The development, implementation and evaluation of Clinical Practice Guidelines in Gulf Cooperation Council (GCC) Countries

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4.1 Abstract

Objective: Our aim was to examine and describe the current situation in Gulf Cooperation Council (GCC) member countries regarding the development, implementation and evaluation of clinical practice guidelines. The objectives were to describe from where the studies originated, what the clinical focus was of each study and examine the methodology and the status of each study (i.e. development, dissemination, implementation and evaluation).

Methods: Review of literature – two stages: Stage 1: screening through an abstract review, followed by independent adjudicator. Stage 2: detailed assessment and classification.

Results: Considering the widespread acceptance that CPG's are useful and effective tools for quality improvement in healthcare, it is worth noting that relatively few studies have been conducted in the GCC region that examine CPG. Furthermore, the reviewers found that the quality of the research methods used could be improved. However, the majority of the studies that were conducted evaluated the effects of guidelines and focused on the 'lifestyle diseases', in particular diabetes and cardiovascular diseases. It is also worth noting that there has been a steady increase in the number of publications over the 10 years period.

Conclusions: More attention needs to be given to developing, disseminating, implementing and evaluating CPG's in the GCC region in order to improve the quality and safety of health care.

4.2 Introduction

Concerns about patient safety, an increased focus on high quality, rising consumer expectations and increased healthcare costs have all highlighted the need to regulate and improve the quality of healthcare services. The term healthcare regulation is used to describe the collective function by an entity (regulator) to act in the interest of the public in order to achieve regulatory objectives[1]. In order to abate or control risks and provide assurances to the society, different regulatory interventions have been introduced to both *deter* particular non-desirable actions and behaviours and *encourage* compliance with desired actions and behaviours. Both forms of regulation (deterrence and compliance) are used extensively in healthcare regulation[2].

Despite the best intentions of regulatory authorities, there still is a dearth of empirical evidence of the overall effectiveness of regulatory interventions on the quality of health care[3–5].

However, studies into the effectiveness of regulatory interventions have found moderate, positive results on the quality and safety of healthcare in relation to two regulatory interventions in particular: accreditation[6] and evidence based best practice guidelines such as Clinical Practice Guidelines[7–9]. The focus of this study is on one of these interventions in particular: This study will provide an overview of the availability, use and effects of guidelines in the Gulf Cooperation Council (GCC) region. This study forms part of a broader investigation into the relationship between regulatory approaches and compliance with regulatory requirements for healthcare organizations and professionals[10].

In clinical practice, clinicians are encouraged to implement and adhere to evidence-based clinical practice guidelines (CPGs), as these are regarded as important tools for quality improvement and patient safety. Clinical practice guidelines are used to translate, adopt and implement best evidence into everyday clinical practice[11].
The Institute of Medicine[12] defines clinical practice guidelines as "*statements that include recommendations intended to optimize patient care that are informed by a systematic review of evidence and an assessment of the benefits and harms of alternative care options*".

The aim of developing clinical guidelines is to produce explicit recommendations that are both scientifically valid and helpful in clinical practice[13]. Implementation can be described as 'a planned process and systematic introduction of innovations or changes of proven value; the aim being that these are given a structural place in professional practice, in the functioning of organizations or in the health care structure[9]. Finally, the evaluation of guidelines considers whether the recommendations in the guideline and pathway are adhered to, whether practices have changed and whether the intended health outcomes have improved[14].

There is evidence that the use of standardized practice is associated with improvements in the quality and safety of care[15–17], as well as cost savings[18]. Since the positive effects are widely acknowledged, healthcare regulatory authorities have regularly endorsed and mandated the development and implementation of guidelines[4]. The effectiveness of clinical practice guidelines in terms of improvement in the quality of care and patient outcomes has been well documented[7,9] which has led to a proliferation of guidelines, often as part of a regulatory intervention.

