

## **Systematic Review**

# **Clinical Governance in Primary Care; Principles, Prerequisites and Barriers: a Systematic Review**

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### **Abstract**

**Introduction:** Primary care organizations are entities through which clinical governance is developed at a confined level. To implement clinical governance in primary care, awareness of principles, prerequisites and barriers of this quality improvement paradigm is necessary. The aim of this study is to gather evidence of implementing clinical governance in primary care organizations.

**Data sources:** The primary search was conducted in July 2012. PubMed, Web of Science, Emerald, Springer link, and MD Consult were searched using the following MESH keywords; “clinical governance” and “primary care”.

**Study selection:** The search was limited to English language journals with no time limitation. Articles that were either quantitative or qualitative on the concepts of implementing clinical governance in primary care were eligible for this study. From the selected articles, data on principles, prerequisites and barriers of clinical governance in primary health care were extracted and classified in the extraction tables.

**Results:** We categorized our findings about the principles of clinical governance in primary care in four groups; general principles, principles related to staff, patient and communication. Prerequisites were classified in eight clusters; same as the seven dimensions of the National Health System (NHS) models of clinical governance. Barriers were sorted out in five categories; structure, organizing, cultural, resource, theoretical and logistical.

**Conclusion:** Primary care organizations must provide budget holdings, incentivized programs, data feedback, peer reviews, education, human relations, health information technology (HIT) support, and resources. Key elements include; enrolled populations, interdisciplinary team approach, HIT interoperability and access between all providers and patients, devolution of hospital based services into the community, inter-sectorial integration, blended payments, and a balance of clinical, corporate, and communal governance.

**Keywords:** Clinical Governance, Primary Health Care, Organization and Administration; Review Literature as Topic

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## Introduction

Primary health care is an essential health care component based on useful, scientific and socially acceptable manners. Due to technology advances, primary care has become generally accessible to people in the community at an affordable cost. Primary care is the individual and the communities first level of contact with the national health system, bringing health care to the living and functional environment of the people. This health care component composes the first element of a long-lasting health care process (PHC). The universal coverage anticipation of the basic services are aspects such as education on methods of prevention, control of prevailing health problems; promotion of food security and proper nutrition; adequate clean water supply and basic sanitation; maternal and child health consisting of family planning; vaccination; prevention and control of locally endemic diseases; appropriate treatment of common diseases and injuries; and the provision of essential drugs. Primary health care is a vital element the in health systems, because it is the first contact of health system with the community<sup>[1]</sup>. Primary health care is accountable to a wide range of people, local community, ministry of health, peers in primary care groups, actual patients and the regulatory organizations of the profession<sup>[2]</sup>. Fiscal difficulties, advances in information, treatment technologies, the stress on patient rights and preferences have seen a shift from hospital-based care to a community-based provision of care with complex needs.

While the focus of most studies are diagnostic and medicinal errors in hospitals<sup>[3]</sup>, primary care organizations are more commonly prone to errors.<sup>[1]</sup> Data obtained from Bettering the Evaluation And Care of Health in United Kingdom (BEACH), suggests that nearly 1% of the general practice consultation in primary care involves dealing with an adverse event<sup>[3]</sup>. Other researchers estimated 3.7 adverse events per 100,000 primary care general practitioner consultations<sup>[4]</sup>. In the Australian primary care organizations, errors were estimated to occur about one in every 1000 consultations<sup>[5]</sup>.

Primary health care environment is prone to errors in areas of staff, processes and organization. In case of error, the consequences will be more severe than of any other level of health care, therefore, quality improving measures such as clinical governance in primary health care is essential<sup>[2]</sup>.

Although system quality improvements for general practices exist, there have been very few attempts to involve all primary care team members in this quality improvement effort. There are some examples of international actions taken to improve the quality of work in primary care such as peer review and individual feedback on clinical performance in New Zealand, lifelong learning in Germany, and revalidation of doctors in Norway and other countries<sup>[6]</sup>. Moreover, quality improvement programs have been implemented as clinical governance in primary health care in countries such as England, Australia, and New Zealand<sup>[5, 7, 8]</sup>.

