From the Division of Global Health (IHCAR),
Department of Public Health Sciences,
Karolinska Institutet, Stockholm, Sweden

Outcome-based Continuing Medical Education

An intervention to improve rational prescribing

Hamideh Mohammadzadeh Esmaily

Karolinska Institutet

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ABSTRACT

Background: Continuing medical education (CME) for doctors has been compulsory in Iran since 1991. Conventional CME programmes are often unsuccessful in improving medical professionals' performance. Modifications of CME elements are necessary to improve the effectiveness of the programmes. It has been proposed that the concept of outcome-based education (OBE) could be more effective than traditional methods as an overarching approach that can influence the entire process of education: decisions about the content, formulation of aims, educational strategies, teaching methods, assessment procedures, and the educational environment. We have therefore evaluated the effectiveness of OBE in CME and how it impacts the prescribing practices of general physicians in primary care (GPs) in the East Azerbaijan Province of Iran. The topic was chosen since the field of rational prescribing has been recognized as a high-priority issue.

Methods: Cluster randomized controlled design. First, outcome-based educational indicators regarding rational prescribing were identified using a two-round Delphi consensus process. In the second phase the agreed indicators were submitted to panels of experts for assessment and determination of the content of a CME programme for GPs. All GPs working in six cities in the East Azerbaijan province in Iran were invited to participate in the educational programme and 159 agreed to take part. The cities were matched and randomly divided into an intervention arm for education within an OBE programme on rational prescribing, and a control arm for a traditional programme on the same subject. The GPs' knowledge and skills were assessed using a pre- and post-test and their prescribing behaviour was assessed through collecting 10% of their prescriptions, nine months before, and three months after the CME programmes. All nine trainers and 12 GPs (out of 58) in the intervention arm were invited to individual interviews four months after participation in the CME programme. A semi-structured open-ended guideline was used in the interviews. Qualitative content analysis was applied to explore the text and to interpret meaning and intention.

Results: Twenty-one learning outcomes were identified through a modified Delphi process. The OBE indicators were used by expert panels to determine six educational topics for the CME programme and define the curricular content for each topic. The six topics were 1) Principles of prescription writing, 2) Adverse drug reactions, 3) Drug interactions, 4) Injections, 5) Antibiotic therapy, and 6) Therapy with anti-inflammatory agents. In total, 112 GPs participated in the programme. There were significant improvements in knowledge and prescribing skills after the training in the intervention arm as well as in comparison with the

changes in the control arm, with an overall intervention effect of 26 percentage units. The GPs in the intervention arm significantly reduced the total number of prescribed drugs and the number of injections per prescription. They increased their compliance with specific requirements for a correct prescription, in particular significantly improved information to the patient. Compared with the control arm, there was no significant improvement regarding prescribing antibiotics and anti-inflammatory agents and some other indicators. Interviews showed that the participants themselves stated improved knowledge and skills to a higher extent than previously attended programmes. Trainers emphasized the effect of outcome-based education on their educational planning, teaching and assessment methods, while the GPs' challenge was how to adapt their learning in the real work environment considering social and economical barriers. Self-described attitudes changed towards more rational prescribing.

Conclusion: The introduction of an outcome-based approach in CME appears to be attractive and effective when creating programmes to improve GPs' knowledge, skills, attitude and performance. The results strongly suggest that CME programmes could be more effective through the use of an OBE approach.

Keywords: Continuing Medical Education, Continuing Professional Development, primary care, outcome-based education, outcome assessment, cluster randomized controlled trial, intervention, prescription, rational prescribing, knowledge, skill, attitude, performance, behaviour change, Iran.

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Esmaily HM, Wahlstrom R, Vahidi R, Dahlgren LO. Trainers' and physicians' experiences and perceptions of outcome-based education in rational prescribing. (Manuscript)

The papers are referred to in the text by their Roman numerals (I-IV)

A good archer is not known by his arrows but by his aim.

"Thomas Fuller"
(1608-1661)

CONTENTS

LIST OF ABBREVIATIONS

ADR	Adverse drug reactions
ATC	Anatomical therapeutic chemical
CI	Confidence intervals
CME	Continuing medical education
CPD	Continuing professional development
EDC	Educational Development Centre
GP	General physician working in primary care
ICC	Intra-cluster correlations
NSAID	Non-steroidal anti-inflammatory drug
OBE	Outcome-based education
PHC	Primary health care
RCT	Randomized controlled trial
SD	Standard deviation
SE	Standard error
WHO	World Health Organization

1 PREFACE

My background is in the educational sciences with a focus on educational technology. I earned my BSc in this field in 1988. Later, I completed my MSc in Educational Management in 2001 during which time I worked as an Educational Planning Officer in the Educational Development Centre (EDC) of Tabriz University of Medical Sciences, one of the five biggest medical universities in Iran. I then became head of the Educational Planning and Faculty Development Group within the EDC.

I have thus more than seven years experience in faculty development and Continuing Medical Education (CME) in Tabriz University of Medical Sciences. The most important part of my duties was to plan and evaluate workshops for faculty members, facilitate workshops and training sessions on "Teaching and student assessment methodologies", and to collaborate with the CME group within the EDC in research on physicians' professional needs and assessment of CME programmes.

All these duties have encouraged me to look at new approaches in medical education, particularly to improve CME programmes. I was given the opportunity to continue my research education at Karolinska Institutet, which is one of the leading medical research universities in the world. I took this opportunity to do a PhD project on outcome-based education, an approach which I felt shows promise within continuing medical education.

2 BACKGROUND

> *"O Lord, grant me an opportunity to improve and extend my training, since there is no limit to knowledge. Help me to correct and supplement my educational defects as the scope of science and its horizon widen day by day. Give me the courage to realize my daily mistakes, so that tomorrow I shall be able to see and understand in a better light what I could not comprehend in the dim light of yesterday".*

This prayer was written by Ebne-Meymoon, a physician and philosopher from the 12th century, as he was thinking about the theme of "Medicine and Lifelong Study". Jehanshah Saleh, [1, 2] a professor of gynaecology at Teheran University in Iran, reminded us of these words half a century ago, at the 2nd World Conference on Medical Education in Chicago in 1959. Even though the prayer was written nine-hundred years ago, we are still confronting the challenges of understanding how we can effectively improve learning throughout a physician's entire career. This thesis is an attempt to shed light on what can be done.

The crucial roles that continuing medical education (CME) and continuing professional development (CPD) have in improving health care professionals' performance [3-6] has now been recognized all over the world [7]. Due to this increased awareness, Bennett [8] has commented that CME will play "a vital new role in health care" in the 21st century. CME has been defined as "any and all ways by which doctors learn after the formal completion of their training" [9]. Quality improvement, evidence-based practice and interdisciplinary collaboration are some of the current issues that demand a different philosophy and approach to learning [10]. The quality of education for health professionals has usually been assessed by evaluating the outcomes of education including both learning and care provision outcomes [11].

According to the literature [12, 13] there is a gap between the actual learning needs of practitioners and educational needs as recognized by bodies of CME. Traditional models of education prevail. While such traditional CME programmes (mainly lecture-based and teacher-centred) may increase physicians' knowledge, the impact on actual performance is usually much lower [14-18]. Considering the broad definition of CME by Davis [9], the intention of CME/CPD is to bridge the gap between health professionals' knowledge and practice [19, 20]. As Oxman and colleagues mentioned as early as in 1995, there are no magic bullets for improving the quality of health care, but if the educational interventions are used appropriately, CME can lead to significant improvements in clinical care [21].

The terms of CME and CPD have often been used interchangeably in the literature. However, Stanton and Grant distinguished between CME and CPD and believed that CPD will become a more learner-centred and common approach [22]. In this text, the term of CME will be used with the understanding that the same strategy could apply for CPD.

In this thesis, I present a series of studies related to evaluation of the effectiveness of an outcome-based approach to CME and how it impacts on the knowledge, skills, and attitudes regarding general physicians' prescribing practices in Iran.

2.1 THEORIES OF AND APPROACHES TO LEARNING AND TEACHING

There is need for theory in order to promote the uptake of research findings. According to Eccles et al., we need a theory-based framework to design, conduct and evaluate educational interventions to be able to influence health professionals' behaviour [23]. Different learning and teaching theories have informed the practice of CME. Keys to understanding the background of this thesis include our current understanding of how adults learn, reflective practice, experiential learning, social learning theory, and knowledge translation. All of these theories and approaches could help provide an effective educational context.

2.1.1 Adult learning

Knowles [24, 25] described the concepts of adult learning based on five assumptions:

- Self-concept: As a person matures, they are capable of determining and meeting their own learning needs, moving from dependency to self-directness.
- Experience: Adults draw upon their experiences to aid their learning.
- Readiness: Readiness to learn is closely related to the tasks facing them in their work and social roles.
- Orientation: Adult learners want to apply their learning to practice immediately; the learning is more problem-centred rather than subject-centred.
- Motivation: The motivation to learn comes more from internal rather than external factors.
- Traditional methods of teaching that are commonly used in CME are to a great extent in conflict with the adult learning approach. This has been confirmed in several systematic reviews of the efficacy of CME in changing doctors' behaviour [15, 16, 21, 26, 27].

2.1.2 Reflective practice

Reflection is the catalyst that moves surface learning to deep learning*. Moon described reflective practice as "a set of abilities and skills, to indicate the taking of a critical stance, an orientation to problem solving or state of mind" [29]. Donald Schön's description of the reflective practitioner [30] as a means of understanding learning in practice, could be a leading model for professional activities.

"Reflective practice" can be divided into five stages of learning; the first stage which is called "knowing-in-action", includes automatic, deeply embedded, action-oriented knowledge and skills that make up most of the practices of physicians. Despite the fact that most professional practice can be managed based on embedded knowledge, the uniqueness, conflict or ambiguity in some encounters causes a "surprise". This is the second stage of Schön's model, e.g., "inconsistent finding on a physical exam", which leads to a third stage called "reflection-in-action". Reflection-in-action happens during physician-patient interaction when the physician reconstructs knowledge and skills in response to the surprise. The fourth stage is "experiment" which means that professionals attempt to gain more information or resolve the dilemma. Finally, a fifth stage called "reflection-on-action" occurs after the patient encounter is completed. It happens when critical analysis occurs considering the effectiveness of the action and the outcomes. This step may complete the loop and impact new knowledge-in-action [31].

2.1.3 Experiential learning

Michael Balint developed a form of peer groups for general practitioners in England based on experiential learning [32, 33]. Balint is referred to as a pioneer in continuing education for general practitioners in the early 1950s. He engaged in weekly sessions of 6-8 doctors focused on their experiences in managing patients, particularly their reaction to difficult patients [34] with special focus on the doctor–patient relationship [35].

Kolb [25] used the concept of experience that learners move from the concrete, e.g., a case, to more abstract, e.g., understanding more about the pathophysiology of a disease, and back again. He described this process as a cycle of concrete experience

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* According to Biggs,[26] the surface approach to learning comes from "the intention to get the task out of the way with minimum trouble while appearing to meet course requirements".

The deep approach comes "from a felt need to engage the task appropriately and meaningfully, so the student tries to use the most appropriate cognitive activities for handling it".

(feeling), reflective observation (watching), abstract conceptualization (thinking) and active experimentation (doing) which can be turned to create new experiences [36].

2.1.4 Expectancy-value theory

Expectancy-value theory, which was introduced by Feather, is a cognitive–motivational theory relating individual's level of motivation to the expectations and value [37].

According to Feather, anyone engaged in a learning activity needs to value the outcomes and have some expectation of success. Motivation is seen as a multiplication of value and expectancy, not an addition, because both factors must be present to achieve motivation. This means that if a trainee gives the course an expectancy or value score of zero, then motivation is zero (Motivation = Expectancy x Value). This theory is mainly relevant in the early stages of learning, in order to stimulate interest and continued engagement in trainees [28, 37].

2.1.5 Knowledge translation

The term knowledge translation appears in the medical and health care literature to focus the utilization of scientific research on health outcomes and behaviour change [38]. According to a definition by the Canadian Institute of Health Research, the purpose of knowledge translation is to address the gap between what is known from research data and what is done in practice settings by key stakeholders with the intention of improving health outcomes and the effectiveness of the health care system [39].