This study analyses the current situation in one of the fastest changing regions in the world: The Gulf region in the Arabian Peninsula. Six countries in the Gulf region (the United Arab Emirates, the Kingdom of Bahrain, the Kingdom of Saudi Arabia, the Sultanate of Oman, the State of Qatar and the State of Kuwait) that shared a common language, religion and history in the Gulf region established a cooperative agreement in 1981, the Gulf Cooperation Council (GCC). The GCC countries collaborate on a variety of areas, including economic development, foreign policy and also healthcare. The GCC Council of Health Ministers is comprised of health ministers from each of the seven member states and convenes biannually. The total, combined population of the six GCC countries was 45 million in 2011, with astonishing population growth rates of up to 850% in the last 3 decades in Qatar and 780% in the United Arab Emirates[19], mainly due to the increase of expatriate worker. During the same period, GCC countries witnessed a rise in life expectancy (for example life expectancy in the United Arab Emirates improved from 69 years in 1980 to 77 years in 2011) and significant improvements in under-five mortality, achieving reductions ranging from 70% to an impressive 91% lower mortality in Oman. Another notable characteristic is the large number of expatriates: nationals are a minority in all GCC countries, except Oman and Saudi Arabia[20].

4.3 Methods

The aims of this review were to investigate the stages of development, implementation and evaluation of clinical practice guidelines in the countries of the GCC region and to present the latest available information, per GCC country and clinical specialty.

Screening

A systematic literature review was conducted in Medline and PubMed databases and Cochrane Library on clinical practice guidelines in the GCC region. Searches included studies published between 2000 and 2013, in the English language. Two reviewers (EK and AA) independently screened the titles and abstracts and selected potentially relevant articles that met the inclusion criteria. Any differences between the two reviewers were referred to a third researcher (CA) for resolution.

The following search strategy was deployed:

#1 Clinical practice guideline OR clinical guidelines OR evidence-based guidelines
#2 Develop* OR availab* OR implement* OR adopt* OR adher* OR compliance OR disseminat* OR evaluat* OR promulgat* OR effect* OR impact
#3 Gulf Cooperation Countries OR GCC OR United Arab Emirates OR UAE OR Oman OR Sultanate of Oman OR Qatar OR Saudi Arabia OR Kingdom of Saudi ArabiaOR Kuwait OR Bahrain OR Kingdom of Bahrain
#4 (#1 AND #2 AND #3)

Data extraction and assessment

Once the articles had been screened and selected for inclusion, the studies were assessed utilizing a standardized template and information on the following was recorded by two researchers (EK and AA):

- Country (countries) where research was carried out
- Disease / condition
- Type of study and research methodology
- Stage of maturity (development, implementation, evaluation)
- Date when study was conducted and publication date

Any discrepancies or disagreements were resolved through discussions, involving the entire research team.

4.4 Results

Selection of publications

The final search was conducted on 2 October 2013 and resulted in 229 articles. Two reviewers independently reviewed the titles and abstract and key words to determine eligibility. Any disputes were referred to a third researcher. This resulted in the selection of 73 papers for further analysis and assessment. Among these 73 articles identified, 58 were selected following the detailed assessment of the studies. Out of these 58 articles, 24 (40.4%) were published by journals from the GCC Region, primarily from Saudi Arabia (32.78% of all articles).

Country or countries of origin

The majority of the publications originated from Saudi Arabia (27), followed by the United Arab Emirates (8), Kuwait (7), Oman (4), Bahrain (3) and Qatar (1). In addition, 2 articles covered the entire Gulf Cooperation Council (GCC) Region and a further six covered the

entire Middle East and North Africa Region (MENA Region). However, the overwhelming majority of articles refer to and compare their findings with international Clinical Practice Guidelines (50 out of 58 articles).

Topic of study: Disease or Condition

Table 1 below indicates what type of disease or condition the articles focused on. Unsurprisingly, the majority of articles (30 out of 58 articles) dealt with the common lifestyle associated diseases in the GCC region (i.e. cardiovascular, diabetes, hypertension and cancer). However, quite a range of topics were studied, including pandemic influenza, smoking cessation, etc.

