

# DOSIS

*Farmaseuttinen aikakauskirja*

Vol. 32 | 2/2015

## SISÄLTÖ

### Table of Contents

**Theme: Integrating Research, Practice Development and Training in Pharmacy**

#### EDITORIAL

Kirsi Kvarnström: New medicines offer opportunities to improve care when adherence to treatment can be improved ..... 3

#### ARTICLES

**Anna-Riia Holmström, Erno Haavisto, Marina Kinnunen, Timo Keistinen, Tarja Pajunen**  
The Finnish Society for Patient Safety – Actions to promote patient and medication safety ..... 6

**Juha Puustinen, Janne Nurminen**  
Long-term benzodiazepine use and the aged – Time to change clinical practice ..... 14

**Katja-Emilia Lillsunde, Marika Pohjanoksa-Mäntylä, Marja Airaksinen, Outi Salminen**  
Faculty staff perspective on interprofessional education in the pharmacy curriculum: drivers, barriers and development needs ..... 20

**Pedro Inácio, Afonco Cavaco**  
Massive Open Online Courses (MOOC): A Tool to Complement Pharmacy Education? ..... 28

**Siva Prasada Reddy Maddirala Venkata, Peter Kielgast**  
The Danish Pharmacy Act 2015: Amendments concerning community pharmacies ..... 37

**Terhi Kurko**  
Use of Nicotine Replacement Therapy in Finland since the Sales Deregulation in 2006 ..... 42

**Anna Westerling, Alan Lyles, Jaana Hynninen, Veikko Haikala, Marja Airaksinen**  
A community pharmacy IT paradox: community pharmacists' self-perception of innovativeness not matched by actual innovations ..... 55

# DOSIS

*Farmaseuttinen aikakauskirja*

*Vol. 32 | 2/2015*

## **Julkaisija**

Suomen Farmasialiitto ry / viestintä  
Mäkelänkatu 2 A 3. krs, 00500 Helsinki  
dosis@farmasialiitto.fi

## **Päätoimittaja**

Prof. Marja Airaksinen  
dosis@farmasialiitto.fi  
marjaairaksinen@gmail.com  
Helsingin yliopisto  
Farmasian tiedekunta  
PL 56, 00014 Helsingin yliopisto

## **Toimituskunta**

Prof. Marja Airaksinen  
Dos. Markus Forsberg  
Dos. Nina Katajavuori  
FaT Joni Palmgrén  
FaT Inka Puumalainen  
Dos. Anneli Ritala-Nurmi  
FaT Pekka Suhonen

## **Toimitus ja ulkoasu**

MCI Press Oy  
Mikonkatu 8 A 8  
00100 Helsinki  
puh. (09) 2525 0250  
info@mcipress.fi  
www.mcipress.fi

## **Ilmoitusmarkkinointi**

Mika Leppinen  
Puh. 050 373 5716  
mika.leppinen@farmasialiitto.fi

ISSN 0783-4233

# **New medical treatments opportunities** to improve care when adherence to treatment can be improved

---

**R**emarkable advances have been achieved in medical treatments, including pharmacotherapy during recent decades. New medicines can be used to treat or cure illnesses, which were previously incurable. For example, rheumatoid arthritis and cancer are now more treatable and it gives hope to the patients.

Patient adherence to treatment is an important part of the success of such pharmacotherapy. The development of new medicines is helping patients to cope better with their illnesses, but good medication adherence is a prerequisite for optimum clinical outcomes. Studies show that measures which increase adherence to treatment of chronic diseases achieve savings in the health care costs and increase the realisation of the objectives directed to health outcomes (Haynes et al. 2002, World Health Organization 2003, Jokisalo 2006).

There is a need for more multiprofessional cooperation to optimize medicine use and adherence in health care. However, the focus of the interventions aimed at improving adherence should be based on individual patients needs. To reach this the health care system and the health care professionals must develop methods to estimate adherence to treatment and the factors, which affect it.

The World Health Organization, WHO (2003)

has defined the adherence to long-term therapy as follows: “the extent to which a person’s behaviour – taking medication, following a diet, and/or executing lifestyle changes, corresponds with agreed recommendations from a health care provider.” This definition of adherence represents the patient’s consciousness of one’s own treatment choices making the patient an active participant. Conscious treatment choices, e.g., how and when to take the medicine, are made in cooperation with the health care professionals. This strengthens adherence to the long-term therapies, which is emphasized by health care providers in the success of the treatment. However, the patient does not always tell the physician or another health care professional about poor adherence in which case the health care providers do not easily recognize problems in treatment.

The concordance on the treatment is a patient centred approach in which the patient and the health care professional are equal partners and the patient is seen as the expert of his own everyday life (Bell et al. 2007, Routasalo et al. 2009). Alternatives of the treatment are discussed with the patient and it is also possible for the patient to refuse treatment. If a patient refuses medical treatment, an attempt should be made to clarify the reason for the refusal. The objective of the agreeing on the treatment is a reasonable decision on a patient’s

own care, which is based on the patient's knowledge, i.e., informed consent, not the authoritarian determining.

The different interventions to improve adherence have been studied but it seems that there are no effective single methods for improving adherence (World Health Organization 2003; Haynes et al. 2008; Routasalo et al. 2009; Kuntz et al. 2014; Lehmann et al. 2014; Nieuwlaat et al. 2014). The optimal care response shown by the clinical laboratory results does not necessarily tell adherence to treatment since the adherence can be low in spite of an optimal care response (Kekäle et al. 2014). Therefore the health care professionals may overestimate adherence to treatment. The patient needs continuous support from the health care professional and he/she must not be left alone with the medical treatment's practical problems. The patient also needs medicines information to be able to take responsibility for his/her own treatment, i.e., to support self-management.

There is a need for changes in the attitudes of health care professionals as well as of patients themselves. The change from the authority role of the health care professional to the trainer of the patient is a big change in our health care system. In the trainer role the health care professional finds out about the patient's wishes and about his everyday life, and combine altogether so that it suits his/her care (Routasalo et al. 2009). Are we going to change our role from the authority into a trainer during our career or will it take a generation to do this successfully? A change in health care professional attitudes and in the operation models is needed. Only after will we be able to require that patients do their part in participating fully in the health care team.

Rational pharmacotherapy reduces the costs of the public health care and increases public health (Ministry of Social Affairs and Health 2011). The results of the pharmacotherapy and benefit to the patient weaken if the medicines are not rationally used. The Medicines Policy 2020 by Ministry of Social Affairs and Health (2011) recommends that the patient must get support to reach the goals of the pharmacotherapy. The patient has to be put in the center and the focus of the interventions should be based on the individual patient's needs. The different public health care actors have to act as the patient's advocate and them having to respect the

decisions made by the patient. For the patient to make decisions, he/she has to be given all possible information. There is a need for more multiprofessional cooperation to optimize medicine use and adherence in health care.

## **THIS DOSIS ISSUE: INTEGRATING RESEARCH, PRACTICE DEVELOPMENT AND TRAINING IN PHARMACY**

This Dosis issue is specially targeted to our international colleagues. A theme selected for the current issue deals with integrating research, practice development and training in pharmacy. This theme was selected, because it is essential to have research evidence to guide policy-making, practice and competence development in different pharmaceutical sectors. As Finland is preparing to undergo during the next years one of the most massive health care reforms in the country's history, pharmacists need to be prepared for the reform by showing evidence for the value of their contributions to patient care in different settings.

The pharmaceutical sector's preparation for the healthcare reform has been guided by Medicines Policy 2020 by Ministry of Social Affairs and Health (2011). The Policy's implementation has been supported by strong long-term programs by Finnish Medicines Agency Fimea on Medicines Information (2012), Optimizing Medication Management of the Aged (2012) and Assuring Safe and Rational Use of Self-Medication (2015). The two first mentioned programs by Fimea have systematically applied research-based information to practice development and have even actively made initiatives to promote research in certain core areas.

Recent years have provided new important forums for pharmacists to be involved in healthcare development and policy making, e.g., through the national patient safety program coordinated by the National Institute for Welfare and Health, and the Finnish Society for Patient Safety which has a special section for medication safety (see Holmström et al. in this issue). The evolution of pharmacists' role in healthcare has been supported by curriculum development targeting to better collaborative and clinical skills to the future generation of graduating pharmacists (see Lillsunde et al., and Inacio and Cavaco in this issue). To fill competence gaps of practicing pharmacists, there is a unique system

of short and long-term trainings applying modern adult learning methods and technologies. The network-based postgraduate specialization training system having programs in industrial pharmacy, community pharmacy and hospital and health centre pharmacy has been acknowledged as a system pointing the way forward for other specialization trainings in Finland which are under reform under the lead of Ministry of Culture and Education. This achievement is an excellent demonstration of the power of proactive, long-term cooperation and development within the pharmacy profession.

The Finnish pharmacists with their evolving know-how and innovations have developed expertise in clinical pharmacy which allows them to participate in patient care more than before. This suc-

cess story in developing expertise and innovations is shown in different articles found in this Dosis.

The success stories of Finnish pharmacists and other Nordic pharmacists will be shared and celebrated in August in Espoo, in southern Finland at the Annual Conference of Nordic pharmacists' unions hosted this year by the Finnish Pharmacists' Association. To learn from each other and share good practices facilitate both Finnish and Nordic pharmacy to develop into a stronger success story.

---

#### →Kirsi Kvarnström

MSc (Pharm), President

Finnish Pharmacists' Association

#### REFERENCES:

Bell J, Airaksinen M, Lyles A, Chen T, Aslani P: Concordance is not synonymous with compliance or adherence. *Br J Clin Pharmacol* 64: 710–713, 2007

Haynes RB, Ackloo E, Sahota N, McDonald HP, Yao X: Interventions for enhancing medication adherence. *Cochrane Database Syst Rev* 2008

Finnish Medicines Agency: Interprofessional network to rationalize pharmacotherapy, 2012. [www.fimea.fi/development/Interprofessional\\_network#sthash.Jtcd7trS.dpuf](http://www.fimea.fi/development/Interprofessional_network#sthash.Jtcd7trS.dpuf)

Finnish Medicines Agency: Kansallinen itsehoito-lääkehjelma (National self-medication drug program, in Finnish). Fimea kehittää, arvioi ja informoi -julkaisusarja 1/2015. [www.fimea.fi/download/28244\\_KAI\\_1\\_2015.pdf](http://www.fimea.fi/download/28244_KAI_1_2015.pdf)

Finnish Medicines Agency: Rational use of medicines through information and guidance. Medicines information services: Current state and strategy for 2020. Fimea develops, assesses and informs. Serial publication: 1/2012. [www.fimea.fi/download/21513\\_KAI\\_JULKAISUSARJA\\_Laakein-formaatiostrategia\\_1\\_2012\\_eng\\_links.pdf](http://www.fimea.fi/download/21513_KAI_JULKAISUSARJA_Laakein-formaatiostrategia_1_2012_eng_links.pdf)

Jokisalo E: Hoitomyönteisyys ja sen edistämiskeinot. *Suom. Lääkärilehti* 61: 1595–1599, 2006

Kekäle M, Talvensaari T, Koskenvesa P, Porkka K, Airaksinen M: Chronic myeloid leukemia patients' adherence to peroral tyrosine kinase inhibitors compared with adherence as estimated by their physicians. *Patient Prefer Adherence* 8: 1619–1627, 2014

Kunz J, Safford M, Singh J et al.: Patient-centered interventions to improve medication management and adherence: A qualitative review of research findings. *Patient Educ Couns* 97:310–326, 2014

Lehmann A, Aslani P, Ahmed R et al: Assessing medication adherence: options to consider. *Int J Clin Pharm* 36: 55–69, 2014

Ministry of Social Affairs and Health: Medicines Policy 2020. Towards efficient, rational and cost-effective use of medicines. Publications 2011: 2. Available from: <http://stm.fi/en/pharmaceutical-service> (accessed 12.06.15)

Nieuwlaat R, Wilczynski N, Navarro T et al.: Interventions for enhancing medication adherence (Review). *Cochrane Database Syst Rev* 2014

Routasalo P, Airaksinen M, Mäntyranta T, Pitkälä K: Potilaan omahoidon tukeminen. *Duodecim* 125: 2351–2359, 2009

World Health Organization (WHO): Adherence to long-term therapies: Evidence for action 2003. Available from: <http://whqlibdoc.who.int/publications/2003/9241545992.pdf>

# The Finnish Society for Patient Safety

– Actions to promote patient and medication safety

---

## →Anna-Riia Holmström

MSc (Pharm), PhD Student  
Clinical Pharmacy Group, Division of  
Pharmacology and Pharmacotherapy  
Faculty of Pharmacy, University of Helsinki  
E-mail: anna-riia.holmstrom@helsinki.fi

## →Ermo Haavisto

MD, Chief Medical Director  
Kymenlaakso Social and Health Services  
E-mail: ermo.haavisto@carea.fi

## →Marina Kinnunen

PhD (Econ), nurse  
Chief Nursing Officer, Vaasa Hospital District  
E-mail: marina.kinnunen@vshp.fi

## →Timo Keistinen

MD, PhD, Ministerial Counsellor  
Ministry of Social Affairs and Health  
E-mail: timo.keistinen@stm.fi

## →Tarja Pajunen

RN, Expert on Social and Health Affairs  
The Organisation  
for Respiratory Health in Finland  
E-mail: tarja.pajunen@hengityslitto.fi

Corresponding author:

## →Anna-Riia Holmström

E-mail: anna-riia.holmstrom@helsinki.fi

## SUMMARY

Patient safety is a central part of quality and risk management in social (e.g., provision of care for elderly people in nursing homes) and healthcare. The Finnish Society for Patient Safety is a non-governmental organisation established in 2010 to promote patient safety and patient safety research in Finland. The Society has promotion of medication safety as one of its key priorities. The Society promotes patient centeredness in its work, and uses a multidisciplinary approach involving voluntary representatives from a wide range of stakeholders, including healthcare organisations and academic institutions, with expertise in patient safety. The Finnish Society for Patient Safety also collaborates with other national stakeholders. One of its latest initiatives involves working with the Ministry of Social Affairs and Health to develop a national Patient and Customer Safety Programme (2015–2020). Other key activities of the Society include education for social and healthcare professionals, promotion of research in patient and medication safety, informing patients, social and healthcare professionals and other stakeholders on patient safety, and publishing material for social and healthcare organisations for promotion of patient safety in their own organisations. An expert group in Safe Pharmacotherapy operates as a part of the Society with a special focus on medication safety promotion in hospital and community settings.

**Key words:** patient safety, medication safety, society, safe pharmacotherapy, research, education, patient and customer safety programme

## INTRODUCTION

Patient safety is a central part of quality and risk management in social (referring to environments providing care for e.g., elderly or disabled people) and healthcare. Patient safety is considered a global health issue (Jha et al. 2010). It has been estimated that one in ten patients is harmed when receiving healthcare in industrialised countries; many such adverse events could be preventable (Institute of Medicine 2000). If the existing international evidence is extrapolated to Finnish healthcare and population of 5.5 million, adverse events are estimated to cause the death of 700–1700 patients annually in Finland (Pasternack 2006).

Medication errors, such as administering a wrong dose of medication to a patient, are one of the most common incidents leading to adverse events (Institute of Medicine 2000). Medication errors can occur during various stages of medication use process, e.g., while prescribing, dispensing or administering a medicine (Institute of Medicine 2006, National Coordinating Council for Medication Error Reporting and Prevention 2015). Prevention of these incidents is the goal of medication safety,

which is one of the main components of patient safety (American Hospital Association et al. 2002).

Studies on medication errors have shown them common and costly; medication errors and other adverse events cost healthcare systems billions of euros each year (Pasternack 2006, Ovretveit 2009). Tackling these major threats to safe patient care requires developing system based strategies (Institute of Medicine 2000, Reason 2000). This means that risks should be managed proactively by improving the healthcare system rather than blaming and shaming individual healthcare professionals for committing errors. These challenges require national level attention and should be a priority in health policy making (Airaksinen et al. 2012).

Patient and medication safety has been actively promoted in Finland since 2006. Several key initiatives, such as the national Patient Safety Strategy (2009–2013), and the Patient Safety Act and Decree as a Part of the new Healthcare Law (2011), have significantly increased governmental actions to initiate system-based patient safety work in Finland (Ministry of Social Affairs and Health 2009a, Airaksinen et al. 2012). As a part of this sequence,

a non-governmental Finnish Patient Safety Society was founded in 2010 to promote patient safety and patient safety related research in Finland (Finnish Society for Patient Safety 2015). The aim of this article is to describe the activities of the Society in the national patient safety promotion and in advancing safe and appropriate medication use.

## ACTIVITIES OF THE FINNISH SOCIETY FOR PATIENT SAFETY

The aim of the Finnish Society for Patient Safety is to ensure that patients receive safe and high quality care in everyday practice of social and healthcare. The core values of the Society are patient-centeredness, openness and independence.

The Society relies on a multidisciplinary base involving voluntary representatives from a wide

range of stakeholders, including healthcare organisations and academic institutions, who have expertise in patient safety (Figure 1). In addition to a Society Board, the Finnish Society for Patient Safety operates four sub-groups, which conduct activities in their own area of specialty (Figure 1). These groups are: patient safety education; safe pharmacotherapy; patient safety experts acting locally in their respective healthcare organisations, and experts from organisations for patients and disabled to give voice to patient issues in patient and medication safety promotion.

The current membership of the Society is very heterogeneous consisting of a variety of organisations, institutions and individuals who have interest in patient and medication safety promotion (Figure 1). The key activity areas of the Society are described in Figure 2. The following paragraphs present examples of some of these activities.

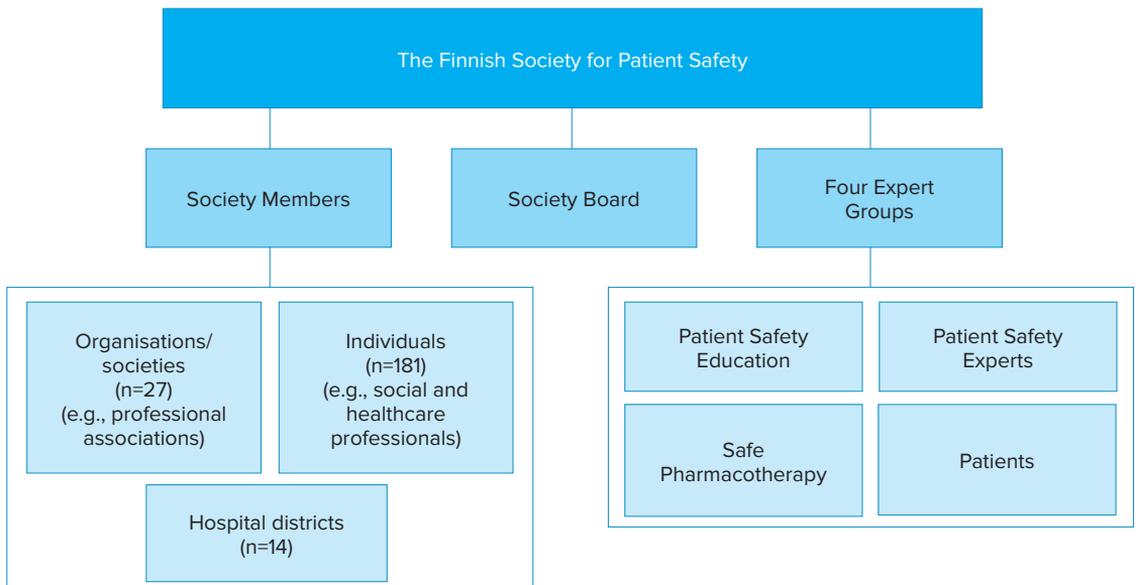


Figure 1. Organisational structure of the Finnish Society for Patient Safety

### **National Patient and Customer Safety Programme (2015–2020) to inform patient safety promotion**

The Finnish Society for Patient Safety collaborates actively with other national stakeholders in patient safety promotion. The latest such collaborative project involves the Ministry of Social Affairs and Health development of a national Patient and Customer Safety Programme (2015–2020), which updates the Patient Safety Strategy (2009–2013) (Ministry of Social Affairs and Health 2009a). The Finnish Society for Patient Safety has been active in program development and in driving the initiation of the program development. The first version of the program was drafted at the Society's recommendation, and was developed further by a program working group. The Society also has taken part in finalising the program and has emphasised throughout the process the need for a strong patient perspective in the new program.

During the former Patient Safety Strategy (2009–2013) (Ministry of Social Affairs and Health 2009a), several nationally important developments occurred. The new legislation on healthcare was enacted requiring healthcare organisations to promote their patient safety. Healthcare organisations have also been required to develop their own plans for promoting patient safety and quality of care, to track what is achieved, and to nominate a patient safety coordinator for their organization. The new Patient and Customer Safety Programme will also include social care settings, e.g., elderly care, which emphasises the role of a patient or customer (referring to customers in social care services) and his or her family in patient and customer safety promotion. The main aspects covered in the new program include: safety culture, enabling e.g., open sharing and learning from adverse events occurring in social and healthcare settings; patient and

---

## **THE FINNISH SOCIETY FOR PATIENT SAFETY**

- Promotes involvement of patients and their families in ensuring patient safety
- Provides an open network for social and healthcare stakeholders, interest groups and stakeholders representing patients
- Follows actively patient safety promotion in Finland and internationally, identifies the priority areas of development, and draws the attention of others in to these issues
- Promotes and takes part in patient safety research and development projects
- Influences national strategies, legislation and authoritative actions in patient safety, and takes part in societal discussion on patient safety
- Promotes patient safety through the actions of four expert groups of the Society
- Acts as a partner in national projects and programs in patient safety
- Participates in organising training in patient safety
- Practices dissemination of informing and publishing on patient safety topics
- Promotes multidisciplinary approach to patient safety

**Figure 2. The main activities of the Finnish Society for Patient Safety**

customer safety management; statutes related to patient and customer safety, and responsibilities of different stakeholders in patient and customer safety promotion. The new National Patient and Customer Safety Programme will be published in autumn 2015.

#### **Education and guides to assist local patient safety work**

The Finnish Society for Patient Safety has education as one of its key activities to use to create competence in patient safety. The Society provides very practice focused training free of charge and welcomes everybody to participate in training. Up to date, approximately 600 nurses, practitioners, pharmacists and other healthcare professionals have received training provided by the Society. In 2014, the Society organized a training-tour for social and healthcare professionals in four hospital districts (in Kuopio, Kouvola, Pori and Oulu). The aim was to enhance basic knowledge and skills in patient safety and to encourage healthcare personnel to promote patient safety in their daily work. Some basic tools, such as medication reconciliation, were introduced and discussed together with the identified local patient safety challenges.

The Finnish Society for Patient Safety also develops guides for social and healthcare organisations to support local patient safety work. In 2012, a Guide for Investigating Severe Adverse Events in Healthcare Organisations was released (Finnish Society for Patient Safety 2012), followed by a national training day introducing an investigation model and providing information for healthcare personnel on how to plan and initiate such an investigation in their own organisations. Another Guide is currently under development on patient

safety related risk management in social and healthcare (to be published in 2015). The Guide is based on the Healthcare Law and its Act (2011) requiring Finnish social and healthcare organisations to develop their own patient safety plans and procedures for proactive management of patient safety risks. The Guide supplements the previously published guide on risks management and safety planning in social and healthcare organisations published by the Ministry of Social Affairs and Health (2011). The Finnish Society for Patient Safety will organize the next national training day on this topic in late autumn 2015 (for the training date and registration information, please follow our websites: [www.potilasturvallisuusyhdistys.fi](http://www.potilasturvallisuusyhdistys.fi)).

