

# BMJ Open Developing a new clinical governance framework for chronic diseases in primary care: an umbrella review

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## ABSTRACT

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

**Setting** Primary care.

**Participants** Chronic Care Model by Wagner *et al* and Clinical Governance statement by Scally *et al* were taken for reference. Each was reviewed, including their various components. We then conceptualised 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 Group to identify organisational interventions in primary care with demonstrated evidence of efficacy.

**Results** All primary healthcare 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 organisational, 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 partnership with the society it serves.

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

## INTRODUCTION

The dramatic increase in the burden of chronic diseases in the last 20 years represents a primary concern for health services, and

## Strengths and limitations of this study

- The study gives 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.

global health system sustainability demands a massive shift to primary care.<sup>1–3</sup> As a consequence, the organisation and provision of primary care now faces new challenges (eg, polypharmacy, multimorbidity, fragmentation of care, frequent transitions of care, a need for strong integration and pressure from patients).<sup>4</sup> There is currently a growing interest in high-income countries to redesign healthcare organisations, focusing on practices that improve the quality of care and guarantee the equitable, timely and effective management of patients with chronic diseases.<sup>5,6</sup> In fact, it is now widely recognised that the care and support needed to live with a long-term condition requires a radical re-design of services, by allowing patients to drive the care planning process and by developing a new management of care for people that is proactive, holistic, preventive and patient-centred as for example defined by the ‘House of Care’ model.<sup>7</sup> 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.<sup>8</sup>

Clinical governance is an umbrella for the systematic administration and coordination of different processes having a direct impact on healthcare delivery, including



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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,<sup>9</sup> and has been implemented in many different countries.<sup>10–13</sup> Until now, it has focused largely on in-hospital care, and met with significant difficulties when transferred to primary care.<sup>14</sup> 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.<sup>15</sup>

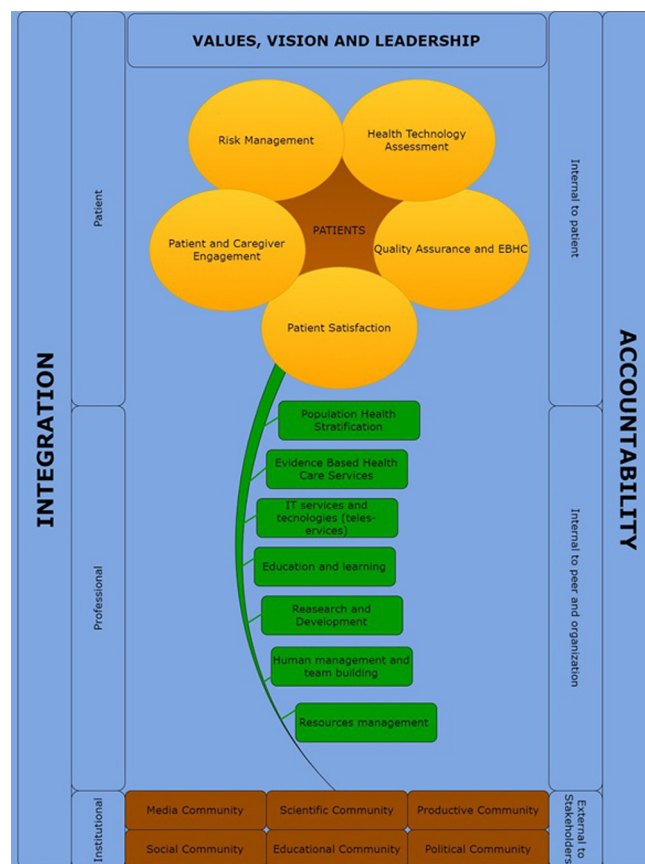
Our paper aims to conceptualise a clinical governance framework and the tools it needs for the effective management of chronic diseases in the primary care setting, allowing to drive an effective change in healthcare services and thereby systematically improving their quality and safety.

## METHODS

For the purposes of our analysis, we used the Chronic Care Model by Wagner *et al*<sup>16</sup> and Clinical Governance statement by Scally *et al*<sup>17</sup> for reference, carefully reviewing each of them and their various components. We then conceptualised a new framework, merging the relevant aspects of both, and also defining and implementing new themes in a way that is relevant for primary care. We ultimately selected five core elements from the original Chronic Care Model (delivery system design, decision support, clinical information systems, self-management support, the community) and six approaches (risk avoidance, coherence, infrastructure, culture, quality methods, poor performance) from the clinical governance framework described by Scally *et al* based on their relevance to primary care and chronic disease management.

We then devised a framework arranged like a sunflower, where the *stem* and *leaves* represent the *structural components* of the system needed to supply and support the *petals*. The petals in turn represent the themes or topics that shape direct actions involving patients or caregivers (the *bud* of the system). The sunflower is rooted in the *earth*, from where its structural components receive inputs in the form of water and nutrients; in healthcare, inputs from the 'soil' enable the provision of primary care, collaboration between service providers and resources from the outside world. The *atmosphere* in which the sunflower grows informs the views and attitudes that guide the actions of both health professionals and patients.

