PHARMACOVIGILANCE IN MUNICIPAL ELDERLY CARE
FROM A NURSING PERSPECTIVE

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Akademisk avhandling

som för avläggande av filosofie doktorsexamen i vårdvetenskap vid Akademin för hälsa, vård och välfärd kommer att offentligen försvaras fredagen den 24 mars 2017, 10.00 i Filen, Mälardalens högskola, Eskilstuna.

Fakultetsopponent: Docent Pernilla Hillerås, Sophiahemmet Höskola
Abstract

Medication management constitutes a large part of registered nurses' (RNs) daily work in municipal elderly care. They are responsible for monitoring multimorbid older persons with extensive treatments, and they often work alone, without daily access to physicians. RNs' drug monitoring is, in this thesis, based on the concept of pharmacovigilance. Pharmacovigilance is about the science and the activities that aim to improve patient care and safety in drug use, that is, to detect, assess, understand and prevent drug-related problems.

The overall aim was to explore conditions for pharmacovigilance from a nursing perspective, focusing on implications of RNs' competence and use of a computerized decision support system (CDSS). Both quantitative and qualitative research methods were used, including a questionnaire (I), focus group discussions (II), individual interviews (III) and an intervention study (IV). In total 216 RNs and 54 older persons participated from 13 special accommodations, located in three different regions.

RNs who had completed further training in pharmacovigilance rated their medication competence higher than those who had not. However, there was no difference between groups in the number of pharmacovigilant activities they performed in clinical practice (I). The RNs appeared to act as “vigilant intermediaries” in drug treatment. They depended on the nursing staff's observations of drug-related problems. The RNs continuously controlled the work of staff and physicians, and attempted to compensate for shortcomings in competence, accessibility and continuity (II). RNs' use of a CDSS was found to affect drug monitoring, including aspects of time, responsibility, standardization of the work, as well as access to knowledge and opportunities for evidence-based care (III). The CDSS detected significantly more drug-related problems when conducting medication reviews, than the RNs did. Nevertheless, this did not result in any significant improvement in the quality of drug use in the follow up, three and six months later (IV).

This thesis contributes to the recognition of pharmacovigilance from a nursing perspective. Increased medication competence seems to be insufficient to generate pharmacovigilant activities. RNs depend on other health care professionals and organizational conditions in order to perform their work. A CDSS has the potential to support RNs, both in structured medication reviews and in daily clinical practice. Inter-professional collaboration is crucial, with or without a CDSS, and the entire team needs to be aware of and take responsibility. Other important conditions is the existence of well-functioning communication channels, competence across the team, and established procedures based on current guidelines.
Coming together is a beginning: keeping together is progress: working together is success

Henry Ford
Abstract

Aims: The overall aim of this thesis was to explore conditions for pharmacovigilance from a nursing perspective, focusing on implications of registered nurses’ (RNs) competence and use of a computerized decision support system (CDSS). The specific aims were to: evaluate RNs’ self-reported competence and activities in pharmacovigilance (I), explore RNs’ experience of medication management in municipal elderly care (II), describe variations in RNs’ perceptions of using a CDSS in drug monitoring (III) and, evaluate the implications of medication reviews led by RNs, supported by a newly introduced CDSS (IV). Methods: Quantitative and qualitative data was used. A postal questionnaire, answered by 168 RNs (I), five focus group discussions with a total of 21 RNs (II), individual face-to-face interviews with 16 RNs (III), and an intervention study with 11 RNs and 54 nursing home residents. The qualitative data were analysed with content analysis (II) and phenomenographic analysis (III). Descriptive and inferential statistics were used for the quantitative data (I, IV). Results: Having completed a dedicated course in pharmacovigilance was the strongest factor for RNs’ self-reported medication competence. However, the RNs did not increase the number of pharmacovigilant activities in clinical practice (I). In municipal elderly care, the RNs played a central role as ‘vigilant intermediaries’, continuously controlling and attempting to compensate for shortcomings, both organizational and in the work of other health care professionals. New strategies were justified to improve RNs’ preconditions for safe medication management (II). A CDSS seemed to be one feasible strategy. RNs perceived the CDSS as supportive in terms of promoting standardized routines, team-collaboration, and providing possibilities for evidence-based clinical practice (III). The clinical effects of RNs’ use of a CDSS were further evaluated in relation to implementation of a CDSS. The CDSS detected significantly more drug-related problems when conducting medication reviews, than the RNs did. Nevertheless, this did not result in any significant improvement in the quality of drug use (IV). Conclusions: This thesis contributes to the recognition of the area of pharmacovigilance from a nursing perspective. RNs’ key role in medication management needs to be recognized and facilitated, in order to enable them to provide person-centered, evidence-based and safe care. Increased medication competence seems to be insufficient to generate pharmacovigilant activities. RNs depend on other health care professionals and organizational conditions. A CDSS has the potential to support RNs, both in structured medication reviews and in daily clinical practice.

Keywords: competence, computerized decision support systems, content analysis, drug monitoring, inter-professional collaboration, nurse, older person, patient, pharmacovigilance, pharmacovigilant activities, phenomenography.
Populärvetenskaplig sammanfattning

Bakgrund: Äldre personer är en stor och växande grupp i samhället vars läkemedelsanvändning har blivit allt mer omfattande under de senaste 20 åren. Många äldre har idag många läkemedel, vilket i kombination med hög ålder och sjuklighet kan leda till läkemedelsrelaterade problem, såsom biverkningar, olämpliga läkemedel och läkemedelskombinationer. En grupp sköra äldre som löper särskilt stor risk att drabbas av läkemedelsrelaterade problem är de som bor i särskilda boenden, och som idag använder i genomsnitt tio läkemedel per person. Läkemedelsbiverkningar kan ha betydande inverkan på äldre personers hälsa och livskvalitet, och kan exempelvis orsaka fallolyckor, blödning, förvirring samt akut inläggning på sjukhus. Många av de läkemedelsrelaterade problemen är möjliga att förebygga.

Sjuksköterskor har en central roll i läkemedelshanteringen och de är involverade i flera steg i läkemedelsprocessen, som exempelvis administration och utvärdering av effekter och bieffekter. Sjuksköterskor anses väl lämpade att övervaka och minska läkemedelsrelaterade problem. De möter också patienten mer frequint än läkaren och kan därmed observera och övervaka förändringar i patientens hälsotillstånd. Sjuksköterskor förväntas ha omfattande kunskaper och kompetens för att fullgöra sina åtaganden i läkemedelshanteringen.


Avhandlingens övergripande syfte var att undersöka förutsättningar för farmakovigilans ur ett sjuksköterskeperspektiv, med fokus på konsekvenser av sjuksköterskors kompetens och användning av datorstöd.
**Metod:** För att besvara syftet användes både kvantitativa och kvalitativa forskningsmetoder. Delstudie I bestod av en enkätstudie, där sjuksköterskor skattade sin kompetens och sina aktiviteter inom farmakovigilans. Vissa av sjuksköterskorna hade deltagit i en utbildning inom farmakovigilans och andra inte. Delstudie II var en fokusgrupintervjusstudie med sjuksköterskor om deras erfarenheter av farmakovigilanta aktiviteter. I delstudie III genomfördes individuella intervjuer med sjuksköterskor om deras uppfattningar av att använda ett datorstöd i läkemedelsövervakning. I delstudie IV utvärderades de kliniska konsekvenserna av läkemedelsproblemen som leddes av sjuksköterskor med datorstöd.

Sammanlagt deltog 216 sjuksköterskor och 54 äldre personer. Tre av delstudierna (II-IV) genomfördes på särskilda boenden, totalt 13 stycken, lokalerade i tre olika regioner. En delstudie inkluderade även sjuksköterskor som arbetade inom andra områden (I).

**Resultat:** Delstudie I visade att 2-5 år efter avslutad kurs skattade de sjuksköterskor som hade genomgått fördjupad utbildning inom farmakovigilans sin kompetens högre än de som inte hade gjort det, både avseende farmakologisk kompetens, och farmakovigilanta aktiviteter. Även i jämförelse med tidigare erfarenhet, ålder, arbetsplatser och övrig utbildning, så var farmakovigilans kursen den viktigaste förklaringen till resultatet. Däremot förelåg ingen skillnad mellan grupperna vad gäller antalet aktiviteter som de faktiskt genomförde i sin kliniska praxis. Eftersom endast utbildning inte tycktes vara tillräckligt, så återstod frågan vilka andra faktorer som påverkar sjuksköterskors farmakovigilanta aktiviteter i klinisk praxis.

Resultatet av delstudie II visade att sjuksköterskor upplevde att de fick förlita sig på omvårdnadspersonalens observationer och rapporteringar av misstänkta läkemedelsrelaterade problem. Läkarna, i sin tur, var beroende av att sjuksköterskorna gjorde bedömningar och kontaktade dem vid behov. Sjuksköterskorna fungerade således som ”vaksamma förmedlare” i läkemedelsshanteringar. Detta gällde även i förhållande till organisatoriska omständigheter där de försökte kompensera för brister i exempelvis kompetens, tillgänglighet och kontinuitet bland omvårdnadspersonal och läkare. Sjuksköterskorna upplevde att de fick ta ett stort ansvar i läkemedelsövervakningen, vilket kunde innebära att de ibland överskred sina befogenheter. Frågor väcktes om hur sjuksköterskors möjligheter att själva upptäcka och förebygga läkemedelsrelaterade problem i sitt dagliga arbete kunde förbättras. Därför tillfrågades de i nästa studie om sina uppfattningar av att använda ett datorstöd för läkemedelsövervakning.

I delstudie IV utvärderades konsekvenserna av sjuksköterskors användning av datorstöd i samband med att det skulle implementeras på fyra äldreboenden. Resultatet visade att datorstödet signalerade fler läkemedelsrelaterade problem än vad sjuksköterskorna upptäckte i samband med läkemedelsgångarna. Dock visades ingen signifikant förbättring i kvaliteten på läkemedelsbehandlingarna, när dessa sedan följes upp efter tre- respektive sex månader.

Slutsatser: Resultatet från denna avhandling bidrar till att uppmärksamma farmakovigilans från ett sjuksköterskeperspektiv. Ökad kompetens hos sjuksköterskor tycks inte vara tillräckligt för att öka deras farmakovigilanta aktiviteter. Sjuksköterskor fungerar som ”vaksamma förmedlare”, då de är beroende av andra professioner samt av en väl fungerande organisation för att kunna utföra sitt jobb. Resultaten pekar på att datorstöd kan stödja deras farmakovigilanta aktiviteter, såväl i strukturerade läkemedels- och patientbehandlingar som i det dagliga arbetet. Teamsamverkan är central i läkemedelsövervakningen, med eller utan datorstöd, och samtliga i teamet behöver vara medveten om och ta sitt ansvar. Andra betydelsefulla förutsättningar är en välfungerande kommunikation, att det finns kompetens i hela teamet samt upprättade rutiner baserade på aktuella riktlinjer.

Nyckelord: datoriserat beslutsstöd, farmakovigilans, farmakovigilanta aktiviteter, fenomenografi, innehållsanalys, interprofessionellt samarbete, kompetens, läkemedelsövervakning, patient, sjuksköterska, äldre person.
List of Papers

This thesis is based on the following papers, which are referred to in the text by their Roman numerals.


