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Research Article

Tabriz Clinical Governance Research Project (TCGRP): Study Protocol

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Abstract

The Tabriz Clinical Governance Research Project (TCGRP) was conducted in Tabriz, East Azerbaijan Province of Iran. The project was done based on the National Clinical Governance Movement of the Iranian health system since 2009. The TCGRP aimed to monitor the progress of clinical governance in Tabriz hospitals. The TCGRP had three components: 1- A comprehensive literature review was conducted to identify draft indicators. 2- Draft indicators were evaluated by experts through Delphi technique and expert panels, 3- The indicators were assessed through data collection at three sampling levels of hospitals, patients and community. All Tabriz hospitals (n=21) with various ownerships were included in the study. Moreover, 3000 patients (inpatients and outpatients) as well as 1050 Tabriz households were investigated. The TCGRP protocol is designed to provide basic performance information for policymakers as well as the researchers in field of clinical governance. Results from TCGRP are assumed to identify the weaknesses and facilitate the development of effective interventions to improve the clinical governance practice.

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Introduction

Health systems are using variety of mechanisms and frameworks to improve the services quality [1, 2]. Clinical governance is a quality improvement framework that introduced by NHS, UK at 1997 [3]. Clinical governance is a framework guaranteeing quality improvement in clinical services at all levels of healthcare provision system. Through it, healthcare organizations will be accountable and responsible for their provided services quality[4, 5]. Clinical governance is a comprehensive concept covering seven topics including Clinical Audit, Clinical Effectiveness, Education and Training, Patient and Public Involvement, Use of Information, staff and staff management and Risk Management [6, 7]. Clinical governance was developed in high income countries, but because of its comprehensive and flexible framework, it was used to Middle and low income countries health systems improvement.

Clinical governance has been introduced as a national framework to improving the quality of services in hospitals from 2009 in Iran. Health system, especially hospitals, has done most efforts to have a progress in clinical governance and quality improvement. These efforts, to be successful and effective, must be reliably measured and evaluated [8]. Regard this; measurement is an inseparable part of quality improvement in health systems and hospitals [9]. Currently, vast methods are used to performance measurement. Using performance indicator is one of the prevalent method to evaluate the performance [10]. Though, there wasn't a valid set of indicators to evaluate the clinical governance performance in hospitals, in Iran. A research project with multiple designs, multipurpose as Tabriz Clinical Governance Research Project (TCGRP) was designed to develop and measure performance indicators of clinical governance. Beside this, the Economic performance indicators developing were one of the aims. Also some other single studies were conducted through clinical

governance movement. The aim of this study was to report the methodology of TCGRP.

