# **Accepted Manuscript**

Strategies for improving medication safety in hospitals: Evolution of clinical pharmacy services

Schepel Lotta, Aronpuro Kirsi, Kvarnström Kirsi, Holmström Anna-Riia, Lehtonen Lasse, Lapatto-Reiniluoto Outi, Laaksonen Raisa, Carlsson Kerstin, Airaksinen Marja

RESEARCH IN SOCIAL & ADMINISTRATIVE PHARMACY

RSAP

PII: S1551-7411(18)30674-0

DOI: https://doi.org/10.1016/j.sapharm.2019.02.004

Reference: RSAP 1215

To appear in: Research in Social & Administrative Pharmacy

Received Date: 3 August 2018
Revised Date: 5 February 2019
Accepted Date: 11 February 2019

Please cite this article as: Lotta S, Kirsi A, Kirsi Kvarnströ., Anna-Riia Holmströ., Lasse L, Outi LR, Raisa L, Kerstin C, Marja A, Strategies for improving medication safety in hospitals: Evolution of clinical pharmacy services, *Research in Social & Administrative Pharmacy* (2019), doi: https://doi.org/10.1016/j.sapharm.2019.02.004.

This is a PDF file of an unedited manuscript that has been accepted for publication. As a service to our customers we are providing this early version of the manuscript. The manuscript will undergo copyediting, typesetting, and review of the resulting proof before it is published in its final form. Please note that during the production process errors may be discovered which could affect the content, and all legal disclaimers that apply to the journal pertain.

1	Title: Strategies for improving medication safety in hospitals: evolution of clinical pharmacy services
2	
3	Authors:
4	Schepel Lotta, Medication Safety Officer (MSc Pharm; PhD) <sup>1,2</sup>
5	Aronpuro Kirsi, Pharmacist (MSc Pharm) <sup>3</sup>
6	Kvarnström Kirsi, Senior Pharmacist-in-Charge (MSc Pharm; PhD student) <sup>1,2</sup>
7	Holmström Anna-Riia, Clinical Instructor (MSc Pharm; PhD) <sup>1,2,3</sup>
8	Lehtonen Lasse, Professor, Chief Administrative Physician (MD; PhD) <sup>4</sup>
9	Lapatto-Reiniluoto Outi, Specialist in Internal Medicine and Clinical Pharmacology (MD; PhD) <sup>4</sup>
10	Laaksonen Raisa, Senior Lecturer (MSc Pharm; PhD, Docent) <sup>2,3</sup>
11	Carlsson Kerstin, Chief Pharmacist (MSc Pharm; MBA) <sup>1</sup>
12	Airaksinen Marja, Professor (MSc Pharm; PhD) <sup>2,3</sup>
13	
14	1. HUS Pharmacy, Hospital Pharmacy of Helsinki University Hospital (HUS), Finland
15 16	2. Specialization Program of Hospital and Health Centre Pharmacy, Clinical Pharmacy Group, Faculty of Pharmacy, University of Helsinki, Finland
17	3. Clinical Pharmacy Group, Faculty of Pharmacy, University of Helsinki, Finland
18	4. Helsinki University Hospital and University of Helsinki, Finland
19	
20	Corresponding author:
21 22 23 24 25 26 27	Lotta Linnea Schepel Mailing address: Stenbäckinkatu 9, FI-00029 HUS, Helsinki Finland e-mail: lotta.schepel@hus.fi tel. + 358 (0) 50 438 6748 (office)  Word count: 4921
28 29	<b>Key words:</b> health systems, medication safety, systems approach, clinical pharmacy, hospital pharmacy, medicines policy
30 31 32	<b>Declarations of interest:</b> Raisa Laaksonen took part in EAHP Pharmine working group, which grounded the EAHP statement work and is a member of EAHP Scientific Committee. Other authors: none.
33 34	<b>Ethical approval:</b> According to the scientific ethical guidelines in Finland, an ethics committee approval was not required for a survey without patient data.
35	Funding: Lasse Lehtonen and Lotta Schepel have received the Finnish Governmental Study Grant for

Helsinki University Hospital (TYH2014224).

36

37 38	ABSTRACT
39	Background: Medication safety risks are the most important preventable factors jeopardizing patient
40	safety. To manage these risks, extending pharmacists' involvement in patient care and patient safety work
41	has been systematically addressed in patient safety initiatives since the early 2000s.
42	
43	Objective: To explore the extent and range of clinical pharmacy services in Finnish hospitals to promote
44	medication safety: 1) in 2011, when the first National Patient Safety Strategy, the new Health Care Act and
45	the Medicines Policy 2020 had been recently enacted; and 2) five years later in 2016.
46	
47	Methods: The study was conducted in 2011 and 2016 as a national online survey targeted to hospital
48	pharmacies (n=24) and medical dispensaries (n=131 in 2011; n=28 in 2016). The questions were analyzed
49	using descriptive statistics and qualitative content analysis.
50	
51	Results: Overall response rate was 60% in 2011 and 52% in 2016. Clinical pharmacy services were provided
52	by 51% of the responding units in 2011, whereas by 85% in 2016. The reported number of clinical
53	pharmacists had increased during the five years. The most notable increase in reported tasks occurred in
54	conducting medication reconciliations (+63% increase in the number of providing units). By 2016
55	pharmacists had extended their tasks particularly towards system-based medication safety work: e.g.
56	developing instructions for medication-use (91% of the responding units), creating and updating
57	medication safety plans (87%) and using medication error reports in developing the process of medication
58	use safer (78%). Pharmacists' participation in long-term continuing education became more common in
59	2016, which was perceived as helpful in extending their responsibilities to improve medication safety.
60	
61	Conclusion: Pharmacists' involvement in patient care and system-based medication safety work was
62	reported to become more common in Finnish hospitals during 2011-2016. This development is in line with
63	patient safety policy initiatives and its impact on patient care outcomes should be followed up.
64	
0-1	
65	
66	
c <b>-</b>	
67	
68	

## 1. INTRODUCTION

Pharmacotherapy is one of the most common interventions in healthcare. Even effective, pharmacotherapies used in hospitals are often challenging to manage: approximately 6% of hospitalized patients experience an adverse drug event during their hospital stay. In many cases, medications used in hospitals are parenterally administered, which increases a risk for medication errors (MEs). Furthermore, hospitalized patients are often unstable and need intensive and continuous monitoring, as well as fast clinical decision-making. System-based patient safety work has shown that medication errors are one of the most important preventable factors jeopardizing patient safety in healthcare. To be safe, pharmacotherapies used in hospitals require well-designed care processes both for individual patients and at the organizational level. Therefore, international patient safety initiatives prioritize strategies and policies to improve safe medication practices. These strategies have emphasized the creation of a safety culture, learning from medication errors through reporting systems and development of preventive actions for prospective risk management.