For each *petal* (ie, theme or topic), we searched for relevant interventions in the Cochrane Library from 2010 to the end of 2016, in the context of chronic care in the primary care setting. The search strategy used in our umbrella review of the Cochrane Library was based on the MeSH terms: ('general practice\*' or 'primary care') and ('chronic disease\*' or 'multimorbidity'), plus one of the following: (1) 'clinical governance'; (2) 'quality



**Figure 1** Framework for primary care management of chronic disease. EBHC, Evidence-based healthcare.

assurance' or 'evidence-based healthcare'; (3) 'satisfaction, patient'; (4) 'risk management'; (5) 'empowerment' or 'health literacy' or 'engagement'; (6) 'health technology assessment' or 'cost-effectiveness' or 'cost-utility'. We also identified all systematic reviews published by the Cochrane Effective Practice and Organisation of Care (EPOC) Group that met our criteria. We included all relevant studies published in the Cochrane Review Database from 2010 to June 2017, and excluded all studies illustrating interventions for a specific disease, or those not involving patients with chronic disease.

## Patient and public involvement

The present study does not involve patients or public.

## 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 centre.
2. The stem represents the underpinning management strategies that support the delivery system, which is the personnel and structures that permit the organisation 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 centre of the flower

Placing personalised patient-centred care at the heart of the system is an important way to create catalysts for change and encourage service re-organisation, by focusing on patients' health needs and motivating health system changes.<sup>18</sup> We define patient-centred care as care that is based on continuous, healing relationships among health professionals, patients and their families; care that is customised based on the patients' needs and values<sup>19</sup>; 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 management, empowerment strategies, risk management and health technology assessment. The Institute of Medicine in the USA (now called National Academy of Medicine) defines *quality management* as the degree to which healthcare services for individuals and populations increase the likelihood of desired health outcomes and are consistent with current professional knowledge.<sup>20</sup> It usually has two facets: quality assurance and quality improvement. In chronic disease management, quality assurance concerns the activities and programmes intended to assure or improve the quality of care in a specified medical setting or programme. The concept includes assessing (measuring) the quality of care, identifying problems or shortcomings in the delivery of care, designing activities to overcome these deficiencies and follow-up monitoring to ensure the effectiveness of any corrective action.<sup>21</sup> Quality improvement involves the process of attaining a new, higher level of performance or quality.<sup>22</sup> Adopting the philosophy of evidence-based medicine in planning the diagnosis, care and follow-up of chronic patients has resulted in a more effective and consistent transfer of the lessons learnt from research into routine practice, helping to reach higher quality standards.<sup>23 24</sup> For example, a review showed that, in 5 of 17 good-quality randomised controlled trials, several different interventions were able to improve both adherence to prescribed medicines and clinical outcomes. These interventions frequently included enhancing support from family, peers or allied health professionals such as pharmacists, who often delivered education, counselling or daily treatment support, even if no common features could be identified to explain their success<sup>25</sup> (table 1A).

However, while many measures of quality of care in the primary care setting have been validated for specific diseases, little has been done to examine the validity or usefulness of these measures in the context of multimorbidity. To guarantee quality assurance, it is necessary to consider the deliberate and systematic coordination of an organisation's people, technology, processes and organisational structure in order to add value through innovation, using research to inform practice.<sup>26</sup> The systematic coordination and organisation of the primary healthcare team to develop proactive, holistic, preventive and patient-centred models of care has primarily been developed for patients with chronic disease and multimorbidity. A review<sup>27</sup> concluded that health-service or patient-oriented interventions designed to improve outcomes in people with multimorbidity in primary care and community settings improved mainly mental health and functional outcomes. Another study<sup>28</sup> demonstrated the benefits of applying new technologies (telemonitoring) for community-dwelling patients care with chronic disease and multimorbidity, which significantly reduced healthcare costs, hospital emergency department admissions, hospital length of stay and mortality.

*Risk management* concerns the systematic identification, assessment and integrated management of current and potential hazards relating to patient care. This is particularly relevant for the care of complex patients with ('multimorbidity').<sup>28</sup> The creation of a culture that is free of blame and encourages an open examination of errors and failures is key to improving quality and learning.

