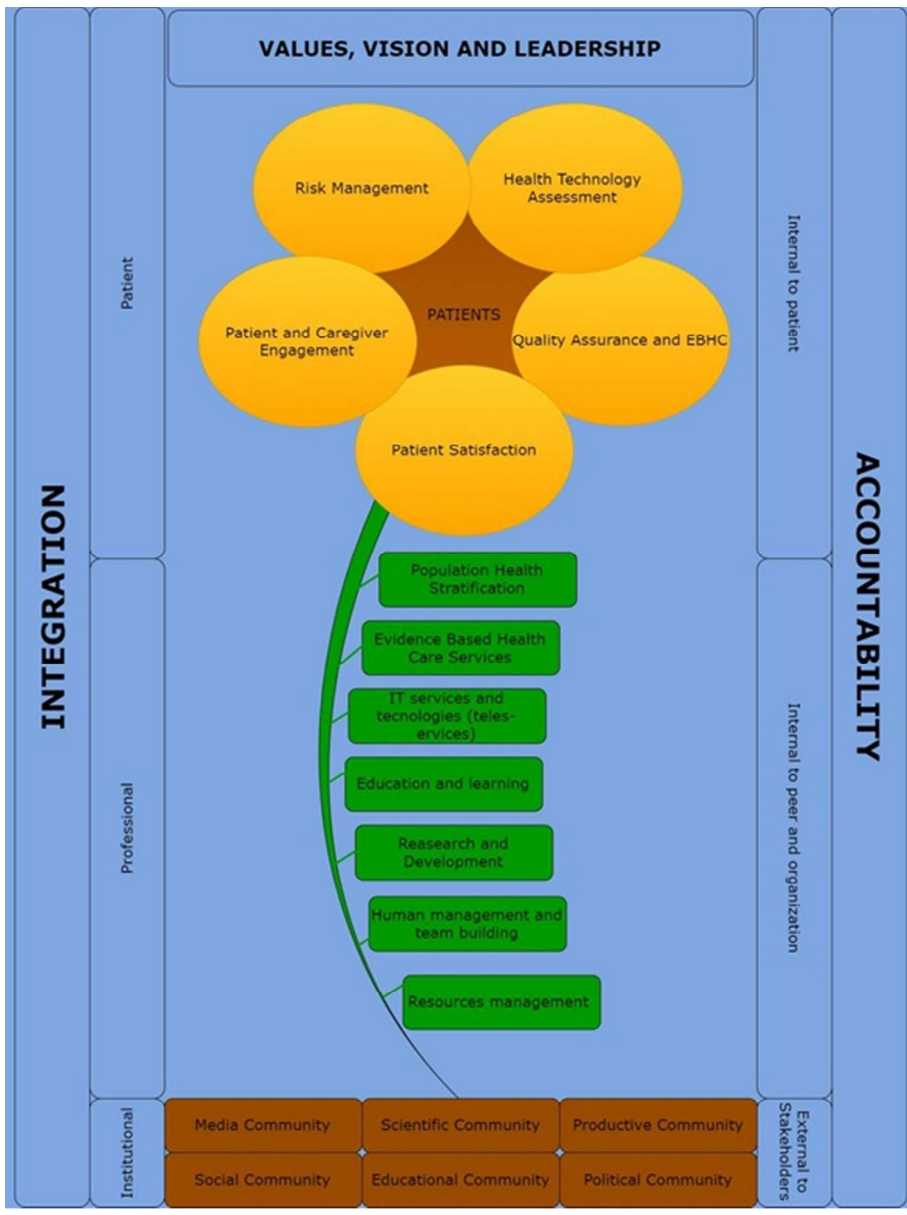
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2 1 Developing a New Clinical Governance Framework for Chronic Diseases in Primary Care: an
3 2 umbrella review
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49 30 of interest.
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51 31 Keywords: primary health care; chronic disease; health care research; health system
52 32 framework;
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1
2 1 Abstract

3
4 2 **Objectives:** Our goal is to conceptualize a clinical governance framework for the effective
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6 3 management of chronic diseases in the primary care setting, which will facilitate a
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8 4 reorganization of healthcare services that systematically improves their performance.
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11 5 **Setting:** Primary care.
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14 6 **Participants:** Wagner's Chronic Care Model and Scally's Clinical Governance statement
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16 7 were taken for reference. Each was reviewed, including their various components. We then
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18 8 conceptualized a new framework, merging the relevant aspects of both
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22 9 **Interventions:** We conducted an umbrella review of all systematic reviews published by the
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24 10 Cochrane Effective Practice and Organisation of Care (EPOC) Group to identify
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26 11 organizational interventions in primary care with demonstrated evidence of efficacy.
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29 12 **Results:** All primary health care systems should be patient-centred. Interventions for patients
30
31 13 and their families should focus on their values; on clinical, professional and institutional
32
33 14 integration; and finally on accountability to patients, peers and society at large. These
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35 15 interventions should be shaped by an approach to their clinical management that achieves
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37 16 the best clinical governance, which includes quality assurance, risk management, technology
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39 17 assessment, management of patient satisfaction, and patient empowerment and
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41 18 engagement. This approach demands the implementation of a system of organizational,
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43 19 functional and professional management based on a population health needs assessment,
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45 20 resource management, evidence-based and patient-oriented research, professional
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47 21 education, team building, and information and communication technologies that support the
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49 22 delivery system. All primary care should be embedded in and founded on an active
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1 partnership with the society it serves.

2 **Conclusions:** A framework for clinical governance will promote an integrated effort to bring
3 together all related activities, melding environmental, administrative, support and clinical
4 elements to ensure a coordinated and integrated approach that sustains the provision of
5 better care for chronic conditions in primary care setting.

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45 2 **Strengths and limitations of this study**
67 3 The study give a new comprehensive framework to drive an effective management of chronic
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9 4 diseases in the primary care setting;
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12 5 A systematic review was made showing all relevant studies in Cochrane Effective Practice
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14 6 and Organisation of Care Group alongside the dimensions of the framework
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17 7 We do not report studies illustrating interventions for a specific unique disease even if chronic
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19 8 disease.
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1 Introduction

2 The dramatic increase in the burden of chronic diseases in the last twenty years represents a
3 primary concern for health services, and global health system sustainability demands a
4 massive shift to primary care [1-3]. As a consequence, the organization and provision of
5 primary care now faces new challenges (e.g. polypharmacy, multimorbidity, fragmentation of
6 care, frequent transitions of care, a need for strong integration, and pressure from patients)
7 [4]. There is currently a growing interest in developed countries to redesign health care
8 organizations, focusing on practices that improve the quality of care and guarantee the
9 equitable, timely and effective management of patients with chronic diseases [5, 6]. In fact, it
10 is now widely recognized that the care and support needed to live with a long-term condition
11 requires a radical re-design of services, by allowing patients to drive the care planning
12 process and by developing a new management of care for people that is proactive, holistic,
13 preventive and patient-centred as for example defined by the “House of Care” model [7]. With
14 these pressures, primary care systems may have difficulty ensuring a coordinated approach,
15 and the lack of clarity concerning their goals has led to divergent approaches, and a slow and
16 often disjointed adoption of changes and improvements. [8]

17 Clinical governance is an umbrella for the systematic administration and coordination of
18 different processes having a direct impact on healthcare delivery, including the management
19 of patients with chronic conditions. It encompasses the tools, methods, and infrastructure
20 devoted to assuring healthcare delivery, continuously improving the quality of the service, and
21 striving towards clinical excellence for patients. Clinical governance was first established in
22 the UK, [9] and has been implemented in many different countries [10-13]. Until now, it has
23 focused largely on in-hospital care, and met with significant difficulties when transferred to

1 primary care. [14] Clinical governance for primary care, focusing on the management of
2 chronic diseases, has specific features and relies on a network of different health
3 professionals working together for their patients' benefit [15] .

4 Our paper aims to conceptualize a clinical governance framework and the tools it needs for
5 the effective management of chronic diseases in the primary care setting, allowing to drive an
6 effective change in healthcare services and thereby systematically improving their quality and
7 safety.

8 9 **Methods**

10 For the purposes of our analysis, we used the Chronic Care Model [16] and Scally's Clinical
11 Governance statement [17] for reference, carefully reviewing each of them and their various
12 components. We then conceptualized a new framework, merging the relevant aspects of
13 both, and also defining and implementing new themes in a way that is relevant for primary
14 care. We ultimately selected five core elements from the original Chronic Care Model
15 (Delivery System Design, Decision Support, Clinical Information Systems, Self-Management
16 Support, The Community) and six approaches (Risk avoidance, Coherence, Infrastructure,
17 Culture, Quality Methods, Poor Performance) from the clinical governance framework
18 described by Scally based on their relevance to primary care and chronic disease
19 management.

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21 We then devised a framework arranged like a sunflower, where the *stem* and *leaves*
22 represent the *structural components* of the system needed to supply and support the *petals*.

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2 1 The petals in turn represent the themes or topics that shape direct actions involving patients
3
4 2 or caregivers (the *bud* of the system). The sunflower is rooted in the *earth*, from where its
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6 3 structural components receive inputs in the form of water and nutrients; in healthcare, inputs
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8 4 from the “soil” enable the provision of primary care, collaboration between service providers,
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10 5 and resources from the outside world. The *atmosphere* in which the sunflower grows informs
11
12 6 the views and attitudes that guide the actions of both health professionals and patients.
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18 8 For each *petal* (i.e. theme or topic), we searched for relevant interventions in the Cochrane
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20 9 Library from 2010 to the end of 2016, in the context of chronic care in the primary care
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22 10 setting. The search strategy used in our umbrella review of the Cochrane Library was based
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24 11 on the MeSH terms: (“general practice*” or “primary care”) and (“chronic disease*” or
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26 12 “multimorbidity”), plus one of the following: 1) “clinical governance”; 2) “quality assurance” or “
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28 13 “evidence-based healthcare”; 3) “satisfaction, patient”; 4) “risk management”; 5)
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30 14 “empowerment” or “health literacy” or “engagement”; 6) “health technology assessment” or
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32 15 “cost-effectiveness” or “cost-utility”. We also identified all systematic reviews published by the
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34 16 Cochrane Effective Practice and Organisation of Care (EPOC) Group that met our criteria.
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36 17 We included all relevant studies published in the Cochrane Review Database from 2010 to
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38 18 06.2017, and excluded all studies illustrating interventions for a specific disease, or those not
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40 19 involving patients with chronic disease.
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48 21 *Patient and Public Involvement*

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50 22 The present study does not involve patients or public
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Results

The resulting conceptual framework is shown in Figure 1. We define three targets where management strategies could be acted:

- 1) The petals consist of the management strategies that directly inform the interventions and clinical practice that acts on and with the patient and their family; primary care delivery happens at the level of the petals level, with the patient at the center.
- 2) The stem represents the underpinning management strategies that support the delivery system, which is the personnel and structures that permit the organization to support the “life of the petals”;
- 3) The ground is the environment in which primary care delivery is located, which gives “nourishment” and foundation.
- 4) Finally, there is the atmosphere, which represents the management strategies that influence the first three targets.