#### **Promotion of research to create evidence in patient and medication safety**

Promotion of patient and medication safety related academic research and development projects are one of the focus areas of the Finnish Society for Patient Safety (**Figure 2**). The latest initiative in this area is related to a voluntary Patient Safety Incident Reporting System (HaiPro), which is used by over 200 Finnish social and healthcare organisations to report adverse events and near misses, including medication errors (Awanic Ltd 2015). Since the establishment of the HaiPro system in 2007, nearly one million reports on adverse events have been filed from different social and healthcare organisations, providing a unique opportunity to explore incidents and patient safety risks in the Finnish social and healthcare. A current project of the Finnish Society for Patient Safety aims to make this data available for high quality academic research and patient safety promotion projects in social and healthcare organisations. This enables

the utilisation of the accumulated data for promotion of patient safety and social and healthcare quality through academic research in Finland.

## ACTIVITIES OF THE SAFE PHARMACOTHERAPY GROUP

The aim of the Safe Pharmacotherapy Group (**Figure 1**) is to provide an open, multidisciplinary discussion and action forum for those interested in promotion of medication safety both in hospital and community settings. The group also acts as a medication safety expert in the joint activities of the Society, such as at previously described training days. Currently, the group consists of 18 social and healthcare professionals with backgrounds in pharmacy, nursing, practical nursing and medicine.

Education of social and healthcare professionals in medication safety is one of the key activities of the Safe Pharmacotherapy Group; it has taken part in organising several training days, e.g., in collaboration with Society member organisations and the other sub-groups of the Society (**Figure 1**). The Group also takes actively part in medication safety promotion at national level, such as an on-going update of the national guidelines for Safe Pharmacotherapy, first published in 2006 (Ministry of Social Affairs and Health 2005). The Guidelines have served as a national key incentive in medication safety promotion for both public and private social and healthcare units (a summarized version of the Guidelines are available in English: Ministry of Social Affairs and Health 2009b, Airaksinen et al. 2012). The Safe Pharmacotherapy group has also taken part in drafting the national Patient and Customer Safety Program to be published in 2015 (see

the section: National Patient and Customer Safety Programme 2015–2020 to inform patient safety promotion).

One of the current activities of the Safe Pharmacotherapy Group is participating in planning of the National Pharmacotherapy Day (Lääkehoidon päivä), coordinated by the Finnish Medicines Agency (Finnish Medicines Agency 2014). The Pharmacotherapy day organized around a particular theme annually is targeted for medication users and social and healthcare professionals in Finland. The Safe Pharmacotherapy Group also publishes information about safe use of medicines for the public and social and healthcare professionals (for further information about the publications, please visit: [www.potilasturvallisuusyhdistys.fi/jaokset\\_laakehoito.aspx](http://www.potilasturvallisuusyhdistys.fi/jaokset_laakehoito.aspx)).

*The Finnish Society for Patient Safety warmly welcomes all organisations, institutions and individuals who have their interests in patient and medication safety promotion to join the Society. To apply the Society membership and for more information and resources, please visit our websites at [www.potilasturvallisuusyhdistys.fi](http://www.potilasturvallisuusyhdistys.fi)*

*Are you interested in participating in the work of the Safe Pharmacotherapy Group?*

*Please contact us: [anna-riia.holmstrom@helsinki.fi](mailto:anna-riia.holmstrom@helsinki.fi)*

*For further information about medication safety and the Safe Pharmacotherapy Group, please visit [www.potilasturvallisuusyhdistys.fi/jaokset\\_laakehoito.aspx](http://www.potilasturvallisuusyhdistys.fi/jaokset_laakehoito.aspx)*

## TIIVISTELMÄ

Potilasturvallisuus on keskeinen osa sosiaali- ja terveydenhuollon laatua ja riskienhallintaa. Suomen Potilasturvallisuusyhdistys on perustettu vuonna 2010 edistämään potilasturvallisuutta ja potilasturvallisuuden tutkimusta Suomessa. Yhdistyksen yhtenä painoalueena on lääkitysturvallisuuden edistäminen. Yhdistyksen toiminnassa potilas on potilasturvallisuuden edistämisen keskiössä. Toiminta on moniammatillista, ja sitä toteuttavat useat vapaaehtoiset potilasturvallisuuden asiantuntijat. Yhdistys toimii myös yhteistyössä muiden kansallisten toimijoiden kanssa potilas- ja lääkitysturvallisuuden edistämiseksi. Viimeisimpänä toimenpiteenään yhdistys on laatinut yhteistyössä sosiaali- ja terveysministeriön kanssa Suomen Potilas- ja asiakasturvallisuuden toimintaohjelman vuosille 2015–2020. Yhdistyksen muihin keskeisimpiin toimenpiteisiin lukeutuvat sosiaali- ja terveydenhuollon ammatillisille suunnattu koulutustoiminta, toimenpiteet potilas- ja lääkitysturvallisuustutkimuksen edistämiseksi, potilasturvallisuuteen liittyvä julkaisutoiminta ja potilasturvallisuuden kehittämistä sosiaali- ja terveydenhuollon organisaatioissa tukevan materiaalin tuottaminen. Potilasturvallisuusyhdistyksen osana toimii Turvallinen lääkehoito -jaos, joka koostuu lääkitysturvallisuuden asiantuntijoista. Jaoksen tehtävänä on lääkitysturvallisuuden edistäminen laitos- ja avohoidossa.

**Avainsanat:** potilasturvallisuus, lääkitysturvallisuus, yhdistys, turvallinen lääkehoito, tutkimus, koulutus, potilas- ja asiakasturvallisuuden toimintaohjelma

---

### →Anna-Riia Holmström

proviisori, jatko-opiskelija  
Kliinisen farmasian ryhmä, farmakologian ja lääkehoidon osasto  
Farmasian tiedekunta, Helsingin yliopisto  
E-mail: anna-riia.holmstrom@helsinki.fi

### →Ermo Haavisto

lääketieteen lisensiaatti, johtajaylilääkäri  
Carea, Kymenlaakson sairaanhoito- ja sosiaalipalvelujen kuntayhtymä  
E-mail: ermo.haavisto@carea.fi

### →Marina Kinnunen

KTT, sairaanhoitaja, hallintoylihoitaja  
Vaasan sairaanhoitopiiri  
E-mail: marina.kinnunen@vshp.fi

### →Timo Keistinen

lääketieteen ja kirurgian tohtori,  
lääkintöneuvos  
Sosiaali- ja terveysministeriö  
E-mail: timo.keistinen@stm.fi

### →Tarja Pajunen

sairaanhoitaja, sosiaali- ja terveysturvan asiantuntija  
Hengitysliitto ry  
E-mail: tarja.pajunen@hengitysliitto.fi

Kirjeenvaihto:

### →Anna-Riia Holmström

E-mail: anna-riia.holmstrom@helsinki.fi

## REFERENCES

- Airaksinen M, Linden-Lahti C, Holmström AR: Medication Safety as Part of Patient Safety: Initiatives and Research in Finland. *Dosis* 28: 214–228, 2012
- American Hospital Association, Health Research and Educational Trust, Institute for Safe Medication Practices: Pathways for Medication Safety – Leading A Strategic Planning Effort, 2002. Available from: [www.ismp.org/tools/pathwaysection1.pdf](http://www.ismp.org/tools/pathwaysection1.pdf)
- Awanic Ltd. Reporting System for Safety Incidents in Healthcare Organizations, 2015. [www.haipro.fi/eng](http://www.haipro.fi/eng)
- Finnish Medicines Agency: National Pharmacotherapy Day – Know your medicines, 2014. [www.laakehoidonpaiva.fi](http://www.laakehoidonpaiva.fi) (In Finnish)
- Finnish Society for Patient Safety: Investigation of Severe Adverse Events – A Guide for Social and Healthcare Organisations. Haavisto E, Helovuori A, Kinnunen M, Peltomaa K (Eds). 2012 Available from: [www.potilasturvallisuusyhdistys.fi/documents/vakavien\\_opas.pdf](http://www.potilasturvallisuusyhdistys.fi/documents/vakavien_opas.pdf)
- Finnish Society for Patient Safety: The Finnish Society for Patient Safety has been established, 2015. [www.potilasturvallisuusyhdistys.fi](http://www.potilasturvallisuusyhdistys.fi)
- Institute of Medicine: To Err is Human – Building a Safer Health System. Kohn LT, Corrigan JM, Donaldson MS (Eds). National Academies Press, 2000
- Institute of Medicine: Preventing Medication Errors. Aspden P, Wolcott JA, Bootman JL, Cronenwett LR (Eds). Committee on Identifying and Preventing Medication Errors. Quality Chasm Series. National Academies Press, 2006
- Jha AK, Prasopa-Plaizier N, Larigoitia I, Bates DW: Patient safety research: an overview of the global evidence. *Qual Saf Healthcare* 19: 42–47, 2010
- Ministry of Social Affairs and Health: Promoting patient safety together. Finnish patient safety strategy 2009–2013. Helsinki: Publications of Ministry of Social Affairs and Health 2009a
- Ministry of Social Affairs and Health: Safe Pharmacotherapy. National guide for pharmacotherapy in social and healthcare. Handbooks of the Ministry of Social Affairs and Health 2005: 32. A summarized version in English: Reports of the Ministry of Social Affairs and Health 2009b: 10. Available from: [www.stm.fi/c/document\\_library/get\\_file?folderId=39503&name=DLFE-9320.pdf](http://www.stm.fi/c/document_library/get_file?folderId=39503&name=DLFE-9320.pdf)
- Ministry of Social Affairs and Health: Risk Management and Safety Planning: A handbook for social welfare and healthcare management and security experts. Helsinki: Publications of Ministry of Social Affairs and Health 2011: 15 (Summary in English)
- National Coordinating Council for Medication Error Reporting and Prevention: About medication errors: What is a medication error? 2015. Available from: [www.nccmerp.org/about-medication-errors](http://www.nccmerp.org/about-medication-errors)
- Overtveit J: Does improving safety save money? A review of evidence of which improvements to quality reduce costs to health service providers. The Health Foundation, 2009
- Pasternack A: Errors in patient care and adverse outcomes. *Duodecim* 122: 2459–70, 2006 (In Finnish)
- Reason J: Human error: models and management. *J West Med* 172: 393–6, 2000

# Long-term benzodiazepine use and the aged

– Time to change clinical practice

---

## →Juha Puustinen

MD, PhD, Docent, Specialist in Neurology, Special Competence in Medical Education  
Satakunta Central Hospital, Unit of Neurology  
University of Helsinki, Clinical Pharmacy Group,  
Division of Pharmacology and Pharmacotherapy  
University of Turku, Family Medicine and Neurology

## →Janne Nurminen

MD, PhD, Specialist in Family Medicine  
University of Turku, Family Medicine

Corresponding author:

## →Juha Puustinen

Satakunta Central Hospital  
Sairaalan tie 3  
28500 Pori  
Finland  
E-mail: juhpuu@utu.fi

## ABSTRACT

Inappropriate long-term use of benzodiazepines is common, and it is associated with many negative health outcomes in the aged. Despite declining trends, the aged are the highest user group of benzodiazepines in Finland.

Benzodiazepine use may predict worse cognitive outcomes both in cognitively intact and already cognitively declined population when compared with benzodiazepine non-users in general aged population, especially when benzodiazepines are combined with other CNS effective drugs. In addition, the concomitant use of two or more benzodiazepines was associated with an increased risk of fractures in men.

Withdrawal from long-term benzodiazepine use is feasible in primary care with psychosocial support. After benzodiazepine withdrawal, cognitive abilities in psychomotor tests did not show improvements for up to six months. Nevertheless, the handgrip strength of women who had withdrawn improved significantly in comparison to non-withdrawers. Melatonin, however, does not aid in benzodiazepine withdrawal.

Patients themselves may ask for repeat prescriptions of benzodiazepines due to lack of knowledge concerning their own medications. Many do not know that benzodiazepines could be gradually stopped with mild withdrawal symptoms, but without the risks of severe adverse effects.

We need to have a multiprofessional focus on educating physicians, nurses and pharmacists about correct benzodiazepine use. In patient education, normal age-related changes in sleep physiology and architecture should be addressed. Non-pharmacological methods for improving sleep should be more often used in clinical practise.

**Key words:** benzodiazepines, long-term use, aged people, clinical practice

## INTRODUCTION

Benzodiazepines were introduced in the 1950s, and they soon replaced previously used hypnotics and anxiolytics, such as barbiturates. Six decades later, they still remain the drugs of choice in many indications. There are not many pharmacological alternatives for short-term insomnia, anxiety, acute management of epileptic seizures, or alcohol withdrawal symptoms.

Quite the contrary to common beliefs, benzodiazepines are quite ineffective even in short-term use as hypnotics. According to a meta-analysis in the aged, total sleep time increased slightly (mean 25 minutes), and the number of night time awakenings decreased (0.6/night) with benzodiazepines when compared with placebo (Glass et al 2005). The risk-benefit ratio was found unfavourable, as the number-needed-to-treat for improved sleep with benzodiazepines compared to placebo was high (NNT=13), whereas the number-needed-to-harm for all adverse effects was much lower (NNH=6; risks for cognitive adverse events OR=4.8 and for psychomotor OR=2.6).

There is no evidence on benefits with regard long-term benzodiazepine use. Thus, long-term benzodiazepine use and benzodiazepines with long half-lives are considered inappropriate according to contemporary guidelines on the pharmacotherapy in the aged (Dimitrow et al 2012).

## BENZODIAZEPINES IN THE AGED

### Benzodiazepine use in Finland

In Finland, benzodiazepines have been the most commonly used psychotropics among the aged (Hartikainen et al 2003; Rikala et al 2011). In 1990, 19% of the aged used these medications, and by the end of the decade the proportion of users had increased to 22% (Linjakumpu et al 2002). The trend of increasing benzodiazepine use continued in the early 2000s (Jyrkkä et al 2006). Despite the decline in recent years, benzodiazepines have remained among the most commonly prescribed psychotropics (Fimea and Kela 2014).

### Ageing and the risks of benzodiazepines

The ageing body undergoes physiological changes, which predispose aged persons to adverse medication effects. The process of normal ageing and

simultaneous interacting morbidities reduce individuals' capacity to tolerate the adverse drug effects. Quite paradoxically, benzodiazepines are most often used by the frailest and most vulnerable aged persons. The highest load of sedative drugs is concentrated in the oldest-old (Linjakumpu et al 2004; Jyrkkä et al 2006) and in those using multiple concomitant medications (Jyrkkä et al 2009). Polypharmacy further predisposes old adults to adverse effects due to drug interactions and other accumulating harmful effects.

Epidemiological studies have shown that benzodiazepine use increases the risk of falls, fractures, mobility disabilities, loss of ADL (activities of daily living) functions, traffic accidents, substance abuse and mortality (Puustinen 2014; Nurminen 2014).

### Finnish benzodiazepine research in the aged

In Finnish studies lead by Professor Sirkka-Liisa Kivelä, benzodiazepine use was related to worse cognitive and functional abilities (Puustinen et al 2007). In general aged population the use may predict worse cognitive outcomes both in cognitively intact and already cognitively declined population when compared with benzodiazepine non-users, especially when benzodiazepines were combined to other CNS effective drugs (Puustinen et al 2011; Puustinen et al 2012). Correspondingly, the concomitant use of two or more benzodiazepines was associated with an increased risk of fractures in men aged 65 year or over (Nurminen et al 2010). Furthermore, within the same general population, the use of an opioid with a benzodiazepine increased the risk of fractures in men (Nurminen et al 2013).

Withdrawal from long-term benzodiazepine use as hypnotics is possible in primary care when a health center physician and a nurse provide psychosocial support and counselling regularly during a one-month withdrawal period and follow-up meetings at two and six months (Lähteenmäki et al 2014). Even 76% of the long-term benzodiazepine users stopped their use during the first month. Six months after the beginning of the withdrawal, 38% remained benzodiazepine-free (Lähteenmäki et al 2014; Puustinen et al 2014). However, melatonin did not aid benzodiazepine withdrawal compared with placebo (Lähteenmäki et al 2014). Three years later, one-third had remained benzodiazepine-free

for three years while one-third had remained regular users and one-third irregular users (Puustinen et al, unpublished observation 2015).

Surprisingly, similar long-term withdrawal results have been achieved by public lectures and one-time counselling by a geriatrician (Salonoja et al 2010; Vaapio et al 2013).

### **Benefits of benzodiazepine withdrawal**

Do patients who withdraw from using a benzodiazepine benefit or suffer withdrawal symptoms, such as rebound insomnia and anxiety?

Cognitive abilities in psychomotor tests either did not show, or showed only modest, improvements for up to six months after benzodiazepine withdrawal (Puustinen et al 2014). This suggests that the cognitive effects of benzodiazepines may be long lasting or even permanent (Puustinen 2014). The handgrip strength of women who had withdrawn improved significantly in comparison to non-withdrawers (Nurminen et al 2014). The associations were weaker for men. However, during the six-month follow-up period, no significant change in balance test results associated with benzodiazepine withdrawal was detected.

Fortunately, those aged who managed to withdraw from benzodiazepines considered their self-perceived qualities of sleep and life better and there were no increase in their symptoms in the long term (Vaapio et al 2015; Lähteenmäki et al, unpublished observation 2015). These findings show that the emerging symptoms during the withdrawal period will pass by within weeks if the withdrawers are educated and supported to tolerate their withdrawal symptoms.

### **Should we focus on patient education?**

We advise physicians prescribing benzodiazepines to be familiar with the clinical recommendations and the risks related to long-term benzodiazepine use. Patients themselves are not always willing to consider or try withdrawing. Why do patients ask for drugs with potential harms and little benefit to be used for years or even decades?

Along with psychological and physical addiction potential, the aged do not know much about the benzodiazepines they have been using (Kleme 2012). Many patients are afraid of withdrawal symptoms that can emerge even when benzodia-

zepines are withdrawn gradually under supervision (Lähteenmäki et al 2014). Many do not know that benzodiazepines could be gradually stopped without the risks for severe adverse effects (Kleme 2013; Lähteenmäki et al 2014).

We are lacking measurable biological markers for drug related benefits or harms, as benzodiazepine residual concentrations do not correlate with clinical outcomes (Huttunen 2014). Additionally, we have no clinical means for prospectively finding those individuals who could easily withdraw and do better without benzodiazepines.

## **CONCLUSIONS**

Benzodiazepines are still needed in some indications. However, the problem is their ongoing, extensive and inappropriate long-term use among the aged. To maintain the high benzodiazepine withdrawal rate obtained during the first withdrawal month by psychosocial support and education, the possibility for regular supportive meetings longer than for a month or two might be needed. We need nurses who are specialized on sleep disturbances to provide counselling in order to avoid unneeded benzodiazepine prescriptions and to achieve supportive network for those willing to withdraw benzodiazepines in the broader population. We also need pharmacists to evaluate patient medication lists and to encourage our patients to ask their physicians whether repeat-prescriptions of benzodiazepines are really necessary.

We need to have a multiprofessional focus on educating physicians, nurses and pharmacists about correct benzodiazepine use. Normal age-related changes in sleep physiology and architecture need to be understood and accepted. Knowledge of diseases and medications having adverse effects on sleep needs to be increased. Furthermore, patients and caregivers need valid information on how sleep is improved non-pharmacologically and, when needed, how the benzodiazepines are correctly used and withdrawn. Non-pharmacological treatments as first-line treatment options for insomnia are recommended in guidelines, and they should also be emphasized in clinical reality.

## TIIVISTELMÄ

Bentsodiatsepiinien sopimaton pitkäaikaiskäyttö iäkkäässä väestössä on yleistä, vaikka käyttö on viime vuosina maassamme vähentynyt. Pitkäaikaiskäyttö on iäkkäillä yhteydessä moniin haitallisiin terveysvaikutuksiin.

Bentsodiatsepiinien käyttö voi ennustaa kasvanutta riskiä kognition laskuun sekä kognitiivisesti terveessä että jo heikentyneessä väestössä verrattuna näitä lääkkeitä käyttämättömiin. Erityisesti bentsodiatsepiinien yhdistäminen muihin keskushermostoon vaikuttaviin lääkkeisiin lisää kognition laskun riskiä. Kahden tai useamman bentsodiatsepiinin käyttö yhdistyy murtumien vaaraan miehillä.

Bentsodiatsepiinivieroitus onnistuu perusterveydenhuollossa psykososiaalisella tuella. Psykomotorinen toimintakyky ei parantunut kuuden kuukauden seuranta-ajalla bentsodiatsepiinivieroituksesta. Naisten puristusvoima parani merkitsevästi verrattuna ei-vieroittujiin. Melatoniinista ei todettu apua vieroituslääkkeenä.

Potilaat saattavat pyytää lääkäreiltään toistuvia bentsodiatsepiinimääräyksiä. Tämän taustalla voi olla tietämättömyys omasta lääkityksestä. Monet potilaat eivät tiedä, että bentsodiatsepiinit voidaan lopettaa vähitellen, jolloin he joutuvat varautumaan lieviin ja ohimeneviin vieroitusoireisiin. Vakavia haittatapah-tumia vähittäisestä vieroituksesta ei ole todettu.

Moniammatillisesti on keskityttävä kouluttamaan lääkäreitä, hoitajia ja farmaseutteja sekä proviisoreja bentsodiatsepiinien oikeasta käytöstä. Potilasonhauksessa normaalit ikääntymiseen liittyvät unen fysiologian ja rakenteen muutokset pitää tunnistaa, opettaa ja hyväksyä. Unen lääkkeettömät hoidot tulee ottaa osaksi kliinistä hoitoa.