Primary care groups are undeveloped organizations, while clinical governance in primary care was initially understood to be an ambitious agenda, so the implementation of clinical governance needs to be further explored<sup>[9,10]</sup>. All members affiliated with primary care need to be familiar with the principles, requirements and barriers to clinical governance as a means to practice evidence based medicine and to reduce variation in access to health services in order to improve the outcomes of health care and improvement of the standard of the care provided<sup>[7,11]</sup>. This study aims to collect existing evidence about the principles, prerequisites and barriers of implementing sufficient and acceptably well clinical governance in primary care, also to help health authorities and primary health care teams to establish more accurate and easier clinical governance in primary care.

## Materials and Methods

This systematic review was conducted in July 2012.

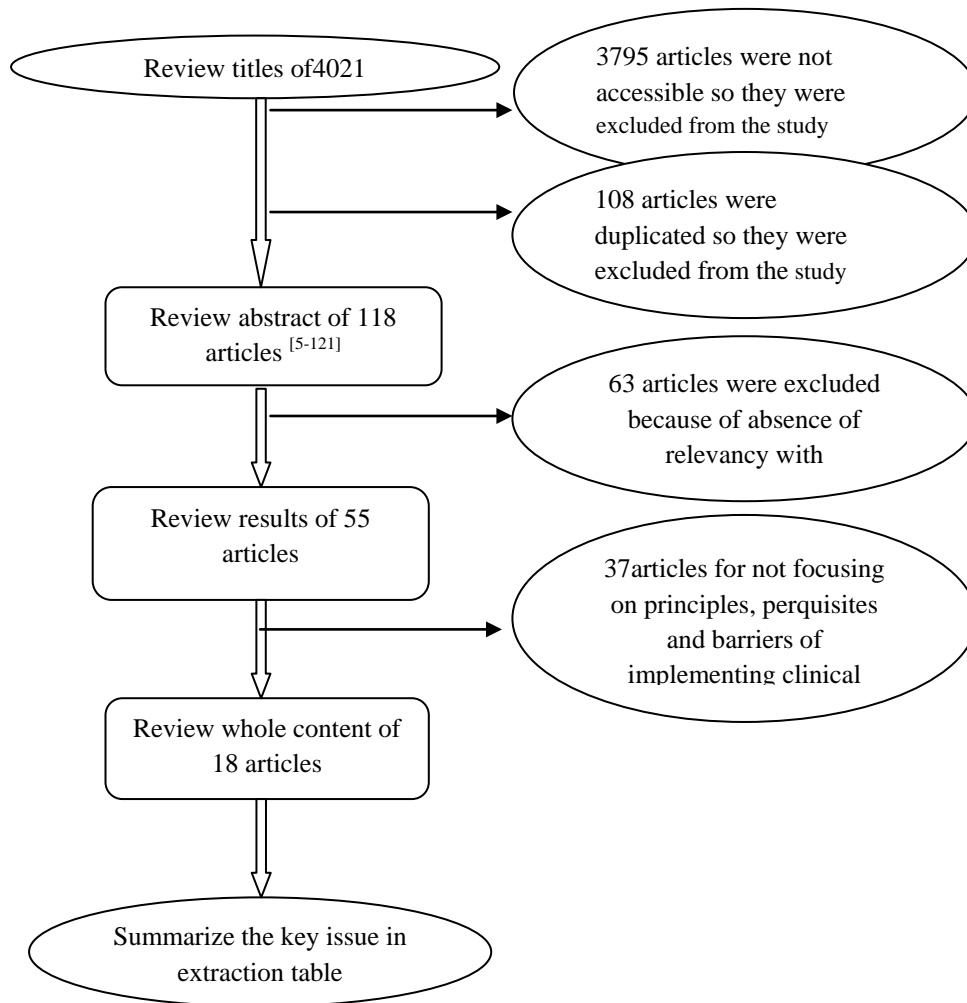
**Eligibility of Studies:** all studies were included if they addressed or consisted of the principles, prerequisites and barriers of implementing clinical governance in primary care. We specifically excluded studies with concepts of implementing clinical governance in hospitals and also studies mentioning nothing about the listed concepts.