The bud is the center of the flower

Placing personalized patient-centred care at the heart of the system is an important way to create catalysts for change and encourage service re-organization, by focusing on patients' health needs and motivating health system changes [18]. We define patient-centred care as care that is based on continuous, healing relationships among health professionals, patients and their families; care that is customized based on the patients' needs and values; [19] ensuring that the patient is the source of control; sharing knowledge and information freely; and maintaining transparency.

1 *The petals define what and how to act on and with the patients*

2 The petals represent the management strategies that should shape directly the interventions
3 on and with the patients. These dimensions include quality management, perceived quality
4 management, empowerment strategies, risk management, and health technology
5 assessment. The Institute of Medicine in the United States (IOM, now called National
6 Academy of Medicine) defines **quality management** as the degree to which health care
7 services for individuals and populations increase the likelihood of desired health outcomes
8 and are consistent with current professional knowledge [20]. It usually has two facets: quality
9 assurance and quality improvement. In chronic disease management, quality assurance
10 concerns the activities and programs intended to assure or improve the quality of care in a
11 specified medical setting or program. The concept includes assessing (measuring)
12 the quality of care, identifying problems or shortcomings in the delivery of care, designing
13 activities to overcome these deficiencies, and follow-up monitoring to ensure the effectiveness
14 of any corrective action. [21] Quality improvement involves the process of attaining a new,
15 higher level of performance or quality [22]. Adopting the philosophy of evidence-based
16 medicine in planning the diagnosis, care and follow-up of chronic patients has resulted in a
17 more effective and consistent transfer of the lessons learned from research into routine
18 practice, helping to reach higher quality standards [23, 24]. For example a review showed
19 that, in 5 of 17 good-quality RCTs, several different interventions were able to improve both
20 adherence to prescribed medicines and clinical outcomes. These interventions frequently
21 included enhancing support from family, peers, or allied health professionals such as
22 pharmacists, who often delivered education, counselling, or daily treatment support, even if
23 no common features could be identified to explain their success [25] (see table1a).

| Table 1a: Systematic reviews about quality improvement | | | | |
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| Author, Year | Title | Objectives | Inclusion criteria | Main findings |
| Nieuwlaat R, et al 2014 (25) | Interventions for enhancing medication adherence | The primary objective of this review is to assess the effects of interventions intended to enhance patient adherence to prescribed medications for medical conditions, on both medication adherence and clinical outcomes. | We included unconfounded RCTs of interventions to improve adherence with prescribed medications, measuring both medication adherence and clinical outcome, with at least 80% follow-up of each group studied and, for long-term treatments, at least six months follow-up for studies with positive findings at earlier time points. | The present update included 109 new studies, bringing the total number to 182. In the 17 studies of the highest quality, interventions were generally complex with several different ways to try to improve medicine adherence. These frequently included enhanced support from family, peers, or allied health professionals such as pharmacists, who often delivered education, counseling, or daily treatment support. Only five of these RCTs improved both medicine adherence and clinical outcomes, and no common characteristics for their success could be identified. Overall, even the most effective interventions did not lead to large improvements. |
| Smith SM et al, 2016 (26) | Interventions for improving outcomes in patients with multimorbidity in primary care and community settings | To determine the effectiveness of health-service or patient-oriented interventions designed to improve outcomes in people with multimorbidity in primary care and community settings. Multimorbidity was defined as two or more chronic conditions in the same individual. | We considered randomised controlled trials (RCTs), non-randomised clinical trials (NRCTs), controlled before-after studies (CBAs), and interrupted time series analyses (ITS) evaluating interventions to improve outcomes for people with multimorbidity in primary care and community settings. This includes studies where participants can have combinations of any condition or have combinations of pre-specified common conditions. The comparison was usual care as delivered in that setting. | Overall the results regarding the effectiveness of interventions were mixed. There were no clear positive improvements in clinical outcomes, health service use, medication adherence, patient-related health behaviours, health professional behaviours or costs. There were modest improvements in mental health outcomes from seven studies that targeted people with depression, and in functional outcomes from two studies targeting functional difficulties in participants. Overall the results indicate that it is difficult to improve outcomes for people with multiple conditions. The review suggests that interventions that are designed to target specific risk factors (for example treatment for depression) or interventions that focus on difficulties that people experience with daily functioning (for example, physiotherapy treatment to improve capacity for physical activity) may be more effective. There is a need for further studies on this topic, particularly involving people with multimorbidity in general across the age ranges |

QUALITY IMPROVEMENT

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| Arditi C et al. 2012 (27) | Computer-generated reminders delivered on paper to healthcare professionals; effects on professional practice and health care outcomes | To evaluate the benefits and harms of rehabilitation interventions directed at maintaining, or improving, physical function for older people in long-term care through the review of randomized and cluster randomized controlled trials. | We included individual or cluster-randomized controlled trials (RCTs) and non-randomized controlled trials (NRCTs) that evaluated the impact of computer-generated reminders delivered on paper to healthcare professionals on processes and/or outcomes of care. | There is moderate quality evidence that computer-generated reminders delivered on paper to healthcare professionals achieve moderate improvement in process of care. Two characteristics emerged as significant predictors of improvement: providing space on the reminder for a response from the clinician and providing an explanation of the reminder’s content or advice. The heterogeneity of the reminder interventions included in this review also suggests that reminders can improve care in various settings under various conditions |
| Thomas RE et al. 2014 (28) | Interventions to increase influenza vaccination rates of those 60 years and older in the community | To assess access, provider, system and societal interventions to increase the uptake of influenza vaccination in people aged 60 years and older in the community. | Randomised controlled trials (RCTs) of interventions to increase influenza vaccination uptake in people aged 60 and older. | There are interventions that are effective for increasing community demand for vaccination, enhancing access and improving provider/system response. In particular effective interventions in this comparison were a letter plus leaflet/postcard compared to a letter, nurses/pharmacists educating plus vaccinating patients, a phone call from a senior, a telephone invitation rather than clinic drop-in, free groceries lottery, and nurses educating and vaccinating patients. We were unable to pool trials of postcard/letter/pamphlets, communications tailored to patients, a customised letter/phone-call or client-based appraisals, but several trials of these interventions showed they were effective. |

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| 1)Krogsbøll LT, et al 2012 (29) | General health checks in adults for reducing morbidity and mortality from disease | We aimed to quantify the benefits and harms of general health checks with an emphasis on patient-relevant outcomes such as morbidity and mortality rather than on surrogate outcomes such as blood pressure and serum cholesterol levels. | We included randomised trials comparing health checks with no health checks in adults unselected for disease or risk factors. We did not include geriatric trials. We defined health checks as screening general populations for more than one disease or risk factor in more than one organ system. | <p>There was no effect on the risk of death, or on the risk of death due to cardiovascular diseases or cancer.</p> <p>We did not find an effect on the risk of illness but one trial found an increased number of people identified with high blood pressure and high cholesterol, and one trial found an increased number with chronic diseases. One trial reported the total number of new diagnoses per participant and found a 20% increase over six years compared to the control group. No trials compared the total number of new prescriptions but two out of four trials found an increased number of people using drugs for high blood pressure. Two out of four trials found that health checks made people feel somewhat healthier, but this result is not reliable. We did not find that health checks had an effect on the number of admissions to hospital, disability, worry, the number of referrals to specialists, additional visits to the physician, or absence from work, but most of these outcomes were poorly studied. None of the trials reported on the number of follow-up tests after positive screening results, or the amount of surgery used.</p> <p>With the large number of participants and deaths included, the long follow-up periods used in the trials, and considering that death from cardiovascular diseases and cancer were not reduced, general health checks are unlikely to be beneficial.</p> |
| Archambault PM 2017 (30) | Collaborative writing applications in healthcare: effects on professional practice and healthcare outcomes | The objectives of this review were to (1) assess the effects of the use of CWAs on process (including the behaviour of healthcare professionals) and patient outcomes, (2) critically appraise and summarise current evidence on the use of resources, costs, and cost-effectiveness associated with CWAs to improve professional practices and patient outcomes, and (3) explore the effects of different CWA features (e.g. open versus closed) and different implementation factors (e.g. the presence of a moderator) on process and patient outcomes. | We included randomised controlled trials (RCTs), non-randomised controlled trials (NRCTs), controlled before-and-after (CBA) studies, interrupted time series (ITS) studies, and repeated measures studies (RMS), in which CWAs were used as an intervention to improve the process of care, patient outcomes, or healthcare costs. | <p>We screened 11,993 studies identified from the electronic database searches and 346 studies from grey literature sources. We analysed the full text of 99 studies. None of the studies met the eligibility criteria; two potentially relevant studies are ongoing.</p> <p>We did not identify any studies that measured the effect of CWAs on how healthcare professionals care for their patients.</p> |

