Publications of the Ministry of Social Affairs and Health 2009:10

Safe Pharmacotherapy

NATIONAL GUIDE FOR PHARMACOTHERAPY IN SOCIAL AND HEALTH CARE

An abbreviated version

MINISTRY OF SOCIAL AFFAIRS AND HEALTH

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National Guide for Pharmacotherapy in Social and Health Care

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Published in Finnish under title: Turvallinen lääkehoito. Valtakunnallinen opas lääkehoidon toteuttamisesta sosiaalija terveydenhuollossa.
Handbooks of the Ministry of Social Affairs and Health, Finland 2005:32.

www.stm.fi/Publications

ISBN 978-952-00-2827-5 (pb)
ISBN 978-952-00-2828-2 (PDF)

ISSN 1236-2050 (print)
ISSN 1797-9854 (online)

URN:ISBN: 978-952-00-2828-2
http://urn.fi/URN:ISBN: 978-952-00-2828-2

Print: Helsinki University Print, Helsinki 2009
Publisher: Ministry of Social Affairs and Health, Finland

SUMMARY

A working group set up by the Finnish Ministry of Social Affairs and Health has drawn up national guidelines for the provision of pharmacotherapy in public and private social and health care units. The purpose of the Safe pharmacotherapy guidelines is to harmonise the principles for the provision of pharmacotherapy, to clarify the division of responsibilities related to its provision, and to define the minimum requirements that must be complied with in all units providing pharmacotherapy. The guidelines also give examples of good practices in pharmacotherapy. The development needs that necessitated the preparation of the guidelines are related, above all, to the definition of questions of responsibility in pharmacotherapy in different sectors, harmonisation of licence practices, induction of staff, and ensuring and maintaining the knowledge and skills in pharmacotherapy.

The general guidelines and principles for pharmacotherapy are the same for all public and private social and health care units and well as for establishments providing pharmacotherapy in other areas. According to the guidelines the provision of pharmacotherapy is based on a pharmacotherapy plan drawn up in the unit or workplace, that serves as the tool for definition and management of the following sub-areas in pharmacotherapy:

- Content and methods of pharmacotherapy
- Ensuring and maintaining the knowledge and skills in pharmacotherapy
- Personnel's responsibilities, obligations and division of labour
- Licence practices
- Pharmaceutical service: ordering, storing and manufacture of medicines, making them ready for use, returning of medicines, information, guidance and advice
- Distribution and administration of medicines
- Informing and advising patients
- Evaluation of the effectiveness of pharmacotherapy
- Documentation and flow of information
- Systems for monitoring and feedback

Pharmacotherapy is a health care activity that is carried out, as a rule, by health care professionals with training in pharmacotherapy and under their responsibility. Licensed health care professionals with appropriate training bear the overall responsibility for the provision of pharmacotherapy, and every employee giving pharmacotherapy or taking part in it is responsible for his/her actions. Foremen guide and supervise the carrying out of pharmacotherapy in accordance with a pharmacotherapy plan, as well as decide on the division of labour and co-operation between the different personnel groups so that the skills and knowledge of all groups are made use of optimally.

The responsibility for the organisation of the drawing up, carrying out and monitoring of a pharmacotherapy plan is vested in the management of the social and health care units. A well organised and managed pharmacotherapy also brings about savings in terms of expenses. The guidelines emphasise the need for developing attitudes and the operational culture through learning from errors and adjusting operational practices based on assessments.

Key words: guidelines, health care, pharmacotherapy, safety

TIIVISTELMÄ

Turvallinen lääkehoito. Valtakunnallinen opas lääkehoidon toteuttamisesta sosiaali- ja terveydenhuollossa.

Sosiaali- ja terveysministeriön asettama työryhmä laati valtakunnallisen oppaan lääkehoidon toteuttamisesta julkisissa ja yksityisissä sosiaali- ja terveydenhuollon toimintayksiköissä. Turvallinen lääkehoito -oppaan tarkoituksena on yhtenäistää lääkehoidon toteuttamisen periaatteet, selkeyttää lääkehoidon toteuttamiseen liittyvä vastuunjako ja määrittää vähimmäisvaatimukset, joiden tulee toteutua kaikissa lääkehoitoa toteutettavissa yksiköissä. Oppaassa on myös esimerkkejä lääkehoidon toteuttamisen hyvistä käytännöistä. Oppaan laatimisen taustalla olevat kehittämistarpeet liittyvät ennen muita lääkehoidon vastuukysymysten määrittämiseen eri toimialoilla, lupakäytäntöjen yhtenäistämiseen, työntekijöiden perehdyttämiseen sekä lääkehoidon osaamisen varmistamiseen ja ylläpitämiseen.

Lääkehoitoa ja verensiirtoja koskevat yleiset ohjeet ja periaatteet ovat samat kaikille terveyden- ja sosiaalihuollon julkisille ja yksityisille toimintayksiköille sekä lääkehoitoa toteutettaville muille alueille. Oppaan mukaan lääkehoidon toteuttaminen perustuu toiminta- ja / tai työyksikössä laadittuun lääkehoitosuunnitelmaan, joka on työväline seuraavien lääkehoidon osa-alueiden määrittämiseen ja hallintaan:

- Lääkehoidon sisältö ja toimintatavat
- Lääkehoidon osaamisen varmistaminen ja ylläpitäminen
- Henkilöstön vastuut, velvollisuudet ja työnjako
- Lupakäytännöt
- Lääkehuolto: lääkkeiden tilaaminen, säilytys, valmistaminen, käyttökuntoon saattaminen, palauttaminen, lääkeinformaatio, ohjaus ja neuvonta
- Lääkkeiden jakaminen ja antaminen
- Potilaiden informointi ja neuvonta
- Lääkehoidon vaikuttavuuden arviointi
- Dokumentointi ja tiedonkulku
- Seuranta- ja palautejärjestelmät

Lääkehoito on terveydenhuollon toimintaa, jota toteutetaan pääsääntöisesti lääkehoidon koulutuksen saaneiden terveydenhuollon ammattihenkilöiden toimesta ja vastuulla. Lääkehoidon koulutuksen saaneet laillistetut terveydenhuollon ammattihenkilöt kantavat kokonaisvastuun lääkehoidon toteuttamisesta, ja jokainen lääkehoitoa toteuttava tai siihen osallistuva kantaa vastuun omasta toiminnastaan. Esimiehet ohjaavat ja valvovat lääkehoidon toteuttamista lääkehoitosuunnitelman mukaisesti sekä päättävät eri henkilöstöryhmien työnjaosta ja yhteistyöstä siten, että jokaisen ammattiryhmän osaaminen hyödynnetään parhaalla mahdollisella tavalla.

Vastuu lääkehoitosuunnitelman laatimisen, toteuttamisen ja seurannan organisoinnista on sosiaali- tai terveydenhuollon toimintayksikön johdolla. Hyvin organisoitu ja hallitusti toteutettu lääkehoito tuo myös kustannussäästöjä. Oppaassa korostetaan asenteiden ja toimintakulttuurin kehittämistä siten, että virheistä opitaan ja toimintatapoja muutetaan arvioinnin perusteella.

Asiasanat: lääkehoito, ohjeet, terveydenhuolto, turvallisuus

REFERAT

Säker läkemedelsbehandling. Nationell handbok för genomförande av läkemedelsbehandling inom social- och hälsovården.

En arbetsgrupp tillsatt av social- och hälsovårdsministeriet har utarbetat en nationell anvisning för genomförande av läkemedelsbehandling vid offentliga och privata social- och hälsovårdens verksamhetsenheter. Avsikten med Säker läkemedelsbehandling –handboken är att harmonisera principerna för läkemedelsbehandling samt tydliggöra ansvarsfördelning i fråga om läkemedelsbehandling och definiera de minimikrav som skall uppfyllas i alla enheter som genomför läkemedelsbehandling. Anvisningen har även exempel på goda praxis för läkemedelsbehandling. De utvecklingsbehov som ligger på bakgrunden till utarbetandet av anvisningen gäller först och främst definiering av ansvarsfrågor angående läkemedelsbehandling på olika verksamhetsgrenar, harmonisering av tillståndsförfaranden, utbildning av personalen och tryggande och upprätthållande av kunnande inom läkemedelsbehandling.

Allmänna anvisningar och principer angående läkemedelsbehandling och blodtransfusioner är de samma för alla offentliga och privata verksamhetsenheter inom social- och hälsovården samt övriga områden där läkemedelsbehandling genomförs. Enligt anvisningen skall läkemedelsbehandling bygga på en plan för läkemedelsbehandling som upprättats vid verksamhets- och/eller arbetsenheten och som är ett verktyg för definition och administration av de följande delområden inom läkemedelsbehandlingen:

- Innehåll i och förfaringssätt för läkemedelsbehandling
- Tryggande och upprätthållande av kunnande inom läkemedelsbehandling
- Personalens ansvar och skyldigheter samt arbetsfördelningen
- Tillståndspraxis
- Läkemedelsförsörjning: beställning, förvaring, tillverkning, framställning till användbart skick och återlämning av läkemedel, läkemedelsinformation, handledning och rådgivning
- Distribuering och tilldelande av läkemedel
- Information och rådgivning till patienter
- Bedömning av läkemedelsbehandlingens effekter
- Dokumentering och informationsspridning
- Uppföljnings- och responssystem

Läkemedelsbehandling är verksamhet inom hälso- och sjukvården som genomförs huvudsakligen av yrkesutbildade personer inom hälso- och sjukvården som utbildats inom och som har ansvaret för läkemedelsbehandlingen. Legitimerade yrkesutbildade personer inom hälso- och sjukvården som har utbildning inom läkemedelsbehandling bär totalansvaret för läkemedelsbehandling, och var och en person som genomför eller deltar i genomförande av läkemedelsbehandling bär ansvaret för sin egen insats. Cheferna styr och övervakar att läkemedelsbehandling genomförs enligt planen för läkemedelsbehandling samt bestämmer om arbetsfördelningen och samarbetet mellan olika personalgrupper så att kunnandet av var och en yrkesgrupp utnyttjas på det bäst möjliga sättet.

Ledningen för en verksamhetsenhet inom social- och hälsovården ansvarar för organisering av planeringen, genomförandet och uppföljningen av läkemedelsbehandlingsplanen.

Läkemedelsbehandling som är väl organiserad och som genomförs på ett samlat sätt medför också kostandsbesparingar. Anvisningen poängterar att attityder och verksamhetskulturer skall utvecklas så att man lär sig av sina misstag och praxis ändras på basis av utvärdering.

Nyckelord: anvisningar, hälso- och sjukvården, läkemedelsbehandling, säkerhet

CONTENT

1 INTRODUCTION

The social and health and social care sector is facing rising levels of risk. Improved process control procedures are thus necessary. As treatment practices develop, patient care is becoming more challenging and is increasingly being provided in non-healthcare settings. Due to population ageing, a growing proportion of care is also being provided in the home. In addition, changes to working practices and job roles mean that the work of medical and nursing staff is becoming increasingly specialised.

Drug therapies offer increasing potential for treatment and their use is on the rise due to the availability of more effective products and new formulations and administration routes. At the same time, adverse effects are also coming under increasing scrutiny. Finnish and international studies suggest that approximately 10 per cent of patients will experience an adverse event during their treatment. Of these, a significant proportion is pharmacotherapy-related. In approximately 1 per cent of cases the effects are severe (Weingart et al 2000, Davis et al 2003, Mustajoki 2005). The European Union (European Commission 2005), the Council of Europe and the World Health Organisation are working together to reduce the incidence of medical errors and to improve patient safety.