In all types of CME/CPD, effective strategies should be applied to transfer knowledge to action. This requires us to consider the impact of interventions on performance and health care outcomes. Quantitative and qualitative research is necessary in this process [38, 40].

An active learning approach with alignment between relevant topics and the curricular design has been found to be more effective in changing physicians' behaviour [26, 27]. Additionally evidence has shown that interactive and multifaceted learning methods in CME were more effective in changing doctors' performance and patients' health, while single educational interventions were less likely to reach this effect [14, 31, 41].

Identifying educational objectives and defining levels of learning help to design appropriate CME programmes to shift from knowledge to performance. Bloom's taxonomy is useful when determining educational objectives [42]. We tried to

describe the learning progress of the doctors in the programme in terms of the knowledge acquired, the understanding of that knowledge, the capacity to apply it, and the capacity to analyze, synthesize and evaluate, by using relevant educational materials, interactive methods, case scenarios and group work [43].

The SOLO taxonomy, which was described by Biggs [28], Miller's pyramid [44] and the Dublin descriptors [45] are other approaches to connect educational outcomes with curriculum, teaching methods and assessment. Biggs defined the levels of understanding for different topics in ascending order of cognitive complexity as "pre-structural", "uni-structural", "multi-structural", "relational" and in the highest level as "extended abstract", which is the level of reflection and generalization [28]. Miller recommended a framework in the form of a pyramid, for assessing clinical competence [46]. Miller's pyramid is a conceptual taxonomy which puts "knowledge" at the bottom of the pyramid, followed by competence ("knows how"), then performance ("shows how") and finally action ("does") at the highest level of the pyramid [44].

The mentioned theories and models provide a road map for developing appropriate interventions and evaluating their results. In this study, we considered the described learning theories and approaches when we designed the educational intervention and decided on evaluation methods. We considered outcome-based education (OBE) as an overarching approach that can influence the entire process of education, through mediating decisions about the content, formulation of aims, educational strategies, teaching methods, assessment procedures, and the educational environment [47].

2.2 TOWARD OUTCOME-BASED EDUCATION

The architect's plan is a key component in the construction of a building. In the same way, a clear statement of the learning outcomes is desired for a medical education programme. OBE has been proposed as a suitable approach in medical education, initially for undergraduate training [48-50], but has increasingly also been introduced in CME [51-54].

2.2.1 What is OBE?

The outcome-based education approach emphasizes educational outcomes rather than the educational process and focuses on the product of medical education such as what kind of doctors will be produced, and with what professional knowledge, skills, abilities, values and attitudes. Educational outcomes must be clearly specified as they determine the curriculum content, the teaching methods, the courses offered, the assessment process and the educational environment [55-57].

Harden described the importance of learning outcomes as a key component of curriculum planning, choosing educational methods and strategies and designing evaluation tools in medical education [58] (Figure 1).

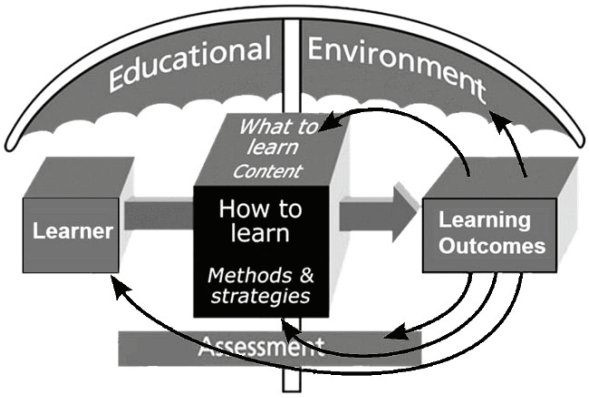

Figure 1: *Outcome-based educational planning, modified after Harden [59]*

2.2.2 Advantages of using OBE

Several advantages have been suggested for adopting an outcome-based model for medical education [48, 60].

1. *Relevance:* OBE helps to focus the relationship between the curriculum and the practice of medicine and on education for capability.
2. *Controversy:* The process of identifying the outcomes promotes discussion of fundamental questions such as what type of health professionals that should be promoted by medical schools or during CME programmes.
3. *Acceptability:* OBE is a model of education which is readily acceptable to most teachers.
4. *Clarity:* The concept of OBE is easily understandable. It is not constrained by educational jargon and is a relatively simple and unambiguous concept.
5. *Provision of framework:* OBE provides a powerful and robust framework for the curriculum.
6. *Accountability:* OBE, by setting out details of the finished product against which the product will be judged, emphasizes accountability and quality assurance.
7. *Self-directed learning:* OBE encourages learners to take more responsibility for their own learning.

8. *Flexibility:* OBE is a potentially flexible approach. It does not dictate the form of course delivery or the educational strategy.
9. *Guide for assessment:* Specification of the intended learning outcomes is essential for the planning and implementation of learner assessment. Outcome-based education is consistent with the move to more performance-based assessment.
10. *Participation in curriculum planning:* Many individuals or groups can contribute to the specification of outcomes. It encourages and facilitates integrated teaching and learning and collaboration between different disciplines in medicine.
11. *Tool for curriculum evaluation:* OBE provides an easy way of evaluating the curriculum effectiveness.
12. *Continuity of education:* OBE, by making explicit the outcomes for each of the phases or stages of education, helps to encourage continuity between basic or undergraduate education, postgraduate or vocational training and continuing education.

OBE determines what is to be achieved and assessed at the end of the training, [61, 62], "In OBE, product defines process" [63].

2.2.3 Outcome-based evaluation

CME developers increasingly attempt to evaluate the effectiveness of CME activities at the highest possible level, which means outcomes at practice level [64].

Davis' group reviewed randomized controlled trial (RCT) studies and concluded that when CME programmes were planned based on identified needs of physicians and incorporated multiple learning activities, their practice changed [15, 41, 65, 66]. The analyses by Davis and his colleagues were influenced by the four level model, which had been described by Dixon [67] for evaluating CME and focused on satisfaction, learning, performance and health status. This model is similar to the well-known model by Kirkpatrick, [68] which was described in 1959.

Donald and Moore [64] have suggested an outcome-based, multi-level evaluation model for CME (Box 1). It is a combination of the models described above.

Level	Outcome	Definition	Example
1	Participation	Registration and attendance	Attendance records
2	Satisfaction	To what extent participants' expectations were met	Satisfaction survey at the end of programmes
3	Learning	Change in knowledge, skills and/or attitude of participants	Pre-post test
4	Performance	Change in practice performance	Case scenarios, observations, simulated patients
5	Patient health	Change in patient health status	Patient data, lab tests
6	Population health	Change in population health status	Morbidity and mortality rate, incidence and prevalence data

Box 1: *Levels of outcome-based CME evaluation, developed by combining Donald [64] and Davis [69].*

Evaluation of some or all of the levels depends on the planner's purposes. The first and second levels are easy to assess using registration data and responses to Likert questionnaires. At the third level, participants' knowledge, attitude and skills could be assessed before and after the educational programme. Assessment of performance at the fourth level of the model is possible by measuring self-reported changes, using simulated patients or clinical documents, which show the actual performance. For evaluation of patient health status, there is a need to access patient data before and after the CME programme. Change in health status of patients and populations can be difficult to interpret as there are several other determining factors that cannot be influenced solely by educating physicians [25, 64]. Changes at these levels also require patient adherence and sometimes social interventions in the health system [25, 64].

2.3 RATIONAL PRESCRIBING

Rational use of medicines has been defined by the World Health Organization (WHO) as the ideal situation where "Patients receive medication appropriate to their clinical needs, in doses that meet their own individual requirements, for an adequate period of time, and at the lowest cost to them and their community" [70].

Prescribing is a core competency required of all doctors. However, for the same disease, a large variation has been found in the type and quantity of medications prescribed as well as in the quality of the prescriptions themselves [71-73]. This variation has even been described as "irrational" [74, 75]. A review study of 50 interventions for rational use of drugs in low- and middle-income countries

indicated overprescribing, multi-drug prescribing, misuse of drugs, use of unnecessary expensive drugs and overuse of antibiotics and injections as common problems of irrational drug use [76]. Prescribing high number of drugs per visit, injections, antibiotics and NSAIDs have been reported in several articles [77-80].

2.4 THE HEALTH SYSTEM IN IRAN

Article 29 of the Constitution of the Islamic Republic of Iran stresses that all citizens of the country have the right of access to the highest level of health [81]. A new health system with a focus on primary health care (PHC), formulated in 1979, has led to a remarkable reform in the health sector in Iran [82, 83].

Public health services are provided through a nation-wide network, which starts from PHC and extends to secondary and tertiary health services. The policies of the government have made the public sector the main provider of PHC over the last three decades. The private sector also plays an important role in health provision, but with more focus on secondary and third level health care [81, 84].

Medical education has been integrated into the Ministry of Health since 1986 with the aim of establishing more efficient coordination between medical education and the needs of the health services. The Ministry of Health and Medical Education is responsible for fulfilling this goal through the implementation of a national health policy. There is at least one public medical university in each of the 30 provinces (41 medical universities in total). The presidents of the universities are the highest health officials in the province. They are in charge of both public health care provision and medical education [84, 85]. Universities of Medical Sciences are responsible for continuing medical education in Iran.

2.4.1 GPs in Iran

General physicians make up a large group of doctors, working in primary and secondary health services in Iran. They graduate from medical schools after seven years of study. They can than continue their education to become a specialist the after three to five years.

There are more than 2000 GPs in the East Azerbaijan province. Almost all of them (95%) work in urban areas with the majority (1695 GPs) in Tabriz, the capital of the province. The majority are men. About twenty-five percent of general physicians are employed in public clinics, while 50% work in private clinics and 25% in both places. GPs working in the public sector receive a monthly salary. They can receive bonuses at the end of each year according to decisions made at each health centre. In the private sector, GPs' income is dependent on direct payment from the patients.

2.4.2 CME in Iran

The role of CME in Iran was established in 1990 by the Iranian parliament and implemented in the year 1991. CME is currently a very important part of an Iranian physician's professional development. Attendance at CME programmes is compulsory after graduation, not only for physicians, but also for other health professionals, like dentists, pharmacists, and lab specialists. In order to continue their professional careers, physicians' CME activities should include 125 credit points per five-year period. Universities and some scientific associations are responsible for arranging CME courses. There are five kinds of CME programmes in Iran: 1) Seminars, congresses, workshops, conferences, 2) Short professional courses, 3) Educational and research activities, 4) Self-directed learning programmes, 5) Fixed-plan programmes.

At least 40% of the 125 points in each five-year period should be earned in fixed-plan programmes. These programmes should consist of 'must knows' for each special profession and the number of participants on each course should not be more than fifty. Different educational methods should be used in the teaching of these programmes.

The educational intervention described and studied in this thesis belongs to the category of "fixed-plan programmes."

2.4.3 Rational prescribing in Iran

There is convincing data that shows excessive prescribing behaviour in Iran [75]. Some studies point to inappropriate, even irrational drug prescribing [86-89]. Most studies about irrational prescribing patterns of doctors in Iran [86, 87, 89, 90] and in other middle and low-income countries [77-80] have indicated the importance of appropriate CME interventions.

According to an unpublished needs assessment study about CME for GPs in the East Azerbaijan province (2002), rational prescribing practice was recognized as a high priority issue. Training in rational prescribing has been part of the CME programmes in Iran for some time, although the impact has not been evaluated. Therefore my study has been conducted in this important field.

2.5 RATIONALE OF THE STUDY

Traditional CME programmes in Iran most often use text-based methods for planning and teacher-centred, lecture-based teaching methods rather than interactive training methods. The main weakness of the present CME programmes is that certifications or credits are given to participants without assessing achieved results

in terms of knowledge, skills and performance. A national survey of CME programmes in Iran indicated that CME programmes were not so effective in attaining the desired outcomes. It was concluded that a change in CME programme elements, mainly in the training and assessment methods, would be necessary to improve the effectiveness of the programmes [91]. Another survey about teaching methods in CME programmes demonstrated that the most important priorities of CME educational programmes were fixed-planned programmes [92]. Most of the CME programmes assessed by other researchers had insufficient educational styles, one important reason being that the trainers knew too little about different methods in education [93].

