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Development of Instruments to Measure the Quality of Patient Counselling

Doctoral dissertation
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ABSTRACT

Even though patient counselling is considered one of the main duties for community pharmacists, studies have indicated that there is room for improvement in counselling performance. In order to enhance patient counselling practise in Finland, a four-year project TIPPA was launched in 2000. A need for patient counselling specific instruments became evident in order to implement new behaviours and to evaluate existing counselling practices.

The aim of this study was to develop instruments to measure the quality of patient counselling. The process was started with a validation of the United States Pharmacopeia (USP) Medication Counselling Behaviour Guidelines. The construct validity and internal consistency of the Guidelines were evaluated by conducting factor analysis and assessing Cronbach's alpha. The statistical analysis indicated that the Guidelines are a valid and reliable instrument. The next step was to assess their usefulness among Finnish pharmacy practitioners 2,5 years after the TIPPA had started by sending a questionnaire to a random sample of community pharmacists (response rate 51%, n=376). More than one quarter (27%) of the respondents were aware of the Guidelines. The Guidelines were made known to the respondents mostly via a book on patient counselling skills (41% of those knowing the Guidelines), continuing education (37%), and in-house training (28 %). Over 60% of those who knew about the Guidelines regarded them as a good or very good instrument for learning the principles of patient counselling. The applicability of the Guidelines as an instrument for self-evaluation of performance in different settings was considered less useful.

Factors related to the quality of patient counselling were determined as part of the training of ten external auditors of counselling practices. A modified Delphi method was used, with two expert panels: Panel 1, consisting of experienced pharmacy practitioners (n=10), and Panel 2, consisting of academic and professional experts (n=10). The final consensus was assessed by a Delphi questionnaire round (response rate 74%, n =26). The first Delphi round yielded a high consensus, the level of agreement varying between 69% and 100%. All the items except one met the predefined criteria for approval. A total of 16 indicators were identified in three quality dimensions: Customer (4 indicators); Process (6 indicators); and Learning and Innovations (6 indicators). Strategy and vision of the pharmacy in patient counseling formed the core of the instrument.

A pseudo customer method that takes into account the professional content of counselling was developed to assess patient counselling practices in community pharmacies during the project. Counselling practices were annually evaluated in sixty selected community pharmacies by using four different scenarios (three self-medications and one prescription). The scoring criteria were based on the USP Guidelines and were divided into two categories: Needs Assessment and Instructions for Use. Two out of the four scenarios used showed a statistically significant increase between the baseline and the final follow-up. The results of the national pseudo customer studies indicate that more emphasis should be paid to customers asking for a self-medication product by a brand name and to customers with repeat prescriptions.

The instruments developed in this study can be used in the evaluation of counselling practices at different levels. At the organisational level, the patient counselling quality assurance instrument can be used in conducting a present state analysis of counselling practices and constructing a long-term development plan. The quality assurance instrument can also be used in an external auditing process of counselling practices. The pseudo customer method can be applied at the organisational and national level to assess counselling performances. Individual pharmacists can use the USP Guidelines in self-evaluation and peer-evaluation of counselling practice. In order to implement good quality patient counselling practices, current practices need to be evaluated in a wider perspective than the customer-pharmacist interaction.

To my husband

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"There is no substitute for hard work"
Thomas A. Edison

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Helsinki, September 2005

Inka Puumalainen

OPERATIONAL DEFINITIONS OF THE KEY TERMS

Audit

Examination and review of activities. Audit can be divided into three types: self audit (self-evaluation), peer audit (peer-evaluation) and external audit. Self and peer audit involve an individual or group auditing their own performance against published standards or personal objectives. External audit occurs when visiting experts audit the practice.

Community pharmacy

A health care unit specialised in medicines. In Finland, the owner must have a Master's degree in pharmacy. A community pharmacy has many obligations, the most important of which is to ensure that medicines needed by the local inhabitants are always available and used safely.

Organization

Consists of a group of individuals working towards shared goals, whose behaviour is modified by rules and structure (Scott 1998).

Patient counselling

An approach that focuses on enhancing problem-solving skills of the patient for the purpose of improving or maintaining the quality of health and the quality of life. The process emphasises that the health professional provides and discusses medication information with the appropriate person to achieve this goal. Counselling is based on the individual patient's needs. The nature of the relationship between the patient and health care provider is interactive and constitutes a collaborative learning process for both parties (United States Pharmacopeia).

Peer-evaluation

A process where the evaluation of actions and performance is conducted by a peer.

Pharmacist

A health care professional specialised in medicines. According to the Medicines Act in Finland, the main duty of a pharmacist is to dispense medicines and to ensure their safe and proper use among the public. In Finland, there are two pharmaceutical degrees: Master's degree (5-year education at the university) and Bachelor's degree (3-year education at the university).

Quality assurance

Activities that assure the acceptable levels of quality (Øvretveit 1992).

Reliability

Reliability assesses reproducibility or stability of data. The methods of testing for reliability include multiple forms; basic tests of internal consistency, test-retest, intra-rater and inter-rater agreement.

Self-evaluation

A process where the aim is to evaluate one's own actions and performance.

Service quality

Service quality is a measure of how well the service level delivered matches customer expectations. Customers assess service by comparing the service they receive (perceptions) with the service they desire (expectations) (Berry et al. 1990).

Validity

A valid measure is one that measures the construct that it is intended to measure. Validity is inferred from the manner in which a scale is constructed, its ability to predict specific events, or its relationship to measure other constructs.

LIST OF ORIGINAL PUBLICATIONS

This thesis is mainly based on the data presented in the following original papers, referred to in the text by Roman numerals I-IV.

I Puumalainen I, Halonen P, Enlund H, Johnson K, Airaksinen M. Validation of the United States Pharmacopeia (USP) Medication Counselling Behaviour Guidelines. Pharm Educ 5:87-96, 2005

II Puumalainen I, Kansanaho H, Varunki M, Ahonen R, Airaksinen M. Usefulness of the USP Medication Counselling Behaviour Guidelines. Pharm World Sci, in press

III Puumalainen I, Kause J, Airaksinen M. Quality assurance instrument focusing on patient counselling. Ann Pharmacother 39:1220-1226, 2005

IV Puumalainen I, Peura S, Kansanaho H, Benrimoj SI, Airaksinen M. Progress in patient counselling practices in Finnish community pharmacies. Int J Pharm Pract 13:149-156, 2005

CONTENTS

1 INTRODUCTION

> **"***I should get used to doing self-evaluation and***
> ***peer-evaluation in daily practice"***
> Community pharmacist responding to survey

Changing existing practices and behaviour patterns in health care have proved to be challenging (Haines and Jones 1994, Armstrong et al. 1996, Grol 1997). Even though patient counselling has long been considered a main duty for community pharmacists and this role has more recently received strong promotion from the profession, changes in actual performances have been moderate (De Young 1996a, Morris et al. 1997, Erickson et al. 1998, Rutter et al. 2004). Studies assessing counselling practices have mostly been cross-sectional and focused on individual factors affecting counselling practices (Blom et al. 1988, Laurier and Poston 1992, Schommer and Wiederholt 1997). Research has indicated that no single factor can explain counselling performance therefore there is a need to use a series of different strategies to promote a change among community pharmacists (Kimberlin et al. 1993, Odenina et al. 1995, Farris and Schopflocher 1999, Roberts et al. 2003).

Also, the role of the patient has shifted from passive information recipient to an active information gatherer and partner in medication use (Chewing and Sleath 1996). Compliance and adherence were the terms used in describing a patient's drug taking behaviour. The new philosophy of concordance challenges health care professionals and patients to take a more active role in medication use (Bond 2004). Concordance is fundamentally different from compliance or adherence: i) it focuses on the consultation process between the patient and the health care professional, and ii) it is based on a notion that this consultation is a negotiation between equals (Marinker and Shaw 2003, Stevenson et al. 2004). Therefore, systematic and long-term development processes are needed at the pharmacy level in order to promote a shift towards two-way communication and new counselling practices. In this process, pharmacists need concrete measures and tools to evaluate and assess their counselling practices.

Pharmacies as organisations should be able to measure their activities, and these measures should be applicable to different kind of audits and assessments. However, there is a lack of reliable and valid measures applicable for community pharmacy settings.

The aim of the current study was to develop instruments to measure the quality of patient counselling during the national TIPPA project (2000–2003). The abbreviation TIPPA stands for the Finnish words "Customized Information for the Benefit of the Patient from the Community Pharmacy". The process was begun by validating the United States Pharmacopeia Medication Counselling Behaviour Guidelines. Their usefulness was assessed among Finnish community pharmacists two and half years after the TIPPA project had started. A comprehensive quality assurance instrument was developed as a part of the training of ten external auditors (known as TIPPA tutors). Finally, a pseudo customer method was developed to assess counselling practices in sixty Finnish community pharmacies over the four-year period.

In this dissertation, I have mainly focused on counselling in the context of community pharmacy even though counselling takes place also in other settings such as in hospitals and clinics. The quality of patient counselling is viewed from an organisational and from an individual pharmacist perspective.

2 CONTEXT OF THIS STUDY

2.1 Finnish pharmacy system

In Finland, medicines (both prescription and non-prescription medicines) are sold to the public only from community pharmacies. Finland has a privately owned pharmacy system with 605 pharmacies and altogether 802 outlets covering the whole country (Table 1). There are two exceptions of the privately owned pharmacies: Helsinki University Pharmacy owned by the University of Helsinki and Kuopio University Pharmacy owned by the University of Kuopio. Helsinki University Pharmacy consists of 17 outlets in Helsinki and some other urban communities. Kuopio University Pharmacy has one outlet in Kuopio.

The pharmacy business in Finland is regulated by the government (National Agency for Medicines) that controls the location, number and ownership of pharmacies. The prices of medicines are the same in all community pharmacies. The sale of medicines (prescription and non-prescription medicines) constitutes 95% of the turnover of the pharmacies (The Association of Finnish Pharmacies 2005).

Table 1. Core characteristics of Finnish pharmacies (2004).

Number of outlets	802 (605 main pharmacies and 197 subsidiaries)
Average annual prescription volume	60 470
Prescriptions/inhabitant	7.8
Population/pharmacy ratio	1: 6 500
Average annual turnover	2.9 million euros
Average number of pharmacists/pharmacy	7

Source: The Association of Finnish Pharmacies and Pharma Industry Finland

The personnel in Finnish pharmacies consists of the pharmacy owner and staff pharmacists with a Master's degree, pharmacists with a Bachelor's degree and technicians with varying educational backgrounds. Approximately 60% of the pharmacy personnel have a pharmaceutical education. The owner of a pharmacy must have a

Master's degree. Only personnel with a degree in pharmacy are allowed to serve and advise customers.

In Finland, pharmacy services have been studied in the field of social pharmacy since the 1980s. Studies have shown that customers are satisfied with community pharmacies and they wish to have professionally oriented pharmacy services (Airaksinen 1996, Väisänen 2003). However, customers want more information especially on pharmacotherapeutic issues such as side-effects and interactions, while pharmacists place a priority on information concerning drug dosage, storage and duration of medical treatment (Airaksinen et al. 1994). Furthermore, customers appreciate and want counselling whereas pharmacists often assume the opposite (Airaksinen et al. 1994, Airaksinen 1996, Katajavuori et al. 2002).

Since 1983, according to the Pharmacy Act (4/1928), it is the duty of community pharmacists to ensure that customers know how to use their medicines properly and safely. Since 1988, pharmacies have been mandated to provide facilities to supply privacy for patient counselling. Prior to 1983, community pharmacists were not allowed to give information to patients unless they asked for it, and even then, the content was limited (Vainio 2004). The professional role of a community pharmacist has changed since the mandate to counsel was introduced in 1983. Today, most Finnish pharmacists perceive their work as that of a drug expert (Savela 2003). Even though the perception of the professional role has fundamentally changed, old traditions such as a misconception that customers do not want information, were still reflected in counselling practices in community pharmacies in the mid (Vainio 2004) and late 1990s (Katajavuori 2005).

2.2 Professional development in community pharmacies

In order to support the professional development of community pharmacies, the Association of Finnish Pharmacies established a national strategy in 1997 (The Association of Finnish Pharmacies 1997). The strategy achieved a wide consensus among the profession and the key stakeholders. According to that strategy, pharmacies compete with their services not with their prices; there is always a pharmacist to serve

and counsel patients; and when medicines (both prescription medicines and non-prescription) are sold information is always provided. Furthermore, community pharmacies take part in national health promotion activities together with other health care professionals. Professional long-term programmes in community pharmacies focus on chronic diseases such as asthma and diabetes (Ministry of Social Affairs and Health et al. 1997, The Association of Finnish Pharmacies and Finnish Diabetes Association 2001). A professional programme focusing on heart diseases will be launched in 2005. The aim of these programmes is to develop the competence of pharmacy staff so they can better guide patients and to encourage local cooperation with other health care professionals.

In Finland, there has been a long-term co-operation between professional bodies, pharmacy schools and authorities to promote a change in patient counselling practices. The first systematic joint attempt was the World Health Organisation EuroPharm Forum's "Questions to Ask About Your Medicines" public awareness campaign in 1993–1996 (Airaksinen et al. 1998, Vainio et al. 2002). The evaluation of the program was conducted by an observational method with measurements at baseline, and three and twelve months after starting the campaign. The results showed improvement in i) customizing the information, and ii) showing empathy to the patients, but iii) did not improve the content of information or the frequency of counselling (Airaksinen et al. 1998). It was understood that community pharmacists need concrete instruments to evaluate and develop counselling practices. In 1998, the Association of Finnish Pharmacies conducted a pseudo customer study to assess counselling performances and to assess the implementation of the professional strategy (The Association of Finnish Pharmacies 1998, unpublished). The results indicated that there was room for improvement and as a consequence, a four-year, joint project TIPPA was launched in 2000.

3 PATIENT COUNSELLING AS A CONCEPT OVER TIME

Patient counselling and advice-giving are terms used in the literature to describe the communication between pharmacists and patients. The term advice-giving is used mostly in the British literature (Raynor 1996). However, there is no clear consensus about these concepts and what constitutes good counselling performance. It appears that pharmacy practice researchers have either omitted or offered sketchy definitions of these key terms (Kirking 1982, De Young 1996b, Raynor 1996).

3.1 Definitions used in the literature

Some researchers have tried to conceptualize the term patient counselling in their studies. One of the earliest definitions was presented by Puckett et al. (1978) as "any oral or written communication (including auxiliary labels) from the practitioner relating to the drug product and its use". This statement was supported by Ross et al. (1981). Kirking (1982) defined patient counselling as "the provision of verbal information that will help patients to use their medications properly". Holland (1992) defined counselling as "the process of giving professional advice about medicines and other health matters". According to Schommer and Wiederholt (1994a), "patient counselling is the provision of advice that is the reasoned opinion of a pharmacist, is subjective, and is patient-oriented within a medication-taking context". Aslanpour and Smith (1997) defined counselling for their study purposes as "the provision of information on medications and related health issues". The term has also been conceptualised as "the means by which one person helps another to clarify their life situation and to decide upon further lines of action", and its aim is "to give the client an opportunity to explore, discover, and clarify ways of living more resourcefully and towards greater well-being" (According to this definition, counselling seeks to enable or empower the patient to decide on a particular course of action and see it through (Blenkinsopp et al. 1999). The key point is that the counsellor is helping the patient to make their own decision, even if that decision varies from that which the counsellor thinks should have been made

(Blenkinsopp et al. 1999). This recent definition reflects the transition from a paternalistic approach to patient autonomy and decision making.