In healthcare operating units, drug therapies are ordinarily administered by healthcare professionals. Health supervisory authorities in Finland have identified gaps in the knowledge and skills of medical and nursing staff involved in the administration of pharmacotherapy. Research has also pointed to shortcomings in the pharmacotherapy skills of graduate public health nurses and practical social and health and social care nurses (Huhtala 1996, Grandell-Niemi 1997, Murtola 1999, Veräjänkorva 2003). In addition, myriad certification procedures and insufficient levels of guidance have been identified at healthcare unit level (Mattila & Isola 2002).

Emergency care staff must have a strong pharmacotherapy skills and knowledge base. Drug-related medical errors in emergency care may prove fatal due to the potency of many of the medications used. Emergency care pharmacotherapy practices and staff qualifications and skills vary greatly.

In addition to healthcare operational units, pharmacotherapy is also administered in social care units and other sectors, such as education and youth work. Pharmacotherapy practices within the social care sector also vary greatly and not all staff have been trained in pharmacotherapy as part of their basic training. It is often unclear who is entitled to administer medicines and what minimum qualifications and skills are required. At times, drug therapies are administered by staff not trained in medication.

Seamless co-operation between health and social care workers, pharmacies and the patient and/ or their representative or next of kin is particularly important

when care is being delivered at the patient's home. In order for drug therapies to be successful, staff must ensure that information and guidance is offered to the patient and that the effects of the treatment are carefully monitored and reviewed. A study into home care arrangements found drug handling and distribution certification practices to be lacking in clarity and consistency and identified a failure on the part of service providers to carry out regular medical error and skills audits. Further training arrangements too were identified as requiring development. Furthermore, the study suggested that co-operation with the next of kin and family is limited and little is being done to encourage them or the patient to participate actively in the pharmacotherapy process (Pietikäinen 2004).

There is a need to clarify lines of responsibility, to harmonise certification practices and staff induction processes, to verify and maintain pharmacotherapy knowledge and skills and to address education and training issues (Mattila & Isola 2002). Many health and social care operational units lack consistent protocols to govern the participation of students and staff with vocational qualifications, Bachelor or Masters degrees in healthcare and social services in pharmacotherapy provision.

The issuing of a prescription is the first step towards safe and high-quality pharmacotherapy. The prescription of medicines in Finland is regulated by the Ministry of Health and Social Affairs (Decree 726/2003). This guidance deals with prescriptions only insofar as they relate to the provision of pharmacotherapy, addressing issues such as prescription errors, clarity and documentation. Particular attention is given to communication strategies and guidance offered to patients at the time of prescription and administration.

The guidance stops short, however, of issuing detailed instructions for the administration of pharmacotherapy. It lays out general principles for the provision of safe and high-quality pharmacotherapy and discusses the specialist requirements placed on the care provided in social and health and social care operational units, emergency care units and service environments where pharmacotherapy is not routinely carried out.

The guide applies to all health and social care units and environments where pharmacotherapy is provided, including health and social care operational units and service environments where pharmacotherapy is not routinely carried out, as well as outsourced and private health and social care service providers. This guide requires all units to prepare a pharmacotherapy plan, which will serve as a practical pharmacotherapy planning and management tool. It highlights the role and responsibilities of management in the planning, organisation and quality-assurance of pharmacotherapy provision. The same pharmacotherapy principles and practices will apply across the board in all units but can be adapted according to local circumstances at unit level.

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2 KEY CONCEPTS

Concepts central to this guide are set out in Table 1 below.

Tab 1. Key concepts

Activity subject to notification	Private sector service providers providing services other than 24-hour private social welfare services must provide advance notification in writing to the relevant local authority of the commencement, substantial alteration to or discontinuation of such a service. Notification is also required in the event of change to the person responsible for service provision. Local authorities must notify the relevant State Provincial Office of such service provision for registration purposes.
Injections	Intradermal, sub-cutaneous or intra-muscular injections and the techniques and procedures (including dosage and asepsis) required for their administration.
Non-prescription medicines	Medicines sold over the counter at pharmacies.
Domiciliary care	Care and services enabling the patient to live primarily in their own home (home care services and related support services, home nursing services, preventative health and social care services, other support services)
Non-parenteral medications	Medications that can be administered without a separate procedure i.e. orally, rectally or as tablets, capsules, drops (including eye drops), ointments, patches, suppositories, inhalers etc.
Medicine	A preparation or substance applied internally or externally for the purpose of treating, alleviating or preventing a medical condition or its symptoms. The term can also be extended to include internally or externally administered substances or combinations of substances used for the purpose of restoring, improving or changing physiological function through pharmacological, immunological or metabolic processes or for the purpose investigating the patient's condition or cause of illness.
Medication error	Any pharmacotherapy-related and preventable adverse event, including medication errors, accidents and near misses.
Licensed healthcare professionals trained in pharmacotherapy	Healthcare professionals whose basic training entails pharmacotherapy training and who have been authorised or licensed for practice by the National Authority for Medicolegal Affairs and are legally entitled to use the occupational title of licensed health and social care professional.
Professionals with protected occupational titles trained in pharmacotherapy	Healthcare professionals with protected occupational titles whose basic training entails pharmcotherapy training, and who are entitled to use a protected occupational title.
Social care professionals trained in pharmacotherapy	Social, social and healthcare and pedagogical qualifications incorporating training in pharmacotherapy.
Non-pharmacotherapy trained staff	Staff participating in the administration of pharmacotherapy excluding healthcare professionals trained in pharmacotherapy and social care professionals trained in pharmacotherapy. This includes healthcare professionals without training in pharmacotherapy, social care professionals without training in pharmacotherapy and other professionals such as teachers and special needs assistants. Also included are the next of kin/ family and personal assistants.
Service environments where pharmacotherapy is not routinely carried out	Environments where pharmacotherapy is not carried out as a typical or core activity, including social welfare services such as nursery services, educations service and services for young people. In these service environments, pharmacotherapy is commonly carried out by persons without training and under a joint agreement between the patient/ client and the relevant member of staff.

Pharmaceutical services	The procurement, preparation, storage and supply of medicines and the provision of pharmaceutical information and guidance to social and healthcare operational units, including wards, out-patient clinics and patients. Pharmaceutical services units include community pharmacies, hospital pharmacies, medicine centres and pharmaceutical wholesalers.
Formulary	A list of medicines set and authorised by specialists at the unit. Primarily made up of regularly used medicines but also contains some less frequently used but necessary medicines. The formulary is designed to standardise and guide the purchase and use of medicines at the unit. The formulary will be kept under review.
CNS agents	Agents acting on the central nervous system include pharmaceutical products - included in the National Agency of Medicines list of CNS agents - prefixed with the letters Z, ZA, P and PA in the National Agency of Medicines list of agents and which can only be dispensed against a prescription - defined as CNS agents under the terms of the marketing authorisation.
Patient/ client	Throughout this guide the term patient is used to denote persons receiving pharmacotherapy. Pharmacotherapy is a healthcare activity and both the activity and the status of the patient are subject to healthcare legislation irrespective of whether the patient is receiving health and social care.
Prescription medicine	Medicines that can only be dispensed against a prescription issued by a doctor, a dentist or a veterinarian.
Social care professionals	Qualification requirements for social care work, where skills acquired as part of a degree in social welfare, social and healthcare and education are necessary for the professional discharging of duties.
Social care unit	Retirement homes, sheltered housing, substance abuse units, nurseries, child protection units, institutional care for the disabled, domiciliary and units providing private social care services, including sheltered housing for mental health patients, sheltered housing and domiciliary and foster care. Also private units providing 24-hour social care services subject to licensing (Act on the supervison of private social care services, 603/1996, available in Finnish and Swedish only)
Social care work unit	Individual work units within a social care unit.
Intravenous treatment	Intravenously provided fluid, medicine, including titration and preparation. Also denotes procedures required in the provision of intravenous therapies, such as peripheral arterial cannulation
Healthcare professionals	Licensed healthcare professionals, authorised healthcare professionals and healthcare professionals with protected occupation titles as defined in the Act on Healthcare Professionals (559/1994).
Healthcare unit	As defined in the Act on the Status and Rights of Patients (785/1992), including primary healthcare units, units providing specialist healthcare services and private healthcare services (units under license for private healthcare provision).
Healthcare work units	Individual work units operating under larger healthcare units, including domiciliary care, emergency and ambulance services and outpatient clinics and departments.
Narcotics	Pharmaceutical products containing substances listed in Schedules I, II and IV of the Single Convention on Narcotic Drugs and Schedules I and II of the Single Convention on Psychotropic Substances (including morphine, methadone, fentanyl, sufentanil and pethidine).

3 PHARMACOTHERAPY – CURRENT OVERVIEW AND CHALLENGES

There is currently significant variation in Finnish pharmacotherapy practices and insufficient action is being taken by social and health and social care units to develop service provision and to ensure that the appropriate staff skills are in place. Changes to the healthcare operational environment, diverse staff educational backgrounds and skills levels, increasing drug potency and medication errors mean that changes to pharmacotherapy practices are warranted. Operational unit supervisory practices are to be enhanced to ensure that pharmacotherapy practices, task allocation and the role of healthcare managers can be clarified. There is also scope for better use to be made of the feedback received through medical injury reports, disciplinary processes, complaints and supervisory authority rulings.

Problems in pharmacotherapy and medication errors are being brought under increasing scrutiny. The no-blame learning culture currently being promoted means that healthcare professionals can feel more comfortable coming forward to report medication errors. However, due to the lack of systematically gathered data, it is difficult to estimate whether the incidence of medication errors has increased in recent years or whether they are more in evidence due to staff being more willing to report them.

Skills gaps are most commonly found in the following areas: awareness of relevant legislation and guidance, drug calculations, knowledge of proportions and dosages and understanding of drug effects (Huhtala 1996, Grandell-Niemi 1997, Murtola 1999, Veräjänkorva 2003). The aims and objectives for pharmacotherapy teaching and core content are set out in the nursing (polytechnic) skills matrixes and in the national core curriculum for the upper secondary vocation nursing qualification and stand-alone qualification requirements (The Finnish National Board of Education 2001, Ministry of Education 2001). Although polytechnics in Finland are entitled to set out their own curricula, they must adhere to skills matrixes issued by the Ministry of Education. The institutions must also follow the practical nursing degree curriculum and competence-based qualification requirements, as set out by the National Board of Education.

Under the skills matrixes, nurses (polytechnic qualification), emergency medical technician/ paramedics (polytechnic qualification) and midwives (polytechnic qualification) must be provided with extensive training in different types of drug therapies. Graduate nurses must be able to carry out pharmacotherapy using different administration routes, intravenous fluid and drug therapies, in accordance with written instructions from manufacturer and supplier (hospital pharmacy). Nurses must be able to monitor the patient's condition and symptoms and

assess drug therapy efficacy both during and after treatment. In addition, nurses must be able to carry out drug calculations and undertake key pharmacotherapy procedures, including injections. Further key areas include patient education and self-care promotion. (Ministry of Education 2001).

The curriculum requires that the basic vocational qualification in social and health and social care (practical nursing qualification) must equip graduates with the skills to administer pharmacotherapy in accordance with instructions received using different administration routes, including intra-muscular and subcutaneous injections and to dispense medications to patients using a tray-system. Graduate practical nurses must be able to monitor and report on drug therapy efficacy, interactions and side effects and provide guidance and counselling to patients. In addition, practical nurses must be able to monitor the patient's condition and symptoms and assess drug therapy efficacy both during and after treatment. (National Board of Education 2001).

Pharmacotherapy teaching offered in polytechnics and vocational colleges continues to vary greatly, however, and the above skills requirements and aims are not always met in the curricula set by the individual institutions. A further issue is the absence of quantitative targets or minimum credit thresholds from the national curriculum requirements. Divergent pharmacotherapy teaching practices are leading to variation in graduate knowledge and skills levels.