Clinical incident reporting is a key feature of a risk management system that can improve identification of errors and how we can learn from them. Leape suggests that successful systems provide a safe non-punitive environment, and are simple, timely and inexpensive.<sup>29</sup> However, the effectiveness of such systems in promoting adverse event recording is not clear. To evaluate the effects of interventions designed to increase clinical incident reporting in healthcare settings, Parmelli *et al* in 2012 conducted a review of four trials with several methodological shortcomings. Despite their limitations, two studies showed the effectiveness of the system implementation: one reported an increase in incident reporting rates, while the second showed a sustained improvement after 9 months.<sup>30</sup>

One review on non-clinical health professional roles found that older people were more likely to receive appropriate medicines with the provision of a pharmacist-led intervention.<sup>31</sup> This service provided by pharmacists that involves identifying, preventing and solving medication-related problems, as well as promoting the correct use of medicines and encouraging health promotion and education. Another strategy found to be useful was computerised support for decision-making. The review focused primarily on process outcomes, and provided only limited evidence of whether these interventions resulted in clinical improvement. Another review found that self-monitoring of medicines and patient

Table 1 Systematic reviews

Author, ref. no	Title	Objectives	Inclusion criteria	Main findings
<b>A: Systematic reviews about quality improvement</b>				
Nieuwlaat R <i>et al</i> <sup>65</sup>	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 randomised controlled trials (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 6 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, counselling 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 <i>et al</i> <sup>67</sup>	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 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 prespecified 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 (eg, treatment for depression) or interventions that focus on difficulties that people experience with daily functioning (eg, 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 <i>et al</i> <sup>77</sup>	Computer-generated reminders delivered on paper to healthcare professionals; effects on professional practice and healthcare 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 RCTs cluster RCTs (CRCTs).	We included individual or CRCTs RCTs and 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 <i>et al</i> <sup>78</sup>	Interventions to increase influenza vaccination rates of those aged 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.	RCTs of interventions to increase influenza vaccination uptake in people aged 60 years 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 with 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.
Krogsbøll LT <i>et al</i> <sup>79</sup>	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 RCTs 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 6 years compared with 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.

Continued

**Table 1** Continued

Author, ref. no	Title	Objectives	Inclusion criteria	Main findings
Archambault PW <sup>60</sup>	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 (eg, open vs closed) and different implementation factors (eg, the presence of a moderator) on process and patient outcomes.	We included RCTs, NRCTs, CBAs, 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 11 983 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.
Fiander M <i>et al</i> <sup>61</sup>	Interventions to increase the use of electronic health information (EHI) 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 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 RCTs, NRCTs, and CROTs, controlled clinical trials (CCTs), ITS and CBAs. The comparisons were: electronic vs printed health information; EHI on different electronic devices (eg, 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 with 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.
Flogdren G <i>et al</i> <sup>63</sup>	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 RCTs and CROTs, CBAs and 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.
Chen CE <i>et al</i> <sup>64</sup>	Walk-in clinics vs 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 with that of traditional physician offices and emergency rooms for people who present with basic medical complaints for either acute or chronic issues.	Study design: RCTs, NRCTs and CBAs. 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 <i>et al</i> <sup>65</sup>	The effect of financial incentives on the quality of healthcare provided by primary care physicians (PCPs)	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 PCPs and to identify: 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; iii. the characteristics of PCPs who have responded to financial incentives.	RCTs, CBAs and ITS evaluating the impact of different financial interventions on the quality of care delivered by 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 healthcare. 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 learnt 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.

Continued

**Table 1** Continued

Author, ref. no	Title	Objectives	Inclusion criteria	Main findings
Young <i>et al</i> <sup>66</sup>	Home or foster home care vs institutional long-term care for functionally dependent older people	To assess the effects of long-term home or foster home care vs institutional care for functionally dependent older people.	We included RCTs and NRCs, CBAs and ITS studies complying with the Cochrane Effective Practice and Organisation of Care (EPoC) Group study design criteria and comparing the effects of long-term home care vs 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 with 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.
Nkansah N <i>et al</i> <sup>67</sup>	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.	RCTs comparing (1) pharmacist services targeted at patients vs services delivered by other health professionals; (2) pharmacist services targeted at patients vs the delivery of no comparable service; (3) pharmacist services targeted at health professionals vs services delivered by other health professionals; (4) pharmacist services targeted at health professionals vs 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 counselling 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 standardised approach to measure and report clinical, humanistic and process outcomes for future randomised 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.
Gonzalves-Bradley DC <i>et al</i> <sup>68</sup>	Discharge planning from hospital	To assess the effectiveness of planning the discharge of individual patients moving from hospital.	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 3 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.
<b>B: Risk management</b>				
Parmelli <i>et al</i> <sup>69</sup>	Interventions to increase clinical incident reporting in healthcare	To assess the effects of interventions designed to increase clinical incident reporting in healthcare settings.	RCTs, CBAs and 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.