**Avainsanat:** bentsodiatsepiinit, pitkäaikaiskäyttö, iäkkäät, kliininen hoitokäytäntö

## REFERENCES

- Dimitrow M, Leikola S, Kivelä SL, Airaksinen M, Mykkänen S, Puustinen J: Iäkkäiden hoidossa vältettävät lääkkeet: katsaus suosituksiin [Inappropriate medication use among the aged. Review of the criteria]. *Duodecim* 129(11): 1159–66, 2013
- Finnish Statistics on Medicines 2013 (online). Fimea and Kela 2014, ISSN-L 0786–2180. [www.fimea.fi](http://www.fimea.fi)
- Glass J, Lanctôt KL, Herrmann N, Sproule BA, Busto UE: Sedative hypnotics in older people with insomnia: meta-analysis of risks and benefits. *BMJ* 331 (7526): 1169, 2005
- Hartikainen S, Rahkonen T, Kautiainen H, Sulkava R: Use of psychotropics among homedwelling nondemented and demented elderly. *Int J Geriatr Psychiatry* 18(12): 1135–1141, 2003
- Huttunen S: Tematsepaamin, oksatsepaamin ja tsopiklonin jäännöspitoisuudet iäkkäillä potilailla. Pitoisuuksien yhteys itse arvioituun terveyteen ja toimintakykyyn [Temazepam, oxazepam and zopiclone residual concentration in aged patients. Associations with self-perceived health and functional abilities] Master's Thesis, University of Helsinki 2014
- Jyrkkä J, Vartiainen L, Hartikainen S, Sulkava R, Enlund H: Increasing use of medicines in elderly persons: a five-year follow-up of the Kuopio 75+ Study. *Eur J Clin Pharmacol* 62 (2): 151–158, 2006
- Jyrkkä J, Enlund H, Korhonen MJ, Sulkava R, Hartikainen S: Patterns of drug use and factors associated with polypharmacy and excessive polypharmacy in elderly persons: results of the Kuopio 75+ study: a cross-sectional analysis. *Drugs Aging* 26(6): 4, 93–503, 2009
- Kleme J: Iäkkäiden tietämys käyttämistään bentsodiatsepiineista ja niiden kaltaisista lääkelaikneista [The elderly patients' knowledge about benzodiazepines and related drugs]. Master's Thesis, University of Helsinki 2012

Linjakumpu T, Hartikainen S, Klaukka T, Koponen H, Kivelä SL, Isoaho R: Psychotropics among the home-dwelling elderly - increasing trends. *Int J Geriatr Psychiatry* 17 (9): 874–883, 2002

Linjakumpu TA, Hartikainen SA, Klaukka TJ, Koponen HJ, Hakko HH, Viilo KM, Haapea M, Kivelä SL, Isoaho RE: Sedative drug use in the home-dwelling elderly. *Ann Pharmacother* 38 (12): 2017–2022, 2004

Nurminen J: The Use of Nervous System Drugs and the Risk of Fractures in Old Adults. PhD's Thesis, *Annales Universitatis Turkuensis*, D1114. Turku 2014

Nurminen J, Puustinen J, Kukola M, Kivelä SL: The use of chemical restraints for older long-term hospital patients: a case report from Finland. *J Elder Abuse Negl* 21 (2): 89–104, 2009

Nurminen J, Puustinen J, Piirtola M, Vahlberg T, Kivelä SL: Psychotropic drugs and the risk of fractures in old age: a prospective population-based study. *BMC Public Health* 10: 396, 2010

Nurminen J, Puustinen J, Piirtola M, Vahlberg T, Lyles A, Kivelä SL: Opioids, antiepileptic and anticholinergic drugs and the risk of fractures in patients 65 years of age and older: a prospective population-based study. *Age Ageing* 42 (3): 318–324, 2013

Nurminen J, Puustinen J, Lähteenmäki R, Vahlberg T, Lyles A, Partinen M, Rähä I, Neuvonen PJ, Kivelä SL: Handgrip strength and balance in older adults following withdrawal from long-term use of temazepam, zopiclone or zolpidem as hypnotics. *BMC Geriatr* 14: 121, 2014.

Lähteenmäki R, Puustinen J, Vahlberg T, Lyles A, Neuvonen PJ, Partinen M, Rähä I, Kivelä SL: Melatonin for sedative withdrawal in older patients with primary insomnia: a randomized double-blind placebo-controlled trial. *Br J Clin Pharmacol* 77 (6): 975–85, 2014

Puustinen J: Benzodiazepines and cognitive functioning on older adults – With emphasis on long-term use and withdrawal. PhD's Thesis, *Annales Universitatis Turkuensis*, D1110. Turku 2014

Puustinen J, Nurminen J, Kukola M, Vahlberg T, Laine K, Kivelä SL: Associations between use of

benzodiazepines or related drugs and health, physical abilities and cognitive function: a non-randomised clinical study in the elderly. *Drugs and Aging*. 24 (12): 1045–59, 2007

Puustinen J, Nurminen J, Löppönen M, Vahlberg T, Isoaho R, Rähä I, Kivelä SL: Use of CNS medications and cognitive decline in the aged: a longitudinal population-based study. *BMC Geriatrics*. 11: 70, 2011

Puustinen J, Nurminen J, Vahlberg T, Lyles A, Isoaho R, Rähä I, Kivelä SL: CNS medications as predictors of precipitous cognitive decline in the cognitively disabled aged: a longitudinal population-based study. *Dementia and Geriatric Cognitive Disorders Extra*. 2 (1): 57–68, 2012

Puustinen J, Lähteenmäki R, Polo-Kantola P, Salo P, Vahlberg T, Lyles A, Neuvonen PJ, Partinen M, Rähä I, Kivelä SL: Effect of withdrawal from long-term use of temazepam, zopiclone or zolpidem as hypnotic agents on cognition in older adults. *Eur J Clin Pharmacol*. 70 (3): 319–29, 2014

Rikala M, Korhonen MJ, Sulkava R, Hartikainen S: Psychotropic drug use in community-dwelling elderly people-characteristics of persistent and incident users. *Eur J Clin Pharmacol* 67 (7): 731–739, 2011

Salonoja M, Salminen M, Aarnio P, Vahlberg T, Kivelä SL: One-time counselling decreases the use of benzodiazepines and related drugs among community-dwelling older persons. *Age Ageing*. 39 (3): 313–9, 2010

Vaapio S, Puustinen J, Nurminen J, Salonoja M, Salminen M: Short report: läkkäiden unilääkevieroituksen tulokset ovat kohtalaisen pysyviä. [Results of long-term benzodiazepine or benzodiazepine-related drugs withdrawal are quite permanent in older people]. *Yleislääkäri* 8: 32–33, 2013

Vaapio S, Puustinen J, Salminen MJ, Vahlberg T, Salonoja M, Lyles A, Kivelä SL: Symptoms Associated with Long-term Benzodiazepine Use in Persons 65 years and Older: A Longitudinal Descriptive Study. *International Journal of Gerontology* 9 (1): 34–39, 2015

# Faculty staff perspective on interprofessional education in the pharmacy curriculum: drivers, barriers and development needs

---

## →Katja-Emilia Lillsunde

MSc (Pharm), Doctoral Student  
Division of Pharmaceutical Biosciences  
Faculty of Pharmacy  
University of Helsinki  
Finland

## →Marika Pohjanoksa-Mäntylä

PhD (Pharm), University Lecturer  
Clinical Pharmacy Group  
Division of Pharmacology and Pharmacotherapy  
Faculty of Pharmacy  
University of Helsinki  
Finland

## →Marja Airaksinen

PhD, Professor  
Clinical Pharmacy Group  
Division of Pharmacology and Pharmacotherapy  
Faculty of Pharmacy  
University of Helsinki  
Finland

## →Outi Salminen

PhD (Pharm), University Lecturer  
Division of Pharmacology and Pharmacotherapy  
Faculty of Pharmacy  
University of Helsinki  
Finland

Corresponding author:

## →Katja-Emilia Lillsunde

[katja-emilia.lillsunde@helsinki.fi](mailto:katja-emilia.lillsunde@helsinki.fi)

## ABSTRACT

**Introduction:** Enhancing interprofessional teamwork in health care has been recognized as essential for improving patient safety. Teamwork skills of future professionals can be strengthened through interprofessional education (IPE), where students from different disciplines learn collaborative skills and practices together.

**Material and method:** An online survey was conducted at the Faculty of Pharmacy, University of Helsinki in spring 2012 to define the status, drivers and barriers and future needs for IPE from the staff point of view. Altogether 36 responses were received.

**Results:** When the survey was being done, few jointly organized study modules (n=3) were carried out at the Faculty and teaching methods rarely supported interaction between students. Geographical distance, lack of collaborative experience and resources were identified as barriers to IPE, while open-mindedness, common practise and mutual research projects were reported as factors encouraging IPE. Developing IPE was seen important especially for enhancing collaborative skills needed in working life.

**Conclusion:** The results reveal a need to develop IPE in the pharmacy curriculum. According to the survey results, focus should be on student-oriented interactive education and improving students' skills to work collaboratively, in order to improve efficiency and patient safety in health care. This has been taken into account in recent curriculum development.

**Keywords:** Interprofessional education, pharmacy curriculum, pharmacy education

## INTRODUCTION

Interprofessional collaboration in health care is defined as professionals from different health care disciplines working together to improve patient care (Parsell and Bligh 1999, Isoherranen 2012, Reeves et al. 2013). In recent years, the importance of combatting errors in patient safety has been recognized worldwide and interprofessional collaboration has been acknowledged as an essential contributor in minimizing adverse events and improving patient safety (Kohn et al. 2001, World Health Organization 2011). Due to the complexity and increasing requirements of today's health care, interprofessional collaboration has been identified as a critical factor in the provision of efficient and effective health care (Reeves et al. 2013). A strong argument is therefore being made for interprofessional education (IPE; e.g. education that involves two or more students from different health care disciplines learning together interactively) and teaching collaborative patient care practises in health care education. The process of implementing interprofessional patient-safety education in health care schools and universities is described by the World Health Organization in its Patient Safety Curriculum Guide (WHO 2011). This guide highlights the need for IPE and provides concrete tools for its integration in existing health-care curricula. The focus is on learning to work in multidisciplinary teams.

In Finland, the need to improve interprofessional co-operation in health care has been incorporated in national health and medicines policy (Ministry of Social Affairs and Health 2011, Finnish Medicines Agency 2012, Järvensivu et al. 2013). As IPE in health care education is the foundation of successful collaboration in working life, there is a strong need for incorporation of IPE into health care curricula. In a previous survey on health care students' views on IPE, conducted in 2010 at the University of Helsinki, medical students (n=104), dental school students (n=39) and pharmacy students (n=63) reported that only a few study modules in their curricula include IPE (Kurko T and Rahkonen O, unpublished data 2010). Even so, attitudes towards increasing IPE in the curricula are positive among these students. The staff perspective on implementation of IPE in the curriculum has not been studied extensively. Therefore, the purpose of this study was to gather evidence on the

status of IPE and to support inclusion of IPE in the pharmacy curriculum development at the Faculty of Pharmacy, University of Helsinki. Additionally, drivers of and barriers to IPE were identified and perceptions of future development needs defined.

## MATERIALS AND METHODS

This study was conducted as an online survey aimed for the staff at the Faculty of Pharmacy, University of Helsinki. The survey consisted of three subtopics supporting the defined research aims: current status of IPE, perceptions of IPE and future development needs of IPE at the Faculty. The survey contained 14 questions, 8 of which were open-ended and 6 structured questions with multiple choices (the survey is provided as supplementary information). One of the questions contained a set of 15 statements that aimed to assess the attitudes of the Faculty staff towards IPE (**Figure 1**). These statements were constructed based on the Readiness for Interprofessional Learning Scale (RIPLS) developed by Parsell and Bligh (1999).

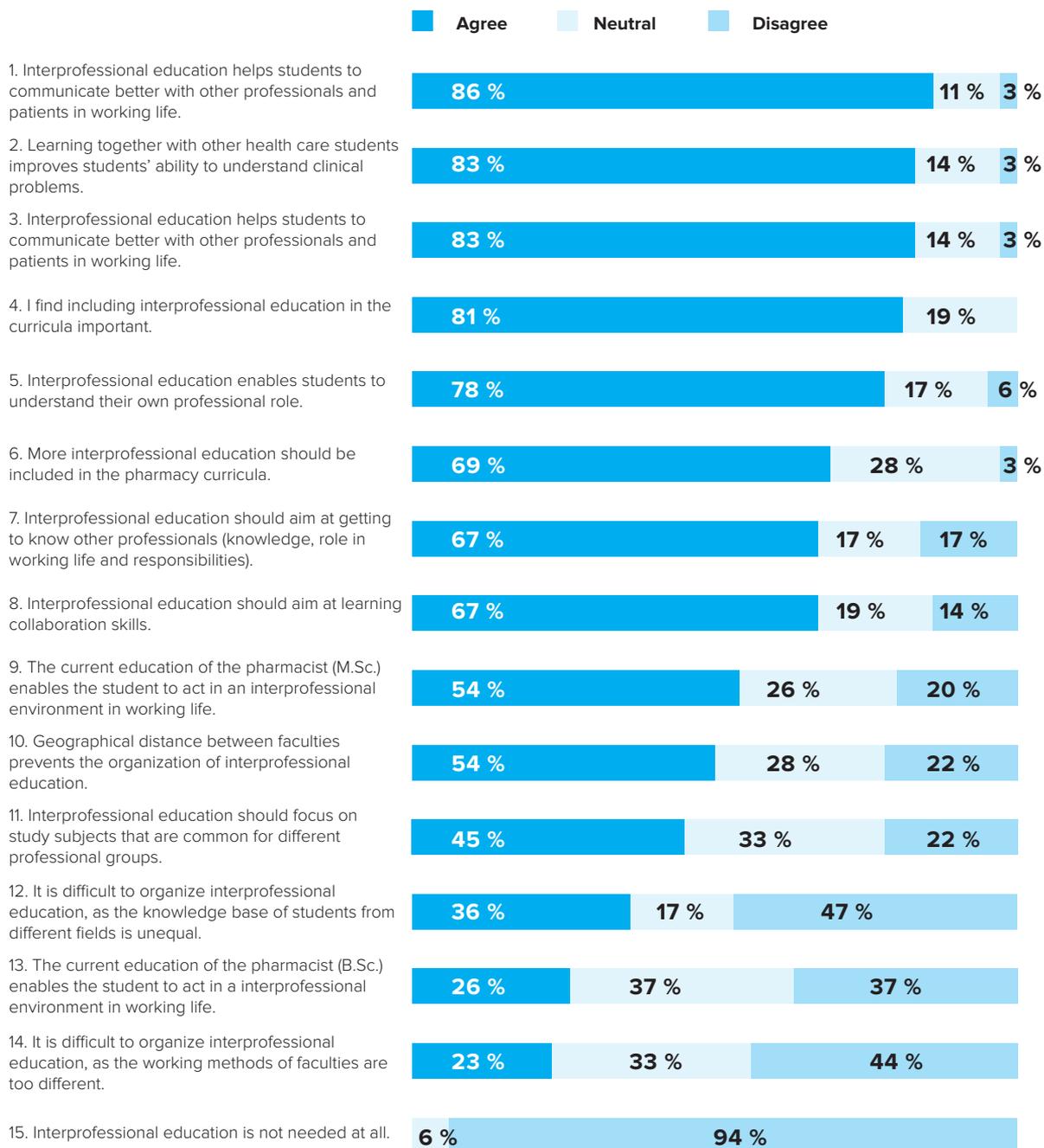
Seven staff members completed the pilot survey aimed to evaluate content and face validity. The pilot was followed by minor changes to the questions and the survey layout. The survey was distributed through the general e-mail list of all Faculty staff members (n=194) in April-May 2012. The survey was sent out in Finnish and English versions, which enabled both native and international staff to participate. After three reminders, completed responses were received from 36 staff members (response rate 19%) representing all Faculty divisions and the Centre for Drug Research, which operates as a part of the Faculty. Results were analysed using PASW Statistics 18 software. The results are presented as frequencies and percentages.

## RESULTS

### Characteristics of participants

Respondents consisted mainly of teaching and research staff at the Faculty of Pharmacy, including professors (n=5, 14% of the respondents), university lecturers (n=6, 17%), postdoctoral researchers (n=6, 17%), doctoral students (n=9, 25%) and researchers (n=2, 6%). Additionally, 22% of the respondents (n=8) belonged to other staff cate-

**Figure 1. Faculty staff (n=36) perceptions of interprofessional education (IPE), drivers and barriers, and future needs at the Faculty of Pharmacy, University of Helsinki.**



gories than the above-mentioned. A majority of respondents reported that they contribute to education at the Faculty as responsible person for a particular study module (n=21, 58%), as lecturer (n=24, 67%) or as teacher for small groups (n=26, 72%).

### Current situation and staff perceptions of IPE

Few jointly organized study modules (n=3) including IPE were carried out at the Faculty of Pharmacy at the time the survey was conducted. These contained a course on smoking cessation in collaboration with the Faculty of Medicine, a mass spectrometry course with the Faculty of Science and a course on veterinary medication in collaboration with the Faculty of Veterinary Medicine. These study module were optional, brief (3-4 ECTS) and mainly consisted of joint lectures.

Faculty staff perceived IPE as an important mechanism to ensure that pharmacy students have proper knowledge, skills and attitudes to practise together with other health care professionals in an effective way later in working life (**Figure 1**). Improved communication between professionals and patients was rated as a benefit of IPE by 86% (n=31) of respondents. A majority also reported that IPE should be implemented throughout the pharmacy curriculum and that it improves students' understanding of clinical problems and their own professional role (**Figure 1**). The Faculty of Medicine was reported as the most important collaborator in terms of IPE (rated as important or very important by 94% of the respondents).

### Drivers and barriers for IPE

Geographical distance was considered as a barrier to collaboration by 50% (n=18) of the respondents (**Figure 1**). Other reported barriers were lack of collaborative traditions and resources, as well as lack of mutual respect and understanding between educational/academic staff and students. On the other hand, open-mindedness and willingness to cooperate amongst both students and teachers were reported as key supportive factors. Common practice and mutual research projects were identified as drivers for IPE.

### Future needs

A majority (69%) of the respondents reported that there should be more interprofessional education

in the pharmacy curriculum (**Figure 1**). The staff viewed learning collaborative skills and getting to know other professionals as the most important aims of IPE. Besides common study subjects, such as biology and chemistry, also patient education and counselling, leadership and language skills were seen as important subjects in IPE.

## DISCUSSION

Our results indicate that even though IPE in the pharmacy curriculum at the University of Helsinki is limited to a few study modules, its importance is recognized by the faculty staff. IPE is seen as a tool to improve pharmacy students' skills to act as a part of interprofessional teams later in working life and help them communicate with both patients and other professionals. This encourages teachers and curriculum developers to devise new IPE modules and methods for the pharmacy curriculum at the University of Helsinki.

The drivers and barriers for IPE identified in the study can be divided into three main categories: structural (such as geographical location), attitudinal (such as prejudice) and economical (e.g., lack of resources to re-organize education). The staff perceives negative attitudes and prejudice as major barriers for IPE. The impact of attitudinal barriers was also recognized in a study by Brock et al. (2013). Brock and co-workers, however, demonstrated that the attitudes of health care students towards team communication can be improved by simulation-based team training. The drivers for IPE identified in this study should be strengthened, for instance, in form of increased research collaboration, which may contribute to decreasing attitudinal barriers amongst teaching and research personnel. Consequently, the barriers should be taken into account and minimized when developing IPE at the faculty. In practice, geographical barriers are challenging, since for instance, the Faculty of Medicine and Faculty of Pharmacy at the University of Helsinki are located in different campus areas. Developing new forms of interactive education, such as online study modules and virtual patient cases, could decrease the impact of geographical distance (Cook et al. 2010, Cavaco et al. 2012, Douglass et al. 2013).

Like the recommendation of the WHO Patient Safety Curriculum Guide (2011), the results of this study imply that IPE should be implemented

throughout the pharmacy curriculum. Integrating IPE from the very beginning of health care education enables students to learn collaborative practise while creating professional identity. According to the WHO Curriculum Guide (2011), the process of integrating interprofessional patient-safety education in a curriculum should begin with of mapping the content of existing education. The evaluation at the Faculty of Pharmacy at the University of Helsinki through this survey and other recent research focusing on students' perceptions is part of the effort to evaluate the content of existing education (Väänänen 2014). In a Cochrane review by Reeves et al. (2013), the authors were not able to draw general conclusions of IPE and its effectiveness. The impact of IPE in the pharmacy curriculum at the University of Helsinki must be evaluated throughout the curriculum development process, to ensure its effectiveness, both in terms of learning outcomes and use of resources.

The focus of IPE in the pharmacy curriculum that now is on shared teaching should be moved towards shared learning. Shared learning means that students gain collaborative skills by actively participating in the education (Parsell et al.1998). An applicable model for implementing IPE is the 3P model (presage, process and product) applied to IPE by Freeth and Reeves (2004). Given the fact that ability to work in interprofessional teams is needed in clinical practice, future IPE should focus also on clinical subjects such as patient safety (World Health Organization 2011). Patient safety is not a traditional stand-alone discipline, but rather integrates all areas of health care. While developing IPE at the Faculty, the current WHO Patient Safety Curriculum Guide and associated accessible learning resources may be utilized.

The Faculty of Pharmacy at the University of Helsinki conducted curriculum reform in its three-year bachelor of pharmacy program in 2012-2014. A major change in the new curriculum, started in 2014, was the creation and enhanced visibility of learning outcomes (Tiippana-Usvasalo et al. 2014). Additionally, the new curriculum was designed to provide students with generic skills needed to work in an environment where interprofessional team-based approaches to patient care are increasingly an imperative. These skills include interactive communication, teamwork and ability to make decisions in stressful situations. The idea of

life-long learning is fostered more openly. These skill-related learning outcomes were constructed together by students, teachers and various stakeholders. Eventually this development should lead to more interprofessional activities and cooperation in developing the courses. These aspects, as well as creation of better clinical skills are also taken into account in developing pharmacy internship and related theoretical studies, which are an essential part of the BSc curriculum (Pitkä et al. 2014). Changing the education of health care professionals towards interprofessional and patient-safety oriented curricula is nevertheless not enough: a strong dialogue with the professional field is also needed. Further research on the impact of IPE and the development needs of interprofessional collaboration both in curricula and working life is therefore vital in Finland, as well as internationally. Knowledge on existing interprofessional practise in working life should also be utilized.

This study was targeted to the staff of the Faculty of Pharmacy: therefore, viewpoints of other health care disciplines were not represented. On the other hand, including only one discipline enabled a more in-depth analysis. The relatively low response rate results from the fact that the survey was sent out to a large e-mail list, which also includes Faculty staff not participating in teaching activities. The questionnaire was not only sent to Faculty teachers, in order to include viewpoints of staff indirectly involved in teaching activities, such as laboratory assistants and administrators. In the future, the developed questionnaire could be used to analyse viewpoints on IPE of educators of other health care disciplines.

## CONCLUSION

The results of this study suggest that IPE in the pharmacy curriculum should be increased, which is in accordance with current recommended policy on IPE and patient care practise. The focus in future developments should be on student-oriented interprofessional education, preferably involving interactive learning and project work. The aim of IPE should be to improve skills and increase knowledge relevant in working life.

## TIIVISTELMÄ:

**Johdanto:** Moniammatillisen yhteistyön lisääminen terveydenhuollossa on tehokas keino parantaa potilasturvallisuutta. Tulevaisuuden ammattilaisten ryhmätyöskentelytaitoja voidaan vahvistaa moniammatillisella opetuksella, jossa opiskelijat useilta oppialoilta yhdessä harjoittelevat yhteistyötaitoja.

**Aineisto ja menetelmä:** Helsingin yliopiston farmasian tiedekunnassa toteutettiin keväällä 2012 koko henkilökunnalle sähköpostikysely, jossa selvitettiin tiedekunnan henkilökunnan näkemyksiä moniammatillisen opetuksen tilasta, sitä edistävästä ja estävästä tekijöistä sekä kehittämistarpeista. Kyselyyn vastasi 36 tiedekunnan henkilökunnan jäsentä.

**Tulokset:** Tiedekunnassa järjestetään vain muutamia (n=3) moniammatillista opetusta sisältäviä opintojaksoja, ja opetusmenetelmät tukevat vain harvoin opiskelijoiden välistä vuorovaikutusta. Moniammatillisen opetuksen toteuttamisen suurimpina esteinä nähtiin maantieteellinen etäisyys kampusten välillä sekä yhteistyöperinteiden ja resurssien puuttuminen, kun taas avoimuus, yhteiset toimintatavat ja jaetut tutkimusprojektit nähtiin edistävänä tekijöinä. Henkilökunta piti moniammatillisen opetuksen lisäämistä tarpeellisenä erityisesti opiskelijoiden työelämän yhteistyötaitojen parantamisen kannalta.