Advice-giving has been referred to as the transfer of information and advice about recommended actions from the pharmacist to an individual patient or customer. Ideally, advice-giving should be a two-way interactive process, where the person is invited to respond and to seek further information should they need it (Blenkinsopp et al. 1999).

Some researchers have even questioned if the term counselling can be used to describe the information exchange between pharmacists and customers in the context of community pharmacy (Raynor 1996, Pilnick 2003). According to these researchers, what pharmacists mean by counselling is the imparting of information as part of a one-way process. In practice, counselling usually involves repeating verbally the information on the medicine label and giving instructions for complying with drug therapy regimens (Vainio 2004). Therefore, one of these researchers suggests that the term concerning advice and explanation about medicines should instead be called medicines consultation (Raynor 1996).

One of the most comprehensive definitions was constructed by United States Pharmacopeia (USP). USP is an independent, science-based, non-profit public health organisation which develops and disseminates quality standards and information about medicines. According to USP, patient counselling is an approach that focuses on enhancing an individual's problem-solving skills for the purpose of improving or maintaining their quality of health and quality of life. The process emphasises that the health professional provides and discusses medication information with the appropriate person to achieve this goal. The physical, psychological, socio-cultural, emotional, and intellectual perspective as well as the health beliefs and values of the individual must be respected. The health care professional's responsibility is to support the person's efforts to develop medication management skills and to move in the direction of self-responsibility with empathy, sincerity and patience. The nature of the relationship between the patient and health care providers is interactive and constitutes a collaborative learning process for both parties.

As consensus on the concept of what constitutes good patient counselling is lacking, it is difficult to compare studies. The precise definition of counselling would also allow

the gathering of rigorous evidence of the effectiveness of this service (Raynor 1996). Also, a precise definition of the concept would help practitioners to understand and internalize the nature and content of good counselling. Furthermore, the understanding of a concept has an impact on the behaviour patterns and attitudes. If pharmacy practitioners lack the understanding of this key concept, it is difficult to change existing performance.

3.2. Research on counselling practice

Studies assessing counselling performance have revealed that counselling is usually based on a monologue model, meaning that the pharmacist gives information to the patients without actively engaging them in the process (Pilinick 2002, Rutter et al. 2004). For example people using antidepressants would need drug information customized to their needs (Enäkoski 2002). The level of information is usually brief, basic and non-individualized. Moreover, the study methods used have mostly been cross-sectional and focused on individual factors affecting counselling practices (Laurier and Poston 1992, Willison and Muzzin 1995, Schommer and Wiederholt 1997, Aslanpour and Smith 1997, Blom et al. 1998, Pilnick 2003). Research has revealed that no single factor can explain counselling practices. However, some factors seem to have an impact on counselling practices. First, studies have shown that pharmacists provide more counselling to patients with newly dispensed prescriptions than to patients with refills (Ascione et al. 1985, Wiederholt et al. 1992, Blom et al. 1993, Sleath 1996, Schommer and Wiederholt 1997, Aslanpour and Smith 1997, Vainio et al. 2002). Second, patients who ask questions are more likely to be counselled than those who do not (Ascione et al. 1985, Schommer and Wiederholt 1997, Vainio et al. 2002). And third, the therapeutic class of the drug seems to have an impact to the provision of patient counselling (Ascione et al. 1985, Aslanpour and Smith 1997, Vainio et al. 2002). Counselling is most likely to be provided for customers with antibiotics and least information is given to patients with gynaecologic preparations, cardiovascular preparations and oral contraceptives (Ascione et al. 1985, Aslanpour and Smith 1997, Vainio et al. 2002). The shift into a preferred customer-oriented negotiation model

where pharmacists actively engage customers into interactive and collaborative discussion has proved to be challenging.

3.3 The content of the guidelines

The definitions of patient counselling are reflections of the traditions of the time. This is shown by the fact that the recommended topics for patient-pharmacist interaction according to patient counselling guidelines vary over time (Table 2). Many professional organisations, researchers and scholars in the 1960s and 1970s published guidelines regarding what practitioners should talk about during a pharmacist-patient interaction (De Young 1996b). Many publications at that time agreed that at a minimum, pharmacists should tell patients (1) how to administer the medication, (2) the time of medication administration and (3) how to recognize and manage side effects (De Young 1996b). The development of guidelines continued in the 1980s and 1990s and they appeared to be slightly more comprehensive compared to the ones published earlier. According to these guidelines pharmacists should tell patients (1) the name of the medication and its purpose, (2) the drug dosage form, its route of administration and the proper dose and administration schedule, (3) how to identify and manage side-effects, (4) how to properly store the medication, (5) any potential drug-drug or drug-food interactions, (6) prescription refill information and (7) what patients should do if they miss a dose (American Society for Health-System Pharmacists 1997, American Society of Consultant Pharmacists 1998). In the United States, the Omnibus Budget Reconciliation Act of 1990 (OBRA`90) has required since 1993 that an "offer to counsel" must be made. According to OBRA`90 counselling should include e.g., the name and description of medication and the duration of therapy (Table 2), Additionally pharmacists have been encouraged to use counselling strategies developed for pharmacists practising in the Indian Health Service (IHS) (Lee et al. 1998). Pharmacists adopting the IHS approach ask patients following questions:

1. What did your doctor tell you the medicine is for?
2. How did the doctor tell you to take the medicine?
3. What did the doctor tell you to expect?

4. Just to make sure I didn't leave anything out, please tell me how you are going to take your medicine

5. What kind of problems have you had with medications in the past? (optional)

The number and the content of items in the guidelines have remained almost the same (Table 2). The guidelines have mostly been recommendations, excluding the OBRA`90 legislation. However, studies assessing the implementation and actual use of existing guidelines in daily practice have not been conducted or published in the peer-reviewed literature.

Table 2. Recommended topics for the pharmacist-patient interaction according to some selected patient counselling Guidelines (Modified from De Young 1996b).

Prescription drug information	Reeder 1989	OBRA` 1990	American Society of Health-System Pharmacists 1997	American Society of Consultant Pharmacists 1998
Medication name, description and/or purpose	x	x	x	x
Route, dosage, dosage form, and administration schedule	x	x	x	x
Directions for preparation and administration		x	x	x
Precautions to be observed			x	x
How to identify and manage adverse effects	x	x	x	x
Techniques for self-monitoring		x	x	x
Proper storage	x	x	x	x
Potential drug-drug, drug-food interactions	x	x	x	x
Radiology and laboratory procedure issues			x	x
Prescription refill information	x	x	x	x
Action to be taken in the event of a missed dose	x	x	x	x

These guidelines reflect the role of the pharmacist and the patient in the interaction, and the nature of patient-practitioner relationship, which, according to these guidelines, is paternalistic. They also seem like check lists of items that should be told to each patient regardless of the individual patient's needs. The specific counselling items included seem to be focused on the drug instead of the patient. Thus, these guidelines do

not seem to support patient-centred counselling that is based on a two-way communication and negotiation.

The literature concerning patient counselling specific guidelines is scarce. In order to develop a practice-oriented patient counselling specific instrument, pharmacy practitioners should also be involved in the development process. If the instruments are only constructed by academics, it may be hard to implement them in practice. Consensus methods provide a good platform to use the expertise of both practitioners and academics.

3.4. Situation in Finland

In Finland, the discussion concerning patient counselling is part of the international shift initiated in the 1970s to a greater role for pharmacists (Vainio 2004). In the 1990s the community pharmacy facilities were renovated to provide privacy for counselling (Table 3). A national survey conducted by the National Agency for Medicines in 1998 indicated that the most important item in developing pharmacy services was extension of patient counselling (Airaksinen et al. 1989, Airaksinen 1996). In the 1990s, the professional strategy for community pharmacies provided a framework to develop professional pharmacy services that have a special focus on patient counselling. However, counselling practices in the 1990s were still drug oriented, and it seemed that the principles agreed on in the 1980s still guided the content of counselling (Vainio 2004).

Table 3. Development of drug information in Finland (Source: WHO EuroPharm Forum 2005).

Year	Action
1983	Pharmacists´ duty to counsel (Pharmacy Act 4/1928)
1986	Guidelines on patient information (multidisciplinary)
1986	The first computerized information database to produce leaflets to consumers (located in pharmacies)
1988	Facilities to assure privacy (Medicines Act 395/1987)
1993–1996	WHO EuroPharm Forum Questions to Ask About Your Medicines public awareness campaign
1994	Patient Information Leaflets (PILs) through EU regulation
1997	The professional strategy for community pharmacies (Association of Finnish Pharmacies)
1998	Codes of Ethics for Community Pharmacies (Association of Finnish Pharmacies and Finnish Pharmacists' Association)
2000–2003	TIPPA Project (operated by the Ministry of Social Affairs and Health, the National Agency for Medicines, the Social Insurances Institute, the Association of Finnish Pharmacies, the Finnish Pharmacists' Association, the University of Helsinki and the University Kuopio, the Pharmaceutical Learning Centre, and the Kuopio University Centre for Training and Development)

3.5 Pharmaceutical care

The philosophy of pharmaceutical care was introduced in 1990 (Hepler and Strand 1990). The goal of pharmaceutical care is the responsible provision of drug therapy to achieve definite outcomes intended to improve a patient's quality of life. This requires a drug therapy system directed toward people's quality of life. One necessary element of such a system is dispensing and patient advice (Hepler 1997). Advice-giving should be for the specific purpose of enabling the patient or caregiver to cooperate in his or her own care to the fullest possible extent under the circumstances. Patient counselling has been one component among many other components in instruments designed to measure pharmaceutical care activities (Odenina and Segal 1996, Larson et al. 2002). However, these instruments are not patient counselling specific and the lack of patient counselling specific instruments is evident. It seems that the concept of patient counselling has been underestimated in the instruments that have been developed to assess the quality of drug therapies and pharmaceutical care services. This may be due to the different payment mechanisms for pharmacy services or different organisation of community pharmacies.

4 STRATEGIES TO IMPROVE PATIENT COUNSELLING PRACTICES

Even though the principles of customer-oriented counselling practices have been promoted extensively among the profession, research has shown deficiencies in actual counselling performance, such as a lack of communication skills, ignoring individual patient's needs and the lack of professional information given to patients (De Young 1996b, Aslanpour and Smith 1997, Fritsch and Lamp 1997, Morris et al. 1997, Erickson et al. 1998, Vainio 2004). This indicates that changing counselling behaviours and attitudes is a long-term process. Therefore, multiple and simultaneous approaches are required. The diverse variables which affect pharmacist-client consultations should also be taken into account in designing interventions to help pharmacists to change their counselling performance (Morrow and Hargie 1987, De Young 1996a).

The change process can be supported by using different strategies. The profession itself can create its own strategy or society can set standards of practice. In this chapter I have divided strategies that have been used to change counselling practices into three different categories: legislative, professional and educational. These strategies can be considered to have a main focus at different levels: at societal level, at organisational level and at individual level (Figure 1).
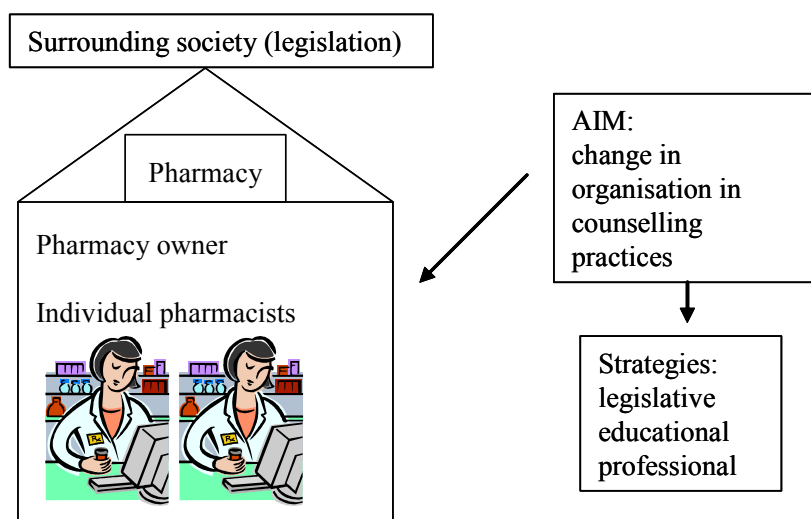
Figure 1. Different levels and strategies in promoting a change in patient counselling practice.

4.1 Legislative strategies

Laws and regulations provide a framework for pharmacists to practice their profession. If patient counselling is mandated by law, it creates norms and standards for counselling practices. In most European countries, the provision of written drug information about prescription medicines and non-prescription medicines is mandated by law (Hartikainen 1999). However, oral counselling is seldom mentioned in mandates and agreements. Moreover, mandates and other agreements usually do not define the minimum content of drug information that should be provided. There are a few exceptions: in Finland and in the United States, specific laws mandate the provision of oral counselling (Pharmacy Act 58/1983, OBRA`90).

In the United States, OBRA´90 requires all pharmacists to provide counselling for Medicaid patients and all State Medicaid Agencies (SMAs) to develop and implement drug use review (DUR) programs (Pugh 1995). OBRA ´90 requires that an "offer to counsel" must be made, and most states require this to be done by a pharmacist, although some states allow a designate or do not address the question. According to OBRA´90, counselling should include the name and description of medication, duration of therapy, common severe adverse effects, proper storage and refill information.

The impact of OBRA´90 has been studied extensively before and after the law took effect in the United States (Pugh 1995, Rumore 1995, Barnes et al. 1996, Lyons et al. 1996, Erickson et al. 1998, Schatz 2003). In general, results indicate that pharmacists are spending more time counselling patients after the law was enacted, but fall short of complete compliance (Rumore et al. 1995, Erickson et al. 1998, Schatz 2003). Barriers for compliance with the law have been assessed. According to studies e.g., lack of time, lack of personnel and privacy, and expense constraints have served as barriers (Pugh 1995, Rumore et al. 1995, Barnes et al. 1996). Some of the pharmacists have also indicated a lack of upper management support for patient counselling (Rumore et al. 1995). Ten years after the law took effect most pharmacies (69%) offered to provide prescription counselling, fulfilling the minimum requirement of legislation (Schatz 2003).

It seems that changes in counselling practices due to legislation are slow (Svarstad et al. 2004, Vainio 2004). However, a recent American study revealed that counselling practices in different states varied significantly according to the intensity of a state's counselling regulation (Svarstad et al. 2004). More intensive regulations increased the likelihood of pharmacist involvement in counselling, provision of risk information, assessment of shopper understanding and amount of oral information given. It seems that it takes time to teach practitioners and pharmacy students the new counselling standards and promote a new role in health care. Other approaches and legislative strategies to improve counselling practices are required to promote a change in behaviour (Nichol and Michael 1992, Svarstad et al. 2004). Furthermore, laws and statutes should also be accompanied by implementation and enforcement systems (Nichol and Michael 1992).

4.2 Professional strategies

Professional organisations can create national strategies to define and promote the role of a community pharmacy and community pharmacists in health care. In Finland, the pharmacy organisations have been proactive in implementing the requirements of the law into practice by developing a professional strategy for community pharmacies (The Association of Finnish Pharmacies 1997).