Continued

**Table 1** Continued

Author, ref. no	Title	Objectives	Inclusion criteria	Main findings
Ryan R <i>et al</i> <sup>69</sup>	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 antimicrobial 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:</p> <ul style="list-style-type: none"> <li>▲ simplified dosing regimens: with positive effects on adherence;</li> <li>▲ 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).</li> </ul> <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"> <li>▲ delayed antibiotic prescriptions: effective to decrease antibiotic use but with mixed effects on clinical outcomes, adverse effects and satisfaction;</li> <li>▲ practical strategies like reminders, cues and/or organisers, reminder packaging and material incentives: with positive, although somewhat mixed effects on adherence;</li> <li>▲ 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;</li> <li>▲ financial incentives: with positive, but mixed, effects on adherence.</li> </ul> <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>
Patterson SM <i>et al</i> <sup>60</sup>	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 aged 65 years of age and older in which a validated measure of appropriateness was used (eg, Beers criteria, Medication Appropriateness Index).	<p>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.</p> <p>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.</p>
Ivers N <i>et al</i> <sup>61</sup>	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.	<p>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.</p>

Continued

Table 1 Continued

Author, ref. no	Title	Objectives	Inclusion criteria	Main findings
Gillaizeau F <i>et al</i> <sup>62</sup>	Computerised advice on drug dosage to improve prescribing practice	To assess whether computerised advice on drug dosage has beneficial effects on patient outcomes compared with routine care (empiric dosing without computer assistance).	We included RCTs, NRCTs, CBAs and ITS of computerised 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 computerised advice (such as therapeutic drug control, clinical improvement, adverse reactions).	Computerised 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 antiepileptic 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, antirejection drugs (drugs taken to prevent rejection of a transplanted organ) and antidepressants.
<b>C: Patient satisfaction</b>				
Alfred DP <i>et al</i> <sup>63</sup>	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 RCTs 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 CRTs testing clinical decision support systems and multidisciplinary interventions that measure well-defined, important resident-related outcomes.
Ballini L <i>et al</i> <sup>63</sup>	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 RCTs, CBAs and 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.
Sheppard S <i>et al</i> <sup>64</sup>	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.	RCTs, 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 <i>et al</i> <sup>64</sup>	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 approaches in clinical consultations.	In the original review, study designs included RCTs, CCTs, CBAs and ITS studies of interventions for healthcare providers that promote patient-centred care in clinical consultations.	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.
<b>D: Patient and caregiver engagement</b>				
Légaré F <i>et al</i> <sup>67</sup>	Interventions for improving the adoption of shared decision making (SDM) by healthcare professionals	To determine the effectiveness of interventions to improve healthcare professionals' adoption of SDM.	RCTs and NRCTs, CBAs and ITS studies evaluating interventions to improve healthcare professionals' adoption of SDM where the primary outcomes were evaluated using observer-based outcome measures or patient-reported outcome measures.	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.

Continued



**Table 1** Continued

Author, ref. no	Title	Objectives	Inclusion criteria	Main findings
Stacey <i>et al</i> <sup>38</sup>	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 RCTs comparing decision aids with usual care and/or alternative interventions. For this update, we excluded studies comparing detailed vs simple decision aids.	Compared with 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 update is evidence indicating improved knowledge and accurate risk perceptions when decision aids are used either within or in preparation for the consultation.
Ciciriello S <i>et al</i> <sup>35</sup>	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.	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.	We found that multimedia education programmes 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 with 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 (ie, 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.  The review findings therefore suggests that multimedia education programmes 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. 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 programmes are needed to make the results of this review more reliable.
<b>E: Cost-effectiveness health technology assessment; cost-effectiveness, cost-utility</b>				
Atherton H <i>et al</i> <sup>36</sup>	Email for clinical communication between patients/caregivers 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.	RCTs, quasi-RCTs, CBAs and ITS 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.	Eight of the trials looked at email compared with standard methods of communication. Where email was compared with 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.  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.  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.  As a result the results of this review should be viewed with caution.  The nature of the results means that we cannot make any recommendations for how email might best be used in clinical practice.

Continued

Table 1 Continued

Author, ref. no	Objectives	Inclusion criteria	Main findings
Flodgren G <i>et al</i> <sup>82</sup>	To assess the effectiveness, acceptability and costs of interactive TM as an alternative to, or in addition to, usual care (ie, face-to-face care or telephone consultation). healthcare outcomes	We considered RCTs 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.	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.  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, eg, the severity of the condition and the disease trajectory of the participants, the function of the intervention, eg, 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.
Weeks G <i>et al</i> <sup>87</sup>	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). primary and secondary care	RCTs, CRCTs, CBAs (with at least two intervention and two control sites) and ITS (with at least three observations before and after the intervention) comparing: (1) non-medical prescribing vs medical prescribing in acute care; (2) non-medical prescribing vs medical prescribing in chronic care; (3) non-medical prescribing vs medical prescribing in secondary care; (4) non-medical care; (5) comparisons between different non-medical prescriber groups and (6) non-medical healthcare providers with formal prescribing training vs 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, glycosylated 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 with medical prescribing for adverse events and resource use outcomes due to the inconsistency and variability in reporting across studies.
<b>F: Leadership, values, vision</b>			
Flodgren G <i>et al</i> <sup>88</sup>	To assess the effectiveness of the use of local opinion leaders in improving professional practice and patient outcomes. healthcare outcomes	Studies eligible for inclusion were RCTs 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 <i>et al</i> <sup>89</sup>	To determine the effects of a pharmaceutical policy restricting the reimbursement of selected medications on drug use, healthcare utilisation, 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 RCTs, NRCTs, ITS analyses, RMS and CBAs 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 (six 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 (eg, sustainable access to publicly financed drug benefits for seniors and low-income populations), also require explicit measurement.
Jia L <i>et al</i> <sup>100</sup>	To assess the effectiveness of strategies for expanding health insurance coverage in vulnerable populations.	RCTs, NRCTs, CBAs and 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.
<b>G: Integration</b>			
Reeves S <i>et al</i> <sup>42</sup>	To assess the impact of practice-based interventions designed to improve IPC among healthcare and social care professionals, compared with 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 with 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.