**Johdopäätökset:** Tulokset osoittavat ilmeisiä kehitystarpeita farmasian koulutusohjelmassa moniammatillisen opetuksen osalta. Henkilökunnan näkemysten mukaan moniammatillisessa opetuksessa tulisi keskittyä opiskelijälähtöiseen ja vuorovaikutteiseen opetukseen, joka parantaa opiskelijoiden yhteistyötaitoja ja sitä kautta terveydenhuollon tehokkuutta ja turvallisuutta. Nämä tarpeet on otettu huomioon tiedekunnan viimeaikaisessa koulutusohjelman kehittämistyössä.

**Avainsanat:** moniammatillinen opetus, farmasian koulutusohjelma, farmasian opetus

---

### →Katja-Emilia Lillsunde

proviisori, tohtorikoulutettava  
Farmaseuttisten biotieteiden osasto  
Farmasian tiedekunta  
Helsingin yliopisto

### →Outi Salminen

FaT, yliopistonlehtori  
Farmakologian ja lääkehoidon osasto  
Farmasian tiedekunta  
Helsingin yliopisto

### →Marika Pohjanoksa-Mäntylä

FaT, yliopistonlehtori  
Kliinisen farmasian ryhmä  
Farmakologian ja lääkehoidon osasto  
Farmasian tiedekunta  
Helsingin yliopisto

Kirjeenvaihto:

### →Katja-Emilia Lillsunde

katja-emilia.lillsunde@helsinki.fi

### →Marja Airaksinen

FaT, professori  
Kliinisen farmasian ryhmä  
Farmakologian ja lääkehoidon osasto  
Farmasian tiedekunta  
Helsingin yliopisto

## REFERENCES

Brock D, Abu-Rish E, Chiu CR et al: Interprofessional education in team communication: working together to improve patient safety. *Postgrad Med J* 89: 642-651, 2013 (republished)

Cavaco AM, Madeira F: European students' experience with virtual patient technology. *Am J Pharm Educ* 76(6): 106, 2012

Cook DA, Erwin PJ, Triola MM: Computerized virtual patients in health professions education: a systematic review and meta-analysis. *Acad Med* 85 (10): 1589–1602, 2010

Douglass MA, Casale JP, Skirvin JA, DiVall MV: A virtual patient software program to improve pharmacy student learning in a comprehensive disease management course, *Am J Pharm Educ* 77 (8): 172, 2013

Finnish Medicines Agency: Rational use of medicines through information and guidance. Medicines Information Services: Current State and the Strategy for 2020. Serial Publication Fimea Develops, Assesses and Informs 1:2012. [www.fimea.fi/download/21513\\_KAI\\_JULKAI-SUSARJA\\_Laakeinformaatiostrategia\\_1\\_2012\\_eng\\_links.pdf](http://www.fimea.fi/download/21513_KAI_JULKAI-SUSARJA_Laakeinformaatiostrategia_1_2012_eng_links.pdf)

Freeth D, Reeves S: Learning to work together: using the presage, process, product (3P) model to highlight decisions and possibilities. *J Interprof Care* 18: 43–56, 2004

Isoherranen K: Uhka vai mahdollisuus – moniammatillista yhteistyötä kehittämässä. Väitöskirja. Helsingin yliopisto, Sosiaalitieteiden laitos. Sosiaalitieteiden laitoksen julkaisuja 2012: 18, Unigrafia, Helsinki, 2012

Järvensivu T, Kumpusalo-Vauhkonen A, Mäntylä A: Lääkkeiden järkevän käytön kehittäminen moniammatillisissa tiimeissä ja verkostoissa. *Dosis* 29 (1) :11–19, 2013

Kohn LT, Corrigan JM, Donaldson MS (eds.): *To err is human – building a safer health system*. Committee on Quality of Health Care in America, Institute of Medicine. National Academy Press, Washington, D.C., USA, 2000

Ministry of Social Affairs and Health: Medicines Policy 2020. Towards efficient, rational and cost-effective use of medicines. Publications 2011:2. Available from: <http://apps.who.int/medicinedocs/documents/s19762en/s19762en.pdf> (accessed June 15, 2015)

Parsell G, Bligh J: The development of a questionnaire to assess the readiness of health care students for interprofessional learning (RIPLS). *Med Educ* 33: 95–100, 1999

Parsell G, Spalding R, Bligh J: Shared goals, shared learning: evaluation of a multiprofessional course for undergraduate students. *Med Educ* 32: 304–311, 1998

Pitkä K, Löfhjelm U, Passi S, Airaksinen M: Integrating Internships with Professional Study in Pharmacy Education in Finland. *Am J Pharm Educ* 78 (9): 173, 2014

Reeves S, Zwarenstein M, Goldman J et al: Interprofessional education: effects on professional practice and health care outcomes. *The Cochrane database of systematic reviews* 3, CD002213, 2013

Tiippana-Usvasalo M, Salminen O, Vuorensola K, Katjavuori N: Outcome-based approach to the curriculum reform – a case study in the Faculty of Pharmacy, University of Helsinki. *ICERI2014 Proceedings*: 4213–4221, 2014

Väänänen S: What a Bachelor's degree pharmacist should know about patient and medication safety? – Implementation in the Faculty of Pharmacy from a pharmacy students' perspective. Bachelor's thesis, University of Helsinki, 2014 (English abstract)

World Health Organization: *Patient Safety Curriculum Guide, Multiprofessional Edition*. WHO Press, Geneva, 2011

## SUPPLEMENTARY INFORMATION

Questionnaire on interprofessional education for the staff at the Faculty of Pharmacy is available upon request from the corresponding author.

# Massive Open Online Courses (MOOC): A Tool to Complement Pharmacy Education?

---

## → Pedro Inácio

Clinical Pharmacy Group  
Division of Pharmacology and Pharmacotherapy  
Faculty of Pharmacy  
University of Helsinki  
Finland

## → Afonso Cavaco

iMed.U LISboa Research Institute for Medicines  
and Pharmaceutical Sciences  
Faculty of Pharmacy  
University of Lisbon  
Portugal

Corresponding author:

## → Pedro Inácio

pedro.inacio@helsinki.fi

## ABSTRACT

**Background:** Massive Open Online Courses (MOOC) are a new phenomenon in e-learning. They allow for a free and flexible enrollment in courses provided by several universities in several areas of knowledge.

**Aims:** To investigate which courses provided by two MOOC platforms can be used to strengthen pharmacists' undergraduate training and knowledge.

**Methods:** Two MOOC platforms were selected and prospectively searched for courses that could be used to complement pharmacy undergraduate studies. The search was performed during June 2015. Only courses starting after June 2015 or were always available courses were selected.

**Results:** The search identified 27 courses covering a wide variety of topics in Biology and Life Sciences, Health and Society, Medicine, and management that could potentially be used to complement pharmacy undergraduate training.

**Conclusion:** MOOCs propose interesting opportunities to further develop the skills of pharmacy undergraduates. However, it is not evident that validation of the knowledge provided through these courses, teaching quality and grading has been done. Further studies regarding MOOCs and pharmacy education are needed.

**Keywords:** pharmacy education, pharmacy, MOOC, e-learning, knowledge assessment

**Competing Interests:** The authors have declared that no competing interests exist.

## INTRODUCTION

Distance learning is not a new phenomenon. The first correspondence courses were set up in the middle of the 19th century, and by the end of the century several institutions were offering courses in several topics. With the aim of widening higher education access, the Open University was created in the United Kingdom (The Open University). At the time, it revolutionized the way correspondence training was delivered, and created an alternative to the traditional form of higher education. Further technological improvements, such as the radio, television or video recorders helped to expand the audience for distance learning. With the development of the Internet and increased online presence, several institutions started to offer online courses. In the meantime, higher education is changing. In Europe, universities are having to adapt to societal and economic changes, while improving accessibility and the quality of teaching. Improved quality seems to be linked to the strengthening of the role of technology and online courses, research and innovation (European University Association). The arrival in 2012 of Massive Open Online Courses (MOOCs) could contribute to improving the access, quality and cost-effectiveness of higher education, while at the same time broadening and innovating the way learning is done (European University Association).

A MOOC is an online course, with open access via the web that enables the participation of a wide range of students (Fionna M. Hollands 2014). The course provides a set of course materials such as videos, reading materials, quizzes and assignments. In addition to the traditional course materials, it allows for interaction between participants through social media communities. Teaching is done by leading scientists and professors of reputed Universities and institutes, such as Johns Hopkins University or Karolinska Institutet. These classes are then available through the MOOC platforms. The MOOCs is still evolving, mostly because of issues about the meaning of “massive” and “open”. Data available from the several MOOC platforms show that MOOCs are already providing educational resources to millions of

students worldwide. The number of MOOCs, and the demand for them, is growing (Andrew P. Kelly 2015). Currently, there are several online platforms offering MOOCs, such as edX, Coursera, Udacity, among others. In Europe, the adoption of this type of technology has been more subdued than in the United States (European University Association).

Pharmacy is a healthcare profession that requires a high level of education and training. In Europe, it involves at least three years of full-time theoretical and practical studies at a university, combined with internships in community and/or hospital pharmacies, under supervision of the pharmaceutical director of the institution (Anonymous).

Due to the ever changing nature of pharmaceutical innovation, knowledge acquired has to be constantly updated. Pharmacists have seen their role increasing in patient counseling, pharmaceutical care and medication reviews in the past few decades (Inoue, Takikawa et al. 2015).

However, pharmaceutical science programs have been primarily designed to train students and conduct academic research much in the same manner as it has been for decades (American College of Clinical Pharmacy). A reorientation of pharmacy education towards different teaching methods is necessary. Pharmacist training should combine the accumulation of knowledge with the acquisition of a set of cognitive and non-cognitive skills during undergraduate and at a professional level (Katajavuori, Hakkarainen et al. 2009). The arrival of MOOCs could help achieve this.

The aim of this study is to investigate which courses provided by two MOOC platforms can be used to strengthen pharmacists' undergraduate training and knowledge.

## METHODS

There are several available platforms providing MOOCs. Two of these are edX and Coursera. EdX is a non-profit MOOC provider founded by the Massachusetts Institute of Technology and Harvard University in 2012. As of May 2015 offers over 500 courses in several areas. Coursera is a for-profit organization, created in 2012. It offers more than

1000 courses, and by May 2015 had over 13 million enrolled students.

As standard comparison, the syllabus of pharmacy degrees offered by two European universities were obtained. The chosen universities were the University of Lisbon and the University of Helsinki. Both universities offer a master degree in pharmaceutical sciences, with study duration of 5 years. Furthermore, both universities have their syllabus adapted to the Bologna Process, which were designed to ensure comparability in the standards and quality of higher education qualifications in the European Union (Anonymous). The prospective search was performed on course offerings at both universities during June 2015. A search was then performed at both MOOC platforms. The criteria for the consideration of which courses would be relevant were: a) relevance of the topic for pharmacy education; b) relevance of the topic to complement the university syllabus; and c) period that the courses would be online. The search was confined to the fields Biology and Life Sciences, Health and Society and Medicine, present in both platforms.

For each course, the content of the MOOC was reviewed and checked against the syllabus of both the University of Lisbon and the University of Helsinki pharmacy course offering to investigate their relevance. The university or institute providing the MOOC was identified, as well as the length of the course and if a certificate could be earned. Only courses that are either available online or would be available in June 2015 or later were considered.

Since this was an exploratory study, no pre-analytical hypotheses were formulated and an open descriptive design was utilized with no power sample calculations and statistical representativeness aims.

## RESULTS

The search identified 27 courses that could be considered relevant to pharmacy education (**Table 1**). Coursera was the one offering quantitatively more courses than edX. Although the main field Biology and Life Sciences, Health and Society and Medicine were chosen, the search identified several courses that integrate other important skills. Examples

of this are “Enhance your Career and Employability Skills” by University of London, and “Successful Negotiation: Essential Strategies and Skills” by University of Michigan. Many courses seem to have the potential to complement and enhance pharmacy students’ skills. The topics range from undergraduate ones to more complex topics. Coursera seems to offer a larger number set of advanced studies courses, such as “Introduction to Systematic Reviews and Meta Analysis” from The Johns Hopkins University. Also Coursera offers courses with topics that can complement final undergraduate pharmacy studies, such as “Successful Negotiation: Essential Strategies and Skills” by the University of Michigan and “Interprofessional Healthcare Informatics” by the University of Minnesota.

American are offering more courses than European universities, while some Asian universities also offer courses. Regardless of geographic origin, most of the courses had the possibility of earning a certificate degree. Some courses don’t indicate the total duration of the course, which can range from 7 hours of explanatory videos to 15 weeks of video tutorials and assignments.

## DISCUSSION

MOOCs are a relatively recent innovation, and are a new addition to the existing online learning options. They have been described as a “disruptive innovation” due to the possibility of exponentially expand access to education and career preparation for millions of people for a fraction of the cost of attending a university physical classroom (Andrew P. Kelly 2015). MOOCs are expected to provide flexibility for students to create their own programs with courses from various institutions, and provide means for continuing education and professional development. Students can acquire new skills that might not be associated with a particular degree. For example, a pharmacy student could enroll in an English literature and grammar course.

MOOCs have been received with enthusiasm because of the potential to provide knowledge through new pedagogic approaches within reach of an unimaginable number of learners. However, there is no indication so far that MOOCs will rep-

**Table 1. Selected courses from the edX and Coursera platforms that could be used to strengthen pharmacists' undergraduate training and knowledge.**

| Platform   | Name of course  | Possibility of earning a certificate | Provider  | Length of study / Hour workload |
|--|---|--------------------------------------|---|---------------------------------|
| edX ( <a href="http://www.edx.org">www.edx.org</a> )                         |   |                                      |   |                                 |
|  | Essential Human Biology: Cells and Tissues  | Yes                                  | University of Adelaide, Australia                     | 5 weeks                         |
|  | Principles of Biochemistry  | Yes                                  | Harvard University, USA                               | 15 weeks                        |
|  | The Immune System: New Developments in Research   | Yes                                  | University of Osaka, Japan                            | 5 weeks                         |
|  | Fundamentals of Neuroscience  | No                                   | Harvard University, USA                               | 12 weeks                        |
|  | The Chemistry of Life   | Yes                                  | University of Osaka, Japan                            | 15 weeks                        |
|  | Human Anatomy   | Yes                                  | The Hong Kong Polytechnic University, Hong Kong       | 8 weeks                         |
|  | Medicating for Mental Health: Judicious Use of Psychiatric Drugs                          | Yes                                  | Colgate University, USA                               | 4 weeks                         |
|  | Epidemics: The Dynamic of Infectious Diseases   | No                                   | University of Hong Kong, Hong Kong                    | 10 weeks                        |
|  | Making Biologic Medicines for Patients: The Principles of Biopharmaceutical Manufacturing | Yes                                  | Massachusetts Institute of Technology, USA            | 6 weeks                         |
|  | Genomic Medicine Gets Personal  | Yes                                  | Georgetown University, USA                            | 8 weeks                         |
|  | Cellular Mechanisms of Brain Function   | Yes                                  | École Polytechnique Fédérale de Lausanne, Switzerland | 8 weeks                         |
| Coursera ( <a href="https://www.coursera.org">https://www.coursera.org</a> ) |   |                                      |   |                                 |
|  | Statistical Reasoning for Public Health: Estimation, inference & interpretation           | Yes                                  | The Johns Hopkins University, USA                     | 8 weeks                         |
|  | Solid Science: Research Methods   | No                                   | University of Amsterdam, The Netherlands              | 6 weeks                         |
|  | Interprofessional Healthcare Informatics  | Yes                                  | University of Minnesota, USA                          | 7 h of videos                   |
|  | HIV: Fear and Hope  | No                                   | University of Michigan, USA                           | 7 weeks                         |

|  |  |     |  |                 |
|--|--|-----|--|-----------------|
|  | Clinical Terminology for International and U.S. Students                       | Yes | University of Pittsburgh, USA            | 6 weeks         |
|  | Introduction to Systematic Reviews and Meta Analysis                           | Yes | The Johns Hopkins University, USA        | 6 weeks         |
|  | Successful Negotiation: Essential Strategies and Skills                        | Yes | University of Michigan, USA              | 8,5 h of videos |
|  | Enhance your Career and Employability Skills                                   | Yes | University of London, UK                 | 6 weeks         |
|  | Sinapses, Neurons and Brains   | Yes | Hebrew University of Jerusalem, Israel   | 16 h of videos  |
|  | Genes and the Human Condition (From Behavior to Biotechnology)                 | Yes | University of Maryland, USA              | 15 h of videos  |
|  | Epidemics: The Dynamic of Infectious Diseases                                  | Yes | Pennsylvania State University, USA       | 20 h of videos  |
|  | The Challenges of Global Health  | Yes | Duke University, USA                     | 16h videos      |
|  | Learning How to Learn: powerful mental tools to help you master tough subjects | Yes | University of California, San Diego, USA | 5 weeks         |
|  | Mathematical Biostatistics Boot Camp 1   | Yes | The Johns Hopkins University, USA        | 7 weeks         |
|  | Introduction to Genomic Technologies   | Yes | The Johns Hopkins University, USA        | 4 weeks         |
|  | Fixing Healthcare Delivery   | Yes | University of Florida, USA               | n.a.            |

lace traditional higher education. Questions about the state of traditional student learning have created an appetite for new technologies. They are a tool, not an end in itself (Andrew P. Kelly 2015).

It is the flexibility and possibility of complementing the skills gained through traditional education that can make MOOCs interesting for pharmacy education. The nature of pharmacy is evolving to a more patient-centered focus (American College of Clinical Pharmacy). The provision of technical knowledge to fulfill this obligation requires the integration of such diverse skills, such as clinical pharmacotherapy, public health, communication, leadership, management, health information technology, as well as a solid training

in the pharmaceutical disciplines. Pharmacy requires life-long learning (Salter, Karia et al. 2014). For this, MOOCs could add a new dimension to teaching. Online learning allows the flexibility for students to pursue their training (Mesquita, Souza et al. 2015). MOOCs can be a tool to enhance pharmacy students' training because there are courses that can help students grasp better certain specific areas, such as immunology and anatomy, as well as develop more advanced skills, such as statistical research methods. Of particular interest are the courses "Enhance your Career and Employability Skills" offered by University of London and "Inter-professional Healthcare Informatics" by the University of Minnesota, as they focus on topics which

are often not well developed during pharmacy studies. For example, the course “Learning How to Learn: powerful mental tools to help you master tough subjects” by the University of California, San Diego can help students develop a better study rhythm (Schneider, Castleberry et al. 2014).

There are differences between the MOOC providers, even though the pedagogic approach is very similar. The results showed that edX offers courses especially suited for early undergraduate studies, whilst Coursera has courses with more advanced scientific content. One of the biggest drawbacks with MOOCs is the rate with which courses are created. Although it is possible to assess some of them after the period in which they are running, it is no longer possible to get a verified certificate. Ideally, courses should follow the “learn at your own pace” which is featured in some courses, allowing for students to join at any time. For that, student evaluation tools would have to be adjusted.

To date, there has been little evidence collected to assess if MOOCs offer a cost-effective mechanism for producing the desirable educational outcomes of scale (Fionna M. Hollands 2014). There has not been a proper evaluation of the value of these courses, provide in terms of enhancing the training of students. Furthermore, two of the biggest issues facing the acceptance of MOOCs is the grading methodology, and the completion rate of the courses. The evaluation relies too much on peer-evaluation, and the assignments vary in terms of difficulty. It is very easy to drop from the courses, entailing no penalties. The certification of participants remains low (European University Association).

The possibility of credits being attributed to

MOOC courses is still contentious, which has mostly to do with the official recognition of these courses. Even though universities themselves provide the teaching, earning credits is still seen as an exclusive of attending a physical classroom. This is changing, however slowly (European University Association). There is room for increasing the role of technology in higher education. To continue to gain followers and validation, MOOCs need to find the balance between automating the assessment process while delivering personalized, authentic learning opportunities.

## CONCLUSION

Changing demographics and trends in higher education means that new solutions are needed. MOOCs could alleviate physical higher education infrastructure constraints and accommodate the growing demand for postsecondary education, provide flexibility, new skills, and further development of university study topics. MOOCs have been presented as remedy for the challenges of higher education. The present study shows that MOOCs propose interesting opportunities to further develop the skills of pharmacy undergraduates. However, there is still a long way to go in terms of acceptance, validation of the knowledge provided through these courses and teaching quality and grading. Further studies regarding MOOCs and pharmacy education are needed.

## TIIVISTELMÄ

**Tausta:** Avoimet massaverkkokurssit (Massive Open Online Courses MOOCs) ovat uusi ilmiö verkko-oppimisessa. Ne mahdollistavat ilmaisen ja joustavan tavan osallistua monien yliopistojen kursseille monilla eri tieteenaloilla.

**Tavoitteet:** Tavoitteena oli tutkia, mitkä kahden avoimia massaverkkokursseja tarjoavan alustan kurseista soveltuisi farmasian perusopetukseen vahvistamaan koulutustarjontaa ja opiskelijoiden tietopohjaa.

**Menetelmä:** Kaksi avoimia massaverkkokursseja tarjoavaa alustaa valittiin ja niistä etsittiin ennakoivasti kursseja, jotka soveltuisivat täydentämään farmasian perusopintoja. Haku tehtiin kesäkuussa 2015. Vain kurssit, jotka alkavat kesäkuussa 2015 tai sen jälkeen tai ovat aina saatavilla, valittiin.

**Tulokset:** Haulla löydettiin 27 kurssia, jotka voisivat soveltua täydentämään farmasian perusopintoja. Kurssien aiheet kattavat laajasti biologiaa ja luonnontieteitä, terveyttä, yhteiskuntaa ja lääketiedettä sekä yleisiä taitoja, kuten johtamistaidot.

**Pohdinta ja päätelmät:** Avoimet massaverkkokurssit (MOOCs) avaavat mielenkiintoisia mahdollisuuksia kehittää farmasian perusopiskelijoiden taitoja. Kuitenkin kurssien tarjoaman tiedon, opetuksen ja oppimisen arvioinnin laatu tulisi arvioida. Lisää tutkimusta tarvitaan avointen massaverkkokurssien soveltamisesta ja soveltuvuudesta farmasian opetukseen.