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Contents

1 The thesis from a health and welfare perspective ........................................1
  1.1 Municipal elderly care in Sweden ........................................................2

2 Background ..................................................................................................3
  2.1 Medication use in elderly care..............................................................3
  2.2 Safe use of medicines ...........................................................................4
    2.2.1 Pharmacovigilance ........................................................................4
    2.2.2 Medication reviews .......................................................................4
    2.2.3 Computerized decision support in medication management ..........5
  2.3 RNs’ medication management .............................................................6
    2.3.1 Medication competence .................................................................7
    2.3.2 RNs in municipal elderly care ......................................................7
    2.3.3 RNs’ use of informatics in medication management ....................8
  2.4 Theoretical perspectives .....................................................................9
    2.4.1 Competence ..................................................................................9
    Core competencies in nursing ..............................................................10
    2.4.2 The interdisciplinary team ..........................................................11
    2.4.3 Implementation of new technology ............................................12

3 Rationale ....................................................................................................14

4 Aims ..........................................................................................................15

5 Methods .....................................................................................................16
  5.1 Participants and setting .......................................................................17
    5.1.1 Study 1 ........................................................................................17
    5.1.2 Study II .......................................................................................17
    5.1.3 Study III ......................................................................................18
    5.1.4 Study IV ......................................................................................18
  5.2 Data collection .....................................................................................18
    5.2.1 Study I Questionnaire ..................................................................19
    5.2.2 Study II Focus group discussions ..............................................19
    5.2.3 Study III Individual interviews .................................................20
    5.2.4 Study IV Quality reports and questionnaires .............................20
      The CDSS .........................................................................................21
      The process ......................................................................................21
  5.3 Data analysis ......................................................................................22
<table>
<thead>
<tr>
<th>Abbreviation</th>
<th>Description</th>
</tr>
</thead>
<tbody>
<tr>
<td>ADR</td>
<td>Adverse Drug Reaction</td>
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<tr>
<td>CDSS</td>
<td>Computerized Decision Support System</td>
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<tr>
<td>DRP</td>
<td>Drug-related problem</td>
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<tr>
<td>HSL</td>
<td>Health and Medical Services Act</td>
</tr>
<tr>
<td>MPA</td>
<td>Medical Product Agency</td>
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<tr>
<td>NBHW</td>
<td>National Board of Health and Welfare</td>
</tr>
<tr>
<td>RN</td>
<td>Registered Nurse</td>
</tr>
<tr>
<td>SALAR</td>
<td>The Swedish Association of Local Authorities and Regions</td>
</tr>
<tr>
<td>SoL</td>
<td>Social Services Act</td>
</tr>
<tr>
<td>SSF</td>
<td>Swedish Society of Nursing</td>
</tr>
<tr>
<td>WHO</td>
<td>World Health Organization</td>
</tr>
</tbody>
</table>
1 The thesis from a health and welfare perspective

Medication use has become a major worldwide problem according to the World Health Organization (WHO) (2012). Adverse reactions to medicines are common and cause illness, disability and even death. Adverse drug reactions (ADRs) have in some countries been ranked among the top ten leading causes of mortality (WHO, 2004). Responsible use of medicines implies that the health systems should ensure that the patients receive the right medicines at the right time and that the patients use medicines appropriately and benefit from them. This becomes an even greater challenge in the light of a continuously aging population in the world (WHO, 2012). In Sweden, about 20% of the population was older than 65 years in 2014. In 20 years there will be over 800,000 people older than 80 years and at the end of the 2040s over one million (Statistics Sweden, 2013; SALAR & National Board of Health and Welfare, 2015). With growing health care needs, it is essential that health care resources are used optimally. According to the National Board of Health and Welfare (NBHW) the municipalities' costs for elderly care amounted to more than 109.2 billion SEK in 2014, which is an increase of 2.6% since 2010 (NBHW, 2016a).

The demographic transition is a challenge for the health care organizations and professionals within it. The ambition to provide good quality of care to each individual, including safety in relation to drug utilization, places high demands on all health care professionals, including RNs. Health care is constantly evolving, and so is the RNs’ role. They will to a greater extent care for older persons, whose health situation is often complicated by illness and extensive medication treatments. This will require good competence in geriatrics and gerontology, something described as lacking in elderly care (NBHW, 2012). The essence of the role and responsibilities of RNs can be regarded as constant, being to promote health, prevent illness, restore health, and to alleviate suffering (SSF, 2014). However, the possibilities and ways to accomplish these will probably change over time, according to the development of society. The perspective of a quickly evolving health care, being
increasingly depending on and interacting with technology and a rapid advancement in knowledge, is a motivation and rationale for this thesis. The development highlights the need for new strategies. In order to provide good care and safe medication treatment for a growing older population, consideration of RNs’ roles and responsibilities in the medication management process is required.

1.1 Municipal elderly care in Sweden

In Sweden, the municipalities have the main responsibility for offering health care in home care, and special housing (a collective term for various types of housing for older people, such as nursing homes and assisted living facilities). Their responsibilities are regulated in the Social Services Act (SoL, SFS 2001:453) and the Health and Medical Services Act (HSL, SFS 1982:763). Approximately 81 000 persons over 65 years of age lived in a permanent special housing in 2014, and every year 20 000-25 000 move into such facilities (NBHW, 2015). The municipalities provide medical care up to the level of RNs, while the county councils are responsible for providing medical care by physicians. The physicians’ engagement is regulated by agreements between the municipalities and county councils (Josefsson, 2009). A medical responsible nurse must be appointed in the municipality (HSL, SFS 1982:763, 24 §), who sees that there are routines for consulting physicians or other health care professionals when needed. This person is responsible for ensuring that the residents receive the care prescribed by the physicians. The responsibilities also involve routines for appropriate and effective medication management (NBHW, 2016b).

RNs in municipal elderly care work in different ways in various parts of the country. They can work directly with the residents or indirectly, as mere consultants, have administrative positions, or a mixture of these. The RNs can be responsible for a small number of residents up to a few hundred (Josefsson, 2009). In this thesis, ‘municipal elderly care’ refers to special housing, and does not include home care.
2 Background

2.1 Medication use in elderly care

High age is the strongest risk factor for severe illness and death. It is the older persons who consume the largest proportion of the health care given (Larsson & Rundgren, 2010). Prescription of medicines is a complex process in relation to old and frail people, due to the characteristics of aging and geriatric medicine (Spinewine et al., 2007). Residents in special housing are among the frailest of older persons. They are often prescribed potentially inappropriate medications, which is associated with drug-related problems (DRP). The prescription of potentially inappropriate medications ranges from 12% among community-dwelling older persons to 40% among nursing home residents, in both Europe and the United States (Gallagher, Barry & Mahoney, 2007). In Sweden, the NBHW has developed indicators for good medication treatment for older persons and thereby defined which medicines and combinations of medicines should be avoided. Since they were first published, the patterns have been changing and recent reports show a decrease in the prescription of inappropriate medicines and combinations (Fastbom & Johnell, 2015; Hovstadius, Petersson, Hellström & Eriksson, 2014; NBHW, 2010; 2016a). However, the total use of medicines has increased continuously over the past 20 years. Those aged 75 and older currently use an average of almost five different medicines while residents in special housing use nearly ten. While this, on the one hand, reflects a positive trend where more and more diseases are treatable, there are, on the other hand, risks with medication treatments. Extensive treatments which entails significant risks of adverse effects, such as fall incidents, bleeding and confusion, may lead to hospitalization. Approximately eight percent of the emergency hospital admissions are estimated to be caused by ADRs and about 60% of those are preventable (Government of Sweden & SALAR, 2015; SALAR & NBHW, 2015; NBHW, 2014; 2016a). The incidence of ADRs still needs to be reduced and new knowledge is needed to ensure older persons’ specific needs for tailored treatments are met (NBHW, 2014; Government of Sweden, 2011).
2.2 Safe use of medicines

2.2.1 Pharmacovigilance
Pharmacovigilance entails the science and activities relating to the detection, assessment, understanding and prevention of adverse effects or any other DRP. The aim of pharmacovigilance is to improve patient care as well as public health and safety in relation to the use of medicines. Additionally pharmacovigilance aims to contribute to the assessments of benefit, harm, effectiveness and risk of medicines, and also to promote education and clinical training. The discipline of pharmacovigilance has developed considerably and it remains a dynamic clinical discipline which will continue to develop according to changing needs and challenges in medication safety (WHO, 2002; 2004).

Knowledge about appropriate and safe use of medicines has grown over the years, but still a considerable gap remains between this knowledge and the actual activities (WHO, 2011). Spontaneous reporting of ADRs is the most widely used method of pharmacovigilance (Hazell & Shakir, 2006). Originally physicians were the only professionals invited to report suspected ADRs but eventually other professionals involved in the care of the patients were invited (WHO, 2002). The monitoring system should be supported, not only by physicians and pharmacists, but also by RNs and other health care professionals. This is essential in order to prevent unnecessary suffering, and also from a financial perspective (Rehan, Chopra & Kumar Kakkar, 2009). In Sweden, all RNs were included as reporters in 2007. The Medical Product Agency (MPA) then gave all RNs a mandate to report suspected ADRs (LVFS, 2012:14). In this thesis the term ‘pharmacovigilant activities’ involves more aspects than just the reporting of ADRs; it also refers to the activities performed in clinical practice that are consistent with the definition of WHO (2004), namely to detect, assess, understand and prevent DRPs.

2.2.2 Medication reviews
Medication reviews are one way to prevent patients being treated with inappropriate drugs, and they have been shown to improve the quality of treatments (Brulhart & Wermeille, 2011; Kragh & Rekman, 2005; Mattison, Afonso, Ngo & Mukamal, 2010; Milos et al., 2013). Medication reviews involve a structured evaluation of a patient’s medicines, with the intention of reaching agreement with the patient about medication treatment, optimizing the benefits and minimizing DRPs (Holland et al., 2007). Since 2012, the
NBHW has required health care providers to offer medication reviews to all patients aged 75 years or older, who are prescribed at least five drugs, or when DRPs may be suspected. Guidelines for the implementation of medication reviews has also been given. Drug-related problems are defined as an inappropriate drug, incorrect dosage, adverse drug reaction, drug-drug interaction, management problem, and insufficient or lack of effect or other problems that are related to the patients’ drug use (NBHW, 2013; SOSFS 2012:9). The implementation of medication reviews differ between and within regions, in relation to symptom evaluation, templates, engaged personnel, responsibilities and documentation (Cronlund, 2011). In 2011 about 67% of people living in special housing had a review of their prescribed medication. The proportion ranged from 0 to 100% among the regions. In 2014, this number was 76%, and further increased to 84% in 2015 (SALAR & NBHW, 2013; 2014; 2015).

Medication reviews often involve several professional groups, including physicians, RNs, assistant nurses and sometimes pharmacological experts. However, previous studies of medication reviews in nursing homes have mainly focused on pharmacists, physicians or multidisciplinary medication reviews (Brulhart & Wermeille, 2011; Finkers, Maring, Boersma & Taxis, 2007; Halvorsen, Ruths, Granas & Viktil, 2010; Lapane, Hughes, Dariello, Cameron & Feinberg, 2011; Milos et al., 2013; Olsson, Curman & Engfeldt, 2010; Zermansky et al., 2006). Studies on nurse-led medication reviews and/or drug monitoring are limited. They have been explored, with promising results, in regard to hospitalized old patients (Bergqvist, Ulfvarson & Karlsson, 2009), people with dementia in nursing homes (Jordan et al, 2014) and in respiratory outpatient clinics (Gabe, Murphy, Jordan, Davies & Russell, 2014). Because of RNs’ independent role and great responsibilities for monitoring the patients’ medication treatments in municipal elderly care, further research from that context is motivated.