Recognizing that OBE can cover the entire process of education, it can be proposed as an effective approach for conducting CME activities. So, the aim of this study was to test if OBE is effective, useful and appropriate in the Iranian context, through an intervention in the field of "Rational prescribing" for GP's during CME programmes.

3 AIM OF THE THESIS

3.1 GENERAL AIM

The overall aim was to evaluate the effectiveness of an outcome-based approach to continuing medical education and how it impacts the prescribing practices of GPs in the East Azerbaijan Province of Iran.

3.2 SPECIFIC AIMS

Identify appropriate educational outcomes for "Rational prescribing" in CME programmes for GPs based on experts' opinions, and develop content and curriculum for this education (Study I).

Evaluate the impact of an outcome-based educational intervention in the field of "Rational Prescribing" on GPs' knowledge and skills (Study II), and prescribing behaviour (Study III) compared to a traditional CME programme.

Explore the trainers' and GPs' perceptions regarding participation in outcome-based education in the field of "Rational prescribing" (Study IV).

3.3 HYPOTHESIS

An outcome-based continuing education intervention will improve GPs' competencies and performance compared to traditional, concurrent CME programmes.

4 OVERVIEW OF METHODS

4.1 STUDY SETTING

The thesis comprises four studies, all implemented in the East Azerbaijan province of Iran. (Figure 1)

Figure 1: *Map of Iran [94] and East Azerbaijan province [95]*

Iran is located in the south-west of Asia, the Middle East. The country has a population of approximately 70 million (2006) [96]. Medical education and most of the socio-economic and health indicators are similar in all 30 provinces (26 provinces at the time of the study). East Azerbaijan has a total population of 3.5 million, located in the north-west of Iran. There are 19 cities in this province with Tabriz as the capital and biggest city. East Azerbaijan receives most of its health and medical services from the Tabriz University of Medical Sciences. In other words, the Tabriz University of Medical Sciences plans and develops educational programmes for all general physicians in primary care (GPs) in this province.

Study participants were recruited among GPs in six cities in the province, not including the capital city of Tabriz. Three cities in the Northern part of the province (in total 289 451 inhabitants) were matched with three cities in the South (in total 288 576 inhabitants) [96], based on a ranking compiled in 2003, which looked at human development factors: economic status, health services, education, sports facilities, agriculture, and communication facilities [97]. This geographic separation was used to reduce the risk of participants interacting with each other and thereby potentially introducing confounding factors. The group of northern cities was then by random (toss of coin) selected as the intervention arm.

4.2 SAMPLE SIZE CALCULATION

The sample size was calculated based on the results of a pilot study among 29 GPs, not participating in the study [98]. The base-line competence level (knowledge and skills) was thus considered to be 40%. In order to achieve 30% improvement in the intervention arm compared with maximum 5% improvement in the control arm, the sample size would be 61 for each arm, assuming a statistical power of 80%, 5% significance level, and independence between the participating GPs.

Assuming that some of the GPs might not want to take part in the research, another 25% was added to the first sample size. Therefore we calculated 77 GPs for each group and consequently 154 GPs for the whole study.

4.3 OVERALL STUDY DESIGN, MATERIAL AND METHODS

The general study design was a cluster randomized controlled trial with two study arms: the intervention arm with an outcome-based education and the control arm with a current CME educational programme. The educational programmes were conducted in the field of rational prescribing, which is an important part of the GPs' therapeutic activities (Figure 2).

At first, educational outcomes in the field of rational prescribing were determined by experts including faculty members of medical universities who were occupied as trainers in the field of prescribing and other stakeholders concerned with CME programmes together with GPs' who had enough experience in this field. Delphi technique and panel discussion were used (Study I).

The study population was composed of all the GPs with a contract with the three main insurance organizations in Iran and working in the six selected cities in the province. They were invited by letter to participate in the CME programmes. Their knowledge and skills regarding the outcome-based indicators, developed in Study I were assessed using questionnaire and case scenarios (Study II). The GPs' prescribing patterns were evaluated by collection of prescriptions from insurance organizations (Study III) before and after the educational programmes.

Faculty members at the Tabriz University of Medical Sciences, who were also employed as trainers in the field of prescribing, were responsible for implementing both CME programmes; the outcome-based educational programme for the intervention arm and the traditional CME programme for the control arm.

The education took place on different occasions for GPs in the intervention and control groups to reduce the risk of participants' interacting with each other.

The views and perceptions of trainers and participants regarding the usefulness and effectiveness of outcome-based education in the field of rational prescribing were explored through qualitative analysis of semi-structured interviews (Study IV).

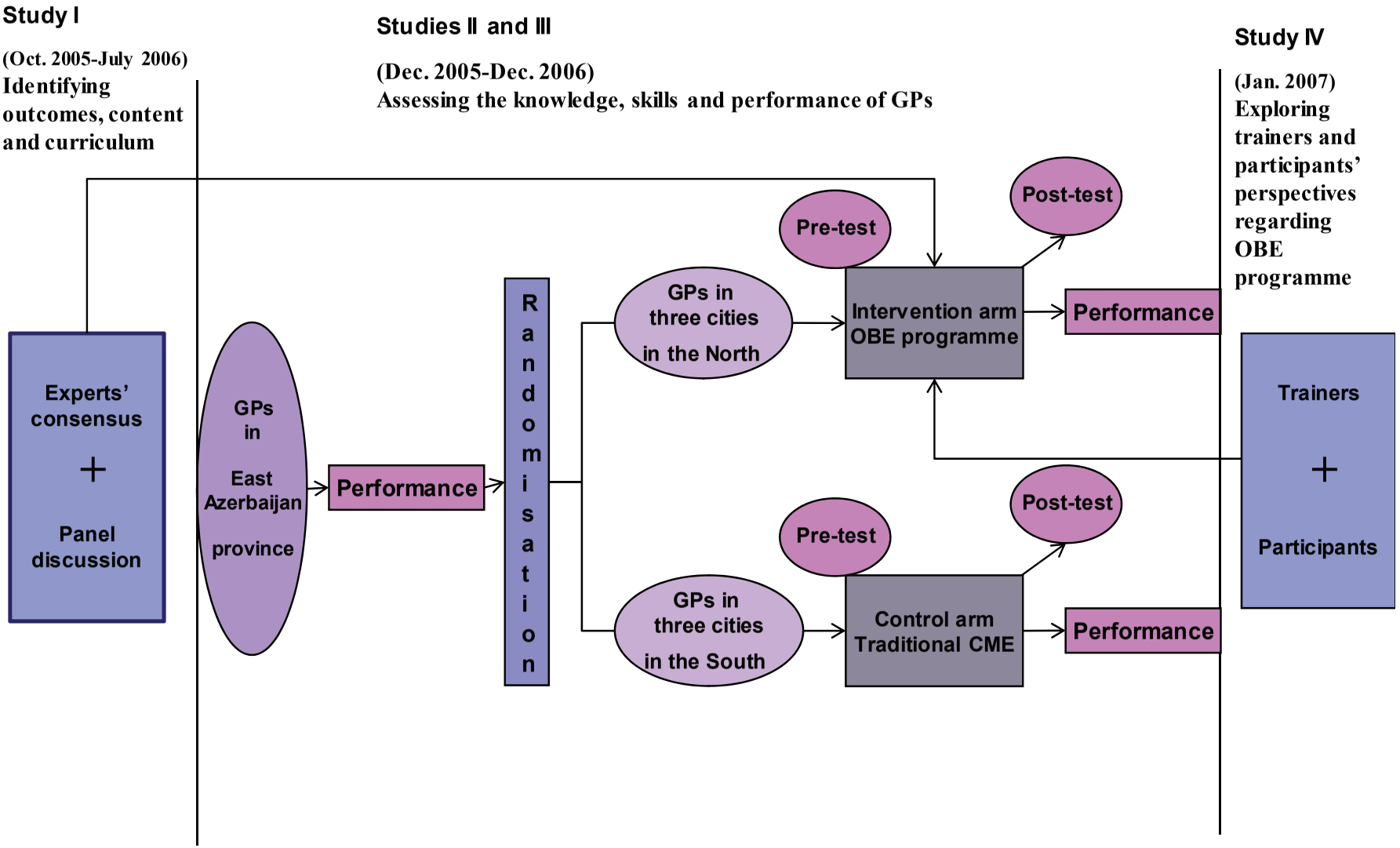

Figure 2: *Overview of four studies*

4.4 ETHICAL CONSIDERATIONS

Ethical approval for this study was obtained from the National Ethics Committee of the Iranian Ministry of Health and Medical Education in 2005.

Participants were made aware of using different educational methods in the intervention and control groups in the CME programme.

To preserve confidentiality, the prescriptions were give code numbers to identify and link prescription information to each GP. The lists containing code numbers of the GPs' names were stored and restricted to study personnel.

Participants filled out knowledge and attitude questionnaires without mentioning their names. All the trainers and GPs who were invited to an interview were informed that their identity was protected and that their answers would be confidentially handled. Their willingness to participate was secured and their informed consent was obtained.

5 METHODS AND RESULTS OF THE FOUR STUDIES

The study design, methods and results of the four studies are described in greater details below.

5.1 STUDY I

5.1.1 Methods

Identifying outcome-based indicators and developing contents and curriculum for CME programme on rational prescribing

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The study was conducted between October 2005 and July 2006 and included three steps: in the first step a two-round Delphi process was conducted to identify the outcome-based educational indicators for GP's CME in the field of rational prescribing. In the second step agreed results were submitted to a panel of experts to assess and finalize the learning outcomes and related indicators. Finally, in the third step teams of experts determined core curricula and assessment questions for different components of the programmes.

The Delphi technique was conceived as a suitable method to obtain the opinion of experts who were working in different Universities of Medical Sciences in Iran without necessarily bringing them together face to face [99]. The modified version of the Delphi technique was used involving a panel of experts [100, 101] in the field of rational prescribing and CME.

Participants
A group of 30 stakeholders was selected purposely. All of them had a background from at least one of the following categories (some represented several categories): 1) seven experienced GPs, 2) four decision makers from Universities of Medical Sciences with a background in pharmacy, pharmacology, or health management and members of the CME committee of the Ministry of Health and Medical Education (MOHME), 3) sixteen pharmacists (seven specialists in pharmacology), 4) six medical specialists. With the exception of the experienced GPs, all the participants were faculty members of four of the Universities of Medical Sciences in Iran as well as being CME trainers.

Delphi process and panel discussion
A small group of experts (part of the research team comprising a pharmacologist, a pharmacist, and two medical specialists together with the author of this thesis)

developed a questionnaire with 16 potential outcome indicators using the following sources: 1) WHO prescribing indicators [102, 103]. 2) Topics covered by CME programmes on prescribing in Iran. 3) Other relevant documents [86, 87, 89, 104].

The participants were asked to give their opinions, whether the potential outcome indicators should be included in a programme on rational prescribing using a 5-point Likert scale (1=totally agree, 2=partly agree, 3=uncertain, 4=partly disagree and 5=totally disagree). The participants were also asked to suggest any other potential learning outcomes, based on their expertise in the area.

A second round of Delphi process was conducted using the revised questionnaire based on assessing the results of returned questionnaires from the first round. In this round the questionnaire consisted of the initial potential learning outcomes from the first round and ten new learning outcomes that had been suggested by the experts. The respondents were asked to determine which of the proposed outcomes should be included in the CME programme by using a 4-point scale (1=totally agree, 2=partly agree, 3=partly disagree and 4=totally disagree) to avoid uncertain answers.

The results of the Delphi process were referred to an assigned panel of experts comprising four CME decision-makers, four pharmacists or pharmacologists, four medical specialists, three GPs, one epidemiologist, and the author of this thesis. The task of the panel was to finalize the educational outcomes and indicators and identify a suitable team among themselves consisting of seven experts to develop the content.

Content development

The previously mentioned team identified six educational topics for an outcome-based CME programme in rational prescribing, based on the results from the panel discussion. To develop the curricular content, a small group of three experts and CME trainers was assigned for each of the six topics. They determined the content for each topic and designed the relevant questions for assessing the participants' knowledge and skills.