Continued

Table 1 Continued

Author, ref. no	Title	Objectives	Inclusion criteria	Main findings
Smith SM <i>et al</i> <sup>01</sup>	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 RCTs, NRCTs, CBAs and 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 <i>et al</i> <sup>02</sup>	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.	RCTs, CCTs, CBAs and ITS where the study reported individual health outcomes arising from interagency collaboration between health and local government agencies compared with 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 with 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 (eg, 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.

CPG, clinical practice guideline; CWA, collaborative writing applications.

self-management programmes were generally effective in improving the use of medicines, adherence to prescriptions, reducing adverse events and improving clinical outcomes. It also found a lower mortality rate among people self-managing their antithrombotic therapy.<sup>30</sup> The same review revealed numerous other promising interventions to improve adherence and other key outcomes related to medicine usage (table 1B).

### Patient satisfaction

*Patient satisfaction* is fundamental in the case of patients with chronic disease who are likely to be involved in a lasting relationship with healthcare services. It is linked to patients' expectations of ideal care and their actual experience of care,<sup>32</sup> and it is considered by most as a multidimensional construct including multiple domains such as accessibility, organisational characteristics of the system, clinical and communication skills and the doctor-patient relationship, among others. Long waiting lists for non-urgent health procedures are quite common and may affect the health professional-patient relationship, causing distress for patients and their caregivers and distrust of the healthcare system. Improving access by implementing an open access or direct booking for some health problems or referrals has been shown to improve patient satisfaction.<sup>33</sup> Home-based interventions for end-of-life care have also been shown to improve both patient and caregivers satisfaction<sup>34</sup> (table 1C).

*Patient and caregiver engagement* refers to a patient-centred and family centred collaborative approach that is tailored to match the fundamental realities of chronic care. Patient and caregiver engagement helps patients discover and develop their inherent capacity to take responsibility for their own life.<sup>35</sup> Empowering patients by providing information and increasing their contribution to the planning of services can greatly influence the development of clinical governance on clinical processes and on organisational matters. Contributions from patients will affect the responsiveness and performance of healthcare services, and the process by means of which quality improvement initiatives are identified and prioritised.<sup>36</sup> Recent reviews of interventions promoting shared medical decision making, with active involvement of both patients and health professionals, have found moderate evidence of better patient involvement. In addition, decision aids (pamphlets, videos or video-based tools) may improve patient's knowledge of their care options, so they feel more informed and better able to participate in decision making<sup>37 38</sup> (table 1D).

*Health technology assessment (HTA)* refers to the systematic assessment of the properties and effects of a health technology, addressing the direct and intended effects of the technology, as well as its indirect and unintended consequences. The main aims of HTA are to inform decision-making regarding health technologies (bearing in mind the finite resources available), to drive the introduction of innovations and to identify ineffective or harmful technologies.<sup>39</sup> Whether it involves introducing

electrostimulators for treating incontinence, or disinvesting in old medical ventilators for long-term domiciliary respiratory support, or a new clinical pathway for diabetes, HTA is a robust method for orienting decision-makers and clinicians towards the best available choices (table 1E).

### The atmosphere

The atmosphere dimensions defined at this level shape the interventions given to patients, as petal dimensions, and describe activities between professionals inside the organisation, as well as the relationship with the civil society. Dimensions of the atmosphere include vision and values, integrated care and accountability.

A well-led organisation will monitor whether the *vision and values* of clinical governance are being clearly and effectively communicated to all members of the staff. This communication gives staff a common and consistent purpose, and clear expectations. A clear vision engenders an open-minded and questioning culture, and ensures that both the ethos and the day-to-day delivery of clinical governance remain an integral part of every clinical service. Apart from health system issues, one of the major barriers to the successful transfer of evidence into locally accepted policies lies in ineffective and unaccountable leaders and managers<sup>40</sup> (table 1F).