2.2.3 Computerized decision support in medication management
The detection of DRPs is a time-consuming process that depend on the skills of the professionals involved, suggesting there is a growing need for computerized systems that could facilitate the process (Yifeng et al., 2010). CDSSs are information systems designed to improve clinical decision-making. The individual patient’s characteristics are matched to a computerized knowledge base and patient-specific recommendations are generated (Garg et al., 2005).
The use of CDSSs has been shown to improve clinical practice, especially systems that provide decision support at the time and location of decision-making (Kawamoto, Houlihan, Balas & Lobach, 2005). CDSSs are also believed to have the potential to change the behaviour of health care professionals and enhance inter-professional collaboration (Kawamoto et al., 2005; Koskela, Sandström, Mäkinen & Liira, 2016). However, further research is needed to elucidate the effectiveness on patients’ health (Garg et al., 2005; Kawamoto et al., 2005). In Sweden, computer-support for medication management has been tested with promising results in hospital clinics, primary care centres (Eliasson et al., 2006) and nursing homes (Bergman, Olsson, Carlsten, Waern & Fastbom, 2007; Ulfvarson, Rahmner, Fastbom, Sjoviker & Karlsson, 2010). Computerized systems have been found to be supportive in the process of identifying and addressing DRPs but still relatively little has been written about how such systems work in settings for older persons (Bernstein, Kogan & Collins, 2014). According to the Swedish drug policy there are increasing technical possibilities to offer prescribers, pharmacists as well as patients’ access to relevant information about current medication. Nevertheless, electronic decision-supports do not have the dissemination in health care which would be needed. An increasing use of electronic decision-supports would provide considerable improvement regarding patient safety, quality of life and cost efficiency (Government of Sweden, 2011).

2.3 RNs’ medication management

RNs have an important role in ensuring medication safety (Choo, Hutchinson & Bucknall, 2010). Medication management constitutes a substantial part of their daily work and they are well placed to monitor and reduce drug-related morbidity (Gabe, et al., 2011). As RNs have been shown to have the capability to identify serious ADRs they could have a more active role when it comes to detecting and reporting DRPs (Bergqvist, Ulfvarson, Andersen Karlsson & von Bahr, 2008; Bäckström, Ekman & Mjörndal, 2007; Mendes, Alves & Batel Marques, 2012; Morrison Griffiths, Walley, Kevin Park, Breckenridge & Pirmohamed, 2003). The fact that RNs are also required to report suspected DRPs to the MPA (LVFS, 2012:14), further reinforces their importance in ensuring medication safety.
2.3.1 Medication competence

RNs are expected to have comprehensive knowledge and competence in order to fulfil their medication management responsibilities safely. Different areas have been suggested to compose the competencies they need, which involve pharmacology, communication, interdisciplinary collaboration, information seeking, calculation, administration, assessment and evaluation, documentation and promoting medication safety as part of patient safety (Sulosaari, Suhonen & Leino-Kilpi, 2011). Despite RNs’ suggested capability to detect and report DRPs, studies suggest deficiencies in their competencies, for instance regarding their knowledge of pharmacology, the mechanisms of drug action and interaction as well as in high-alert medications (Hsaio et al., 2010; King, 2004; Ndosi & Newell, 2009). RNs’ described unsatisfactory medication competence entails a potential risk for medication errors, under-reporting of ADRs and hence inability to secure safe medication for the patients (De Angelis, Colaceci, Giusti, Vellone & Alvaro, 2015; Simonsen, Johansson, Daehlin, Osvik & Farup, 2011; Simonsen, Daehlin, Johansson & Farup, 2014). Additional educational programs have been found to increase RNs’ medication competence and spontaneous reporting of ADRs (Bäckström et al., 2007; Hajebi, Mortazavi, Salamzadeh & Zian, 2010; Lim, Chiu, Dohrmann & Tan, 2010; Valente & Murray, 2011). However, these programs usually comprise limited training activities, evaluated shortly after their completion, and do not assess the impact from a longer term perspective. Neither do the studies specifically focus on the comprehension of the concept of pharmacovigilance in its entirety and from a nursing perspective.

2.3.2 RNs in municipal elderly care

In municipal elderly care, RNs are often responsible for a large number of patients in need of advanced nursing care (Bowers, Lauring & Jacobson, 2001; Furåker & Nilsson, 2013; Nilsson, Lundgren & Furuåker, 2009). In Sweden, deficiencies have been noted to exist within the area of elderly care and many RNs are not prepared for the demands put on them (NBHW, 2012). They work alone without daily access to the physician (Karlsson, Ekman & Fagerberg, 2009). They have a coordinative function, which requires medical and geriatric competence, for which they are not sufficiently prepared by just having a basic nursing education. According to the NBHW only 1.6% of the RNs working in municipal elderly care have a specialist education in this area of knowledge. In addition, the RNs have been shown to
have little control over their work situation. They have a consultative role in relation to the nursing staff and thus need to rely on them, and make assessments based on second-hand information (Furåker & Nilsson et al., 2013; Gustafsson, Fagerberg & Asp, 2010; Juthberg & Sundin, 2010; NBHW, 2012; Nilsson et al., 2009). Managing medication is the most frequent activity among RNs in municipal elderly care, and their complex role requires constant vigilant thinking to make sure that their patients receive the appropriate medication (Eisenhauer, Hurley & Dolan, 2007). It has been suggested that the complexity of medication treatments in these settings demands more highly educated RNs to ensure patient safety (Dilles, Vander Stichele, van Rompaey, van Bortel & Elsvier, 2010). Additional education about medicines has been rated as the most urgently needed area of education among RNs working in municipal elderly care in Sweden (Karlstedt, Wadensten, Fagerberg & Pöder, 2015). A significant part of RNs responsibilities is to monitor, evaluate and observe signs of DRPs. This involves observations of physical, functional and mental status, which may include, for example, performance of activities in daily living, sleeping, eating, orientation, mood and memory (Touhy & Jett, 2013). Nevertheless, it has been reported that there is an extreme shortage of monitoring of health status as well as drug effects in nursing homes (Nordin Olsson, 2012). RNs even seem to have doubts concerning their responsibility in drug monitoring (Dilles, Elseviers, van Rompaey, van Bortel & Vander Stichele, 2011). Hence, RNs’ medication management needs to be further explored, in order to determine what factors facilitate and hinder their drug monitoring.

2.3.3 RNs’ use of informatics in medication management

Nursing informatics refers to how the science of nursing, computer technology, and information science are integrated to improve the quality of care. Medication administration, technology intervention and the use of decision support systems are areas identified as emerging themes within nursing informatics (Carrington & Tiase, 2013). CDSSs integrated with the patients’ medical record, can increase accessibility and compliance to guidelines and other support systems (Liljequist & Törnvall, 2013) and are increasingly used by RNs to support their clinical practice. CDSSs can provide RNs with drug-related information (Doran et al., 2010) and also allow targeted observations on ADRs, which contributes to the detection and reporting of ADRs (Dilles, Vander Stichele, van Bortel & Elseviers, 2013). In home care, a CDSS was
found useful for nurses to obtain profiles of the patients’ medication, regarding drug-drug interactions, duplications and unsuitable drugs (Johansson, Petersson & Nilsson, 2010). However, no previous studies seem to have been performed regarding RNs’ overall perceptions of using a CDSS for drug monitoring and in relation to medication reviews in municipal elderly care.

There is a growing awareness of the quality effects of incorporating informatics into the work flow of RNs providing care for older patients (Bowles, Dykes & Demiris, 2015). It has therefore been introduced in various health care settings, such as acute care and hospitals, but is rare in elderly care (Bowles, Dykes & Demiris, 2015; Carrington & Tiasse, 2013; Fossum, Alexander, Ehnfors & Ehrenberg, 2011; Lapane et al., 2011). These settings are considerably behind other health providers in adopting informatics (Zhang et al., 2016). Hampering factors could be that RNs in communities, rural areas, and special housing may work more isolated and are not always able to benefit from innovations in informatics (Doran et al., 2010). This working situation would motivate further research and development of strategies and tools to enhance their clinical practice and patient safety, also regarding medication management.

2.4 Theoretical perspectives

The theoretical perspective of this thesis is the concept of competence and furthermore the core competencies that are deemed necessary to provide qualitatively good care. The reference to these competencies is made in order to clarify the RNs’ profession. Teamwork and informatics, being two of the core competencies, are further described on the basis of determinants of successful collaboration and theories on implementing new technology. The perspectives will form a theoretical basis for the discussion and implications.

2.4.1 Competence

Starting points for the definition of competence are the individual and the work. The individual has more or less space to define and perform the work depending on for instance the utilized technology and the work organization. Competence is here understood as an individuals' potential ability in relation to a certain task, situation and context. This can be understood to mean that the person is not competent in him/herself but in relation to something
The individual ability for action implies that the individual possesses knowledge, and intellectual and practical skills (Ellström, 1992).

There seems to be little consensus regarding the definition of competence in relation to nursing practice (Cowan, Norman & Coopamah, 2005; Girot, 1993; Scott Tilley, 2008; Smith, 2012). Several studies point out that competence is not absolute, it is continuously dynamic and requires adaption to the multitude of settings where nursing competence is applied, developed and evaluated (Mendes, da Cruz & Angelo, 2014; Smith, 2012). Giro (1993) describes the attributes of nurses’ competence in terms of trust, caring communication skills, and knowledge/adaptability. Pearson, FitzGerald, and Walsh (2002) state that competence is not a directly observable quality; it could rather be described as attributes that underlie and enable competent performance in an occupation. In a literature review, Cowan and co-workers (2005) argues for an agreement to embrace a holistic conception of competence. This refers to an understanding that “nursing practice requires the application of complex combinations of knowledge, performance, skills, values and attitudes” (Cowan et al., 2005, p.361).

There is a difference in between having competence and how this competence is used or expressed (Tveiten, 2003). It seems to be problematic to decide what to assess, whether competence should be assessed globally or through multiple competencies (Watson, Stimpson, Topping & Porock, 2002). The attributes of RNs’ clinical role are described in terms of a complex interaction between RNs and patients. Underlying factors in this interaction are critical thinking, informed experience and clinical autonomy (Mendes et al., 2014). However, change is constant in nursing practice due to research and technological development, implying that continuous development is required for RNs to be able to act competently in clinical practice (Axley, 2008).

**Core competencies in nursing**

The efforts to develop the core competencies started in 2002 at the Institute of Medicine of the National Academies (IOM). The IOM has as its primary task to provide policy-makers and the public with advice and guidance about health-related issues. The goal of the core competencies was to develop strategies for restructuring all health education to better conform to the future health care. New competencies were considered necessary to reduce care suffering, and to improve the quality and safety of the care provided. The work was finished in 2007 by the Quality and Safety Education for Nurses (Leksell
& Lepp, 2013) and resulted in six core competencies: patient-centred care, teamwork, evidence-based care, quality improvement, safety, and informatics (Cronenwett et al., 2007; Institute of Medicine, 2003). These competencies should be found in all professionals in health care, and they require collaboration across professional boundaries. The Swedish Society of Nursing (SSF) has for several years worked to disseminate knowledge about the core competences (SSF, 2010).