The Council of Europe was among the first ministry level institutions in Europe to establish recommendations to improve medication safety as part of patient safety in 2006.<sup>5-6</sup> These medication safety recommendations focused on safety culture and considered e.g. early detection of adverse drug events, the setup of medication error reporting systems, strengthening awareness and learning of professionals, introducing electronic prescribing, improving naming, labelling and packaging, and improving medicines information practices. Council of Europe has continued its long-term commitment to medication safety work under the European Directorate of Quality of Medicines (EDQM) with a program to create pharmaceutical care indicators.<sup>8-9</sup> Also, European Union (EU) and its stakeholder organizations have coordinated efforts to encourage the member countries to take actions to improve patient and medication safety.<sup>10-11</sup> Most lately EU integrated medication safety with drug safety, i.e. pharmacovigilance initiatives through a Directive enacted in 2012.<sup>12</sup>

All the patient and medication safety initiatives, recommendations and policies over the years have been based on interprofessional team work principles. <sup>4-7</sup> As pharmacists as healthcare professionals are specialized in pharmacotherapies, they have been encouraged to take more responsibility of managing safe medication practices in different settings. E.g. EDQM invited European governments and policy-makers to implement the principles and working methods of clinical pharmacy and pharmaceutical care in their national healthcare systems. <sup>8-9</sup> Clinical pharmacy is an area of pharmacy concerned with the science and practice of rational and appropriate medication use. <sup>13-14</sup> According to the principles of pharmaceutical care, pharmacists are expected to ensure the quality and safety of medication therapies in patient care, with

emphasis on collaborative care and patient interaction.<sup>14-17</sup> Even though pharmaceutical care and patient-centered clinical pharmacy services have been shown to improve quality, safety and efficiency of care and reduce its costs, <sup>18-21</sup> their diffusion to many healthcare systems, e.g. in Europe, <sup>22</sup> has been slow. Growing evidence of patient safety risks cumulating from medications, also in Finnish healthcare, have created a need to develop new strategies and policies to manage these risks. <sup>23-26</sup> The aim of this study was to explore the extent and range of clinical pharmacy services in Finnish hospitals to promote medication safety: 1) in 2011, when the first National Patient Safety Strategy<sup>27</sup>, the new Health Care Act<sup>28</sup> and the Medicines Policy 2020<sup>24</sup> had been recently enacted; and 2) five years later in 2016.

# 2. MATERIALS AND METHODS

# 2.1. Context of the study

In Finland municipalities are responsible for organizing primary healthcare services, which are mainly provided by municipal health centers. The secondary special healthcare is organized by central hospitals, each of them located in their own hospital districts (n=21) covered by federations of municipalities (including Åland). For special tertiary healthcare, Finland is divided into five responsibility areas, each with a university hospital. Private healthcare services complete the public health services. Hospital pharmacies (n=24) are located in university hospitals, central hospitals and in some larger health centers with inpatient wards. Medicine dispensaries supply medicines in smaller inpatient healthcare units in the public and private sectors. Some of them operate independently as part of the healthcare organization and others in the public sector operate under hospital pharmacies. The number of medicine dispensaries had remarkably decreased from 94 to 55 between 2011 and 2016 (Finnish Medicines agency, unpublished statistics 2012), while the number of hospital pharmacies (n=24) remained the same. The number of independent medicine dispensaries decreased because of a strategic trend to merge small medicine dispensaries into larger hospital pharmacies in the region. The goal of the merges was to release resources from administrative and logistic work to be reallocated to more patient care oriented clinical pharmacy services.

Clinical pharmacy as a concept was defined in Finland in 2010 for initiating a national specialization program for hospital and health center pharmacists with special reference to systems approach to patient and medication safety.<sup>31</sup> The following definition was constructed based on an inventory of definitions by key international clinical pharmacy organizations: *Clinical pharmacy is a health science focusing on pharmacists' contributions to medicines optimization and health promotion. Clinical pharmacy emphasizes rational medicine use and promoting it, development and evaluation of pharmaceutical services, medicines management, and medication safety. Prerequisites for clinical pharmacy are interprofessional collaboration* 

and collaboration with patients. Clinical pharmacy covers all social and healthcare settings in inpatient and outpatient care where pharmacotherapy is part of the care of the patients. The concept "ward pharmacy" has a longer history in Finland and it has been defined as "a medication management at hospital wards conducted by pharmaceutical staff". The ward pharmacy as a concept reflects the long-time core mission of Finnish hospital pharmacists in the management of medicines supply and logistics. The first clinical pharmacy posts in Finnish hospitals were established in the end of the 1980s, but the development of clinical pharmacy services has been slow. Where the involved in patient care and to provide clinical pharmacy services as a part of the healthcare team. The first steps towards more systematic training in pharmacists' clinical skills were taken through national accreditation training for comprehensive medication reviews which started in 2005. It has had spillover effects on undergraduate training, specialization training of community and hospital pharmacists, and practice development.

In Finland, increasing pharmacists' involvement in patient care and assuring safe medication practices in hospitals was recommended for the first time in 2006 when Ministry of Social Affairs and Health guided each healthcare unit to set up a medication safety plan, i.e., an organization-based medication risk management plan.<sup>23</sup> The plan should have a description of the system, processes, resources and persons in charge for safe pharmacotherapies. The plan became obligatory as part of the patient safety risk management plan in 2011 when the new Health Care Act was enacted.<sup>28</sup> Implementation of these patient and medication safety initiatives were supported by the National Patient Safety Program in 2011-2014.<sup>27</sup> The Medicines Policy 2020, established in 2011, also supported the same strategic objectives with special emphasis on the pharmaceutical sector's contributions to safe and rational pharmacotherapy.<sup>24</sup> The recommended actions have been conveyed through international recommendations, particularly by The Council of Europe,<sup>5-6</sup> The European Union,<sup>10-11</sup> WHO,<sup>38</sup> research data derived from reporting systems for patient safety incidents,<sup>25,39</sup> and benchmarking best practices.