**Avainsanat:** farmasian opetus, farmasia, MOOC, verkko-oppiminen, tiedon arviointi

**Sidonnaisuudet:** Kirjoittajilla ei ole tähän artikkeliin liittyviä sidonnaisuuksia.

---

Kirjeenvaihto:

→ [Pedro Inácio](#)

pedro.inacio@helsinki.fi

## REFERENCES

- American College of Clinical: Standards of Practice for Clinical Pharmacists
- Anonymous The Bologna Declaration of 19 June 1999 (accessed 28 June 2015). [www.eua.be/eua/jsp/en/upload/OFFDOC\\_BP\\_bologna\\_declaration.1068714825768.pdf](http://www.eua.be/eua/jsp/en/upload/OFFDOC_BP_bologna_declaration.1068714825768.pdf)
- Association, E. U. Massive Open Online Courses – January 2014 (accessed 28 June 2015). [www.eua.be/Libraries/Publication/MOOCs\\_Update\\_January\\_2014.sflb.ashx](http://www.eua.be/Libraries/Publication/MOOCs_Update_January_2014.sflb.ashx)
- Association, E. U. Massive Open Online Courses - January 2014 (accessed 8 June 2015). [www.eua.be/Libraries/Publication/MOOCs\\_Update\\_January\\_2014.sflb.ashx](http://www.eua.be/Libraries/Publication/MOOCs_Update_January_2014.sflb.ashx)
- Association, E. U. Trends: Learning and Teaching in European Universities, 2015. Available from: [http://www.eua.be/Libraries/Publications\\_homepage\\_list/EUA\\_Trends\\_2015\\_web.sflb.ashx](http://www.eua.be/Libraries/Publications_homepage_list/EUA_Trends_2015_web.sflb.ashx)
- Fionna M. Hollands, Devayani Tirthali: MOOCs: Expectations and Reality, 2104 (accessed 14 May 2015). [www.academicpartnerships.com/sites/default/files/MOOCs\\_Expectations\\_and\\_Reality.pdf](http://www.academicpartnerships.com/sites/default/files/MOOCs_Expectations_and_Reality.pdf)
- Inoue, Y., M. Takikawa, Y. Morita, K. Takao, I. Kanamoto and K. Sugibayashi: A comparison of pharmacists' role functions across various nations: The importance of screening. *Res Social Adm Pharm* 2015.
- Katajavuori, N., K. Hakkarainen, T. Kuosa, M. Airaksinen, J. Hirvonen and Y. Holm: Curriculum Reform in Finnish Pharmacy Education. *American Journal of Pharmaceutical Education* 73(8): 151, 2009
- Kelly, A. P. Disruptor, Distractor, or What? A Policymakers's Guide to Massive Open Online Courses. Bellwether Education Partners, 2014. Available from: [http://bellwethereducation.org/sites/default/files/BW\\_MOOC\\_Final.pdf](http://bellwethereducation.org/sites/default/files/BW_MOOC_Final.pdf)
- Mesquita, A. R., W. M. Souza, T. C. Boaventura, I. M. C. Barros, A. R. Antonioli, W. B. Silva and D. P. Lyra Júnior: The Effect of Active Learning Methodologies on the Teaching of Pharmaceutical Care in a Brazilian Pharmacy Faculty. *PLoS ONE* 10 (5), 2015
- Pharmacy, A.C.o.C.: A vision of pharmacy's future roles, responsibilities, and manpower needs in the United States. *Pharmacotherapy* 20 (8): 991–1020, 2000
- Salter, S. M., A. Karia, F. M. Sanfilippo and R. M. Clifford: Effectiveness of E-learning in Pharmacy Education. *American Journal of Pharmaceutical Education* 78 (4): 83, 2014
- Schneider, E. F., A. N. Castleberry, J. Vuk and C. D. Stowe: Pharmacy Students' Ability to Think About Thinking. *American Journal of Pharmaceutical Education* 78 (8): 148, 2014
- University, T. O. The Open University Annual Report 2013–2014 (accessed 28 June 2015). [www.open.ac.uk/about/main/sites/www.open.ac.uk/about.main/files/files/ecms/web-content/about-annual-report-2013-14](http://www.open.ac.uk/about/main/sites/www.open.ac.uk/about.main/files/files/ecms/web-content/about-annual-report-2013-14)

# The Danish Pharmacy Act 2015: amendments concerning community pharmacies

---

## →Siva Prasada Reddy

### Maddirala Venkata

MPharm, RPh, PhD Student  
Clinical Pharmacy Group, Division of  
Pharmacology and Pharmacotherapy  
University of Helsinki, Finland

Taastrup Pharmacy  
Taastrup Hovedgade 60  
Taastrup, DK-2630, Denmark  
prassu117@yahoo.com

## →Peter Kielgast

PhD, Proprietor Pharmacist  
Taastrup Pharmacy  
Taastrup Hovedgade 60  
Taastrup, DK-2630, Denmark  
taastrup@apoteket.dk

Corresponding Author:

## →Siva Prasada Reddy

### Maddirala Venkata

prassu117@yahoo.com

---

## ABSTRACT

On April 28, 2015, Danish Parliament adopted a new Pharmacy Act, which will become law on July 1, 2015. The law officially recognizes community pharmacies as a part of primary health care system in Denmark. Pharmacies are subject to comprehensive state regulation by the Danish Medicines Agency with regard to product prices, location, and number of pharmacies. Legislation allows existing pharmacies to compete with other pharmacies and open up to seven branch pharmacies, including shop-in-shop pharmacies within 75km radius of the main pharmacy. This will create new opportunities for pharmacies to help and support patients by offering mandatory additional services, such as medication interviews for chronic patients when referred by a physician, changes in subsidies to operate pharmacy units, open up of new online-pharmacies and regulations on product range that pharmacies can sell other than medicines.

**Key words:** Denmark, Pharmacy Act, Amendments in Pharmacy Act, Pharmacies in Denmark

## INTRODUCTION ON PHARMACY ACT AND PHARMACY SYSTEM IN DENMARK

Amendments to the Danish Pharmacy Act will become law on July 1, 2015 (Danish Act on Pharmacy Practice 2015). These amendments officially recognize community pharmacies as a part of the primary health care system in Denmark. Pharmacies are regulated by the Danish Medicines Agency and the Ministry of Health (Danish Act on Pharmacy Practice 1995). As in many other European Union countries, a pharmacy is a licensed business owned by a pharmacist (MSc), who may also own up to four pharmacy outlets or independent pharmacies at the same time. The owner is economically responsible for financing and operating his or her pharmacy business (The Danish Pharmacy Owners Association 2015).

Denmark has a population of 5.5 million. As of 2014, there are 221 privately owned pharmacies, 17 supplementary pharmacy licences, 73 branch pharmacies and 116 pharmacy outlets served only by pharmaconomists with 3 years professional education (with 180 ETCS points, Danish College of Pharmacy Practice 2007) to fulfill the medicine needs of the population. Apart from these, in rural or scarcely populated areas there are 600 non-pharmacy outlets selling over-the-counter medicines under supervision of a pharmacy and 250 medicine delivery/pick-up facilities located in local corner stores where the pharmacy delivers medicines in sealed packets (Herborg et al. 2007, Danish Medicines Agency 2015).

The objective of this review is to give an overview of the Pharmacy Act in Denmark and to briefly elaborate the new legislative amendments in the pharmacy sector.

### ESSENCE OF THE AMENDMENTS TO THE PHARMACY ACT

It is still true that it is the pharmacist who can own a pharmacy and still true that the Danish Medicines Agency in cooperation with the Ministry of Health who decide who can be the owner of a pharmacy (Danish Act on Pharmacy Practice 2015). The politicians and policy makers are trying to create more competition between pharmacies, without involv-

ing supermarkets, other types of chains as owners. The new law gives the opportunity to compete with other pharmacies by opening up to seven branch pharmacies, including shop-in-shop pharmacies within 75km radius of the main pharmacy. This creates new opportunities for pharmacies to offer additional services to the patients, such as mandatory medication interviews for chronic patients when referred by a physician. Changes in subsidies to operate pharmacy units, open up of new “online only” pharmacies and limitations on product range that the pharmacies can sell other than medicines.

### PHARMACY ACT IN DENMARK

The Danish Pharmacy Act prescribes regulations for pharmacy operations in Denmark, including the conditions under which pharmacy licenses are granted. The Act also establishes the functions that pharmacies are responsible for, as well as the conditions for establishing, moving and closing pharmacy units. Furthermore, the Act contains provisions on regulatory inspection and control of pharmacies and its activities. The amendments reconfirm that pharmacies are part of health care sector which opens new opportunities for pharmacies to help and support patients. These amendments mainly deal with freer accesses to establish new branch pharmacies, veterinary departments and pharmacy outlets. They change procedure of Danish Medicines Agency on the announcement and grants of pharmacy licenses and selection of pharmacy owners for hospital pharmacies and repealing government guaranteed loan to the pharmacies. These elements are discussed briefly in the following sections.

### ADOPTION PROCESS OF THE NEW PHARMACY ACT

In 2009, politicians and the policy makers were to determine whether the liberalization of veterinary drugs should be extended to the human field. The Danish Minister of Health introduced a legislative proposal with the purpose of “modernizing the pharmacy sector”. Many proposals have been in play for liberalization both from politicians and commercial stakeholders. The pressure from commercial stakeholder for liberalization has often been strong. However, the new Danish Pharmacy

Act modernizes the regulation but does not liberalize pharmacy sector completely like it was done in Sweden and Norway. Though there are challenges both financially and practically, the professional bodies in pharmacy sector see this new Act as a positive result, as the sector is not open for commercial stakeholders.

## **FULL MAJORITY AT THE PARLIAMENT IN DENMARK**

After years of attempts, on 28th April 2015, Danish Parliament finally adopted a new pharmacy act. Of total 102 votes, 97 parliamentarians voted in favor of adopting the new pharmacy act. No one voted against and there were 5 abstentions, which shows that all the political parties supported the new Act. It is therefore less likely that there will be another political debate on liberalization again soon. Politicians and policy makers in Denmark have made clear that pharmacies are part of the health care sector. Politicians have "approved" that pharmacies are the only organizations which have right to sell medication and counsel patients on their use.

## **FREEDOM TO ESTABLISH UP TO SEVEN BRANCHES WITHIN 75 KM**

As per the new Act, an existing licensed pharmacy can freely establish up to seven branches within a radius of 75 km from the main pharmacy. It is also possible to set up branches in supermarkets, emergency clinics and hospitals. The existing owner pharmacist has also freedom to move into new premises, close down a branch pharmacy or pharmacy outlets under the same license. A pharmacy owner may not operate a maximum of eight prescription-handling units, thereof veterinary departments of pharmacies and medicine delivery units are not included. A pharmacist closing down a pharmacy branch may only sell interior, furniture and inventory at a price that does not exceed its book value, thus, no goodwill will be paid. The state would not economically guarantee the pharmacy business anymore by issuing loan guarantees. The future/upcoming pharmacy owners have to find their own finance resources and develop economic plans.

## **SHOP-IN-SHOP BRANCH PHARMACIES**

The pharmacy owners can now open shop-in-shop branch pharmacies. Ensuring precise framework for shop-in-shop pharmacies has been an important objective of the legislation, which is in the process. In such shop-in-shop pharmacies, there should be a clear economical, physical and visual separation between the pharmacy and host store. Detailed guidelines in this regard are being worked out by the Ministry of Health in coordination with Danish Medicines Agency.

## **ADDITIONAL SERVICES TO THE PATIENTS**

The new legislation requires that all pharmacies should offer medication interviews and on top of that, more services to be offered on debate. According to the new Act, pharmacies are obliged to provide medication interviews to newly diagnosed chronic patients. It must be offered to the patients by referral from a doctor. Interviews with the patients should be about adherence and must be provided by pharmacists. The conversation requires a prior appointment and cannot be done at the counter. Generally, such interviews are expected to take 15–20 minutes. At least 14 days before, the pharmacy must provide information to the patient on when and where the interview will take place. The services should be provided to the patient free of cost. Hence, the pharmacies need to make strategies to sustain economically. This part of the law takes effect from January 1, 2016.

At the next gross negotiations about pharmacy profit margin for the sale of prescription medicines between the Ministry of Health and Pharmacy owners Association, the politicians will also discuss the medication reviews for chronic patients. However, before they make final decision about including medication reviews for chronic patients, a pilot project on a small population will be conducted. The politicians have also identified the opportunities about the pharmacist prescribing and want to debate a proposal to do this.

## E-PHARMACIES

The Act has provision for two “internet only pharmacies”. Today, a physical pharmacy can operate an online-pharmacy, but as per the new Act, two “internet only pharmacy” licenses will be issued and these can be operated without having a physical pharmacy store involved. The Executive Order on the internet pharmacies is on its way, which will define the obligatory services that must be offered by these e-pharmacies. Patients must have opportunities like online text-chat, webcam-chat, e-mail or phone, to contact internet pharmacies for patient counseling. Information and counseling must be offered to patients buying medicine online and it should be available during normal pharmacy business hours.

## SUBSIDIES TO RUN BRANCH PHARMACIES

Currently, Danish pharmacies are financially guaranteed by offering subsidies by the government to operate branch pharmacies and pharmacy outlets. These subsidies will be exempted in a phased manner over 5 years, between 2017 and 2022. Pharmacies operating branches in a radius of 10 km from the main pharmacies will not receive subsidies. Only branch pharmacies handling the prescription medicine located more than 10 km will get the subsidies. The Ministry of Health will assess individual cases of branches close to the 10 km limitation. Subsidies for supplementary units will lapse. Pharmacies operating pharmacy outlets in less than 5km radius from the prescription handling unit will also not receive subsidies. The equalization scheme, a profit sharing scheme which means more profit gaining pharmacies must contribute their wealth with less profit gaining pharmacies, to provide better access in rural and remote areas, is being maintained as it is in the current Act.

## REGULATIONS ON PRODUCT RANGE AT THE PHARMACIES

The Danish Medicines Agency will establish the rules on products other than medicines that the pharmacies can sell. There will be positive and negative lists. The positive list includes medical devices, condoms, plaster, pregnancy and other test devices, nutritional supplements, including vita-

mins, hygiene products, including creams, shampoo, toothpaste, sunscreen products, cleansers, toothbrushes, etc. The draft negative list includes kitchen equipment, clothes, shoes, bags, toys, books, groceries, candy, mints, spices, and cosmetics like perfumes, nail polish, mascara, etc.

## PRESENCE OF PHARMACIST

Presence of pharmacist (Master of Science in Pharmacy) throughout the pharmacy opening hours is maintained, which also applies to supplementary units. It is not mandatory to have a pharmacist present at the branch pharmacy, but the pharmacist from main pharmacy should be accessible at any point throughout the operating hours. There must be at least a pharmacist present during operating hours per 3 pharmacies/branch pharmacies and other professional staff could include pharmaconomists.

## PHARMACY OPENING HOURS

Currently, Denmark has a limited number of 24/7 pharmacies under special regulations and benefits. This 24/7 operation will be completely revised in the amended Act. Current 24/7 operating rules will be abolished and replaced by about 34 pharmacies with longer operating hours from 06:00 to 24:00 hours all week days. There will be no more compulsory 24/7 pharmacies running with subsidies. As per the new amendments, any pharmacy can obtain permission to operate 24/7, but without subsidies. Pharmacies with long operating hours must offer home delivery to citizens when it is decided by a doctor as a result of an accident or an emergency service.

### Time frame for the implementation:

- The amended Pharmacy Act takes effect on July 1, 2015.
- Obligatory medicine interviews to newly diagnosed chronic patients takes effect January 1, 2016.
- Regulations on pharmacies with long operating hours will take effect January 1, 2017.
- Regulations on subsidies to run branch pharmacies/pharmacy outlets will be implemented between 2017–2022.

## REFERENCES

Danish Act on Pharmacy Practice. Order no. 580, May 5, 2015 (Bekendtgørelse af lov om apoteksvirksomhed. LBK nr. 580 af 04/05/2015). [www.lovtidende.dk/pdf.aspx?id=169966](http://www.lovtidende.dk/pdf.aspx?id=169966). Accessed on June 8, 2015

Danish Act on Pharmacy Practice. Order no. 657, July 28, 1995 with later amendments (Bekendtgørelse af lov om apoteksvirksomhed. LBK nr. 657 af 28/07/1995 med senere Ændringer)

Danish College of Pharmacy Practice: Curriculum: Danish Education of Pharmaconomists. Danish College of Pharmacy Practice, September 2007. [http://net.pharmakon.dk/data/files/FkU/Uddannelsesordning\\_UK.pdf](http://net.pharmakon.dk/data/files/FkU/Uddannelsesordning_UK.pdf). Accessed June 25, 2015

Danish Medicines Agency: Number of Pharmacies in Denmark. <http://sundhedsstyrelsen.dk/en/medicines/sale/pharmacies>. Accessed on June 7, 2015.

The Danish Pharmacy Owners Association (Apotekerforeningen): Information on Pharmacy sector in Denmark. [www.apotekerforeningen.dk/~media/Apotekerforeningen/pdf/Information%20in%20English%20%20nyt%20apotekerforeningen%20dk.ashx](http://www.apotekerforeningen.dk/~media/Apotekerforeningen/pdf/Information%20in%20English%20%20nyt%20apotekerforeningen%20dk.ashx). Accessed June 25, 2015

Herborg H, Sørensen EW, Frøkjær B: Pharmaceutical Care in Community Pharmacies: Practice and Research in Denmark. *Ann Pharmacother* 41: 681-689, 2007

Starup P: Apotekerlov vedtaget af bredt flertal. *Farmaci*, nr 5: 16-17, 2015. [www.apotekerforeningen.dk/Farmaci/~media/Apotekerforeningen/fagbladetfarmaci/2015/05/artikler/Apotekerlov%20vedtaget%20af%20bredt%20flertal%20%20Farmaci%202015%20nr%2005.ashx](http://www.apotekerforeningen.dk/Farmaci/~media/Apotekerforeningen/fagbladetfarmaci/2015/05/artikler/Apotekerlov%20vedtaget%20af%20bredt%20flertal%20%20Farmaci%202015%20nr%2005.ashx). Accessed on June 7, 2015

# Outcomes of the deregulation of nicotine replacement therapy products: A review on reported evidence in Finland and other countries

---

## → Terhi Kurko

PhD Student, MSc (Pharm)  
Clinical Pharmacy Group, Social Pharmacy  
Division of Pharmacology and Pharmacotherapy  
Faculty of Pharmacy  
University of Helsinki  
terhi.a.kurko@helsinki.fi or terhi.kurko@utu.fi

## ABSTRACT

Nicotine Replacement Therapy (NRT) products are the most commonly used smoking cessation (SC) pharmacotherapy. Over the past decades, the role of NRT products in SC has changed and they have been deregulated in many countries, including Finland where deregulation was enacted in 2006. This means that the products can be purchased in a variety of sales outlets without the supervision or guidance of any health professional. The objective of this non-systematic literature review was to summarise experiences of the NRT deregulation in Finland and internationally to describe what is known about the reflections of NRT deregulation on NRT sales, smoking rate and NRT use patterns. This literature review is based on the following academic dissertation dealing with the deregulation of nicotine replacement therapy products in Finland: Kurko T. Deregulation of Nicotine Replacement Therapy Products in Finland: Reasons for Pharmaceutical Policy Changes and Reflections on Smoking Cessation Practices. *Dissertationes Scholae Doctoralis Ad Sanitatem Investigandam Universitatis Helsinkiensis* 47, 2015. <https://helda.helsinki.fi/handle/10138/154702>

**Key words:** Nicotine replacement therapy products, deregulation and real-life use

---

## INTRODUCTION

Tobacco control and promotion of smoking cessation (SC) are key global public health priorities (World Health Organization 2015) because the use of tobacco products is the key factor for many serious public health hazards (US Department of Health and Human Services 2014). Very recent study shows that even two thirds of regular smokers die prematurely as a result of their smoking (Banks et al. 2015). Tobacco use causes the chronic condition of tobacco dependence, which includes physiological, psychological, behavioural and social aspects of dependence (Royal College of Physicians 2000, Benowitz 2009). As a result several attempts to quit and comprehensive support are usually needed to reach permanent abstinence from tobacco use (Etter and Stapleton 2006, Fiore and Baker 2011). Many evidence-based guidelines consider the combination of effective behavioural support and pharmacotherapy as the cornerstone of the treatment of tobacco dependence (Fiore et al. 2008, National Institute for Clinical Excellence 2008, The Finnish Medical Society Duodecim 2012).

Nicotine Replacement Therapy (NRT) products, which have been in the pharmaceutical market for over three decades, are the most commonly used smoking cessation (SC) pharmacotherapy (Stead

et al. 2012, Cahill et al. 2014). NRT products are a group of nicotine containing pharmaceuticals intended to reduce withdrawal symptoms caused by the abstinence of smoking, and thus, support SC (Stead et al. 2012a). NRT products' use is based on the idea that it is too difficult for an individual smoker to overcome simultaneously psychological and physiological tobacco dependence (Russell et al. 1980, Sees 1990). Therefore, NRT products are indicated for helping to overcome withdrawal symptoms and to help quitters to concentrate on the psychological aspect of their nicotine dependence.

Over the past decades, the role of NRT products in SC has changed (**Figure 1**). At first, NRT products were prescription medicines intended to be used under the supervision and guidance of health care professionals. Of different health care professional groups, community pharmacists are considered to be in the key position to provide counselling on NRT use (Brewster et al. 2005, Brock et al. 2007, The Finnish Medical Society Duodecim 2012). This is because, in many countries during the 1990's, NRT products were released from prescription-only status to non-prescription medicines sold at pharmacies. After this switch, at the international

organizational level, advancing SC was suggested to be key areas for pharmacists to promote public health (World Health Organization and EuroPharm Forum 1998). As a result in many countries educational interventions were implemented to increase pharmacists' involvement in SC (Brock et al. 2007, Kurko et al. 2011). Also new community pharmacy services were developed to support SC more comprehensively. According to the systematic reviews conducted, community pharmacists' support may increase SC rates (Sinclair et al. 2004, Cramp et al. 2007, Dent et al. 2007, Saba et al. 2014).

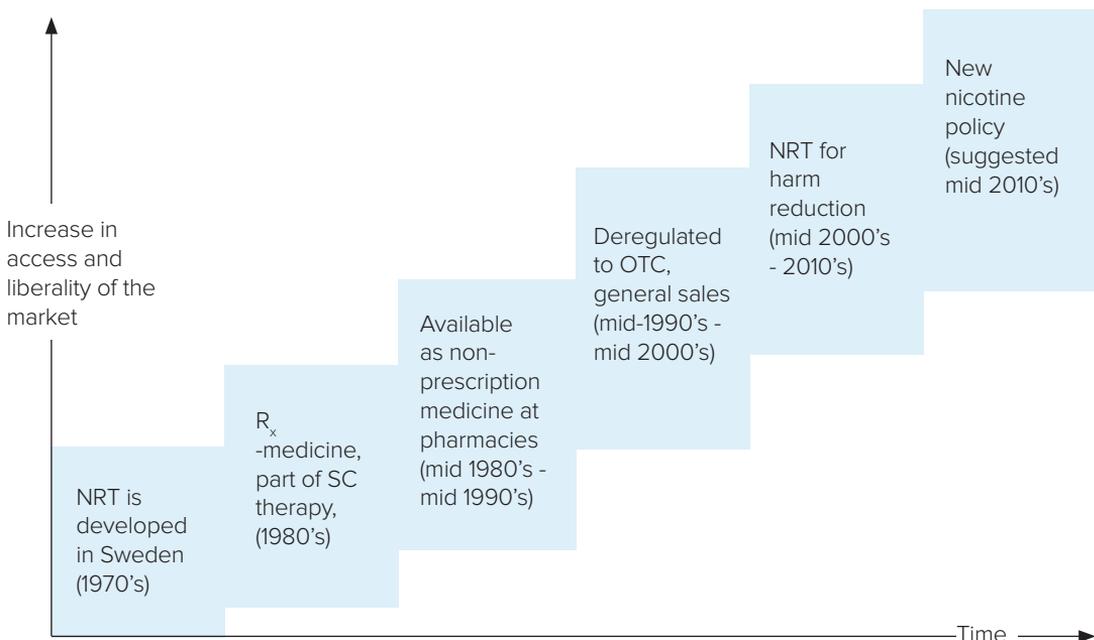
Between 1996–2006, NRT products were deregulated in many countries. This means that these products can be purchased in a variety of sales outlets outside pharmacies, including grocery stores, supermarkets, kiosks and gas stations without the supervision or guidance of any health professional (Shiffman and Sweeney 2008). The deregulations took place, because it was expected that the wider availability of NRT would significantly increase NRT utilization. This in turn would significantly increase quit attempts, these attempts would increase SC, and thus, provide significant public

health benefits (McNeill and Raw 2002, Shiffman and Sweeney 2008).