Patient-centred care, named person-centred care by the SSF, is characterized by the person being seen and understood as a unique individual with individual needs, values and expectations. Teamwork, relates to RNs’ possibilities to contribute to the team performance through their competence and responsibilities in nursing care. Evidence-based care, meaning integrating the patients’ unique preconditions and expectations with the best available evidence, is another essential competence for RNs. Quality improvements are continuous processes directed towards whatever benefits the patients and their families. RNs need to understand how the organizations and their systems are constructed, and recognize the importance of following and measuring what is being accomplished over time. Safety, or safe care, involves RNs’ recognition of the importance of safety work to prevent mistakes so that patients will not be harmed. The final core competence, informatics, deals with the need for RNs to engage in the development of information- and communication systems which support nursing care (Cronenwett et al., 2007; Forsberg, 2016; SSF, 2010).

2.4.2 The interdisciplinary team

Teamwork has become a condition for effective practice in health care. Collaboration is essential to ensure qualified health care and teamwork is the main context in which collaborative patient-centred care is provided. (D’Amour, Ferrada-Videla, San Martin Rodriguez, Beaulieu & Rodriquez, 2005; San Martin-Rodríguez, Beaulieu, D’Amour & Ferrada-Videla, 2005). Concepts related to collaboration are sharing, partnership, interdependency and power, which reveal collaboration to be a complex and dynamic process involving several competencies (D’Amour et al., 2005). Norsen, Opladen, and Quinn (1995) have defined the competencies required as cooperation, assertiveness, responsibility, communication, autonomy and coordination.

The complexity of health problems is growing, making inter-professional collaboration increasingly important (D’Amour et al., 2005). In addition, the
rapid social, economic and technical changes are having profound effects on
health care, requiring a broad spectrum of knowledge among the profession-
als (Fagin, 1992). This development points to the need for increased collabor-
ation. According to San Martín-Rodríguez and co-workers (2005) collabor-
ation between health professionals require the presence of several elements.
Nevertheless, the health professionals cannot create all necessary conditions
themselves, due to the complexity of health care systems. Processes inside
the organization as well as in the organization’s external environment, play
important roles in order to develop and consolidate collaborative processes
in health care teams. San Martín-Rodríguez and co-workers (2005) argue
that successful collaboration can be attributed to three determinants,
described as interactional, organizational and systemic. The interactional
determinants deal with interpersonal relationships among team members.
Willingness to commit to a collaborative process is also essential. Trust is
identified as one of the key elements required for the development of
collaborative practice, and so is communication. Mutual respect is another
interactional element, implying the recognition of the various professionals’
contributions in the team. The organizational determinants define the
attributes of the organization, favouring an inter-professional collaboration.
The organizational structure has a strong influence, whereas a decentralized
and flexible structure is preferred before a hierarchal one. The philosophy of
the organizations also has an impact, since it should support a collaborative
practice. Additionally, administrative support is required as well as team
resources, in terms of availability of time to interact. Coordination and
communication mechanisms can support the collaboration, for example
through formalization of rules, standards and policies. The systemic
determinants are elements outside the organization. The social system is one
such element, involving differences based on gender stereotypes, social
status and power disparity. Cultural differences and the educational system
also affect how professionals perceive collaborative work. The professional
systems can be characterized by autonomy and control rather than
collegiality, and thereby have a significant effect on the development of
collaborative processes.

2.4.3 Implementation of new technology
The implementation of new technology in clinical practice is complex. Suc-
cessful implementation of a CDSS in health care is dependent on several
things, such as individual cognitive factors, the design of the technology and
the relationship between these and more social and environmental factors (Dowding et al., 2009). Numerous theories, models and frameworks for implementation are proposed in the literature. Rogers’ Theory of Diffusion has been widely applied, suggesting attributes by which an innovation can be described. Rogers refer to the attributes as the relative advantages, compatibility, complexity, trialability and observability of the innovation (Rogers, 2003). The relative advantages refer to the degree to which an innovation is perceived as better than the existing practice, while compatibility is the degree to which the innovation is perceived as consistent with existing values, needs and experiences. Complexity is about the perceived difficulties in understanding and using the innovation. Trialability deals with the possibilities to experiment with the innovation on a limited basis. Innovations which initially can be tried will generally be adopted more quickly. Finally, Observability deals with the visibility of the innovation to others. The more visible the results, the more likely the innovation will be adopted.

Additionally there are several determinant frameworks which comprise hindering and facilitating variables affecting implementation outcomes (Nilsen, 2015). One framework, previously used by RNs, is the Consolidated Framework for Advancing Implementation Research (CFIR). It is a meta-theoretical framework from which the researchers can select the parts that are relevant for their context. It is composed of five major domains. The first involves the characteristics of the intervention being implemented, for instance regarding adaptability, complexity and costs. The next two domains, inner and outer setting, can include the social as well as structural and cultural contexts through which the implementation process will proceed. The fourth domain of the CFIR is the individuals involved. This includes aspects of knowledge, beliefs, self-efficacy and other personal attributes. The fifth domain relates to the process itself: planning, engaging, executing and evaluating (Damschroder et al., 2009). The CFIR can be used to explore what factors influence an implementation.
3 Rationale

Medication management constitutes a large part of RNs’ work in municipal elderly care. They are responsible for monitoring patients with extensive medication treatments, in need of advanced nursing care, and they often work alone without daily access to physicians. It is also known that DRPs are common in these settings, problems which often are preventable. RNs’ medication management has previously been explored from several different perspectives, including their pharmacological knowledge and competence, as well as their detection and reporting of ADRs. Although previous research is relatively comprehensive, there is a lack of research focusing on pharmacovigilance from a nursing perspective. Pharmacovigilance, being a wide-ranging concept, is related to the detection, assessment, understanding and prevention of adverse effects or any other DRP. Neither have RNs’ perceptions or use of CDSSs, in relation to their pharmacovigilant activities, been explored. The literature shows that CDSSs have the potential to improve RNs’ decision-making in clinical practice, but there is still a lack of knowledge regarding their use of CDSSs in relation to medication management.

Change is constant in nursing practice, implying that continuous development is required to be able to act competently in clinical practice. Extended knowledge and understanding of the conditions for pharmacovigilance from a nursing perspective will enhance the possibilities to facilitate RNs’ work and enable them to act also in future health care. This could further improve the conditions to provide qualitatively good and safe care.
4 Aims

The overall aim of this thesis is to explore conditions for pharmacovigilance from a nursing perspective, focusing on implications of RNs’ competence and use of computerized decision support systems. The specific aims are:

Study I To describe and evaluate RNs’ self-reported competence and activities in pharmacovigilance in relation to age, education, workplace and nursing experience.

Study II To explore RNs’ experience of medication management in municipal care of the elderly in Sweden, with focus on their pharmacovigilant activities.

Study III To describe variations in RNs’ perceptions of using a computerized decision support system in drug monitoring.

Study IV To evaluate the implications of medication reviews led by RNs, supported by a newly introduced CDSS, with focus on (1) RNs’ observations of DRPs compared to what the CDSS signals, (2) the changes in the quality of medication treatments, and (3) RNs’ views of how the CDSS affects their medication management.
To accomplish the overall aim of the thesis, both quantitative and qualitative data were used. Initially the area of pharmacovigilance was explored, being a relatively unknown field in relation to the nursing profession. This included exploring and evaluating RNs’ self-rated competence and activities in pharmacovigilance (study I, II). The following studies focused on the implications of RNs’ use of a CDSS in drug monitoring. This included describing RNs’ perceptions of using a CDSS (study III) as well as an intervention, exploring the clinical implications (study IV). An overview of studies I-IV is presented in Table 1.

Table 1: Overview of the studies in the thesis.

<table>
<thead>
<tr>
<th>Study</th>
<th>Design</th>
<th>Sample and informants</th>
<th>Data collection</th>
<th>Data analysis</th>
</tr>
</thead>
<tbody>
<tr>
<td>I</td>
<td>Cross-sectional, quantitative</td>
<td>168 RNs</td>
<td>Questionnaire</td>
<td>Fisher’s test, Mann-Whitney U-test, logistic regression model</td>
</tr>
<tr>
<td>II</td>
<td>Explorative, qualitative design</td>
<td>21 RNs</td>
<td>Focus group discussions</td>
<td>Inductive content analysis</td>
</tr>
<tr>
<td>III</td>
<td>Descriptive, qualitative</td>
<td>16 RNs</td>
<td>Individual interviews</td>
<td>Phenomenographic analysis</td>
</tr>
<tr>
<td>IV</td>
<td>Quasi-experimental one-group design, three and six months follow-up</td>
<td>11 RNs, 54 patients</td>
<td>Quality reports, questionnaires</td>
<td>McNemars statistics, Kruskall Wallis H test</td>
</tr>
</tbody>
</table>
5.1 Participants and setting

Altogether, 216 RNs and 54 nursing home patients participated in the studies. Three of the studies were conducted in municipal elderly care, in total 13 settings, located in three different regions. The settings mainly consisted of nursing homes, including units for both general elderly care and dementia care, but also assisted living facilities (study II, III, IV). One study also included RNs working in other care settings (study I).

5.1.1 Study 1

To evaluate RNs’ competence and activities in pharmacovigilance, the participants in this study consisted of RNs who had applied to additional courses within the area. Purposive sampling was used to recruit the participants. During 2008-2011, the RNs had applied to additional courses including the area of pharmacovigilance, at Mälardalen University. The courses stressed the pharmacovigilance perspective, and aimed to increase the RNs’ competence in detecting and reporting suspected DRPs, as well as to monitor medication safety in their clinical practice. One group of RNs (exposed) had participated in one of the courses during the stated time period and the other group (unexposed) had applied to a course but for different reasons had not attended. In total 168 RNs, working in different parts of Sweden, participated in the study.

5.1.2 Study II

To gain deeper knowledge about RNs’ pharmacovigilant activities, the focus in this study was on RNs in clinical practice. Convenience sampling was used for recruiting the participants. The study was conducted in five municipal elderly care settings, situated in two different regions in the central part of Sweden. The settings consisted of nursing homes and assisted living facilities. Altogether, the settings housed over 600 residents and there were between four and six RNs employed in each setting. In total, 21 RNs, four men and 17 women participated in the study.
5.1.3 Study III

RNs’ pharmacovigilant activities were further investigated, in terms of using a CDSS in drug monitoring. Purposive sampling was used to recruit the participants. The RNs were working in four nursing homes located in one region in the central of Sweden, altogether housing about 250 residents. This region had worked actively with procedures of medication reviews and implementation of CDSSs and the included nursing homes had implemented a routine of conducting yearly medication reviews for all residents, according to Swedish regulations (NBHW, 2013). They had also adopted the use of a web-based CDSS as a support in this process. In total, 16 RNs, two men and 14 women participated in the study. Their experience of using the CDSS ranged between six months and 3.5 years.

5.1.4 Study IV

The clinical effects of RNs’ use of a CDSS in drug monitoring were investigated in this intervention study. Purposive sampling was performed. The settings were selected on the basis of having the intention to implement the CDSS in their daily practice. The study was carried out in four nursing homes located in two different regions in the central part of Sweden, representing both rural and urban districts. Three nursing homes began the process in relation to the current study and one had recently started to use the CDSS. The nursing homes ranged in size from 40-74 beds, altogether housing about 220 residents.

The inclusion criteria for the RNs were that they were employed at the nursing home and participating in medication reviews. The participating patients were recruited by the RNs, based on the criteria to firstly be aged 75 or older and prescribed a minimum of five drugs. Secondly, they had to be able to respond adequately to questions in a symptom assessment. Eleven RNs actively participated and 54 patients were included in the study.