In Australia, the pharmacy profession has negotiated agreements with the government to incorporate new, remunerated professional services into community pharmacies (Roberts et al. 2003). The current agreement is called the Third Community Pharmacy Agreement and it is valid until 2005. The Agreement included funding for a Pharmacy Development Program, which aimed to promote the enhanced involvement of community pharmacy in the pursuit of quality and cost effective service delivery (Pharmacy Guild of Australia 2000a). The program incorporated the delivery of Home Medicines Review (HMR) and Consumer Medicines Information (CMI). Funding from the government was also obtained for a quality assurance and professional practice standards program, known as the Quality Care Pharmacy Program (QCPP), the platform to which remuneration for the new professional services has been linked (Pharmacy

Guild of Australia 2000b). One reason for this approach was that in order for the community pharmacy network in Australia to stay viable, new professional services were needed (Roberts et al. 2003). The larger framework for this agreement comes from the National Medicines Policy that was launched in 1999. It aims to improve positive health outcomes for all Australians through their access to and wise use of medicines. The policy has four central objectives: timely access to the medicines that Australians need, at a cost individuals and the community can afford; that medicines meet appropriate standards of quality, safety and efficacy; quality use of medicines; and maintaining a responsible and viable medicines industry.

In Australia, the uptake of the QCPP, HMR and CMI has been increasing (Roberts et al. 2004). However, the rate of the adoption has not been as fast as was expected, and research has been conducted to assess the facilitators for change (Roberts et al. 2003, Roberts et al. 2004). These facilitators included e.g., relationship with doctors, remuneration, pharmacy layout and communication/teamwork (Roberts et al. 2004).

Similar movement among the profession has also occurred in e.g. in England and Scotland, where the role of community pharmacy has been developed as part of national health care plans (National Health Service 2000, Scottish Executive 2002). However, it seems that there is a lack of comprehensive, professional strategies among pharmacy organisations worldwide.

4.3 Educational strategies

Basic education provides a foundation to promote new professional practices and behaviours for pharmacy students. Continuing professional development is required to fulfil the need of working life pharmacists to gain new knowledge and the skills needed in a modern working environment. In Finland, there are still many pharmacists working in community pharmacies that have not been instructed in patient counselling, communication and pharmacologic skills during their basic education. Therefore, continuing education has an important role to play to update their skills and knowledge.

4.3.1 Basic education

The content of basic education should reflect the changes in the pharmacist's professional role and take into account the new role of the patient (Newton 1991, Katajavuori 2005). The pharmacy curriculum has traditionally been based on natural sciences e.g. chemistry. However, in the United States and in Great Britain, the content of the pharmacy curricula has changed towards clinical pharmacy as clinical skills are needed in practice (Svarstad 1994, Shaw 2002). Also, patient counselling and communication skills courses are essential components in basic and continuing education. Furthermore, the teaching methods should reflect the modern philosophy of learning (Katajavuori 2005). At Kuopio University, Faculty of Pharmacy, patient counselling has been a part of basic education since the beginning of the training of pharmacists in the 1970s (Vainio 2004). However, the first patient counselling course that was integrated with communication skills training was organised in 1995. Premises for pharmacy students to practice their counselling skills in a pharmacy environment were provided in 1987. As part of the Bologna declaration, pharmacy schools are now re-evaluating the content of basic education and re-defining the goals for the pharmacy curriculum (Hirvonen 2004). According to new goals, graduating pharmacists (B.Sc.Pharm) should be able to counsel the patients about prescription and non-prescription medicines, assess patient symptoms refer them to other health care professionals if needed. Also, graduating pharmacists should have the skills for continuing professional development (Holm and Hiltunen 2004).

4.3.2 Continuing professional development

Continuing professional development is one way to promote the new counselling role to practising pharmacists. In a changing, increasingly complex profession, and with rapid medical and technological advances, the need for continuing professional development is evident (Rouse 2004). Several courses have been designed to improve pharmacists' counselling skills (Lee et al. 1998, Vainio et al. 2001, Kansanaho et al. 2003). A strong direct correlation between the amount of voluntary continuing

professional education undertaken and the frequency of counselling has been indicated (Holland 1992). Continuing education is also one of the factors influencing the provision of pharmaceutical care (Odenina et al. 1995). However, the long-term impact on performance is not known, as evaluation has focused on the immediate impact of courses. Furthermore, the impact of training seems to deteriorate with time (Morrow and Hargie 1987b). In order to change counselling practices, long-term courses are needed (Kansanaho et al. 2003). Also, pharmacy owners should be willing to provide time and other resources to facilitate the desired change (Kansanaho et al. 2003). Pharmacists' training should be systematic, taking into account the needs of the individual pharmacist and the needs of the whole pharmacy. This aspect has not been studied extensively even though the problems in implementing new behaviours are well-known. One should also take into account factors related to the organiser of continuing education, e.g., whether it is organised by the drug industry or by a non-profit organisation. These aspects may be reflected in the content of continuing education and may lead to or reveal conflict(s) of interest.

In the Netherlands, a systematic educational intervention was designed to improve patient education activities undertaken by pharmacy technicians (Pronk 2002). The intervention included course work and on-the-job training. The participants (n=28) carried out an inventory of existing practices in their pharmacy and then constructed a plan in order to change these. The intervention led to an increase in structured work with regard to patient education in participating pharmacies.

In the United States, programs aiming to promote and implement pharmaceutical care in community pharmacies were run in the 1990s (Blumi et al. 1998, Kassam et al. 1999). The results of these programs (e.g., Practice Enhancement Program PEP, Project ImPACT) showed that pharmacists increased communication with patients and other health care professionals and the outcomes of drug therapies improved among targeted patient groups (Blumi et al. 2000, Volume et al. 2001).

In Australia, a new technique that combined a pseudo customer methodology and continuing education was developed to change practice behaviour (De Almeida Neto et al. 2001). This training methodology uses the pseudo customer as a change mechanism to shape practice behaviour. The new concept starts by workshop training that is

followed by pseudo customer visits. After the visits participants are given immediate feedback and coaching from an experienced pharmacy educator. This methodology has been successfully applied e.g., to pharmacists dealing with non-prescription analgesics in Australia and in Switzerland (De Almeida Neto et al. 2001, Sigrist et al. 2002). The results indicate that combining training with pseudo customer visits with immediate feedback support the learning process and its sustainability.

4.4 Organizational approach

In the change process, regardless of the strategy chosen, a pharmacy can be viewed as an organisation. Thus, organisational theories can be used in development and change management projects in the community pharmacy setting. However, only a few studies assessing patient counselling have defined variables related to community pharmacy as an organisation. The study by Roberts et al. (2003) identified facilitators for the practice change process from both a business and a professional perspective. These included: remuneration of implementation and/or service; external support or assistance; reorganisation of the pharmacy's structure and function; communication; leadership and delegation of tasks. Other studies have also confirmed that the role of management is essential in changing existing practices in community pharmacies (Kansanaho et al. 2003).

One of the most used models that describe how to implement change effectively in organisations is Rogers' Diffusion of Innovations theory (Rogers 1995, Rogers 2004). This theory has been used in a wide range of disciplines including anthropology, education, rural and general sociology and health and mental sociology (Rogers 2004). Diffusion is the process trough which an innovation, defined as an idea perceived as new, spreads via certain communication channels over time among the members of a social system. This theory describes the process of dissemination of new behaviours, objects, factors and situations that are of influence to this process. The Diffusion of Innovation theory can be used to understand the uptake process of a new professional service in community pharmacy (Chen et al. 1999, Pronk 2002, Roberts et al. 2004). It

can also explain why people do not react the same way and at the same time to the changes suggested.

4.5. Summary

It is likely that all the three strategies (legislative, professional and educational) are needed to promote a change among the profession. It is difficult to evaluate which strategy is the most effective. It seems, however, that the profession needs to have a strong vision about its future, and concrete actions are needed to meet that vision. Furthermore, community pharmacists need supportive actions in the implementation process of new professional behaviours and services. In general, it seems that there is a need to restructure the whole environment or system in which pharmacists practice to achieve sustainable changes in counselling performance (Dickson and Rodowskas 1975, Kimberlin et al. 1993, Odenina et al. 1995, Farris and Schopflocher 1999, Roberts et al. 2003). Also, remuneration of the services may facilitate the change process (Roberts et al. 2004).

5 EXISTING INSTRUMENTS AND METHODS TO ASSESS PATIENT COUNSELLING PERFORMANCES

Evaluation of existing practices is important as it can direct the development actions taken in the pharmacy. Evaluation should be planned and systematic. The evaluation requires measures that are relevant to its objectives and sensitive to the anticipated outcomes (Smith 2002). Measures are needed as they provide information on current practices and therefore, can be used to develop and improve performances. Measures should also be applicable to different kind of audits. The audit function can be divided into three types: self audit (self-evaluation), peer audit (peer-evaluation) and external audit. Self- and peer-audit involve an individual or a group auditing their own performance against published standards or personal objectives. External audit occurs when persons outside the organisation audit the practice.

The common features for an applicable and good measurement are validity and reliability (internal consistency). A valid measure is one that taps the construct that it is intended to tap (Kidder et al. 1981). Validity is inferred from the manner in which a scale is constructed, its ability to predict specific events, or its relationship to measure other constructs (DeVellis 1991). There are several other types of validity, e.g. construct validity, face validity and criterion validity; however, all types of validity are addressing the same issue of the degree of confidence that can be placed on the inferences drawn from scale scores (Bowling 1997). Reliability, or internal consistency, is concerned with error in measurement. A reliable measure is one that has a small error component and, therefore, does not fluctuate randomly from one moment to the next (Kidder et al. 1981).

5.1 Concept of service quality

As patient counselling is a professional service, it is important to understand what constitutes good service quality. Assessing the quality of patient counselling services can be problematic because of the special nature of these services. Three basic characteristics of services - intangibility, heterogeneity and inseparability - need to be

taken into account in the assessment models (Parasuraman et al 1985). Because services are mostly a combination of both performance and products, precise manufacturing specifications concerning uniform quality can rarely be set. Services are also heterogeneous: their performance often varies from producer to producer, from customer to customer. Production and consumption of many services are inseparable. Thus, quality occurs during service delivery, usually in an interaction between the client and the contact person of the firm.

Quality in health care has been defined by Øvretveit (1992) as "fully meeting the needs of those who need the service most, at the lowest cost to the organisation, within limits and directives set by higher authorities and purchasers". Furthermore, Øvretveit divides health service quality into three dimensions: Client Quality (what clients and providers want from service), Professional Quality (the good quality of health care professionals and techniques provided) and Management Quality (the most effective and productive use of resources).

Service quality is a measure of how well the service level delivered matches customer expectations. Customers assess service by comparing the service they receive (perceptions) with the service they desire (expectations). A company can achieve a strong reputation for quality service only when it consistently exceeds customer service expectations (Berry et al. 1990). Service quality, as perceived by customers, can be defined as the extent of discrepancy between customer expectations or desires and their perceptions (Berry et al. 1990).

However, customers do not necessarily appreciate the same things as professionals or rate services similarly. It is challenging to evaluate service quality because of the difficulties involved in delineating and measuring the concept of service quality. One of the earliest models was developed by Grönroos (1984) who defined quality as functional and technical dimensions. Technical quality refers to what is offered to the customer, while functional quality refers to how it is offered. The total quality will be expressed as a sum of the functional and technical qualities. Applied to pharmacy services, technical quality refers to the quality of the product (drug) dispensed, while functional quality refers to the working patterns and technology used in the dispensing process (Airaksinen 1996).

5.1.2 Instruments to measure service quality

Factors related to functional quality (how the service is offered) can be understood by the well-known theory of Parasuraman et al. (1988). Their definition of service quality was based on an explanatory study yielding 10 key categories of service quality (accessibility, communication, competence, courtesy, credibility, reliability, responsiveness, security, tangibles, and understanding/knowing the customer). However, it was revealed that customers can only distinguish between five dimensions and factor analysis was conducted to extract these five. The instrument developed was named as SERVQUAL (Table 4). The instrument has also been used in community pharmacy settings (Hedvall and Paltschik 1991, Airaksinen 1996, Pritchard and Perri 1997). Hedvall and Paltschik (1991) proposed a four-concept, pharmacy-specific solution (Table 4). Professionalism and milieu are the preconditions for the service offered. The pharmacists can give added value to their customers by emphasising commitment and confidentiality. Airaksinen (1996) assessed customer satisfaction with community pharmacy services in Finland, identifying a three factor solution (Table 4). Pritchard and Perri (1997) used SERVQUAL as a basis for their own scale that was developed to measure the quality of service in a retail pharmacy. The scale measured both perceived quality and expected quality and contained 26 items.

Community pharmacy specific solutions highlight the professional dimension of the services indicating that pharmacists need professional competence to provide good quality services to their customers. Also, pharmacists should show empathy to their customers. Furthermore, the pharmacy milieu should provide customers privacy and the possibility to ask questions.

Table 4. Some of the existing service quality instruments and their applicability to pharmacy services.

Instrument	Dimensions
SERVQUAL (Parasuraman et al. 1988)	**Tangibles** (the appearance of physical facilities, equipment, personnel and communication materials) **Reliability** (the ability to perform the promised service dependably and accurately) **Responsiveness** (the willigness to help customers and to provide prompt service) **Assurance** (the knowledge and courtesy of employees and their ability to convey trust and confidence) **Empathy** (the provision of caring, individualized attention to customers)
Hedvall and Paltschik (1991)	**Professionalism** (having the customer's best interest at heart and performing the duties of the pharmacist promptly and accurately), **Commitment** (making a special effort to serve the customers particularly by giving them advice about the product purchased) **Confidentiality** (creating an atmosphere enabling customers to feel that they are cared for and enabling them to feel free to discuss problems and ask questions) **Milieu** (the physical premise of the pharmacy)
Airaksinen 1996	**Professional trustworthiness** (professional competence and trustworthiness) **Functional quality** (adequacy of time for pharmacist-customer interactions, the queuing time and the way customers are treated) **Privacy** (possibility of talking about medicines confidentially in a pharmacy setting)
Pritchard and Perri 1997	**Tangibles** (the physical facilities, equipment) **Reliability/assurance** (ability to perform the promised service accurately, politeness of the employees) **Responsiveness/Empathy** (the caring and individualized attention provided to customers, having customers best interest at heart)

5.2 Pseudo customer method

One method that can be used to assess counselling performance is the pseudo customer method (Smith 2002). Even though there are other methods to evaluate counselling practices e.g., questionnaires, I have focused on a pseudo customer method. This is due to the fact that this observational method has proved to be a more reliable survey method with respect to the accuracy and consistency of counselling activities compared with self-completion questionnaires and diaries (Ortiz et al. 1998). Pseudo customer studies have been used intensively in marketing research, where "mystery shopping" (the term used in marketing research) is routinely used to assess the performance of the outlets (Wilson 2001). Mystery shopping has its origins in the field of cultural anthropology (Wilson 2001). In a mystery shopping study (sometimes also

referred to as a shopping survey), the front-line operations of a business are evaluated by an anonymous trained observer. Typically, the observer enters the outlet to be evaluated posing as an average customer and, immediately after engaging in what appears to be a normal customer interaction, completes a detailed report on various aspects of the service and shopping environment at the outlet. Mystery shopping is best suited when assessing objective characteristics of outlet operations, such as the store environment (Finn and Kayandé 1999).