The deregulation was a turning point in NRT products therapeutic role (Shiffman and Sweeney 2008, Keane 2013). This is because after deregulation NRT products' availability and sole use without guidance has been emphasized in SC, but the need for healthcare professionals' support, underlined in the first NRT guidelines, has been given less attention. As a consequence, after the deregulation, NRT products have been turning from medicines into consumer products (Keane 2013). Medical authorities in different countries have also approved NRT products use for harm reduction indications. This means that the products can be used for minimizing the amount of cigarettes smoked, and thus, minimizing the harm of tobacco use by the use of less toxic and carcinogenic nicotine substances (Stead and Lancaster 2007, Le Houezec et al. 2011).

These trends are currently accelerating as many stakeholders advocate for a far more liberal nicotine policy (Le Houezec et al. 2011, Fagerström and Brigdman 2014). This new policy would fully liberalize NRT regulation, change NRTs to non-medical products from legal approach and inc-

**Figure 1. Development of NRT lifecycle during decades (modified from Shiffman and Sweeney 2008, Le Houezec et al. 2011, Elam and Gunnarson 2012, Keane 2013).**



rease their nicotine doses and delivery rates to act as a more effective substitute for tobacco use. NRT deregulation has also been used as a justification for extending the deregulation practices to other over-the counter (OTC) medicines (Shiffman and Sweeney 2008, European Commission 2013). This “OTC paradigm” means to extend OTC treatment use beyond acute symptomatic conditions to long-term use for treatment of chronic, asymptomatic conditions and for support of preventive lifestyle changes (Shiffman and Sweeney 2008).

It is worthwhile to assess the outcomes of NRT deregulation in different countries. Currently, over

a period of ten to twenty years after the NRT deregulation in various countries (**Table 1**), evidence has been gathered on the reflections of NRT deregulation in SC. The aim of this non-systematic literature review is to assess what is known about the reflections of NRT deregulation to NRT utilization, smoking rate and how NRT is used in real life.

## MATERIALS AND METHODS

This non-systematic literature review is based on the recent academic dissertation dealing with the deregulation of NRT products in Finland (Kurko

**Table 1. Reflections of NRT deregulation to NRT sales and smoking rates.**

| Country (year of NRT deregulation)           | NRT sales and use after deregulation  | Smoking rate before and after deregulation   | References   |
|--|---|--|--|
| Australia (2005)                             | NA  | 22% in 2004<br>21% in 2007<br>20% in 2010  | (Ellerman et al. 2011, Winstalley and White 2012)  |
| Finland (2006)                               | 5.19 DDD* in 2005<br>6.25 DDD in 2006<br>9.99 DDD in 2013<br><br>Sales in DDDs increased 80% during 2006-2013 | 22.2% in 2005<br>21.8% in 2006<br>16.7% in 2013  | (Finnish Medicines Agency and Social Insurance Institution 2013, Indicator bank SOTKAnet® 2015)                          |
| UK (NRT gum 1999, rest of NRT forms in 2002) | Number of estimated NRT treatment weeks increased from 450 000 in 1999 to 900 000 in 2002 **                  | 30% of men,<br>26% of women in 1998<br>29% of men,<br>25% of women in 2000<br>25% of men,<br>23% of women in 2005<br>22% of men,<br>19% of women in 2012<br>Smoking rate declined annually 0.4% during 1999-2005 | (West et al. 2005, Cancer Research UK 2014)  |
| USA (1996)                                   | Number of NRT assisted quit attempts doubled from 2.5 Million (in 1995) to 5.8 Million (in 1997)              | 24.7% in 1995<br>24.7% in 1997,<br>17.8% in 2013<br>Rate of all adult smokers making a quit attempt<br>45.8% in 1995<br>40.8% in 1997<br>42.7% in 2013   | (Centers for Disease Control and Prevention 1997; 2007; 2014 Shiffman et al. 1997, Amodei and Lamb 2008, Zu et al. 2012) |

\* DDD is for Defined Daily Dosages (World Health Organization and Norwegian Institute on Public Health 2014).

\*\* In the UK in addition to the deregulation, all SC medications were included in the reimbursement scheme and bupropion became available as a prescription medicine in 2000. These changes together resulted in dramatic increased the use of SC medications in the UK from the estimated approximately 450 00 treatment weeks in January 1999 to 900 000 treatment weeks in January 2002 (West et al. 2005).

2015). It consists of four original peer reviewed studies assessing NRT deregulation from the perspectives of pharmaceutical policy-making (Kurko et al. 2012), community pharmacists as service providers (Kurko et al. 2009; 2010) and NRT users (Kurko et al. 2014). NRT deregulations have taken place in many countries. Most of the published evidence on this matter is from the USA, but there is also some evidence from the UK and Australia. Therefore, in addition to Finland, this review will describe the reflections of NRT deregulation in these countries. The evidence describing real life NRT usage patterns is based on the literature search conducted from the Scopus Database during April-June 2014 and updated during May 2015.

## RESULTS

### Reflections of NRT deregulation on NRT utilization and smoking prevalence

Based on evidence from the reviewed countries, the utilization of NRT has sizeably increased following the NRT deregulation (**Table 1**). The US sales statistics suggest that after the NRT deregulation the use of NRT gum and patch doubled compared to the use before deregulation (Shiffman et al. 1997, Reed et al. 2005). In Finland, particularly the sales of NRT gum have increased radically after the deregulation (Finnish Agency for Medicines and Social Insurance Institution 2014). In 2013, only 20 % of the products were bought at pharmacies and the rest of the product sales took place in food stores, kiosks, gas stations or restaurants.

Population-based studies have provided evidence that increased use of NRT products has also increased the number of quit attempts which included NRT use (Pierce and Gilpin 2002, Thorndike et al. 2002, Helakorpi et al. 2005, Amodei and Lamb 2008, Zhu et al. 2012, Héllöndan et al. 2013). Though, it is still unclear how much NRT is used in actual quit attempts and how much for other purposes (Amodei and Lamb 2008).

In all the reviewed countries smoking rate decreased after deregulation. However, the decrease in smoking rates did not accelerated after deregulation (**Table 1**). For example, in the USA during the ten years following the NRT deregulation (1996–2006), smoking rate had declined 3.9 % (Centers

for Disease Control and Prevention 1997; 2007, Amodei and Lamb 2008). Compared with the 12.5 % drop in the smoking rate over the ten-year period of 1974–1985 in the USA the reflection of NRT deregulation on smoking rate is modest.

This pattern is similar in the other reviewed countries. In the UK, West et al. (2005) have estimated that NRT deregulation has most optimistically resulted in an annual reduction of smoking prevalence of 0.1 % during 1999–2001 (**Table 1**). This reduction is so marginal, that it is impossible to reliably detect it in annual smoking prevalence surveys. Compared with other regulatory changes leading to the increase in SC medications use, NRT deregulation was not associated with a statistically significant increase in SC rate (West et al. 2005).

## NRT USE PATTERNS IN REAL-LIFE

### NRT use for a short period

NRT is recommended to be used for three months gradually decreasing the dosage. This is because the majority of relapses take place either during the first eight days or three first months after a quitting attempt (Hughes et al. 2004a, Cummings and Mahoney 2008, Fiore and Baker 2011). One of the most common reasons for relapse is that individuals are not using pharmacotherapy long enough to overcome withdrawal symptoms (Sims and Fiore 2002, Hughes et al. 2004a). In contrast to NRT trials, in population-based studies NRT is typically used for less than four weeks (see **Table 2**). NRT bought without counselling is used for a far shorter period than prescription NRTs (Pierce et al. 2006, Beard et al. 2015).

### Use of too low a dosage

NRT users typically use only about 50 % of the recommended doses (**Table 2**). This is particularly the case with all the oral forms of NRT. Sometimes the products are also used with the wrong technique, (for example chewing NRT gum as normal gum) or with refreshments, which hinders the adsorption of nicotine. Furthermore, some NRT users tend to underestimate their level of dependence and use the mildest oral NRT form (Shiffman et al. 2008c).

Smokers and quitters have many reasons why they either do not use NRT at all or use it for only

a very short time or with inadequate dosing. The most commonly reported reasons are negative attitude or fears about NRT, disbelief in NRT safety and efficacy, negative experiences, perception of not needing NRT, high price of the products or relapse back to smoking (Burns and Levinson 2008, Balmford et al. 2011, Kurko et al. 2014).

### **Concurrent smoking and NRT use, and NRT use for other purposes than quitting**

Traditionally, concurrent use of NRT and smoking is forbidden in the instructions for NRT use, and it

is seen as a reason for NRT treatment failure (Shaw et al. 1998, Sims and Fiore 2002). In real life, concurrent (dual) use of a NRT product and tobacco is common (Thorndike et al. 2002, Hughes, et al. 2004, Balmford et al. 2011, Beard et al. 2013).

NRT use in smoking reduction before quitting (pre-cessation use) is approved as a therapeutic option in many countries. According to the Cochrane systematic review, the use of NRT products nearly doubled the odds on reducing the number of smoked cigarettes per day by 50 % (Stead and Lancaster 2007). However, only a minority was able to main-

**Table 2. Examples of NRT real-life use patterns.**

#### **Examples of use with too a short time**

- A majority uses NRT for a shorter time than recommended (8-12 weeks) (Shaw et al. 1998, Sims and Fiore 2002, Gilpin et al. 2006, Burns and Levinson 2008, Balmford et al. 2011).

#### **Examples of use with too a small dosage**

- NRT users typically use only about 50% of recommended doses of SC medicines (Shiffman et al. 2008a,b). Level of adherence is associated with success rate of SC (Shiffman et al. 2002, Burns and Levinson 2008, Shiffman et al. 2008a,b).
- Quitters who used NRT gum used at least the minimum recommended daily dose were more successful in abstinence in the sixth week compared to those not using the product with the recommended dose (Shiffman et al. 2002).

#### **Examples of dual use of NRT and cigarettes**

- NRT is used to maintain cigarette smoking when smoking is not allowed by providing nicotine into the body (Shaw et al. 1998, Sims and Fiore 2002).
- Concurrent use of NRT inhaler or NRT gum and tobacco is common in population-based studies (Hughes et al. 2004, Hughes et al. 2005, Beard et al. 2013).
- NRT use for smoking reduction or temporary abstinence is common. NRT use in these attempts was associated with previous quit attempts (Beard et al. 2013;2015).
- Although rare, the off-label use of an inhaler is related to a repeatedly concurrent use with tobacco or inhaler use for non-cessation reasons (Hughes et al. 2005).
- Currently, smoking reduction with NRT patch use is recommended as a NRT pre-cessation strategy, especially for patients who otherwise would not be able to quit (Royal College of Physicians 2007, Wang et al. 2008, Sims and Fiore 2011).

#### **Examples of NRT use for other purposes than quitting**

- Reduction of the number of cigarettes smoked with NRT use is recommend in the UK for patients unwilling to quit (National Institute for Clinical Excellence 2013).
- In a four-country study, between 20-30% of NRT users used NRT for purposes other than for quitting (Hammond et al. 2008).
- In Finland, according to the national survey of the Health and Health Behaviour among Finnish adult population in 2013 (Helldán et al. 2013), 6.5% of the respondents who smoked during past year, had used NRT for other purposes than quitting. In 2005, before deregulation, the corresponding rate was 2.9% (Helakorpi et al. 2005).

#### **Long-term use and dependence on NRT**

- According to population-based studies the prevalence of dependence on any NRT product is approximately 1% of all NRT users (Hughes, et al. 2004, Hughes et al. 2005).
- Definition of long term NRT use varies but it is typically defined as use over one year (Hajek et al. 2007, Shiffman et al. 2008c, Borup et al. 2014).
- The smokers who are most dependent on tobacco, use NRT for longer periods (Hajek et al. 2007, Shiffman et al. 2008c, Borup et al. 2014).

tain this reduction in smoking for a longer period. Currently, UK is the only country which has licensed NRT use for other purposes than for quitting (National Institute for Clinical Excellence 2013). Typically these purposes are reduction in the number of cigarettes smoked and temporary abstinence. However, this kind of use of NRT products often takes place also in other countries (**Table 2**).

### Long-term use and dependence on NRT

Nicotine is the key dependence causing agent in tobacco products. Therefore, it was a concern whether deregulated NRT would cause dependence among the population. According to population-based studies, the prevalence of dependence on any NRT product is low, approximately 1 % of all NRT users (Hughes, et al. 2004, Hughes et al. 2005). Though, it has been suggested that dependence on NRT is under-investigated phenomenon, and therefore, it could actually be more prevalent than is currently expected (Dome 2011). Some smokers and quitters fear NRT dependence and this fear hinders NRT use (Bansal et al. 2004, Kurko et al. 2014).

Less than 10 % of NRT users in real-life use NRT for long-term (> 1 year) (West et al. 2000, Sims and Fiore 2002, Hajek et al. 2007). Long-term use of NRT is recommended as a therapeutic option for highly dependent smokers (Fiore and Baker 2011, The Finnish Medical Society Duodecim 2012), because it is considered NRT as a much safer option compared to smoking. However, because of the limited knowledge about the long term effects, long-term use over a number of years may not be the best solution for every quitter (Dome 2011, Grando 2014).

## DISCUSSION

This review, combining evidence from Finland, Australia, UK and USA showed that after the deregulation of NRT its use has nearly doubled in the reviewed countries. The fundamental reason for NRT deregulations worldwide has been the expectation that NRT deregulation would lead to a significant reduction in the prevalence of smoking. This review cannot provide compelling evidence supporting that expectation, despite the radical increase in NRT use. In the reviewed countries the

smoking rate has steadily decreased. However, the decrease has not been as radical as was suggested during the deregulation process and is not following the increased NRT use.

This review also found a great variety in NRT usage patterns. These patterns are not always optimal. To illustrate usage patterns, the use of too low a dosage or too short a treatment period compared with the instructions, is common (**Table 2**). In addition, a small proportion of NRT users experience dependency on NRT products or use the products for long term.

The results of this review question the importance of sole NRT use without behavioural support in gaining permanent abstinence (Amodei and Lamb 2008, see **Table 1 and 2**). It seems that the mere purchase of the NRT product does not guarantee that the product is used in a quit attempt or that the attempt leads to permanent abstinence (Amodei and Lamb 2008, Walsh, Kotz et al. 2014). This was also confirmed by the experiences of Finnish smokers and quitters: NRT use alone is not crucial for obtaining permanent abstinence (Kurko et al. 2014). According to Finnish smokers and quitters abstinence is highly dependent on cognitive and behavioural components which include perceived self-efficacy and the ability to learn new habits, planning strategies for overcoming temptations to smoke and maintain the decision.

Based on these findings, some NRT users would need customized medicines information which addresses their perceptions related to NRT (Vogt et al. 2008, Amodei and Lamb 2008, Raupach and van Schayck 2011). Combining counselling with the use of NRT also supports smokers' motivation towards quitting and remaining abstinent (Fiore et al. 2008, Stead et al. 2012b). There are many NRT strengths, dosage forms and administration routes. For these reasons NRT users would benefit from the help of health professionals who can tailor the most suitable strength and form of NRT therapy according to their personal smoking status and health condition. They can also give practical instructions on the use of the different drug forms. The planned use of NRT for pre-cessation and smoking reduction with NRT use should be included in the counselling from health care professionals (Wang et al. 2008). Otherwise, there is a great probability that these strategies will not be successful.

In addition to basic NRT use counselling, some smokers and quitters could benefit from even a more comprehensive approach; an individually tailored SC plan (Raupach and van Schayck 2011). This plan could take advantage of the smoker's own willingness to quit and make lifestyle changes. It could support optimal SC pharmacotherapy, and among NRT users it could prevent the feared NRT dependence. However, support of optimal SC medication use is only one part of the individualized plan. Instead, the SC plan should also include several non-medical methods supporting SC. For example behavioural support strengthens quitters' empowerment, helps in the prevention of relapses and maintaining the permanent lifestyle change.

Of the different health care professional groups, especially community pharmacists are in a key position to provide such individualized counselling for NRT users. However, as health care service providers, community pharmacists do not prefer taking a proactive role to SC, because they fear affecting customers' privacy (Brewster et al. 2005, Kurko et al. 2011). Therefore, for community pharmacists' participation in SC it is important to have a natural and feasible situation for SC counselling, such as while dispensing SC medicines. Some Finnish evidence suggests that after NRT deregulation community pharmacists' motivation towards NRT and SC counselling decreased (Kurko et al. 2009, Kurko 2015). However, while NRT products' successful use obviously needs counselling, it is important to maintain community pharmacists' skills and expertise available for supporting SC. It is also worthwhile to make pharmacists' contributions in SC visible and acknowledged, e.g., by raising public awareness of the fact that NRT products work better if NRT use is combined with individualized counselling and SC plan.

Currently, the dramatic expansion of the popularity of electronic cigarettes is influencing SC practises and opinions worldwide (World Health Organization 2014). Compared to NRT, e-cigarettes have limited or no evidence-base on efficacy and safety in SC (World Health Organization 2014). However, some recent British population-based evidence even suggests that e-cigarettes are more effective in SC than NRT bought from general sales (Brown et al. 2014). Also this matter highlights the need to make NRT users more aware of

the importance of the planned use of NRT and its use in combination with behavioural support components. Finally, it is important to re-evaluate the current role of NRT products in SC: will they become less important treatment option in SC? Furthermore, there is a need to assess the value of counselling provided by pharmacists in the SC pharmacotherapy. For instance, could the suboptimal usage patterns of NRT be avoided through pharmacists' support, guidance and making individualised SC plans? This is important in the battle against tobacco pandemic and for not maintaining needless nicotine use among the population.

## METHODOLOGICAL CONSIDERATIONS

The aim of this review was to provide an evidence-based update on current knowledge of the outcomes of NRT deregulation to SC practises. Therefore, this narrative, non-systematic review focused on several viewpoints instead of making a systematic review. It is challenging to reliably detect the reflections of NRT deregulation on smoking statistics. This is because smoking prevalence of adults is dependent on the number of adolescent smokers who continue to smoke into their adulthood, the number of smokers who die, the number of quit attempts and on quitters' ability to remain abstinent (Hatsukami et al. 2008, Hughes 2011). SC is also influenced by several developments taking place in the society, such as changes in legislation and general attitude towards smoking. All these factors influence on the smoking rate concurrently, making it hard to directly estimate the effects of NRT deregulation on smoking prevalence. However, it seems that smoking prevalence in the reviewed countries has been steadily decreasing during the past decades, and this development has not detectable accelerated after NRT deregulation. It is also notable that the pharmaceutical market differs between the reviewed countries. For example in the UK in addition being OTC medicines, NRT products can be purchased by prescription and they are reimbursed. In the USA all OTC medicines are typically sold in general sales.

## TIIVISTELMÄ:

Nikotiinikorvaushoitovalmisteiden myyntikanavien laajentamisen heijasteet tupakasta vieroitukseen: katsaus suomalaiseen ja kansainväliseen tutkimusnäyttöön

Nikotiinikorvaushoitovalmisteet ovat yleisimmin käytettyjä tupakasta vieroituksen lääkehoitoja, jotka tulivat markkinoille 1970-luvulla. Vuosien saatossa näiden valmisteiden hoidollinen rooli tupakasta vieroituksessa ja saatavuus ovat muuttuneet. Monissa maissa valmisteiden myyntikanavia on laajennettu ruokakaappoihin, kioskeihin ja huoltoasemille ostettavaksi ilman terveydenhuollon ammattilaisen antamaa neuvontaa. Suomessa myyntikanavien laajentaminen tapahtui 2006. Tämän ei-systemoidun kirjallisuuskatsauksen tavoitteena on selvittää, mitä nikotiinikorvaushoitovalmisteiden myyntikanavien laajentamisen heijasteista tupakasta vieroitukseen ja valmisteiden käyttöön tiedetään tutkimuskirjallisuuden perusteella. Kirjallisuuskatsaus perustuu seuraavaan nikotiinikorvaushoitovalmisteiden myyntikanavien laajentamisen syitä ja heijasteita Suomessa tutkineeseen väitöskirjaan: Kurko T. *Deregulation of Nicotine Replacement Therapy Products in Finland: Reasons for Pharmaceutical Policy Changes and Reflections on Smoking Cessation Practices*. *Dissertationes Scholae Doctoralis Ad Sanitatem Investigandam Universitatis Helsinkiensis* 47, 2015. <https://helda.helsinki.fi/handle/10138/154702>

**Avainsanat:** Nikotiinikorvaushoitovalmisteet, tupakointi, lääkkeiden käyttötavat, myyntikanavien laajentaminen

---

### → Terhi Kurko

proviisori, väitellyt

Kliinisen farmasian ryhmä, sosiaalfarmasia

Farmakologian ja lääkehoidon osasto

Farmasian tiedekunta

Helsingin yliopisto

terhi.a.kurko@helsinki.fi tai terhi.kurko@utu.fi

## KIRJALLISUUSLUETTELO

- Amodei N, Lamb RJ: Over-the-Counter Nicotine Replacement Therapy: Can Its Impact on Smoking Cessation Be Enhanced? *Psychol Addict Behav* 22: 472–485, 2008
- Balmford J, Borland R, Hammond D, Cummings KM: Adherence to and Reasons for Premature Discontinuation From Stop-Smoking Medications: Data From the ITC Four-Country Survey. *Nicotine Tobacco Res* 13(2): 94–102, 2011
- Banks E, Joshy G, Weber MF, Liu B, Grenfell R et al: Tobacco smoking and all-cause mortality in a large Australian cohort study: findings from a mature epidemic with current low smoking prevalence. *BMC Medicine* 13:38, 2015 (doi:10.1186/s12916-015-0281-z)
- Bansal MA, Cummings KM, Hyland A, Giovino GA: Stop-smoking medications: Who uses them, who misuses them, and who is misinformed about them? *Nicotine Tobacco Res* 6: S303–S310, 2004
- Beard E, Michie S, Fidler J, West R: Use of nicotine replacement therapy in situations involving temporary abstinence from smoking: A national survey of English smokers. *Addict Behav* 38: 1876–1879, 2013
- Beard E, Bruguera C, McNeill A, Brown J, West R: Association of amount and duration of NRT use in smokers with cigarette consumption and motivation to stop smoking: A national survey of smokers in England. *Addict Behav* 40: 33–38, 2015
- Benowitz NL: Pharmacology of Nicotine: Addiction, Smoking-Induced Disease, and Therapeutics. *Annu Rev Pharmacol Toxicol* 49: 57–71, 2009
- Borup G, Mikkelsen KL, Tønnesen P, Christrup LL: Exploratory survey study of long-term users of nicotine replacement therapy in Danish consumers. *Harm Reduction Journal* 11:35, 2014 (doi:10.1186/1477-7517-11-35)
- Brewster JM, Ashley MJ, Laurier CL, Diose R, Victor C, Ferrence R, Cohen J: On the front line of smoking cessation: Pharmacists practices and self-perception. *CPJ/RPC* 138: 32–38, 2005
- Brock T, Taylor D, Wulji T: Curbing the tobacco pandemic: the global role for pharmacy. The School of Pharmacy, University of London and International Pharmaceutical Federation (FIP), 2007. [www.fip.org/files/fip/news/curbing\\_global\\_pandemic.pdf](http://www.fip.org/files/fip/news/curbing_global_pandemic.pdf)
- Brown J, Beard E, Kotz D, Michie S, West R: Real-world effectiveness of e-cigarettes when used to aid smoking cessation: A cross-sectional population study. *Addiction* 109: 1531–1540, 2014
- Burns EK, Levinson AH: Discontinuation of Nicotine Replacement Therapy Among Smoking-Cessation Attempters. *Am J Prev Med* 34: 212–215, 2008
- Cahill K, Stevens S, Lancaster T: Pharmacological treatments for smoking cessation. *JAMA* 311: 193–194, 2014
- Cancer Research UK. Tobacco Statistics, trends over time. Accessed May 30th 2015. Available from: [www.cancerresearchuk.org/health-professional/cancer-statistics/risk/tobacco](http://www.cancerresearchuk.org/health-professional/cancer-statistics/risk/tobacco)
- Centers for Disease Control and Prevention: Cigarette smoking among adults - United States 1995. *Morbidity and Mortality Weekly Report* 46: 1217–1220, 1997
- Centers for Disease Control and Prevention: Cigarette smoking among adults - United States 2006. *Morbidity and Mortality Weekly Report* 56: 1157–1161, 2007
- Centers for Disease Control and Prevention: Current Cigarette Smoking Among Adults—United States, 2005–2013. *Morbidity and Mortality Weekly Report* 63 (47) :1108–12, 2014
- Cramp GJ, Mitchell C, Steer C, Pflieger S: An evaluation of a rural community pharmacy-based smoking-cessation counselling and nicotine replacement therapy initiative. *Int J Pharm Pract* 15: 113–121, 2007
- Cummings KM, Hyland A, Giovino GA, Hastrup JL, Bauer JE, Bansal MA: Are smokers adequately informed about the health risks of smoking and medicinal nicotine? *Nicotine Tob Res* 6 (Suppl 3): S333–S340, 2004