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| | Fiander M, et al. 2015 (31) | Interventions to increase the use of electronic health information by healthcare practitioners to improve clinical practice and patient outcomes | To assess the effects of interventions aimed at improving or increasing healthcare practitioners' use of electronic health information (EHI) on professional practice and patient outcomes. | We included studies that evaluated the effects of interventions to improve or increase the use of EHI by healthcare practitioners on professional practice and patient outcomes. We defined EHI as information accessed on a computer. We defined 'use' as logging into EHI. We considered any healthcare practitioner involved in patient care. We included randomized, non-randomized, and cluster randomized controlled trials (RCTs, NRCTs, CRCTs), controlled clinical trials (CCTs), interrupted time series (ITS), and controlled before-and-after studies (CBAs).The comparisons were: electronic versus printed health information; EHI on different electronic devices (e.g. desktop, laptop or tablet computers, etc.; cell / mobile phones); EHI via different user interfaces; EHI provided with or without an educational or training component; and EHI compared to no other type or source of information. | The results of this review showed that when provided with a combination of EHI and training, practitioners used the information more often. Two studies measured doctors' use of electronic treatment guidelines, but showed that the electronic aspect of the guidelines did not mean that doctors followed the guidelines. This review provided no information on whether more frequent use of EHI translated into improved clinical practice or whether patients were better off when doctors or nurses used health information when treating them. |
| | Flodgren G et al. 2016 (32) | Tools developed and disseminated by guideline producers to promote the uptake of their guidelines | To evaluate the effectiveness of implementation tools developed and disseminated by guideline producers, which accompany or follow the publication of a CPG, to promote uptake. A secondary objective is to determine which approaches to guideline implementation are most effective. | We included randomised controlled trials (RCTs) and cluster-RCTs, controlled before-and-after studies (CBAs) and interrupted time series (ITS) studies evaluating the effects of guideline implementation tools developed by recognised guideline producers to improve the uptake of their own guidelines. The guideline could target any clinical area. | Two of the four included studies reported on how well healthcare professionals stick to guideline recommendations when providing care to their patients, depending on whether they received a CPG with a tool aimed at improving the use of the CPG, or if they received the CPG only. The results of this review show that healthcare professionals who received a guideline tool together with the CPG on the management of non-specific low back pain or ordering thyroid-function tests probably stick more closely to the recommendations, compared with those who received the CPG only. A guideline tool aimed at improving the use of a guideline, may lead to little or no difference in cost to the health service. |

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| 1 2 3 4 5 6 7 8 9 10 11 | Chen CE et al. 2017 (33) | Walk-in clinics versus physician offices and emergency rooms for urgent care and chronic disease management | To assess the quality of care and patient satisfaction of walk-in clinics compared to that of traditional physician offices and emergency rooms for people who present with basic medical complaints for either acute or chronic issues. | Study design: randomized trials, non-randomized trials, and controlled before-after studies. Population: standalone physical clinics not requiring advance appointments or registration, that provided basic medical care without expectation of follow-up. Comparisons: traditional primary care practices or emergency rooms. | Walk-in clinics are growing in popularity around the world, but it is unclear if the medical care provided by walk-in clinics is comparable to that of physicians' offices or emergency rooms. |
| 12 13 14 15 16 17 18 19 20 21 22 23 24 25 26 27 28 29 30 31 32 33 34 35 36 37 | Scott A. et al. 2011 (34) | The effect of financial incentives on the quality of health care provided by primary care physicians | <p>The aim of this review is to examine the effect of changes in the method and level of payment on the quality of care provided by primary care physicians (PCPs) and to identify:</p> <ul style="list-style-type: none"> i) the different types of financial incentives that have improved quality; ii) the characteristics of patient populations for whom quality of care has been improved by financial incentives; and iii) the characteristics of PCPs who have responded to financial incentives. | Randomised controlled trials (RCT), controlled before and after studies (CBA), and interrupted time series analyses (ITS) evaluating the impact of different financial interventions on the quality of care delivered by primary healthcare physicians (PCPs). Quality of care was defined as patient reported outcome measures, clinical behaviours, and intermediate clinical and physiological measures. | The use of financial incentives to reward PCPs for improving the quality of primary healthcare services is growing. However, there is insufficient evidence to support or not support the use of financial incentives to improve the quality of primary health care. Implementation should proceed with caution and incentive schemes should be more carefully designed before implementation. In addition to basing incentive design more on theory, there is a large literature discussing experiences with these schemes that can be used to draw out a number of lessons that can be learned and that could be used to influence or modify the design of incentive schemes. More rigorous study designs need to be used to account for the selection of physicians into incentive schemes. The use of instrumental variable techniques should be considered to assist with the identification of treatment effects in the presence of selection bias and other sources of unobserved heterogeneity. In randomised trials, care must be taken in using the correct unit of analysis and more attention should be paid to blinding. Studies should also examine the potential unintended consequences of incentive schemes by having a stronger theoretical basis, including a broader range of outcomes, and conducting more extensive subgroup analysis. Studies should more consistently describe i) the type of payment scheme at baseline or in the control group, ii) how payments to medical groups were used and distributed within the groups, and iii) the size of the new payments as a percentage of total revenue. Further research comparing the relative costs and effects of financial incentives with other behaviour change interventions is also required. |

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| 1 2 3 4 5 6 7 8 9 10 11 12 13 | Young et al. 2017 (35) | Home or foster home care versus institutional long-term care for functionally dependent older people | To assess the effects of long-term home or foster home care versus institutional care for functionally dependent older people. | We included randomised and non-randomised trials, controlled before-after studies and interrupted time series studies complying with the EPOC study design criteria and comparing the effects of long-term home care versus institutional care for functionally dependent older people. | There are insufficient high-quality published data to support any particular model of care for functionally dependent older people. Community-based care was not consistently beneficial across all the included studies; there were some data suggesting that community-based care may be associated with improved quality of life and physical function compared to institutional care. However, community alternatives to institutional care may be associated with increased risk of hospitalisation. Future studies should assess healthcare utilisation, perform economic analysis, and consider caregiver burden. |
| 14 15 16 17 18 19 20 21 22 23 24 25 26 27 | Nkansah N. et al. 2010 (36) | Effect of outpatient pharmacists' non-dispensing roles on patient outcomes and prescribing patterns | To examine the effect of outpatient pharmacists' non-dispensing roles on patient and health professional outcomes. | Randomized controlled trials comparing 1. Pharmacist services targeted at patients versus services delivered by other health professionals; 2. Pharmacist services targeted at patients versus the delivery of no comparable service; 3. Pharmacist services targeted at health professionals versus services delivered by other health professionals; 4. Pharmacist services targeted at health professionals versus the delivery of no comparable service. | Only one included study compared pharmacist services with other health professional services, hence we are unable to draw conclusions regarding comparisons 1 and 3. Most included studies supported the role of pharmacists in medication/therapeutic management, patient counseling, and providing health professional education with the goal of improving patient process of care and clinical outcomes, and of educational outreach visits on physician prescribing patterns. There was great heterogeneity in the types of outcomes measured across all studies. Therefore a standardized approach to measure and report clinical, humanistic, and process outcomes for future randomized controlled studies evaluating the impact of outpatient pharmacists is needed. Heterogeneity in study comparison groups, outcomes, and measures makes it challenging to make generalised statements regarding the impact of pharmacists in specific settings, disease states, and patient populations. |
| 28 29 30 31 32 33 34 | Gonçalves-Bradley DC, et al 2016 (37) | Discharge planning from hospital | To assess the effectiveness of planning the discharge of individual patients moving from hospital. | Randomised controlled trials (RCTs) that compared an individualised discharge plan with routine discharge care that was not tailored to individual participants. Participants were hospital inpatients. | A discharge plan tailored to the individual patient probably brings about a small reduction in hospital length of stay and reduces the risk of readmission to hospital at three months follow-up for older people with a medical condition. Discharge planning may lead to increased satisfaction with healthcare for patients and professionals. There is little evidence that discharge planning reduces costs to the health service. |

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4 2 However, while many measures of quality of care in the primary care setting have been
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6 3 validated for specific diseases, little has been done to examine the validity or usefulness of
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8 4 these measures in the context of multimorbidity. To guarantee quality assurance it is
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10 5 necessary to consider the deliberate and systematic coordination of an organization's people,
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12 6 technology, processes, and organizational structure in order to add value through innovation,
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14 7 using research to inform practice [38] The systematic coordination and organization of the
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16 8 primary health care team to develop proactive, holistic, preventive and patient-centred models
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18 9 of care has primarily been developed for patients with chronic disease and multimorbidity. A
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20 10 review [26] concluded that health-service or patient-oriented interventions designed to
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22 11 improve outcomes in people with multimorbidity in primary care and community settings
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24 12 improved mainly mental health and functional outcomes. Another study [39] demonstrated the
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26 13 benefits of applying new technologies (telemonitoring) for community-dwelling patients care
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28 14 with chronic disease and multimorbidity, which significantly reduced health care costs,
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30 15 hospital ED admissions, hospital length of stay, and mortality.
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4 2 **Risk management** concerns the systematic identification, assessment and integrated
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6 3 management of current and potential hazards relating to patient care. This is particularly
7
8 4 relevant for the care of complex patients with (“multimorbidity”). [39] The creation of a culture
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10 5 that is free of blame and encourages an open examination of errors and failures is key to
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12 6 improving quality and learning.
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17 8 Clinical incident reporting is a key feature of a risk management system that can improve
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19 9 identification of errors and how we can learn from them. Leape suggests that successful
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21 10 systems provide a safe non-punitive environment, and are simple, timely and inexpensive
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23 11 [40]. However, the effectiveness of such systems in promoting adverse event recording is not
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25 12 clear. To evaluate the effects of interventions designed to increase clinical incident reporting
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27 13 in healthcare settings, Parmelli and colleagues in 2012 conducted a review of four trials with
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29 14 several methodological shortcomings. Despite their limitations, two studies showed the
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31 15 effectiveness of the system implementation: one reported an increase in incident reporting
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33 16 rates, while the second showed a sustained improvement after nine months [41].
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38 17 One review on non-clinical health professional roles, found that older people were more likely
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40 18 to receive appropriate medicines with the provision of a pharmacist led intervention. [42] This
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42 19 service provided by pharmacists that involves identifying, preventing and solving medication-
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44 20 related problems, as well as promoting the correct use of medicines and encouraging health
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46 21 promotion and education. Another strategy found to be useful was computerized support for
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48 22 decision-making. The review focused primarily on process outcomes, and provided only
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50 23 limited evidence of whether these interventions resulted in clinical improvement. Another
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2 1 review found that self-monitoring of medicines and patient self-management programs were
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4 2 generally effective in improving the use of medicines, adherence to prescriptions, reducing
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6 3 adverse events, and improving clinical outcomes. It also found a lower mortality rate among
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8 4 people self-managing their antithrombotic therapy. [41] The same review revealed numerous
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10 5 other promising interventions to improve adherence and other key outcomes related to
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12 6 medicine usage (see Table 1b).
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For peer review only