Data collected by mystery shoppers can be reported in the form of rating scales, checklists, and open-ended responses (Finn and Kayandé 1999). The results are then used to compare the performance of particular outlets and their employees, to monitor outlet performance over time, and to identify areas where outlets are in most need of improvement. Mystery shoppers are increasingly being used to benchmark the performance of important competitors or even of outlets in other industry sectors which might provide a performance standard (Finn and Kayandé 1999).

In health care, the term pseudo customer or pseudo patient is commonly used. Pseudo customers can be used overtly (i.e., the simulated patient assumes the role of a patient and the person who is being assessed is aware that this is not a genuine patient) or, covertly (i.e., where the person being audited are unaware of the simulated patient's identity or purpose). The basic rationale for using covert simulated patients is that a testee's performance alters when the existence of the test is known (Watson et al. 2004).

The ethical issues should also be considered when the pseudo customer method is used covertly. These studies are a popular and valuable method of obtaining data for research on topics of importance to the future of pharmacy, documenting what actually goes on in pharmacies rather than what pharmacists report (Smith 2002). However, many studies present potential or actual conflicts and compromises between safeguarding the rights of study participants to make informed decisions about their involvement, while not jeopardising the validity of research. Also, when researching sensitive topics there is possibly a need to compromise between achieving study objectives and adherence to high ethical standards (Smith 2002).

A pseudo customer is an individual trained to present particular scenarios: staff whose work is being audited are unaware of the simulated patient's identity. The visit

may take place at anytime within a given time frame. The pseudo customer is trained to follow a standard script.

The first pseudo customer studies in the context of community pharmacy took place at the end of 1960s and at the beginning of the 1970s in the United States (Knapp et al. 1969, Wertheimer et al. 1973). They showed pharmacists in an unfavourable light regarding counselling patients on the use of their drugs. The pseudo customer studies continued in the United States and in other countries to assess the quality and content of counselling practices in community pharmacies (Rowles et al. 1974, Vanderveen et al. 1978, Vanderveen and Jirak 1990, Goodburn et al. 1991, Barnett et al. 1992, Krska et al. 1994, Willison and Muzzin 1995, Lamsam and Kropff 1998, Lyszkiewich et al. 2001, Watson et al. 2002, Schatz et al. 2003, Svarstad et al. 2004). The results of the studies indicate that counselling practices vary greatly and there is still room for improvement.

The method has evolved since its introduction in the field of pharmacy practice research when it was mostly used to assess individual pharmacists' performances. Recent studies have used the pseudo customer method as a tool to provide immediate feedback to community pharmacists during educational interventions and as a tool to change practice behaviour (De Almeida Neto et al. 2001, Sigrist et al. 2002, Berger et al. 2005) Also, a virtual pseudo customer has been used to assess the information provided through the Internet (Bessel et al. 2003, Kulovaara 2005).

5.2.1 Validity and reliability of the pseudo customer method

The reliability of any research method can be defined as the extent to which similar observations made by different researchers would provide the same results (Wilson 2001). The literature concerning the validity and reliability of the pseudo customer method is scarce. Covert pseudo customers have face validity when the target health professional does not know or suspect that they are being confronted by a simulated patient. In a study by Watson et al. (2004) only 1% of the pseudo customer visits were detected and reported by pharmacy staff. The risk of detection is theoretically greater in pharmacies in rural areas where "new faces" are easily spotted.

The use of objective measurement and the careful selection and training of the shoppers can increase the reliability of the method (Wilson 2001). Objective measurement is clearly possible in verifying that an activity did happen and in situations where attributes can be counted. However, judgements on the physical appearance of the premises and service personnel as well as the actions of employees in terms of politeness, product knowledge, and helpfulness are more subjective. Therefore, this subjectivity is minimized by using highly structured response mechanisms such as rating scales with descriptive labels. To further improve reliability, the process is calibrated by showing mystery shoppers videos or photographs of service environments or encounters to illustrate the appropriate rating for a specific type of encounter.

Mystery shoppers seem to provide reasonably reliable ratings of the performance of retail outlets (Finn and Kayandé 1999). The reliability of mystery shopping data is much higher than that of customer surveys, when the data are used for the same problem of scaling outlets. There is presumably an advantage in mystery shoppers knowing they are going to be evaluating an outlet, whereas customers typically only find out after the fact when they are presented with the survey request. There may also be further advantage in having individuals who have been trained to be observant providing the assessment (Finn and Kayandé 1999). Especially in the community pharmacy setting, a customer does not have enough knowledge to assess the professional content of advice given. A normal customer might consider friendly service as sufficient whereas pseudo customers can assess the actual content of counselling. Krska et al. (1994) concluded that determining the patient's experience of the services does not provide a true reflection of the advisory service of the pharmacists and simulations may be more accurate.

Scoring criteria and the selection of scenarios have a crucial impact on the results of pseudo customer studies. Scoring criteria should be developed to take into account the needs assessment of individual patients and information tailored to patients' needs. Different scenarios should take into account both non-prescription and prescription medicines and the choice of the products available. Also, long-term medication scenarios should be developed. Validity of the research findings can be improved by

audio-taping the simulated patient visits. Then the tapes can be compared with the filled data collection forms (Luck and Peabody 2002).

5.3 Patient counselling specific instruments

The evaluation of patient counselling performances requires agreement regarding the features against which performances should be assessed. "Expert panels" or consensus methods such as the Delphi method or the nominal group technique have been used for this purpose (Jones and Hunter 1995, Cantrill et al. 1996, Ward et al. 2000). These techniques have been applied to establish criteria to assess patient counselling in the pharmacy (Ward et al. 2000). Some researchers have also used patient satisfaction scales as a basis for their instruments (MacKeigan and Larson 1989). Data on patient satisfaction can serve as an indicator of service quality (Pasco 1983). There is a lot of material concerning patient satisfaction instruments in the field of health care and community pharmacy (Ware and Hays 1988, MacKeigan and Larson 1989, Schommer and Wiederholt 1994b). However, as my main focus is patient counselling, I have concentrated on the instruments that assess patient counselling practices.

Existing patient counselling instruments are shown in Table 5. The Purdue Pharmacist Directive Guidance (PPDG) measure can be applied to measure directive guidance conducted by pharmaceutical personnel and its impact on the patient's behaviour, and on the outcomes of medical care. It was based on an existing inventory of socially supportive behaviours (Gupchup et al. 1996). The PPDG scale is pharmacy specific, but it does not include specific items to measure the quality of patient counselling. Community pharmacists or patients were not consulted in the development process. However, the measure is short and easily administered. It can be used in research directed toward identifying variation across pharmacies in levels of directive guidance provided to customers. This scale has been further developed to meet the needs of hypertensive patients (Sen and Thomas 2000).

The criteria developed by Ward et al. (2000) combined consensus techniques with the viewpoint of practicing community pharmacists. The criteria were developed by an expert panel using the nominal group technique. To ensure feasibility of the criteria, it was sent to six

practicing community pharmacists. As a result, the 10 criteria developed by the nominal group were reduced to eight criteria (Table 5). However, in reliability testing, predefined levels were met excluding three criteria. These excluding criteria were rational content of advice, rational product choice and referral to another health professional. The instrument demonstrated greater reliability in assessing the process of patient counselling (criteria 1,3,4,6) than the appropriateness of advice or action to be taken (criteria 5,7,8). Further work is required in order to refine criteria that did not meet the predefined standards of reliability. Furthermore, the implementation of the criteria into practice should be taken into account.

United States Pharmacopeia (USP) started the development of a comprehensive medication counselling assessment inventory in 1994. The intent was to construct an evaluation tool that contains items having potential application to a variety of medication counselling contexts. According to USP, the tool should take into account the entire counselling process; interactive communication between the health care provider and the patient; the patient's information needs in self management of the treatment; and setting goals for the treatment (Table 5). The exact definition for patient counselling was also applied to the development process. The development process of the instrument combined the use of an expert panel and the collection of existing instruments. The USP Guidelines provide a comprehensive framework to evaluate counselling performances (Appendix 1).

Table 5. Patient counselling specific instruments.

Measure	Theoretical model	Development process	Validity/reliability testing	Items/dimensions
The Purdue Pharmacist Directive Guidance (PPDG) (Gupchup et al. 1996)	Inventory of Socially Supportive Behaviours (Barrera and Ainley 1983)	Phone interview	Validity testing: factor analysis Reliability testing: Cronbach's alpha	Two dimensions: Instruction (6 items) and Feedback and Goal Setting (4 items)
Criteria for assessing the appropriateness of patient counselling in community pharmacies (Ward et al. 2000)		Consensus method using expert panel (Nominal Group Technique)	Face, content and consensual validity assessed by sending the criteria to community pharmacists Reliability testing: survey among community pharmacists who used the instrument to assess a sample of vignettes of patient counselling scenarios	8 items: 1.General communication skills 2.Information gathered by pharmacy staff 3.How the information is gathered 4.Issues to be considered before giving advice 5.Rational content of advice given 6.How advice is given 7. Rational product choice 8. Referral
United States Pharmacopeia (USP) Medication Counselling Behaviour Guidelines	Definition of patient counselling: an approach that focuses on enhancing individual problem-solving skills for the purpose of improving or maintaining quality of health and quality of life. The process emphasises that the health professional provides and discusses medication information with the appropriate person to achieve this goal. The physical, psychological, socio-cultural, emotional, and intellectual perspective as well as the health beliefs and values of the individual must be respected.	USP Consumer Interests Health Education Panel (members representing consumers, hospitals, schools of pharmacy and medicine and drug industry) gathered existing instruments from health care institutions, pharmacy schools and practice settings, Guidelines developed from the existing instruments	Validity and reliability testing at this phase: Consensus method	35 items, 4 dimensions 1. Introduction 2. Content 3. Process followed 4. Conclusion

6 AIMS OF THE STUDY

The overall aim of this study was to develop instruments to measure the quality of patient counselling needed in Finnish community pharmacies during the TIPPA project (2000–2003).

The specific objectives of this study were:

1. To assess the validity and internal consistency of the USP Medication Counselling Behaviour Guidelines.

2. To assess the perceived usefulness of the USP Medication Counselling Behaviour Guidelines among Finnish community pharmacists.

3. To develop a patient counselling specific quality assurance instrument for self-audit and external audit of patient counselling practices.

4. To develop a pseudo customer method to assess the professional content of patient counselling practices in Finnish community pharmacies during TIPPA project (2000–2003).

7 MATERIALS AND METHODS

7.1 The TIPPA Project (2000–2003)

The TIPPA Project involved all the important parties in the field of pharmacy ensuring broad representation and commitment (Table 6). This was significant because for the first time, the Ministry of Social Affairs and Health and a major third-party payer (Social Insurance Institute) took part in a joint project related to the professional development of community pharmacy services.

The Project consisted of various planned and co-ordinated activities supporting a long-term development process at the pharmacy level (Table 6). The activities took place at a national and local level. Emphasis was paid both to basic and to continuing professional development. The main operational goal was to implement a new patient counselling model based on concordance and two-way communication. This was promoted by encouraging pharmacies to develop long-term strategic plans. These long-term plans included a present state analysis of counselling practices and a step-wise plan to achieve strategic goals. In basic education, patient counselling and communication skills courses were modified to better meet the needs of customer-oriented counselling practices. In continuing professional development, e.g. a new long-term patient counselling course was developed (Kansanaho et al. 2003).

Based on previous experience, pharmacists need concrete tools and instrument(s) to evaluate and improve their counselling performance (Airaksinen et al. 1998). During the project, several practical tools were provided, e.g. a patient counselling and communication skills book, electronic, easy-to-use database on prescription medicines, a manual on good patient counselling and guidelines for self-medication.

The United States Pharmacopeia (USP) Medication Counselling Behaviour Guidelines were chosen as the main instrument to promote two-way communication and customer-oriented patient counselling. This decision was based on the notion that these Guidelines were considered applicable in a community pharmacy setting and they were regarded as comprehensive. Furthermore, there were not many alternatives available (see chapter 5). The Guidelines were translated to Finnish (Hakkarainen and Airaksinen

2001). The Guidelines were first used in the education of pharmacy students to teach the principles of patient counselling. In continuing education, the Guidelines were systematically used to promote self-evaluation of counselling practices. They were also integrated into patient counselling and communication skills study books and a quality manual (TIPPA Final Report 2005). Also, in the beginning of the TIPPA project the Finnish Pharmacists' Association sent the Guidelines to all pharmacists working in community pharmacies.

The progress of patient counselling practices was evaluated during the project by using a pseudo customer method. Also several other research projects were conducted during the project to provide evidence of the changes that occurred in patient counselling practices and actions taken in community pharmacies (Varunki 2003, Kansanaho et al. 2004, TIPPA Final Report 2005). In addition, the implementation of the tools provided was assessed during the project (Varunki 2003, Kansanaho et al. 2005, Saario 2005).

Table 6. Outline of the TIPPA Project.

TIPPA (2000–2003)

TIPPA was a 4-year national joint project to promote the implementation of a professional strategy by enhancing patient counselling in Finnish community pharmacies.

The Project was operated by the Ministry of Social Affairs and Health, the National Agency for Medicines, the Social Insurances Institute, the Association of Finnish Pharmacies, the Finnish Pharmacists' Association, the University of Helsinki and the University Kuopio, the Pharmaceutical Learning Centre, and the Kuopio University Centre for Training and Development.

Drug policy goals

TIPPA aimed at promoting the rational use of medicines; decreasing the negative effects of inappropriate use of medicines, including self-medication; and decreasing costs by enhanced patient counselling.

Operational goals

Phase 1 (2000–2001): Introducing practitioners to new counselling behaviours (raising awareness), developing resources and tools specifically for patient counselling (e.g. easy-to-use electronic prescription drugs database, handbooks on self-medication, manual on quality assurance of counselling practices, handbook on patient counselling and communication).

Phase 2 (2001–2002): Facilitating self-assessment of counselling practices and processing long-term development plans, training of TIPPA tutors

Phase 3 (2002–2003): Implementing and promoting the use of patient-counselling resources; assessment of the implementation of TIPPA resources and tools.

Phase 4 (2003): Evaluation and reporting. Constructing a new action plan based on the evaluation

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7.2 Study design

The study commenced with an assessment of the validity and internal consistency of the USP Medication Counselling Behaviour Guidelines in co-operation with United States Pharmacopeia (I). Their usefulness in improving patient counselling practices in Finnish community pharmacies was assessed two and half years after the TIPPA project had started (II). During the TIPPA Project, the need for a more comprehensive quality assurance instrument became evident. Ten experienced community pharmacists, with Masters degrees in pharmacy (M.Sc.Pharm), were trained to act as external auditors of patient counselling practices (TIPPA tutors), and a patient counselling specific instrument was needed for the process. The instrument was constructed during the training of the TIPPA tutors in 2001 (III). As the aim of the TIPPA project was to

enhance patient counselling in community pharmacies, a pseudo customer method was developed to assess the progress that occurred in counselling practices during the project in 2000–2003 (IV).