*Integrated care* is a concept that brings together the inputs, delivery, management and organisation of services related to patients' diagnosis, treatment, care, rehabilitation and health promotion. As individuals move across healthcare settings and services, the model of care requires integration and cooperation between a multiplicity of professionals. This integration and cooperation demands a high degree of collaboration between healthcare professionals involved in these services, as well as organisational support. This integration should operate within a primary care system, and through effective communications between specialist and primary care providers, to guarantee better transitions of care for patients with chronic disease. The latter has significant positive effects in reducing hospital readmissions and mortality<sup>41-43</sup> (table 1G).

A robust, comprehensive and transparent *accountability*, with measurement of performance in healthcare activities can ensure that the system is accountable to society at large, to health professionals and others involved in delivering care and to patients. A fundamental shift is needed from a demand-driven model valuing the volume of the production, to a new model where the providers are accountable for the care outcomes and value that matter to patients and the broader population. Driving accountability for outcomes and value leads to several key benefits: it encourages innovation along entire care pathways, to raise quality and reduce cost; it incentivises collaboration between providers to coordinate care to deliver outcomes; it clarifies for policy-makers what is being achieved by the money being spent and it gives people a stronger voice in their own care and in defining what

matters.<sup>44 45</sup> Such a system can support effective auditing, which can improve care processes in health districts over the long term.<sup>45</sup>

### The stem defines the means to reach the petals

It is also important to ensure that key underpinning strategies (such as information technology, education and training, research and dissemination) support the delivery system to reach the defined petals dimensions. For example, any service re-organisation should involve building better information communication and technology systems, to enable a better exchange of information throughout a newly rearranged organisation. An effective workforce also needs appropriate technical support, such as access to valid best evidence, to support its clinical decisions. To be useful, the data in information systems must be valid, up-to-date and presented in a way that offers insight. It should also be integrated with the electronic health record, and not provide excessive alerts that lead to 'alert fatigue'. Finally, it should focus on research that provides evidence of improved patient-oriented outcomes, rather than disease or surrogate markers of improvement.<sup>46</sup>

Data to highlight differences in patient outcomes, shortfalls in standards, comparisons with other services and time trends are essential. Interconnected electronic health records support clinicians' efforts to improve outcomes across the full continuum of care, while ensuring accountability, engaging patients in making decisions and managing their care, improving safety and care coordination and avoiding any waste of resources.<sup>47</sup> Data are essential to managing performance, normally in relation to two subsets of activities: performance evaluation and performance improvement. Both make use of indicators for assessment purposes, and the latter also to monitor a healthcare organisation's performance during an improvement process.<sup>48</sup> For patients with multiple chronic conditions, it is also necessary to devise team indicators and indicators that encompass all the care provided to a given patient.

Improving the training of healthcare professionals will be important in any effort to re-organise a healthcare system. For example, if more nurses are going to take on the role of case study managers, they will need additional training to build their skill base.<sup>49</sup> Ideally, continuing professional education should not be limited to updating professionals' technical skills, knowledge of new research and improved clinical decision-making. In addition, it should enable all members of the staff to develop skills that allow them to practice to the maximum of their training, and to assure that their skills are aligned with the organisation's objectives.

### The earth defines the ground where primary care is delivered

Community participation should be part of healthcare service planning and evaluation. It is also essential to mobilise community resources to meet the needs of people with long-term conditions, creating a culture and

mechanisms that promote safe, good-quality care. It has been suggested that positive outcomes for people with long-term conditions are only achieved when individuals and their families and community partners are informed, motivated and work together.<sup>50</sup> Families and individuals are then supported by the broader community, which in turn influences the broader policy environment, and vice versa. In this model, integrated policies span different types of disease and prevention strategies, consistent financing, the development of human resources, legislative frameworks and partnerships.

## DISCUSSION

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

### Quality assurance

There are numerous challenges to providing coordinated and high-quality primary care to patients with chronic disease. For instance, the quality of the management of patients with multiple chronic conditions should be examined, taking the completeness of care into account.<sup>51 52</sup> There is often a lengthy gap between the generation of new research-based evidence and the application of this evidence in clinical practice. This is true for clinical management, and for organisational management of patients. Knowledge management is achieved by creating, sharing and applying knowledge, as well as through feeding the valuable lessons learnt and best practices into the 'corporate memory' to foster continued organisational learning.<sup>51</sup> This broad remit of knowledge management and the sharing of knowledge among organisational fields includes developing values, structures and information technology. It places emphasis on how value can be added: the petals should be revitalised by the atmosphere and ground. Moreover, quality assurance in patients with chronic illness implies using measures to assess the impact of interventions for chronic conditions on a patient's daily functioning and quality of life. A number of measures from the Medical Outcomes Study have been used in studies of multimorbidity in primary healthcare.<sup>53</sup> An advantage of using such measures for patients with multimorbidity lies in that it does not focus on the care provided for specific diseases. Overuse of healthcare has also been assessed by examining hospitalisation rates for ambulatory care sensitive conditions, that is, conditions for which it is believed that well-organised delivery of high-quality primary care services can prevent the need for hospitalisation.<sup>54 55</sup> Overuse of healthcare has also been measured in terms of the frequency of hospitalisation and emergency department attendance for patients with multiple morbidities.<sup>56</sup> These measures are not disease-specific, so they could