Data was extracted from reviews and systematic review studies, case studies, cross sectional studies and qualitative studies, which

specifically aimed to express concepts about the principles, prerequisites and barriers of implementing clinical governance in primary care.

**Search Strategy:** Five electronic databases (Pub Med, Web of Science, Emerald, Springer link, and MD Consult) were searched by one researcher using the following Mesh headings; “clinical governance” + (and) “primary care”. The search was limited to the English language journals and with no time limitation.

Titles and abstracts of all papers identified by the electronic search were inspected by researchers. Papers which clearly failed to satisfy the inclusion criteria for this study were discarded. We subsequently searched the reference lists of the retrieved articles and hand searched the journals with clinical governance in primary care content. This included the following journals; Healthcare Management, and Quality in Health Care and clinical governance. The search process is shown in Figure 1. Meta-analysis was not performed in this study because of the heterogeneity of the included studies. The remainder of articles were studied briefly and Concepts and issues addressed were extracted and classified in appendixes 1. The qualitative process was carried out by application of content analyses approach and the aim was to clarify the stated elements in the literatures which would lead to a greater understanding of principles, prerequisites and barriers of implementing clinical governance in primary care.



**Figure 1.** Different stages of doing research

## Results

Full texts of all 18 articles were studied and the main concepts about principles of implementing clinical governance in primary care were extracted in Table 1.

After identifying the principles of implementing clinical governance in primary care groups, the second step was to collect

prerequisites for the effective implementation of clinical governance in primary care. We categorized these prerequisites in eight groups; leadership, information, education and learning, clinical audit, risk management, staff management, clinical effectiveness and patient involvement. These findings are summarized in Table 2.

**Table 1.** principles of implementing clinical governance in primary health care

Principles of Clinical governance in primary care			
General Principles	Emphasis on entire health system <sup>[19]</sup>	Focus on ability to be self critical and learn constructively from mistakes <sup>[19]</sup>	principles related to staff
	Clinical audit <sup>[10,94]</sup>	Emphasis on Multi professional team work <sup>[6]</sup>	
	Focus on Developing existing activities to improve the quality <sup>[6]</sup>	Applying to all staff <sup>[9]</sup>	
	Corporate approach to quality management <sup>[37]</sup>	Opposed to professional self regulation <sup>[9]</sup>	
	Emphasis on Shared and Continues organization learning <sup>[10,19,17,120,94,37,5]</sup>	Focus on Continually professional development <sup>[53]</sup>	
	Focus on Reducing variation in access to health services <sup>[53]</sup>	Emphasis on Improving performance <sup>[5]</sup>	
	Focus on Developing systems for quality improvement <sup>[6]</sup>	Emphasis on Developing teams for quality improvement <sup>[11,17,19, 120]</sup>	principles related to patient
	Focus on efficiency in use of recourses <sup>[8]</sup>	Focusing on improving quality of patient care <sup>[9]</sup>	
	Risk management <sup>[37,52,121]</sup>	Demanding involvement of patients and the wider public <sup>[9]</sup>	
	Improving Safety <sup>[5,11,121,120]</sup>	Focus on Patient satisfaction <sup>[121]</sup>	
	collective responsibility for the quality of care <sup>[10]</sup>	Focus on Protecting patients <sup>[6]</sup>	
	Evidence based practice <sup>[10,11,27,52,53,94]</sup>	Focusing on individual patients and whole population <sup>[6]</sup>	Principles related to communication
	Emphasis on Innovation practice <sup>[27]</sup>	Demanding true partnership between clinicians, managers and patients <sup>[9]</sup>	
	Emphasis on Research and development <sup>[27]</sup>	Focus on Inter professional and inter sectoral collaboration <sup>[5]</sup>	
	Emphasis on Reducing Complaints <sup>[10,11,27,37,53,94]</sup>	Emphasis on Clinical leadership <sup>[6,17,53]</sup>	
Emphasis on Reducing adverse events <sup>[52,27]</sup>	Emphasis on Clinical supervision <sup>[53]</sup>		
Focus on clinical standards at local level <sup>[52]</sup>	Focus on Keeping High quality data and record <sup>[10]</sup>		
Focus on Learning from experiences <sup>[94]</sup>			
Focus on Improving the standard of care <sup>[52]</sup>	Emphasis on Communication openness <sup>[120]</sup>		
Focus on Improving accountability <sup>[17,19]</sup>			