The results from each of the small groups were distributed to the five other teams one week prior to a final review meeting. At this meeting, ideas about the curricular content and the knowledge-skill questionnaire were discussed and consensus was reached after a revision of some of the content and questions. The final curricular content was used for conducting the OBE programme in the intervention arm.

5.1.2 Results

What are the identified outcome-based indicators and developed contents and curriculum for CME programme on rational prescribing?

The Delphi process

Twenty-one out of 30 experts who had been invited to participate in the study returned completed questionnaires in the first round. Ten new potential outcomes were added to the 16 initial indicators based on the experts' suggestions and were returned to the experts for new assessment. All but one responded with new ratings (Table 1).

The nine invited experts, who did not answer despite sending the reminder later, were contacted to ask for the reason. Six of them mentioned that they were very busy and three of them did not see any personal benefit in participating.

The panel discussion

Seventeen panellists finalized the learning outcomes during two meetings based on the results of the Delphi process and considering current CME strategies. They accepted all but two of the outcomes, where at least 16 of the 20 experts had agreed that they should be part of the educational programme. The two excepted indicators were "Writing main complaint of the patient in the prescription" and "Appropriate number of vitamins". The panel also added one outcome related to prescribing of corticosteroids. At the end of the second meeting, 21 learning outcomes and assessment indicators had been identified (Table 2).

The content

The team of seven experts responsible for determining content divided the 21 learning outcomes into six topics for the educational programme:

1. Principles of prescription writing
2. Adverse drug reactions (ADR)
3. Interactions of drugs
4. Antibiotic therapy
5. Therapy with anti-inflammatory agents
6. Injections

The content and appropriate questions for assessment were then developed for each topic by smaller teams of three professionals. To ensure the content validity, the curricula were distributed to all six groups' members and finalized through group discussion during their last meeting together (Appendix 1).

Table 1 *Potential learning outcomes as assessed through the Delphi process*

Potential outcomes for Rational Prescribing (round 1)	**Agreement* (n=21)**	**Agreement* (n=20)**
Upon completion of the course, a doctor will be able to write a prescription that includes or considers:	**Round 1**	**Round 2**
Date of the prescription	21	20
Name and age of the patient	21	20
Name and identification number of Iranian Medical Council of the prescriber**	21	20
Main complaint of the patient	11	16
Legible hand writing	20	20
Generic name of the drugs	16	18
Administration form of drugs	20	20
Strength of the drugs and dose frequency	20	20
Adequate duration of treatment	16	20
Latin abbreviation of terminology in drug use order	12	17
Appropriate number of drugs	16	20
To consider homogeneity of prescription per individual (all drugs prescribed pertain to the same individual)	18	19
Not prescribing drugs with the same pharmacological effect	14	19
Not prescribing drugs which have negative interactions with each other	17	19
Appropriate number and amount of antibiotics	19	20
Appropriate number of injections	17	20
Suggested potential outcomes (added in round 2)		
Contact telephone number of the prescriber		17
Refill information		18
Initial diagnosis		15
Time and manner of drug use		17
Necessary precautions		16
Necessary notifications about signals to continue or stop drug use		13
Notification about side effects of drugs in the prescription		6
Name of the foods which have negative interactions on drug efficacy and the treatment process		8
Appropriate no. of NSAID (non-steroidal anti-inflammatory) drugs		20
Appropriate number of vitamins		19

* Sum of the number of respondents who answered “partly agree” and “totally agree”

** Compulsory in Iran

Table 2 *Rational prescribing outcomes and indicators for GP's CME programmes as agreed by an expert panel*

Outcomes	Assessment Indicator
Upon completion of the course, a participant should be able to:	
1. Write the date of the prescription	1. Date of the prescription
2. Write the name of the patient	2. Name of the patient
3. Write the age of the patient	3. Age of the patient
4. Write the name and identification number of the Iranian Medical Council for the prescriber	4. Name and identification number of Iranian Medical Council of the prescriber
5. Write the contact telephone number of prescriber	5. Contact telephone number of prescriber
6. Write refill information	6. Refill information
7. Write the prescription clearly	7. Legible handwriting
8. Write the generic name of the drugs	8. Generic names of drugs
9. Write the administration form of the drugs	9. Administration form of drugs
10. Write the strength of the drugs (dose and dose frequency)	10. Strength of the drugs
11. Write the duration of treatment	11. Treatment duration
12. Use the Latin abbreviation of terminology in drug use order	12. Use Latin abbreviation terminology
13. Write the time and manner of drug use	13. Time and manner of drug use
14. Write the necessary precautions	14. Necessary precautions
15. Prescribe the appropriate number of drugs	15. Appropriate number of drugs
16. Consider homogeneity of prescription per individual (all drugs prescribed pertain to the same individual)	16. Homogeneity of prescriptions
17. Avoid prescribing drugs with the same pharmacological effect	17. Number of drugs in the same pharmacological group
18. Avoid prescribing drugs which have negative interactions with each other	18. Number of interactive drugs per prescription
19. Prescribe the appropriate number and amount of antibiotics	19. Number and amount of antibiotics per prescription and proportion of antibiotics prescribed
20. Prescribe the appropriate number of injections	20. Number of injections per prescription and proportion of injections prescribed
21. Prescribe the appropriate number of anti-l inflammatory agents [corticosteroids and non-steroidal anti-inflammatory drugs (NSAID)]	21. Appropriate number of anti-inflammatory agents [corticosteroids and non-steroidal anti-inflammatory drugs (NSAID)]

5.2 STUDY II AND STUDY III

5.2.1 Methods

Evaluating the effectiveness of an outcome-based educational intervention on GPs' knowledge and skills and prescribing performance compared to a traditional CME programme in the field of "Rational Prescribing".

Selection of participants

All GPs working in six cities in East Azerbaijan Province in Iran were selected as participants of the study, provided that they had contract with one or more of the three major government controlled health insurance organizations (Social Security Organization; Medical Services Organization; Armed Forces Medical Services Organization), which pay the drug expenses for over 85% of the Iranian population [75]. Insurance organizations keep records of all reimbursed prescriptions. This allows for prescribing behaviour of individual doctors to be assessed. The GPs who had no contract were working in a specialized clinic or working part-time with only a few patients.

All 159 eligible GPs received invitation letters *aux mains* explaining the programme and offering CME credit points free of charge, if the course was completed. All GPs responded by returning a reply form indicating whether they agreed to participate or not.

Selection of trainers

The trainers of the intervention and control programmes were faculty members of Tabriz University of Medical Sciences and were experienced CME trainers. They were selected based on the annual evaluation of teaching performance and formal evaluation of CME trainers conducted by the CME Centre at the University. To maintain internal validity, trainers were matched in pairs based on their evaluation results and the topics they had taught previously. From this list of pairs, one group of eight trainers (3 women, 5 men; 4 medical specialists, 4 pharmacists) was assigned to teach in the control arm in the conventional manner, and the other group of eight trainers (2 women, 6 men; 4 medical specialists, 4 pharmacists) was assigned to the intervention programme. One trainer (a pharmacist) was later added by the curriculum development group to complement the medical specialist during one topic in the intervention programme.

Teacher training and development of a course plan

The training programme for the teachers in the intervention arm was conducted during a three-day workshop, one month prior to the CME intervention. The workshop contained sessions on outcome-based education, adult learning, communication skills, training methods, and how to design training sessions. Those responsible for the workshop were all faculty members working in the medical education field. The course plan, as well as the lesson plans for each topic, were finalized by the selected teachers themselves, based on the learning outcomes. The preliminary information from GPs prescriptions, which had been collected as base-line data were used when preparing the educational package.

An example of how a lesson plan was developed is shown in Box 2.

Box 2: *Example of how teaching methods and learning activities were developed related to the outcome 'Prescribe the appropriate number of injections'.*

Outline	Teaching method	Learning activities	Teacher's assessment
State objectives of lesson (5 m.)	Presentation		
Consideration of real needs for prescribing injections (15 m.)	Questions/answers Activating presentation	Answers/questions Brain storming	Quality of participation
Mechanism of injections (15 m.)	Activating presentation Questions/answers	Questioning Answer to questions	Answers to teachers' questions
Indications for injections (15 m.)	Activating presentation Questions/answers	Questioning Answer to questions	Answers to teachers' questions
Important factors in prescribing injections (20 m.)	Show samples of real prescriptions	Group discussion	Results from individual examples
Prevalence of using injections in the world and in Iran (10 m.)	Activating presentation	Bring up and discuss own knowledge and experience	Quality of participation
Conclusion [review of the topic, answer to questions] (10 m.)	Presentation	Feedback from the group	Quality of participation

The educational programmes

The educational programmes for the control and intervention arm were conducted at the Educational Development Centre (EDC) in Tabriz University of Medical Sciences in August and September 2006, respectively. Participants in each study arm were divided in two equal groups. Both programmes had the same topics: 1) principles of prescription writing, 2) adverse reactions to drugs, 3) drug interactions, 4) injections, 5) antibiotic therapy, and 6) therapy with anti-inflammatory agents. The CME programme for the control arm used the same traditional teaching methods as in previously conducted programmes. For the intervention arm, the training was based on the lesson plans from the teacher training workshop, using interactive and learner-centred teaching techniques, e.g., activating presentations, question/answer, case studies, case reports, large and small group discussions, and role playing. Supplementary self-learning educational materials were sent to the intervention group after completion of the programme.

The need for full attendance during the course was emphasized in both programmes. The physical environment was the same for both groups. Both programmes were offered over two days, but the number of hours differed as a reflection of the different educational methods used, eleven for the control group using didactic techniques and sixteen for the intervention group, which used more interactive learning methods.

Evaluation tools

Knowledge and skills

The GPs' knowledge and skills regarding rational prescribing were assessed at the start of the programmes and after one month. The test was designed and validated during Study I. Reliability of the test after a pilot study among 29 GPs, not participating in the study, was determined to be 0.74 (Cronbach's coefficient alpha).

The test consisted of 30 questions with a maximum score of 53. Participants' knowledge was assessed with multiple choice and short answer questions and their prescribing skills were tested with two case scenarios and three copies of actual "irrational" prescriptions.

Performance

Prescription data for all 159 GPs were collected nine months before and for 111 participants (one GP in control arm left the province) three months after the CME programmes. Ten percent of each GP's total number of prescriptions for individual patients during the selected month, was randomly collected from the insurance organizations.

The information on the prescriptions was entered into a database by three expert dispensers, who were members of the "Rational Prescribing Committee" of the two larger insurance organizations. A standard reference book [105] was used to identify drugs for which information on time and manner of intake of drugs, as well as precautions, was needed. To maintain the internal validity of data entrance, one GP and one pharmacist randomly checked about 20% of the entered prescription data with the original prescriptions, and found an error rate of 2.5%. Anatomical Therapeutic Chemical (ATC) classification codes [106] were used for coding the drugs for the analysis. The assessment was made on 16 out of the 21 outcome indicators developed in Study I (Table 3).

TABLE 3 *Outcomes and assessment indicators*

Outcomes	Assessment indicators
Prescription	
1. Prescribe appropriate number of drugs	1. Appropriate number of drugs
2. Prescribe appropriate number of antibiotics	2. Number of antibiotics per prescription and proportion of antibiotics prescribed
3. Prescribe appropriate number of injections	**3. Number of injections per prescription and proportion of injections prescribed**
4. Prescribe appropriate number of anti-inflammatory agents [corticosteroids and non-steroidal anti-inflammatory drugs (NSAID)]	4. Appropriate number of anti-inflammatory agents [corticosteroids and non-steroidal anti-inflammatory drugs (NSAID)] and proportion
5. Write name and Iranian Medical Council identification number of the prescriber	5. Name and Iranian Medical Council identification number of prescriber
6. Write prescription clearly	6. Legible handwriting
Drugs	
7. Write generic name of drugs	7. Generic names of drugs
8. Write formulation of drugs	8. Correct formulation of drugs
9. Write strength of drugs	9. Strength of the drugs
10. Write daily dose of drugs	10. Daily dose of drugs
11. Write duration of treatment	11. Treatment duration
12. Write time of drug use	12. Time of drug use
13. Write manner of drug use	13. Manner of drug use
14. Write necessary precautions	14. Necessary precautions
15. Avoid prescribing drugs with the same pharmacological effect	15. Number of drugs in the same pharmacological group
16. Avoid prescribing drugs which have negative interaction with each other	16. Number of interactive drugs per prescription

Quality of educational programmes

In order to assess how well the intervention arm followed the OBE approach and to provide a comparison with the control arm, two observers, the author of this thesis and a GP (both of whom were planners and educators of teacher training programmes at the EDC), assessed the trainers' and participants' activities in both large and small group sessions in the intervention arm using a checklist developed at the EDC. In the control arm, the same observers rated only the activities of the trainers, as small group learning activities were not used. All six topics of the educational programmes were

assessed using a 3-point Likert scale regarding level of accomplishment (1= Fully, 2= To some extent, 3= Not at all).