# 2.2. Study design and method

This study was conducted as a national online survey targeted at all hospital pharmacies and medicine dispensaries serving inpatient healthcare units. The survey was first conducted in 2011 and repeated in 2016 for a follow-up of developments.

# 2.3. Development of the survey instrument

Six semi-structured theme interviews were conducted to develop the survey instrument in 2011. The interviewees were selected by purposive sampling to present the widest range of clinical pharmacy services in Finnish hospitals at that time. Recruitment was facilitated by the Finnish Pharmacists' Association and

the Faculty of Pharmacy, University of Helsinki, Finland. Interviewees were working on the wards or as leaders of clinical pharmacy teams in different hospitals and health centers with inpatient wards. In addition to the interviews, information gathered from practice development projects in Finland and international scientific literature was used for developing the survey instrument. Definitions for clinical pharmacy, 13-14 pharmaceutical care, 15-17 and patient and medication safety from systems approach 5-6 were used to outline the range of services included in the structured list of the survey instrument. Medication safety and prospective risk management aspects were emphasized in the selection of the tasks and services.<sup>5-6,40-41</sup> In order to get a better understanding of the evolution of pharmacists' contributions to patient care and medication safety a detailed list of tasks (n=29) was developed. The more detailed list was expected to increase sensitivity of the measures compared to using general statements of services, such as counseling patients on their medications, or checking and reviewing medications. As Finnish hospital pharmacists do not have a long history in providing other than logistic services, we intentionally included also clinical tasks that are not so "advanced" but reflect merely early phase of clinical pharmacy service implementation in the 1960s, e.g., provision of drug information to ward personnel. These services are still an important part of the infrastructure needed for medication safety and risk management. 41 They also can perform as indicators for transition from early phase clinical pharmacy services towards more advanced and sophisticated ones. The list of tasks and services included in the survey is presented in Figure 3.

The final survey instrument was divided into three parts: 1) questions gathering background information on the respondent's healthcare organization; 2) questions for hospital pharmacies/medicine dispensaries providing clinical pharmacy services to inpatient care; and 3) questions for non-providers of clinical pharmacy services (Figure 1). The questions employed a five-point Likert scale, multiple choice questions and open fields for responses. Structured questions were used to gather the background information of the responding units, the current range of clinical pharmacy services provided, how they are planned and managed, and the evaluated benefits and outcomes (if studied in the responding unit) of these services. The survey instrument was piloted for content and face-validity with three clinical pharmacists from separate organizations. Time required for responding to the survey varied between 10-40 minutes depending on the range of the services provided by the respondent's organization.

The same online survey instrument was utilized in the follow-up survey in 2016 (Figure 1). Most of the questions remained the same, but some of the open-ended questions were changed to structured questions in 2016. The structured list of clinical pharmacy services was updated (Figure 3) for the survey in 2016 by adding 12 services implemented after the first survey in 2011. Furthermore, the updated list also contained such clinical pharmacy services that were set as a goal by the European Association of Hospital Pharmacists (EAHP) for delivering hospital pharmacy services in every European health system.<sup>42</sup> In 2011,

the respondents were asked to submit any available reports on the studies they had conducted to show the outcomes of the services they provided. Reports received in 2011 (n=9) were used to develop a structured list of benefits and outcomes to the 2016 survey (see Figure 6).

# 2.4. Conducting the survey in 2011 and 2016

The online survey was conducted in 2011 and in 2016. The survey was e-mailed to all chief hospital pharmacists (n=24 in 2011 and 2016) and all managers of the medicine dispensaries (n= 94 in 2011 and n=55 in 2016). The e-mail addresses of the chief hospital pharmacists were received from the Faculty of Pharmacy, University of Helsinki. The managers of the medicine dispensaries were contacted using the membership register of The Finnish Pharmacists' Association provided by the officer of the Association. While there were 55 managers of medicine dispensaries in 2016, only the managers of the independent ones, not managed by hospital pharmacies, were invited to participate in the survey (n=28 out of 55 managers). This is because information on clinical pharmacy services provided by the non-independent medicine dispensaries were covered by the responses from the hospital pharmacies under which they opera ted. The chiefs and managers were asked to forward the survey to the pharmacists in their organization who provided or managed clinical pharmacy services so that that there would be one coordinated response per organization. The survey was planned to be open for two weeks and two reminders were sent during that period. After the period, a third e-mail reminder was sent, and the survey was extended to be open for one more week for responses.

## 2.5. Data analysis

The structured questions were analyzed with descriptive statistics using Microsoft Excel.<sup>43</sup> The responses from hospital pharmacies and medicine dispensaries were analyzed separately to identify differences in the operations of these units. Likewise, in some questions the responses from hospital pharmacies were divided into university hospitals, central hospitals and community hospitals to identify differences between these hospital pharmacies. The open-ended questions were analyzed by applying a conventional content analysis.<sup>44</sup> Systems approach to human errors and risk management as illustrated in the Reason's Human Error Theory was applied to illustrate reported tasks where clinical pharmacists contributed to medication safety at all stages of the medication-use process.<sup>45</sup>

## 2.6. Study ethics

According to the scientific ethical guidelines in Finland, an ethics committee approval was not required for a survey without patient data.<sup>46</sup> The survey participants were informed that the participation was voluntary and responding to the survey implied an informed consent. The invitation to participate in the survey was sent by e-mail, including a cover letter with a description of the study and a link to an online questionnaire.

Detailed information of the responding organizations was not asked for, only whether the unit was a hospital pharmacy or a medication dispensary and the county in which the unit was located. All responses were confidential.

## 3. RESULTS

# 3.1. Survey participants and coverage

In 2011, the responses were received from 20/24 of the hospital pharmacies (83%) and 51/94 medicine dispensaries (54%), yielding an overall response rate of 60% (n=71/118). In 2011, the hospital pharmacies were not asked if they were university, central or community hospital pharmacies, but the total coverage was 83%. In 2016, 18/24 of hospital pharmacies (75%) and 9/28 of the independent medicine dispensaries (32%) responded to the follow-up survey resulting in an overall response rate of 52% (n=27/52, Figure 2). Among the respondents in 2016 were all five university hospital pharmacies (100%), 13 central hospital pharmacies and one community hospital pharmacy (Figure 2) covering 74% (n=14/19) of the central and community hospital pharmacies, which provide clinical pharmacy services to the largest inpatient healthcare units.