**Table 2.** prerequisites for effective implementation of clinical governance in primary health care

Prerequisites of Clinical governance in primary care

Leadership prerequisites	
Establishing clinical leadership <sup>[6,7,17]</sup>	Establishing accountability <sup>[5,6,17,19,27,94]</sup>
Requires culture and cultural change <sup>[6,9,17]</sup>	Establishing working relationship <sup>[6]</sup>
Using the power of incentives <sup>[8,37]</sup>	Definition of the organization for clinical quality assurance <sup>[121]</sup>
Definition responsibility for clinical quality assurance <sup>[121]</sup>	Definition authority for clinical quality assurance <sup>[121]</sup>
Definition resource available for clinical quality assurance <sup>[121]</sup>	Description of the clinical governance system and the appropriate procedure to establish, maintain and manage that system <sup>[121]</sup>
Establishing necessary infrastructure to manage <sup>[8]</sup>	Definition of services stake holders, users and how they are consulted and involved in service

Definition and documentation of procedures to control all critical aspects of clinical care <sup>[121]</sup>	delivery and development <sup>[121]</sup> Identification of the arrangement for initial assessment and periodic re assessment of all suppliers, the performance of which may impact upon the quality of clinical care <sup>[121]</sup>
Demonstration that all the performance assessment activities result in clear and tangible service improvement <sup>[121]</sup>	Preparation of an annual report to inform stake holders of clinical governance achievement and activity <sup>[121]</sup>
Multilevel approaches to change at individual, the group or team, the overall organization and the larger system <sup>[17]</sup>	formulating a clinical governance development plan <sup>[6]</sup>
Consideration of ethics such as: encouraging, facilitating, supporting, engaging, inspiring, reflecting, arm- twisting ,being a resource and advocate <sup>[17]</sup>	Establishing peer groups <sup>[8]</sup>
Implementing national service frameworks and local health improvement priorities <sup>[11]</sup>	Making clinical governance part of the everyday routine of primary care groups/teams <sup>[17]</sup>
Increased commitment to the development of people and services <sup>[94]</sup>	Requires change at three levels; by individual health care professionals, teams and primary care organization <sup>[9]</sup>
Supporting needed skills ,advice , etc <sup>[17]</sup>	Establishing baseline assessment of capacity and capability <sup>[6]</sup>
<b>Information prerequisites</b>	
Establishing conducting among staffs <sup>[6]</sup>	Investing in adequate information technology hardware, software and training <sup>[11]</sup>
Assessing local needs <sup>[11]</sup>	Producing comparative data for practices <sup>[11]</sup>
Clarifying reporting arrangement for clinical governance <sup>[6]</sup>	Coordinating relevant information at national level and facilitated locally <sup>[11]</sup>
Preparation of Benchmarked data <sup>[37]</sup>	Implementing clinical decision support systems for consultations <sup>[11]</sup>
Identification of documents and data those are relevant to clinical governance <sup>[121]</sup>	Definition standards used for clinical records <sup>[121]</sup>
Establishing Comprehensive system of communication and decision making <sup>[27]</sup>	Drawing on the experience of quality management systems in other organization <sup>[27]</sup>
Accessing to care providers own data on prescribing test orders, referral patterns and the demographic patterns and illness of their patients <sup>[5]</sup>	Improving clinical records <sup>[53,121]</sup>
Extending computerization in primary care and making internal and email facilities more widely available <sup>[53]</sup>	Disseminating additional knowledge and information on determinants of population health <sup>[11]</sup>
<b>Education and learning prerequisites</b>	
Establishing Organizational development <sup>[6]</sup>	Doing More research to improve safety ,sustainability, efficiency and responsiveness <sup>[5]</sup>
Training and education personals and teams <sup>[6]</sup>	Learning from other primary care groups <sup>[11]</sup>
<b>Clinical audit prerequisites</b>	
Supporting audit activities particularly for single handed and small practice <sup>[6]</sup>	Identifying the practices need for quality improvement <sup>[11]</sup>
Establishing annual appraisal of procedures <sup>[121]</sup>	Assessing inequalities in primary health care <sup>[11]</sup>
Identification of arrangements for external and internal audits and stake holder consultation <sup>[121]</sup>	
<b>Risk management prerequisites</b>	