Methods

Design

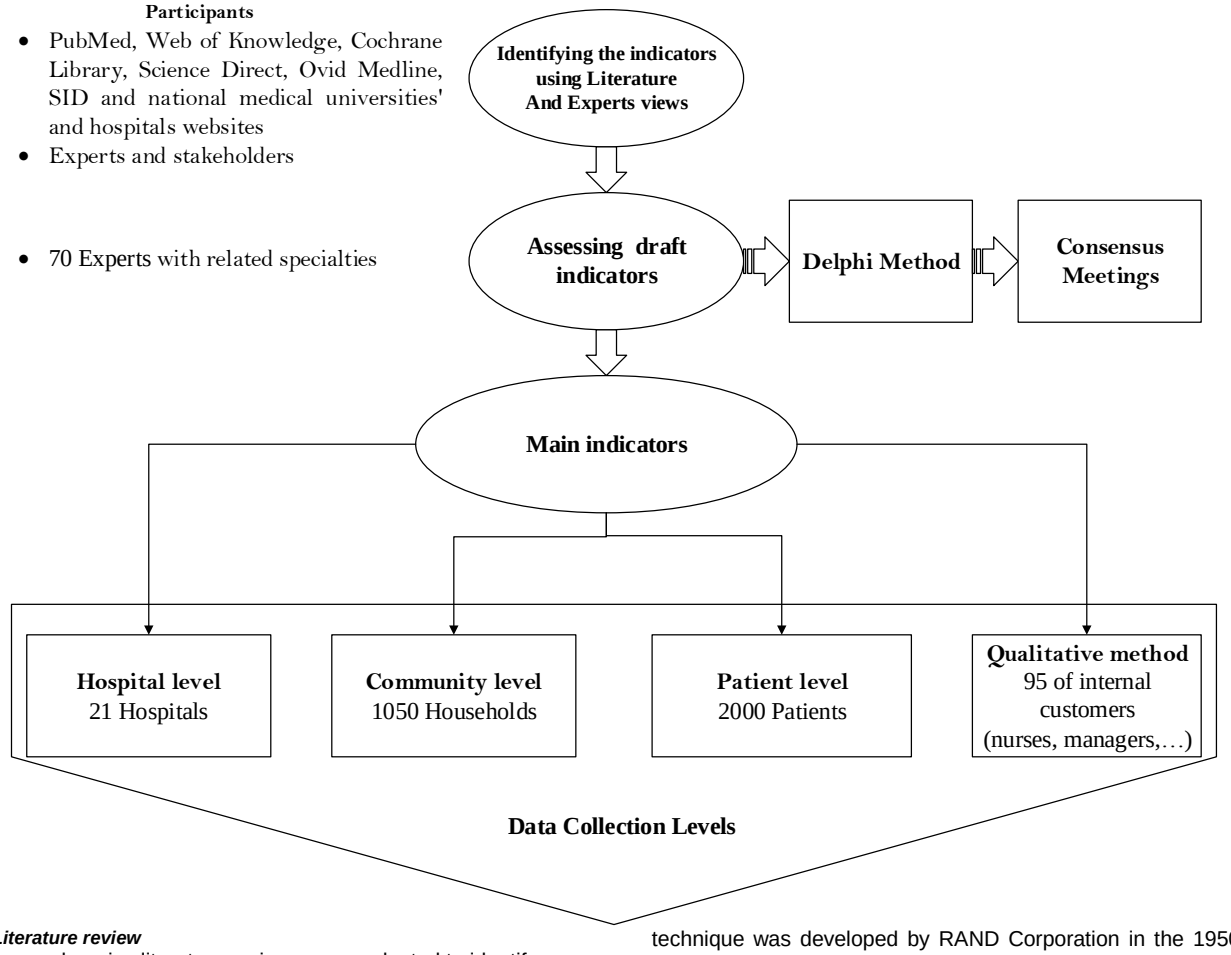
Tabriz Clinical Governance Research Project (TCGRP) was conducted within a defined geographic area of Islamic Republic of Iran, East Azerbaijan, Tabriz in 2013-14. It was done as 4 postgraduate Thesis. All the hospitals of Tabriz were included in the study. Patients who were referred to the hospitals and Tabriz population were the study population.

The TCGRP had three components: 1- A comprehensive literature review was conducted to identifying draft indicators. 2- Draft indicators were evaluated by experts through Delphi technique and expert panels, 3- Data for indicators were collected in three levels of hospitals, patients and community. The project was divided into four parts to work a group on the topic.

1- Risk management and Clinical Effectiveness group
2- Clinical audit, Education and Training, Patient and Public involvement group
3- Use of Information group
4- Economic group

Each group was including experts with related specialties and an MSc student as coordinator. The whole methodology of the TCGRP has been shown in Figure 1.

Figure 1- Methodology Diagram



1- Literature review

A comprehensive literature review was conducted to identify suitable indicators. PubMed, Web of Knowledge, Cochrane Library, Science Direct, Ovid Medline, SID and National Medical Universities' and Hospitals websites were searched and reviewed. Grey literature and reference of references were used to identify more studies.

Keywords were: healthcare quality, clinical governance, risk management, clinical effectiveness, clinical audit, education and training, patient and public involvement/ participation, use of information, economic performance, financial assessment, hospital, key performance indicators, Index, indicator, evaluation, measurement and combination of these words with the logical functions (AND,OR). Also, Focus group discussions were held to identifying draft indicators.

Draft indicators were extracted using literature and experts views in each group and were categorised preliminary.

2- Indicators assessment

Delphi method was used to assess the indicators. Delphi technique was developed by RAND Corporation in the 1950s. The objective was to develop a technique to obtain the most reliable consensus of a group of experts[11] . Delphi method facilitates the systematic process of developing indicators [12]. It is a method to extract, evaluate and match experts' independent opinions [13]. Delphi method combines the experts' opinion and empirically derived information in decisions [12, 13]. Moreover experts anonymity, comments and controlled feedback of panel group response promote consensus [14, 15]. Also panel selection, time frame, high costs and low response rate are the areas that could be limited the Delphi study results [16].

Because of the panel subjects' distance, to have expert's opinion on the evidences and to avoid interactions between panels' opinion we used Delphi method. Although to have the interactive opinions, we held panel meetings.