5.2 Data collection

The data for the articles in the thesis was collected through questionnaires (studies I and IV), interviews (studies II and III) and quality reports from the CDSS (IV).
5.2.1 Study I Questionnaire

A 45-item questionnaire was developed with questions inspired by the meaning of pharmacovigilance (WHO, 2004; WHO, 2012) and of RN’s medication competence (Sulosaari et al., 2011). The process of designing the questionnaire was guided by Charlton (2000). It started with a literature search, followed by construction of questions which subsequently were repeatedly discussed and revised within the research group. When a pool of questions had been gathered, they were tested for validity in a pre-test among in total five teaching colleagues, who were also RNs, and RNs in clinical practice who were not involved in the study. They commented on wordings, the scales used, and whether the questions were relevant to the aim of the study. This was followed by a face validation among RNs who had been either exposed or unexposed to the current courses. These RNs were selected through convenience sampling, based on living in geographically nearby areas. Finally, after some further small changes in the questionnaire, a pilot study was performed. The questionnaire included questions within the areas of theoretical knowledge, assessment and decision-making, and also of practical skills including information retrieval and pharmacovigilant activities. The RNs estimated their competence as well as the frequency of performing the activities connected to detection, assessment and prevention of DRPs, during the previous six months.

The questionnaire was sent out by postal mail in April 2013 to all RNs who had participated (exposed) in one of the courses during 2008-2011 (n=124). For the unexposed group (n=459) a stratified random sampling was made from all of the eight previously conducted courses (n=124). The final response rates were 60% (exposed) and 54% (unexposed).

5.2.2 Study II Focus group discussions

Data was derived from five focus group discussions with in total 21 RNs, working in five different municipal elderly care setting. The discussions were carried out during May and June 2014. They were preceded by a pilot discussion to validate the questions. The nursing homes were selected by the community head nurses and municipal administrators. The inclusion criterion was that they should have a minimum of four RNs employed; this was in order to enable a focus group discussion. Pre-existing groups can challenge each other in the discussions (Kitzinger, 1995) and are also suitable if
the purpose is to gain in-depth insight (Kreuger & Casey, 2000). The discussion guide was developed according to Kreuger and Casey (2000) with the key question focusing on how the participants perceived their role in drug monitoring and what barriers and facilitators they could identify.

5.2.3 Study III Individual interviews

Individual semi-structured interviews were performed with 16 RNs in 2015. The community head nurse provided information about which nursing homes met the criterion of using the CDSS on a regular basis and also made the initial contact with them. The interviews were preceded by two pilot interviews to validate the entry questions in relation to the phenomena in focus, being the use of a CDSS. The preferred method of data generation in phenomenography is the semi-structured interview (Marton & Booth, 1997) and it should be carried out as a dialogue (Mann, Dall’Alba & Radcliffe, 2007). In the interviews the same entry question was asked, ‘What are your perceptions of using a CDSS in drug monitoring’, followed by, ‘When and how do you perceive a CDSS as supportive or as impeding your work?’ These were followed by probing questions to encourage the participants to develop and clarify their answers.

5.2.4 Study IV Quality reports and questionnaires

Multiple methods of data collection were used to provide a more complete picture of the implications of the RNs’ use of a CDSS in medication reviews. Data was derived from quality reports, with the outcome measures of number of drugs and DRPs reported by the CDSS. Data was also collected through two questionnaires. In Q1 the RNs documented their own suspected DRPs, corresponding to the quality reports from the CDSS. Additional observations, e.g. untreated symptoms, unclear indications, and lack of adherence were also documented as potential DRPs. In Q2 the RNs estimated how the CDSS had influenced their medication management. The study start in December 2014 was preceded by information and introduction meetings with nursing home managers, community head nurses and the participating RNs. The RNs were also offered specific training in how the CDSS worked. The inclusion of patients lasted from January 2015 until October 2015. All patients in the four nursing homes, who met the inclusion criteria were offered the opportunity to participate in the study, as well as those admitted
during the inclusion period. With a total intervention period of six months, including a follow-up after three months, the data collection was completed in April 2016.

The CDSS
The CDSS used in the current study is a web-based system which can be used by physicians as well as RNs. The system can retrieve patient-specific information from the available drug lists, electronic medical records and symptom assessments, and then provide quality reports based on the indicators compiled from the NBHW (2010) and from local drug committees. The quality reports provide warnings and explanations about the quality of drug use, e.g. inappropriate drugs, drug-drug interactions, drug duplications, and possible ADRs.

The process
The data collection process involved three stages. The RNs prepared the medication reviews by collecting the information, entering it into the system and presenting the quality report to the physician while performing the medication reviews (Figure 1). The process was followed closely and the nursing homes were initially visited every week, in order to give support and opportunities to ask questions. As RNs became more accustomed to using the CDSS, the visits were partly replaced by telephone and mail correspondence. Nevertheless, they received support throughout the study when needed, for instance with login issues or questions about the software functions. This service was provided in collaboration with the vendor of the product.
5.3 Data analysis

Studies I and IV were analysed quantitatively while qualitative analysis was used in studies II and III.
5.3.1 Studies I and IV - Statistical analysis

The statistical Package for the Social Sciences (SPSS)™ Version 19 or 22 software was used for the statistical analyses.

**Study I**
Fisher’s test was performed to evaluate differences between groups regarding reasons for not participating in the study and also for analysing demographic data. A Mann-Whitney U-test was used to compare the exposed and unexposed groups concerning self-reported medication competence and pharmacovigilant activities. The P-value was set to 0.001 according to Bonferroni correction (Bland & Altman, 1995). The Odds ratio (OR) was calculated using logistic regression, allowing for adjustments by covariates, giving a 95% confidence interval.

**Study IV**
Non-parametric statistics were used due to a skewed distribution of data. Kruskall Wallis H test was used to calculate changes in the quality of the medication treatments three and six months after conducting the medication review. A P-value of <0.05 was regarded as statistically significant. McNemars statistics were used to compare the differences between RNs and CDSS reports of DRPs. RNs’ views of how the CDSS had affected their medication management were displayed by medians and quartiles.

5.3.2 Study II - Inductive content analysis

The data from the focus group discussions were analysed by content analysis (Krippendorff, 2013). The analysis process was performed in several steps guided by Graneheim and Lundman (2004). The steps included to obtain a sense of the whole in the text whereupon meaning units were identified. The meaning units consisted of words, sentences and paragraphs associated through their content. Subsequently, the meaning units were condensed and labelled with codes at a low level of abstraction. The codes were subsequently abstracted into three categories and eight sub-categories. Finally, the underlying meaning of the different categories was formulated into a theme.
5.3.3 Study III – Phenomenographic analysis

The data from the interviews were analysed in accordance with a phenomenographic approach. Phenomenography is a method for mapping the qualitatively different ways in which people experience, conceptualize, perceive, and understand phenomena of the world. The descriptive variations of experiences have both structural and referential aspects, which are connected to each other. The structural way of experiencing something refers to discernment of the whole as well as the parts and their relationship within the whole, while the referential aspect refers to the meaning and the overall attributes of the phenomena (Marton & Booth, 1997). The analysis was guided by Dahlgren and Fallsberg (1991) who describe seven steps in the process, including familiarization, condensation, comparison, grouping, articulating, labelling and contrasting. These steps entailed that the interviews were read to get acquainted with the details. Then significant statements were selected that represented the entire dialogue concerning the phenomena, and these were subsequently compared to identify variations and agreements. The answers were compiled and structural as well as referential aspects were formed. Finally the obtained aspects were compared regarding similarities and differences.
5.4 Ethical considerations

The studies in this thesis have been approved by the Regional Ethical Review Board in Uppsala, documents No. 2012/540, 2013/488 and amendment application 2013/488/1. The studies were conducted in accordance with the Helsinki Declaration (World Medical Association, 2013). All participants in studies I, II, III and IV received written information about the studies and informed consent forms were signed by the participants in studies II, III and IV. They were all informed about their right to withdraw from the study at any time. In study I the RNs were informed that answering and returning the questionnaire was considered as informed consent to participate in the study.

The participants were not expected to be exposed to any risks by participating in the studies. The questionnaires and interviews (I, II, III) all dealt with RNs’ experiences of competence and activities related to pharmacovigilance, something that was not anticipated to cause any physical or psychological harm. Study IV also included nursing home patients, whose participation meant that the researchers were allowed to look at their medication lists. The fact that the medication reviews were conducted by means of a CDSS did not affect the patients. It was still the RNs and physicians who planned the reviews and the physicians who decided on changes in the treatments. The patients were subjected to various examinations, including a blood test, and a symptom assessment in which they were asked if they experienced any symptoms. However, these procedures are normally a part of the preparation for a medication review, although all patients had not previously been subject to such a structured form of evaluation, following a template. This could, however, be considered beneficial for the patients, as they might receive a more thorough review of their medication and possible DRPs. All actions, including the recruitment, examinations and symptom assessments, were communicated and performed by RNs who knew the patients well, a process which might have limited any possible extra strain for the patients. Doing research on vulnerable groups, such as frail older persons, should always involve careful ethical considerations (Oliver, 2010), these might be especially important in the presence of cognitive impairment. This aspect was considered in study IV, where one inclusion criterion was that the patients were to be able to describe their health condition by adequately answering to questions in a symptom assessment. This criterion could have been assessed in other ways, for instance by performing a Mini Mental State Examination (Folstein, Folstein & McHugh, 1975). However, this was not
chosen due to ethical considerations. Instead the responsibility was given to the RNs, who knew the patients.

Ethical issues should continuously be reflected upon, in all stages of the research process, which in the current studies was done in relation to designing the studies, collecting and analysing data. The role of the researcher is another important matter which was especially reflected upon in the intervention study (IV). The study required collaboration between the researchers and the vendor of the CDSS. Although the collaboration did not imply any financial involvement, the researcher’s role must be clearly defined. According to the Swedish Research Council (2011) the researchers’ approach should always be characterized by openness and they should make clear where they stand. In relation to study IV, involving the introduction and starting-point for using a CDSS in medication reviews, the researcher could easily have been thought to represent the company. Subsequently, it was pointed out that the researcher’s role was to follow the process and study the implications, and thus she was not responsible for implementing it. Since the researcher inevitably became involved in the process, this distinction was considered important to make.
6 Results

6.1 Medication competence in relation to pharmacovigilant activities

The exposure to completed dedicated courses in pharmacovigilance was the strongest factor for RNs’ self-reported medication competence, although it did not increase the number of RNs’ pharmacovigilant activities.

Overall the RNs rated their medication competence as high. The exposed RNs reported a significant ($P \leq 0.001$) higher level of knowledge, assessment and information retrieval compared with the unexposed. They rated themselves higher in knowledge of pharmacokinetics, drug interactions, cause of DRPs and the concept of pharmacovigilance. The exposed RNs also reported higher competence in detecting drug interactions, reporting ADRs to the MPA, and using a drug interaction database. However, there was no significant difference between the two groups in the activities of implementing or using their knowledge and competence, that is, within pharmacovigilant activities. When adjusted for age, workplace, nursing experience, specialist nursing degree and additional courses in medicine/pharmacology, a higher OR was observed among the exposed RNs in all outcomes.