Establishing Critical incident, adverse event and significant event monitoring <sup>[53]</sup>	Documentation of clinical risk assessments that is appropriate to activity, a clinical incident reporting system and a complaint procedure <sup>[121]</sup>
Establishing Non-punitive response to errors <sup>[120]</sup>	Definition of the controls in place for critical equipment <sup>[121]</sup>
Establishing Feedback and communication about errors <sup>[120]</sup>	Providing Management support for patient safety <sup>[120]</sup>
<b>staff management prerequisites</b>	
Engaging practitioners as partners in a quality improvement <sup>[5]</sup>	Encouraging <sup>[6,17,19,120]</sup>
Definition of the arrangements for staff performance review, personal development plans, continual professional development records, induction system and registration <sup>[121]</sup>	Defining roles and responsibility of staff <sup>[17,121]</sup>
Establishing Personal development plans or personal learning plans <sup>[53]</sup>	Understanding priorities and monitoring staff progress toward agreed standards. <sup>[11]</sup>
Encouraging clinicians to reflect their education needs and meet those needs <sup>[94]</sup>	Establishing personalized feedback to members <sup>[8]</sup>
<b>Establishing Open and the participate culture<sup>[6]</sup></b>	
<b>Clinical effectiveness prerequisites</b>	
Sharing best practice <sup>[37]</sup>	Developing clinical indicator around key areas <sup>[53]</sup>
Dissemination of good practice, ideas and innovation <sup>[10]</sup>	Providing Access to and use of evidence based guidance on cost effective care <sup>[10,11,27,52,53,94]</sup>
<b>Patient involvement prerequisites</b>	
emphasizing on patient care and the protection of patient <sup>[94]</sup>	Establishing Patient surveys <sup>[94]</sup>
Designing complaint procedure <sup>[53,121]</sup>	Establishing Complaints management or revalidation <sup>[94]</sup>

Final stage of the study included collection of barriers in implementing clinical governance in primary care from literature as highlighted in

table3. We have segregated these barriers into five groups; structure & organizing, cultural, resource, theoretical and Logistical barriers.