Table 1 Publications by topic

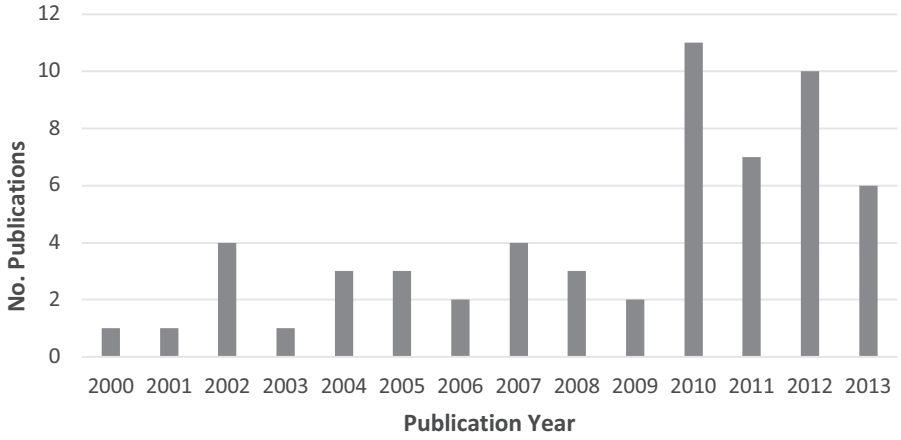
	n (%)
Diabetes	14 (24.1%)
Other	12 (20.7%)
Asthma	7 (12.1%)
Cancer	6 (10.3%)
Infectious diseases	5 (8.6%)
Hypertension	4 (6.9%)
Communicable diseases	3 (5.2%)
Community Acquired Pneumonia	3 (5.2%)
Cardiovascular disease	2 (3.4%)
N/A	2 (3.4%)

Two articles did not deal with a specific topic, one article[21] dealt with the attitudes and self-reported behaviours of healthcare professionals toward clinical practice guidelines in a hospital in Saudi Arabia and the second article[22] described a brief background on clinical practice guidelines in Saudi Arabia.

Publication date

There has been a steady increase in the number of articles published over the last 15 years, as shown Figure 1 below, with a marked increase since 2010. Over 60% of all articles were published in the last 4 years.

Figure 1 Publications by year



Stages and study design

A small number of publications simply reproduce the guidelines in an article format, for example the Osteoporosis Guidelines in Saudi Arabia[23] and GCC Guidelines for Community-Acquired Pneumonia[24] and a larger number describe the entire process for developing guidelines. In total, 20 articles describe the development of a guideline, most often based on a literature review and expert consultation. However, only one study[25] utilises the AGREE Instrument to evaluate the quality of the CPG. A number of articles also make reference to guidelines developed by regional GCC working groups, such as the GCC Community-Acquired Pneumonia Working Group[26–28] and the MENA Region–National Comprehensive Cancer Network Breast Cancer Guidelines[29].

In total 7 publications focused solely on the implementation process and systematic introduction of the guidelines into practice, mainly using surveys as methodology, for example the implementation of Asthma Guidelines in Oman[30].

In terms of publication productivity, it is difficult to infer anything from this number of articles, since there have been very few comparative studies. However, it appears to be lower than what could be expected, considering the population size. A study[31] into the quantity and quality of biomedical publications between 2001-2005 found that the 12 countries selected from the Arab world (including the GCC region) producing significantly fewer biomedical publications of lower quality than other Middle Eastern countries (Turkey, Israel and Iran). Other studies have found similar results[32,33].

Finally, the majority of the publications (31 out of 58) described findings from evaluating the adherence to guidelines or the effects of the implementation of guidelines. The research

methodology to evaluate adherence and effects included cross sectional studies, case series, retrospective reviews of medical records and in one study, a randomised controlled trial[34]. These evaluation studies are important as they attempt to discover whether practices have changed and whether the intended outcomes have been achieved.

A closer review of these evaluation studies indicate that out of the 31 studies, 25 concentrated solely on evaluating the adherence to the processes, for example the self-reported adherence of primary care physicians in Bahrain to the WHO-recommended guidelines for the management of acute diarrhoea[35]. Two studies focused solely on the effects of the guidelines[36,37] and a further six remaining studies focused on both the adherence to guidelines as well as the effects, for example, one study from the UAE looked at the physician's adherence to diabetes guidelines and its effects on the health outcomes of patients[38]. Most of these studies used evaluation studies used methods such as chart reviews of patient files and reviews of medical records, such as[26,39,40], and a smaller number used prospective cross-sectional reviews through observation, for example[35,41,42] or surveys for healthcare professionals[43] and patients[44]. A number of studies used a combination of methods, for example medical records reviews and physician surveys[45].

The reviewers looked in particular at the methodological quality of the 31 studies that evaluated the adherence to and effects of Clinical Practice Guidelines. This part of the review focused on three criteria in particular: whether a standardized and validated evaluation tool with clear requirements based on an established Clinical Practice Guideline was used; whether the evaluation reflected existing international and national guidelines and whether the appropriate study design was used and clearly described. Table 3 summarizes the findings.