6.2 ‘Vigilant intermediaries’ in medication treatments

The RNs play a central but also complex role as ‘vigilant intermediaries’ in the medication management process. The RNs’ experiences were manifested in three categories, revealing how they ‘act as mediators between health care professionals’, ‘assume extended responsibilities’, and attempt to ‘compensate for organizational deficits’.

To be able to monitor medication treatments and ensure medication safety, RNs experienced that they depend on other health care professionals, mainly...
referring to nursing staff and physicians, while also acting as mediators between them. Vicarious assessments made by the nursing staff working in the wards served as the basis for RNs’ pharmacovigilant activities. In this sense the nursing staff were described as the RNs’ “eyes and tools”. This approach requires the existence of mutual trust, implying that RNs need to trust that the nursing staff will detect and report potential DRPs. The physicians, in their turn, need to be confident that RNs will make sound assessments and get in touch with them if necessary. This chain of assessments and actions require continuous communication, and extensive knowledge and competence within the team.

The division of responsibilities was somewhat unclear between the RNs and the physicians, as the RNs experienced that they were given full authority to monitor the treatments. They felt responsible for the physicians’ actions, with the result that they constantly checked and reminded them of their obligations. RNs occasionally assumed expanded responsibilities in the medication management process, either to prevent patients from suffering or because of uncertainties about their areas of responsibility.

RNs also acted as intermediaries in relation to the organization, and they attempted to compensate for elements that impeded their pharmacovigilant activities. Administrative tasks were one such element, described as depriving them of valuable time that could have been used for bed-side care and monitoring their patients. However, the received information, e.g. from quality registers, was also perceived as a supplement to the “clinical eye”. The accessibility of the nursing staff and physicians was another impeding element. Physicians who were difficult to contact, and problems with staffing, such as lack of continuity, were factors hampering their work.

6.3 RNs’ use of a CDSS for drug monitoring affect clinical practice

RNs’ perceptions of using a CDSS in drug monitoring were constituted of the four referential aspects of ‘time’, giving ‘standardization’, obtained knowledge and ‘evidence’, and division of ‘responsibility’.

Aspects of time in relation to using the CDSS were evident, ranging from being time-consuming to time-saving. The CDSS was time-consuming in the
sense that it was yet another computer system, increasing RNs’ administrative
tasks. They could, however, still see benefits of using the CDSS. The time-
saving aspect was connected to the amount of time required for conducting
medication reviews, which they perceived had been reduced. Thereby the RNs
were able to more quickly take necessary measures regarding the patients’
treatment.

The phenomena was also expressed in terms of giving standardization to the
procedure for medication reviews. This procedure meant that certain data had
to be obtained and entered into the system. The process affected the RNs own
working routines, becoming more uniform and explicit, and also increased the
involvement of other health care professionals. The standardized process ad-
ditionally provided possibilities for control. The RNs perceived they could
obtain an overall picture of the patients’ health condition and medication treat-
ments, and follow it over time. Overall control was also possible through with-
drawal of statistics from the CDSS.

RNs perceived that by using the CDSS they received further pharmacological
knowledge. This knowledge increased their pharmacovigilant awareness,
making them more attentive in general and alerting them to potential risks.
The gained knowledge prepared them for facing the physicians and for dis-
cussing and suggesting specific actions. With the assumption that the quality
reports from the CDSS were based on the latest research and guidelines, the
system could be perceived to promote evidence-based practice and thus pa-
tient safety.

All referential aspects could be viewed in relation to the division of responsi-
bilities between RNs and physicians for using the CDSS, and ultimately the
responsibility for the patients’ medication treatments. Some RNs perceived
that the CDSS was a tool mainly for them, while some requested greater in-
volvevement and interaction with the physicians. Yet others perceived that it
should primarily be the physicians’ responsibility to assess the quality reports.

6.4 Implications of computer-supported medication
reviews - led by RNs

The CDSS detected more possible DRPs than the RNs did when preparing for
the medication reviews. There were significant differences regarding potential
ADRs and drug-drug interactions between the CDSS and the RNs’ reports. The most frequent symptoms which the RNs assessed to be an ADR were dizziness, fatigue, dry mouth and nausea. There were no significant differences in reporting of inappropriate drugs or drug duplications. Besides the above DRP, the RNs reported on other problems outside the scope of the CDSS. Most common were untreated symptoms and conditions, especially pain. This was followed by lack of adherence to prescription, and other suspected DRPs, for instance frequent urination and low blood pressure.

The medication review was followed up after three and six months and quality audited according to number of drugs and the selected quality indicators (NBHW, 2010). There was no significant improvement in either the number of drugs or the quality indicators (inappropriate drugs, drug-drug interactions, drug duplications or three or more concurrent psychotropic drugs).

The RNs did not experience the CDSS to significantly affect their medication management during the study period (mostly md=3 on a 1-5 scale). The assertions receiving the lowest scores concerned discussions with relatives (md=2) and facilitation of accessing and using pharmaceutical information (md=2). The assertions receiving the highest score (md=4) dealt with discussions with the patients about their medication treatments, which they experienced had increased. Most RNs also wanted to continue to use the CDSS (md=4).
7 Discussion

7.1 Main findings
The four studies have addressed different aspects of pharmacovigilance from a nursing perspective. The findings indicate that competence is not enough for generating pharmacovigilant activities among RNs (study I). RNs’ activities were also influenced by other elements. In municipal elderly care, RNs were shown to act as vigilant intermediaries in the patients’ medication treatments. RNs depended on other health care professionals as well as organizational conditions to be able to monitor medication treatments. New strategies were requested to facilitate RNs’ pharmacovigilant activities (study II). A CDSS proved to be one feasible way to do this. RNs who were using a CDSS for drug monitoring, perceived it to support and facilitate their work in several ways (study III). However, there were no clinical effects of RNs’ use of a CDSS. Computer-supported medication reviews, led by RNs, did not generate any significant improvement in the quality of drug use in relation to implementing the CDSS. However, the CDSS detected significantly more DRPs than the RNs did (study IV).

The discussion will be based on the main findings related to the aim of the thesis, which was to explore conditions for pharmacovigilance from a nursing perspective.

7.2 Inter-professional collaboration - the basis for pharmacovigilance
RNs’ pharmacovigilant activities rely on a chain of actions, based on a functioning inter-professional collaboration, which in this thesis mainly refers to collaboration between RNs, nursing staff and physicians. The decisions made by the physicians depend on the work of RNs. The RNs in turn rely on the nursing staff and thus also act as mediators between the nursing staff and
physicians (study II). It has previously been stated that RNs in municipal elderly care have little control over their work situation and need to rely on other professional groups to make assessments based on second-hand information (Furåker & Nilsson, 2013; Juthberg & Sundin, 2010; Nilsson et al, 2009; Norell, Ziegert & Kihlgren, 2013). This appears to apply to their pharmacovigilant activities as well (study II). The idea that drug monitoring requires an inter-professional approach is not new; it has been suggested in previous studies as well (Halvorsen et al., 2010; Steinman, Handler, Gurwitz, Schiff & Covinsky, 2011). However, it seems to be even more important when considering the fact that despite RNs’ indispensable role, they appear to work as vigilant intermediaries, at a distance from nursing staff, physicians and patients (study II). It is generally known that the complexity of health problems is growing, making an inter-professional approach increasingly important (D'Amour et al., 2005). This should also apply to drug monitoring in municipal elderly care, considering the complexity of the given care, involving frail older persons with extensive medication treatments. According to study III, the use of a CDSS has the potential to encourage inter-professional collaboration, a phenomenon previously described by Kawamoto et al. (2005) and Koskela et al. (2016).

7.2.1 The competence of the team

The inter-professional approach was also evident in relation to the competence required in drug monitoring. The findings showed that increased medication competence among RNs alone does not generate more pharmacovigilant activities. Despite the completion of additional courses, stressing the pharmacovigilant perspective, they did not report a higher frequency of activities in clinical practice (study I). The results can be seen in relation to the holistic conception of competence, suggesting that competence involves complex combinations of knowledge, performance, skills, values and attitudes (Cowan et al., 2005). This might be one reason that clinical competence is hard to measure (Watson et al., 2002). Competence is also continuously dynamic and requires adaption to where it is applied (Mendes et al., 2014; Smith, 2012), which points to the complexity of RNs’ competence needs in clinical practice. Because of the complexity of RNs’ pharmacovigilant activities, inter-professional collaboration would be desirable. This was also evident in study II, as the RNs experienced that the entire teams’ competence was a prerequisite for safe drug monitoring. To possess good knowledge and competence in pharmacology and older persons’ illnesses in general, was considered necessary.
since they had to collaborate on the patients’ medication treatments. When the RNs identified lack of competence among nursing staff and physicians, they attempted to compensate for that themselves.

7.2.2 Everyone’s responsibility

Inter-professional collaboration also involves the issue of responsibility within the team. The health care professionals’ interdependence implied that everyone took their own responsibility for monitoring the patients’ medication treatments. Whether the RNs worked with the support of a CDSS or not, the question of responsibility was emphasized in relation to the nursing staff and the physicians (study II, III), both in terms of uncertainty about the division of responsibilities in drug monitoring (study II) and as regards the responsibility to use the CDSS, and subsequently view and act on the generated reports (study III).

Medication management is a task frequently delegated to the nursing staff (Bystedt, Eriksson & Wilde-Larsson, 2011). According to the findings the RNs also depend on the nursing staff to monitor the effects and possible adverse effects of medication (study II). A significant part of RNs’ responsibilities should be to monitor, evaluate and observe signs of DRPs and it has been argued that RNs should be at the forefront of drug monitoring (Gabe et al., 2011; Jordan et al., 2014; Touhy & Jett, 2013). Instead, it appears that they need to rely on others. There was also an uncertainty regarding the division of responsibility in relation to the physicians. The physicians are ultimately accountable for the patients’ medication but still the RNs were given the full authority to monitor treatments, implying that they occasionally exceeded their responsibilities. Similar results were found in relation to using the CDSS in medication reviews, where RNs had different perceptions of who actually was responsible for using the CDSS and viewing the reports (study II, III).

Previous research has revealed that RNs have doubts concerning their responsibility for monitoring effects and adverse effects (Dilles et al., 2011), which is partly consistent with the present findings. Although here there seems to be more uncertainty about who is doing what and who is responsible, an attitude that emphasizes the importance of explicit as well as individual responsibility-taking on all levels.
7.2.3 Determinants for inter-professional collaboration in drug monitoring

Whether the RNs were working with a CDSS or not, the need for inter-professional collaboration in drug monitoring was a recurrent aspect (study II, III, IV). The findings can be seen in relation to the determinants of successful collaboration described by San Martín-Rodríguez and co-workers (2005), as all three determinants - interactional, organizational and systemic - can be recognized in the findings. The interactional determinants were prominent in study II. According to what San Martín-Rodríguez and co-workers (2005) describe, mutual trust and well-functioning communication are two important preconditions required for the collaboration between the health-professionals. Mutual respect and willingness to collaborate, could also be recognized, even if not explicitly described in the results. The organizational determinants were evident in studies II, III, IV. The RNs’ pharmacovigilant activities were dependent on the competence of other health care professionals as well as their accessibility, conditions which ultimately are controlled by the organization. The support and resources given by the organization also had an impact on the use of the CDSS. RNs could perceive time constraints, both in relation to using the CDSS and in the time dedicated by the physicians. According to San Martín-Rodríguez and co-workers (2005) the organization must support and motivate collaborative processes and also see there is available time to collaborate. These requirements would need to be recognized in order to achieve an effective collaboration, generating in an improved quality of medication treatments. Regarding the systemic determinants, a power disparity could be discerned in the relation between RNs and physicians (study II, III, IV). This was manifested in the structure of their collaboration, which to large extent was determined by the individual physicians’ preferences. The procedures for medication reviews were decided by the physicians, and could therefore differ considerably in content and implementation (study II). This also applied to their involvement and engagement in evaluating the CDSS reports (study III, IV). This is probably a matter of individual differences but still, according to San Martín-Rodríguez and co-workers (2005), professional territories can have a significant effect on the collaborative processes. However, these should to some extent be manageable by the organization, by establishing clear guidelines and agreements.
7.3 A CDSS can support RNs in their decision-making

Previous research reports that CDSSs can provide RNs with drug-related information (Doran et al., 2010) and also allow targeted observations which contribute to the detection of ADRs (Dilles et al., 2013). A medical decision support system was found useful for nurses to obtain profiles of the patients’ medication, regarding drug-drug interactions, duplications and unsuitable drugs (Johansson et al., 2010). These studies only partly emanated from municipal elderly care. Nevertheless, similar effects were revealed in the present findings where RNs found the CDSS useful from a time-perspective, for an educational purpose and for detecting DRPs (study III).