be used to assess overall quality of care for patients with multiple health problems. One of the main challenges, which takes a different form in each context, is to develop appropriate incentives that promote and encourage a collective commitment to this alternative paradigm of continuous performance improvement.<sup>57</sup> The organisational leadership should maintain the organisation's focus on the use of information for improvement rather than sanction or punishment. This involves being able to establish a trusting and working relationship with the potential users, and to move away from a controlling or paternalistic approach.

### Client satisfaction

An important consequence of how care of patients with chronic disease is managed relates to perceived quality or satisfaction, which itself is associated with the health of the population as a whole.<sup>32</sup> Patient satisfaction is associated with clinical outcomes, patient retention and medical malpractice claims, so it is a proxy, but nonetheless is a very effective indicator of the success of a primary care system. Different tools have been developed to assess perceived health quality for chronic diseases. A recent European project<sup>58</sup> focused on perceptions of quality in primary healthcare in seven countries, highlighting the natural impact of waiting time on patient satisfaction, and the more complex association between equity and access to primary healthcare services. There is strong evidence that one of the most important determinants affecting satisfaction with health services is the patient-practitioner relationship, including the information the former receives from the latter.<sup>59</sup> This is a crucial issue in the long-term management of chronic conditions. Different conceptual frameworks have been created to understand patient satisfaction, which is recognised as a critical issue to developing service improvement strategies. For example, Dagger *et al*<sup>32</sup> have proposed service quality as a multidimensional, higher order construct, with four overarching dimensions (interpersonal quality, technical quality, environment quality and administrative quality) and nine subdimensions. They suggest that consumers assess service quality at a global level, a dimensional level and at a subdimensional level, with each level influencing perceptions at the level above.

### Patient activation and self-management

The evidence linking patient activation, including person's beliefs, motivation and actions for self-care, with health outcomes, the patient experience and cost has grown substantially over the past decade.<sup>60</sup> Higher activation levels in chronically ill patients are associated with higher levels of adherence to treatments, self-monitoring of conditions and regular chronic care. Patient activation to enhance patients' skills, knowledge and confidence in their ability to take healthy action and manage their disease should therefore be one of the main goals of a primary care health system. Patient activation can increase the motivation for self-management for chronic diseases,

such as creating durable healthy lifestyle changes and improving adherence to treatment recommendations. In this respect, self-management reaches beyond traditional disease management by incorporating the wider concept of prevention, emphasising the notion that people who are chronically ill still need preventive services to promote their wellness and mitigate any further deterioration of their health. Self-management is consequently an excellent way to address chronic conditions as a major public health issue.<sup>61</sup> Researchers have also placed a strong emphasis on the crucial role of family in patient self-management, recognising that enhancing families' self-management generates better health outcomes.<sup>62</sup> Despite its important beneficial effects, many factors threaten effective empowerment, including individual patient characteristics, poor technological or IT infrastructure, poor educational or communications strategies and communication and language barriers between healthcare providers and patients.

### Performance monitoring

Where performance monitoring systems are adopted as a management approach, performance tends to be better than when such systems are not in place. Reverse causality could be argued, higher quality primary care organisations may be more likely to implement performance evaluation. Healthcare professionals are generally keen to measure, know and demonstrate that they are making an important difference for their patients. Although there is little evidence of its effect on health outcomes or overall value for money,<sup>63 64</sup> the emphasis on performance management in primary care is growing. A recent report highlighted how performance management is influenced by its own understanding, the systems used and the evaluator-evaluated relationship.<sup>48</sup> Performance management needs an appropriate set of valid of indicators relevant to primary care practice that recognise the complexities of different clinical pathways, multimorbidity, educational and counselling activities, goals and other activities typical in primary care.<sup>65</sup>

An example of such indicators was identified by the Australian Institute of Primary Care,<sup>66</sup> which classified them as discipline-specific, disease-specific or systemic; these indicators could effectively inform primary care governance. Where instances of poor quality were not assessed, the management was to be ineffective, staff concerns about standards of care were marginalised or worse, adequate improvement systems were not in place and the service was not seen through the patients' eyes. Clinical pathways are quite popular as a format for translating guidelines into practice and facilitating an integrated approach to care that is supported by scientific evidence, but is also respectful of organisational issues. These pathways design an optimal pathway (or series of pathways) for managing clinical problems within a healthcare organisation. Their development engages all of the professionals responsible for managing the

disease or problem, and provides an opportunity to establish clinical and organisational indicators, and to define information flows. Certainly, the management of multiple conditions using clinical pathways requires a comprehensive approach that should consider many aspects, such as establishing the patient's priorities, evaluating the disease and treatment burdens and having a discussion of the benefits and risks of specific interventions. As part of the patient-health professional relationship, the individualised management plan constitutes the foundation of a shared explicit decision-making process. It is a written agreement that includes all relevant decisions, such as starting or stopping a treatment, anticipating the possible disease evolution and future healthcare appointments. It should assign responsibility for processes and interventions to specific health professionals, to ensure appropriate communication with the patient and caregivers, and with other providers.<sup>67 68</sup>