Table 3 Methodological quality of evaluation studies

Review Criteria		Percentage
1	Standardized/validated evaluation tool was used reflecting CPG requirements	54.8%
2	Study refers to existing international and national guidelines	80.6%
3	Appropriate study design was used and clearly described, i.e. cross-sectional studies, intervention studies (RCT), cohort studies, reviews)	67.7%

In terms of the strength of the evidence (see Table 4 below), a high proportion of evaluation studies that looked at the effects of guidelines on patient outcomes showed strong positive results. Whereas only a small proportion of the studies that reviewed healthcare professional's adherence showed strong levels of adherence with guidelines.

Table 4 Summary of the findings of evaluation studies

	Strong/significant results	Moderate results	Poor results
Adherence	32.3%	19.4%	48.4%
Patient outcomes	75.0%	12.5%	12.5%

4.5 Discussion

The main finding that emerged from this research is that the development, implementation and evaluation of Clinical Practice Guidelines is still in its infancy in the GCC Region. The relatively small number of studies that were found, screened and reviewed concentrated on evaluating the effects of particular guidelines and described the development and implementation process. The majority of articles originated from Saudi Arabia and the studies focused on the lifestyle diseases most prevalent in the region.

Quantity: Publication productivity

The underlying premise of this study is that the publication of articles on the development, dissemination, implementation and evaluation of Clinical Practice Guidelines is an indicator or proxy for the current situation in the GCC region in terms of evidence-based healthcare practice.

It is essential that Clinical Practice Guidelines are adapted to the complex social, cultural and economic situation in a region in order for the guidelines to have optimal effect[46]. However, the total number of articles found, screened and selected, 58 in total, is relatively small, considering the combined population of the entire GCC region. Other researchers, such as[24,47], also found a scarcity of studies into the development, dissemination and evaluation of Clinical Practice Guidelines from the Gulf Region. It is worth noting that according to the SJR-SCImago Journal & Country Rank[48], the six counties are ranked as follows in term of the number of citeable documents in the subject area of Medicine: Saudi Arabia (41st in the world), Kuwait (60), United Arab Emirates (62), Oman (77), Qatar (82) and Bahrain (92). In comparison, countries such as the US have seen a proliferation of guidelines with over 700 guidelines accepted by its national guideline authority, the National Guideline Clearinghouse, in 2008 alone[12].

Apart from a few initiatives such as the MENA – NCCN Breast Cancer Guidelines network, there appears to be a shortage of professional associations and regulatory authorities involved in guidelines development, review and adoption. It is worth pointing out that out of 98 member organizations of the Guidelines International Network (G-I-N) only 2 hail from the GCC Region[49]. In comparison, in many countries the efforts to standardize healthcare and improve quality and patient safety agencies have resulted in the establishment of national repositories of guidelines, such as the National Institute for Health and Care Excellence (NICE) in England that has published over 100 pathways and almost 200 guidelines to date[50]. In the US the National Clearinghouse has published almost 3,000 guidelines and internationally, the Guidelines International Network's database currently lists almost 4,000 Clinical Practice Guidelines[12]. This proliferation has resulted in an increased number of guidelines in place in healthcare providers.

Quality: Implementation and Adherence

Considering the widespread evidence of the positive effects of the implementation of Clinical Practice Guidelines on the process and outcome of healthcare, it is encouraging that recently there has been a significant increase in the number of publications coming from the GCC Region, in particular since 2010.

It has been estimated that around 70% of the population of the GCC Region is overweight and around one third of the population obese[19]. Therefore, it is important to note that the majority of the publications address the clinical needs associated with the so-called 'life style diseases' in the region (diabetes, hypertension, etc.).

Whilst it is encouraging that a significant number of research publications attempted to review and evaluate the effects and adherence to guidelines, there is room for improvement of the methodological quality of these studies. Only a small majority of the evaluation studies (54.8%) used a standardized and validated evaluation tool with clear requirements based on an established Clinical Practice Guideline and around one third of the evaluation studies used an appropriated research method.