| Table 1b: Systematic reviews about risk management | | | | | |
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| | Author, Year | Title | Objectives | Inclusion criteria | Main findings |
| RISK MANAGEMENT | Parmelli et al. 2012 (41) | Interventions to increase clinical incident reporting in health care | To assess the effects of interventions designed to increase clinical incident reporting in healthcare settings. | Randomised controlled trials (RCT), controlled before-after studies (CBA) and interrupted time series (ITS) of interventions designed to increase clinical incident reporting in healthcare. | Because of the limitations of the studies it is not possible to draw conclusions for clinical practice. Anyone introducing a system into practice should give careful consideration to conducting an evaluation using a robust design. |
| | Ryan R, et al 2014 (43) | Interventions to improve safe and effective medicines use by consumers: an overview of systematic reviews | To assess the effects of interventions which target healthcare consumers to promote safe and effective medicines use, by synthesising review-level evidence. | We included systematic reviews published on the Cochrane Database of Systematic Reviews and the Database of Abstracts of Reviews of Effects. We identified relevant reviews by hand searching databases from their start dates to March 2012. | Looking across reviews, for most outcomes, medicines self-monitoring and self-management programmes appear generally effective to improve medicines use, adherence, adverse events and clinical outcomes; and to reduce mortality in people self-managing antithrombotic therapy. However, some participants were unable to complete these interventions, suggesting they may not be suitable for everyone. Other promising interventions to improve adherence and other key medicines-use outcomes, which require further investigation to be more certain of their effects, include: <ul style="list-style-type: none"> · simplified dosing regimens: with positive effects on adherence; · interventions involving pharmacists in medicines management, such as medicines reviews (with positive effects on adherence and use, medicines problems and clinical outcomes) and pharmaceutical care services (consultation between pharmacist and patient to resolve medicines problems, develop a care plan and provide follow-up; with positive effects on adherence and knowledge). Several other strategies showed some positive effects, particularly relating to adherence, and other outcomes, but their effects were less consistent overall and so need further study. These included: <ul style="list-style-type: none"> · delayed antibiotic prescriptions: effective to decrease antibiotic use but with mixed effects on clinical outcomes, adverse effects and satisfaction; · practical strategies like reminders, cues and/or organisers, reminder packaging and material incentives: with positive, although somewhat mixed effects on adherence; · education delivered with self-management skills training, counselling, support, training or enhanced follow-up; information and counselling delivered together; or education/information as part of pharmacist-delivered packages of care: with positive effects on adherence, medicines use, clinical outcomes and knowledge, but with mixed effects in some studies; · financial incentives: with positive, but mixed, effects on adherence. Several strategies also showed promise in promoting immunisation uptake, but require further study to be more certain of their effects. These included organisational interventions; reminders and recall; financial incentives; home visits; free vaccination; lay health worker interventions; and facilitators working with physicians to promote immunisation uptake. Education and/or information strategies also showed some positive but even less consistent effects on immunisation uptake, and need further assessment of effectiveness and investigation of heterogeneity. |

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| Patterson SM, et al 2014 (44) | Interventions to improve the appropriate use of polypharmacy for older people | This review sought to determine which interventions, alone or in combination, are effective in improving the appropriate use of polypharmacy and reducing medication-related problems in older people. | A range of study designs were eligible. Eligible studies described interventions affecting prescribing aimed at improving appropriate polypharmacy in people 65 years of age and older in which a validated measure of appropriateness was used (e.g. Beers criteria, Medication Appropriateness Index (MAI)). | This review examines studies in which healthcare professionals have taken action to make sure that older people are receiving the most effective and safest medication for their illness. Actions taken included providing pharmaceutical care, a service provided by pharmacists that involves identifying, preventing and resolving medication-related problems, as well as promoting the correct use of medications and encouraging health promotion and education. Another strategy was computerised decision support, which involves a programme on the doctor's computer that helps him/her to select appropriate treatment. This review provides limited evidence that interventions, such as pharmaceutical care, may be successful in ensuring that older people are receiving the right medicines, but it is not clear whether this always results in clinical improvement. |
| Ivers N. et al 2012 (45) | Audit and feedback: effects on professional practice and healthcare outcomes | To assess the effects of audit and feedback on the practice of healthcare professionals and patient outcomes and to examine factors that may explain variation in the effectiveness of audit and feedback. | Randomised trials of audit and feedback (defined as a summary of clinical performance over a specified period of time) that reported objectively measured health professional practice or patient outcomes. In the case of multifaceted interventions, only trials in which audit and feedback was considered the core, essential aspect of at least one intervention arm were included. | Audit and feedback generally leads to small but potentially important improvements in professional practice. The effectiveness of audit and feedback seems to depend on baseline performance and how the feedback is provided. Future studies of audit and feedback should directly compare different ways of providing feedback. |

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| <p>Gillaizeau F. et al. 2013 (46)</p> | <p>Computerized advice on drug dosage to improve prescribing practice</p> | <p>To assess whether computerized advice on drug dosage has beneficial effects on patient outcomes compared with routine care (empiric dosing without computer assistance).</p> | <p>We included randomized controlled trials, non-randomized controlled trials, controlled before-and-after studies and interrupted time series analyses of computerized advice on drug dosage. The participants were healthcare professionals responsible for patient care. The outcomes were any objectively measured change in the health of patients resulting from computerized advice (such as therapeutic drug control, clinical improvement, adverse reactions).</p> | <p>Computerized advice for drug dosage can benefit people taking certain drugs compared with empiric dosing (where a dose is chosen based on a doctor's observations and experience) without computer assistance. When using the computer system, healthcare professionals prescribed appropriately higher doses of the drugs initially for aminoglycoside antibiotics and the correct drug dose was reached more quickly for oral anticoagulants. It significantly decreased thromboembolism (blood clotting) events for anticoagulants and tended to reduce unwanted effects for aminoglycoside antibiotics and anti-rejection drugs (although not an important difference). It tended to reduce the length of hospital stay compared with routine care with comparable or better cost-effectiveness. There was no evidence of effects on death or clinical side events for insulin (low blood sugar (hypoglycaemia)), anaesthetic agents, anti-rejection drugs (drugs taken to prevent rejection of a transplanted organ) and antidepressants.</p> |
| <p>Allred DP et al. 2016 (47)</p> | <p>Interventions to optimise prescribing for older people in care homes</p> | <p>The objective of the review was to determine the effect of interventions to optimise overall prescribing for older people living in care homes.</p> | <p>We included randomised controlled trials evaluating interventions aimed at optimising prescribing for older people (aged 65 years or older) living in institutionalised care facilities. Studies were included if they measured one or more of the following primary outcomes: adverse drug events; hospital admissions; mortality; or secondary outcomes, quality of life (using validated instrument); medication-related problems; medication appropriateness (using validated instrument); medicine costs.</p> | <p>We could not draw robust conclusions from the evidence due to variability in design, interventions, outcomes and results. The interventions implemented in the studies in this review led to the identification and resolution of medication-related problems and improvements in medication appropriateness, however evidence of a consistent effect on resident-related outcomes was not found. There is a need for high-quality cluster-randomised controlled trials testing clinical decision support systems and multidisciplinary interventions that measure well-defined, important resident-related outcomes.</p> |

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2 1 **Patient satisfaction** is fundamental in the case of patients with chronic disease who are
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4 2 likely to be involved in a lasting relationship with healthcare services. It is linked to patients'
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6 3 expectations of ideal care and their actual experience of care [48], and it is considered by
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8 4 most as a multi-dimensional construct including multiple domains such as accessibility,
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10 5 organizational characteristics of the system, clinical and communication skills, and the doctor-
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12 6 patient relationship, among others. Long waiting lists for non-urgent health procedures are
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14 7 quite common and may affect the health professional-patient relationship, causing distress for
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16 8 patients and their caregivers and distrust of the health care system. Improving access by
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18 9 implementing an open access or direct booking for some health problems or referrals has
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20 10 been shown to improve patient satisfaction [49]. Home-based interventions for end-of-life care
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23 11 have also been shown to improve both patient and caregivers satisfaction [50] (see table 1c).
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Table 1c: Systematic reviews about patient satisfaction