The way in which pharmacotherapy skills are acquired in the work place also varies. The current core curriculum and skills matrixes fail to specify a target for participation in the administration of drug therapies during on-the-job learning and supervised training and the number of credits available for such placements. There is also variation in the level of resourcing and time allocated to guidance and the skills and attitudes of the supervisors involved. The continuing professional education offered to supervisors and teachers must also be improved. Studies have shown that teachers tend to focus on their own areas of expertise at the expense of areas that are significant for the students' professional development (Veräjänkorva & Leino-Kilpi 1998).

The differences in training are leading to significant variation in new graduates' pharmacotherapy skills and knowledge. It is the employer's responsibility to assess to what extent the employee is able to participate in the administration of drug therapies, as this too can vary considerably. In particular, clarification is required on the participation of students and professionals with protected occupations titles in the provision of pharmacotherapy and related lines of responsibility. As drug therapies are also widely administered in environments where this constitutes a non-routine part of the service, including social welfare operational units, guidance is required on the participation of non-healthcare staff in pharmacotherapy provision.

Pharmcotherapy practices currently vary widely among social welfare and healthcare operational units. A report on Finnish hospital districts examined the process used to certify nurses in pharmacotherapy provision (Mattila & Isola 2002). It identified significant variation between hospital districts and units, with some units found to employ a multi-stage, systematic certification processes and others having no written process in place. Disparate certification models were also found.

Under a previous National Board of Health circular (1929/1987), doctors were responsible for the granting of certificates in hospitals and health centres, with nurses mainly in charge of pharmacotherapy provision, supported by other healthcare professionals with the required training and skills. Following the review of the Medicines Act and the abrogation of the National Board of Health circular, no guidance has been issued. It should be noted, however, that practice in this regard has continued to follow the principles laid down in the circular. In the event that tasks are delegated to another healthcare professional, the employer must provide the necessary training, ensure that the employee in question has the skills required for the allocated tasks and provide a unit-specific certificate or work order.

Hospital and health centre pharmaceutical staff are mainly based in hospital pharmacies and medicine centres. In broad definition, ward pharmacy, is the provision of a full range of pharmaceutical services to a ward or a clinic. The development of ward pharmacy services in Finland began in the 1980s. Pharmacists were initially brought in to oncology wards to prepare chemotherapy dilutions and other medicines but their involvement soon extended to other areas, including the provision of pharmaceutical advice, the preparation and distribution of medicines, the ordering of medicines from the pharmacy and the management of ward medical stocks. This was intended to ease nursing workloads. Since 2000, pharmacists' involvement has again increased to comprise pharmaceutical advice, the provision of pharmacology training to nurses and quality control (Lehtomäki et al 2005).

Until now, there have been no guidelines on the provision of pharmacotherapy in emergency care. Shortcomings have also been identified in monitoring practices. As a result, it has not been clear where overall responsibility for the administration of pharmacotherapy has rested. Pharmacotherapy procedures have also been inconsistent. The level and extent of training received by emergency care staff also varies significantly by profession. The different professions involved in the provision of emergency care services include fire officer - ambulance attendants, hospital and ambulance attendants, rescue staff, practical nurses, nurses, emergency care nurses (polytechnic qualification) and doctors, including emergency care specialists.

In emergency care, pharmacotherapy is commonly administered under little supervision. Emergency care staff must be able to carry out initial patient assessments to allow the commencement of appropriate treatment. The range of medications used includes many highly potent, intensive care drugs whose side effects must be managed swiftly and without a doctor being present. The majority of incidents requiring emergency care take place outside of health centres and hospitals. Patient transport staff are generally given additional pharmacotherapy training. All hospital districts and health centres now employ doctors with particular operational responsibility for emergency care and patient transport, which has resulted in improvements in this area. There remains scope for enhanced co-operation between primary and secondary health and social care services to improve emergency care practices and guidelines, however.

In the social welfare sector and service environments where pharmacotherapy is not routinely carried out, it is administered in a variety of environments and by staff with varying levels of qualification and training. In the social welfare sector, pharmacotherapy is administered in retirement homes, care homes for children and the disabled, different types of sheltered accommodation for the elderly, the disabled, substance abuse and psychiatric patients, in different types of kindergartens and nurseries, foster care and in the clients' own homes. In addition, pharmacotherapy can be administered in schools and at after-school clubs.

Current social welfare legislation does not cover staff participation in pharmacotherapy. Guidance and supervision arrangements and lines of responsibility also often remain unclear. In many instances, service providers have failed to take a proactive approach to the management of pharmacotherapy provision, planning has been insufficient and patient safety structures have not been fit for purpose. There is significant variation in staff training and competence levels and it is often unclear what qualifications or training are required for participation in pharmacotherapy provision. Further training practices also vary.

In sectors where pharmacotherapy is not typically provided, administration is often carried out by untrained staff. This occurs most commonly in the day care or school setting, where staff administer medications supplied by the guardian. In these instances, the guardian is responsible for delivering the medication and ensuring that sufficient instructions are provided. The relevant member of staff is responsible for administration. Particular challenges in this scenario include the definition of lines of responsibility and accountability as well as staff skills verification.

Due to polypharmacy, the most challenging pharmacotherapy is often administered by the elderly in the home setting. Drug incompatibilities may result in severe side effects, unnecessary suffering and increased public cost. Several international studies have shown polypharmacy and drug incompatibilities to be common among the elderly. Furthermore, it has been found that polypharmacy and the number of doctors involved in the treatment of any one patient increase the risk of drug interactions (Barat et al 2000, Halkin et al 2001, Björkman et al 2002, Socialstyrelsen 2004.) In Finland, too, polypharmacy and drug incompatibilities, inadequate pharmacotherapy monitoring and assessment (Linjakumpu et al 2002) and communications strategies (Kansanaho et al 2002) are coming under the spotlight.

Automated drug distribution systems support rational and cost-efficient pharmacotherapy provision and allow staff to dedicate more time to patient care. These systems are particularly useful in units where not enough staff are trained in pharmacotherapy. Further benefits include the full medication review of each patient that is carried out prior to the commencement of the automated service. The review is designed to eliminate any unnecessary medications, drug overlaps and harmful interactions and can be carried out by the pharmacy in co-operation with the doctor and, where relevant, other healthcare professionals. The process also brings cost savings. Studies suggest that savings are generated through reduced drug wastage and staff workloads (Larsson & Block 1998, Riksförsäkringsverket 2001, Econ Senter For Okonomisk Analyse As 2002, Saikkonen 2003).

Considerable additional benefits are achieved through medication reviews and reduced numbers of medication errors.

There is currently no systematic process for gathering data on medication errors, including near misses, in Finland. Danish legislation, for example, requires systematic monitoring of all medication errors. No such requirement or system exists in Finland. International studies have found that approximately 10% of all patients experience an adverse event during their treatment. Of these a significant proportion are related to drug treatments (Institute of Medicine 2000) and the majority are preventable (Hughes & Ortiz 2005).

The Peijas Hospital Viisas oppii virheistä ("To err is to learn")(VIIVI) project was set up to record daily medical errors with the view to developing processes for reducing treatment errors (HUS 2004, Mustajoki 2005). The results show that the most common errors were prescription, documentation, distribution and administration-related. In the majority of cases the errors did not warrant further treatment. The VIIVI findings are in line with international studies, which suggest that the majority of adverse events are non-serious and only one per cent go on to cause severe harm (Institute of Medicine 2000, Weingart et al 200, Davis et al. 2003).

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4 THE PHARMACOTHERAPY PROCESS

Pharmacotherapy is a key form of medical intervention and an important component of patient care as a whole. It is always a form of health and medical care, regardless of where it is being administered. At its best, pharmacotherapy is multidisciplinary work across unit and organisational boundaries, between the patient, the doctor and the administering staff. Pharmacy staff and advice and counselling services have an increasing role to play in both pharmacies and social and healthcare settings.

The commencement, adjustment and discontinuation of drug therapies is initiated by the doctor in consultation with the patient. Successful pharmacotherapy is dependent upon correct prescription practice (Finnish Pharmacists' Association & Union of Health and Social Care Professionals Tehy ry 2003). The doctor undertakes an assessment of the patient's drug therapy needs taking into account the patient's health status, illnesses, earlier medications and allergies. This is then used to draw up an individual drug treatment plan. In future, electronic support software combining information from relevant clinical guidelines and the patient's own records will be used to assist in the selection of medication. Drug treatments are commenced when indicated by the patient's individual needs and their continuation is subject to a positive response. The treating doctor must for their part ensure that the information provided to the patient meets the requirements set out in the Act on the Status and Rights of Patients and the Decree on Prescriptions.

Prescriptions are to be issued on the basis of need as established by investigation or other clinical method. Provided that the appropriate training has been made available, nurses and public health nurses can be delegated/ authorised to participate in the assessment of the patient's needs (Hukkanen & Vallimies-Patomäki 2005). Issues to consider when issuing a prescription are indication, efficacy, safety and cost. Prescriptions must be clear and unambiguous and contain all information required for safe administration.

Diagnostic errors include misdiagnosis and delay. Errors in the assessment of treatment need result from failure to take into account medication allergies, polypharmacy, contraindications and drug interactions. Medication errors include the wrong active ingredient (non-proprietary name, INN) or preparation, pharmaceutical form, dosage strength or concentration, route of administration and treatment duration. Erroneous or unclear prescriptions can lead to misunderstandings and treatment errors. Guidance errors include the provision of inadequate or contradictory information. Figure 1 sets out the risks associated with pharmacotherapy from the point of view of the doctor. (Centre for Pharmacotherapy Development ROHTO.)

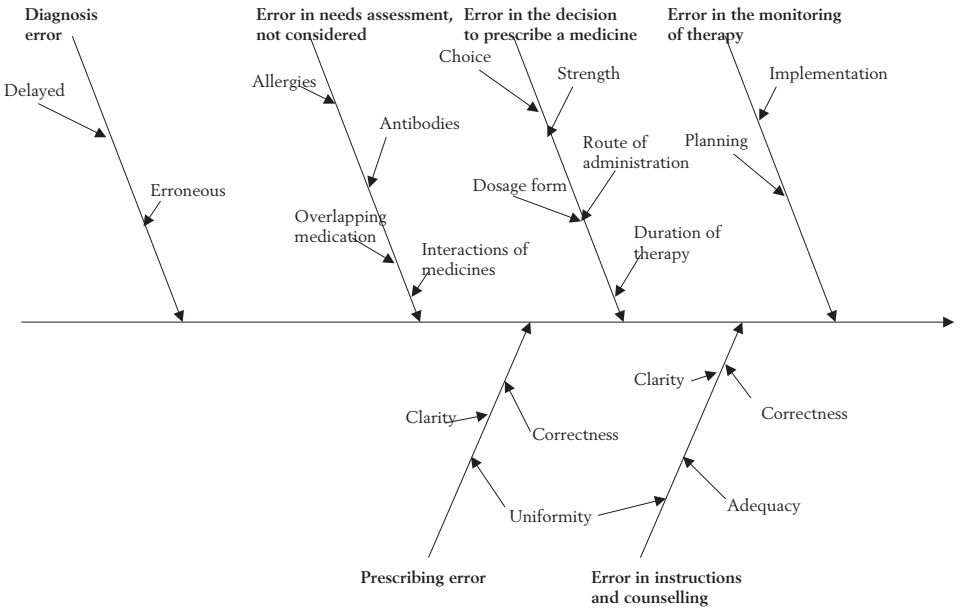

Fig 1. Pharmacotherapy risks – the doctor's perspective

Pharmacotherapy is administered as prescribed by the doctor. Those administering drug treatments must make sure that they have understood the prescription correctly, prepared the medicines in accordance with the instructions provided and ensure that the correct medications are administered in the correct dosage and formulation, at the right time, via the correct administration route. Medicines that are not ready for use will be prepared by staff with pharmacotherapy training in a controlled environment such as a hospital pharmacy. The preparation process must be fully documented. Where medications are prepared for use at a ward or at home, all relevant regulations and guidelines (e.g. National Agency of Medicines Decree 5/2002, available in Finnish and Swedish only) must be observed.