1-2- In round one, a tabulated list of indicators was sent to the members of the expert panel. They were instructed to

individually rate the indicators on a 9-point scale based on the aspects of importance and Feasibility.
For each indicator, the experts' ratings were summarized into a median rating. In round 1, indicators with the median score less than 4 were excluded, score >4 and <7 were selected to the second round of Delphi and indicators with score of >7 were confirmed as the final indicators. Also panel consensus meetings were established to finalizing the indicators.
Linstone (1978) suggests that "a suitable minimum panel size is seven". however, the decision about panel size is empirical, taking into consideration factors such as time and expense[17].
Expert panels of each group were included:
Group 1: Risk management and Clinical Effectiveness
23 expert members with the specialities of Epidemiology (n=2), Health Services Management (n=2), Urology (n=2), Social Physician (n=2), Emergency Medicine (n=1), Infectious Disease (n=1), Mental Disease (n=1), Medical Informatics (n=1), Pathology (n=1), Environmental Health (n=1), Public Health (n=2), Medical Equipment(n=1), Nursing (n=2), Rehabilitation (n=2), Quality Improvement (n=1), Infection Control (n=1).
On the base of panel member's expertise, indicators were divided to several categories and were sent to the member with related speciality.
Group2: clinical audit, education and training and patient and public involvement
Eight expert members with the specialities of Health Services Management (n=2), Epidemiology (n=1), Medical Informatics (n=1), Nurse (n=1), General Physicians (n=2, were manager in the system) and Social Physician (n=1).
Group3:Use of information
Expert members (n=14) with the field of Medical Informatics, Medical librarianship and information, Health Services Management (n=3), urology (EBM centre chief), Medical records, Emergency Medicine (n=2), General Physician (n=2, were manager in hospital) and hospital evaluation expert.
Group 4: Economic performance
Expert members (n=25) including experts in Health Economy (n=4), Health Services Management (n=7), Budgeting and accounting experts in Tabriz Medical University (n=5), General Physician (n=4, also were manager in health system), Hospital assessment expert (n=5).
2-2 Panel members were encouraged to give specialized visions on indicators. In each round, the indicators were adopted based on the experts' opinions.
3-2 Also new indicators were proposed by the experts in the domains of the indicators. These indicators were presented to the member to assess them.
4-2 Panel consensus meeting:
To finalize the indicators, as needed for each group, panel consensus meetings were held. Content reliability of the indicators was discussed and in the case of need, indicators were corrected on the base of experts' opinions.
5-2 Tools development:
To measure some indicators that needed to measure as a scale, valid and reliable questionnaires were developed or adopted, including:
Community: A questionnaire was designed including, demographic data for the households' members, socioeconomic situation, healthcare costs of the households and its effect and public trust questionnaires (Persian version).
5-2-1 Public trust questionnaire: Back translation method was used to translate the questionnaire to Persian. The validity of the Persian version of the public trust questionnaire was confirmed by the experts.
The reliability of the questionnaire with a pilot study was confirmed (α= 0.86, n=30). The reliability of the questionnaire and its sections are shown in table 1.

Number	sections	α
1	Patient-centeredness	0.829
2	Macro level policies	0.276
3	Professional expertise	0.656
4	Quality of care	0.688
5	Communication and provision of information	0.732
6	Quality of cooperation	0.566

5-2-2 Patients right questionnaire: This questionnaire was developed and used in Amini and et al (2013) [18] in Tabriz and was a standard questionnaire.
5-2-3 Inpatient satisfaction questionnaire: This questionnaire was extracted and merged from several studies. Inpatient satisfaction questionnaire was translated to Persian. Back translation method was used to translation. The validity of the Persian version of the questionnaire was confirmed by the experts.
The reliability of the questionnaire was confirmed using a pilot study (α=0.95). The reliability of the questionnaire and its sections are shown in table 2.

Number	Questionnaire sections	α
1	Physicians services	0.91
2	Nursing services	0.93
3	Physical space of the hospital	0.623
4	Welfare	0.745
5	General occasion	0.832
6	Observing Private adytum of the patients	0.958
7	Hospital pureness	0.761
8	Discharge process	0.596

5-2-4 Outpatients' satisfaction questionnaire: The questionnaire was developed in jannati and et al (2010) study [19].
5-2-5 Clinical governance climate questionnaire [20]: Two round Back translation method was used to translate the questionnaire to Persian. The validity of the questionnaire was proved, using the experts' opinion. The reliability of the questionnaire was approved using test-retest.
5-2-6 Job satisfaction questionnaire: The questionnaire was developed and validated in Bagheri et al (2013) study [21].