## 3.2. Reported clinical pharmacy services in 2016 compared to 2011

The relative number of responding units providing clinical pharmacy services increased during 2011-2016 from 51% to 85% (Table 1). Thus, the proportion of the units reporting non-provision of clinical pharmacy services decreased from 49% in 2011 to 15% in 2016. The main reported reason for not providing clinical pharmacy services was the small number of pharmacy staff, which was commonly 1-2 pharmacists in medicine dispensaries. The reported number of clinical pharmacists and hospital units receiving clinical pharmacy services had increased during the five-year study period (Table 1). More typically they were reported to split their work time between 2-3 units both in 2011 and 2016, only a small number of the clinical pharmacists were reported to work in one unit (ward, clinic). According to the responses of the both surveys, the services were most commonly available in surgical and internal medicine wards. All five university hospitals reported having clinical pharmacy services in intensive care, pediatric and oncology units in 2016.

# 3.2.1 Evolution of reported tasks of clinical pharmacists

Reported tasks performed by clinical pharmacists in 2011 and 2016 are presented in Figure 3. The figure shows extension and implementation of the new tasks, most of which were related to improving

medication safety. Of the twelve reported new tasks in 2016, most widely performed were tasks assuring medication safety at the organizational level, such as developing instructions for medication use and medication therapy (91% reported), taking part in creating and updating medication safety plans (87%), taking part in multiprofessional working groups (87%) and developing medication-use processes by using data from medication error reports (78%, Figure 3). In 2016 clinical pharmacy services covered all crucial stages of the medication-use process (Figure 4). The reported major new contributions within the five years period was the new role in developing, auditing and instructing the medication use-process with the system approach, <sup>45</sup> conducting medication reconciliations (+63%) and counselling patients (+39%, Figure 3).

Clinical pharmacists were reported having access to patient records in almost all (96%) and access to laboratory results in the majority (83%) of the responding units in 2016 (this was not asked in 2011). The proportion of logistic tasks (e.g. ordering and stock control) remained the same (83% reported, Figure 3). In 2016, the respondents were asked to estimate how much time was spent on logistic tasks compared to other tasks. More than half (59%, n=16) of the respondents estimated that 5-50% of the time was spent on logistic tasks, while in almost one-third of the units (30%, n=8), less than 5% of the working time was used. A variation between the tasks of different clinical pharmacists was reported: some performed only logistic tasks, while others had none. Additionally, the respondents reported in an open question their perceptions about the most important tasks actually performed by the clinical pharmacists in their organization at the time of the survey: drug information to ward personnel (48%, n=13), medication reconciliation (33%, n=9), inducting ward personnel (26%, n=7), and developing the medication-use process (22%, n=6).

## 3.2.2 Strategy, management and future plans of clinical pharmacy services

In 2011, less than half (42%) of the responding units reported having a manager dedicated to clinical pharmacy services, while in 2016 the majority (74%) reported this (Table 1). A plan or strategy for clinical pharmacy services was reported to been devised in 20% of the responding units in 2011, while in 63% of the units in 2016 (Table 1). In 2016, half of the responding units (52%) were familiar with the European Statements of Hospital Pharmacy<sup>42</sup> that could be utilized to guide the development of a strategy for hospital pharmacy services.

Both in 2011 and 2016, the most common plan for the future in the responding hospital pharmacies and medicine dispensaries was reported to be to extend the clinical pharmacy services to new care units within their healthcare organization. In 2016, almost half (44%) of the responding units reported to have a plan to re-develop and extend the clinical pharmacists' role to be more clinical and patient-oriented. Similar plans were reported already in 2011, but a need for continuing education to adopt a more patient oriented role was recognized. The use of information and automation technology was reported as a key in changing the

logistics role of clinical pharmacists in both years. In 2016, 30% of the respondents had the opinion that clinical pharmacy services should increasingly be provided in primary care, nursing homes, home care and social care units. Additionally, in 2016, almost two-thirds (62%) of the responding units thought that pharmacists could take a position as medication safety officers or coordinators in the future, while the rest (38%) had no opinion.

## 3.3 Reported importance of continuing education

Participation in long-term continuing education was reported to have been increased during 2011-2016 (Figure 5). Only one hospital pharmacy and one medicine dispensary reported that their clinical pharmacists had not participated in any long-term continuing education by 2016. It was perceived that the clinical pharmacists were able to use the expertise acquired through the long-term continuing education well (70% of the responding units) or slightly (30%). Almost half (48%) of the respondents thought that participating in continuing education had supported the development of the patient-centered tasks of clinical pharmacists.

# 3.4 Assessed benefits and outcomes of clinical pharmacy services

Of the responding units, 33% (n=9) reported having assessed the benefits and outcomes of clinical pharmacy services since 2011 (Figure 6). The results were typically reported internally to their own organization (n=7), in the national congresses (n=4) or in national scientific journals (n=2). Increased multiprofessional collaboration, saved working time of nurses and savings in drug consumption were the most commonly reported assessed and achieved benefits and outcomes in 2011 and 2016. In 2016, common patient safety benefits which were not surveyed or reported in 2011 were the increased reporting of medication errors (n=5) and increased number of accurate medication charts (n=5).

# 4. DISCUSSION

Responses to this national study suggest changes in the pharmacists' involvement in patient care and assuring medication safety in Finnish hospitals within a time period of five years in 2011-2016. This change can be seen in the workforce resources and tasks performed by clinical pharmacists in care units (Figure 3, Figure 4). Their contributions were reported to be extended towards interventions prioritized in international and national patient and medication safety recommendations. Also, clinical pharmacists' competences were reported to have evolved through continuing education and specialization programs towards supporting patient and medication safety initiatives (Figure 5).