One additional finding, not described in previous reports, was the fact that the CDSS affected the RNs’ clinical practice by standardizing the process of performing medication reviews. The standardization implied that all RNs would perform and document the medication reviews in the same way (study III). According to the NBHW all health care providers are required to offer medication reviews to patients aged 75 or older, and who are prescribed at least five drugs or when DRPs may be suspected. Guidelines for the implementation of these have also been given (NBHW, 2013; SOSF 2012:9). Nevertheless it has been found that the implementation of medication reviews differs between and within regions (Cronlund, 2011). Nor do all patients in special housing receive a yearly review of their medication (SALAR & NBHW, 2014; 2015). From this perspective, RNs’ use of a CDSS could be considered beneficial for complying with existing guidelines. It could also be seen as a way to prevent the physicians’ own preferences guiding the process, despite what the guidelines state, as was revealed in study II.

Another outstanding finding was that the CDSS seemed to strengthen the RNs in their decision-making by preparing them to bring up potential DRPs and discuss actions with the physicians (study III). The CDSS was also proved to detect more DRPs than the RNs did when preparing for medication reviews (study IV). Thereby the RNs became alerted to potential risks, which facilitated their pharmacovigilant activities. This should be beneficial considering RNs’ important role in ensuring medication safety (Choo et al., 2010) and in view of their distant position, acting as vigilant intermediaries in the medication treatments (study II).
There are studies pointing to potential risks or negative consequences to implementing CDSSs in clinical practice. The effects on nursing performance and patient outcomes have been questioned, and some systems have even been suggested to cause medication errors (Koppel et al., 2005; Randell et al., 2007). On the other hand, a recent study shows that health information technology has resulted in improved care and interventions for older persons. The study highlights examples of research led by RNs regarding the use of CDSSs, electronic health records and telehealth, with a focus on older persons (Bowles et al., 2015). In the studies of the current thesis the RNs seem to be satisfied overall with the use of a CDSS (study III, IV). The consequences that were somewhat negative were associated with aspects of time and responsibility. Then again, as Bowles and co-workers (2015) point out, it is important to recognize that these systems are “decision-supports” and nothing else. The individual patient’s needs must always be the primary focus. Moreover, when it comes to performing medication reviews, the physicians’ judgements are of course central, since they have the ultimate medical responsibility.

7.3.1 Computer-supported medication review led by RNs

Previous studies on nurse-led medication reviews are limited. Nurse-led medication reviews and monitoring have been explored, with promising results, in older hospitalized patients (Bergqvist et al., 2009), people with dementia in nursing homes (Jordan et al., 2014) and in respiratory outpatient clinics (Gabe et al., 2014). However, these have not been based on RNs’ use of a CDSS. Study III showed that RNs who were using the CDSS in their clinical practice, found it supportive in several ways. However, when evaluating the quality effects in study IV, no improvements were shown regarding the quality of medication treatments, with reference to the quality indicators stated by the NBHW (2010). The CDSS warned about significantly more DRPs than the RNs themselves detected when preparing for the medication reviews, but this was not reflected in the drug prescriptions (study IV). The impact of a CDSS on drug monitoring depends on to what extent the physicians act on the alerts presented (Judge et al., 2006). This could be an aspect to consider in relation to the lack of effects on quality of drug use, since the physicians’ actions in response to the CDSS reports might have differed considerably between the nursing homes. Nor were the individual RNs actions in response to the CDSS reports studied, whether they audited them before
they handed them over to the physicians, or not. The actions of the physicians and RNs may to some extent depend on the issue of responsibility and work routines. Since the CDSS was recently introduced, the health care professionals, including RNs, had not established clear procedures for how to collaborate around the medication reviews (study IV).

The RN-led medication reviews implied that the RNs conducted the symptom assessments together with the patients, and subsequently entered all information into the CDSS (study IV). This routine could explain their experience of having more discussion with the patients about their treatments after starting to use the CDSS. RNs’ increased involvement could enhance their possibilities to detect and assess possible DRPs. This process should be advantageous, both considering issues of the nursing staffs’ competence and the RNs’ mediating role (study II).

7.3.2 Lessons learned from implementation of a CDSS in medication reviews

Due to the fact that study IV was performed in relation to an implementation, many lessons have been learned regarding the implementation process. To what extent the implementation process was successful or not, differed between the nursing homes. Thus, my reflection on experienced hindering and facilitating factors could perhaps contribute to future studies in this context. Rogers’ Theory of Diffusion and the CFIR was helpful in attempting to evaluate the process (Damschroder et al., 2009; Rogers, 2003).

*Intervention characteristics.* The nursing homes could initially try the CDSS on a small scale, allowing them to build experience and time to reflect upon the change, something described as a key feature in promoting successful adaption (Damschroder et al., 2009; Rogers, 2003). Despite this, the outcomes were different. One reason could be the complexity of the implementation, that is, whether it is perceived as difficult to use or departs greatly from existing practice (Damschroder et al., 2009; Rogers, 2003). Some nursing homes already worked systematically with planned medication reviews according to existing guidelines, a process which was not as developed in others. Additionally, their documentation was to a greater extent computer based, already from the start. The changes were thus smaller for those RNs, which probably made the implementation of the CDSS easier.
Outer and inner setting. Organizational factors, e.g. the culture and the implementation climate, are critical barriers when it comes to achieving change (Damschroder et al, 2009). The process seemed to be easier where the climate was perceived as more permissive and the RNs as well as their immediate manager seemed to share the perception of the importance of the intervention. In other settings, the RNs were more divided in their beliefs. Nor did they seem to have the same assistance or requirements from their managers. One essential difference was related to the stability of the team. According to Damschroder and co-workers (2009), an implementation is more likely to succeed when members remain within the team for an adequate period of time, i.e. in work places with a low staff turnover. The process ran more smoothly in nursing homes with a stable team of RNs and a permanent physician, compared to when there was a change of RNs and they also had different physicians on the rounds. According to Rogers (2003), adoption of an innovation is more likely to succeed when the results are visible to the individuals. This differed between the nursing homes in terms of how the RNs’ preparatory work, including the CDSS reports, was received by the physicians and whether or not it generated any actions on their part. This influenced whether the implementation was successful or not.

Characteristics of individuals. Individuals’ attitudes and skills in using the intervention are important for adopting it (Damschroder et al., 2009; Rogers, 2003). Some RNs appeared to be more confident about their ability to use the CDSS, which can be interpreted to show they had a higher degree of self-efficacy, which also seemed to facilitate the process. According to Damschroder and co-workers (2009), individuals with high self-efficacy are more likely to embrace the intervention, even if there are obstacles along the way. In contrast to this, other RNs seemed to have low beliefs in their own capabilities to learn about the functions of a new computer system.

Process. To attract and involve appropriate people in the implementation and use of the intervention are described as factors for success (Damschroder et al., 2009). This was not planned for in the present study but in reality some RNs took on more responsibility and tried to support the others. They were in that sense ‘opinion leaders’, although not formally appointed (Damschroder et al., 2009). When such an RN for some reason ceased to be an ‘opinion leader’, this affected the implementation process negatively. Another difference concerns the feedback about the progress and quality of the implementation, something that can affect the process (Damschroder et al.,
2009). The process seemed to proceed more smoothly in those nursing homes where it was possible to gather all RNs during the visits and have a common discussion. This was in contrast to where it was difficult to get the group together, despite regular visits, e-mails and phone calls.

In summary, conditions suggested to facilitate the implementation of a CDSS in medication reviews would be:

- The health care professionals are accustomed to work systematically with planned medication reviews, even without a CDSS
- The RNs have previous experience of using informatics in their daily work, otherwise, they should be offered individualized training on the basis of their previous experiences. This also implies testing the CDSS on a small scale
- Physicians’ involvement in education about the CDSS and in the establishment of routines
- A relatively stable team of RNs and physicians
- Appointment of ‘opinion leaders’ during the process
- Commitment from the managers
- Opportunities for continuous feedback and reflections on the progress and of results.

Apart from these suggested facilitators, the applicability of the technology itself is of course essential.

7.4 Methodological considerations

The use of both qualitative and quantitative methods was required to capture the overall and specific aims of this thesis. This approach was also considered to add another dimension to the results, which a quantitative or qualitative design alone would not sufficiently provide. The strengths and limitations will be further discussed for each of the studies.

7.4.1 Study I

The participants were purposely recruited on the basis of having applied to additional courses stressing the pharmacovigilance perspective. Hence, the RNs probably had a special interest in the area, which might limit the generalizability of the findings. However, a strength was that these courses were
planned and carried out in consultation with the MPA. Thus their content, being both theoretically and clinically oriented, was deemed to be consistent with the pharmacovigilance perspective.

A questionnaire was developed by the authors as no one previously was considered suitable, possibly because pharmacovigilance from a nursing perspective is still quite an unexplored field. According to Streiner and Norman (2008) the motivation for developing a new tool is the belief that previous scales do not completely cover the domain of the study, which was considered to apply here. The process of developing the questionnaire was guided by Charlton (2000), including a test for validity in a pre-test, followed by a face validation and a pilot study. Additional tests for reliability and validity could preferably have been performed when constructing the questionnaire, such as establishing a test-retest reliability and a factor analysis. However, the main focus of this thesis was not to develop and validate a questionnaire. It was a novel approach to initiate the exploration of the relatively unknown area of pharmacovigilance, in relation to nursing. To take inspiration from specific courses in the area was considered to be a feasible way to accomplish this. There was a good internal consistency within the areas in the developed questionnaire (Cronbach’s α 0.73-0.83), nevertheless, it would have been desirable to use a previously tested and validated questionnaire. The questionnaire consisted of self-rating questions, with inherent concern regarding validity and accuracy, including the risk of measurement reactivity (French & Sutton, 2010) and reporting bias (Fadnes, Taube & Tylleskär, 2009), where RNs may over-report in relation to their competence. Nevertheless, the use of a questionnaire was necessary in order to reach RNs who worked in different settings and workplaces all over Sweden. The response rate was acceptable and there was no difference between the groups in the reasons given for non-participation. The P-value was initially set to <0.05. To avoid false significant results due to multiple comparisons, the P-value was adjusted to 0.001 according to the Bonferroni method (Bland & Altman, 1995). Without this adjustment there would have been significantly more differences between the two groups regarding the medication competence, but not so many in pharmacovigilant activities.