| | Author, Year | Title | Objectives | Inclusion criteria | Main findings |
|-----------------------------|------------------------------|---|--|---|--|
| PATIENT SATISFACTION | Ballini L. et al. 2015 (49) | Interventions to reduce waiting times for elective procedures | To assess the effectiveness of interventions aimed at reducing waiting times for elective care, both diagnostic and therapeutic. | We considered randomised controlled trials (RCTs), controlled before-after studies (CBAs) and interrupted time series (ITS) designs that met EPOC minimum criteria and evaluated the effectiveness of any intervention aimed at reducing waiting times for any type of elective procedure. We considered studies reporting one or more of the following outcomes: number or proportion of participants whose waiting times were above or below a specific time threshold, or participants' mean or median waiting times. Comparators could include any type of active intervention or standard practice. | As only a handful of low-quality studies are presently available, we cannot draw any firm conclusions about the effectiveness of the evaluated interventions in reducing waiting times. However, interventions involving the provision of more accessible services (open access or direct booking/referral) show some promise. |
| | Shepeprd S. et al. 2016 (50) | Hospital at home: home-based end-of-life care | To determine if providing home-based end-of-life care reduces the likelihood of dying in hospital and what effect this has on patients' symptoms, quality of life, health service costs, and caregivers, compared with inpatient hospital or hospice care. | Randomised controlled trials, interrupted time series, or controlled before and after studies evaluating the effectiveness of home-based end-of-life care with inpatient hospital or hospice care for people aged 18 years and older. | The evidence included in this review supports the use of home-based end-of-life care programmes for increasing the number of people who will die at home, although the numbers of people admitted to hospital while receiving end-of-life care should be monitored. Future research should systematically assess the impact of home-based end-of-life care on caregivers. |
| | Dwamena F, et al 2012 (51) | Interventions for providers to promote a patient-centred approach in clinical consultations | To assess the effects of interventions for healthcare providers that aim to promote patient-centred care (PCC) approaches in clinical consultations. | In the original review, study designs included randomized controlled trials, controlled clinical trials, controlled before and after studies, and interrupted time series studies of interventions for healthcare providers that promote patient-centred care in clinical consultations. In the present update, we were able to limit the studies to randomized controlled trials, thus limiting the likelihood of sampling error. This is especially important because the providers who volunteer for studies of PCC methods are likely to be different from the general population of providers. | Interventions to promote patient-centred care within clinical consultations are effective across studies in transferring patient-centred skills to providers. However the effects on patient satisfaction, health behaviour and health status are mixed. There is some indication that complex interventions directed at providers and patients that include condition-specific educational materials have beneficial effects on health behaviour and health status, outcomes not assessed in studies reviewed previously. The latter conclusion is tentative at this time and requires more data. The heterogeneity of outcomes, and the use of single item consultation and health behaviour measures limit the strength of the conclusions. |

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2 1 **Patient and caregiver engagement** refers to a patient- and family-centred collaborative
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4 2 approach that is tailored to match the fundamental realities of chronic care. Patient and
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6 3 caregiver engagement helps patients discover and develop their inherent capacity to take
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8 4 responsibility for their own life. [52] Empowering patients by providing information and
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10 5 increasing their contribution to the planning of services can greatly influence the development
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12 6 of clinical governance, not only on clinical processes, but also on organizational matters.
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14 7 Contributions from patients will affect not just the responsiveness and performance of
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16 8 healthcare services, but also the process by means of which quality improvement initiatives
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18 9 are identified and prioritized. [53]. Recent reviews of interventions promoting shared medical
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20 10 decision making, with active involvement of both patients and health professionals, have
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22 11 found moderate evidence of better patient involvement. In addition, decision aids (pamphlets,
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24 12 videos or video-based tools) may improve patient's knowledge of their care options, so they
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26 13 feel more informed and better able to participate in decision making [54, 55] (see Table1d) .
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| Table 1d: Systematic reviews about patient and caregiver engagement | | | | | |
|---|---------------------------|--|---|--|--|
| | Author, Year | Title | Objectives | Inclusion criteria | Main findings |
| PATIENT AND CAREGIVER ENGAGEMENT | Légaré F. et al 2014 (54) | Interventions for improving the adoption of shared decision making by healthcare professionals | To determine the effectiveness of interventions to improve healthcare professionals' adoption of SDM. | Randomised and non-randomised controlled trials, controlled before-and-after studies and interrupted time series studies evaluating interventions to improve healthcare professionals' adoption of SDM where the primary outcomes were evaluated using observer-based outcome measures (OBOM) or patient-reported outcome measures (PROM). | It is uncertain whether interventions to improve adoption of SDM are effective given the low quality of the evidence. However, any intervention that actively targets patients, healthcare professionals, or both, is better than none. Also, interventions targeting patients and healthcare professionals together show more promise than those targeting only one or the other. |
| | Stacey et al. 2017 (55) | Decision Aids for People Facing Health Treatment or Screening Decisions | To assess the effects of decision aids in people facing treatment or screening decisions. | We included published randomized controlled trials comparing decision aids to usual care and/or alternative interventions. For this update, we excluded studies comparing detailed versus simple decision aids. | Compared to usual care across a wide variety of decision contexts, people exposed to decision aids feel more knowledgeable, better informed, and clearer about their values, and they probably have a more active role in decision making and more accurate risk perceptions. There is growing evidence that decision aids may improve values-congruent choices. There are no adverse effects on health outcomes or satisfaction. New for this updated is evidence indicating improved knowledge and accurate risk perceptions when decision aids are used either within or in preparation for the consultation. |

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| | Ciciriello S, et al 2013 (56) | Multimedia educational interventions for consumers about prescribed and over-the-counter medications | To assess the effects of multimedia patient education interventions about prescribed and over-the-counter medications in people of all ages, including children and carers. | Randomised controlled trials (RCTs) and quasi-RCTs of multimedia-based patient education about prescribed or over-the-counter medications in people of all ages, including children and carers, if the intervention had been targeted for their use. | <p>We found that multimedia education programs about medications are superior to no education or education provided as part of usual clinical care in improving patient knowledge. There was wide variability in the results from the six studies that compared multimedia education to usual care or no education. However, all but one of the six studies favoured multimedia education. We also found that multimedia education is superior to usual care or no education in improving skill levels. The review also suggested that multimedia was at least as effective as other forms of education, including written education or brief education from a health provider. However, these findings were based on a small number of studies, many of which were of low quality.</p> <p>Multimedia education did not improve compliance with medications (i.e. the degree to which a patient correctly follows advice about his or her medication) compared with usual care or no education. We could not determine the effect of multimedia education on other outcomes, such as patient satisfaction, self-efficacy (confidence in their ability to perform health-related tasks) and health outcomes.</p> <p>The review findings therefore suggests that multimedia education programs about medications could be used alongside usual care provided by health providers. There is not enough evidence to recommend it as a replacement for written education or education by a health professional. Multimedia education could be used instead of detailed education given by a health provider when it is not possible or practical for health professionals to provide this service.</p> <p>This review found that there were differences between the types of education provided to the control groups and what results were measured. This limited the ability to summarise results across studies, so most of the conclusions of this review were based on results from a small number of studies. More studies of multimedia educational programs are needed to make the results of this review more reliable.</p> |
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6 3 **Health Technology Assessment (HTA)** refers to the systematic assessment of the
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8 4 properties and effects of a health technology, addressing the direct and intended effects of
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10 5 the technology, as well as its indirect and unintended consequences. The main aims of HTA
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12 6 are to inform decision-making regarding health technologies (bearing in mind the finite
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14 7 resources available), to drive the introduction of innovations, and to identify ineffective or
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16 8 harmful technologies. [57] Whether it involves introducing electro-stimulators for treating
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18 9 incontinence, or disinvesting in old medical ventilators for long-term domiciliary respiratory
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20 10 support, or a new clinical pathway for diabetes, HTA is a robust method for orienting decision-
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22 11 makers and clinicians towards the best available choices (see Table 1e).
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Table 1e: Systematic reviews about cost effectiveness

| | Author, Year | Title | Objectives | Inclusion criteria | Main findings |
|--|-----------------------------|--|---|---|---|
| HTA; COST-EFFECTIVENESS, COST-UTILITY | Atherton H et al, 2012 (58) | Email for clinical communication between patients/care givers and healthcare professionals | To assess the effects of healthcare professionals and patients using email to communicate with each other, on patient outcomes, health service performance, service efficiency and acceptability. | Randomised controlled trials, quasi-randomised trials, controlled before and after studies and interrupted time series studies examining interventions using email to allow patients to communicate clinical concerns to a healthcare professional and receive a reply, and taking the form of 1) unsecured email 2) secure email or 3) web messaging. All healthcare professionals, patients and caregivers in all settings were considered. | <p>Eight of the trials looked at email compared with standard methods of communication. Where email was compared to standard methods of communication we found that we could not properly determine what effect email was having on patient/caregiver outcomes, as there were missing data and the results of the different studies varied. For health service use outcomes the situation was the same, but some results seemed to show that an email intervention may lead to an increased number of emails and telephone calls being received by healthcare professionals.</p> <p>One of the trials looked at email counselling compared with telephone counselling. We found that it only looked at patient outcomes, and found few differences between groups. Where there were differences these showed that telephone counselling leads to greater changes in lifestyle than email counselling.</p> <p>None of the trials measured how email affects healthcare professionals and only one measured whether email can cause harm. All of the trials were biased in some way and when we measured the quality of all of the results we found them to be of low or very low quality.</p> <p>As a result the results of this review should be viewed with caution.</p> <p>The nature of the results means that we cannot make any recommendations for how email might best be used in clinical practice.</p> |
| | Flodgren G, et al 2016 (59) | Interactive telemedicine: effects on professional practice and health care outcomes | To assess the effectiveness, acceptability and costs of interactive TM as an alternative to, or in addition to, usual care (i.e. face-to-face care, or telephone consultation). | We considered randomised controlled trials of interactive TM that involved direct patient-provider interaction and was delivered in addition to, or substituting for, usual care compared with usual care alone, to participants with any clinical condition. We excluded telephone only interventions and wholly automatic self-management TM interventions. | <p>The findings in our review indicate that the use of TM in the management of heart failure appears to lead to similar health outcomes as face-to-face or telephone delivery of care; there is evidence that TM can improve the control of blood glucose in those with diabetes.</p> <p>The cost to a health service, and acceptability by patients and healthcare professionals, is not clear due to limited data reported for these outcomes. The effectiveness of TM may depend on a number of different factors, including those related to the study population e.g. the severity of the condition and the disease trajectory of the participants, the function of the intervention e.g., if it is used for monitoring a chronic condition, or to provide access to diagnostic services, as well as the healthcare provider and healthcare system involved in delivering the intervention.</p> |