**Table 3.** Barriers of implementing clinical governance in primary health care

<b>Barriers of Clinical governance in primary care</b>	
<b>Structure &amp; Organizing barriers</b>	
Immature primary care organizations <sup>[9]</sup>	Bureaucratic control in upstream levels of the health system <sup>[8]</sup>
Too few staff to implement clinical governance <sup>[37]</sup>	Initial lack of confidence in primary care providers <sup>[17]</sup>
Lack of clarity of rules between primary care groups and health authority <sup>[37]</sup>	Lack of clarity about carrots and sticks <sup>[17]</sup>
Lack of support or suspicion by practice staff, especially doctors <sup>[37]</sup>	Issues of hierarchy, gender and varied educational achievements in team members <sup>[94]</sup>
The fragmentation of primary care across multiple small providers means that there is no	bringing both quality assurance and improvement integrated in to routine every day practice in

clear professional or managerial hierarchy through which to derive implementation <sup>[6]</sup>	health care <sup>[52]</sup>
Feeling isolated (an outsider) from other parts of the health <sup>[17]</sup>	Continued disengagement by some practices and staff <sup>[37]</sup>
Sense of powerlessness in primary care providers <sup>[17]</sup>	
Cultural barriers	
Difficulties occur among practice teams to adopt clinical governance systems <sup>[11]</sup>	Move away from professional development based on uni-disciplinary education towards multidisciplinary team based learning <sup>[94]</sup>
Dominated rules of doctors in the health system <sup>[17]</sup>	Increased personnel stress <sup>[17]</sup>
The level of autonomy and independence of the practitioners <sup>[19]</sup>	
Resource barriers	
Lack of time to absorb, understand, translate and convey of clinical governance concepts <sup>[17]</sup>	Infrastructure issues such as information technology <sup>[6,11,17,53]</sup>
Differences in primary care groups/teams ability to use computer <sup>[21]</sup>	The embryonic state of information technology in primary care organizations <sup>[6]</sup>
The high Cost of generating some performance indicators <sup>[21]</sup>	
Theoretical barriers	
Lack of adequate direction <sup>[17]</sup>	Difficulties in extracting data and in defining the numerator and denominators of performance indicators <sup>[21]</sup>
Identifying good practice in other area and encouraging its introduction locally <sup>[11]</sup>	Steep learning curve in clinical governance concepts <sup>[17]</sup>
The lack of good information on practice <sup>[5,6,17,37,53]</sup>	
Logistical barriers	
Existence of External control in primary care organization <sup>[17]</sup>	Focus on Short term ( political ) gains <sup>[17]</sup>
Perceived political pressure to deliver rapidly on specific tasks <sup>[19]</sup>	Logistical difficulties in implementing clinical governance <sup>[17]</sup>

## Discussion

In this study, we have divided all principles of clinical governance in primary care into four categories; general principles, staff related principles, patients and communication. General principles constituent elements are similar to other models of clinical governance such as the World Health Organization (WHO) model, which consists of such areas as; clinical effectiveness, clinical audit, openness, risk management, education & training and

research & development<sup>[12]</sup>, and also the England National Health System(NHS) model that covers principles of Patient and public involvement, Clinical risk management, Clinical Audit, Clinical effectiveness, Staffing and staff management, Education, training and continuing personal and professional development and Use of information<sup>[13]</sup>.

In Braithwaite and Travaglia's model of clinical governance, principles of clinical governance advocate a positive attitude



towards quality and safety, planning and organizing governance structures for safety and quality, and using data and evidence sponsoring patient focus <sup>[14]</sup>, while Jaggs-Fowler research principles are clinical audit, leadership, evidence-based practice dissemination of good practice, ideas and innovation, clinical risk reduction, detection of adverse events, learning lessons from complaints, addressing poor clinical performance, professional development programs, high-quality data and record keeping. <sup>[15]</sup> All of these principles have been taken under consideration in our study.