TIPPA project 2000–2003

| 1999 | 2000 | 2001 | 2002 | 2003 |

| Validation of the USP Guidelines (I) | Annual pseudo customer studies were started (2000–2003) (IV) | Development of the quality assurance instrument (III) | Assessment of the usefulness of the USP Guidelines 2,5 years after the project started (II) |
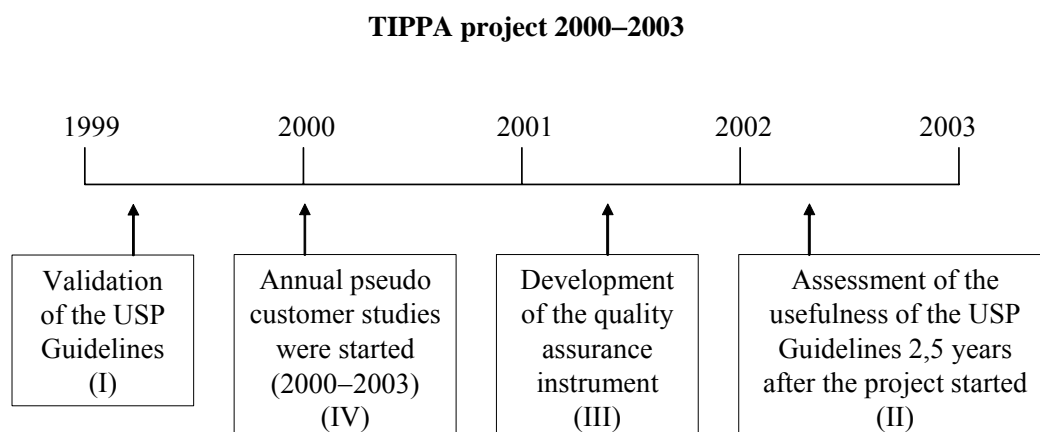
Figure 2. Outline of the studies (I-IV) conducted during 1999–2003.

Table 7. Methods used in original publications (I-IV).

STUDY	METHOD	CRITERIA	STATISTICS
I	Validity and reliability assessment • 36 pharmacists rated the six selected videotaped counselling sessions (n=216)	USP medication counselling behaviour guidelines (Appendix 1) • 35 items • 4 subscales: Introduction, Content, Process and Conclusion	Correlation analysis (Pearson coefficient) Factor analysis with varimax rotation Internal consistency with Cronbach's alpha
II	Survey • postal questionnaire • a sample of every fifth pharmacists on the register (n=734) • response rate 51% (n=374)	How well the respondents knew the Guidelines • the applicability of the Guidelines in patient counselling and in self-evaluation • their usefulness as an instrument to learn the principles of patient counselling in different settings	Descriptive statistics (means, standard deviations, Cross-tabs method, Chi-square tests)
III	Modified Delphi • 2 expert groups (n=20) • Delphi questionnaire (n=35) • response rate 74% (n=26)	5-point Likert scale • the item should be retained: $\geq$ 75% of participants scored the item $\geq$ 4 • the item should be excluded: $\geq$ 75% of participants scored the item $\leq$ 2 • no consensus: item which failed to meet either of the other criteria.	
IV	Pseudo customer study (2000–2003) • 60 community pharmacies • baseline and 3 annual follow-ups • 4 scenarios (n=960)	Scoring criteria divided into 2 subscales: Needs assessment and Instructions to Use (Appendix 2) Based on USP Guidelines Maximum score 5–8 according to the scenario	Total scores and scores for subscales Descriptive statistics (means, standard deviations) Non-parametric Friedman test

7.3 Validation of the USP Medication Counselling Behaviour Guidelines (I)

This study was conducted in cooperation with United States Pharmacopeia (USP). Thirty-six pharmacists from Maryland and Washington, DC were recruited to evaluate six selected videotaped vignettes by using the Medication Counselling Behaviour Guidelines (n=216). Videotaped vignettes were provided by the national Patient Counselling Competition in the USA. The event has been organized annually by the USP in co-operation with the American Pharmaceutical Association. The competition provided an opportunity for pharmacy students to practice their counselling skills. The scenarios used simulated real counselling sessions on prescription medications in the community pharmacy. The sessions were videotaped and evaluated. After evaluation, the students were given feedback on their counselling skills. Six videotaped sessions, involving four female and two male pharmacists, were selected to represent different types of scenarios. The selected videotapes were among the tapes of the finalists of the Patient Counselling Competition in 1995–1997. The tapes were obtained for research purposes, consequently they are not freely available.

All the 35 items of the Medication Counselling Behaviour Guidelines were subjected to basic correlation analysis with Pearson coefficient before conducting factor analysis. A limit of 0.3 was set to the correlations; items that did not have a correlation of 0.3 with any item were excluded from the scale. This was done because high inter-correlation between the items facilitates the determination of patterns of constructs in the data.

To determine the construct validity of the scale, all the items having correlations above 0.3 with at least one variable were subjected to factor analysis with the extraction method of principal component analysis. Principal component analysis was chosen as the analysis method as it applies to determining the components rather than explaining the variance between the original variables and new components (DeVellis 1991). The rotation method was an orthogonal varimax with Kaiser normalization. In factor analysis, reference axes are rotated to increase interpretability of factors. Depending on angular separation of reference axes, the rotation can be either orthogonal or oblique.

Internal consistency was assessed by calculating Cronbach's alpha values. Alpha

values above 0.7 were considered as good (Nunnally and Bernstein 1994). The analysis was conducted for both the original scale and the new scale which was constructed from the original using principal component analysis.

7.4 Finnish community pharmacists' perceptions of the usefulness of the USP Guidelines (II)

Staff pharmacists from community pharmacies were selected as a target group for this study as they are the personnel group responsible for customer service in Finnish community pharmacies. A sample of every fifth pharmacist on the register was produced alphabetically from the professional membership lists of those pharmacists with a Bachelor's Degree (the Finnish Pharmacists' Association) and those with a Master's Degree (the Finnish Pharmacists' Association and the Society of Pharmacists). A total sample of 734 registered pharmacists was surveyed. The initial mailing included a letter of transmittal guaranteeing anonymity, the questionnaire and return envelope. The letters were mailed out on university stationery. Two reminder letters were sent out, the first in August and the second in September in 2002.

A total of 376 responses were received (response rate 51%). The characteristics of the respondents were similar to those of the target population (II, Table 1). The mean age of the respondents was 35 years.

The questionnaire included both structured and open-ended questions concerning the usefulness of the Guidelines, altogether 12 questions (Appendix 3). The respondents were asked how well they knew the Guidelines, where they had learnt about the Guidelines, the applicability of the Guidelines in patient counselling and in self-evaluation, and their usefulness as an instrument to learn the principles of patient counselling in different settings. The respondents were also asked to describe the ways of using the Guidelines in practice and to provide suggestions for improvement and reasons for not using the Guidelines.

Descriptive statistics on the sample characteristics and questionnaire items were computed, including means, standard deviations (SDs) and frequency distributions. Cross-tabulation methods and the Chi-square test were used to assess the dependency

between different variables. P-values less than 0.05 were considered to be significant. The open-ended questions were analyzed based on their thematic content (Pietilä 1976). The data were analysed using the SPSS 10.1 statistical software.

7.5 Development of the patient counselling specific quality assurance instrument (III)

The method used in this study was a modified Delphi method. Delphi can be characterized as a method for structuring a group communication process so that the process is effective in allowing a group of individuals, as a whole, to deal with a complex problem (Linstone and Turoff 1975). Experts are invited to give their opinions on the specific matter by participating in several questionnaire rounds, which are repeated until an acceptable degree of consensus is obtained. The development of consensus guidelines or standards where research based evidence is absent or inconclusive are typical applications of the method.

The first phase is usually conducted by the researcher, who selects the material that is provided to the experts; commonly one panel is used, with some exceptions (Duffield 1993). However, in our study we chose an approach based on the practical expertise of the panel members, and the Delphi method was considered feasible for this purpose.

Two expert panels were established: one with ten experienced practitioners being trained to become external auditors of patient counselling practice in the national TIPPA Project (Panel 1), and the other consisting of the members of the executive committee of the Project (n=10) with academic and professional expertise (Panel 2). Panel 1 made the first draft with factors related to the quality of patient counselling based on a brainstorming session. The structure and related measures of the tool were reviewed by the second panel and piloted by the first panel in ten pharmacies.

Final consensus was assessed by a Delphi questionnaire sent to the members of Panels 1 and 2, the employers of Panel 1 (n=5) and to the members of the executive board (n=10) of the TIPPA project, altogether to 35 people (response rate 74%). The participants were asked to rate the applicability of each quality dimension and related indicators, the general structure of the instrument, and items related to the vision and

strategy (n=28) on a 5-point Likert scale ranging from 1 (= fully disagree) to 5 (= fully agree).

The respondents were also asked to comment if any factors that influence patient counselling quality were missing from the instrument. The following definitions of consensus were established before data analysis: consensus that the items should be retained: ≥ 75% of participants scored the item ≥ 4; consensus that the item should be excluded: ≥ 75% of participants scored the item ≤ 2; no consensus: item which failed to meet either of the other criteria. The percentages were calculated using the SPSS 10.1 statistical software.

7.6 Development of the pseudo customer method to assess patient counselling practices among Finnish community pharmacists (IV)

The data for this study were collected by using a pseudo customer method. The pseudo customer visits were conducted in a purposive sample of 60 community pharmacies out of the total number of about 600 pharmacies, having different geographic location, size in terms of annual prescription volume and service design (IV, Table 1).

A scoring system was developed to analyze the interactions between the pseudo customer and the pharmacist. The scoring criteria were based on the United States Pharmacopeia (USP) Medication Counselling Behaviour Guidelines. Total scores and scores for two subscales "Needs Assessment" and "Instructions to Use" were calculated for each visit (Appendix 2). The "Needs Assessment" subscale included items related to clinical assessment, such as who is the medicine for and what are the patient's symptoms. The "Instructions to Use" subscale included information on how to use the medicine, such as the dosage and the duration of the treatment. Both of these subscales were customized according to each individual scenario. One point was allocated for each item, yielding a maximum score between 5−8 depending on the scenario (Appendix 2).

Four different scenarios (Appendix 2) were used in each pharmacy, yielding 240 visits per each time point measured (baseline in December 1999 – March 2000, and

three follow-ups in December 2000-January 2001; November 2001-December 2001; and January 2003-February 2003, respectively). In total, 960 interactions were analysed, 240 interactions per each scenario.

The scenarios were selected to represent different types of common requests in pharmacies. The three self-medication scenarios were based on sales statistics, representing some of the typical symptoms for self-medication (National Agency for Medicines and Social Insurance Institution 1999). Scenario four for a prescription medication consisted of two different approaches with a new (baseline and the second follow up) and a repeat prescription (the first and the third follow up).

The visits were conducted by a research institute that specialized in pseudo customer studies. The research institute trained the pseudo-customers according to instructions by the TIPPA Executive Committee, and the institute independently selected the study pharmacies.

Pseudo customers made notes immediately after each visit using a structured form customized to each scenario. During the baseline, structured data forms were the only method to record the interaction. The method was further developed in co-operation with the University of Sydney, Australia. Based on their experience, some of the interactions were also audio-taped during the three follow-up studies (n=37). These tapes were transcribed verbatim.

In addition to calculating total scores and scores for subscales for each visit, descriptive statistics were computed, including means, standard deviations (SDs) and frequency distributions by using SPSS 10.1 statistical software. The total scores for three self-medication scenarios were summarized in each time point measured.

All Finnish community pharmacies received an information leaflet about the pseudo customer study by the Association of Finnish Pharmacies four weeks before the baseline assessment. Pharmacies could decline to participate by informing the Association of Finnish Pharmacies, and seven did so. Pharmacies were blinded for the scenarios, pseudo customers and time of visits. No reminders were sent during the project. Those community pharmacies that took part of the project, received the information on their scorings only after the TIPPA project had finished.

8 RESULTS

8.1 Validity and internal consistency of the USP Guidelines (I)

The study showed that the USP Medication Counselling Behaviour Guidelines are a flexible tool that can be used and modified in several ways without threatening its validity and reliability. Statistical analysis indicated good construct validity and internal consistency of the original Guidelines. Cronbach's alpha for the whole original scale was 0.91 and for the four original subscales Introduction 0.70, Content 0.86, Process 0.86, and Conclusion 0.80, respectively.

Further statistical analysis with the scale using factor analysis yielded three strong components explaining 57% of the variance that were interpreted as "Communication" (17 items), "Management of the Treatment" (12 items) and "Warnings and Precautions" (6 items) based on their content.

However, there were some negative high loadings on the components. Thus, it was decided to conduct one more principal component analysis using Oblimin rotation with Kaiser Normalization as a rotation method (Nunnally and Bernstein 1994). The four-component solution explained 76% of the variance, and did not have any strong negative loadings (Table 7). These four components were named as "Needs Assessment" (9 items), "Precautions and Warnings" (8 items), "Management of the Treatment" (13 items), and "Communication" (5 items). Based on these results, a new scale was constructed (Table 7).

This 4-component solution showed also high internal consistency with a Cronbach's alpha 0.85 for the whole scale, and 0.87, 0.88, 0.95, and 0.75 for the new subscales, respectively.

Table 7. The new scale based on the results of the four-component solution with rotation method of Oblimin with Kaiser Normalization.

Component	Loading
Component 1. Needs assessment (Cronbach's alpha 0.87)	
1. Obtains pertinent initial drug related information (e.g. allergies, other medications, age, etc)	1.010
2. Responds with understanding/empathic responses	.987
3. Reviews patient record prior to counselling	.908
4. Explains the purpose of the counselling session	.897
5. Presents facts and concepts in a logical order	.849
6. Uses appropriate counselling aids to support counselling	.837
7. Assesses any actual and/or potential concerns or problems of importance to the patient	.774
8. Determines if the patient has any other medical conditions which could influence the effects of this drug or influence the likelihood of an adverse reaction	.563
9. Conducts appropriate counselling introduction by identifying self and the patient or patient`s agent	.545
Component 2. Precautions and Warnings (Cronbach's alpha 0.88)	
10. Explores with the patient potential problems in taking the medication as prescribed (e.g. cost, access, etc.)	.886
11. Discusses potential (significant) side effects	.874
12. Warns patient about taking other medications, including OTCs, herbals/botanicals and alcohol, which could inhibit or interact with the prescribed medication	.825
13. Discusses significant drug-drug, drug-food, and drug-disease interactions	.817
14. Discusses precautions (activities to avoid, etc.)	.793
15. Explains in precise terms what to do if the patient misses a dose	.682
16. Discusses how to prevent or manage the side effects of the drug if they do occur	.577
17. Helps patient generate solutions to potential problems	.400
Component 3. Management of the Treatment (Cronbach's alpha 0.95)	
18. Discusses storage recommendations, ancillary instructions (e.g. shake well, refrigerate, etc.)	.953
19. Explains how long it will take for the drug to show an effect	.920
20. Tells patient when he/she is due back for a refill	.917
21. Summarizes by acknowledging and/or emphasizing key points of information	.888
22. Emphasizes the benefits of completing the medication as prescribed	.852
23. Helps patient to plan follow-up and next steps	.851
24. Provides an opportunity for final concerns or questions	.841
25. Verifies patient's understanding via feedback	.730
26. Maintains control and direction of the counselling session	.677
27. Assists the patient in developing a plan to incorporate the medication regimen into his/her daily routine	.653
28. Uses open-ended questions	.593
29. Explains the dosage regimen, including scheduling and duration of therapy when appropriate	.522
30. Probes for additional information	.428

Table 7. continued

Component 4. Communication (Cronbach's alpha 0.75)	
31. Uses language the patient is likely to understand	.868
32. Provides accurate information	.593
33. Discusses the name and indication of the medication	.553
34. Displays effective nonverbal behaviors:	
a. Appropriate eye contact	
b. Voice is audible; tone and pace are good	.506
c. Body language, postures and gestures support the spoken message	
d. Distance between the health care professional and patient is appropriate	
35. Assesses the patient`s understanding of the reason(s) for the therapy	.396

8.2 Perceived usefulness of the USP Guidelines among Finnish community pharmacists (II)

More than one quarter (27%) of the respondents was aware of the Guidelines. The Guidelines were made known to the respondents mostly by the patient counselling skills study book (41% of those knowing the Guidelines), continuing education (37%), and by in-house training (28 %). Over 60% (n=68) of those who knew the Guidelines regarded them as a good or very good instrument for learning the principles of patient counselling. The applicability of the Guidelines as an instrument for self-evaluation of performance in different settings was considered less useful, with approximately 50% regarding them as a good or very good instrument in this respect.