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| | Weeks G, et al 2016 (60) | Non-medical prescribing versus medical prescribing for acute and chronic disease management in primary and secondary care | To assess clinical, patient-reported, and resource use outcomes of non-medical prescribing for managing acute and chronic health conditions in primary and secondary care settings compared with medical prescribing (usual care). | Randomised controlled trials (RCTs), cluster-RCTs, controlled before-and-after (CBA) studies (with at least two intervention and two control sites) and interrupted time series analysis (with at least three observations before and after the intervention) comparing: 1. Nonmedical prescribing versus medical prescribing in acute care; 2. non-medical prescribing versus medical prescribing in chronic care; 3. non-medical prescribing versus medical prescribing in secondary care; 4 non-medical prescribing versus medical prescribing in primary care; 5. comparisons between different non-medical prescriber groups; and 6. non-medical healthcare providers with formal prescribing training versus those without formal prescribing training. | The findings suggest that non-medical prescribers, practising with varying but high levels of prescribing autonomy, in a range of settings, were as effective as usual care medical prescribers. Non-medical prescribers can deliver comparable outcomes for systolic blood pressure, glycated haemoglobin, low-density lipoprotein, medication adherence, patient satisfaction, and health-related quality of life. It was difficult to determine the impact of non-medical prescribing compared to medical prescribing for adverse events and resource use outcomes due to the inconsistency and variability in reporting across studies. |
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2 1 *The atmosphere*
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4 2 The atmosphere dimensions defined at this level shape not only the interventions given to
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6 3 patients, as petal dimensions, but also describe activities between professionals inside the
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8 4 organization, as well as the relationship with the civil society. Dimensions of the atmosphere
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10 5 include vision and values, integrated care, and accountability.
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15 7 A well-led organization will monitor whether the **vision and values** of clinical governance are
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17 8 being clearly and effectively communicated to all members of the staff. This communication
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19 9 gives staff a common and consistent purpose, and clear expectations. A clear vision
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21 10 engenders an open-minded and questioning culture, and ensures that both the ethos and the
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23 11 day-to-day delivery of clinical governance remain an integral part of every clinical service.
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27 12 Apart from health system issues, one of the major barriers to the successful transfer of
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29 13 evidence into locally-accepted policies lies in ineffective and unaccountable leaders and
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31 14 managers [61] (see table 1f).
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| Table 1f: Systematic reviews about Leadership, values, vision | | | | | |
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| LEADERSHIP, VALUES, VISION | Author, Year | Title | Objectives | Inclusion criteria | Main findings |
| | Flodgren G. et al. 2011 (62) | Local opinion leaders: effects on professional practice and health care outcomes | To assess the effectiveness of the use of local opinion leaders in improving professional practice and patient outcomes. | Studies eligible for inclusion were randomised controlled trials investigating the effectiveness of using opinion leaders to disseminate evidence-based practice and reporting objective measures of professional performance and/or health outcomes | Opinion leaders alone or in combination with other interventions may successfully promote evidence-based practice, but effectiveness varies both within and between studies. These results are based on heterogeneous studies differing in terms of type of intervention, setting, and outcomes measured. In most of the studies the role of the opinion leader was not clearly described, and it is therefore not possible to say what the best way is to optimise the effectiveness of opinion leaders. |
| | Green C J et al. 2010 (63) | Pharmaceutical policies: effects of restrictions on reimbursement | To determine the effects of a pharmaceutical policy restricting the reimbursement of selected medications on drug use, health care utilization, health outcomes and costs (expenditures). | Included were studies of pharmaceutical policies that restrict coverage and reimbursement of selected drugs or drug classes, often using additional patient specific information related to health status or need. We included randomised controlled trials, non-randomised controlled trials, interrupted time series (ITS) analyses, repeated measures studies and controlled before-after studies set in large care systems or jurisdictions. | Implementing restrictions to coverage and reimbursement of selected medications can decrease third-party drug spending without increasing the use of other health services (6 studies). Relaxing reimbursement rules for drugs used for secondary prevention can also remove barriers to access. Policy design, however, needs to be based on research quantifying the harm and benefit profiles of target and alternative drugs to avoid unwanted health system and health effects. Health impact evaluation should be conducted where drugs are not interchangeable. Impacts on health equity, relating to the fair and just distribution of health benefits in society (sustainable access to publically financed drug benefits for seniors and low income populations, for example), also require explicit measurement. |
| | Jia L. et al. 2014 (64) | Strategies for expanding health insurance coverage in vulnerable populations | To assess the effectiveness of strategies for expanding health insurance coverage in vulnerable populations. | Randomised controlled trials (RCTs), non-randomised controlled trials (NRCTs), controlled before-after (CBA) studies and Interrupted time series (ITS) studies that evaluated the effects of strategies on increasing health insurance coverage for vulnerable populations. We defined strategies as measures to improve the enrolment of vulnerable populations into health insurance schemes. Two categories and six specified strategies were identified as the interventions. | Community-based case managers who provide health insurance information, application support, and negotiate with the insurer probably increase enrolment of children in health insurance schemes. However, the transferability of this intervention to other populations or other settings is uncertain. Handing out insurance application materials in hospital emergency departments may help increase the enrolment of children in health insurance schemes. Further studies evaluating the effectiveness of different strategies for expanding health insurance coverage in vulnerable population are needed in different settings, with careful attention given to study design. |

1
2 1 **Integrated care** is a concept that brings together the inputs, delivery, management and
3
4 2 organization of services related to patients' diagnosis, treatment, care, rehabilitation and
5
6 3 health promotion. As individuals move across healthcare settings and services, the model of
7
8 4 care requires integration and cooperation between a multiplicity of professionals. This
9
10 5 integration and cooperation demands a high degree of collaboration between healthcare
11
12 6 professionals involved in these services, as well as organizational support. This integration
13
14 7 should operate not only within a primary care system, but also through effective
15
16 8 communications between specialist and primary care providers, to guarantee better
17
18 9 transitions of care for patients with chronic disease. The latter has significant positive effects
19
20 10 in reducing hospital readmissions and mortality [65-67] (see table 1g).
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Table 1g: Systematic reviews about integration

| | Author, Year | Title | Objectives | Inclusion criteria | Main findings |
|--------------------|---------------------------|---|---|--|---|
| INTEGRATION | Reeves S et al. 2017 (66) | Interprofessional collaboration to improve professional practice and healthcare outcomes | To assess the impact of practice-based interventions designed to improve interprofessional collaboration (IPC) amongst health and social care professionals, compared to usual care or to an alternative intervention, on at least one of the following primary outcomes: patient health outcomes, clinical process or efficiency outcomes or secondary outcomes (collaborative behaviour). | We included randomised trials of practice-based IPC interventions involving health and social care professionals compared to usual care or to an alternative intervention. | Given that the certainty of evidence from the included studies was judged to be low to very low, there is not sufficient evidence to draw clear conclusions on the effects of IPC interventions. Nevertheless, due to the difficulties health professionals encounter when collaborating in clinical practice, it is encouraging that research on the number of interventions to improve IPC has increased since this review was last updated. While this field is developing, further rigorous, mixed-method studies are required. Future studies should focus on longer acclimatisation periods before evaluating newly implemented IPC interventions, and use longer follow-up to generate a more informed understanding of the effects of IPC on clinical practice. |
| | Smith SM et al. 2017 (68) | Shared care across the interface between primary and specialty care in management of long term conditions | To determine the effectiveness of shared care health service interventions designed to improve the management of chronic disease across the primary/specialty care interface. | We considered randomised controlled trials (RCTs), non-randomised controlled trials (NRCTs), controlled before-after studies (CBAs) and interrupted time series analyses (ITS) evaluating the effectiveness of shared care interventions for people with chronic conditions in primary care and community settings. The intervention was compared with usual care in that setting. | This review suggests that shared care is effective for managing depression. Shared care interventions for other conditions should be developed within research settings, so that further evidence can be considered before they are introduced routinely into health systems. |

| | | | | | |
|--|---------------------------|---|--|--|---|
| | Hayes SL, et al 2012 (69) | Collaboration between local health and local government agencies for health improvement | To evaluate the effects of interagency collaboration between local health and local government agencies on health outcomes in any population or age group. | Randomized controlled trials (RCTs), controlled clinical trials (CCTs), controlled before-and-after studies (CBAs) and interrupted time series (ITS) where the study reported individual health outcomes arising from interagency collaboration between health and local government agencies compared to standard care. Studies were selected independently in duplicate, with no restriction on population subgroup or disease. | Collaboration between local health and local government is commonly considered best practice. However, the review did not identify any reliable evidence that interagency collaboration, compared to standard services, necessarily leads to health improvement. A few studies identified component benefits but these were not reflected in overall outcome scores and could have resulted from the use of significant additional resources. Although agencies appear enthusiastic about collaboration, difficulties in the primary studies and incomplete implementation of initiatives have prevented the development of a strong evidence base. If these weaknesses are addressed in future studies (for example by providing greater detail on the implementation of programmes; using more robust designs, integrated process evaluations to show how well the partners of the collaboration worked together, and measurement of health outcomes) it could provide a better understanding of what might work and why. It is possible that local collaborative partnerships delivering environmental interventions may result in health gain but the evidence base for this is very limited. Evaluations of interagency collaborative arrangements face many challenges. The results demonstrate that collaborative community partnerships can be established to deliver interventions but it is important to agree goals, methods of working, monitoring and evaluation before implementation to protect programme fidelity and increase the potential for effectiveness. |
|--|---------------------------|---|--|--|---|

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2 1 A robust, comprehensive, and transparent **accountability**, with measurement of performance
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4 2 in healthcare activities can ensure that the system is accountable to society at large, to health
5
6 3 professionals and others involved in delivering care, and to patients. A fundamental shift is
7
8 4 needed from a demand-driven model valuing the volume of the production, to a new model
9
10 5 where the providers are accountable for the care outcomes and value that matter to patients
11
12 6 and the broader population. Driving accountability for outcomes and value leads to several
13
14 7 key benefits: it encourages innovation along entire care pathways, to raise quality and reduce
15
16 8 cost; it incentivizes collaboration between providers to co-ordinate care to deliver outcomes; it
17
18 9 clarifies for policy-makers what is being achieved by the money being spent; and it gives
19
20 10 people a stronger voice in their own care and in defining what matters.[70, 71] Such a system
21
22 11 can support effective auditing, which can improve care processes in health districts over the
23
24 12 long term. [71]