In addition, the actual published results have been mixed. In Qatar, for example, adherence to diabetes guidelines was classified as intermediate, with an overall adherence rating of 68.1%[51]. Compliance with paediatric asthma guidelines in a large emergency department in Saudi Arabia was considered to be poor, with only 3 out of 8 recommendations applied consistently[40]. Adherence to community-acquired pneumonia guidelines in Oman was the subject of another study[26], which found very poor adherence to local guidelines. Similarly, a study in Kuwait[52] found the adherence to antibiotic prescribing guidelines was low, with only 30.4% of prescriptions fully adhering to the guidelines. In terms of hypertension management in one region in Saudi Arabia[53], the study concluded that most physicians did not adhere to the guidelines and lack the necessary knowledge. A study in the United Arab Emirates[43] found that whilst physicians have favourable attitudes towards smoking cessation counselling guidelines, their actual practice fell below recommendations. However, in another study from Saudi Arabia[21], both the physician's attitude towards the guidelines as well as the self-reported adherence was high, which was attributed to the credibility and respectability of the source of the guidelines.

These findings in relation to a weak adherence to guidelines by healthcare professionals confirms the mixed findings from other studies[7,51] and can be explained by the fact that the development of Clinical Practice Guidelines often does not meet the required standards set by international and national organizations such as the US Institute of Medicine or UK based National Institute for Clinical Excellence (NICE).

In addition, many evaluation studies reviewed adherence and outcomes against non-specific best practice requirement, such as medical nutritional treatment based on recommendations from the American Diabetes Association[34], rather than Clinical Practice Guidelines developed regionally or locally. Other explanations for the lack of adherence include lack of education and training[53], absence of clear implementation strategies[17,18], poor access to the evidence[12] and lack of awareness and familiarity amongst healthcare professionals[54]. Interestingly, the lack of perceived credibility of the guidelines was also cited as an explanation for poor adherence to the guidelines[21,40].

In terms of the effects on patient outcomes, it should also be noted that the studies that evaluated the effects of guidelines on health outcomes showed a largely positive, strong impact. Out of the 8 studies that looked at the effects of the adherence with the guidelines on patient outcomes, five reported significant positive results[38,41,55–57]. It is worth noting however, that only a small number (8 out of 58) evaluated effects on patient outcomes.

In terms of research methodology used, there is still a lot of room for improvement. Only one study[34] [34] used a Randomised Control Trial (RCT) and a large number of studies simply described the process for developing a guideline. Furthermore, the research methodology used was often descriptive and seldom were the guidelines appraised for their quality. This finding is consistent with other recent reviews of international guidelines, which found that the quality scores against the AGREE appraisal instrument were moderate to weak[25,58].

4.6 Conclusion

The overall goal of the research was to review how countries in the GCC region have developed, implemented and evaluated clinical practice guidelines. The GCC region has seen unprecedented economic and demographic growth, as well as social and cultural change. As a consequence, the prevalence of lifestyle diseases such as diabetes and cardiovascular diseases is widespread[51]. It is therefore encouraging that many of the Clinical Practice Guidelines developed and implemented in the GCC Region focus on these diseases in particular.

As described above, the relatively small number of research articles published in the GCC Region over the 13-year period raises concerns about the likelihood to successfully address any evidence gap and attain better quality outcomes. This is a particular concern to the GCC region since the healthcare sector relies on the experience and expertise of healthcare professional from a wide variety of different backgrounds. In addition, whilst some evaluation studies were methodologically robust, many studies focused on generic practice

requirements rather than evaluating the effects of and adherence to specific, relevant Clinical Practice Guidelines. A more rigorous approach to the development and evaluation of Clinical Practice Guidelines needs to be established to address these methodological weaknesses.

Despite all this, a number of positive signs may indicate that there is a gradual change occurring, as evidenced by the recent increase in number of studies, as well as an emphasis on evaluating the effectiveness and a focus on lifestyle diseases.

Further in-depth research exploring the reasons behind non-adherence to Clinical Practice Guidelines is needed as this will enable regulators, healthcare providers and healthcare professionals to apply the required clinical practice in a consistent manner, resulting in better outcomes for patients. In particular, further research need to look at the application of regulatory mechanisms using a procedural justice approach towards regulatory requirements that support the argument that when health care authorities use fair procedures rather than sanctions, health care professionals are more likely to overcome barriers to achieving adherence to guidelines[59].

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