7.4.2 Study II
Trustworthiness was assured through different actions. The credibility of the study was assured through consideration of selections of participants and the
approach to gathering data (Graneheim & Lundman, 2004). Regarding the recruitment procedure, the settings were randomly picked by the community head nurse. The selection was somewhat restricted since they had to have a minimum of four RNs employed, to enable focus group discussions. Focus group discussions were considered suitable because RNs’ pharmacovigilant activities represent a relatively unexplored field, and according to Wong (2008), focus groups may aid in conceptualization and the generation of hypotheses. Group processes can help people to explore and clarify their views. In pre-existing groups, as in this study, colleagues can relate and challenge each other in the discussions (Kitzinger, 1995). However, focus groups also have limitations. One limitation concerns their susceptibility to bias, because dominant participants may have a great impact on the group (Kitzinger, 1995; Wong, 2008). The moderator was aware of this and could thereby counter this risk during the discussions. Another well-known limitation is the difficulty of assembling the groups (Morgan, 1998), which also was the case here. Consequently, two groups ended up with three participants. However, small groups are suitable if the purpose is to gain more in-depth insight (Krueger & Casey, 2000) or when the topic is complex and the participants have a high level of involvement in the topic (Morgan, 1998). The credibility of the results was also assured through a continuous dialogue to seek agreement on categories and themes. In addition, representative quotations from the transcribed text were shown (Graneheim & Lundman, 2004).

Dependability was addressed regarding the risk of inconsistency during data collection (Graneheim & Lundman, 2004). Inevitably, new insights are gained during the process of interviewing, which may influence the focus and follow-up questions in subsequent interviews. To avoid too much alteration of the questions asked in the different groups, an interview guide was developed according to Krueger and Casey (2000). This interview guide was constructed in collaboration with the other authors. Furthermore, all interviews were performed by one author, a process which would increase trustworthiness.

In order to facilitate transferability, details were given regarding RNs’ role in municipal elderly care. The participants were working in different settings and thus had a variety of experiences to share and discuss with each other. These variations could be regarded as increasing transferability of the findings. Furthermore, the selection of participants, and the process of data collection and analysis were thoroughly described. Hence, it is for the readers to
judge whether the findings are transferable or not (Graneheim & Lundman, 
2004).

7.4.3 Study III
The strength of a phenomenographic approach is that it provides knowledge
about variations in ways people experience a phenomena (Marton & Booth,
1997). Thus, the basic assumption rests on differences rather than finding the
singular essence of a phenomena (Dahlgren & Fallsberg, 1991; Sjöström & Dahlgren, 
2002). This, in combination with the fact that phenomenography is
suitable for exploring the use of information technology (Stenfors-Hayes et
al., 2013), was the motivation for choosing this approach.

The credibility, involving the relationship between the empirical data and the
derived aspects (Sjöström & Dahlgren, 2002), was assured by a precise de-
scription of the research process. Excerpts from the interviews were provided,
so the readers would be able to consider the relevance of the findings. Credi-
bility also involves the researchers’ role (Sin, 2010; Stenfors-Hayes et al.,
2013). This was a relevant issue in the interview situations. Then there is an
obvious risk that participants may try to adjust their answers to what they be-
lieve the researcher wants to hear. This was countered by encouraging the par-
ticipants to speak freely and express their true opinions about using the CDSS.
The researcher’s role was also considered in relation to avoiding asking lead-
ing questions, and in the process of analysis. Continuous discussions were
carried out during the analysis, when defining the structural and referential
aspect. This was important due to the first author’s pre-understanding of the
context and the CDSS. The transferability of the results could be influenced
by the recruitment to the study. The recruitment was limited to the settings
that presently were using the CDSS in their clinical practice. They previously
had established routines of performing yearly medication reviews, which does
not apply to all nursing homes. Thus, the transferability of the results to other
settings would require taking the actual context into account.

7.4.4 Study IV
A strength of this study is that it was performed in clinical practice. Interven-
tion research has been requested regarding nurse-led drug monitoring (Gabe
et al., 2011). The recruited nursing homes were situated in two different re-
gions, rural and urban, which could be considered to strengthen the validity of
the study. The study depended on cooperation with a vendor managing the CDSS. Thus the recruitment of nursing homes was restricted to the regions the CDSS was established in. A criterion which further limited the number of available nursing homes was that they had to be about to or having the intention to implement the CDSS in their daily practice. This was necessary, given the purpose of the study.

The number of participating nursing home residents was lower than anticipated. More than expected could not participate due to physical or cognitive impairment, making them unable to collaborate in the symptom assessment. Because those residents could be expected to have extensive medication treatments, this might have affected the results. Furthermore, as they normally have more trouble expressing their experienced problems and needs, they might also be the ones benefiting the most from having their medication reviewed. It is a challenge to conduct research on vulnerable populations, considering the informed consent process. According to Barron, Duffey, Byrd, Campbell and Ferrucci (2004) frail older persons must naturally be protected, although protection should not prevent research on this important population. For future similar studies it might be possible to use symptom assessment forms intended for persons with cognitive impairment, but the problem with informed consent still remains.

The study had a quasi-experimental one-group pre-test/post-test design. Quasi-experiments are studies that aim to evaluate interventions, but without using randomization. The randomized controlled trial is generally considered to have the highest level of credibility, but many researchers choose not to randomize the interventions for different reasons. In this study, randomization was not done because of difficulties in randomizing both by location and participant, and also due to the small available sample size (Harris et al., 2006). Neither was there a control group, which can be regarded as a limitation; however, ours was a commonly used design in the medical informatics literature (Harris et al., 2006).

The outcome variables were chosen based on existing indicators, which also have been used in previous studies (Olsson et al., 2010) and this fact could be seen to strengthen the validity. The quality reports generated from the CDSS obviously depend on what information is entered into it. Consequently, if some information is lacking, then the reports may not be complete. However, to reduce this risk the RNs were thoroughly informed of
what information to enter and also received continuous support throughout the study. The preconditions for implementing RN-led medication reviews were somewhat different between the nursing homes. There were variations in existing routines and guidelines regarding the performance of medication reviews and also in computer skills and physicians’ engagement. The RNs’ different prerequisites for adapting the new work method, including the use of a CDSS, could have affected the results. On the other hand this factor could also increase the generalizability of the study.
8 Conclusions and implications

This thesis can contribute to recognition of the area of pharmacovigilance from a nursing perspective, and on the basis of its entire meaning to detect, assess, understand and prevent ADRs or any other DRP (WHO, 2004). The main conclusions of the thesis are as follows:

- Increased medication competence of RNs does not seem to be enough to increase their pharmacovigilant activities in clinical practice. RNs appear to act as vigilant intermediaries in the patients’ medication treatments, implying that they depend on other health care professionals and organizational conditions to be able to perform their work.

- RNs can be supported by a CDSS in their pharmacovigilant activities. Assisted by a CDSS, the RNs can be at the forefront of structured medication reviews. The CDSS also have the potential to support them in their daily clinical practice. However, to improve the quality of medication treatment, an inter-professional approach is needed.

RNs’ key role in medication management in municipal elderly care needs to be recognized and facilitated. This could be done by increasing RNs’ opportunities to participate in bed-side care and thereby monitor the patients themselves or, according to the present organization of Swedish municipal elderly care, by supporting them in their current role. A central condition for RNs’ work is the existence of an inter-professional approach where each individual recognizes their responsibility in relation to drug monitoring. This means wearing their “vigilant glasses” whenever they suspect problems or detect changes in health conditions among the residents. Another important condition is the existence of well-functioning communication channels, for safe transmission of information. Possession of competence, not only among the RNs but the entire team, and established routines, based on current guidelines are other central conditions. Although the results of this thesis mainly refer to the inter-professional collaboration between RNs, nursing staff and physicians, it is important to also recognize other health care professionals
and of course the patients themselves. Physiotherapists, occupational therapist, psychologists and other professionals who are involved in the care of the patients may all provide essential information which may be related to the medication treatment.

The findings show that the use of a CDSS can help RNs to work more autonomously and can enhance patient safety in relation to drug utilization, but at the same time it depends on an inter-professional collaboration. Thus, the findings could be applied to both RNs’ own use of the CDSS, as well as to the use in structured medication reviews, led by RNs. RNs’ own use refers to how a CDSS has the potential to be a support in their daily practice whenever the RNs suspect a DRP, either based on their own or other health care professionals’ or the patients’ experiences. In the yearly structured medication reviews, the CDSS could provide a structure for the implementation, implying that all patients receive equal medication reviews. This can also increase the RNs’ interaction with the patients, on the basis that they perform the symptom assessment themselves. The medication reviews could then be prepared accordingly, and the CDSS reports subsequently audited and discussed in the team, including health care professionals and patients.

Even though these implications refer to municipal elderly care where RNs have a relatively autonomous role, they could be applied in other contexts. RNs could be supported by CDSSs in drug monitoring in most health care settings where they manage medication.

8.1 The thesis in relation to the core competencies

This thesis on care sciences has explored the area of pharmacovigilance from a nursing perspective, including the use of a CDSS. This is a considerably unexplored area, but is still relevant for RNs’ professional role and in relation to the six core competencies in nursing. Informatics is an important competence in order to work in the present and future health care. The large amount of information, (e.g. drug-related) must be systematically organized in a way that is easy to access, and the RNs can thereby be provided with evidence on which they can base their care (study III, IV). Evidence-based care is defined as an important area for improvement since it is well-known that RNs do not practice evidence-based care on a regular basis (Forsberg, 2016). The use of informatics has the potential to support evidence-based care (study III), by providing information based on recent research and integrating the patients’
unique preconditions. Concerning drug-related information, it can be considered as mostly medically-oriented. Nevertheless, medication management is one of RNs’ most common tasks in municipal elderly care. It is however essential to further include the evidence-based nursing perspective in the CDSSs (study IV). Current evidence-based guidelines and standardized procedures, including documentation, could give prerequisites for control and subsequently quality improvements (study III, IV). Overall, teamwork proved to form the basis for safe medication management (studies I, II, III, IV). The whole team’s diverse competencies are needed and collaboration is a key factor for patient-centered and safe care. The main objective of this thesis, even if not evident in the separate studies, is the older person, whose health situation is complicated by illness and extensive medical treatments. Safety in relation to medication management is essential for an individual’s health and well-being and, according to Lindh and Sahlqvist (2016), great emphasis should be put on individualizing the treatments, and thereby making them as safe as possible.

8.2 Future research

One important perspective is missing in this thesis, namely that of the patients. Obviously the patient is the most important person in the team, but their participation has not been explored here. Subsequently their voices also need to be heard. Further research should focus on the medication management process, including the consequences of the use of a CDSS, from the patient’s point of view. Such studies are currently planned. Based on the results of this thesis, further studies could explore how RNs’ pharmacovigilant activities can be further facilitated in special housing, and also in home care. This may involve a further development and validation of the questionnaire in study I. One important premise for facilitating RNs’ pharmacovigilant activities would be to more clearly identify and measure the phenomena.

Future studies may also involve additional possibilities for RNs to be supported by informatics in their drug monitoring, in order to increase patient safety. This would also involve further studies of the implementation process of informatics, in order for it to be successfully carried out. Other professionals’ involvement also need to be further studied, on the basis of the importance of an inter-professional approach in drug monitoring and medication reviews.
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53


59