Skilled and knowledgeable staff are a pre-requisite for high-quality pharmacotherapy provision. Where necessary, staff without training in pharmacotherapy in their basic qualification may assist healthcare professionals and social care professionals with pharmacotherapy training in the provision of pharmacotherapy. However, it must be ensured that those providing pharmacotherapy have written permission to do so and have obtained the required knowledge and skills through training.

Efficacy assessment is a key part of pharmacotherapy provision. In in-patient care, staff involved in the provision of pharmacotherapy monitor the patient's condition and observe any potential side effects. In ambulatory care, the patient's self-management skills and knowledge of potential adverse effects are particular-

ly important. Also important are good working relationships between care staff and staff involved in the provision of drug treatment. Staff administering the treatment assess treatment efficacy in co-operation with the doctor and patient. Administration and efficacy must be appropriately documented. A positive response is a pre-requisite for treatment continuation. In the event of side effects or insufficient treatment response, the doctor will decide on whether treatment is to be continued and/ or adjusted.

Errors in the receipt of prescriptions may result from the prescription content being misunderstood or the prescription being incorrectly transcribed/ documented in the patient records. Such errors can occur during prescription transfer or when the prescription is copied onto the so-called prescription chart or communicated orally. Errors related to patient identity, medication type, preparation and strength or concentration can occur when medicines are administered. Preparation errors can occur during dosing, division and crushing of medicines. Administration errors include incorrect time of administration, incorrect administration routes and methods, strength and dosage. The medication may also be missed or given to the wrong patient. Guidance-related errors are the same as for doctors. Errors in assessing treatment efficacy can lead to insufficient information being communicated to the doctor. Figure 2 sets out the risks associated with pharmacotherapy from the point of view of administering staff. Figure 3 sets out the risks associated with pharmacotherapy from the point of view of domiciliary care, nursing home and sheltered accommodation staff. (Centre for Pharmacotherapy Development ROHTO.)

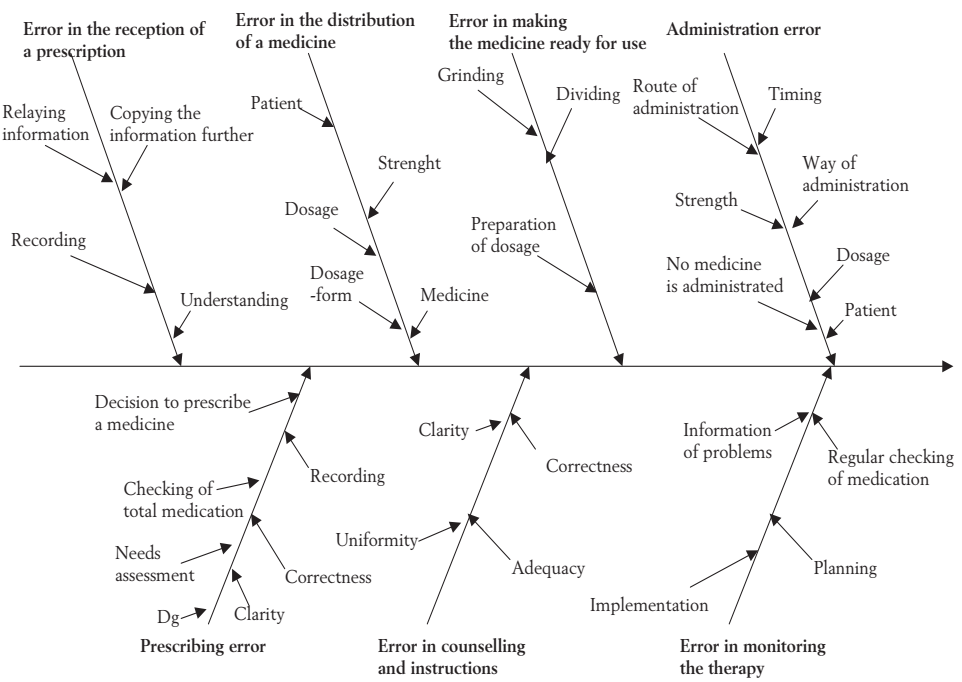

Fig 2. Pharmacotherapy risks – administering staff perspective

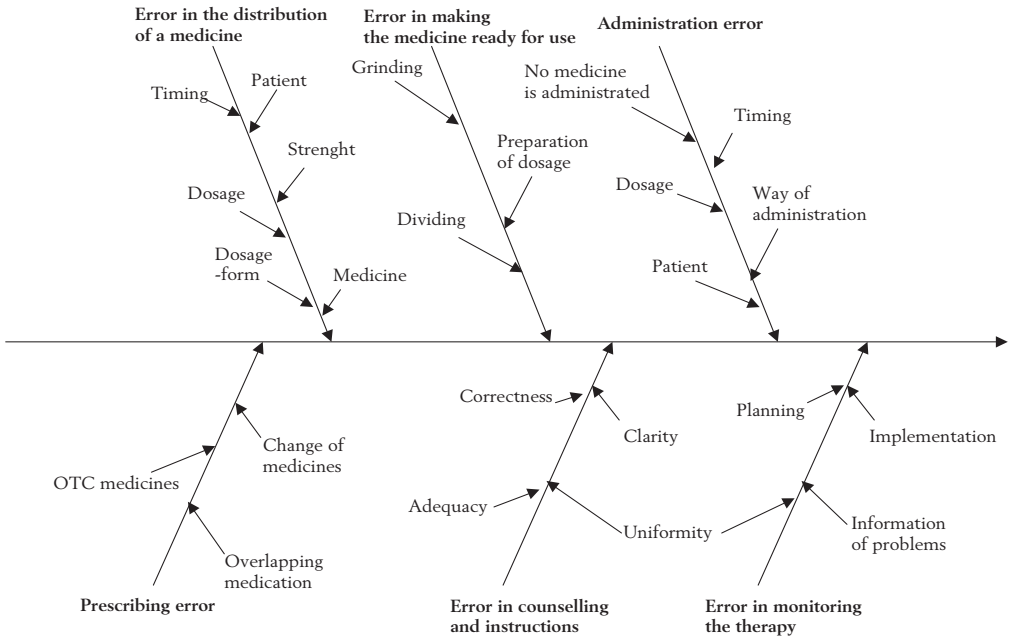

Fig 3. Pharmcotherapy risks – the domiciliary care, nursing home and sheltered accommodation perspective

Community pharmacies, hospital pharmacies and medicine centres play a key role in safe pharmacotherapy provision. Communication errors may take place when medicine orders placed at the ward are received and processed at the pharmacy. Preparation errors include deficiencies in ingredient quality and the pharmaceutical and microbiological processes used. Delivery errors may be due to inappropriate storage or insufficient security arrangements allowing third party access to the medication. Documentation errors may result from insufficient information or inaccurate or unclear notes. Figure 4 sets out sets out the risks associated with pharmacotherapy from the hospital pharmacy point of view. Figure 5 sets out the risks associated with pharmacotherapy from the community pharmacy point of view. (Centre for Pharmacotherapy Development ROHTO).

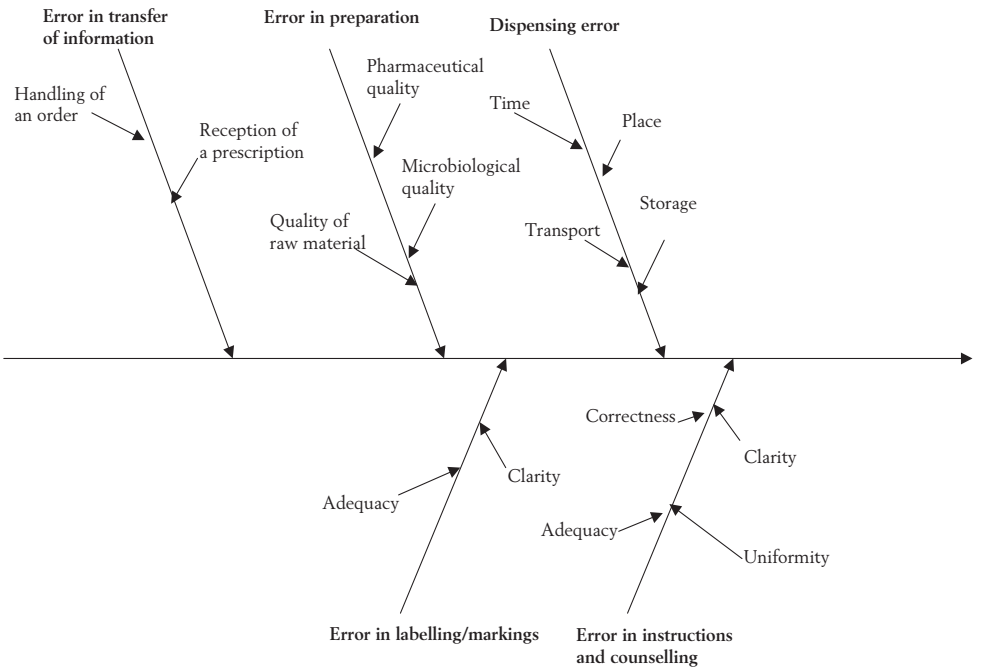

Fig 4. Pharmacotherapy risks, hospital pharmacy perspective

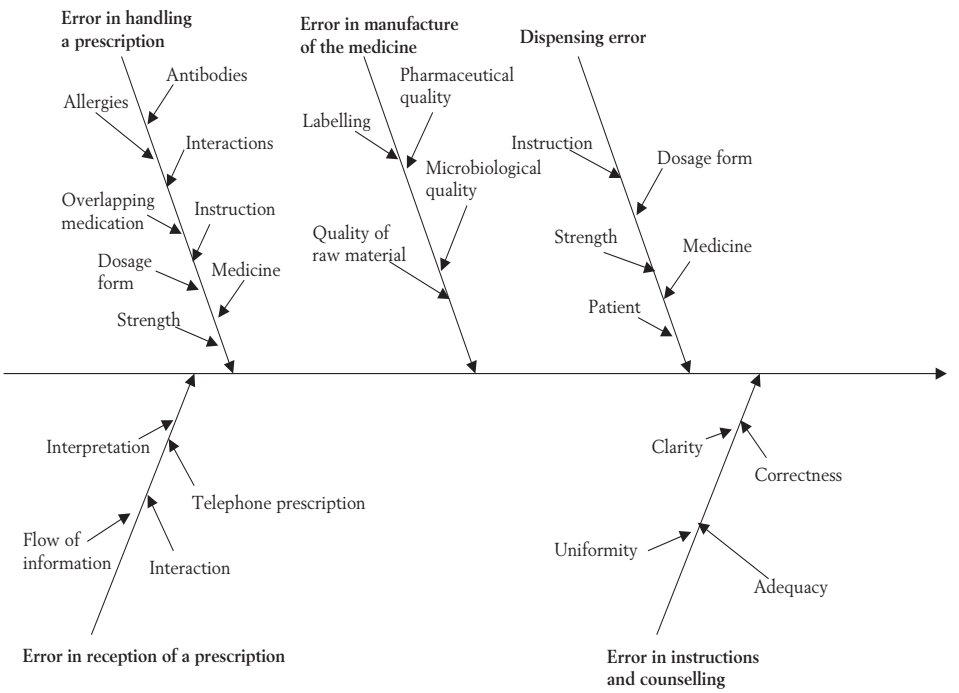

Fig 5. Pharmacotherapy risks – community pharmacy perspective

In ambulatory care, the patient's general state of health and their knowledge and skills influence their ability to self-manage their condition and thus the outcome of their treatment. Where possible, the patient should be invited to participate in the planning of their drug therapy and be aware of its aims and any monitoring and assessment taking place. The treating doctor and other staff must be available to offer guidance and counselling and respond to any questions the patient may have. The prescribing doctor must ensure that the patients or their next of kin have correctly understood dosage and administration instructions. Doctors' obligations in this regard are set out in more detail in the Ministry of Social Affairs and Health Decree on prescriptions (726/2003, available in Finnish and Swedish only).