3- Qualitative study

Qualitative method was used to assess the experience and subjective aspects of clinical governance movement. Seven FGDs (2 for teaching hospitals, 1 for private hospitals, 1 for social security and military hospitals, 1 for township hospitals and 2 mix FGDs were held to get the nurses experience of clinical governance movement in their hospitals and Tabriz health system. From the all types of hospitals, 65 nurses were participated in the FGDs.

4- Data collection

This was done in three levels of hospitals, community and patients.

4-1 Hospitals: All the active hospitals of Tabriz were included in the study. 10 teaching hospital, 7 private, 2 arm forces and 2 for social security organization. A data collection form was designed to gather the hospital level indicators. The form has four parts: Nominator, Denominator, the rate and explanation. Tabulated forms of the indicators were sent to the hospitals. Then the responsive group of the hospitals was educated to how gather the data for each indicator. At a particular time, with the presence of a team of researchers, documents for the indicators were checked and discussed and the indicators data were finalized.

Individual interviews were done in each hospital with nursing managers, clinical governance manager, medical records official, safety officer and executive manager about the

information cycle in their hospitals.

4-2 Community: indicators and variables in community level were measured in this level. Public trust in healthcare, healthcare costs and its effects on the households and some other demographic variables were covered in this level of the study.

Random Cluster sampling was used for sampling. Tabriz households Address and phone number list, 2013, was used as sampling framework. Start point of every cluster was selected randomly, using the communication organization software. Sampling unite was the household and headman or informed member of the household was the response basis.

To calculate the sample size, proportion formula (N=z2 p (1-p)/d2) was used as α= 5%, d= 10-20% and p in the interval of 10% to 90%. The calculated sample size was multiplied by design effect (= 1.5). Finally, Sample size calculated about 1050 households, 70 clusters with 15 households. Face-to-face interview was used to collect data from households.

4-3 Patient level: inpatient and outpatients distribution in 2012 was used as sample calculation framework. The framework for the sampling was Inpatients list in the hospital wards. Also consecutive sampling was used for outpatients.

Sample size calculation was the same with the community level and 3000 patients (1230 inpatients and 1770 outpatients) were included in the study. Of total sample, 2000 samples were studied in Tabriz hospitals in two phases, in warm season (September) and cold season (December). The remaining, 1000 patients, were selected from other cities hospitals in East Azerbaijan-Iran.

Systematic random method was used for Patient selecting in hospitals (inpatients). Also 1/6 of patients (inpatient and outpatients) total sample were interviewed in Fridays.

Inclusion criteria:

Experts: specialist at the field, working in health system, tendency to participation

Hospitals: being in Tabriz, being active.

Households: a minimum of 6 months residency in Tabriz in a year.

Patients: recourse to deliver a service from hospital, ability to answer the questions, consent to participation, being patient career.

Discussion

In order to evaluate performance and success degree of clinical governance in hospitals it is inevitable to use functional indicators which show degree of success and improvement in performance of clinical governance. In response to more transparency, better accountability, and improving service qualities, functional indicators have key role. One of the other main functionalities of indicators is to evaluate and measure performance and the degree to which predetermined goals have been reached [22].

Using literature review, expert panel and Delphi technique to develop the performance indicators was prevalent in previous studies [23-26]. As indicated in previous studies, Delphi method can be a useful and systematic approach to consensus building about a real subject [13, 14, 27, 28] and facilitate the systematic cycle of indicator development [26]. This technique is a method to summarize, assess and compare the experts' opinions and combining them with the evidences to make a decision [29] so it will be a useful method to developing the new indicators.

Multiple designs of the project with the multi level data collection provide a base to analyze the results of the study with a multi level perspective and enable the researchers to evaluate the correlation and impression of the variables in different level. It is seemed that multi level impressions of the variables could be extracted from the results and it will provide evidence based information to the policymakers. Regarding the results, decision makers could plan interventional programs to the hospitals situation. This study provides a baseline to compare the health system progress through clinical governance and services quality improvement. In other view, researchers could use the results of the TCGRP to conduct their researches based on the systems weaknesses as identified in this study. Regarding this, the indicators which were developed in TCGRP are preliminary. Because of lack of a standard level for majority of them, the indicators must be periodically measured so several measurements could provide criteria's to introduce a standard level for the indicators.

While this project was done with the supervision of Tabriz University of Medical Sciences, all the hospitals were included. Some of the hospitals didn't have enough cooperation with the project team. As a health policy maker and presidency role of Ministry of Health and Medical Education, MOHME (Medical Universities in local), must address instructions which indicating cooperation degree with higher levels of health system as a rating criteria for hospitals.

Conflict of interests: The authors declare no conflict of interest.

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