The themes emerging from the open-ended question *"How have you used the USP Guidelines?"* were related to customizing patient counselling and using the Guidelines in in-house training. Many examples reflected the fact that respondents used the Guidelines in processing patient counselling into different components (introduction, content, process and conclusion). They also utilised them in tutoring pharmacy students during their practical training period, indicating that they were an instrument for teaching the principles of patient counselling.

The themes emerging from the second open-ended question, *"How would you improve the applicability of the Guidelines in patient counselling in practice?"*, were related to the fact that they should be simplified and made shorter. Respondents thought

that the principles should be explained and practical examples should be given when training pharmacists to use the Guidelines. Suggestions for improving the applicability of the Guidelines in self-evaluation included giving practical examples and using exercises.

The themes emerging from the third open-ended question, "*Why are the Guidelines not applicable in practice?*", were related to the length and comprehensiveness of the Guidelines. The reasons why the Guidelines were not applicable included the following: the Guidelines are too theoretical, too complex and too detailed. Lack of time for counselling, the impracticality of the Guidelines, and the attitude of the employers in the pharmacy were also mentioned as barriers to the use of the Guidelines.

8.3 Patient counselling specific quality assurance instrument (III)

The brainstorming session by Panel 1 yielded 7 factors related to the quality of patient counselling. Panel 1 agreed to choose three of these as the main quality dimensions, and place the remaining factors under these dimensions. These dimensions were named on the basis of their content as follows: Customer, Personnel, and Technical Resources.

As the structure was similar to the Balanced Scorecard, Panel 2 decided to use that as a model for the instrument. The Balanced Scorecard is a quality management system that enables an organisation to clarify its vision and strategy and translate them into action (Kaplan and Norton 1996). The indicators of the original Balanced Scorecard view organizational performance from four perspectives: Financial, Customer, Internal Business Process, and Learning and Growth. However, its structure is flexible to permit local modifications, including the number of quality dimensions.

Vision and strategy of the pharmacy in patient counselling became the core element of the instrument developed (Figure 3). The financial dimension was left out of the instrument as it was considered to be measured by general quality assurance systems in pharmacies. Three patient counselling specific quality dimensions that need to be taken into account in strategic planning and systematic long-term development processes are as follows:

Customer: The Customer dimension consists of indicators that enable one to understand the customers' specific information and communication needs. These indicators include systematic assessment of customers' drug use patterns and disease profiles, and customer feedback using traditional customer satisfaction questionnaires or pseudo-customer studies.

Process: The goal of the Process dimension is to integrate patient counselling into the process of dispensing prescription and non-prescription medicines. Drug information sources, both electronic and manual, should be accessible during dispensing, and the personnel should be able to use them. The pharmacy premises should permit private patient consultations. In the pharmacy, pharmacists should establish guidelines concerning patient counselling practices. Such guidelines should also be arranged with other local heath care professionals.

Learning and innovations: The Learning and Innovations dimension relates to the competency of the pharmacy personnel: they should have adequate skills and knowledge to meet customers' needs. The principles of customer-oriented counselling should be known and internalized by the pharmacists. This can be supported by constructing systematic in-house and continuing education plans for individual pharmacists. Self-evaluation and peer-evaluation of performance can be used to evaluate patient counselling practices. In regular development discussions with the pharmacy personnel, particular attention can be paid to patient counselling skills and setting goals for personal development.

8.3.1 Delphi questionnaire round

The level of agreement of the individual indicators (n=28) varied from 69 % to 100% (III, Table 2). Eighteen of the 28 indicators (64%) reached a consensus rate higher than 90%. Only one indicator (concerning the use of peer audit as an instrument to assess performance) did not meet the criteria for approval reaching the agreement level of 69%. Only one questionnaire round was needed as the respondents had a high consensus

about the indicators and they did not recommend any additional items for the instrument.
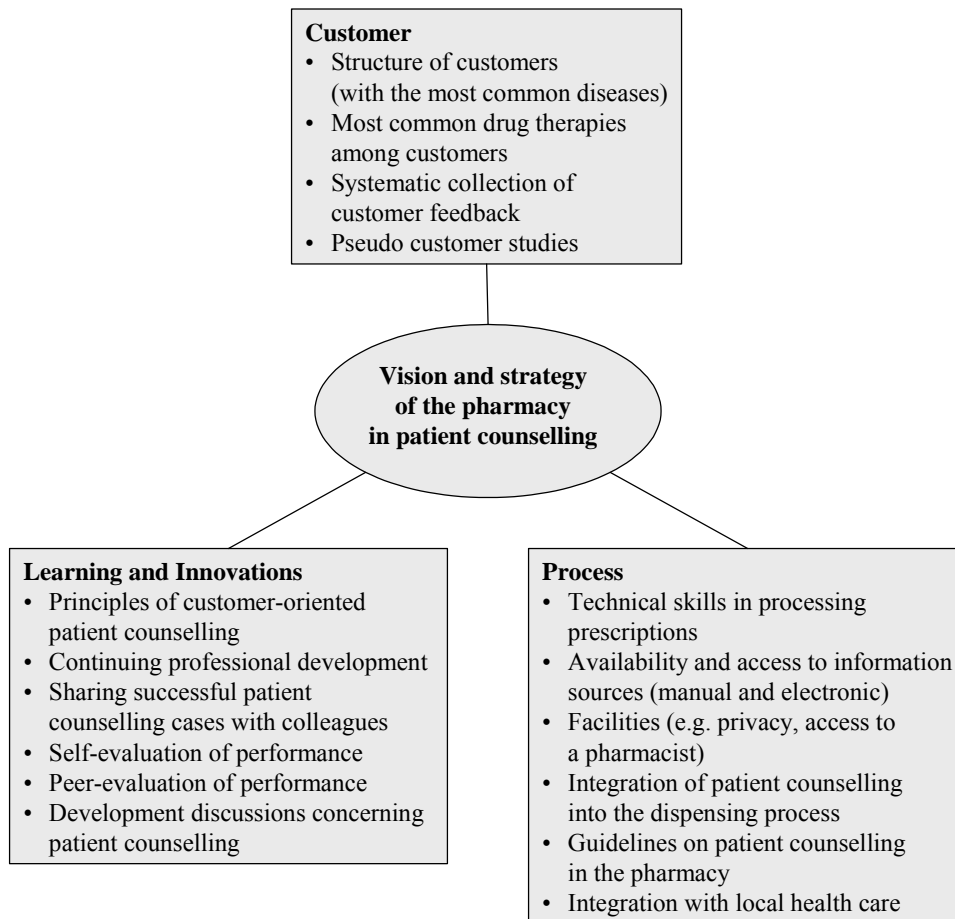
Figure 3. Quality dimensions with related indicators.

8.4 Progress in patient counselling practices during the TIPPA project (IV)

The results of the pseudo customer study showed that the amount and quality of counselling varied greatly between the different scenarios used. The proportion of pseudo customers receiving at least one piece of information included in the scoring criteria increased from 44% at the baseline in 2000 to 61% at the third follow-up in

2003. Two out of the four scenarios showed a statistically significant difference (p<0.05) between the baseline and the third follow-up. This concerned both total scores and scores for both subscales "Needs Assessment" and "Instructions to Use" in scenario 1 (IV, Figure 1). For scenario four concerning a prescription medicine, total scores, and the subscale "Instructions to Use" showed a statistically significant increase in scores for a new (p=0.004) and a repeat prescription (p=0.03) (IV, Figure 2).

The amount of information provided to the pseudo customers showed an increase, measured as scores obtained per visit. This was the case with three out of the four scenarios used. The only exception was the direct product request (Scenario 3) where the proportion of pseudo customers receiving information remained relatively stable during each time point measured. The proportion of pseudo customers receiving no information included in the scoring criteria decreased in two out of the four scenarios during the project (IV, Table 3).

Statistical analysis of the aggregated total scores of the three self medication scenarios between the baseline and the third measurement revealed no significant differences, p=0,439 (the baseline: mean 3.77, SD±2.36; the first follow up: mean 3.42, SD±2.61; the second follow up: mean 3.77, SD±2.52; and the third follow up: mean 3.82, SD ±3.03).

8.5 Summary of the results

In this study, patient counselling specific instruments were developed to assess counselling practices in community pharmacies. The instruments can be used in evaluating counselling practices at different levels. At the organisational level, the patient counselling specific quality assurance tool can be used in conducting a present state analysis of counselling performance and then constructing a long-term development plan. The quality assurance instrument can also be used in an external audit of counselling practices. The pseudo customer method can be applied at the organisational and national level to assess counselling performances. Individual pharmacists can use the USP Guidelines to assess their own performance. USP Guidelines are also suitable for peer-evaluation.
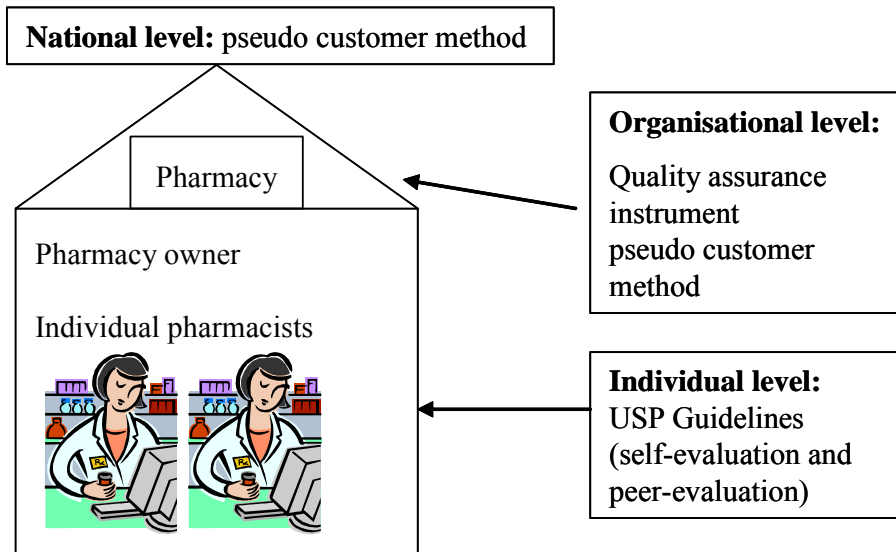
**Figure 4.** Developed instruments and their use at different levels.

9 DISCUSSION

9.1 Context of this study

The data for this study was mostly collected during 2000–2003 when the national patient counselling development project TIPPA was run. TIPPA was the leading professional project among the pharmacy profession in Finland since its beginning in 2000. It was also a quality improvement project targeted at community pharmacies. Research has revealed some preconditions for successful quality improvement projects such as senior management commitment, sufficient resources, careful programme management and practical and relevant training which personnel can use immediately (Øvretveit and Gustafson 2002). In the action plan for TIPPA, these aspects were taken into account by e.g., involving the pharmacy owners to the project, providing pharmacists with concrete tools and instrument to enhance counselling and by providing continuing education. The TIPPA project was a unique intervention that mobilised resources and multidisciplinary actions over a period of years to change counselling practice. Implementing change is usually not a single action but involves a well planned stepwise process, including a combination of interventions, linked to specific obstacles to change (Haines and Jones 1994, Armstrong et al. 1996, Grol 1997, Helin-Salmivaara et al. 2003).

In order to promote a change in counselling performance, community pharmacists needed a concept of what constitutes good counselling. The literature review revealed that there is a lack of instruments to assess and evaluate counselling practices. The USP Guidelines were considered to be applicable, even though their comprehensiveness and length were predicted to result in some resistance among the practitioners. In addition, they were developed in the United States, where the professional context and culture are different. However, the decision was based on the fact that the Guidelines provide a comprehensive framework to gain an understanding of customer-oriented counselling practices and two-way communication. Furthermore, they are applicable both to self-evaluation and to peer-evaluation.

During the project, the change process at the organisational level was facilitated by training external auditors of counselling practices. Their mission at the pharmacies was to help the pharmacy owner and pharmacists to conduct a present state analysis of counselling practices and then to construct a long-term development plan. For this purpose, a patient counselling specific instrument was developed by use of a modified Delphi method. This method was chosen as consensus methods are applicable when the aim is to develop guidelines or standards where research-based evidence is absent or inconclusive (Cantrill et al. 1996). The use of a modified Delphi method provided the possibility to use two expert panels and to combine the expertise of practising pharmacists with the expertise of pharmacists working in academic and professional organizations.

The evaluation of the actions taken in pharmacies, and the implementation of the instruments provided were an essential part of the programme. The information provided by the evaluation was crucial as subsequent activities taken during the project were based on this evaluation process: the project aimed at reflectivity and flexibility. In order to assess counselling practices and the changes that occurred in them, a pseudo customer method was developed. The scoring criteria were based on the USP Guidelines and emphasised the professional content of counselling. However, it is noteworthy that the use of different scoring criteria concerning e.g., technical aspects of medicines (such as the drug formula or price), would likely have lead to different results. Nevertheless, a similar method may be adopted in the future to develop different scoring systems. The decision was based on the notion that we wanted to gain information about professionally oriented counselling practices.

9.1.1. Activities after the TIPPA project

Professional community pharmacy services are undergoing further development as part of the new action plan following the TIPPA project. Key stakeholders in the field of pharmacy have found nationally co-ordinated, long-term activities necessary to promote health policy goals through professional community pharmacy services. It was agreed that there is a need to continue this co-operation in the form of national co-ordination of

activities with a special focus on integrating community pharmacists into local multidisciplinary teams. The goals of the TIPPA project and the new action plan are in line with the professional strategy for community pharmacies. The professional community pharmacy strategy is also supported by the National Pharmaceutical Drug Policy for 2010 established by the Ministry of Social Affairs and Health in 2003. According to this policy statement, good medical treatment requires that information about medicines and their appropriate use be given by pharmacy staff.

9.2 Key findings

9.2.1 Patient counselling specific instruments

The results of this study revealed that the quality of patient counselling is determined by several dimensions. Customers' needs, professional competence of the personnel and the dispensing process should be taken into account in the development process of counselling practices. Similar dimensions have been found also in previous studies assessing service quality in the context of health care (Hedvall and Paltschik 1991, Øvretveit 1992, Airaksinen 1996, Pritchard and Perri 1997). Our results also show the importance of management in improving quality. Although the quality of pharmacy services depends upon individual factors, such as having appropriate facilities and competent personnel, it is the organisation of these resources and supporting information systems that really enable effective quality management. In order to implement high quality patient counselling, current practices need to be evaluated from a wider perspective than the customer-pharmacist interaction.