The opinions of the participants about the quality and usefulness of the educational programmes were collected using the national assessment questionnaire with a five step Likert scale (5=very much, 4=much, 3=moderate, 2=little, 1=very little) which had been used for the last twelve years to assesses CME programmes in Iran.

Data analysis

Knowledge and skills

Independent samples t-test and chi-square test were used to compare the characteristics of intervention and control groups with respect to sex, age and work experience of the participants. Test scores were compared as repeated measurements before and after the intervention. As no personal identifier was included in the data set, tests for independent observations were therefore used.

Differences in test scores were first computed pre and post-test and compared between the intervention and the control arms using the Mann-Whitney U test. The intervention effect was analyzed as the interaction term of being in the intervention arm after the intervention in an ordinary least squares regression model. The interaction term corresponds to the effect of the intervention adjusted for the development over time in the control group.

Performance

Outcome indicators, which related to the number of drugs, injections, antibiotics, NSAIDs and corticosteroids, were assessed related to all prescribed medicines to an individual patient during one encounter. Drug prescription items, including writing of generic name, formulation, strength, daily dose, time, manner and precautions were computed as a categorical variable for each drug in each prescription (correct=1; incorrect =0). Potential drug interactions and poly-pharmacy were detected using a customized computer programme (Monitor) [107], which computed the average number of drugs with possible interactions and duplications per prescription for each GP. The mean scores for each indicator for the intervention and control arm, before and after the intervention were calculated, and the differences were compared using an independent t-test. The intervention effect was estimated from observations of those who participated in the study. Linear regression with robust standard error method was used to adjust for intra-cluster correlations (ICC).

Quality of educational programmes

We compared the opinions of the participating GPs in the intervention and control arms to determine whether there were any significant differences. Independent-sample t-test was used to examine the differences between the two groups.

For all analyses a p-value of 0.05 was considered statistically significant and 95% confidence intervals (CI) were reported. Analyses were carried out using STATA 10 and SPSS 15.

5.2.2 Results

Does an outcome-based educational programme improve the GPs' knowledge, skills and performance in the field of rational prescribing?

Participants

Sixty-six GPs out of 74, who were working in the northern part of the province, accepted the invitation to participate in the intervention programme, and 58 (88%) actually came. In the control arm, 85 GPs were eligible, 71 confirmed their participation, and 54 (76%) finally participated in the control programme. The diagram shows the flow of participants through each stage of the randomized trial (Figure 3).

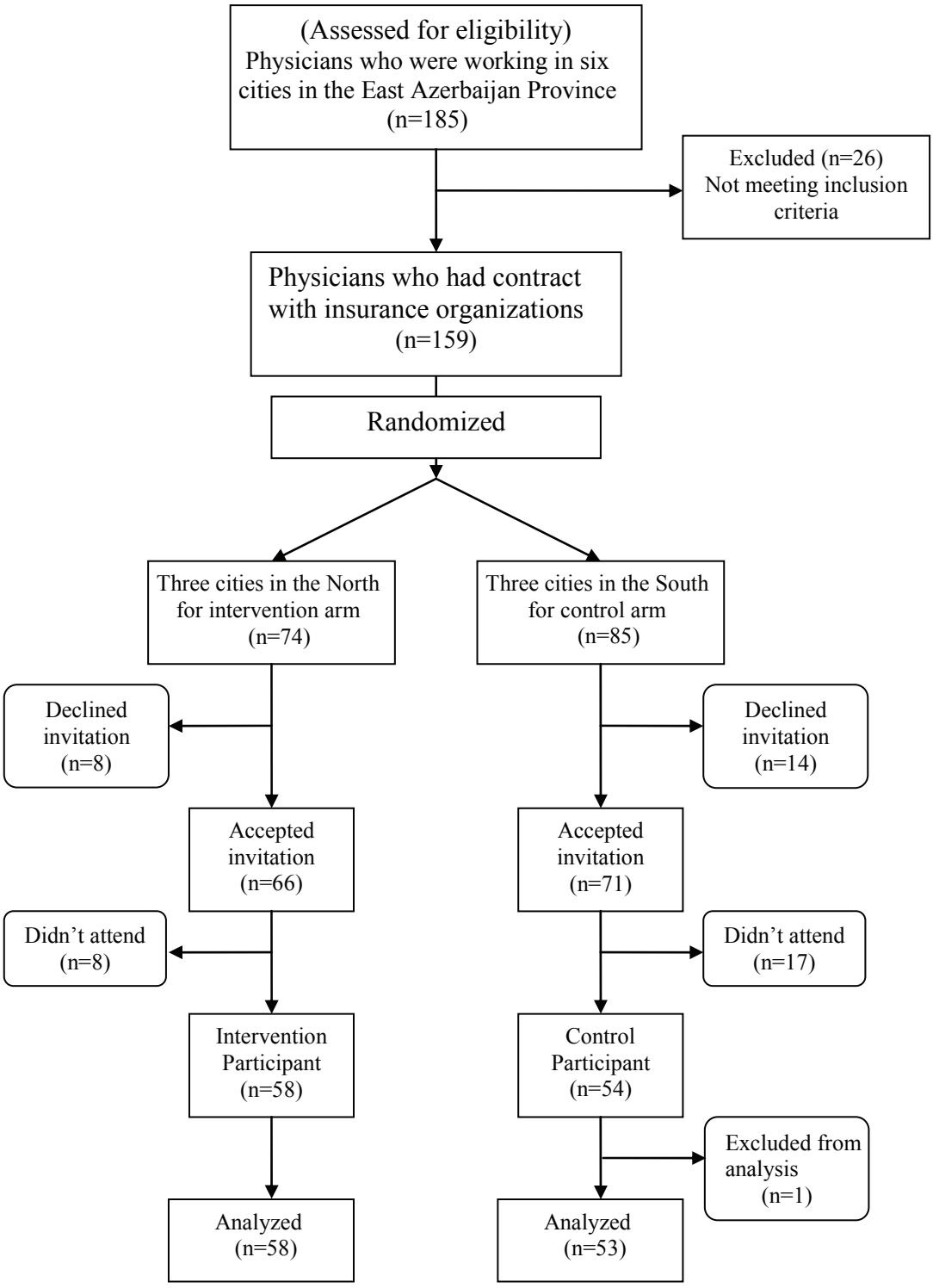

FIGURE 3 *Participation flowchart*

We didn't find any significant difference between non-participants and participants, nor between participants in the intervention and control arms in terms of age, sex and work experience (Table 4).

Knowledge and skills

There was no significant difference in knowledge or skills between the control and intervention arms before participation in the educational programmes. After the programmes GPs in the intervention arm demonstrated a significant improvement, both in comparison with the pre-test and with GPs in the control arm, where no significant change was detected. The overall intervention effect was 26 percentage units for the total knowledge score (Table 5).

We found significant improvements in the intervention arm in all six topics of the educational programme with intervention effects ranging from 15 to 34 percentage units (Table 6).

TABLE 4 *General characteristics of eligible GPs for participation in the educational programmes*

General characteristics	Non-participants N=46*	Participants N=112	P-Value	Intervention N=58	Control N=54**	P-Value
Male n (%)	37 (80)	77 (71)	0.24	42 (72)	35 (70)	0.78
Age (in years) Mean (SD)	42 (9.2)	40 (6.5)	0.07	39 (6.8)	41 (6.1)	0.23
Work Experience Mean (SD)	12 (7.2)	11 (4.9)	0.43	10 (5.2)	11 (4.4)	0.42

* An 82 year old GP with 53 years' work experience was excluded from the non-participant group before analysis
** Four missing cases for "sex"

TABLE 5 *Total score (maximum =53) for the knowledge and skills test for GPs in the intervention and control group*

	Pre-test			Post-test			Intervention Effect	
	Intervention Mean (SD) (n=58)	Control Mean (SD) (n=54)	p-value	Intervention Mean (SD) (n=58)	Control Mean (SD) (n=53)	p-value	Intervention effect (SE)	p-value
Score	22.2 (4.7)	21.8 (4.6)	0.626	37.3 (3.8)	23.1 (3.8)	<0.001	13.8 (1.1)	<0.001
% of Total Score	42 (8.9)	41 (8.7)		70 (7.2)	44 (7.2)			
Diff. Pre-Post (%)				29	2.5		26	

Table 6 *Total score for the knowledge and skills test for GPs in the intervention (n=58) and the control (n=54) groups for the six different curricular topics*

Topic (Maximal score)	Pre- test			Post- test			Intervention Effect	
	Intervention Mean (SD) %*	Control Mean (SD) %	p-value	Intervention Mean (SD) %	Control Mean (SD) %	p-value	Intervention Effect (SE) Percentage	p-value
1. Principles of prescription writing (19)	7.2 (3.1) 33	6.7 (3.0) 35	0.58	14.4 (2.5) 76	7.4 (2.6) 39	<0.001	6.5 (0.8) 34	<0.001
2. Adverse reactions to drugs (9)	4.2 (1.1) 47	4.2 (1.2) 47	0.90	6.3 (1.1) 70	4.3 (1.2) 48	<0.001	2.0 (0.3) 22	<0.001
3. Drug interactions (4)	2.1 (1.1) 53	2.2 (0.9) 55	0.37	2.8 (1.0) 70	2.3 (0.9) 58	0.007	0.6 (0.3) 15	0.022
4. Injections (3)	1.9 (0.7) 63	2.0 (0.4) 67	0.29	2.5 (0.7) 83	2.0 (0.5) 67	<0.001	0.5 (0.2) 17	0.001
5. Antibiotic therapy (11)	4.0 (2.0) 36	4.0 (1.9) 36	0.91	5.9 (1.7) 54	4.1 (1.4) 37	<0.001	1.8 (0.5) 16	<0.001
6. Anti-inflammatory agents therapy (7)	2.7 (1.2) 39	2.5 (1.2) 36	0.37	5.2 (1.0) 74	2.7 (1.1) 39	<0.001	2.4 (0.3) 34	<0.001

* Percentage of maximum score for each topic

Performance

We evaluated 13 480 prescriptions issued by 159 GPs in the baseline (8 052) and by 111 GPs after the intervention (5 428). One GP in the control arm was excluded from the analysis as no prescriptions were found after the programme. The assessment indicators were evaluated from two perspectives: 1) Indicators related to components of the whole prescription (all drugs at one encounter), 2) Indicators applicable to each drug prescribed.

The prescribing behaviour of participants and non-participants did not show any differences in the baseline evaluation.

1) The mean number of drugs per prescription decreased significantly from 4.11 to 3.89 in the intervention arm, whilst there was no change in the control arm. Similarly, the mean number of injections per prescription decreased significantly from 0.95 to 0.80 in the intervention arm, with no change in the control arm. However, the percentage of prescriptions with at least one injection was still high in the intervention arm (52%).

There were no significant differences between the intervention and control arms in the number per prescription of antibiotics, non-steroidal anti-inflammatory drugs (NSAIDs) or corticosteroids, although corticosteroid prescribing was reduced in the intervention arm and NSAIDs were reduced in both arms (Table 7).

The name and identification number of the prescriber were included in almost all prescriptions in both groups before and after the intervention. The doctor's handwriting was illegible in one out of ten prescriptions.

2) The GPs in the intervention arm significantly improved their written explanations of specific times, manner and precautions necessary when taking the medications compared with the control arm, with intervention effects of 13, 36 and 42 percentage units, respectively. There was no change for prescribing drugs in the same pharmacological group, or drugs with possible interactions (Table 8).