These reported developments in pharmacists' performance in Finnish hospitals can be considered as result of various contributing factors. This quite fast extension of their tasks would not have been possible without the support of national patient and medication safety initiatives and guidelines, <sup>23-24,27,47</sup> pharmacists' involvement in establishing these policies, and making long-term continuing education available for pharmacists with the focus on systems approach to patient and medication safety. <sup>38,45</sup> The first steps in creating awareness of medication safety risks and actual errors were taken through a patient safety incident reporting system, which was implemented in Finland in 2007 in the first healthcare units, as have been recommended by international and national guidelines. <sup>4-7,23-24,28,47</sup> Since then, reporting and learning from medication errors and related research have extended to more than 200 Finnish healthcare organizations, revealing medication safety risks and their characteristics, which has laid the foundation for more prospectively managing the risks. <sup>25,39,48</sup> This work has facilitated the clinical pharmacists' participation in multiprofessional patient safety work, as has been suggested e.g., by the Council of Europe and EDQM. <sup>5-6,8-9</sup>

The system-based actions to improve medication safety that were reported to be widely performed by clinical pharmacists in Finnish hospitals in 2016 (Figure 3) cover well the crucial stages of the medication-use process (Figure 4). The actions reported to be performed are in line with the European hospital pharmacy statements, particularly with the statements concerning pharmacists ensuring quality assurance strategies for medicine use processes (5.2), reporting of adverse drug reactions and medication errors (5.4) and ensuring that the information needed for safe medicines use, including both preparation and administration, is accessible at the point of care (5.9).<sup>42</sup>

During the five years, the most notable reported increase had happened with conducting medication reconciliations, e.g., on admission (+63%), despite not being reported as a future plan in 2011. Medication reconciliation was not explicitly mentioned as a concept in patient safety and medicines policy documents published in Finland in the beginning of the 2000s.<sup>23-24</sup> In many other countries and international recommendations medication reconciliation has been prioritized as one of the key strategies to prevent adverse drug events and improve patient safety at all transitions in care.<sup>7,49</sup> In the United States (US), medication reconciliation was recommended already in 2005 in the Hospitals' National Patient Safety Goals established by the US Joint Commission on Accreditation of Healthcare Organizations which also established guidelines for performing medication reconciliation.<sup>50</sup> In Europe, medication reconciliation has been prioritized e.g., by the second European Union (EU) patient safety and quality program (PASQ).<sup>11</sup> Despite recommendations and guidelines, medication reconciliation practices are challenging to perform and EAHP evaluated that it was the most poorly implemented statement (4.4) in Europe in 2015.<sup>42,51</sup> The reasons for this were that pharmacists usually had no access to patient information systems or direct

contact to patients. In our survey in 2016, clinical pharmacists were reported to have access to patient records in almost all (96%) responding units, which is in line with the European hospital pharmacy statements (statement 4.3).<sup>42</sup> Pharmacists should also ensure accurate recording of all allergy and other relevant medicine-related information in the patient's health record (5.8).<sup>42</sup> The importance of reconciled medication charts has been identified recently in Finland in the Rational Pharmacotherapy Action Plan 2018-2022 to be taken into account in the ongoing social and healthcare reform.<sup>26,52</sup>

A positive development was reported in strategic planning and managing clinical pharmacy services in hospitals. However, the content and quality of clinical pharmacy services are not uniform even inside the same organization. More than half of the responding units (52%) reported being familiar with the European Statements of Hospital Pharmacy<sup>42</sup> in 2016. The Statements could be utilized to standardize the content and availability of clinical pharmacy services. Common future plans that were reported related to changing the focus of clinical pharmacists' role on patient-oriented tasks instead of drug logistics. Automation technology (e.g., automated dispensing systems) which is arriving in Finnish hospitals, was expected to release clinical pharmacists' time from logistic tasks to providing pharmaceutical care services that improve medication safety.<sup>53</sup> Furthermore, the Finnish healthcare reform<sup>52</sup> will enable the reform of current legislation<sup>54</sup> related to the number of hospital pharmacies with overlapping responsibilities.<sup>53</sup> This will also release hospital pharmacy staff for patient care. It is crucial to be prepared with clinical pharmacy skills to be able to provide pharmaceutical care at this point.

Pharmacists' participation in long-term continuing education, related to pharmaceutical care and system-based medication safety work, was reported to be increased during the five years (Figure 5). The majority (70 %) of the respondents reported that they are able to satisfactorily use their expertise achieved from long-term continuing education and almost half (48 %) of the respondents thought that continuing education had helped them to adopt a more patient-oriented role. The history of long-term continuing education of clinical pharmacy and medication safety is fairly short in Finland: during the first decade of the 21st century, the Faculty of Pharmacy in the University of Helsinki started systematic research and education about patient and medication safety issues. Clinical pharmacy oriented hospital pharmacy specialization program has been available since 2010.<sup>31,55</sup> Post-graduate accreditation training for comprehensive medication review (CRM) started in 2005.<sup>37,56</sup> Later also a shorter, one-year training for expertise in medication reviews and accreditation training for expertise in ward pharmacy has been available. The post-graduate clinical pharmacy specialization and accreditation training have facilitated the shift of clinical pharmacists' tasks from drug logistics to patient-centered work. Furthermore, the education of basic degrees in pharmacy is under reform to meet the growing need for clinical pharmacy skills. The latter is also addressed in the European hospital pharmacy statement 6.1.<sup>42</sup>

The relative proportion of responding organizations which reported having evaluated the benefits or outcomes of clinical pharmacy services had increased from 16 % to 33% during 2011-2016. According to the respondents, the most common evaluated and achieved benefits in 2016 were related to the work of nurses e.g. saved their working time, improved their pharmacotherapy skills and increased their collaboration with pharmacists (Figure 6). Also, savings in drug consumption, increased number of accurate medication charts and increased medication error reporting were common. However, only a few organizations had published their results nationally and international publications were missing. This area needs development, as is also pointed out in the European hospital pharmacy statements (6.4)<sup>42</sup> and in the national Rational Pharmacotherapy Action Plan.<sup>57</sup> Furthermore, documenting clinical pharmacy interventions for the patient's health record, according to the European hospital pharmacy statement 4.3<sup>42</sup> enables more effective outcomes research related to clinical pharmacy services' impact on e.g. readmissions, treatment periods and mortality. Hospital pharmacists should be encouraged and educated for measuring and studying outcomes of clinical pharmacy services to achieve more rigorous evidence.

# 4.1 Strengths and limitations

The results of this national study can be generalized for hospital inpatient care in Finland even though the overall response rates were moderate (60% in 2011 and in 52% in 2016). Despite the moderate response rates, the coverage of the responses in terms of the coverage of the largest inpatient units with hospital pharmacies were 83% in 2011 and 75% in 2016. The survey method was applicable to study national development for strategic management purposes as in other follow-up survey studies in US<sup>19</sup> and Europe<sup>22</sup>, even though it has methodical limitations e.g. compared to using actual performance data or observation method. The target group of the survey was knowledgeable for providing data of the recent developments and the status of the clinical pharmacy services. Addressing the survey to all hospital clinical pharmacists would be interesting in the future. Clinical pharmacy services' impact on patient care outcomes should also be followed up with more rigorous methods.