The indication for the prescription must be explained and instructions for use must be provided. The patient must also be made aware of potential adverse effects and when they should contact the treating doctor or other healthcare staff. The patient must also be informed of potential side effects, interactions with other medications or alcohol and drugs and the impact on their performance, including driving ability. It is also advisable for the patient's next of kin to be made aware of the drug's effects. Guidance and counselling are central to successful and safe pharmacotherapy. The patient may refuse drug therapies recommended by the doctor and is entitled to receive appropriate alternative treatment. However, there is no obligation to deliver treatment demanded by the patient.

Errors occurring during the taking of medications may result from the medication being taken at the wrong time, in the wrong preparation or in the wrong quantity, amount, volume etc. Guidance errors may be caused by shortcomings in the guidance content or the way in which it is received by the patient. Problems may also be caused by ill-informed self-medication practices, such as the use of over-the-counter medications the doctor is unaware of. Figure 6 sets out the risks associated with pharmacotherapy from the point of view of the patient. (Centre for Pharmacotherapy Development ROHTO).

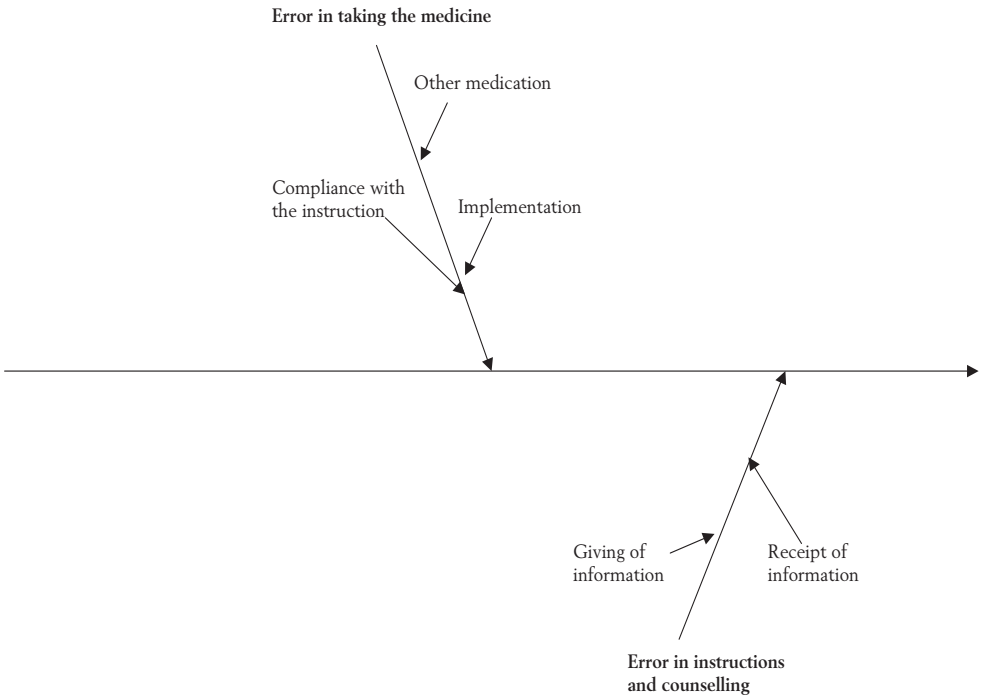

Fig 6. Pharmacotherapy risks – the patient's perspective

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5 PHARMACOTHERAPY

The same general principles and guidelines apply to the provision of pharmacotherapy services in all public and private social and health and social care units as well as environments where pharmacotherapy is not routinely carried out. Pharmacotherapy is to be provided in accordance with a health and social care unit-specific or work unit-specific plan detailing all pharmacotherapy. All health and social care and/or work units are required to have a pharmacotherapy plan in place. The pharmacotherapy plan is a key management and quality assurance tool. The exact content of the plan is determined by the unit's activities and the type of pharmacotherapy provided. This reflects the fact that competency requirements placed, for example, on the provision of pharmacotherapy in intensive care units differ considerably from standard in-patient ward requirements.

Competency requirements will be determined at operational unit level and should be used to guide the production of the work unit-level pharmacotherapy plan. Units with similar functions are encouraged to cooperate in the drawing up of the plan. Table 2 provides a break down of the pharmacotherapy plan content.

Tab 2. The pharmacotherapy plan

- Pharmacotherapy: content and processes
- Verifying and maintaining pharmacotherapy knowledge and skills
- Staff duties and responsibilities and task allocation
- Certification practices
- Pharmaceutical services: ordering, storing, manufacture, preparation and return of medicines; provision of information, guidance and advice
- Distribution and administration of medicines
- Informing and counselling patients
- Efficacy assessments
- Recordkeeping and information flow
- Feedback and monitoring systems

A pharmacotherapy plan should contain an analysis of the health and social care and/ or work unit pharmacotherapy activity and needs, a process description, a staff structure chart and job descriptions, a definition of lines of responsibility and a pharmacotherapy skills assessment together with a skills verification and maintenance plan. It should also include details of the staff certification

process. In addition, the plan must cover pharmaceutical services, record keeping practices, efficacy assessments as well as patient information and guidance practices. A feedback system is to be implemented for gathering data on medicine errors, which can be used for monitoring and learning purposes. Every effort is to be made to promote a culture of openness and learning.

Management teams are responsible for organising the preparation, implementation and monitoring of the pharmacotherapy plan. They will be supported by the medical director, nursing director, pharmacotherapy clinical lead or unit (e.g. hospital pharmacy or medicine centre) and nursing staff providing pharmacotherapy. Plans for social service providers and service environments where pharmacotherapy is not routinely carried out will be drawn up in co-operation between the management team, the clinical lead and the nursing staff providing pharmacotherapy. The plan is to be reviewed annually and updated as necessary. Hospital districts co-ordinate the preparation of the pharmacotherapy plans regionally. The preparation and implementation of the plan is supervised by the County Administrative Boards, who may request access to the plan in conjunction with a licence inspection or other supervisory visit. Table 3 sets out the process from the guidance and supervisory authority, education and training provider and health and social care unit perspective.

Tab 3. The pharmacotherapy process – supervisory authority, education and training provider and health and social care unit perspective

Body	Process
Ministry for Social Affairs and Health	Legislation General supervisory, guidance and management duties
National Agency for Medicines	Supervision and guidance of pharmaceutical services and medicinal products and medical devices.
Ministry of Education Finnish National Board of Education	Ministry of Education: curriculum recommendations Finnish National Board of Education: curriculum orders
Polytechnics, vocational colleges	Curriculum planning and implementation Skills examinations for practical nurses from 1 August 2006
Hospital districts, Health boards	Regional co-ordination of pharmacotherapy plan Co-ordination of feedback system Co-ordinating continuing professional education Maintenance of continuing professional education and further training registers Maintenance of pharmacotherapy certification register
Health and social care unit	Co-ordination of pharmacotherapy plan preparation, implementation, monitoring and assessment Definition of competencies required at work unit level Identifying units where pharmacotherapy plans prepared jointly/ independently Certification principles and delegation of responsibility Co-ordinating continuing professional education Feedback utilisation
Work unit	Pharmacotherapy plan preparation, implementation, monitoring and assessment Feedback utilisation
Administering staff, consultants, senior nurses, hospital pharmacy/ ward pharmacy	Pharmacotherapy plan implementation Ensuring skills, workforce planning, training provision Certification implementation
Social and health and social care professionals with pharmacotherapy training	Pharmacotherapy provision Reporting of errors Professional skills maintenance and development
County Administrative Boards	Reporting Guidance and supervision of health and social care organisations and professionals
National Authority for Medicolegal Affairs	Reporting Supervision and guidance of healthcare organisations and professionals

5.1 Pharmacotherapy practices and procedures

Pharmacotherapy content, practices and procedures are set out in the pharmacotherapy plan. Comprehensive operational knowledge and analysis of related problem areas and risk factors is required for the effective management and development of pharmacotherapy services at the operational and work unit levels. At the planning stage, cognisance should be taken of the fact that pharmacotherapy provision is healthcare activity provided, as a rule, by and under the responsibility of health and social care professionals trained in pharmacotherapy. The unit's own pharmacotherapy competency requirements determine the scope of the pharmacotherapy plan. Table 4 sets out the pharmacotherapy content and procedures.

Tab 4. Pharmacotherapy content and procedures

- Determining unit pharmacotherapy competency requirement
- Determining unit pharmacotherapy practices
- Determining problem areas and risk factors
- Identification and development of pharmacotherapy key areas
- Description of pharmacotherapy processes

Table 5 sets out the pharmacotherapy accountability framework and process from the patient and administering staff perspective.

Tab 5. Pharmacotherapy process, patient and administering staff perspective

Actor	**Process**
Patient	Pharmacotherapy need
Doctor	Assessing the need for pharmacotherapy, diagnosis, prescriptions, informing and counselling patients, planning follow-up treatment
Patient/ administering staff/ next of kin	Obtaining medication
Pharmaceutical staff	Preparation, delivery, information
Patient/ administering staff/ next of kin	Preparation, administration, information, guidance, monitoring and assessment
Patient	Treatment completed, indication for follow-up assessed

5.2 Verifying and maintaining pharmacotherapy knowledge and skills

Administering staff should be aware of the role of pharmacotherapy in the wider treatment context. They are also expected to understand the full treatment span including the prescription indication, the agent prescribed, dosage and administration route. They should also be able to assess treatment efficacy. Technical skills alone are not sufficient, however; the administration of pharmacotherapy also requires a sound understanding of ethico-legal issues, pharmacology, physiology, pathophysiology and drug calculations. In addition, staff must have knowledge of treatment effects, drug handling and delivery methods as well as drug acquisition and disposal. An understanding of dosage forms, preparations and their properties is necessary to ensure that correct handling procedures are followed when preparing and administering medications. As an example, safe pharamcotherapy requires that sterile preparations are protected from contamination and the slow-release properties of orally administered medications are not destroyed through crushing.

Each work unit must have in place an induction plan, setting out unit-specific pharmacotherapy procedures, which each new, temporary or student employee must familiarise themselves with. During the induction process, the unit supervisor or other staff member in charge of induction must ensure that employees have the basic skills required for the provision of pharmacotherapy, obtained through basic training. Further guidelines on skills testing, tailored to reflect the type of drug therapies provided, will be made available at unit-level. The unit may require an employee to distribute medicines two to five times under the supervision of the induction provider before they can be certified to undertake the task independently. At the end of the induction period, the head of the work unit will determine whether the employee has sufficient knowledge of the health and social care / work unit pharmacotherapy practices and whether the induction aims have been achieved.

Health and social care / work units are required to produce an assessment of the skills and knowledge required for pharmacotherapy provision and to identify training needs. Staff skills and knowledge are to be maintained, developed and monitored in accordance with national legislation and guidance (Ministry of Social Affairs and Health, 2004) The employer is required to provide training that meets staff and unit development needs. The employer is responsible for providing continuing professional education to health and social care staff with basic training in pharmacotherapy. The employer is also responsible for providing training to staff who are involved in the provision of pharmacotherapy but who have no basic training in this area. Staff involved in the provision of pharmacotherapy are required to maintain their skills and to participate in training provided by the employer. Training and electronic learning materials and environments are being developed through regional co-operation, coordinated by hospital districts.