GPs in both study arms prescribed about 97% of the drugs using the generic name and almost all wrote a correct formulation of drugs, dose (strength), and course of the treatment in their prescriptions (more than 99%). However, for 10% of the drugs, the prescribed dose frequency, as an instruction for patient use, was not included.

Quality of the educational programmes

The observations of the training sessions indicated that the general characteristics of the teaching and learning environment were more constructive for active learning in the intervention compared to the control groups (Appendix 2).

Group activities in the intervention programme were facilitated in a supportive fashion. The observation checklists for the group work showed that the goals for the group work were clearly explained and that the small group members actively participated in the discussions. Participants were able to interact face-to-face with ease and an active listening style dominated.

The results of the participants' written assessment at the end of the courses showed significant differences between the participants' opinions in the intervention and control arms about the items of the questionnaire related to content and curriculum. GPs in the intervention arm rated the quality of the intervention programme higher than the control group (Table 9).

TABLE 7 *Prescription-related outcome indicators for GPs in the intervention and control arm. Coef= regression coefficients; 95% CI confidence intervals*

Outcome indicators	Pre-test			Post-test			Intervention Effect	
	Intervention Mean (SD) percentage*	Control Mean (SD) percentage	P-value	Intervention Mean (SD percentage	Control Mean (SD) percentage	P-value	Coef.	95% CI
1. No. of drugs/prescription	4.11 (0.65)	4.17 (0.56)	0.38	3.89 (0.45)	4.18 (0.71)	0.009	-0.20	(-0.71, 0.32)
2. No. of antibiotics/prescription % prescriptions with antibiotic	0.81 (0.19) 61	0.84 (0.30) 59	0.46	0.83 (0.19) 63	0.88 (0.33) 60	0.34	-0.01	(-0.21, 0.19)
3. No. of injections/prescription % prescriptions with injections	0.95 (0.32) 59	1.02 (0.49) 59	0.44	0.80 (0.28) 52	1.04 (0.53) 58	0.004	-0.18	(-0.42, 0.07)
4. No. of NSAIDs/ prescription % prescriptions with NSAID	0.55 (0.19) 45	0.55 (0.26) 43	0.95	0.44 (0.13)** 38	0.47 (0.27)** 39	0.50	-0.03	(-0.19, 0.13)
5. No. of corticoster./prescription % prescriptions with corticoster.	0.42 (0.19) 39	0.42 (0.21) 38	0.9	0.35 (0.14)** 32	0.39 (0.21) 37	0.16	-0.05	(-0.17, 0.07)

* Percentage of prescriptions including each item

** Significant difference only compared with pre-test

TABLE 8 *Drug-related outcome indicators as proportions of all drugs for GPs in the intervention and control arm. Coef= regression coefficients; 95% CI confidence intervals*

Outcome indicators	Pre-test			Post-test			Intervention Effect	
	Intervention Mean (SD)	Control Mean (SD)	P-value	Intervention Mean (SD	Control Mean (SD)	P-value	Coef.	95% CI
1. Time of drug intake	0.57 (0.28)	0.47 (0.34)	0.11	0.74 (0.68)	0.51 (0.3)	<0.001	0.13	(-0.002, 0.26)
2. Manner of drug intake	0.20 (0.20)	0.19 (0.21)	0.93	0.60 (0.28)	0.23 (0.23)	<0.001	0.36	(0.27, 0.46)
3. Necessary precaution of drug use	0.13 (0.27)	0.15 (0.28)	0.79	0.58 (0.39)	0.19 (0.32)	<0.001	0.42	(0.21, 0.62)
4. Drugs with:								
- Interaction C	0.08 (0.07)	0.07 (0.07)	0.37	0.08 (0.06)	0.09 (0.08)	0.40	-0.02	(-0.07, 0.02)
- Interaction D	0.009 (0.02)	0.01 (0.02)	0.87	0.01 (0.02)	0.01 (0.02)	0.23	0.004	(-0.00, 0.01)
5. Drugs with same pharmacological effect	0.13 (0.08)	0.15 (0.15)	0.46	0.10 (0.06)	0.13 (0.14)	0.13	-0.01	(-0.08, 0.06)

Table 9 *Participants' assessment of the courses in the intervention group (N=58) and control group (N=54)*

Items of evaluation	Groups	N	Mean	Std. Deviation	P-Value
Success of program me to strengthen your correct previous knowledge	Intervention	58	4.36	.693	< 0.001
	Control	54	3.50	1.005	
Success of programme to give you new scientific information	Intervention	58	4.16	.721	< 0.001
	Control	53	3.40	.947	
Suitability of programme content with your professional needs	Intervention	57	4.30	.778	0.001
	Control	54	3.74	1.013	
Success of programme to motivate you to read more deeply related texts	Intervention	55	4.15	.731	< 0.001
	Control	53	3.51	1.012	
Arrangement of programme subjects in logical consecution	Intervention	57	4.11	1.07	0.001
	Control	53	3.45	1.030	
Proportionate of time and content of each subject	Intervention	56	4.11	.908	0.001
	Control	53	3.51	.953	
Opportunity of audience for active participation in discussions	Intervention	56	4.23	.853	< 0.001
	Control	54	3.48	.926	
Amount of CME points	Intervention	58	3.31	1.366	0.34
	Control	49	3.08	1.038	
Your satisfaction regarding use of educational materials	Intervention	57	4.09	.912	0.01
	Control	53	3.64	.857	

5.3 STUDY IV

5.3.1 Methods

Exploring the trainers' and GPs' perceptions regarding participation in outcome-based education in the field of "Rational prescribing".

Participants

All nine trainers and 12 participating GPs (out of 58) in the OBE programme were selected using purposeful sampling and were invited to individual interviews four months after participation in the programme. GPs were selected based on variation in age, gender, years in practice and city of practice. Data saturation [108] for GPs was

reached after twelve interviews (5 women, 7 men), as no new information emerged from the data.

Data collection

Semi-structured guides were used for the interviews. Content validity of the guidelines was verified by experts in the medical education field. All interviews were conducted in January 2007 by the author, some face-to-face and some by telephone and were recorded on audiotape with the permission of the interviewees. The venue and time of the interview were selected by the participants. The interviews with the GPs were conducted in the local language (Azeri), translated into Farsi and then transcribed verbatim, while the interviews with the trainers were conducted in Farsi and then transcribed.

The interview transcripts were compared with the recorded files for accuracy. Some of the interviews and all meaning units were translated into English by the author and two of the Iranian research team members verified the accuracy of the translations.

The trainers were asked to explain their point of view regarding the OBE approach and to describe how it had influenced their educational strategies and methods. How participants were involved in the OBE programme was also compared with other CME programmes (Appendix 3). The GPs were encouraged to describe their experiences of the educational programme that they took part in; to explore their views on what aspects of the outcome-based education they found more effective with regards to improving their knowledge, attitudes, skills and performance (Appendix 4).

Data analysis

Qualitative content analysis was used for analysis of the transcribed data considering what the transcripts comprised and through interpretation of meaning and intention [109-112]. The descriptive analysis was referred to the manifest content and described the obvious components of the text. The interpretive level was expressed as the latent content, although contrast between descriptive and interpretive level is indeterminate [112]. Therefore, attention should be paid to both the manifest and latent content all over the analysis of data [113, 114].

All parts of the interviews were read and re-read by the author of this thesis to capture a sense of the whole. Then the meaning units were identified by underlining key phrases and words in the text. The meaning units were subsequently labelled with suitable codes. Another member of the research team re-coded some of the texts and meaning units, serving as an inter-rater and thus increasing the reliability of the codes. The themes discerned through the analysis as meaning units and codes were reduced to suitable sub-themes under main themes, which were checked with the other authors until consensus was reached [115]

For trustworthiness, member, peer and expert check was done. In this regard, transcripts and some primary results were checked with participants and all were checked by some experienced colleagues and an expert in qualitative analysis.

Direct quotes were provided to illustrate and exemplify the themes as well as the sub-themes, to give the reader an opportunity to assess the feasibility of the themes and sub-themes suggested by the authors. The origin of the quotes is indicated through a "P" for participants (trainees) and "T" for trainers.

5.3.2 Findings

What are the trainers' and GPs' perceptions regarding outcome-based education?

Trainees

All but one of the GPs had participated in several CME programmes during his or her professional career. One third had participated in at least one Rational Prescribing CME programme before the outcome-based programme (OBE) in this study.

The GPs' perceptions regarding the outcome-based education can be captured in five themes: 1) Usefulness of the programme, 2) Content and process features of the programme, 3) Effects on motivation, 4) Impact of the programme on the participants, 5) Barriers to application.

Theme 1: Usefulness of the programme

Participants clearly expressed that the programme was useful, cost-effective and oriented towards health outcomes. There was some dissatisfaction about the antibiotic therapy session, but the overall conviction was that the programme was useful for improving everyday clinical prescribing behaviour.

> *"I learned lots of scientific and practical issues about prescription writing during this programme despite 15 years of work experience. Most of the other CME programmes which I have participated in were not adapted to GPs' professional needs. Some of them are specialized. Some of them are very primitive. Doctors participate in those programmes only to receive CME points…" (P3)*

Interviewees said that a positive element of the programme was that they had opportunities to learn from one another by sharing knowledge and discussing real experiences.

> *"Because of using the workshop method, we had good interaction with each other…we were talking about our experiences in different subjects…when*

asking the questions sometimes colleagues liked to answer the questions… I mean before teachers." (P7)

Another useful aspect of the programme was receiving up-to-date information throughout the programme. In their opinion, trainers provided new information, unlike what usually occurred CME programmes.

Theme 2: Content and process features of the programme

Participants reported that the content of the OBE programme was different than the other CME programmes in which they had previously participated. Information about new drugs on the market was especially relevant and appreciated.

Several mentioned that the teaching methods were unlike teaching methods in other CME programmes. Teaching collaboration between medical doctors and pharmacists was a new experience. The roundtable arrangement, which fostered an open environment and close interaction between trainers and participants, was valued highly.

The participants were surprised when, for the first time, they received two updated handouts one month after the CME programme, the information on which they found relevant. The GPs also appreciated the unprecedented exams, which provided an opportunity to make self-assessments.

Theme 3: Effects on motivation

The interviewees explained that after participating in the programme, they were more motivated to read and learn about rational prescribing and related topics. They emphasized the major role played by the trainers to motivate them.

Theme 4: Impact of the programme on the participants

Some GPs noted that they had previously recognized their irrational performance, and changed their behaviour by applying principles of prescription writing acquired through the programme. Some of them believed that they were already thoughtful about rational prescription before the programme, but that they now were even more encouraged to practice according to their beliefs. Most believed that they had decreased the number of drugs per prescription and reduced the number of injections, which gave them a sense of satisfaction and pride. They strongly requested assessment of their prescribing.

The GPs repeatedly mentioned that they and their colleagues needed to change their attitude to rational prescribing. Nevertheless, some said that this kind of programme could change their attitude but not necessarily their performance, due to external barriers.

"It is very good to participate in this kind of programme and I am sure the programme changed the attitude of most of my colleagues regarding prescribing but it is not possible to fly by one wing. The health system should be changed to consider doctors' economical situation." (P6)

Attempting to change their patients' attitude regarding rational prescribing was stressed as an essential issue in some interviews, as well as patient education.

"… one day I had a patient, my diagnosis was a viral cold. When I explained to him about the medicines which I prescribed, he told me, what about penicillin, why don't you write penicillin for me, if I don't take penicillin I never recover. I remembered the discussions we had on workshops about patient education and tried to explain to him that for viral diseases not only are antibiotics not useful but they also create some problems in the future. I talked a bit about antibiotic resistance… apparently he accepted and left my office. I don't know if he went to another doctor to receive antibiotics or not but I was satisfied with making the right decision." (P1)

The GPs stressed the role of mass media in educating people about the rational use of drugs and the dangers of self-treatment.

Theme 5: Barriers to application

Most participants believed that pharmacists and doctors play a key role in shaping patterns of irrational drug use. Pharmacists give drugs to patients without prescriptions, and doctors follow patients' irrational requests and sometimes prescribe incorrect drugs without considering the side effects. It was clear that some doctors felt forced to accept patients' requests in order to keep them as clients.