The role of management in bringing about change is essential (Kansanaho et al. 2003, Roberts et al. 2003). The vision and strategy of the pharmacy in patient counselling formed the core of the developed instrument, indicating the important role of the pharmacy owner in the development process. The evaluation process in the pharmacy should be managed and lead by the pharmacy owner. The decision of which measures to use is strategic in nature: it is said that people do what is being measured. If the pharmacy owner is not involved with the development project, it is difficult to

implement new practices (Kansanaho et al. 2003, Varunki 2003). The organisational culture in the pharmacies should be studied in the development projects. However, there is limited published data in this area, with most studies that assess counselling practices focusing on the individual patient- or pharmacist-related factors (Laurier and Poston 1992, Willison and Muzzin 1995, Schommer and Wiederholt 1997, Aslanpour and Smith 1997, Blom et al. 1998, Pilnick 2003).

Evaluation of counselling performance in community pharmacies is not very common among community pharmacists in Finland. This was revealed by the fact that the USP Guidelines were not well known among community pharmacists two and one-half years after the project had started. However, those who knew about the Guidelines regarded them as useful in learning the principles of patient counselling in different settings. According to the respondents, the length and comprehensiveness of the Guidelines are the greatest barriers to applying them into practice. This may indicate that respondents viewed them as an obligatory checklist which has to be covered with every customer. It may also point out that learning to use a new tool to customize patient counselling in practice is difficult. It seems that practitioners lack reflective skills to evaluate their own behaviour and performance. Other studies conducted among Finnish pharmacy practitioners indicate the same (Kansanaho et al. 2003, Katajavuori 2005). This finding was supported by the fact that the survey respondents did not provide many examples of using them in self-evaluation and that they were considered less useful in self-evaluation than in learning the principles of patient counselling. Also, peer-evaluation of performance was the only item in the Delphi questionnaire that did not meet the predefined level of acceptance. However, in order to become an expert, reflective skills and the ability to evaluate one's own performance are essential (Katajavuori 2005). Critical thinking skills are also needed to understand the larger systems embedded in the counselling Guidelines. Pharmacists can e.g., use specific open-ended questions to define patient's information needs or communication style. Pharmacists can also use the concepts of health counselling to define their own counselling role (Kansanaho et al. 2005).

There is a need to find a new approach in teaching the pharmacy students and working life pharmacists the principles of self- and peer-evaluation. Our study results

indicated that pharmacists who had graduated earlier and had more working experience knew the guidelines better. This may indicate that pharmacists who have more working experience have a better understanding of the evaluation and the reasons for it.

The response rate to the questionnaire assessing the use of USP Guidelines was moderate. This low response rate may be due to a fact that the survey was conducted during the summer time and that it was part of a larger study assessing the implementation of the whole project. According to the literature, response rates have varied among health care professionals (e.g. doctors, nurses and pharmacists) from 24% to 85% (Smith 2002). However, non-response bias must be taken into account when interpreting the results. Comparison of the respondent's characteristics to the target population on the basis of mean age, academic degree and geographic location of the pharmacy indicated that the study population was representative of the target population. In order to gain a deeper understanding of the ways practitioners use the Guidelines, focus group discussions or other qualitative methods can be used.

The Guidelines should be developed further to make them more applicable in practice e.g., by providing shorter modifications. Also, the wordings of the items should be changed to better meet the needs of concordance based practices. In the existing version of the Guidelines, some of the wording indicate a paternalistic approach to counselling. As pharmacists use the Guidelines as the basis for good counselling, the Guidelines should reflect the current philosophy of appropriate customer-pharmacist interaction(s). The Guidelines have also been integrated into the IPSF (International Pharmaceutical Students' Federation) communication skills booklet (International Pharmaceutical Students' Federation 2005).

A pseudo customer method was used as a tool to assess progress in the professional content of counselling practice. The pseudo customer method has been used extensively in the field of pharmacy practice to assess counselling performance (Willison and Muzzin 1995, Watson et al. 2001). The current use of the method is focused on promoting a change in behaviour patterns based on the provision of immediate feedback after the pseudo customer visit (De Almeida Neto et al. 2001, Berger et al. 2005).

The instruments developed in this study can be used as a tool to improve the quality of counselling performance. Community pharmacists are aware of the principles of

quality assurance e.g., through compounding, but it seems to be difficult to extend these principles into professional community pharmacy services such as patient counselling. However, some community pharmacies in Finland have extensive quality assurance systems and some of the pharmacies are certified based on ISO 9001:2000 standard (Association of Finnish Pharmacies 2004). According to a recent study, 64% of the pharmacies did systematic quality work (Kivijärvi 2004). Thus, there is a need to integrate patient counselling specific instruments into these existing quality assurance systems in community pharmacies.

9.2.2 Validity of the instruments

Most of the instruments in the literature have been developed by academics, which may bias instrument development towards research goals which might not directly align with actual practice. In this study, we wanted to use the expertise of practicing pharmacists in the development process to ensure the practicality of the resulting instruments.

The validity of the USP Guidelines was assessed by conducting factor analysis. The factor analysis was first conducted with varimax as a rotation method. However, there were some negative loadings with the three component solution that may be due to high correlations between the items of the original scale. Negative loadings can be used in analyses just like any other variable, although they will be strongly collinear with the measures used to generate them (Nunnally and Bernstein, 1994). This problem was solved by using the oblique analytical method of rotation called Oblimin with Kaiser Normalization. Oblique analytical methods show a greater variety of methods than do orthogonal rotation methods (Nunnally and Bernstein, 1994). Methodologically this solution was the most preferable because the aim was to find a theoretically stable solution (Nunnally and Bernstein, 1994).

Factor analysis and internal consistency assessment indicated that the USP Guidelines are a valid and reliable instrument. One reason for this may be that the USP Guidelines were based on a synthesis of several measures developed independently by different

institutions and experts. As part of the development process, each measure may have been previously subjected to validity and reliability assessments.

Assessing inter-rater reliability is also an important part of the validation process. In this study, inter-rater reliability analysis was also conducted by calculating kappa values. However, the use of kappa proved to be problematic. Because we had multiple raters and the rating scale ranged from 0-10. In these conditions, kappa as an indicator of inter-rater reliability can be misleading (DeVellis 1991, Rae 1998). Originally, the use of kappa was restricted to situations where the number of raters was two and the scale was more limited (DeVellis 1991). In this study, the material used was based on pharmacy students' excellent counselling performances. This may have limited the variability on the variable of interest leaving little room for rater disagreement. In practice, greater variability in performance is likely to occur.

The quality assurance instrument was developed by using a modified Delphi method: both expert panels worked as a group to develop the instrument, and the Delphi questionnaire was sent to experts after the instrument was constructed. Thus, the requirement of anonymity between the members of the panels was not fully accomplished, although the responses to the Delphi questionnaire were anonymous. In any case, anonymity may reduce the sense of personal responsibility for the end product, making participants unaccountable, and deprive them of the potential benefits of direct group discussion (Stewart et al. 1999). One strategy to maximise validity of the results is to use panels whose members are both experts and have the power to implement the decisions if they choose (Cantrill et al. 1996). In Panel 2, some of the participants were representatives of the professional pharmacy organisations and therefore, had the power to implement and promote the use of the instrument. Also, only one round with the consensus questionnaire was required, as it yielded a high consensus, and the participants did not suggest any additional items for the instrument. However, the method is flexible, and several modifications have been applied in previous studies (Duffield 1993, Stewart et al. 1999, Campbell et al. 2000).

In our quality assurance instrument, all the indicators that were accepted had been piloted in practice in community pharmacies. The content validity of the instrument proved to be good, as a high consensus on the content of the instrument was achieved,

and no new dimensions were proposed. The only item that did not meet the predefined criteria concerned peer-evaluation. This may partly be explained on the fact that Finnish pharmacists are not familiar with peer-evaluation as a method of assessing professional performance. However, since peer-evaluation has proved to be an essential part of learning and personal development, it was included in the final instrument despite the low agreement rate.

The use of the modified Delphi method proved to be applicable in the development process. We were able to develop a practically oriented instrument that yielded high agreement rate among the experts including pharmacy owners and professional organisation representatives. This is an important aspect as the pharmacy owners are in a key position in the implementation of the instrument. The use of the traditional Delphi method may have yielded different results if only the practicing pharmacists attended the Delphi questionnaire round after the construction of the instrument by the academics.

The pseudo customer visits were conducted by a research institute that was also responsible for assuring the reliability of the method. During the baseline, structured data forms were used to assess the intervention. During the three follow-ups, the interactions were also audio-taped. Interactions which were audio-taped were transcribed verbatim and analysed. Audio-taping was done to increase the reliability of the method. However, as the research company was responsible for quality assurance, we do not have exact information about the assessments. In addition, we do not have access to the tapes. The pseudo customers were trained according the instructions from the TIPPA executive board and the board also developed the scenarios used. Furthermore the scenarios were further reviewed by the Department of Pharmacology, University of Helsinki to ensure their validity.

In our study, the scoring criteria used in the pseudo customer studies were based on USP Guidelines and the same criterion was used for both new and repeat prescriptions. Reliability assessments of the scoring criteria were not conducted beforehand. A variety of scenarios were used, however, it was not possible to cover every therapeutic area or scenario. Also more scenarios would have been needed to reflect the whole range of drug therapies and pharmacist-customer consultations relevant to them.

9.2.3 Counselling practices in community pharmacies during the TIPPA project

Results from the pseudo customer studies during the TIPPA project indicated that counselling practices lack a systematic quality approach; counselling received by pseudo customers varied a lot depending on the particular scenario used.

The prescription scenario was divided into two approaches with new and repeat prescription to assess whether any variations occur with these two. Pseudo customers presenting a new prescription received some counselling whereas pseudo customers with repeat prescriptions received practically no counselling. It appears that pharmacists use a prescription's status as a cue to define customer's counselling needs. This may reflect the fact that pharmacy practitioners do not have a clear understanding of their role in supporting patients on long-term therapies and in taking shared responsibility for reaching therapeutic outcomes. Pharmacists seem to think that customers on long-term medications know how to use their medicines appropriately and they do not need or want any information. However, there is evidence that patients with chronic diseases need on-going information and support with their drug therapies (Närhi 2002, Jokisalo et al. 2002). Furthermore, according to a recent report, only approximately 50% of people with chronic conditions in developed countries use their medicines as directed (World Health Organisation 2003).

Pseudo customers with direct product requests that contain potential iatrogenetic interaction received very little counselling. This seems to reflect the fact that pharmacists make an assumption about the customers' information needs based on one's medication (Vainio 2004). Thus, pharmacists generally do not assess patients' needs by asking questions. It appears that the principles of customer-oriented counselling are not yet internalized among practitioners. In continuing education courses, working-life pharmacists often report that customers asking for products by brand name are difficult to handle. These assumptions can be seen in the behaviour patterns of pharmacists. It seems that community pharmacists are selling medicines instead of treatments. Also, the nature of a direct product request should be taken into account: a symptom-based scenario initiates more discussion as the customer needs to describe the symptoms instead of just asking for a product (Berger et al. 2005).

The results of pseudo customer studies indicate there is a need for additional improvement in existing counselling practices. However, the proportion of pseudo customers receiving at least one piece of information increased from 44% at the baseline to 61% at the third follow-up. This is a significant change, as previous research has shown that the proportion of customers receiving information has remained almost stable (approximately 40%) in the 1990s (Airaksinen et al. 1994, Vainio 2004). Even though TIPPA was the leading development project taking place in pharmacies at that time, we do not know if the changes that occurred were due to TIPPA or to some other reason. The formal evaluation of the TIPPA project two and half years after the project started determined that pharmacists were very aware of the project and used the information tools provided (Varunki 2003, Kansanaho et al. 2005). However, this kind of evaluation was not conducted in the pharmacies taking part in the pseudo customer studies. We know that some individual pharmacies yielded high ratings during the pseudo customer studies, but we lack information on the factors that have an impact on their performance. These factors may be related e.g., to participation in other quality assurance projects, motivation of the pharmacists, commitment of pharmacy owner to and intensive continuing education among the pharmacists. These aspects could be investigated e.g., by using pseudo customer visits with immediate feedback.

Further assessment of the pseudo-customer study results revealed some statistically significant differences between study pharmacies and pharmacists (Lahdelma 2005). Regardless of the scenario used, most counselling was given in Pirkanmaa area. In scenario four (a new prescription), pharmacies with separate booths yielded higher ratings than pharmacies with traditional facilities (counter). This may indicate that with a modern lay-out that provides more privacy for prescription consultation produces a better opportunity for counselling. However, there were no differences with the repeat prescription scenario. Furthermore, smaller pharmacies (annual prescription volume below 50 000) received higher ratings than bigger pharmacies in scenario three. Younger pharmacists (less than 40 years) gave more counselling than older pharmacists in scenario two. This may indicate that younger pharmacists are more able to discuss gynaecological issues with customers (Lahdelma 2005). However, as these results vary

according to the scenarios used, more research is needed on the facilitators of counselling practices and actions taken in these individual pharmacies.

Changing existing practices is a long-term project and even four years may not be long enough. Community pharmacies need to be further supported in their counselling development process by e.g., promoting the use of patient counselling specific instruments and organising long-term continuing education concerning patient counselling. Pharmacists should be encouraged to construct long-term development plans to implement good quality patient counselling practice(s). Furthermore community pharmacies should be encouraged to continue the quality assurance work concerning their professional services. These aspects need to be taken account also in basic education. In order to make the improvements arising from the TIPPA project durable over time, the profession needs to commit to further development work. The new action plans provides a good platform to develop new services and improve the professional value of pharmacists in health care.

9.3. Ethical considerations

Co-operation of study participants, and obtaining data that accurately reflect activities and behaviours of individuals under observation are essential for the success of any study (Smith 2002). Also, the high quality of the study, correct interpretation and reliability of results are considered important ethical principles of scientific research (Smith 2002). Study results should be expressed so that individual study participants can not be identified.

In the survey, the participants had a possibility of not responding. The data have been used so that individual pharmacists can not be identified. Citations are used with consideration to avoid the identification of individual pharmacists. With the Delphi questionnaire the participants had also a possibility not to respond.

Before the pseudo customer study was started, all the Finnish community pharmacies were informed by the Association of Finnish Pharmacies through a written information leaflet. Pharmacies were allowed to deny their participation in the study by informing the Association of Finnish Pharmacies, with seven pharmacies refusing. Participating

pharmacies were blinded for the scenarios, pseudo customers and time of visits. During the project, no reminders were sent. All of the participating pharmacies were given a written summary of their performances after the final follow-up was conducted.

The material for the validation study was provided by the national Patient Counselling Event in the United States. The students' performances were videotaped and the vignettes were used for the study. The students' consent was obtained for this purpose.

9.4 Further research

More discussion and research are needed to discover the optimum way of influencing patient counselling practices in pharmacies. More research is also needed on the facilitators of counselling practices and actions taken in these individual pharmacies.

The patient counselling specific quality assurance instrument was sent to all community pharmacies in the form of a 100-page manual. Further research is needed to evaluate the use of the quality assurance instrument in practice. Also, further research is required to identify the implications of using the instruments for quality of care.

Audio-taped scripts of the pseudo customer visits would give a better understanding of the problems in current counselling patterns and the therapeutic information discussed. According to our experiences, the data in future studies should be audio-taped to conduct a more detailed analysis. Also, the pseudo customer method needs to be developed further, e.g., to find out the most reliable way of quantitatively scoring the interaction. Sensitivity of the measure (i.e., at what point does the measurement indicates a change) is crucial for the reliability of the results and therefore, research should be conducted to assess this. Also, validity testing of the method should be conducted e.g., by comparing the audio-taped scripts with structured data collection forms.