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34 15 *The stem defines the means to reach the petals*

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36 16 It is also important to ensure that key underpinning strategies (such as information
37
38 17 technology, education and training, research and dissemination) support the delivery system
39
40 18 to reach the defined petals dimensions. For example, any service re-organization should
41
42 19 involve building better information communication and technology (ICT) systems, to enable a
43
44 20 better exchange of information throughout a newly rearranged organization. An effective
45
46 21 workforce also needs appropriate technical support, such as access to valid best evidence, to
47
48 22 support its clinical decisions. To be useful, the data in information systems must be valid, up-
49
50 23 to-date, and presented in a way that offers insight. It should also be integrated with the

1
2 1 electronic health record, and not provide excessive alerts that lead to “alert fatigue”. Finally, it
3
4 2 should focus on research that provides evidence of improved patient-oriented outcomes,
5
6 3 rather than disease or surrogate markers of improvement. [72]
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11 5 Data to highlight differences in patient outcomes, shortfalls in standards, comparisons with
12
13 6 other services, and time trends are essential. Interconnected electronic health records
14
15 7 support clinicians’ efforts to improve outcomes across the full continuum of care, while
16
17 8 ensuring accountability, engaging patients in making decisions and managing their care,
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19 9 improving safety and care coordination, and avoiding any waste of resources. [73] Data are
20
21 10 essential to managing performance, normally in relation to two subsets of activities:
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23 11 performance evaluation, and performance improvement. Both make use of indicators for
24
25 12 assessment purposes, and the latter also to monitor a healthcare organization’s performance
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27 13 during an improvement process [74]. For patients with multiple chronic conditions, it is also
28
29 14 necessary to devise team indicators and indicators that encompass all the care provided to a
30
31 15 given patient.
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39 17 Improving the training of health care professionals will be important in any effort to re-
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41 18 organize a health care system. For example, if more nurses are going to take on the role of
42
43 19 case study managers, they will need additional training to build their skill base. [75] Ideally,
44
45 20 continuing professional education should not be limited to updating professionals’ technical
46
47 21 skills, knowledge of new research, and improved clinical decision-making. In addition, it
48
49 22 should enable all members of the staff to develop skills that allow them to practice to the
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51 23 maximum of their training, and to assure that their skills are aligned with the organization's
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1 objectives.

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7 3 *The earth defines the ground where primary care is delivered*

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9 4 Community participation should be part of healthcare service planning and evaluation. It is
10
11 5 also essential to mobilize community resources to meet the needs of people with long-term
12
13 6 conditions, creating a culture and mechanisms that promote safe, good-quality care. It has
14
15
16 7 been suggested that positive outcomes for people with long-term conditions are only achieved
17
18 8 when not only individuals and their families but also community partners are informed,
19
20 9 motivated, and work together. [76] Families and individuals are then supported by the broader
21
22
23 10 community, which in turn influences the broader policy environment, and vice versa. In this
24
25 11 model, integrated policies span different types of disease and prevention strategies,
26
27 12 consistent financing, the development of human resources, legislative frameworks, and
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30 13 partnerships.

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33 14 **Discussion**

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36 16 A framework for clinical governance promotes an integrated effort to bring together all
37
38 17 relevant activities, melding environmental, administrative, support and clinical elements to
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40 18 ensure a coordinated and integrated approach, and thus sustain the provision of better care
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43 19 for patients with chronic disease and multimorbidity.

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46 20 *Quality assurance*

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49 21 There are numerous challenges to providing coordinated and high-quality primary care to
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51 22 patients with chronic disease. For instance, the quality of the management of patients with
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54 23 multiple chronic conditions should be examined, taking the completeness of care into

1 account. [77, 78] There is often a lengthy gap between the generation of new research-based
2 evidence and the application of this evidence in clinical practice. This is true not only for
3
4 2 evidence and the application of this evidence in clinical practice. This is true not only for
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6 3 clinical management, but also for organizational management of patients. Knowledge
7
8 4 management is achieved by creating, sharing, and applying knowledge, as well as through
9
10 5 feeding the valuable lessons learned and best practices into the “corporate memory” to foster
11
12 6 continued organizational learning. [77] This broad remit of knowledge management and the
13
14 7 sharing of knowledge amongst organizational fields includes developing values, structures
15
16 8 and information technology. It places emphasis on how value can be added: the petals should
17
18 9 be revitalized by the atmosphere and ground. Moreover, quality assurance in patients with
19
20 10 chronic illness implies using measures to assess the impact of interventions for chronic
21
22 11 conditions on a patient’s daily functioning and quality of life. A number of measures from the
23
24 12 Medical Outcomes Study have been used in studies of multi-morbidity in primary healthcare
25
26 13 [79]. An advantage of using such measures for patients with multimorbidity lies in that it does
27
28 14 not focus on the care provided for specific diseases. Overuse of healthcare has also been
29
30 15 assessed by examining hospitalization rates for ambulatory care sensitive conditions (ACSC),
31
32 16 i.e. conditions for which it is believed that well organized delivery of high quality primary care
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34 17 services can prevent the need for hospitalization [80, 81]. Overuse of healthcare has also
35
36 18 been measured in terms of the frequency of hospitalization and emergency department
37
38 19 attendance for patients with multiple morbidities [82]. These measures are not disease-
39
40 20 specific, so they could be used to assess overall quality of care for patients with multiple
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42 21 health problems. One of the main challenges, which takes a different form in each context, is
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44 22 to develop appropriate incentives that promote and encourage a collective commitment to this
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46 23 alternative paradigm of continuous performance improvement [83]. The organizational
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1 leadership should maintain the organization's focus on the use of information for improvement
2 rather than sanction or punishment. This involves being able to establish a trusting and
3 working relationship with the potential users, and to move away from a controlling or
4 paternalistic approach.

5 *Client Satisfaction*

6 An important consequence of how care of patients with chronic disease is managed relates to
7 perceived quality or satisfaction, which itself is associated with the health of the population as
8 a whole [48]. Patient satisfaction is associated with clinical outcomes, patient retention, and
9 medical malpractice claims, so it is a proxy, but nonetheless is a very effective indicator of the
10 success of a primary care system. Different tools have been developed to assess perceived
11 health quality for chronic diseases. A recent European project [84][focused on perceptions of
12 quality in primary health care in seven countries, highlighting the natural impact of waiting
13 time on patient satisfaction, and the more complex association between equity and access to
14 primary health care services. There is strong evidence that one of the most important
15 determinants affecting satisfaction with health services is the patient-practitioner relationship,
16 including the information the former receives from the latter. [85] This is a crucial issue in the
17 long-term management of chronic conditions. Different conceptual frameworks have been
18 created to understand patient satisfaction, which is recognised as a critical issue to
19 developing service improvement strategies. For example Dagger et al. [48] have proposed
20 service quality as a multidimensional, higher order construct, with four overarching
21 dimensions (interpersonal quality, technical quality, environment quality and administrative
22 quality) and nine sub-dimensions. They suggest that consumers assess service quality at a
23 global level, a dimensional level and at a sub-dimensional level, with each level influencing

1 perceptions at the level above.

2 *Patient Activation and Self Management*

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3 The evidence linking patient activation, including person's beliefs, motivation, and actions for
4 self-care, with health outcomes, the patient experience, and cost has grown substantially over
5 the past decade. [86] Higher activation levels in chronically ill patients are associated with
6 higher levels of adherence to treatments, self-monitoring of conditions, and regular chronic
7 care. Patient activation to enhance patients' skills, knowledge and confidence in their ability to
8 take healthy action and manage their disease should therefore be one of the main goals of a
9 primary care health system. Patient activation can increase the motivation for self-
10 management for chronic diseases, such as creating durable healthy lifestyle changes and
11 improving adherence to treatment recommendations. In this respect, self-management
12 reaches beyond traditional disease management by incorporating the wider concept of
13 prevention, emphasizing the notion that people who are chronically ill still need preventive
14 services to promote their wellness and mitigate any further deterioration of their health. Self-
15 management is consequently an excellent way to address chronic conditions as a major
16 public health issue [87]. Researchers have also placed a strong emphasis on the crucial role
17 of family in patient self-management, recognizing that enhancing families' self-management
18 generates better health outcomes [88]. Despite its important beneficial effects, many factors
19 threaten effective empowerment, including individual patient characteristics, poor
20 technological or IT infrastructure, poor educational or communications strategies, and
21 communication and language barriers between healthcare providers and patients.

22 *Performance Monitoring*

23 Where performance monitoring systems are adopted as a management approach,

1 performance tends to be better than when such systems are not in place, although reverse
2 causality could be argued higher quality primary care organizations may be more likely to
3 implement performance evaluation. Healthcare professionals are generally keen to measure,
4 know, and demonstrate that they are making an important difference for their patients.
5 Although there is little evidence of its effect on health outcomes or overall value for money
6 [89, 90], the emphasis on performance management in primary care is growing. A recent
7 report highlighted how performance management is influenced by its own understanding, the
8 systems used, and the evaluator- evaluated relationship. [74] Performance management
9 needs an appropriate set of valid of indicators relevant to primary care practice that recognize
10 the complexities of different clinical pathways, multimorbidity, educational and counselling
11 activities, goals, and other activities typical in primary care. [91]

12 An example of such indicators was identified by the Australian Institute of Primary Care, [92]
13 which classified them as discipline-specific, disease-specific, or systemic; these indicators
14 could effectively inform primary care governance. Where instances of poor quality were not
15 assessed, the management was to be ineffective, staff concerns about standards of care
16 were marginalized or worse, adequate improvement systems were not in place, and the
17 service was not seen through the patients' eyes. Clinical pathways are quite popular as a
18 format for translating guidelines into practice and facilitating an integrated approach to care
19 that is supported by scientific evidence, but is also respectful of organizational issues. These
20 pathways design an optimal pathway (or series of pathways) for managing clinical problems
21 within a healthcare organization. Their development engages all of the professionals
22 responsible for managing the disease or problem, and provides an opportunity to establish
23 clinical and organizational indicators, and to define information flows. Certainly, the