Some also expressed fear that if they did not follow the patients' or guardians' irrational requests, they might face physically violent retaliation. Doctors also explained the difficulties posed by patients who have pursued long-term self-treatment without sufficient effect, especially with regards to antibiotics. Lack of time was another reason GPs mentioned as a barrier to patient education and rational prescribing.

Trainers

All trainers had previous CME teaching experience and some had been acting as scientific coordinators in CME programmes for several years. The trainers' perceptions regarding the outcome-based education can be captured in four themes: 1) Thinking in outcome-based terms, 2) Improving the learning environment, 3) Usefulness of assessments, 4) Inter-professional education.

Theme 1: Thinking in outcome-based terms

For the trainers, identifying the outcomes of education and defining the expectations of trainees helped them to better prepare the educational programme. Considering outcomes helped them to determine the relevant material and plan suitable methods of teaching and assessment. From the trainers' point of view, the content of the programme should not focus on classical medicine, but clinical issues and GPs' "must-knows".

> *"This programme had a very great effect on my attitude as a teacher regarding the education. I taught in several CME programmes before, but now I notice that we must consider outcomes of education…education should not be transferring series of theoretical issues from books and articles without thinking that who are the trainees and what is the expectations of them after education." (T6)*

There was a strong belief that OBE is an appropriate approach to CME because of the complexity of adult learning. OBE contributed to the success of the programme by fostering a supportive environment and motivating doctors to actively participate.

The trainers predicted that the programme would have an effect on participants' attitudes and performance based on the discussions during the programme and the feedback they received, but emphasized the need for follow-up programmes to improve GPs' practice.

Theme 2: Improving learning environment

The trainers said that they followed different educational strategies and planning techniques compared with previous CME programmes. Based on the OBE framework, they compiled outcome-oriented plans and interactive, problem-based teaching methods.

All the trainers emphasized the influence of the teacher-training workshop on their performance. The workshop helped to cultivate new ideas, form an educational framework, design different teaching methods, and focus on useful topics. Some believed that all faculty members would benefit from participating in such a workshop. The short length of the workshop was mentioned several times by trainers, who believed that a more comprehensive workshop would improve their performance.

> *"In our country, university teachers –especially in medical universities- are specialists in their professions. But regarding teaching they don't receive structured education. If they are successful, it's because of their individual characteristics and if they are not, the reason is same. We weren't educated as teachers and we just follow the traditional education methods. Even though the OBE workshop was very short, we understood that we must change our*

methods…we faced new methods, which were considerable when designing the educational programme…just great. In my opinion all faculty members during their professional life must participate in this kind of workshop, not only once, but continuously…" (T6)

The trainers expressed satisfaction regarding GPs' involvement in the educational process and recognized the GPs' satisfaction with the programme. The participants' active listening, eagerness to contribute to discussions, and relevant questions were mentioned by trainers as an exciting part of their teaching experience.

Theme 3: Usefulness of assessments

The interviewees appreciated being able to access the results of the programme using the designed assessment tools. It was new for some to know ahead of time what would be assessed during and after the programme and which tools would be used. The assessment results were valuable feedback for use in future educational planning.

The trainers expressed a willingness to know if the programme had any effect on the GPs' competence level. Interviewees acknowledged the difficulty in changing GPs' behaviour despite well-planned educational programmes, and stressed the importance of education as a key prerequisite for behaviour changes.

Some mentioned other factors that influence prescription, such as diagnosis, cultural and economic factors. They believed that education about principles of prescription writing must become a subject in undergraduate education before entering practice: *"creating a right behaviour is much better than trying to correct the wrong one"* (T4).

Theme 4: Interprofessional education

The interviewees appreciated the teamwork among themselves. They described the positive feeling when the group of multi-disciplinary trainers collaborated to train the target group in a concerted manner.

"In this programme we build almost everything together with other colleagues. We taught together also… For example I knew what my colleague is going to teach, so I didn't repeat it…, unlike the other CME programmes which we are invited to teach without any information about the rest of it..." (T1)

6 DISCUSSION

The findings presented in this thesis indicate that an outcome-based intervention within the context of CME can impact the knowledge, skills, attitudes, and performance of GPs in Iran. Our findings thereby suggest that continuing medical education programmes could benefit from using an OBE approach, not only for training in rational prescribing, but presumably also in other fields. This was directly pointed out by both the trainers and participants involved in the study. Our findings also show that the impact was greater on GPs' knowledge and skills than on their performance, calling for further attention to approaches that can reduce the know-do gap [116].

6.1 GENERAL DISCUSSION

We found an overall improvement of 26 percentage units in the total score of GPs' knowledge and skills compared with the traditional concurrent CME programme. There was widespread self-reported agreement that OBE changed the participants' attitudes also. The difference between the intervention and control arms in our study could be related to the constructive alignment [28] of the curriculum, where the outcomes, content, educational methodology, and assessment built upon each other. This resulted in a structure, which was followed consistently by the trainers in the intervention arm. Another advantage of using OBE was that it brought professionals together to design and implement the educational programme.

The theoretical foundation for OBE comes from undergraduate education. The OBE approach has been successfully introduced in several medical schools [117, 118]. In the Scottish example, the emphasis was on the relationship between outcomes and integration of the knowledge, skills and attitude in the practice of medicine [54]. Since then, OBE has increasingly become applied to CME [119].

In this project, we started by identifying outcomes and outcome-based indicators. Outcomes helped trainers to design the educational materials and methods and explain precisely to GPs what was expected of them after the programme. In this way, participants had a clear picture of which outcomes they should gain after finishing the course.

The Delphi technique was used in order to gather the opinions of several experts from heterogenic groups [120] and to reach a consensus about outcomes and indicators for rational prescribing [121]. Panels of selected experts were also included to better validate the outcomes and further develop programme content and curricula. This modified version of the Delphi technique together with panel discussions has been used in other Delphi studies to identify prescribing errors in order to increase the

validity of the findings [122, 123]. Based on the outcomes, curricular content was determined by an expert team and an appropriate questionnaire was developed, since statements of change by the learner should readily be assessed after the educational experience [56].

Understanding the theories of physician education and characteristics of useful CME interventions helps to provide effective CME and enhance learning [124]. In this study, the principles of adult learning theory helped trainers to design the educational programme based on GPs' characteristics as an adult learner, their readiness to learn, the role of learners' experiences and their self concept [24]. According to the course plan, trainers engaged participants in learning activities and provided real examples of irrational prescribing, thereby enhancing programme relevance. This approach raised the value of the topic (expectancy-value theory) and motivated participants to improve their practice [28].

After a systematic review, Cochrane et al. [116] categorized major types of barriers to optimal care: professional barriers (cognitive-behavioural and attitudinal), barriers embedded in practice guidelines, patient barriers (attitudes, support and resources), and system barriers. There is a need for a strong conceptual model, which can both identify barriers to knowledge translation and guide the development of intervention designs [39]. Our findings showed a gap between knowledge and skills (II) and actual performance (III), which is in parallel with other studies. The results of the interview study (IV) shed some light on the barriers experienced by the GPs to implement their knowledge in clinical practices. The assumptions underlying the concept of knowledge translation [124] further helped us in our attempt to understand this gap between knowing and doing in our setting. Designed group discussions played an important role in participants' learning and attitude change regarding rational prescribing, as mentioned by themselves (Study IV). It was a new experience for most GPs to participate in discussions on experiences of every day clinical practice in an interactive programme, as most traditional CME programmes in Iran are teacher-centred and didactic. The GPs especially enjoyed the time set aside for questions and discussions on highly relevant subjects in relation to their needs and expectations, which increased their satisfaction, as was also mentioned in another study [125]. Many medical schools use peer education [126], and it has been increasingly recommended in CME to encourage participants to learn from and stimulate one another [127].

Inter-professional training was a new approach in this programme and may have contributed to the effectiveness of OBE. Inter-professional education is challenging, but by demonstrating trust in each other, communicating respectfully, pursuing common goals [128] and using appropriate teaching and learning approaches, it is possible to make it function well [129].

As in any educational intervention, the extent to which participants modify their prescribing performance after the course was of major interest as part of the learning evaluation. Previous studies have indicated irrational prescribing patterns both among GPs in Iran [86, 87, 89, 90], and in other low and middle-income countries [77-80]. The mean number of drugs reported per prescription has been shown to range from 3.4 to 4.4 in different provinces of Iran [86, 87, 89], which corresponds to our findings, but is higher than in, e.g., South Africa (2.3) [77], Nepal (2.9) [130], India (2.8) [131] and Pakistan (2.9) [132]. Rational prescribing is related to diagnostic and therapeutic efficacy, but a reduction of the number of drugs is a positive sign in itself as poly-pharmacy is a contributing factor for hospitalization [133], and for the frequency of adverse drug reactions and drug interactions [134]. Another considerable problem is overprescribing of injections in low and middle-income countries [134], which has been shown to reach more than 50% of each prescription in Iran [88], similar to our base-line results (Study III).

In our study, the GPs' prescribing behaviour significantly improved after participation in the OBE programme, compared with the control arm, regarding some of the rational prescribing indicators such as number of drugs and injections per prescription, and frequency of writing explanation of times, manner and necessary precautions when taking the medications. Receiving correct information on the correct use of drugs is necessary for patient adherence [130]. Patients should be aware of how to take drugs as well as how to avoid some adverse effects [135]. However, the post-intervention assessment reveals that more should be done to reach levels closer to full compliance for these indicators.

The results didn't show statistically significant changes for some other indicators, such as prescribing antibiotics and anti-inflammatory agents (corticosteroids and NSAIDs), although there were indications of a slight improvement for some of them. Inappropriate use of antibiotics is a health care problem in countries all over the world, not least in low and middle-income countries [136]. Antibiotic resistance is a rising problem created by the overuse of antibiotics [137]. In our study, six out of ten prescriptions included at least one antibiotic. Studies in Nepal and India have shown similar results [130, 131].

Based on the results of the knowledge and skills assessment and participants' self-reported behaviour change, we had expected to find clear improvements among GPs participating in the OBE intervention when assessing their performance. However, the analysis showed neither high levels of progress nor as much change as we had expected.

One contributing factor could be that the number of participants was lower than planned due to unexpected drop-outs, and with respect to the robust method of

analysis we used to adjust for ICC. Another important reason for failing to achieve a positive improvement, which was also raised by GPs during the interviews, could be the influences on physicians' performance by political, socio-economic and socio-cultural factors, health system setting, and patients' demands and beliefs [76, 138]. Workload, high number of patients and time pressure [139], and feelings of insecurity can be added according to our study findings (IV) as some additional barriers to rational prescribing. Without changing or solving such fundamental aspects, educational programmes may not, on their own, be enough to improve rational prescribing [90].

The importance of patient education to reduce irrational and misuse of drugs [76, 90] was one aspect of the OBE programme, and this was also stressed by the interviewed GPs. Patients' awareness regarding risks of irrational use of drugs should be enhanced. Beside the responsibility of doctors to engage in a dialogue with patients to raise such awareness, it was also emphasized that mass media have a role in terms of patient education as a way of achieving a consensual view between patient and doctor [140].

6.2 METHODOLOGICAL CONSIDERATIONS

Most of the experts during the Delphi process were CME decision-makers or trainers, while one third of them were GPs representing the target audience in an attempt to improve the relevance of the programme [125]. In these ways, we tried to bridge the gap between the actual learning needs of individual practitioners and the educational content that is considered to meet assumed needs, a problem that has been described in the educational literature [12, 141].

The outcomes derived from the original Delphi process were further modified by the panel of experts. Two of the confirmed learning outcomes were excluded and one outcome related to the prescribing of corticosteroids was added during the panel discussions concerning the policy of the programme and applicability of outcomes.

When comparing the curricular content of the course with the outcomes, one will discover that one of the topics, "adverse reactions to drugs" (ADR), is not directly linked to any outcome. ADR has been seen to be a result of irrational prescribing. [88, 130, 133]. Thus, knowledge about the consequences of irrational prescribing can motivate a change in participants' behaviour. However, if the course was supposed to have been designed with an OBE approach, why wasn't ADR identified as an outcome?