Each health and social care unit has in place a continuing professional educa-

tion register and other monitoring systems, which will be used to assess and review skills and training needs and participation. Monitoring can also be carried out in regional or local cooperation, in which case hospital districts and health boards can use the register to store information on pharmacotherapy training provision, staff participation and cost and certification practices. The register can also be used for skills and training review tool and to facilitate the assessment of pharmacotherapy skills during the annual performance review process. Table 6 sets out the information required for inclusion in the pharmacotherapy plan.

Tab 6. Pharmacotherapy skills requirements, verifying and maintaining pharmacotherapy knowledge and skills

- Identifying knowledge and skills requirements
- Assessing staff skills and training needs
- Pharmacotherapy induction – written plan, unit-specific instructions, verifying skills and knowledge obtained through basic education
- Verifying and maintaining skills and knowledge - testing, performance reviews, assessing training efficacy
- Skills maintenance and development – training participation in accordance with continuing professional education plan
- Continuing professional education register maintained by the hospital district or health board

5.3 Staff accountability, duties and task allocation

The health and social care / work unit staff structure, duties and responsibilities are set out in the pharmacotherapy plan. The health and social care unit management board and health and social care/ medical director are responsible for pharmacotherapy planning and implementation in cooperation with the nursing director and the health and social care unit/ work unit pharmacotherapy clinical lead. Line managers are responsible for ensuring that staff participating in pharmacotherapy provision are in possession of the necessary skills and knowledge and able to carry out their duties in the appropriate conditions. Line managers guide and monitor the provision of pharmacotherapy in accordance with the pharmacotherapy plan. They are also responsible for managing task allocation and co-operation between the different professions to ensure that optimal use is made of the skills and knowledge available.

Doctors manage the prescription of medicines and therefore have overall responsibility for pharmacotherapy provision. Healthcare professionals (as defined in the Act on Heathcare Professionals) are responsible for the administration of drug therapies in accordance with the doctors' instructions. Doctors assess treat-

ment needs and efficacy, and provide information and advice in cooperation with healthcare professionals trained in pharmacotherapy. Doctors must take congnisance of the requirements the prescribed therapies place on the staff administering them. For example, this means taking account of the arrangements required for the night-time administration of intravenous treatments when no staff with pharmacotherapy training may be on duty.

Licensed healthcare professionals with pharmacotherapy training have overall responsibility for pharmacotherapy provision at unit-level. Overall responsibility is defined as responsibility for task allocation, the provision of related guidance, supervision and counselling as well as service functionality. These tasks are included in the duties of ward managers and nursing directors. However, all staff involved in pharmacotherapy provision are responsible for their own actions.

Intravenous fluid and drug therapies and patient controlled analgesia (PCA) can only be administered by licensed healthcare professionals trained in pharmacotherapy. Radiographers, for example, can participate in imaging investigations and procedures requiring intravenous medication. However, participation is subject to skills verification, additional training where applicable and certification by a doctor employed at the same health and social care unit. Temporary staff may participate in the administration of intravenous drug therapies if their skills and knowledge have been verified and they have undertaken further training on intravenous pharmacotherapy. In addition, they must be in possession of a certificate entitling them to undertake these tasks (For more information, see Chapter 5.4 Certification). Licensed healthcare professionals with pharmacotherapy training are allowed to administer central nervous system agents in accordance with the principles outlined in Table 8.

In addition to licensed healthcare professionals, professionals with protected occupational titles (as defined in the Act on Healthcare Professionals) trained in pharmacotherapy can dispense and administer non-parenteral medications. In addition, they can administer intra-muscular and subcutaneous injections provided that their knowledge and skills have been verified, they have received the appropriate induction training and are in possession of a written certificate entitling them to undertake the task in question. Healthcare professionals with protected occupational titles who have received pharmacotherapy training can also change fluid bags provided they contain no medication and commence fluid therapy in an emergency situation, where no licensed healthcare professional with pharmacotherapy training is available. Professionals with protected occupational titles who have received pharmacotherapy training are also authorized to administer adrenaline and subcutaneous colloid and crystalloid treatment in the event of cardiac arrest where no licensed healthcare professional is available. In addition, healthcare professionals with protected occupation titles who have received pharmacotherapy training may participate in the administration of non-parenteral medications affecting the central nervous system. As before, regular verification of skills and knowledge, further training and written certification are required.

The above principles apply to the provision of pharmacotherapy in emergency care with the exception of rescue staff and fire officer-ambulance attendants without pharmacotherapy training who participate in the administration of ba-

sic drug therapies. Their skills and knowledge must be verified and they must be provided with training in accordance with the above requirements. There will be a five-year transitional period, during which all staff participating in the provision of advanced pharmacotherapy must have obtained a healthcare qualification incorporating pharmacotherapy training that is equivalent to the basic qualification undertaken by licensed healthcare professionals. With regard to emergency care, the skills requirement must be observed earlier. In addition, skills verification processes must be developed to reflect the level of pharmacotherapy provided.

The lines of accountability described above also apply to the provision of pharmacotherapy services in social care units and service environments where pharmacotherapy is not routinely carried out. Overall responsibility rests with the unit medical director. The responsibility for pharmacotherapy provision rests with a healthcare professional with pharmacotherapy training. The doctor is responsible for prescriptions and prescription accuracy. Employees distributing and administering medications are responsible for ensuring that these tasks have been carried out in accordance with instructions provided by the prescribing doctor. Thus, staff participating in the provision of pharmacotherapy are responsible for their own actions. A social care professional trained in pharmacotherapy may administer non-parenteral medications. They may also administer subcutaneous injections, subject to further training, skills verification and certification.

Joint working with healthcare professionals trained in pharmacotherapy is particularly important for staff in service environments where pharmacotherapy is not routinely carried out. Staff with no training in pharmacotherapy may participate in the administration of non-parenteral medication and sub-cutaneous injections in exceptional cases only or on a case-by-case basis and following appropriate further training. Training can only be provided by a licensed healthcare professional and the certificate issued by the medical director. Skills must be regularly verified. The training organiser is responsible for training quality, the licensed healthcare professional for ensuring that sufficient proof of skill has been provided and the certifying doctor for determining task-specific minimum skill and training requirements. The provision of pharmacotherapy in these instances is based on an agreement between the patient and/ or their next of kin, the administering staff and the unit management/ senior staff. Staff administering pharmacotherapy are responsible for their own actions when undertaking this activity. The employer is responsible for ensuring that the service provided complies with all relevant legislation.

Appropriate further training is defined as training that equips the trainee to undertake the tasks in question. Such training qualifies the employee to participate in pharmacotherapy activities at the level pharmacotherapy is provided at their unit of employment. Job descriptions and pharmacotherapy responsibilities, delegation procedures and multi-disciplinary working are detailed in the pharmacotherapy plan.

Students studying for a basic vocational qualification in social and health and social care (practical nursing qualification) and undertaking work placements are to be provided with training that is suited to their level of training under the immediate guidance and supervision of their placement supervisor. Placement su-

pervisors are responsible for the work carried out by the students. Nursing, public health nursing, paramedicine and midwifery students undertaking polytechnic-level qualifications also participate in the administration of more advanced pharmacotherapy, including intravenous fluid and drug therapies and cannulation under the guidance and supervision of their designated supervisors. Supervisors must be qualified to administer the relevant drug therapies. The supervision of students is carried out in accordance with recommendations issued by the Ministry of Social Affairs and Health (Heinonen 2003).

Participation in supervised placements and on the job training is subject to the students having obtained the necessary theoretical knowledge and skills as well as proficiency in drug calculations. Students must be able to demonstrate the extent of their pharmacotherapy studies and passes obtained in pharmacotherapy and drug calculcations, if so requested by the unit. Agreements between training organisers and educational institutions concerning supervised training and on the job training must take account of the level of skill required of students, the extent to which they will participate in pharmacotherapy provision during their placement and the learning aims. Where a student temporarily undertakes the duties of a healthcare professional, the employer must determine the extent to which the student can participate in pharmacotherapy provision taking into account the student's skills and the level of pharmacotherapy provided at the unit .

It is appropriate for health and social care units to utilise pharmacological and pharmaceutical expertise (head dispensers, pharmacists) and for each team to have in place a designated pharmacology co-ordinator. Both play a key role in the provision and development of the pharmacotherapy service offered by the unit. Ward pharmacy specialist knowledge can be utilised, for example, by appointing a rotating pharmacist. Social care and out-patient units can make use of this by developing their co-operation with community pharmacies. (See Chapter 5.5 Pharmaceutical services.) Table 7 sets out the staff whose duties and responsibilities are defined in the health and social care / work unit or team pharmacotherapy plan.

Tab 7. Staff providing pharmacotherapy and their duties

- Defining the duties and responsibilites of staff participating in the planning, organisation and provision of pharmacotherapy:
  - Health and social care unit and/ or work unit management
  - Medical/ Nursing Director
  - Senior doctor and senior nurse
  - Pharmacotherapy clinical lead
  - Licensed healthcare professionals trained in pharmacotherapy
  - Professionals with protected occupational titles trained in pharmacotherapy
  - Social care professionals trained in pharmacotherapy
  - Temporary staff
  - Staff not trained in pharmacotherapy
  - Trainee students or students temporarily employed as healthcare professionals
- Task allocation, delegation and multi-disciplinary working

Table 8 sets out staff capacities and skills for participating in pharmacotherapy provision on the basis of current qualification requirements. For more detailed information on staff providing pharmacotherapy, please see Fig 10.

Tab 8. Staff capabilities and skills for participating in pharmacotherapy provision on the basis of current qualification requirements

Staff providing pharmacotherapy	**Skills obtained through basic education**	**Verifying skills, further training**	**Responsibility/ certification**
Licensed healthcare professionals trained in pharmacotherapy	• ordering, storing and preparation and dispensing of medicines, • non-parenteral medicines • intradermal, subcutaneous and intramuscular injections • vaccinations • intravenous fluid and drug therapies • participation in epidural injections	• intravenous fluid and drug therapies • participation in epidural injections, including PCA • vaccinations	Certification: Health and social care Unit Medical Director or delegated doctor Proof of competence: Experienced licensed healthcare professional
Healthcare professionals with protected occupations titles trained in pharmacotherapy	• dispensing of medicines • non-parenteral medications • subcutaneous and intramuscular injections	• ordering of medicines • subcutaneous and intramuscular injections • changing non-medicated continued infusion liquids and bags of fluid • emergency care, see Appendix 8	Certification: Health and social care Unit Medical Director or delegated doctor Skills test: Licensed healthcare professional
Social care professionals trained in pharmacotherapy	• administration of dispensed non-parenteral medications • dosing of medicines at the patients home	• subcutaneous injections	Certification: Health and social care Unit Medical Director or delegated doctor Skills test: Licensed healthcare professional
Staff not trained in pharmacotherapy		• administration of non-parenteral medicines in patient-specific doses • subcutaneous injections • dosing of medicines at patients home	As agreed • patient, medications and situation-specific Certification: Operational Unit Medical Director or delegated doctor Skills test: Licensed healthcare professional
Students	• students required to present proof of pharmacotherapy studies	• training provider and education institution to agree on placement/ work placed learning content	• employer representative (pharmacotherapy clinical lead or ward manager) assesses the students pharmacotherapy skills and

5.4 Certification procedures

The pharmacothrerapy plan sets out certification procedures entitling holders to different levels of pharmacotherapy practice and related communications strategies. All operational units providing pharmacotherapy services are required to implement certification and skill verification procedures. The registration of pharmacotherapy certificates can be linked to the further training register and expanded to a regional, hospital district or health board level service. This facilitates the movement of staff between units.