1 management of multiple conditions using clinical pathways requires a comprehensive
2 approach that should consider many aspects, such as establishing the patient's priorities,
3 evaluating the disease and treatment burdens, and having a discussion of the benefits and
4 risks of specific interventions. As part of the patient-health professional relationship, the
5 individualised management plan constitutes the foundation of a shared explicit decision-
6 making process. It is a written agreement that includes all relevant decisions, such as starting
7 or stopping a treatment, anticipating the possible disease evolution, and future healthcare
8 appointments. It should assign responsibility for processes and interventions to specific health
9 professionals, to ensure appropriate communication with the patient and caregivers, and with
10 other providers. [93, 94]

11 *Clinical Risk Management*

12 In 2012, the WHO prioritized clinical risk management in primary care, forming its Safer
13 Primary Care Expert Working Group that recently produced a technical series. [95, 96]
14 International data suggest that safety incidents in primary care are mainly diagnostic and
15 prescribing errors, with a rate estimated between less than 1 and up to 24 safety incidents per
16 100 consultations reviewed. [97] Key elements influencing patient safety are related to
17 structural and technological prerequisites (e.g. electronic health records, decision support
18 systems), including organizational structure (e.g. leadership, governance structure,
19 organization of work shifts, workload); human factors (e.g. individual perception, diligence,
20 decision-making ability, professionalism, interpersonal and group dynamics); and community
21 characteristics (e.g. epidemiological profile, resilience), and external influences (e.g. media
22 and public opinion). At the international level, the commitment to improving safety in primary
23 care has focused mainly on building and implementing incident-reporting systems, and on

1
2 1 proactive or reactive risk analysis systems (e.g. analysis of critical incidents and adverse
3
4 2 events, root cause analysis, failure mode effect analysis). Several interventions in primary
5
6 3 care at the local level have been suggested by national agencies, including improving incident
7
8 4 and adverse event reporting, integrating comprehensive risk management systems, and
9
10 5 continuous learning environments. Specifically, pharmacist-led medication review,
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12 6 computerised physician order entry, computerised decision support systems, error alert
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14 7 systems and education of professionals have all been shown to be effective interventions that
15
16 8 could potentially prevent up to half of all errors. [97]
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21 9 *Education and Learning*

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24 10 A continuous, proactive learning environment in primary care enables health professionals to
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26 11 deepen their knowledge and expand their skills, which even at the end of formal postgraduate
27
28 12 professional medical are insufficient to ensure competence and performance over a life-long
29
30 13 career. In addition, continuing professional development systems whose relevance has been
31
32 14 widely recognized [98],. Ways to keep clinicians updated with practice relevant information
33
34 15 have evolved since the late 1990's, in the form of useful criteria to identify patient-oriented,
35
36 16 evidence-based information. One example is the Information Mastery framework, which
37
38 17 emphasizes Patient-Oriented Evidence that Matters (POEMs) of Slawson and Shaughnessy.
39
40 18 [72] POEMs are studies that are relevant to primary care decision-making, have been
41
42 19 assessed for validity, and have the potential to change practice. Each year, only about 200 to
43
44 20 250 studies from the top 100 clinical journals meet these criteria. An evolution of this concept
45
46 21 has been translated into an online resource, Essential Evidence Plus, which is unique in
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48 22 comparison to other point-of-care tools in that it provides daily emailed POEMs to
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50 23 subscribers. [99]
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2 1 Regarding the telephone and email consultation skills of clinicians, which are important for
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4 2 effective remote consulting, we do not yet have strong evidence regarding how health
5
6 3 professionals should be trained to make the best use of this communication challenge.[78]
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9 4 Educational gaming is potentially a way to improve health professionals' knowledge and skills,
10
11 5 in particular for its motivating competitive nature. However, evidence of its effectiveness is
12
13 6 limited, with only two studies identified and no difference seen between the intervention and
14
15 7 control groups. [100]
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18 8 Interprofessional education is increasingly recommended as an approach that has the
19
20 9 potential to improve communication between different types of healthcare providers, as well
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22 10 as an improved understanding of the skills and capabilities of different team members, and
23
24 11 better team functioning. However, the evidence regarding its effectiveness is limited. In one
25
26 12 study, improvements in diabetic health outcomes, greater attainment of healthcare quality
27
28 13 goals, and improved patient satisfaction and team behaviour have been reported and
29
30 14 sustained over time [101].
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35 15 This framework however has a number of limits. First of all the umbrella review considered
36
37 16 only Cochrane Effective Practice and Organisation of Care (EPOC) Group and Cochrane
38
39 17 Library database, other systematic review or meta-analysis non included in this paper could
40
41 18 be examined to support and develop evidence based health care management. Another limit
42
43 19 is the difficult to derive evidence easily transferable by researches in health care services. In
44
45 20 fact the generalizability or transferability of health care services research findings from one
46
47 21 setting to another could be also often problematic, in fact the importance of local
48
49 22 organizational context and culture, and the structural differences in health organizations and
50
51 23 health systems make challenging the exportation of organizational models. However the a

1
2 1 culture that supports and encourages innovation in organizational models should stimulate
3
4 2 managers in routinely reviewing the findings of relevant research studies and research
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6 3 syntheses before making important decisions.[102]
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11 12 13 5 *Conclusions*

14
15 6 The number of patients with chronic diseases will continue to increase with the aging of the
16
17 7 population, and the ongoing existence of risk factors for chronic diseases. We offer this
18
19 8 framework with the aim of shedding light on how to reorganize primary care health systems,
20
21 9 identifying and implementing an organic approach to optimizing care for patients with chronic
22
23 10 disease. Implementing such a framework will be a responsibility shared by the public and
24
25 11 private health sectors, as well as by the communities where patients live and the primary
26
27 12 health system operates. Strengthening partnerships with and between these sectors will be
28
29 13 crucial to achieving the vision of a quality of care for multiple chronic conditions.
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35 14 **Contributorship Statement**

36 15 Alessandra Buja, Roberto Toffanin and Vincenzo Baldo: conceptualization, design of the
37 16 methodologies, wrote and approved the final manuscript as submitted.

38 17 Mirko Claus: review analysis, wrote and revised the manuscript, approved the final
39 18 manuscript as submitted.

40 19 Gianfranco Damiani: conceptualization, supervision of the study, approved the final
41 20 manuscript as submitted.

42 21 Mark Ebell and Walter Ricciardi: supervision, critically reviewed the manuscript, approved the
43 22 final manuscript as submitted.

44 23
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46 24 **Data sharing statement:** not pertinent
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Figure 1: Framework for primary care management of chronic disease

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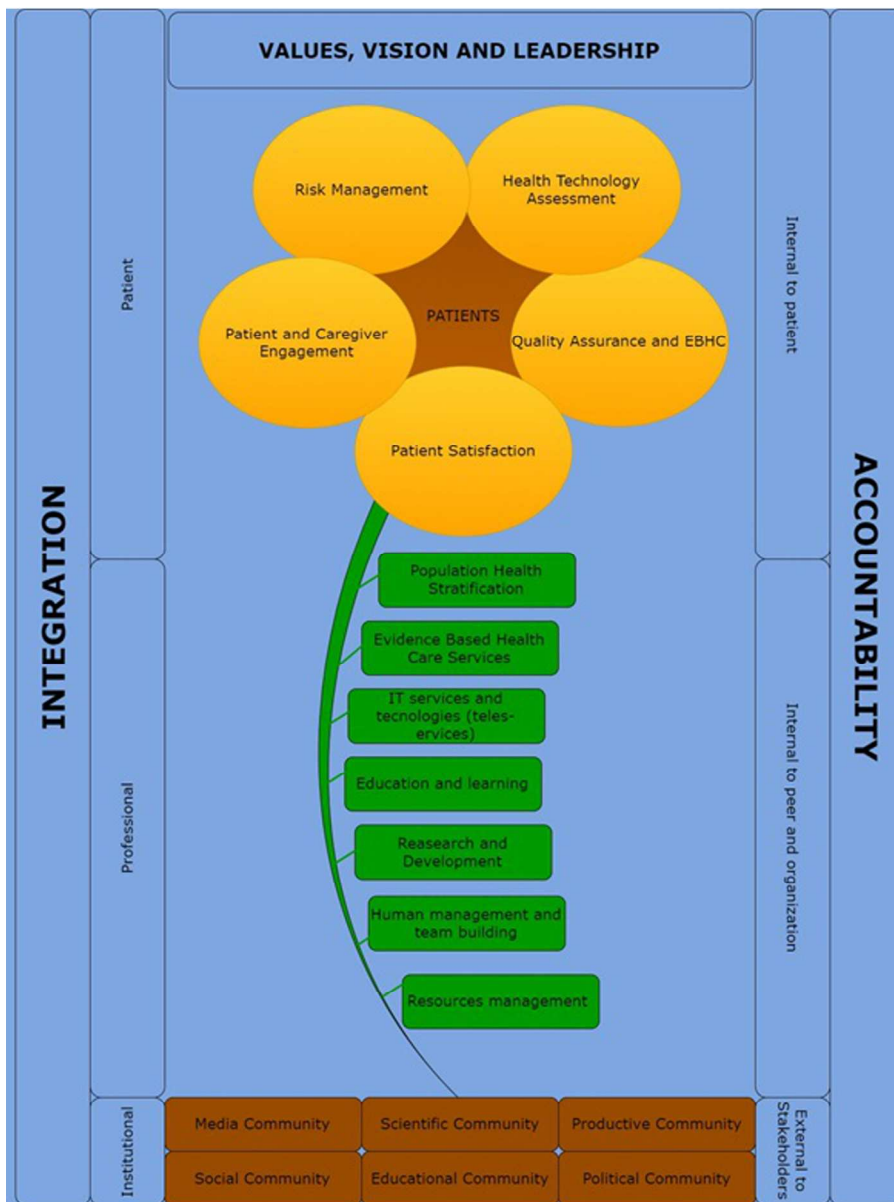
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