## 4.2 Clinical and practical implications

Evolution of clinical pharmacy services to ensure medication safety and their impact on patient care outcomes should be followed-up regularly also in the future. In 2016, more than half (62%) of the responding organizations thought that pharmacists could be working as medication safety officers in the future. The first post for a medication safety officer (pharmacists) was launched in Finland in 2017 in the Helsinki University Hospital. A national focal point for coordinating medication safety research, practice and competence development should be established <sup>26,58-59</sup> as has been recommended by the Council of Europe already in 2006<sup>5-6</sup>, and repeated by other key documents guiding patient and medication safety work.

		ACCEPTED MANUSCRIPT			
451					
452					
453					
454					
455	5.	CONCLUSIONS			
456	Ph	armacists' involvement in patient care and system-based medication safety work was reported to			
457	become more common and planned in Finnish hospitals during 2011-2016. This development is in line with				
458	international and national system-based patient safety guidelines and policy initiatives and should be				
459	со	ntinued. Availability of patient-centered and system-based continuing education and accreditation			
460	tra	ining has had important impact in this shift towards patient-oriented services.			
461					
462	AK	NOWLEDGEMENTS			
463	The research group wants to thank the respondents of the both surveys, the interviewees of the theme				
464	interviews helping the development of the survey instrument and The Finnish Pharmacists' Association for				
465	he	p in e-mailing the survey to the medicine dispensaries.			
466					
467	RE	FERENCES			
468	1.	Krähenbühl-Melcher A, Schlienger R, Lampert M et al. Drug-related problems in hospitals: a review of			
469		the recent literature. Drug Saf 2007;30:379–407.			
470	2.	Westbrook J, Rob M, Woods A, Parry D. Errors in the administration of intravenous medications in			
471		hospital and the role of correct procedures and nurse experience. BMJ Qual Saf 2011;20:1027-1034.			
472	3.	Keers RN, Williams SD, Cooke J, Ashcroft DM: Prevalence and nature of medication administration			
473		errors in health care settings: a systematic review of direct observational evidence. Ann Pharmacother			
474		2013;47:237-256.			
475	4.	Kohn LT, Corrigan JM, Donaldson MS. To Err Is Human. Washington, DC: National Academy Press; 2000.			
476	5.	Council of Europe: Committee of Ministers. Recommendation Rec (2006)7 of the Committee of			
477		Ministers to member states on management of patient safety and prevention of adverse events in			
478		health care, 2006a. https://wcd.coe.int/ViewDoc.jsp?id=1005439&Site=CM. Accessed 03.08.2018.			
479	6.	Council of Europe: Creation of a better medication safety culture in Europe: Building up safe medication			
480		practices. Expert Group on Safe Medication Practices (P-SP-PH/SAFE), 2006b.			
481		http://www.coe.int/t/e/social_cohesion/soc%2Dsp/Medication%20Safety%20Report.pdf. Accessed			

482

03.08.2018.

- 483 7. The World Health Organization: Medication Without Harm Global Patient Safety Challenge on
- 484 Medication Safety. Geneva: World Health Organization, 2017. Licence: CC BY-NC-SA 3.0 IGO.
- 485 http://apps.who.int/iris/bitstream/10665/255263/1/WHO-HIS-SDS-2017.6-eng.pdf?ua=1&ua=1.
- 486 Accessed 03.08.2018.
- 487 8. European Directorate for the Quality of Medicines & Health Care: Pharmaceutical Care Policies and
- 488 Practices for Safer, More Responsible and Cost-Effective Health System. Council of Europe, 2012.
- https://www.edqm.eu/medias/fichiers/policies\_and\_practices\_for\_a\_safer\_more\_responsibl.pdf.
- 490 Accessed 03.08.2018.
- 9. European Directorate for the Quality of Medicines & Health Care: The EDQM Pharmaceutical Care
- 492 Quality Indicators Project. Final report. 2017
- 493 10. EUNetPaS (European Union Network for Patient Safety), 2008:
- 494 http://ns208606.ovh.net/~extranet/index.php?option=com\_content&task=view&id=1&Itemid=2
- 495 Accessed 03.08.2018.
- 496 11. The European Union Network for Patient Safety and Quality of Care (PaSQ): What is the Project about?
- 497 PaSQ 2012. Availabe at: http://www.pasq.eu/Project/Project.aspx. Accessed 03.08.2018.
- 498 12. Directive 2010/84/EU of the European Parliament and of the Council of 15 December 2010 amending,
- as regards pharmacovigilance, Directive 2001/83/EC on the Community code relating to medicinal
- products for human use. Off J Eur Union 348:74–99.
- 13. American College of Clinical Pharmacy (ACCP), 2008. The Definition of Clinical Pharmacy.
- 502 Pharmacotherapy, 28(6):816-817.
- 14. The European Society of Clinical Pharmacy (ESCP), 2017. What is clinical pharmacy? Available at:
- 504 http://www.escpweb.org/content/escp-mission-vision. [Accessed January 16, 2018].
- 505 15. Hepler CD, Strand LM: Opportunities and responsibilities in pharmaceutical care. Am J Hosp Pharm
- 506 1990;47(3):533-543.
- 16. American Society of Hospital Pharmacists: ASHP Statement on pharmaceutical care. Am J Hosp Pharm
- 508 1993;50(1):1720-1723.
- 509 17. Cipolle RJ, Strand LM, Morley PC: Pharmaceutical care practice: the clinicians guide. 2nd edition. New
- York, NY; McGraw-Hill 2004.
- 18. Kaboli PJ, Hoth AB, McClimon BJ, Schnipper JL: Clinical Pharmacists and Inpatients Medical Care A
- 512 Systematic Review. Arc Int Med 2006;166: 955-964.
- 19. Bond CA, Raehl CL: 2006 National Clinical Pharmacy Services Survey: Clinical Pharmacy Services,
- 514 Collaborative Drug Management, Medication Errors and Pharmacy Technology. Pharmacotherapy
- 515 2008;28(1):1-13.
- 20. Perez A, Doloresco F, Hoffman J, Meek P, Touchette D, Vermeulen L, Schumonck G: Economic
- 517 Evaluations of Clinical Pharmacy Services 2001 2005. Pharmacotherapy 2008;28(11): 285e-323e.