### Clinical risk management

In 2012, WHO prioritised clinical risk management in primary care, forming its Safer Primary Care Expert Working Group that recently produced a technical series.<sup>69 70</sup> International data suggest that safety incidents in primary care are mainly diagnostic and prescribing errors, with a rate estimated between <1 and up to 24 safety incidents per 100 consultations reviewed.<sup>71</sup> Key elements influencing patient safety are related to structural and technological prerequisites (eg, electronic health records, decision support systems), including organisational structure (eg, leadership, governance structure, organisation of work shifts, workload); human factors (eg, individual perception, diligence, decision-making ability, professionalism, interpersonal and group dynamics) and community characteristics (eg, epidemiological profile, resilience), and external influences (eg, media and public opinion). At the international level, the commitment to improving safety in primary care has focused mainly on building and implementing incident-reporting systems, and on proactive or reactive risk analysis systems (eg, analysis of critical incidents and adverse events, root cause analysis, failure mode effect analysis). Several interventions in primary care at the local level have been suggested by national agencies, including improving incident and adverse event reporting, integrating comprehensive risk management systems and continuous learning environments. Specifically, pharmacist-led medication review, computerised physician order entry, computerised decision support systems, error alert systems and education of professionals have all been shown to be effective interventions that could potentially prevent up to half of all errors.<sup>71</sup>

### Education and learning

A continuous, proactive learning environment in primary care enables health professionals to deepen their knowledge and expand their skills, which even at the end of

formal postgraduate professional medical are insufficient to ensure competence and performance over a life-long career. In addition, continuing professional development systems whose relevance has been widely recognised,<sup>72</sup>. Ways to keep clinicians updated with practice relevant information have evolved since the late 1990s, in the form of useful criteria to identify patient-oriented, evidence-based information. One example is the Information Mastery framework, which emphasises Patient-Oriented Evidence that Matters (POEMs) of Slawson *et al.*<sup>46</sup> POEMs are studies that are relevant to primary care decision-making, have been assessed for validity and have the potential to change practice. Each year, only about 200–250 studies from the top 100 clinical journals meet these criteria. An evolution of this concept has been translated into an online resource, Essential Evidence Plus, which is unique in comparison to other point-of-care tools in that it provides daily emailed POEMs to subscribers.<sup>73</sup>

Regarding the telephone and email consultation skills of clinicians, which are important for effective remote consulting, we do not yet have strong evidence regarding how health professionals should be trained to make the best use of this communication challenge.<sup>52</sup> Educational gaming is potentially a way to improve health professionals' knowledge and skills, in particular for its motivating competitive nature. However, evidence of its effectiveness is limited, with only two studies identified and no difference seen between the intervention and control groups.<sup>74</sup>

Interprofessional education is increasingly recommended as an approach that has the potential to improve communication between different types of healthcare providers, as well as an improved understanding of the skills and capabilities of different team members, and better team functioning. However, the evidence regarding its effectiveness is limited. In one study, improvements in diabetic health outcomes, greater attainment of healthcare quality goals and improved patient satisfaction and team behaviour have been reported and sustained over time.<sup>75</sup>

This framework however has a number of limitations. First of all, the umbrella review considered only EPOC Group and Cochrane Library database, other systematic review or meta-analysis not included in this paper could be examined to support and develop evidence-based healthcare management. Another limitation is the difficult to derive evidence easily transferable by researches in healthcare services. In fact, the generalisability or transferability of healthcare services research findings from one setting to another could be also often problematic. Furthermore, the importance of local organisational context and culture, and the structural differences in health organisations and health systems make challenging the exportation of organisational models. However, the a culture that supports and encourages innovation in organisational models should stimulate managers in routinely reviewing the findings of relevant

research studies and research syntheses before making important decisions.<sup>76</sup>

## CONCLUSIONS

The number of patients with chronic diseases will continue to increase with the ageing of the population, and the ongoing existence of risk factors for chronic diseases. We offer this framework with the aim of shedding light on how to reorganise primary care health systems, identifying and implementing an organic approach to optimising care for patients with chronic disease. Implementing such a framework will be a responsibility shared by the public and private health sectors, as well as by the communities where patients live and the primary health system operates. Strengthening partnerships with and between these sectors will be crucial to achieving the vision of a quality of care for multiple chronic conditions.

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