A possible explanation for why the initial Delphi process did not elicit a topic that content developers deemed essential could be the formulation of the instructions for the Delphi process. The task was to identify what should be included when the doctor

writes a prescription, but information on ADR cannot be written directly in the prescription. However, because ADR has to be considered before a particular drug is chosen, content developers included this topic in the curriculum. While it would have been possible to develop direct outcomes and indicators for ADR, it can be seen as indirectly being part of and of importance in achieving some of the other outcomes.

Another concern is the quality of the outcomes and the indicators that were formulated. Outcomes can be analyzed based on how clear and specific they are [48], if they are measurable, cover the domains of knowledge, skills, and attitudes, and if they are of a manageable number [142]. Most of the outcomes meet these criteria. However, the word "appropriate" (found in outcomes 15 and 19-21) was harder to measure. We put the stress on curriculum, educational package, teaching methods, rules and assessment procedure. Considering constructive alignment [28] provided a structure that teachers could use when designing their teaching and learning activities. Looking at the results of the observations from the sessions, teachers in the intervention group followed this structure consistently, which could be an additional explanation why a significant improvement was seen in all topics.

The number of teachers in the intervention and control arms was almost identical, but teachers in the intervention arm taught together in pairs. The benefits of being able to answer questions and conduct discussions together as well as complete each other's presentations could be one of the reasons for the increased effectiveness of the intervention programme.

Considering cost-effectiveness and feasibility, an outcome-based approach in the initial set-up to determine the outcomes and develop the curriculum required a large amount of time and a large number of people. In this study, there were costs involved in turning these outcomes into a programme due to the fact that such a course did not exist previously. These costs should be seen as a function of starting a new course and there is little reason to assume that they need to be repeated. Moreover, if there is an increase in rational prescribing after an OBE programme, this will result in safer and more cost-effective treatments, leading to less expenditure, which is believed to save costs both for individuals and society [77].

It could be argued that the difference in results between the two programmes is mainly due to an increase in the length of the intervention course by five hours. The argument would then be that by increasing the control course by five hours we would achieve the same results. A probably more plausible reason for the difference is the approach of the trainers in the teaching and learning activities that resulted from the use of the OBE approach. Trainers began by presenting the outcomes. They then developed the context by illustrating the relevance of these outcomes to everyday professional life with questions to the participants as well as actual examples of

irrational prescribing. The trainers in the intervention group also interacted with the participants to a higher degree, stimulated the posing of questions, and encouraged discussions [143]. Workshops and small group discussions were used so that participants could learn from and stimulate each other, but the trainers were not involved during the group activities.

The sample size calculation was based on data from our pilot testing of the knowledge and skills questionnaire. Our assumptions were confirmed by the results in Study II, which reduces the risk of ignoring true differences because of a too low number of study units (type II error) and makes our findings more valid. The results in Study III only partly corresponded to the assumptions and it seems that a higher number of study units would have been beneficial for some of the outcome variables. We assessed a total of 16 variables in Study III, which may cause some concern regarding the risk of obtaining significant results by chance (type I error) [144]. We did not correct for this in the statistical analysis, but the finding that there was a significant improvement for all three instructions to the patient minimizes the risk of over-emphasizing the results.

In any qualitative research project, three issues of trustworthiness should be considered in order to evaluate and generate the findings: credibility, dependability and transferability [112]. In Study IV, credibility and dependability were enhanced through a thorough analysis, where one co-author separately coded some of the interviews and the other two co-authors took part in discussions on the emerging codes, sub-themes and themes until consensus was reached. Furthermore, I invited the participants and some experienced colleagues outside the research team to give comments on the results of the analysis. This study aimed at exploring the perceptions of the trainers and GPs after participation in this particular CME programme and can not be generalized as findings in themselves (transferability). However, as an example of how participation in an OBE programme is experienced by participants, it can to some extent be transferred to other settings [112].

We were somewhat restricted in our efforts to assess properly some of the prescribing indicators, in particular those related to drug interaction and ADR, as we had no information about diagnosis or co-morbidity. We cannot therefore assess with certainty whether the high number of drugs per prescription or the high number of injections are appropriate or not, although it is not possible to consider any plausible reason for the excessive use of injections in the context of primary care.

6.3 STRENGTHS OF THE STUDY

The validity of our findings is enhanced by the design of the study, which allows for comparison between the new approach to CME and the concurrent way of conducting

CME programmes. Different teaching and assessment tools were used to improve and evaluate the participants' competence and performance. We assessed both the GPs' knowledge and skills, using a questionnaire, and their performance, using real prescriptions from their practices.

Based on the literature reviewed, it is suggested that teachers and evaluators should avoid teaching and assessing pure knowledge and/or general skills. Instead, knowledge and skills should be integrated with each other, as was successfully achieved in this study. It has also been recommended to avoid suggesting self-directed learning and self-assessment until the capacity to do this has been established among trainees [145]. However, understanding more about reflection in practice and initiating collaboration between trainees and supervisors may help the trainees to meet self-assessment needs [146].

It's a strength of the study design that the prescribing data were collected during the same time of the year for both pre- and post-evaluation. Thereby potential confounding effects due to different prescribing patterns at different times of the year could be avoided and comparisons of the prescriptions before and after the intervention became more valid and meaningful.

This study was conducted in two different geographical areas without regular professional contacts in order to avoid any contamination between participants in the two study arms. The cities were matched in pairs for both arms considering confounding factors. Both study arms had equal opportunities of being assigned as intervention arm.

It is a strength of the study that the characteristics of the participants in the control and intervention arms were similar. Coupled with the fact that there was no significant difference in mean pre-test scores, this suggests that the groups were evenly matched.

The participants of the OBE programme received the educational handouts related to each topic during the programme and also two additional handouts one month after the programme. They found it very important for two reasons: firstly, they mentioned that the handouts were like guidelines. Secondly, they felt encouraged by the concerns of the CME providers and trainers even after they had finished the programme.

6.4 LIMITATIONS

The fact that participants came from only one province in Iran reduces the generalizability of the findings. However, there is no existing evidence to suggest that

these doctors would perform differently compared to doctors in similar settings elsewhere.

Nine of the experts who were invited to participate in the Delphi process did not answer, despite the reminder we sent out one month later. They were contacted by e-mail and/or telephone; six said that they were too busy to answer while three did not wish to participate, as they saw no personal benefit.

Another limitation of the study was the drop out of eight participants from the intervention group and seventeen from the control group. Stated reasons were sickness, travel, and sudden scheduling conflicts. One interesting observation was that the incentive to encourage participation that we had settled on – offering the programme and CME credits free of charge – actually seemed to contribute to the late decision by these would-be participants not to attend as they had not made any advance payment.

6.5 RECOMMENDATIONS AND SUGGESTIONS

On the basis of our findings, I would recommend implementation and dissemination of OBE as an approach for teaching, learning and assessment in CME.

To health policy makers: Attention should be paid to factors outside the domain of education that may affect rational prescribing, e.g., monitoring of appropriate dispensing of drugs in pharmacies, doctors' economic incentives and general work load.

To CME strategists: OBE should be considered as a useful approach in other CME programmes, and should be conducted continuously to keep doctors up-to-date, improve their competencies, and achieve a performance change. So designing series of CME programmes in the same field and inviting and encouraging GPs to follow the planned programmes is suggested.

To faculty development centres: Teacher training workshops should be arranged continuously to improve university faculty members' educational competencies regarding designing the framework of the education, teaching methods, and assessment.

To CME trainers: Trainers are recommended to pay closer attention to actively engaging GPs in the learning process by designing and implementing comprehensive and inter-professional outcome-based programmes. Participation in teacher training programmes should be a natural part of continuous professional development.

To general physicians: GPs are recommended to take a more active role in bridging the gap between knowing and doing, through participation in well-designed learning

activities, sharing their professional experiences in group discussions and motivating the trainers by asking relevant questions. Combined with an OBE approach, this can potentially create CME programmes that meet the needs of GPs.

6.6 FURTHER STUDIES

This study was conducted in the area of rational prescribing. Further development and modifications of CME programmes are needed to achieve a higher impact. New studies are needed to identify optimal content of programmes, as well as duration, need for follow-up and usefulness of more widespread peer group learning.

6.7 CONCLUSIONS

This thesis has shown that an outcome-based intervention in CME can improve GPs' knowledge and skills, and to a lesser extent their performance. The OBE programme was more effective than a concurrently offered traditional lecture-based programme in supporting general physicians to develop their competencies. It contributed to a substantial improvement in communication between doctors and patients on the use of medications. While the reduction of irrational drug prescribing was limited, it was of sufficient importance to recommend that OBE become an integral part of CME programme planning. The results support the hypothesis that CME programmes can become more effective through the use of an OBE approach. OBE is one more step we can take within medicine to help reduce the know-do gap.

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9 APPENDICES

Appendix 1 *Curricular content for the programme on rational prescribing as developed by teams of CME trainers*

Topics for the rational prescribing curriculum

1- Principles of prescription writing (1-16)*

History of prescription writing

Classification of drugs

Definition and format

Elements of prescription writing

Measurements

Mistakes and errors in prescription writing

Abbreviations

Poor prescriptions

Rational prescriptions

2- Adverse reactions to drugs

Background

Epidemiology

Etiology

Exaggeration of an intended pharmacologic action of the drugs

Toxicity unrelated to a drug's primary pharmacological activity:

- Cytotoxic Reactions

- Immunologic Mechanisms

Diagnosis and treatment of adverse drug reactions

3- Drug Interactions (17, 18)

Important mechanisms of drug interactions

Common drug interactions in the practice of general physicians

4- Injections (20)

Consideration of real needs for prescribing injections

Mechanism of injections

Indications for injections

Important factors in prescribing injections

Prevalence of prescribing injections in the world and in Iran

5- Antibiotic therapy (19)

Value of taking culture samples for infections

Assessment of infectious organisms

Importance of host factors in selection of antibiotics

Adherence to correct indications

Selection of antibacterial drug(s)

Important factors for choosing form, dose and course of antibiotics

Importance of switching antibiotics based on culture and antibiogram results

Pharmacology of antibiotic groups:

- Betalactamases
- Tetracyclines
- Aminoglycosides
- Macrolides
- Fluoroquinolones
- Sulfonamides

6- Anti-inflammatory agents therapy (21)

A) Corticosteroids

Indications

Emphasis on reducing injections

Adverse effects

Important interactions

B) Non steroidal anti inflammatory drugs (NSAIDs)

Indications

Adverse effects

Drug Interactions

Contraindications

* Numbers in parentheses refer to the related outcomes

Appendix 2 *Total observational checklist scores for the intervention and control groups from the two observers covering the six different curricular topics*

Item	Intervention Group			Control Group		
	Fully accomplished	To some extent	Not at all	Fully accomplished	To some extent	Not at all
1. Educational goals were clearly explained in the beginning	10	2	-	-	2	10
2. Opportunity for active participation in discussions for all participants	12	-	-	-	4	8
3. Trainers encourage participants to actively participate in all activities	11	1	-	-	1	11
4. Trainers manage time well	7	5	-	2	10	-
5. The class has a friendly atmosphere	12	-	-	1	10	1
6. Educational materials are given to participants	10	2	-	-	-	12
7. Educational references related to the topic are presented	7	3	2	-	-	12

Appendix 3 *The interview framework for trainers*

The framework for interview with outcome-based education trainers

- Can I ask your point of view regarding outcome-based education?
- Did you have the same educational strategies and methods in the outcome-based programme as you usually had in other CME programmes?
- Did the outcome-based programme participants behave as usual as in other CME programmes?
- Do you have any further comments about outcome-based education?
- Is there anything else you would like to mention?

Appendix 4 *The interview framework for trainees*

The framework for interview with GPs participating in outcome-based education

- Have you participated in any CME programmes before the outcome-based one?
- Have you participated in any rational prescribing CME programme before the outcome-based one?
- Tell me about the outcome-based programme you participated in (content, trainers, teaching methods, your own contribution during the educational programme, educational materials you received, evaluation methods)
- How do you feel about your prescribing after participating in the outcome-based programme?
- Is there anything else you would like to mention?