10 CONCLUSIONS

Based on the results of this study, the following conclusions can be drawn:

1. Patient counselling instruments developed in this study can be used at different levels in the evaluation process: at the organisational and at the individual level.

2. The quality of patient counselling consists of several dimensions: understanding the needs of the customers, personnel training and integrating patient counselling into the routine dispensing process.

3. In order to implement good quality counselling practices, current practices should be evaluated in a wider perspective than the customer-pharmacist interaction.

4. The modified Delphi method proved to be applicable in developing a patient counselling specific quality assurance instrument.

5. The USP Medication Counselling Behaviour Guidelines proved to be a valid and reliable instrument for evaluating patient counselling practices.

6. The applicability of the Guidelines was considered less useful for self-evaluation than for learning the principles of customer-oriented patient counselling.

7. The developed pseudo customer method proved to be applicable to making a national assessment of the professional content of counselling practices.

8. The results of the pseudo customer studies indicate that there is still a need to improve existing counselling practices.

9. Based on the methodology employed, validity testing of the USP Guidelines was scientifically rigorous. The evidence of their applicability in practices may be more limited due to a moderate response rate and the survey method. Even though the modified Delphi method was applicable in developing the patient counselling specific instrument, this research method is yet to be validated. The scoring criteria developed for the pseudo customer studies were not validated beforehand.

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APPENDICES

Appendix 1. USP Medication Counselling Behaviour Guidelines

CATEGORY 1: COUNSELLING INTRODUCTION ITEMS
CHECKLIST   **RATING**

Y	N	N/A		N/A	Not Done		Poor		Unsatisfactory		Satisfactory		Excellent	
			1. Conducts appropriate counselling introduction by identifying self and the patient or patient's agent.	0	1	2	3	4	5	6	7	8	9	10
			2. Explains the purpose of the counseling session.	0	1	2	3	4	5	6	7	8	9	10
			3. Reviews patient record prior to counseling.	0	1	2	3	4	5	6	7	8	9	10
			4. Obtains pertinent initial drug related information (e.g., allergies, other medications, age, etc.).	0	1	2	3	4	5	6	7	8	9	10
			5. Warns patient about taking other medications, including OTCs, herbals/botanicals, and alcohol, which could inhibit or interact with the prescribed medication.	0	1	2	3	4	5	6	7	8	9	10
			6. Determines if the patient has any other medical conditions which could influence the effects of this drug or influence the likelihood of an adverse reaction.	0	1	2	3	4	5	6	7	8	9	10
			7. Assesses the patient's understanding of the reason(s) for the therapy.	0	1	2	3	4	5	6	7	8	9	10
			8. Assesses any actual and/or potential concerns or problems of importance to the patient.	0	1	2	3	4	5	6	7	8	9	10

CATEGORY 2: COUNSELING CONTENT ITEMS

CHECKLIST						RATING									
Y	N	N/A		N/A	Not Done	Poor	Unsatisfactory			Satisfactory		Excellent			
			9. Discusses the name and indication of the medication.		0	1	2	3	4	5	6	7	8	9	10
			10. Explains the dosage regimen, including scheduling and duration of therapy when appropriate.		0	1	2	3	4	5	6	7	8	9	10
			11. Assists the patient in developing a plan to incorporate the medication regimen into his/her daily routine.		0	1	2	3	4	5	6	7	8	9	10
			12. Explains how long it will take for the drug to show an effect.		0	1	2	3	4	5	6	7	8	9	10
			13. Discusses storage recommendations, ancillary instructions (e.g., shake well, refrigerate, etc.).		0	1	2	3	4	5	6	7	8	9	10
			14. Tells patient when he/she is due back for a re-fill.		0	1	2	3	4	5	6	7	8	9	10
			15. Emphasizes the benefits of completing the medication as prescribed.		0	1	2	3	4	5	6	7	8	9	10
			16. Discusses potential (significant) side effects.		0	1	2	3	4	5	6	7	8	9	10
			17. Discusses how to prevent or manage the side effects of the drug if they do occur.		0	1	2	3	4	5	6	7	8	9	10
			18. Discusses precautions (activities to avoid, etc.).		0	1	2	3	4	5	6	7	8	9	10
			19. Discusses significant drug-drug, drug-food, and drug-disease interactions.		0	1	2	3	4	5	6	7	8	9	10
			20. Explains in precise terms what to do if the patient misses a dose.		0	1	2	3	4	5	6	7	8	9	10
			21. Explores with the patient potential problems in taking the medication as prescribed (e.g. cost, access, etc.).		0	1	2	3	4	5	6	7	8	9	10
			22. Helps patient generate solutions to potential problems.		0	1	2	3	4	5	6	7	8	9	10
			23. Provides accurate information.		0	1	2	3	4	5	6	7	8	9	10

CATEGORY 3: COUNSELING PROCESS ITEMS

CHECKLIST   **RATING**

Y	N	N/A		N/A	Not Done		Poor	Unsatisfactory			Satisfactory		Excellent		
			24. Uses language the patient is likely to understand.		0	1	2	3	4	5	6	7	8	9	10
			25. Uses appropriate counselling aids to support counselling.		0	1	2	3	4	5	6	7	8	9	10
			26. Responds with understanding/empathic responses.		0	1	2	3	4	5	6	7	8	9	10
			27. Presents facts and concepts in a logical order.		0	1	2	3	4	5	6	7	8	9	10
			28. Maintains control and direction of the counselling session.		0	1	2	3	4	5	6	7	8	9	10
			29. Probes for additional information.		0	1	2	3	4	5	6	7	8	9	10
			30. Uses open-ended questions.		0	1	2	3	4	5	6	7	8	9	10
			31. Displays effective nonverbal behaviours:		0	1	2	3	4	5	6	7	8	9	10
			a. Appropriate eye contact.		0	1	2	3	4	5	6	7	8	9	10
			b. Voice is audible; tone and pace are good.		0	1	2	3	4	5	6	7	8	9	10
			c. Body language, postures, and gestures support the spoken message.		0	1	2	3	4	5	6	7	8	9	10
			d. Distance between the health care professional and patient is appropriate.		0	1	2	3	4	5	6	7	8	9	10

CATEGORY 4: COUNSELING CONCLUSION ITEMS

CHECKLIST   **RATING**

Y	N	N/A		N/A	Not Done		Poor	Unsatisfactory			Satisfactory		Excellent		
			32. Verifies patient's understanding, via feedback.		0	1	2	3	4	5	6	7	8	9	10
			33. Summarizes by acknowledging and/or emphasizing key points of information.		0	1	2	3	4	5	6	7	8	9	10
			34. Provides an opportunity for final concerns or questions.		0	1	2	3	4	5	6	7	8	9	10
			35. Helps patient to plan follow-up and next steps.		0	1	2	3	4	5	6	7	8	9	10

Appendix 2. Description of the scenarios and scoring criteria for pseudo customer studies

SCENARIO	SCORING CRITERIA	SCORE
		Score range
1. Self medication (a product request)	**Needs assessment**	**0 – 5**
A customer enters the pharmacy and asks for a	Is the medicine for an adult or a child	1
nasal spray. The medicine is intended for an adult	Are the symptoms due to allergy or flu	1
suffering from a runny nose and a mild flu. The	**Instructions to use**	
symptoms make it difficult for the customer to	How to administer the spray into the	
sleep at night. The customer does not have any	nose	1
allergies and has used nasal sprays occasionally.	Harmful effects of long-term use	1
	Consequences of long-term use	1
		Score range
2. Self medication (a symptom-based request)	**Needs assessment**	**0 – 6**
A young (under 25 years) female customer enters	What are the symptoms	1
the pharmacy. She asks medicine for symptoms	If she had experienced the symptoms	
that are related to vaginal fungal infection. She	before, were they similar	1
has not had any infection before and she has not	**Instructions to use**	
used any fungal medications. The symptoms	Administration of the pessary	1
(rush, leucorrhoea) had started a couple of days	Should be taken as a course	1
ago. She has just finished taking antibiotics (can't	Should be taken at bed time	1
remember the name of the tablets, 10 days course,	If the medicine has not had an effect in	
1 tablet per day). She does not take contraceptives	four days, must visit a doctor	1
and she has visited a gynaecologist 2 or 3 years		
ago.		
		Score range
3. Self medication (a direct product request)	**Needs assessment**	**0 – 8**
A customer (a young man) enters the pharmacy	Are both of the medicines for the	
and asks for analgesics by a brand name	customer himself	1
(ketoprofen) and a brand of H2 receptor	The reason he is taking these medicines	1
antagonist (ranitidin). The customer has suffered	How long has he been using analgesics	1
from headache for a long time, for which he has	How long has he been using ranitidine	1
used ketoprofen, sometimes also ibuprofen or	**Instructions to use**	
aspirin. He has had a prescription for ibuprofen	Customer is being told about ranitidine	
600mg which was given to him due to work place	products: 1-2 tablet per day	1
ergonomics. The doctor had also mentioned a	Should be taken as a one week's course	1
possibility of physical treatments, if the symptoms	If symptoms do not disappear, must	
would not disappear by adding exercise and	visit a doctor	1
changing work place ergonomics. The customer	Analgesics may have caused the	
has not had time to see a physician since; instead	stomach ache	1
he has bought analgesics without prescription. He		
consumes 2-3 tablets almost daily. He has been		
taking analgesics for almost six months. Lately he		
has been suffering from stomach ache and		
heartburn (customer implies it is due to stress and		
too much coffee). His colleague has recommended		
this H2 inhibitor and he has decided to try it. The		
customer has not considered seeing a doctor for		
his stomach ache.		

4. Prescription medicine	Needs assessment	Score range 0 – 7
A woman (born in 1964) enters the pharmacy with a Ventoline® (salbutamol) inhaler prescription. The customer has had a cough for a month due to flu. At home, her family complaints about her coughing at night time. She has used some cough medicine that she had at home but it didn't seem to help. Her colleagues made her to see a physician and the doctor prescribed Ventoline® inhaler, which expands the airways and is usually used for the treatment of asthma. The doctor tells her to take the medicine regularly for a week and after that only for acute symptoms. She can also use the cough medicine she has at home, if necessary.	Has she used the medicine before	1
	What did the doctor tell her about her medication	1
	Is the drug intended for the treatment of asthma	1
	Instructions to use	
	Technical instructions to use the inhalator	1
	Information about how the drug works	1
	Possible adverse effects were discussed	1
	Dosage information was given	1

Appendix 3. USP questionnaire

USP (United States Pharmacopeia) has developed Medication Counselling Behaviour Guidelines. The USP Guidelines consist of 35 items that highlight the basic components of a medication counselling session: 1) Introduction; 2) Content; 3) Process Followed; and 4) Conclusion. The aim of the Guidelines is to promote two-way communication and customer-oriented patient counselling and they can be used in evaluating patient counselling practices.

1. How well do you know the Guidelines?
    1. Very well
    2. Quite well
    3. To some extend
    4. Poorly
    5. Not at all

2. How did you get to know the Guidelines?
    1. Through basic education
    2. Through continuing education
    3. Through in-house-training
    4. Through patient counselling and communication skill book
    5. Through something else, describe _____

3. Are the USP Guidelines applicable in patient counselling?
    1. Very applicable → answer the question a)
    2. Quite applicable → answer the question a)
    3. Quite poorly applicable → answer the question b)
    4. Very poorly applicable → answer the question b)
    5. Not at all → answer the question b)

    a) How have you used to Guidelines in practice?
    b) Why are the Guidelines not applicable in practice? _____

4. How useful are the Guidelines in learning the principles of patient counselling and self-evaluation in different settings?
Response options:
1=Very useful, 2=Quite useful, 3= No opinion, 4=Not useful, 5=Not at all useful

	Principles of patient counselling	Principles of self-evaluation
In basic education	1 2 3 4 5	1 2 3 4 5
In continuing education	1 2 3 4 5	1 2 3 4 5
In self learning	1 2 3 4 5	1 2 3 4 5

5. How would you improve the applicability of the Guidelines in patient counselling in practice?
_____

6. How would you improve the applicability of the Guidelines in self evaluation?
_____

DEMOGRAPHIC DATA

A. Age
   1. < 30 years
   2. 30-39 years
   3. 40-49 years
   4. 50 years and over

B. Education
   1. B.Sc.Pharm.
   2. M.Sc.Pharm.
   3. Other? _____
   4. Graduation year _____

D. Working years in the community pharmacy _____

F. Annual prescription volume in your pharmacy in 2000
   1. < 30 000
   2. 30 000–60 000
   3. 60 001–100 000
   4. over 100 000

G. Location of your pharmacy
   1. Metropolitan area (Helsinki, Espoo, Vantaa, Kauniainen)
   2. Other southern part of Finland
   3. Eastern Finland
   4. Northern Finland (Lapland)
   5. Western Finland
   6. Central Finland

Appendix 4. Delphi questionnaire

The response option are given below, please choose a proper one according to your opinion
5=totally agree 4=agree 3=I don't know 2=disagree 1=totally disagree

1. The three dimensions (customer, learning and innovations, process) describe well the quality factors of patient counselling

2. In order to assess the needs and expectations of the customers, the following measures can be used
   a) assessing the structure of customers
   b) assessing the most common drug therapies used among the customers
   c) systematic collection of customer feedback
   d) using pseudo customers

3. In order to assess the competence of the personnel, the following measures can be used
   a) knowing the principles of customer oriented patient
   b) constructing continuing development plan for the whole pharmacy
   c) constructing continuing development plan for individual pharmacists
   d) sharing patient counselling cased with colleagues
   e) self evaluation of performance
   f) peer evaluation of performance
   g) development discussions concerning patient counselling

4. In order to the foster the technical process following measures can be used
   a) ensuring technical skills in processing prescriptions
   b) availability and access to drug information
   c) integration of patient counselling into the dispensing process
   d) Guidelines on the content of patient counselling within the pharmacy
   e) Integration with local health care

5. In my opinion, the core idea of patient counselling development plan is the vision of the pharmacy in patient

6. In my opinion, the principles of constructing a long-term development plan can be applied in my pharmacy

7. In my opinion the quality manual can be used as a tool to develop the quality of patient counselling in community pharmacies

Please provide feedback about the structure of the manual/measures included
_____

Background information:
1) TIPPA-tutor
2) member of the TIPPA executive committee
3) member of the TIPPA executive board
4) the employer of the TIPPA tutor´s

LIST OF ORIGINAL PUBLICATIONS

I   Puumalainen I, Halonen P, Enlund H, Johnson K, Airaksinen M. Validation of the United States Pharmacopeia (USP) Medication Counselling Behaviour Guidelines. Pharm Educ 5:87-96, 2005

II   Puumalainen I, Kansanaho H, Varunki M, Ahonen R, Airaksinen M. Usefulness of the USP Medication Counselling Behavior Guidelines. Pharm World Sci, in press

III Puumalainen I, Kause J, Airaksinen M. Quality assurance instrument focusing on patient counselling. Ann Pharmacother 39:1220-1226, 2005

IV   Puumalainen I, Peura S, Kansanaho H, Benrimoj SI, Airaksinen M. Progress in patient counselling practices in Finnish community pharmacies. Int J Pharm Pract 13:149-156, 2005