Most studies have highlighted the significant role of leadership in establishing clinical governance in primary health care. Godden et.al (2002) declared four prerequisites to establishing clinical governance in primary health care, firstly, establishing leadership, accountability and working arrangement, secondly, carrying out a baseline assessment of capacity and capability, thirdly, formulating and getting agreements for a development plan, and finally clarifying reporting arrangements for clinical governance <sup>[7]</sup>. Other studies also stated some prerequisites such as; understanding of the need for a multi-level approach for example at the individuals level or group or a team, and the overall organization of a larger system in which individuals and organization are embedded, Cultural change, increased accountability and an increased commitment to the development of staff and services and a renewal of the emphasis on patient care and the protection of

patient <sup>[16, 17]</sup>. In order to cover all prerequisites of implementing clinical governance in primary care, we have put our prerequisites on seven pillars of NHS models because this model was the most widely cited formal model of clinical governance <sup>[5, 6, 10, 15]</sup>. We have added leadership prerequisites due to the important roles of leaders and managers in execution of clinical governance in primary care.

“Buetow et.al Introduced the following requirements for clinical governance: A management and organizational framework, A “duty of quality” which relates to organizations as a whole and not just individuals within the organization, A comprehensive strategy to be developed by each organization linked loosely to professional development programs, A named individual appointed within each provider organization who has responsibility for improving quality of care, A focus on clinical leadership through greater external accountability, A focus on processes of care including clinical decision making on concepts of appropriateness, clinical effectiveness and evidence-based care set in the context of a nationally coordinated program of clinical guidelines, development including service standards for priority areas”<sup>[18]</sup>. Barriers of establishing clinical governance in primary care as our study classification are: structural & organizing, cultural, resource, theoretical and Logistical barriers. Campbell et al (2002) categorized the main barriers in 6 group; practicalities of implementation, role of the leadership, relationship, emotional impact, long-term uncertainty, the wider agenda <sup>[17]</sup>.

Marshal et al found that senior primary care managers regard culture and cultural change as important barriers in clinical governance<sup>[19]</sup> although the lack of good information on practice in Australia is a critical constraint for clinical governance activities<sup>[5]</sup>. Other researchers believed that, lack of time and support (administrative, information technology), the pace of change needed to implement clinical governance, volume of work, blame culture, too few staff, limited dedicated resources, lack of information technology skills and logistical difficulties are a number of difficulties with clinical governance in primary care. Eliminating these barriers should improve the quality of patient care and also it is essential in order to achieve an impact on the health of the population<sup>[17, 20, 21]</sup>. All of these difficulties were located in our research.

Bureaucratic control in upstream levels of the health system is one of the most important obstacles in establishing clinical governance in primary health care. Primary care professionals may lack the skills to accept clinical governance which compromises usual clinical practice, and due to the lack in strategic direction, is too time consuming to be operationally helpful. The actions needed to improve practice are frequently irresolute to professionals, many of whom lack the resources needed achieve progress. Clinical governance has led to a cultural change. There is a lack of evidence that these approaches attain better patient outcomes and thus

uncertainty about them may not actually reflect a lack of understanding by professionals<sup>[8,18-22]</sup>.

## **Conclusion**

The ultimate goal of clinical governance is improving the health of population. Increasing health authorities' knowledge of principles, prerequisites and barriers in the establishment of clinical governance in primary care can facilitate progress towards this goal. Clinical governance in primary health care is likely to work best if bureaucratic control is kept to a minimum while ensuring suitable accountability. Shared leadership is needed to establish the necessary infrastructure to manage clinical activity such as staffing, information systems, peer groups, clinical guidelines, quality initiatives, personalized feedback to members, and relationship building professional incentives, such as the ability to use savings to develop new services is likely to be more effective in motivating practitioners than personal gain. Clinical governance needs leadership to build relationships in a total primary health care service, including other health professionals and with communities provided budget holding, incentivized programs, data feedback, peer review, education, human relations, HIT support, and resources. Key elements include enrolled populations, an interdisciplinary team approach, HIT interoperability and access between all providers as well as patients, devolution of hospital based services into the community, inter-sectorial integration, blended payments,

and a balance of clinical, corporate, and community governance.

Study limitation: Clinical governance is a new issue in primary care and only a few

numbers of countries have applied this approach in their health system. Although we had accessed limited free databases to search references in our study.

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