Dent LA, Harris KJ, Noonan CW: Tobacco Interventions Delivered by Pharmacists: A Summary and Systematic Review. *Pharmacotherapy* 27: 1040–1051, 2007

Dome P: Over-the-counter nicotine replacement therapy for everyone: Is it the best solution? *Med Hypotheses* 77: 1048–1050, 2011

Hudmon KS, LaCivita C: Creating a road map for pharmacy's role in the cessation of tobacco use. *AJHP* 63: 564–566, 2006

Ellerman A, Ford C, Stillman S: Smoking Cessation: Pharmacotherapies. in Scollo, MM and Winstanley, MH [editors]. *Tobacco in Australia: Facts and issues*. 4th edn. Melbourne: Cancer Council Victoria; 2012. Available from: [www.tobaccoin-australia.org.au](http://www.tobaccoin-australia.org.au)

Fagerström KO, Bridgman K: Tobacco harm reduction: The need for new products that can compete with cigarettes. *Addict Behav* 39: 507–511, 2014

Finnish Medicines Agency Fimea, Social Insurance Institution: *Finnish Statistics on Medicines 2013*. Edita Prima Oy, Helsinki 2014

Fiore MC, Baker TB: Treating Smokers in the Health Care Setting. *N Engl J Med* 365: 1222–1231, 2011

Fiore MC, Jaen CR, Baker TB, Bailey WC, Curry SJ: *Treating Tobacco Use and Dependence: 2008 Update 2008*

Gilpin E, Messer K, Pierce J: Population effectiveness of pharmaceutical aids for smoking cessation: What is associated with increased success? *Nicotine Tob Res* 8: 661–669, 2006

Grando SA: Connections of nicotine to cancer. *Nature Reviews* 14: 419–429, 2014

Hajek P, McRobbie H, Gillison F: Dependence potential of nicotine replacement treatments: Effects of product type, patient characteristics, and cost to user. *Prev Med* 44: 230–234, 2007

Hammond D, Reid JL, Driezen P, Cummings KM, Borland R, Fong GT, McNeill A: Smokers' use of nicotine replacement therapy for reasons other than stopping smoking: findings from the ITC

Four Country Survey. *Addiction* 103: 1696–1703, 2008

Hatsukami DK, Stead LF, Gupta PC: Tobacco addiction. *Lancet* 371: 2027–2038, 2008

Helakorpi S, Patja K, Prättälä R, Uutela A: *Health Behaviour and Health among the Finnish Adult Population, Spring 2005*. Publications of the National Public Health Institute, B18/2005. Available from: [www.julkari.fi/bitstream/handle/10024/78777/2005b18.pdf?sequence=1](http://www.julkari.fi/bitstream/handle/10024/78777/2005b18.pdf?sequence=1)

Helldán A, Helakorpi S, Virtanen S, Uutela A: *Health Behaviour and Health Among the Finnish Adult Population, Spring 2013*. National Institute for Health and Welfare, 21/2013. Available from: [www.julkari.fi/bitstream/handle/10024/110841/URN\\_ISBN\\_978-952-302-051-1.pdf?sequence=1](http://www.julkari.fi/bitstream/handle/10024/110841/URN_ISBN_978-952-302-051-1.pdf?sequence=1)

Hughes JR, Adams EH, Franzon MA, Maquire MK, Guary J: A prospective study of off-label use of, abuse of, and dependence on nicotine inhaler. *Tob Control* 14: 49–54, 2005

Hughes JR: The hardening hypothesis: Is the ability to quit decreasing due to increasing nicotine dependence? A review and commentary. *Drug Alcohol Depend* 117: 111–117, 2011

Hughes JR, Pillitteri JL, Callas PW, Callahan R, Kenny M: Misuse of and dependence on over-the-counter nicotine gum in a volunteer sample. *Nicotine Tobacco Res* 6: 79–84, 2004

Indicator bank SOTKANET®. The Finnish National Institute for Health and Welfare, 2015 [www.sotkanet.fi/sotkanet/fi/index](http://www.sotkanet.fi/sotkanet/fi/index)

Keane H: Making smokers different with nicotine: NRT and quitting. *Int J Drug Policy* 24: 189–195, 2013

Kotz D, Brown J, West R: 'Real-world' effectiveness of smoking cessation treatments: a population study. *Addiction* 109 (3): 491–9, 2014

Kurko T, Linden K, Vasama M, Pietilä K, Airaksinen M: Nicotine replacement therapy practices in Finland one year after deregulation of the product sales—Has anything changed from the community pharmacy perspective? *Health Policy* 91: 277–285, 2009

Kurko T, Linden K, Pietilä K, Sandstrom P, Airaksinen M: Community pharmacists' involvement in smoking cessation: familiarity and implementation of the National smoking cessation guideline in Finland. *BMC Public Health* 10: 444, 2010.

Kurko T, Linden K, Kolstela M, Pietilä K, Airaksinen M: Is nicotine replacement therapy overvalued in smoking cessation? Analysis of smokers' and quitters' communication in social media. *Health Expectations 2014 (On-line early view)*

Kurko T, Salimäki J, Airaksinen M, Silén S, Pietilä K: The development and importance of Finnish community pharmacies' involvement in smoking cessation in 1985-2011. *Dosis* 27(3):140–152, 2011 [English abstract]

Kurko T, Silvast A, Wahlroos H, Pietilä K, Airaksinen M: Is pharmaceutical policy evidence-informed? A case of the deregulation process of nicotine replacement therapy products in Finland. *Health Policy* 105: 246–255, 2012

LE Houezec J, Mcneill A, Britton J: Tobacco, nicotine and harm reduction. *Drug Alcohol Rev* 30: 119–123, 2011

McNeill A, Foulds J, Bates C. Regulation of nicotine replacement therapies (NRT): a critique of current practice. *Addiction*, 96: 1757–1768, 2001

National Institute for Health and Clinical Excellence: Smoking cessation services in primary care, pharmacies, local authorities and workplaces, particularly for manual working groups, pregnant women and hard to reach communities. *NICE Public Health Guidance* 10, 2008

National Institute for Health Care and Excellence: Tobacco: harm-reduction approaches to smoking. *NICE Public Health Guidance* 45, 2013.

Paul CL, Walsh RA, Girgis A: Nicotine replacement therapy products over the counter: real-life use in the Australian community. *Aust N Z J Public Health* 27: 491–495, 2003

Raupach T, van Schayck CP: Pharmacotherapy for smoking cessation: current advances and research topics. *CNS Drugs* 25: 371–82, 2011

Royal College of Physicians: Nicotine Addiction in Britain: A Report of the Tobacco Advisory

Group of the Royal College of Physicians. Royal College of Physicians of London. Tobacco Advisory Group, London, Great Britain, 2000.

Russell MAH: Nicotine intake and its regulation. *J Psychosom Res* 24: 253–264, 1980

Saba M, Diep J, Saini B, Dhipayom T: Meta-analysis of the effectiveness of smoking cessation interventions in community pharmacy. *J Clin Pharm Ther* 39: 240–247, 2014

Sees KL: Cigarette smoking, nicotine dependence, and treatment. *West J Med* 152: 578–584, 1990

Shaw JP, Ferry DG, Pethica D, Brenner D, Tucker IG. Usage patterns of transdermal nicotine when purchased as a non-prescription medicine from pharmacies. *Tob Control* 7: 161–167, 1998

Shiffman S, Ferguson SG, Rohay J, Gitchell JG: Perceived safety and efficacy of nicotine replacement therapies among US smokers and ex-smokers: Relationship with use and compliance. *Addiction* 103: 1371–1378, 2008b

Shiffman S, Gitchell J, Pinney JM, Burton SL, Kemper KE, Lara EA: Public health benefit of over-the-counter nicotine medications. *Tob Control* 6: 306–310, 1997

Shiffman S, Hughes JR, Pillitteri JL, Burton SL: Persistent use of nicotine replacement therapy: An analysis of actual purchase patterns in a population based sample. *Tob Control* 12: 310–316, 2003

Shiffman S, Rolf CN, Hellebusch SJ, et al.: Real-world efficacy of prescription and over-the-counter nicotine replacement therapy. *Addiction* 97: 505–516, 2002a

Shiffman S, Sweeney CT, Ferguson SG, Sem-bower MA, Gitchell JG: Relationship between adherence to daily nicotine patch use and treatment efficacy: Secondary analysis of a 10 week randomized, double-blind, placebo-controlled clinical trial simulating over-the-counter use in adult smokers. *Clin Ther* 30: 1852–1858, 2008a

Shiffman S, Sweeney CT: Ten years after the Rx-to-OTC switch of nicotine replacement therapy: What have we learned about the benefits and

risks of non-prescription availability? Health Policy 86: 17–26, 2008

Sims TH, Fiore MC: Pharmacotherapy for treating tobacco dependence. What is the ideal duration of therapy? Drugs 16: 653–662, 2002

Stead LF, Lancaster T: Interventions to reduce harm from continued tobacco use. Cochrane Database Syst Rev: CD005231, 2007

Stead LF, Lancaster T: Behavioural interventions as adjuncts to pharmacotherapy for smoking cessation. Cochrane Database Syst Rev: CD009670/2012, 2012b

Stead LF, Perera R, Bullen C, Mant D, Hartmann-Boyce J, Cahill K, Lancaster T: Nicotine replacement therapy for smoking cessation. Cochrane Database Syst Rev: CD000146, 2012a

The Finnish Medical Society Duodecim. Tobacco dependency and cessation. The Finnish Medical Society Duodecim 2012. [www.kaypahoito.fi/web/kh/suosituksset/suositus?id=hoi40020](http://www.kaypahoito.fi/web/kh/suosituksset/suositus?id=hoi40020) [In Finnish]

Thorndike AN, Biener L, Rigotti NA: Effect on smoking cessation of switching nicotine replacement therapy to over-the-counter status. Am J Public Health 92: 437–442, 2002

US Department of Health and Human Services. The Health Consequences of Smoking: 50 Years of Progress. A Report of the Surgeon General. Atlanta, GA: US Department of Health and Human Services, Centers for Disease Control and Prevention, National Centre for Chronic Disease Prevention and Health Promotion, Office on Smoking and Health, 2014. Available from: [www.surgeongeneral.gov/library/reports/50-years-of-progress/50-years-of-progress-by-section.html](http://www.surgeongeneral.gov/library/reports/50-years-of-progress/50-years-of-progress-by-section.html)

Walsh RA: Over-the-counter nicotine replacement therapy: a methodological review of the evidence supporting its effectiveness. Drug Alcohol Rev 27: 529–547, 2008

Wang D, Connock M, Barton P, Fry-Smith A, Aveyard P, Moore D: 'Cut down to quit' with nicotine replacement therapies in smoking cessation: a systematic review of effectiveness and economic analysis. Health Technol Assess 12 (2), 2008

West R, DiMarino ME, Gitchell J, McNeill A: Impact of UK policy initiatives on use of medicines to aid smoking cessation. Tob Control 14: 166–171, 2005

Winstalley M, White V: Trends in the prevalence of smoking. In Scollo, MM and Winstanley, MH [editors]. Tobacco in Australia: Facts and issues. 4th edn. Melbourne: Cancer Council Victoria; 2012. Available from: [www.tobaccoinaustralia.org.au/chapter-1-prevalence](http://www.tobaccoinaustralia.org.au/chapter-1-prevalence)

World Health Organization, EuroPharmForum: Pharmacists and action on tobacco, 1998. Available from: [www.euro.who.int/document/E61288.pdf](http://www.euro.who.int/document/E61288.pdf)

World Health Organization: Electronic nicotine delivery systems. A report from WHO 2014. Available from: [apps.who.int/gb/fctc/PDF/cop6/FCTC\\_COP6\\_10-en.pdf?ua=1](http://apps.who.int/gb/fctc/PDF/cop6/FCTC_COP6_10-en.pdf?ua=1)

World Health Organization and Norwegian Institute on Public Health. Definitions and General consideration, 2014. Available from: [www.whocc.no/ddd/definition\\_and\\_general\\_considera/](http://www.whocc.no/ddd/definition_and_general_considera/)

World Health Organization: Framework Convention on Tobacco Control. World Health Organization 2015. Available from: [www.who.int/fctc/en/](http://www.who.int/fctc/en/)



# A community pharmacy IT paradox:

community pharmacists'  
self-perception of innovativeness  
not matched by actual innovations

---

→ **Anna Westerling**

PhD (Pharm),  
Managing Pharmacist  
Espoo 3rd Pharmacy

→ **Alan Lyles**

Professor  
University of Baltimore, USA

→ **Jaana Hynninen**

PhD (Pharm)  
Helsinki 36th Pharmacy

→ **Veikko Haikala**

PhD (Pharm)

→ **Marja Airaksinen**

Professor, Clinical Pharmacy  
Group  
Faculty of Pharmacy,  
University of Helsinki

Correspondence:

→ **Anna Westerling**

[anna.westerling@fimnet.fi](mailto:anna.westerling@fimnet.fi)

## ABSTRACT

**Purpose:** Roger's theory on diffusion of innovations has guided generation of innovations in diverse industries. In addition to guiding the innovation generation process, this theory helps to assess the readiness of a target population to adopt an innovation. This study applied Roger's theory to identify information technology (IT) innovations that facilitate patient care services in community pharmacies, to evaluate their development process, and to assess community pharmacists' readiness to adopt them.

**Methods:** The research employed triangulated qualitative and quantitative data collected by: (1) interviewing a purposive sample of 14 experts; and (2) surveying representative samples of Finnish community pharmacy owners (response rate 53%, n=308) and pharmacists (response rate 22%, n=373).

**Results:** Although community pharmacists self-report being receptive to adopting innovations, actual IT innovations supporting patient care services are rare and focus on limited areas. According to our results, IT systems development processes differed from Rogers' six phases, with the most neglected phase being systematic research before IT system development. Also, few of the implemented innovations had undergone the evaluation phase for actual results.

**Conclusions:** The diffusion of innovations framework is a useful tool for planning IT systems for community pharmacies. It could provide systematic guidance for future projects (1) to ensure that potential innovations are based on a sufficient understanding of the problems that they are intended to solve, and (2) to encourage strong leadership for research, development and the innovation process so that community pharmacists' potential innovativeness is utilized, and that professional needs and strategic priorities will be considered.

**Keywords:** Community pharmacy, Information technology, Innovation, Strategy

## INTRODUCTION

Roger's theory on the diffusion of innovations has been used as a tool to guide the generation of innovations in diverse industries since the 1960s. In addition to guiding the actual innovation generation process, this theory helps to assess the readiness of a target population to adopt an innovation. According to Rogers (Rogers 2003), an innovation is a "new idea, practice or object perceived by a person or unit", and its diffusion occurs through channels and within a timeframe. Initially, the diffusion of innovation model was used to understand agricultural innovations and their adoption. Subsequently, it has been widely and productively applied in many industries, including health care (Haider and Kreps 2004, Schommer et al. 2010).

According to this model, the generation and implementation of innovations occur over six phases: (1) recognition of a problem or need; (2) research on it, which can be basic or applied research or both; (3) development of an idea for a new product or service to meet potential adopters' requirements; (4) commercialization, which converts the idea into a product or service, is usually performed by private companies; (5) diffusion and adoption; (6) consequences of the innovation, which can result from its adoption, partial adoption or rejection by individuals or social systems. Rogers' adopters' taxonomy categorizes individuals and social systems according to their innovativeness and readiness to adopt innovations. Innovators, the first adopters, are venturesome and able to cope with a high degree of uncertainty. Early Adopters are role models and opinion leaders in their localities. The Early Majority frequently and deliberately interact, adopting new ideas just before the average system member. The Late Majority, however are sceptical and cautious, adopting innovations only after the average system member does. Laggards are traditional: they are suspicious, with a point of reference in the past.

Health care services constantly and rapidly change practices, with information technology (IT) playing a key role at different operational functions ranging from patient care to business management (Westerling 2011). Medication management is a critical element of pharmaceutical health care, requiring special IT which are in-

tegrated with other patient care systems. This is an emerging priority for community pharmacies that are increasingly involved in patient care in outpatient settings. Although community pharmacies have been using IT since the 1970s, little is reported about how these systems have been generated and how the development processes have been coordinated and led. Existing studies on medication management related IT innovations have evaluated their diffusion in hospitals or in physicians' practices, environments which differ from community pharmacies in critical ways (Anderson 2007, Jamal et al. 2009, Ludwick and Doucette 2009). Likewise, little is known about community pharmacists' willingness to adopt innovations. This has been explored in two national studies, one in the Netherlands (Pronk et al. 2002) and the other in Finland (Saario 2005). Both studies evaluated the diffusion of pharmaceutical care in community pharmacies by examining the adoption of patient-oriented services and assessing pharmacists' perceived innovativeness. No previous study has assessed the entire innovation generation process in a community pharmacy context. The current study applied Roger's theory to identify IT innovations that facilitate patient care services in community pharmacies, to evaluate their development process, and to assess community pharmacists' readiness to adopt these innovations.

## METHODS

### Study design

The triangulation process combined qualitative semi-structured theme interviews (Clark 2003, Tong et al. 2007) with a purposive sample of 14 international experts from eight developed countries, and a quantitative national survey among representative samples of Finnish community pharmacy owners (mail survey: response rate 53%, n=308), and community pharmacists (online survey: response rate 22%, n=373).

### Interview of international experts

#### Study participants

A purposive sampling strategy was employed to seek perspectives from a broad range of informants with expertise in pharmaceutical care (Hepler and Strand 1990) implementation and IT development

in community pharmacy practice. Informants were selected from eight developed countries with advanced community pharmacy systems (**Table 1**). Sample selection was based on the potential interviewees' contributions to the literature and/or professional practice. The final sample size was achieved when data saturation occurred. Potential informants were told of the study by e-mail and invited to participate. All participants provided written informed consent for participation.

### Interview guide and data collection

The semi-structured interview guide consisted of topics and open-ended questions derived from Rogers' theory (Rogers 2003) (**Appendix 1**). The

guide was used to stimulate open discussion on pre-determined themes (Silverman 2000) in order to elicit the experts' opinions on IT innovations and their diffusion into the community pharmacy practice. It was pre-tested for face-validity in one pilot interview, and no modification was deemed necessary. Data from the pilot interview were not included in the final analyses. Most of the interviews (n=9) took place at the World Congress of Pharmacy and Pharmaceutical Sciences in 2007–2008, as it was a feasible way to perform in-person interviews with selected informants. The in-person interviews lasted between 22 to 73 minutes each. Interviews with Finnish informants were conducted in Finland in 2007–2008. One of the experts was interviewed

### Study participants (n=14)

| Employment status   | n |
|---|---|
| University professor  | 3 |
| Researcher  | 2 |
| Pharmacy owner  | 3 |
| Manager in a national association                             | 2 |
| IT expert in a national association                           | 2 |
| Manager in a private company                                  | 1 |
| Government policy analyst specialized in medicines management | 1 |
| Country   |   |
| Australia   | 2 |
| Finland   | 4 |
| The Netherlands   | 2 |
| Portugal  | 1 |
| Sweden  | 1 |
| Switzerland   | 1 |
| The United Kingdom  | 1 |
| The United States   | 2 |
| Gender  |   |
| Female  | 7 |
| Male  | 7 |
| Language  |   |
| Native English  | 5 |
| Other language  | 9 |

**Table 1. Demographics of international experts (n=14)**

by e-mail. The interviews were conducted in English, except with Finnish participants, which were conducted in Finnish.

### Data analyses and coding framework

All interviews were digitally audio-taped and transcribed verbatim. Finnish participants' transcribed interviews were translated into English. These transcripts were repeatedly read by a researcher while listening to the audiotapes to achieve a consistent comparison to identify emerging patterns and key themes (Boeije 2002). Single words, sentences or groups of sentences related to a particular theme were coded by one researcher and independently verified by another researcher. Rogers' theory guided this qualitative analysis. Themes emerging from the data were grouped into the six phases of the Generation of Innovations Process (Rogers 2003). Any differences in interpretation between the researchers were resolved through discussion. Once key themes were identified, the transcripts were purposively re-read to detect any discussion that deviated from them. When interpreting the data, researchers remained aware of and assiduously worked to preclude any potential biases.

## PHARMACISTS AS INNOVATORS: A NATIONAL SURVEY OF FINNISH COMMUNITY PHARMACY PRACTITIONERS

### Sample

A national cross-sectional survey of all community pharmacy owners, pharmacy managers and staff pharmacists was conducted in Finland in 2006–2007. The survey assessed their innovativeness and readiness to adopt innovations as defined by Rogers (Rogers 2003). All recipients were requested to respond anonymously. Data were collected by 1) a mail survey sent to all Finnish independent pharmacy owners (n=580) through the Association of Finnish Pharmacies (AFP) in December 2006; the study was closed after two electronic reminders via the owners' national intranet in three weeks' time; and 2) an electronic email survey sent to all members of the Finnish Pharmacists' Association in January 2007, n=1709 (MSc and BSc pharmacists) and the

Finnish Pharmacists' Society (MSc pharmacists) employed in community pharmacies, via the University of Helsinki; the study was closed after one e-mail reminder.