The pharmacotherapy plan sets out the levels of pharmacotherapy practice and defines situations where pharmacotherapy certification is required in addition to the professional qualification and pharmacotherapy studies. The plan also specifies medications, which are subject to certification and those that can be administered without consultation with a doctor. Pharmacotherapy certification is unit-specific. The pharmacotherapy plan will also specify certification scope as certificates can also be issued on a team-, drug- or patient-specific basis. The plan must also account for certificates entitling staff to place medication orders. Certificates entitling staff to practice pharmacotherapy will be stored at the health and social care and/ or team unit. Ease of access must be ensured to facilitate the flow of information and smooth service delivery. All staff practicing pharmacotherapy must hold copies of all valid certificates issued to them. Verification of theoretical skills is by regular written examination. Practical skills are verified by skills examination. The development of electronic learning environments has made useful skill updating and testing tools available.

The administration of intravenous fluid and drug therapies, other advanced pharmacotherapy procedures is always subject to further training, skills verification and certification by the health and social care unit medical director. Intravenous drug administration and other advanced pharmacotherapy skills are verified at the unit where the employee is based. Verification should be carried out regularly, approximately every 2-5 years depending on the health and social care unit and/ or team pharmacotherapy requirements and the level of skill required. Intravenous injection and vaccination skills are subject to verification and certification. Certificates must be issued in the unit where the employee is based. Further training must be made available where required.

Intramuscular and subcutaneous injection skills (with the exception of licensed healthcare professional trained in pharmacotherapy) are subject to verification and certification issued in the unit where the employee is based. Further training must be made available where required. Setting out certification procedures for the administration of non-parenteral medications is particularly important in social care units and service environments where pharmacotherapy is not routinely carried out. Administration of non-parenteral medicines by staff who are not health and social care professionals trained in pharmacotherapy is subject to verification, appropriate training and certification by the unit medical director. Table 9 sets out the main points regarding certification.

Tab 9. Certification procedures

- Skills obtained through basic training and their assessment
- Level of expertise: identifying additional skill and knowledge requirements
- Further and other additional training, skills test and certificate
- Certificate to undertake additional tasks
- Definition of pharmacotherapy procedures/ medications/ patient groups requiring certification
- Period of validity and re-validation

5.5 Pharmaceutical services

The pharmacotherapy plan is required to cover key pharmaceutical services such as medical stock management and the ordering, storage, preparation, return and disposal of medicines. In addition, the plan takes account of the role of pharmaceutical services in the provision of guidance and information on medicines Pharmaceutical services are provided in accordance with relevant administrative regulations issued by the National Agency of Medicines (5/2001 and 5/2002). Pharmaceutical staff expertise is used to inspect health and social care unit medical supplies and cabinets. Ward pharmacists improve the availability of medicines and the monitoring and recycling of medicines approaching their use-by date. In order to ensure cost-effective and safe pharmacotherapy provision, it is advisable for each operational unit to have in place an expert group representing the different medical specialties and having knowledge of the Finnish current care guidelines, which together with the hospital pharmacy or medicine centre can determine the unit's basic formulary. The group will work to harmonise and guide the acquisition and use of medicines at the unit. Formulary criteria include safety and appropriateness. Social and healthcare units obtain their stocks through the hospital pharmacy, the medicine centre or a community pharmacy. Medications requiring specialist skills and/ or equipment due to their state or handling requirements (including radiopharmaceuticals and medical gases) can be purchased and delivered directly to the unit using them in accordance with instructions provided by the hospital pharmacy or medicine centre. Hospital pharmacies and medicine centres supply medicines to the wards and other operational units on the basis of a written, electronic or faxed order form. If the order is placed verbally or over the phone, it should be confirmed at the earliest possible opportunity in writing, electronically or by fax. Pharmaceutical staff must make sure the authenticity of the orders and deliveries and to clarify any problems prior to delivery. The pharmacotherapy plan must specify what qualifications and training are required for ordering formulary medicines from the hospital pharmacy or medicine centre. When ordering non-formulary medicines or medicines whose release

is subject to a special permit from the National Agency of Medicines (excluding medicines subject to a limited period permit), the order must be countersigned by the doctor-in-charge or other delegated doctor. An order for narcotic substances or alcohol must be countersigned by the doctor in charge of the ward or unit, or other delegated doctor. Narcotic substances and alcohol can only be supplied on the basis of an order submitted in writing. Medicines are to be delivered in their original packaging. The original packaging should not be split unless there is express reason to do so.

Whenever possible, medicines are prepared for use in the hospital pharmacy or medicine centre. However, the medicine can also be prepared for use on the ward, in another health and social care unit or at the patient's home, in which case written instructions from the community pharmacy, hospital pharmacy or medicine centre must be followed. The environment and location in which medicines are prepared must be suitable and fit for purpose. As a rule, medicines should be prepared for use in an area that has been especially designed for this purpose and where suitable controls are in place. Manufacturer or marketing authorisation holders' instructions must be followed when preparing medicines for use. Particular care should be taken to ensure that correct working methods (e.g. aseptic techniques) are employed and potential incompatibilities with regard to medicines, solutions and packaging materials are considered. The microbiological and chemical preservability should be observed when preparing medicines for use. Particular care should be taken when handling sterile pharmaceutical products. In addition, practitioners should ensure that the correct storage, usability window and documentation procedures are followed. Instructions should also be followed when medicines are prepared for use in the domiciliary care context. Where pharmaceutical products pose a hazard for the operator or the patient (e.g. radiopharmaceuticals and cytotoxic medications), health and safety legislation and standards must be adhered to.

Stock monitoring arrangements should be in place to ensure that medicines that are out of date or otherwise unsuitable for use are immediately removed. Under Finnish waste legislation all medicinal waste is classified as hazardous waste and must be handled in accordance with local authority instructions. Medicines stored on the wards or at other health and social care units that are unused, out of date, banned or otherwise unsuitable for use must be returned to the hospital pharmacy or medicine centre. Please note that medicines stored at the patient's home or in units purchasing medicines through a community pharmacy that are out of date, unsuitable for use, no longer required or classed as a narcotic should be returned to the community pharmacy.

Annual ward visits conducted by the hopital pharmacy and medicine centre are designed to ensure that drug safety and appropriate procedures and working methods are observed on the wards and other units. The visits may be conducted less frequently in exceptional circumstances or where appropriate, for example, where the storage and handling of medicines is limited and no particular problems have been identified.

Medicines at the health and social care and/ or work unit should be stored in an area that can be locked and is sufficiently spacious and fit for its purpose. En-

suring that medicines with a similar apperance or purpose are stored separately in different areas reduces the risk of error and enhances patient safety. Medicines should be stored separately from other products and equipment. Particular care should be taken to ensure that correct storage conditions are observed. Stocks should be checked regularly by the work unit staff to ensure that medicines are not out of date or otherwise unsuitable for use. Key handling and access priviledges should be arranged in such a way as to prevent unauthorised access to the medicine cabinet or store. Particular care should be taken with medicines that are subject to misuse. Where misuse is suspected, the hospital pharmacy, medicine centre and management or security department should be contacted.

Medicines required in the provision of emergency care can be stored outwith the medicine cabinet or store in the treatment room or as part of ambulance or other ambulatory emergency care staff equipment. In the "hospital at home" context, medicines administered in the patient's home can be stored as part of the health care unit equipment. Medicines requiring specialist storage should be checked regularly. Particular care should be taken to ensure that they are fit for use and readily accessible. With regard to illicit narcotics and central nervous system agents, the Narcotics Act and related standards must be observed. Table 10 sets out the key points on pharmaceutical services.

Tab 10. Pharmaceutical services

- Unit formulary
- Ordering and delivery of medicines
- Storage of medicines, storage areas and monitoring of storage conditions
- Manufacture and preparation for use
- Return and disposal of medicines
- Pharamaceutical information
- Pharmaceutical guidance and advice

5.6 Distribution and administration of medicines

As a rule, medicines are distributed in accordance with the original prescription. The distribution of medicines should be carried out in areas and conditions that are fit for purpose. A calm working environment prevents medication errors and promotes patient safety. Double-checking is recommended for medicine preparation to reduce the occurrence of errors. Already prepared medicines are to be stored in locked areas and clearly labelled to prevent errors during administration.

The pharmacotherapy plan should incorporate measures for ensuring the correct dosing/ administration of medicines. These measures include the documen-

tation of the patient's name and required time of administration on the container. Automated drug distributions systems can be particularly useful in health and social care and work units where few staff are trained in drug distribution. Suitable and appropriate working methods and equipment should always be employed. In addition, all relevant administrative regulations and normative guidelines must be observed. Staff are also responsible for observing the effects of the administered medication. Table 11 sets out the key points on the distribution and administration of medicines.

Tab 11. Distribution and administration of medicines

- Carried out in accordance with the original written/ electronic prescription
- Appropriate storage areas and distribution conditions
- Double-checking of medicines before administration
- Unit dose drug distribution systems
- Storage of distributed medicines
- Unit dose (e.g. medicine container) documentation requirement
- Double checking dosage prior to administration
- Identifying patient prior to administration
- Monitoring medicine effects

5.7 Patient information and advice

The pharmacotherapy plan sets out guidelines on the provision of information and guidance to the patient and their representative, including verbal and written instructions and monitoring instructions. The doctor, the administering staff and the pharmaceutical staff are required to provide information and offer guidance and instruction to the patient in all pharmacotherapy-related matters throughout the treatment process. This allows the patient to take part in the planning, administration and assessment of their drug treatment. It is particularly important to ensure that the patient has understood the information provided to them. The provision of information and guidance is designed to support treatment compliance. The patient must always be informed of any medication errors and adverse effects that may have occurred or may occur in future. Table 12 sets out key points on the patient information and advice.

Tab 12. Informing and advising patients

- Patient participation and treatment compliance
- Provision of information
- Guidance and instruction (verbal/ written)
- Ensuring patient has understood instructions provided
- Informing patient of medication errors

5.8 Evaluating treatment effectiveness

The pharmacotherapy plan sets out the procedures for assessing the effectiveness and appropriateness of treatment at the health and social care unit. The assessment of effectiveness encompassess the monitoring and assessment of expected therapeutic effects, potential side effects and adverse effects and drug interactions. When issuing a prescription, the doctor must ensure that the person administering the medication is aware of effects that require monitoring during and after administration. In addition, the plan should cover the documentation and reporting of drug effects. The plan also determines the situations where a doctor should be informed and consulted. These include situations where the patient is unintentionally administered the wrong medication. The doctor will carry out a regular review of the patient's drug therapy needs and adjust treatment as required. Table13 sets out the key points regarding effectiveness assessments.

Tab 13. Evaluating pharmacotherapy effectiveness

- Appropriateness of pharmacotherapy
- Expected benefits and therapeutic effects
- Side and adverse effects
- Interactions
- Drug overlaps
- Monitoring of effects
- Procedures in case of incorrect administration or dosage
- Regular review of drug treatments

5.9 Documentation and information flow

Establishing good documentation practices is a key function of the pharmacotherapy plan. Health and social care units must comply with legislation on documentation and recordkeeping (Act on the Status and Rights of Patients 785/1992, Ministry of Social Affairs and Health Decree on the Creation and Storage of Health Records 99/2001 (available in Finnish and Swedish only)). Particular emphasis should be placed on the health and social care/ work unit documentation practices and their implementation. Particular care should be taken to ensure that when consulting or reporting to the doctor, the discussions and the time they take place are appropriately recorded.

The pharmacotherapy plan must take account of pharmacotherapy continuity and information flow with due regard for data protection measures. Particular

emphasis should be placed on working practices that promote the updating of patient medicine lists in order to prevent drug overlaps, adverse interactions and attendant problems. The accuracy of the list of medicines is to be verified when the patient is discharged. Table 14 sets out the key points on documentation and information flow.

Tab 14. Documentation and information flow

- Recordkeeping
- Pharmacotherapy follow-up plan
- Information flow between units
- Data protection issues
- Accurate and current medication lists: allergies, interactions, overlaps

5.10 Monitoring and feedback systems

Information generated through the monitoring and feedback systems supports operational development. Pharmacotherapy service provision is monitored regularly at the health and social care work unit level in accordance with the pharmacotherapy plan. Error reporting is central to the pharmacotherapy plan. Steps must be taken to ensure that medication errors are monitored, followed up and learned from. Health and social care units are required to introduce standard medication error reporting forms. In future, a national electronic register can be used to facilitate learning.

Particular emphasis should be placed on maximising opportunities for learning from errors and feedback. Reporting systems work best in organisations where the atmosphere is open and constructive and the focus is on learning and follow-up. The plan must also set out the process for notifying patients of medication errors. Patients must, at a minimum, be notified of all errors that have or may have serious consequences. Table 15 sets out the key points on monitoring and feedback systems.

Tab 15. Monitoring and feedback systems

- Error reporting and documentation
- Patient notification
- Error reporting systems
- Monitoring and follow-up
- Making use of feedback
- Learning from errors and adjusting working methods

Drug safety is kept under constant monitoring and review. Data on adverse reactions occurring in Finland is gathered in the national adverse reactions register. Doctors and dentists are encouraged to report all confirmed or suspected adverse drug reactions. Adverse drug reactions are reported to the National Agency of Medicines using the prescribed form (available from the internet at www.laakelaitos.fi/uploads/lomakkeet/Haittavaikutusilmoitus.pdf). More detail on the reporting of adverse effects is available from the National Agency of Medicines guideline (1/2005), in effect until the end of 2010.

The Medical Devices Act (1505/1994, 345/2000 as amended, available in Finnish and Swedish only) requires all patient safety incidents resulting from the professional use medical devices to be reported to the National Agency of Medicines. The Act also requires all social and helthcare operational units to have in place a system for the recording and handling of patient safety incidents resulting from the use of medical devices. (National Agency of Medicine Guidance 4/2005, available in Finnish and Swedish only.)

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6 AGENTS ACTING ON THE CENTRAL NERVOUS SYSTEM AND ACTUAL NARCOTICS

A list of agents acting on the central nervous system (CNS agents) is provided by the National Agency of Medicines. Due to their pharmacological properties, both CNS agents and actual narcotics are classified as having potential for misuse (National Authority for Medicolegal Affairs 2002). To prevent abuse, it is important to ensure that the prescription is medically indicated, current and recent medications are reviewed to prevent interactions, that communication between the patient, the doctor and the pharmacy is improved and the effectiveness of the treatment is assessed prior to the issuing of another prescription. CNS agents may impair performance in traffic. A red triangle and the text "May impair performance in traffic" are displayed on their packaging. Table 16 contains examples of CNS agents.

Tab 16. CNS Agents (Agents acting on the central nervous system)

CNS-t	Ordinary medications containing CNS agents, including benzodiazepines, sedatives and hypnotics and analgesia containing codeine
CNS-a	Medications containing CNS agents available on one-off prescription only (as defined in the Decree on Prescriptions 726/2003, available in Finnish and Swedish only), including opiates and moderate analgetics

Patient consent for the sharing of CNS medication information is currently being obtained in too infrequently. Consent can be obtained at the doctor's surgery, clinic etc or at the pharmacy using a form authorised for use by the data protection ombudsman. By signing the form, the patient commits to obtaining their medication from one surgery or other healthcare unit and one pharmacy only. Other pharmacies can be notified of the arrangement.

Actual narcotics are defined as substances contained in Schedules I, II and IV of the Single Convention on Narcotic Drugs 1961 and in Schedules I and II of the Convention on Psychotropic Substances 1971 (including morphine, methadone, fentanyl, sufentanil and pethidine). In in-patient care, the consumption of the above medicines is tracked using a package-specific consumption sheet. Medicines classed as actual narcotics can only be prescribed to out-patients using a designated narcotics prescription form that is retained by the pharmacy. Medicines containing actual narcotics can be ordered to healthcare institutions with a medicine order. The Ministry of Social Affairs and Health Decree on the Prescription of Medicines (726/2003, available in Finnish and Swedish only) lays down

provisions on the ordering of medicines and the prescription of CNS agents and actual narcotics.

When actual narcotics are supplied to a social or healthcare unit, each package must be accompanied with a consumption sheet specifiying the name of the product, amount, date of delivery and name of the ward or operational unit. The name of the patient, the amount administered, the name of the doctor and person administering the medication and the date must be documented on the sheet. When the contents of the package have been used up, the consumption sheet along with details of any accidental wastage must be signed off by the doctor in charge of the unit or another authorised doctor and returned to the pharmacy, the hospital pharmacy or medicine centre.

Particular care should be taken when administering CNS agents and actual narcotics in the hospital as fatal medication errors are possible. Wherever possible, PCA infusions and titrations must be prepared at the hospital pharmacy or by the ward pharmacist. It is recommended that the dosing of narcotic agents is double-checked by another member of staff and that staff administering them are trained to observe their effects. (Paaskoski 2004.)

In domiciliary care, particular care should be taken to ensure that the patient, family care givers and personal assistants are given sufficient guidance and advice to prevent unauthorised access to the patient's medicines (Pennanen 2004). The importance of keeping these medications away from third parties in the interests of abuse prevention should be particularly emphasised. Table 17 sets out key points on CNS agents and narcotics.

Tab 17. CNS agents and narcotics

- Therapeutic use
- Clinical indication
- Prescription
- Communication between patient, doctor and pharmacy
- Prescription and record-keeping procedures
- Evaluating effectiveness
- Pharmacy supply procedures

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Pennanen P. 2004. Opioidihoitoa määräävän lääkärin huomioitavaa. In Kalso E, Paakkari P. & Stenberg I. (Ed.). 2004. Opioidit pitkäaikaisessa kivussa. Lääkelaitos. T-Print, Hyvinkää.

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7 REHABILITATION, REPLACEMENT AND MAINTENANCE THERAPY FOR OPIATE DEPENDENCE

The use of buprenorphine and methadone for opiate withdrawal, replacement and maintenance therapy is regulated by the Ministry of Social Affairs and Health Decree 289/2002. As a rule, indications for treatment should be assessed and treatment initiated in a hospital setting. Administration can be continued in co-operation with a municipal federation hospital district unit, health centre, substance abuse unit or prison service healthcare unit with sufficient resources in place. All units administering this treatment must appoint a named lead clinician to oversee the service and notify the relevant state provincial office of the appointment. The state provincial office is responsible for registering the unit and the lead clinician with the National Authority for Medicolegal Affairs. As the treatment of opiate dependence requires specialist skills, the National Authority for Medicolegal Affairs requires all private units administering this treatment to obtain a private healthcare service provider licence from the relevant state provincial office. The treatment of opiate dependence should be based on a separate treatment plan covering both medical and psychosocial treatment and their monitoring. The above medicines can only be prescribed and ordered by the lead clinician or delegated doctor. The medicines cannot be prescribed through the pharmacy. They must be administered in a controlled environment in the relevant unit. However, patients demonstrating good compliance can be supplied medicines up to the equivalent of an eight-day supply.

The procedures for the ordering and documenting of the above medicines are set out in the Decree on Prescriptions 726/2003 (available in Finnish and Swedish only). They must be stored in a cabinet or area that is secured by a lock. Best record-keeping practice must be observed. This is to ensure that no personal medications are allocated and no medications are left unadministered. The medicines can be administered by a healthcare professional or social care professional with sufficient training in pharmacotherapy. Administration must be documented in the patient records. Table 18 sets out the key points on rehabilitation, replacement and maintenance therapy for opiate dependence.

Tab 18. Rehabilitation, replacement and maintenance therapy for opiate dependence

- Therapeutic use of medicines
- Ensuring availability of sufficient resources
- Assessing indication for treatment
- Preparation of treatment plan
- Ordering and storage of medicines
- Administration of medicines
- Record-keeping
- Evaluating treatment effectiveness

References

Finlex – Finnish legislation online. http://www.finlex.fi/fi/.

Appendix 1. Pharmacotherapy in social and healthcare working group

Chair:
Pirjo Pennanen, Medical Counsellor, National Authority for Medicolegal Affairs

Vice-Chair:
Marjukka Vallimies-Patomäki, Ministerial Adviser, Ministry of Social Affairs and Health

Members:
Counsellor Eija Koivuranta, Ministry of Social Affairs and Health, until 15 May 2005
Counsellor Riitta-Maija Jouttimäki, Ministry of Social Affairs and Health, from 16 May 2005
Viveca Arrhenius, Ministerial Adviser, Ministry of Social Affairs and Health
Terttu Jääskeläinen, Counsellor of Education, Ministry of Education
Riston Suominen, Senior Pharmaceutical Officer, National Agency for Medicines
Antti Laine, Provincial Medical Officer, State Provincial Office of Southern Finland
Synnöve Amberla, Ministerial Adviser, Association of Finnish Local and Regional Authorities
Jouni Kurola, Medical Specialist, Kuopio University Hospital
Kaija Heikura, Chief Executive, Hospital District of Souther Karelia
Markku Mattila, City of Oulu Social and Healthcare Service
Sari Ahonen, Head of Department, City of Turku Social Services
Jaana Lehtomäki, Hospital Pharmacist, Turku University Hospital
Expert members:
Seija Ginström, Senior Doctor, Finnish Medical Association
Tuula Pitkänen, Union of Health and Social Care Professionals (Tehy)
Marita Ritmala-Castrén, Finnish Nursing Association
Raija Moilanen, Finnish Union of Practical Nurses
Harri Ovaskainen, Pharmaceutical Director, Finnish Pharmacists' Association
Sari Laaki, Regional Planner, Talentia
Kaijamaija Parviainen, Education Planner, Trade Union for the Public and Welfare Sectors

Secretariat:
Riitta Aejmelaeus, Medical Director, Centre for Pharmacotherapy Development ROHTO
Anne Markkula, Midwife, Student

Appendix 2. Verbal consultation and written evidence

24 May 2005
Oral evidence received from:

- Sirpa Peura, Pharmaceutical Director, Association of Finnish Pharmacies
- Jari Vepsäläinen, Provincial Medical Officer, State Provincial Office of Eastern Finland
- Markku Poutala, Assistant Head of Department, Trade Union of Education in Finland
- Anneli Juutinen, Director, Finnish Patients' Association
- Sirkka Keikkala, Medical Director, Jyväskylä Social and Healthcare Service Centre
- Seija Piirainen SHJ, SHO, Midwife, Association of Finnish Midwives
- Councillor Kirsti Riihelä, Provincial Medical Officer, Member of Advisory Board for Health and Welfare in Emergency Conditions, Emergency Care and Training Committee
- Martti Heinonen, Legal Counsel, Pharma Industry Finland
- Eeva-Liisa Urjanheimo, Chair, Public Health Nurses Association in Finland
- Teuvo Kontio, Chair, Finnish Ambulance Attendants' Association
- Sirkka Lappalainen, Chair, Network of Health Polytechnics
- Ritva Korte, Director of Education, Social and Healthcare Education Network

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SOSIAALI- JA TERVEYSMINISTERIÖN JULKAISUJA **ISSN 1236-2050 (painettu)**
SOCIAL- OCH HÄLSOVÅRDSMINISTERIETS PUBLIKATIONER **ISSN 1797-9854 (verkkojulkaisu)**
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