### The survey instrument and data analysis

Innovativeness and readiness to adopt innovations were assessed according to the instrument developed by Rogers (Rogers 2003) (**Appendix 2**). The survey instrument was piloted in a convenience sample of 28 pharmacy practitioners to determine face validity, and no refinements were required. The subjective innovativeness of the survey respondents was queried and the results were compared to earlier national studies conducted among community pharmacists in the Netherlands in 2002 (Pronk et al. 2002) and in Finland in 2005 (Saario 2005). Survey data were analysed using the Statistical Package for Social Sciences (SPSS) for Windows, version 14.0.

## RESULTS

### Processes for generating community pharmacy IT innovations

The interviewed experts named 14 different IT innovations for community pharmacies which were classified into three main categories (**Figure 1**). Each respondent named 0–5 different innovations, of which ePrescribing and other IT systems supporting electronic health data management and community pharmacy's involvement in patients' medication management were most often mentioned. Some interviewees, however, had difficulty in naming specific IT innovations.

*"I don't think we have many... ..I don't personally keep them particularly innovative, they tend to target to what pharmacist are used to using, so they have made the program very simple, very basic."*

**Figure 2** presents the typical characteristics of the Generation of Innovation processes for the community pharmacy IT development found in the qualitative analysis. According to the interviewees, the stimuli for IT development in community pharmacies were Patient Safety; Support for a New Service Model; Patient Care Responsibilities; International Trends; Business Idea of a Com-

**Figure 1. Key community pharmacy IT innovations according to 14 international informants from 8 countries with developed community pharmacy systems.**

**Electronic Health Records (EHR)**

Electronic prescribing (n=5)  
Electronic record management system:  
shared patient data (n=2)  
Web-messaging between the patient,  
the physician and pharmacies (n=2)  
Safety alert systems and decision support (n=1)

**Extranet applications**

Databases (n=1)  
Portals of Suppliers: Drug companies  
messaging to the pharmacies (n=1)  
Medical device dictionary (n=1)

**IT based medication management  
in community pharmacy**

Medication reviews (n=3)  
Disease management (n=2)  
Drug-drug interactions screening (n=2)  
Drug related problems documentation instrument,  
database and e-learning (n=1)  
Prospective DUR (n=1)  
Self-care program for decision making (n=1)  
Database search according  
to patient characteristics (n=1)

mercial Company; Legislation to Enhance Electronic Services; Low Profits for Pharmaceuticals; and Consequence of Another Innovation. Most interviewees reported patient safety as the starting point for development, and ePrescribing was the most often mentioned innovation to address patient safety. Patient care orientation emerged as an international trend that was pushing new services whose performance required IT support. Some reported patients' healthcare needs, such as smoking cessation, as initiators. Alternatively, several experts mentioned economic pressures as a driving force for IT innovations.

Many of the innovations mentioned by the experts did not have research as a starting point (**Figure 2**): less than half were developed following systematic research or even pilot research. Only one respondent mentioned research in general: there is lots of research on large-scale development projects concerning health information technology, electronic health records (EHR), including electronic prescribing, and integration of the health care providers' IT systems. Some experts were unaware of specific research initiatives. In most of the IT development processes described by the experts, the coordinator of the process was a governmental unit, and only in a few processes was it a private company. The development processes had taken from 5–6 up to 25 years. Leadership was mentioned as an important factor in the lack of research and lack of leadership was mentioned as a problem.

*“The will of the politicians has been that the project starts, but there has not actually been any coordinator and this is the first big problem of the whole project.”*

Only one expert described the development process as involving team work, and this respondent noted a governmental role. In this process there was cooperation between the technologists and the pharmacists who defined the software functionalities needed in pharmacies. Some of the innovations described by the interviewees were still in the development process, while others had been commercialized and were being sold to users.

Many of the interviewees seemed to have a critical attitude towards commercial companies and emphasized the importance of role of na-

tional governments in IT development projects (**Figure 2**). Some reported an innovation which had been developed as a public project led by the government, but which had been subsequently commercialized and delivered by private providers. Interviewees were also queried as to whether the IT innovation's diffusion process had been organized. This was a difficult question for most of the respondents. One described the matter as a leadership issue spanning 25 years of attempts to organize the process. One stated that the diffusion process was not organized at all, but occurred organically. Interviewees also described the users' adoption of the innovation. Some thought users were receptive to the innovation. Only one had experience with Rogers' adopters' taxonomy:

*“There has been a big variation... you know you have these early innovators and the laggards. In almost every pharmacy you find these. One very important thing is the attitude of the pharmacy manager, if he or she finds it important or not. And also to have coaches, fire soldiers, someone who really fond of and enjoys and finds it very important to do something, is enthusiastic and committed.”*

Consequences of IT innovations were systematically evaluated in only few cases (**Figure 2**); most of the opinions were based on interviewees' own estimations. According to users' feedback, some interviewees reported that an IT innovation had met the needs of its users and had improved quality of care or patient safety. Some interviewees were also satisfied with an innovation, but felt that there is still much to do to support pharmaceutical services in community pharmacies. One interviewee could not discuss the benefits of an innovation, as there had not been evaluative research on it. One thought that an innovation has not met the needs of its users or improved the quality of care. However, interviewees could clearly see that one innovation stimulated further innovations.

*“...if you look the time before home medication review (HMR), it really started with residential care and then it went to HMR then it went to drug information then it went to disease state management. So you can see how the innovation over time is spreading.”*

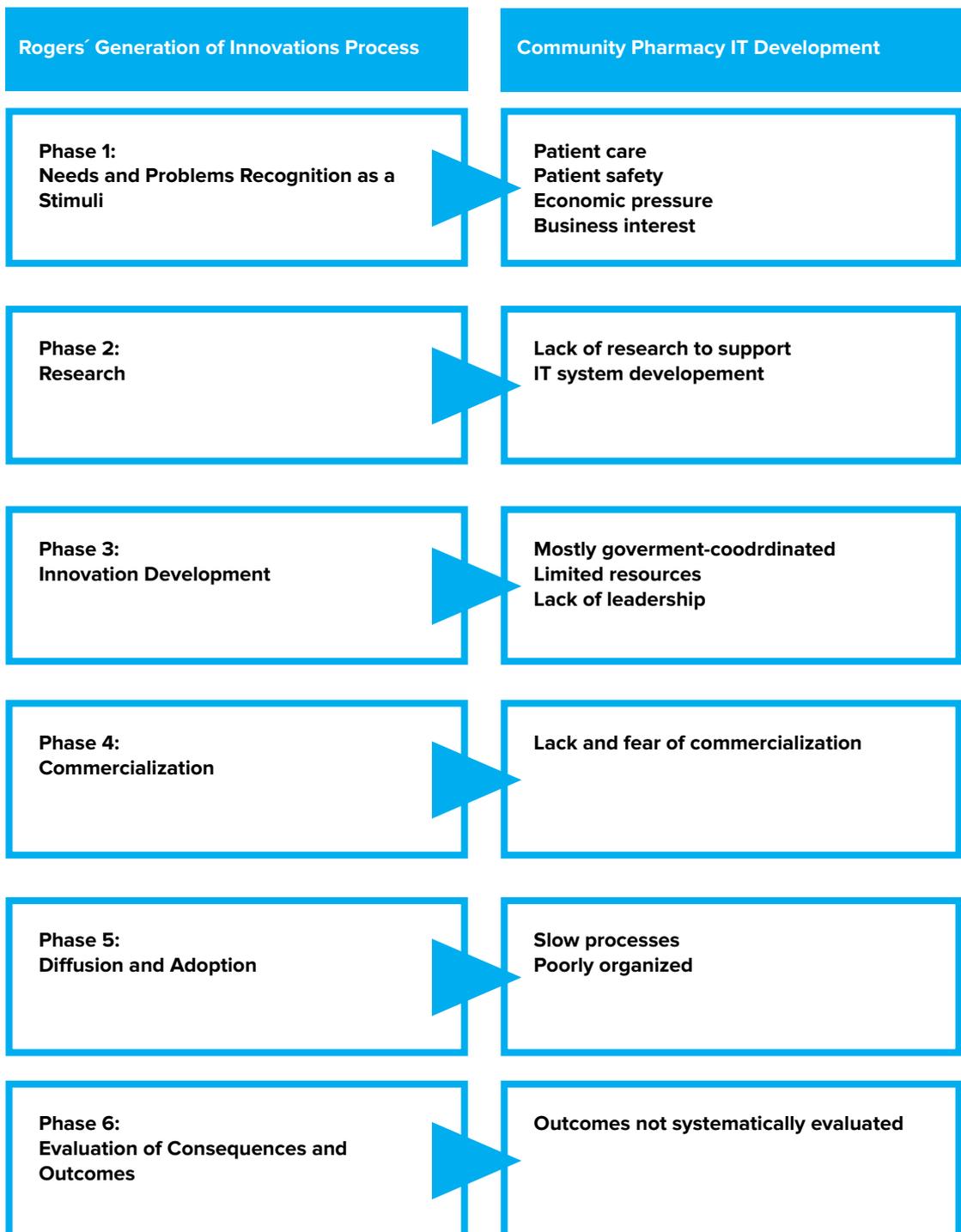


Figure 2. Key features of community pharmacy IT innovation development processes compared to the Rogers theory of Generation of Innovation (Rogers 2003).

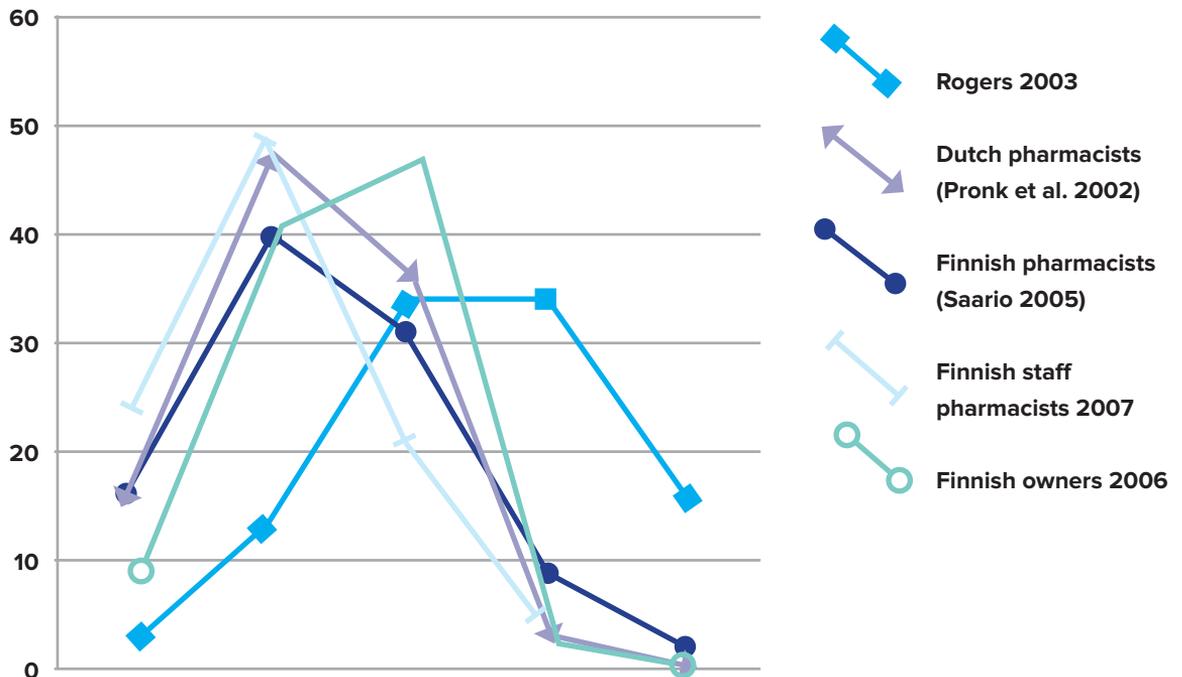
**Perception of Finnish community pharmacy practitioners' innovativeness**

Respondents were representative of the target population in terms of gender, age and geographical distribution (Westerling et al. 2010). The shapes of the diffusion curves based on their replies generally followed the bell distribution reported by Rogers in 2003 (Figure 3). However, the pharmacists' curves were skewed more towards the innovator than in the laggard categories, which deviated from Rogers' generic model. One interviewee described pharmacy and innovations as follows:

*“On the field of pharmacy there has not been very strong tradition for the generation of innovations, at least in Finland, hardly anywhere. Maybe lately there have been some trends that people have set up firms to do something brand new, but there have not been strong traditions for that.”*

**Lessons learned and general recommendations**

Interviewees were asked to nominate barriers and facilitators to innovation. Barriers included: Funding; Priorities Set by the Management; Techni-



**Figure 3. Self-reported innovativeness of Finnish and Dutch pharmacists compared to Rogers' innovativeness curve (Pronk 2002, Rogers 2003, Saario 2005).**

cal Issues; Market Competition; and Privacy Protection. Facilitators included: Good Management; Attitude and Will; Funding; Good Quality of the Technical Solutions; Information; and Collaboration between Organizations. The interviewees were also asked for general recommendations of issues that should be taken into account in the development of new IT systems. Some thought that the system should be simple and modular so that new functionalities could be added. Another believed the most important element would be to listen to end users during the process. A good consultation process was also mentioned, as was research to assess the effectiveness of new technologies for improving appropriateness of drug use before a system's implementation.

*"We have to go forward just to decide when and how to do it. And then all the barriers and strengths are to show up and of course on the bottom line people say: "Well, it is a good idea, but we cannot do it for several reasons. ... So it is part of leadership here, it is part of making the vision real. But people will have to do it! So it is mobilizing the innovation."*

## DISCUSSION

According to our findings, the processes for generating community pharmacy IT innovations only partially followed the six phases described by Rogers' theory. The most neglected phase was performing systematic research before proceeding to the IT system's development. The next most common gap was with evaluation of results after implementation. Lack of research on the process was more evident when the responsible entity was a private company. Failure to perform a systematic needs assessment may lead to a very limited understanding of the user's perspective. This inadequate understanding may then influence the evolution of subsequent innovations (Rogers 2003). Previous studies on health information technology have concluded that technology should be developed through research and based on evidence (Hanney et al. 2007, Noorani et al. 2007).

A majority of the community pharmacy IT development processes described by the informants were coordinated by governments and had not been commercialized as of the time of this study. Although there are private business solutions for community pharmacy services in most of the countries involved in the study (Rigby 2004, Jackson et al. 2006, McMahan 2008), the interviewees emphasized the role of national governments in the development phase. Although organization and control by national governments was appreciated, it was, nonetheless, reported to lead to a slow and bureaucratic IT development process. The expert interviews attribute this to a lack of leadership and funding throughout the innovation process. Our findings are consistent with previous implementation studies of community pharmacy residency programs in the US (Schommer et al. 2010), and electronic health record (EHR) systems in multiple countries (Deutsch et al. 2010). These studies have concluded that strategic, organizational and human challenges are more complex and more difficult to cope with than is the technology alone (Deutsch et al. 2010). It may be possible that governmental coordination contributes to the present situation in which there have been fewer innovations in community pharmacy IT. This study suggests that the pharmacy profession should assume more responsibility for development of IT tools that support their practise.

Our study showed that community pharmacists in Finland and in the Netherlands have much higher self-reported innovativeness than that of populations included in Rogers' classical studies (Rogers 2003). This finding may indicate a real difference in innovativeness favoring community pharmacists. Rogers' theory and adopters curve (**Figure 1**) are based on observational data gathered in the 1950s. Both community pharmacists' studies are based on surveys assessing self-perception of innovativeness. Another explanation for the difference in findings between Rogers' early work and the present study may be the time frame: it is possible that nowadays change occurs faster and the social pressure to adopt innovations is higher. As

a consequence, the bell shape of the adopters curve would move in the direction of the innovators category, even if the theoretical underpinnings do not change. This specific development should be explored with broader populations than community pharmacists alone; to see if there has been a shift of the adopter curve.

According to our results, both Finnish pharmacy owners and employed pharmacists define themselves as innovators willing to adopt IT innovations. However, it is a paradox that the actual rate of IT systems innovations has been slow in Finnish community pharmacies. Is this a consequence of authorities having strict control over community pharmacies, resulting in more constrained resources being available for implementing innovative IT systems? Development of community pharmacy IT can be seen a health policy issue, as well as a leadership issue. Collectively, these driving forces are steering the strategy and coordination required for the development and implementation of innovative IT systems.

## CONCLUSIONS

The development processes for IT and related community pharmacy innovations do not entirely fol-

low Rogers' theory on the diffusion of innovations. Specifically, community pharmacy IT developments lack research, organization, leadership and user involvement in the process. The diffusion of innovations framework could provide systematic guidance for future projects to ensure that potential innovations are based on a sufficient understanding of the pharmacy practice problem that they are to solve. According to the results from self-perception, the profession's willingness to innovative is high, but has led to a limited number of practical IT innovations.

## ACKNOWLEDGEMENTS

We are grateful for financial support by the Association of Finnish Pharmacies covering part of the cost of data collection. The authors thank Dr. Simon Bell, formerly University of Helsinki, currently University of South Australia, for his expertise and valuable comments in planning the study design and in preparation of the manuscript.

### APPENDIX 1.

#### Generation of Innovations (interview guide)

What led to the development process of the innovation?  
Was there any research before the development process started?  
Select one most important innovation and describe the development process.  
Was the innovation commercialized, or will it be?  
How the users adopted the innovation?  
What are the consequences of the innovation: has it met the needs and expectations of its users?  
Can you identify further needs for innovation development in the community pharmacy IT systems?

### APPENDIX 2.

#### Innovativeness (interview guide)

Which of following choices describes best your own attitude to the changes and new function models?

1. I want to be involved in testing and developing immediately
2. I take the innovations in use quicker than average and I am pleased to tell about them to other people
3. I do not take the innovations in use until the benefits are shown
4. I need time to considering and support
5. I do not wish changes, I am happy with the situation nowadays and I like routines
6. Do not know

## REFERENCES

- Anderson JG: Social, ethical and legal barriers to e-health. *Int J Med Inform* 76 (5–6): 480–483, 2007
- Boeije H: A purposeful approach to the constant comparative method in the analysis of qualitative interviews. *Quality & Quantity* 36: 391–409, 2002
- Clark J: Qualitative research review guidelines – RATS. How to peer review a qualitative manuscript. In Godlee F, Jefferson T, editors. *Peer Review in Health Sciences*. 2nd ed. London: BMJ Books, 219–235, 2003. Available from: <http://www.biomedcentral.com/info/ifora/rats>
- Deutsch E, Duftschmid G, Dorda W: Critical areas of national health record programs – Is our focus correct? *Int J Med Inform* 79 (3): 211–22, 2010
- Haider M, Kreps GL: Forty years of Diffusion of Innovations: Utility and Value in Public Health. *J Health Commun*. 9: 3–11, 2004
- Hanney S, Buxton M, Green C, Coulson D, Raftery J: An assessment of the impact of the NHS Health Technology Assessment Programme. *Health Technol Assess* 11 (53): 1–180, 2007
- Hepler CD, Strand LM: Opportunities and responsibilities in pharmaceutical care. *Am J Hosp Pharm* 47: 533–543, 1990
- Jackson CL, Bolen S, Brancati FL, Batts-Turner ML, Gary TL: A systematic review of interactive computer-assisted technology in diabetes care. *J Gen Intern Med* 21: 105–110, 2006
- Jamal A, McKenzie K, Clark M: The impact of health information technology on the quality of medical and health care: a systematic review. *HIM J* 38 (3): 26–37, 2009
- Ludwick DA, Doucette J: Adopting electronic medical records in primary care: lessons learned from health information systems implementation experience in seven countries. *Int J Med Inform* 78 (1): 22–31, 2009
- McMahan R: Operationalizing MTM through the use of Health Information Technology. *J Manag Care Pharm* 14 (2): 18–21, 2008
- Noorani HZ, Husereau DR, Boudreau R, Skidmore B: Priority setting for health technology assessments: a systematic review of current practical approaches. *Int J Technology Assess Health Care* 23(3): 310–315, 2007
- Pronk MC, Blom LT, Jonkers R, Rogers EM, Bakker A, de Blaey KJ: Patient oriented activities in Dutch community pharmacy: diffusion of innovations. *Pharm World Sci* 24 (4): 154–161, 2002
- Rigby D: MMR software packages reviewed. *Australian Pharmacist* 23 (7): 510–512, 2004
- Rogers EM: *Diffusion of Innovations*. 5th ed. New York: Free Press, 2003
- Saario H: Diffusion of innovations in community pharmacies – a questionnaire based survey. Master's Thesis. University of Helsinki, 2005
- Schommer JC, Bonnarens JK, Brown LM, Goode JV: Value of community pharmacy residency programs: College of pharmacy and practice site perspectives. *J Am Pharm Assoc* 50 (3): 72–88, 2010
- Silverman D: *Doing Qualitative Research. A Practical Handbook*. Trowbridge, Wilshire: SAGE Publications Ltd, The Cromwell Press Ltd, 2000
- Tong A, Sainsbury P, Craig J: Consolidated criteria for reporting qualitative research (COREQ): a 32-item checklist for interviews and focus groups. *Int J Qual Health Care* 19: 349–359, 2007
- Westerling A: *Information Technology Development Needs in Community Pharmacies: A Strategic Approach*. Academic Dissertation. University of Helsinki, 2011. Available from: <https://helda.helsinki.fi/handle/10138/28196>
- Westerling AM, Hynninen JT, Haikala VE, Airaksinen MS: Opinion comparison concerning future information technology in Finnish community pharmacies. *Pharm World Sci* 32 (6): 787–794, 2010

# Pohjoismainen kliinisen farmasian yhteistyöverkosto

– Nordic Networking Group  
for Clinical Pharmacy (NNGCP)

Have you been wondering how we can easily learn and communicate with clinical pharmacist colleagues from other Nordic Countries? It has been now made easy through NNGCP – Nordic Networking Group for Clinical Pharmacy. Countries currently involved in NNGCP are Iceland, Denmark, Norway, Sweden, Estonia and Finland.

NNGCP, an annual meeting of Nordic clinical pharmacists (mainly from hospitals) is organized for the sixth time in Tartu Estonia, in 3-5th of June 2015. It is held at the same time together with the Nordic Social Pharmacy and Health Services Research Conference (NSPC). Every year approximately 60-100 clinical pharmacists willing to develop clinical pharmacy in their home countries get together in order to share knowledge and meet colleagues.

The main purpose of the NNGCP is to create a platform where clinical pharmacists from all the Nordic Countries, in a friendly and informal atmosphere, can share experiences and discuss challenges in everyday clinical pharmacy practice and research projects. Another goal is to provide a platform for creating new research projects in collaboration between clinical pharmacists from hospitals and academia.

In previous years various topics have been presented and discussed by clinical pharmacists in the annual NNGCP meetings. Last year the NNGCP meeting focused on clinical pharmacy in primary health care, psychiatry and antibiotics. Every other year the NNGCP also organizes short country update presentations to learn how member countries are developing new clinical pharmacy services.

## **Wish to have further information and register for the NNGCP meeting in Tartu?**

Send an e-mail to NNGCP contact person in Finland:

Niina Laine, MSc, Clinical Pharmacy

E-mail: [niina.laine@helsinki.fi](mailto:niina.laine@helsinki.fi)

*Niina Laine, NNGCP*