- 518 21. Touchette DR, Doloresco F, Suda KJ, Perez A, Turner S, Jalundhwala Y, Tangonan MC, Hoffman JM:
- Economic Evaluations of Clinical Pharmacy Services 2006-2010. Pharmacotherapy 2014;34(8):771–793.
- 520 22. Frontini R, Miharija-Gala T, Sykora J: EAHP survey 2010 on hospital pharmacy in Europe: parts 4 and 5.
- 521 Clinical services and patient safety. Eur J Hosp Pharm 2013;20: 69–73.
- 522 23. Ministry of Social Affairs and Health. Safe Pharmacotherapy. A National Guide for Medication
- 523 Management in Social and Health Care organizations. Helsinki 2006.
- http://julkaisut.valtioneuvosto.fi/bitstream/handle/10024/71944/Opp200532-vanhentunut-
- leima.pdf?sequence=1&isAllowed=y. Accessed 03.08.2018.
- 526 24. The Ministry of Social Affairs and Health (MSAH): Medicines Policy 2020: Towards efficient, safe,
- rational and cost-effective use of medicines. Reports of the Ministry of Social Affairs and Health
- 528 10:2011. http://www.stm.fi/julkaisut/nayta/-/\_julkaisu/1551199. Accessed 03.08.2018.
- 529 25. Holmström A-R: Learning from Medication Errors in Healthcare How to Make Medication Error
- Reporting Systems Work? (dissertation). University of Helsinki, 2017. Available at:
- 531 https://helda.helsinki.fi/handle/10138/179230.
- 532 26. Ministry of Social Affairs and Health: Rational Pharmacotherapy Action Plan. Final report. Reports and
- Memorandums of the Ministry of Social Affairs and Health 19/2018. (English summary)
- 534 http://urn.fi/URN:ISBN:978-952-00-3930-1. Accessed 03.08.2018.
- 27. National Institute for Health and Welfare: Finnish National Programme on Patient Safety, 2011.
- 536 Available at: http://www.thl.fi/en\_US/web/potilasturvallisuus-en. Accessed 03.08.2018.
- 537 28. The Finnish Health Care Act 1326/2011
- 538 29. Finnish Medicines Agency 2017. List of hospital pharmacies 31.3.2017.
- 539 http://www.fimea.fi/apteekit/sairaala-apteekit ja laakekeskukset/lista sairaala-apteekeista. Accessed
- 540 03.08.2018.
- 30. Finnish Medicines Agency 2017. List of medicine dispensaries 31.3.2017.
- 542 http://www.fimea.fi/apteekit/sairaala-apteekit\_ja\_laakekeskukset/lista\_laakekeskuksista Accessed
- 543 03.08.2018.
- 31. Lyles A, Shermock K, Linden-Lahti C, Laaksonen R, Hakoinen S and Airaksinen M. International experts
- brought together to offer clinical skills qualifications to practicing hospital pharmacists. International
- Pharmacy Journal. 2015;33(1):32-33. World Health Organization WHO: Patient Safety Programme.
- http://www.who.int/patientsafety/about/en/ Accessed 03.08.2018.
- 32. Tiiro V, Airaksinen M, Suominen R: Lääkelogistiikasta kliiniseen farmasiaan. Dosis 2005;21(4): 278 286.
- 549 (English summary).
- 33. Ryynänen E, Tyynismaa L, Linden-Lahti C, Carlsson C, Laitinen-Parkkonen P, Airaksinen M, Laaksonen R:
- 551 Clinical Pharmacy in Hospitals and on Hospital Wards in Finland. Dosis 2013;29(1): 28-38. (English
- summary).

- 34. Hartikainen PA, Koskinen T, Vainio K: Finnish pharmacists' perceptions of their work on the wards in
- hospitals and health centres. Eur J Hosp Pharm 2014;21: 251-254.
- 35. Maddirala Venkata SPR, Kielgast P, Udhumansha U, Airaksinen M. Public Health and Patient Care
- Aspects in Indian Pharmacy Curricula: A Comparison with USA, Finland and Denmark. Indian J Pharm
- 557 Educ Res 2016;50(1):1–8.
- 36. The International Pharmaceutical Federation FIP: The Nanjing Statements on Pharmacy and
- 559 Pharmaceutical Sciences Education. FIP 2017.
- https://www.fip.org/files/fip/PharmacyEducation/Global\_Conference\_docs/Nanjing\_Statements.pdf
- 561 Accessed 03.08.2018.
- 37. Leikola SN, Tuomainen L, Ovaskainen H, Peura S, Sevon-Vilkman N, Tanskanen P, Airaksinen M:
- 563 Continuing education course to attain collaborative comprehensive medication review competencies.
- 564 Am J Pharm Educ 2009;23:108, 2009.
- 38. World Health Organization WHO: Patient Safety Programme.
- http://www.who.int/patientsafety/about/en/ Accessed 03.08.2018.
- 39. Härkänen M, Turunen H, Vehviläinen-Julkunen K: Differences Between Methods of Detecting
- Medication Errors: A Secondary Analysis of Medication Administration Errors Using Incident Reports,
- the Global Trigger Tool Method, and Observations. J Pat Saf 2016;00: 00-00. (E-pub ahead of print).
- 570 40. Cohen MR: Medication errors. Second edition, American Pharmacists Association 2010.
- 41. Institute for Safe Medication Practices (ISMP), 2011. Medication Safety Self Assessment for Hospitals
- 572 2011. Available at: https://ismp.org/selfassessments/Hospital/2011/Default.asp. [Accessed November
- 573 14, 2016].
- 42. The European Statements of Hospital Pharmacy. Eur J Hosp Pharm 2014;21:256-258.
- 43. Howell, D: Statistical Methods for Psychology 8th ed., Belmont, USA: Cengage Learning, 2013.
- 576 44. Hsieh HF and Shannon S: Three Approaches to Qualitative Content Analysis. Qual Health Res
- 577 2005;15(9): 1277-88.
- 45. Reason J: Human error: models and management BMJ 2000;320: 786-770.
- 579 46. Finnish National Board on Research Integrity: Ethical review in human sciences.
- 580 http://www.tenk.fi/en/ethical-review-in-human-sciences. Accessed 03.08.2018.
- 581 47. Ministry of Social Affairs and Health. Promoting Patient Safety Together Finnish Patient Safety
- 582 Strategy 2009-2013, Helsinki 2009.
- 583 48. Lapatto-Reiniluoto O, Patinen L, Niemi M et el. Drug-Related Inadvertent Deaths in a University Hospital
- A Declining Trend. Basic Clin Pharmacol Toxicol 2015;117:421-6.
- 49. Institute for Healthcare Improvement. How-to Guide: Prevent Adverse Drug Events by Implementing
- Medication Reconciliation, Cambridge, MA 2011. Available at:

- http://www.ihi.org/resources/Pages/Tools/HowtoGuidePreventAdverseDrugEvents.aspx. Accessed
- 588 Januray 16, 2018.
- 589 50. Joint Commission Accreditation of Health Care organizations (JCAHO). The 2005 National Patient Safety
- 590 Goals. Patient Safety First 2005; 81(1).
- 51. Underhill J, Gibbons N: EAHP European Statements baseline survey 2015: methodology. Eur J Hosp
- 592 Pharm 2016;23:65–68.
- 593 52. Kangas O, Kalliomaa-Puha L: Finland: The government's social and healthcare reform is facing
- problems. ESPN Flash Report 2018/2. file:///C:/Users/HUS33127004/Downloads/ESPN%20-
- 595 %20Flash%20Report%202018-%2002%20-%20Fl%20-%20Ja52uary%202018.pdf. Accessed 03.08.2018.
- 596 53. Ministry of Social Affairs and Health: Pharmaceutical services in the operating environment of health
- and social services Working group report (English summary). Reports and Memorandums of the
- 598 Ministry of Social Affairs and Health 6/2018. Available at: http://urn.fi/URN:ISBN:978-952-00-3903-5.
- 599 54. The Finnish Medicines Act 395/87
- 55. Laaksonen R, Laitinen-Parkkonen P, Lindén-Lahti C, Salminen S, Airaksinen M: Tutkimus osana sairaala-
- ja terveyskeskusfarmasian erikoistumiskoulutusta. Dosis 2011;27(2): 68 75. (English summary).
- 56. Leikola S, Kanninen J, Puustinen J: Lääkehoidon kokonaisarviointi lääkärin työkaluna. Suomen
- 603 Lääkärilehti 71(18): 1327-30, 2016 (English summary).
- 57. Ministry of Social Affairs and Health: Effective use of research data: Research strategy for rational
- 605 pharmacotherapy 2018-2022 (English summary). Reports and Memorandums of the Ministry of Social
- 606 Affairs and Health 7/2018. Available at: http://urn.fi/URN:ISBN:978-952-00-3905-9.
- 58. Schepel L, Holmström A-R, Kvarnström K, Airaksinen M: Lääkitysturvallisuuden kansallisen
- 608 koordinaation tarve Suomessa. Dosis 2017,33(2): 109-112. (English summary).
- 59. Hakoinen S, Airaksinen M, Laitinen-Parkkonen P: Lääkekaaoksen hallinta sote-muutoksessa nykytila,
- haasteet ja ratkaisuehdotukset. KAKS- Kunnallisalan kehittämissäätiö, Otavan Kirjapaino Oy, Keuruu
- 611 2017. Available at: https://kaks.fi/wp-content/uploads/2017/09/tutkimusjulkaisu\_106\_nettiin.pdf.
- Accesses February 12, 2018. (In Finnish).

**Table 1.** Clinical pharmacy services in hospital pharmacies and medicine dispensaries responding the surveys in 2011 (n=71/118) and 2016 (n=27/52). It should be noted, that the total number of medicine dispensaries has remarkably decreased during 2011-2016 in Finland, while the number of hospital pharmacies has remained the same.

Clinical pharmacy services	2011 (n=71)	2016 (n=27)	
F	n (%)	n (%)	
Responding units not providing clinical pharmacy services	35 (49%)	4 (15%)	
Responding units providing clinical pharmacy services	36 (51%)	23 (85%)	
- hospital pharmacies	16 (44%)	17 (74%)	
- medicine dispensaries	20 (56 %)	6 (26%)	
Reported number of full-time* working clinical pharmacists	103	134-215**	
Reported number of part-time working clinical pharmacists	54	13-65**	
Reported number of hospital units receiving full-time* clinical pharmacy services	108	179-201**	
Reported number of hospital units receiving part-time clinical pharmacy services	134	192-236**	
Responding units having a manager, whose working time was dedicated to	30 (42%)	20 (74%)	
management of clinical pharmacy services		,	
Responding units having a plan or strategy for clinical pharmacy services	14 (20%)	17 (63%)	

<sup>\*</sup>Full-time = office hours from 8:00 a.m. to 4:00 p.m. during week days.

<sup>\*\*</sup>Ranges were used in the 2016 survey and actual numbers were asked in the 2011 survey.

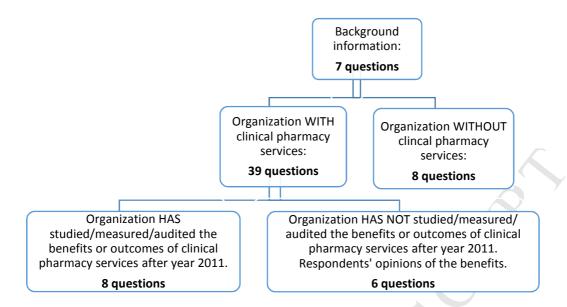
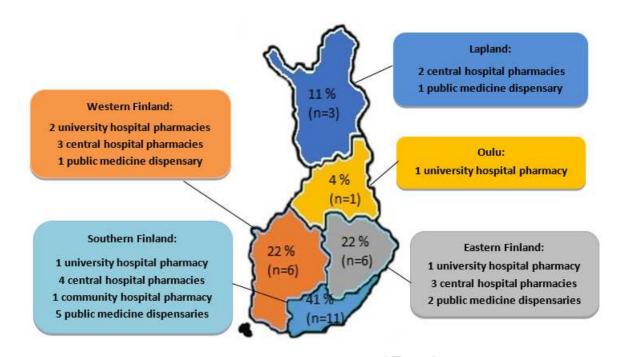
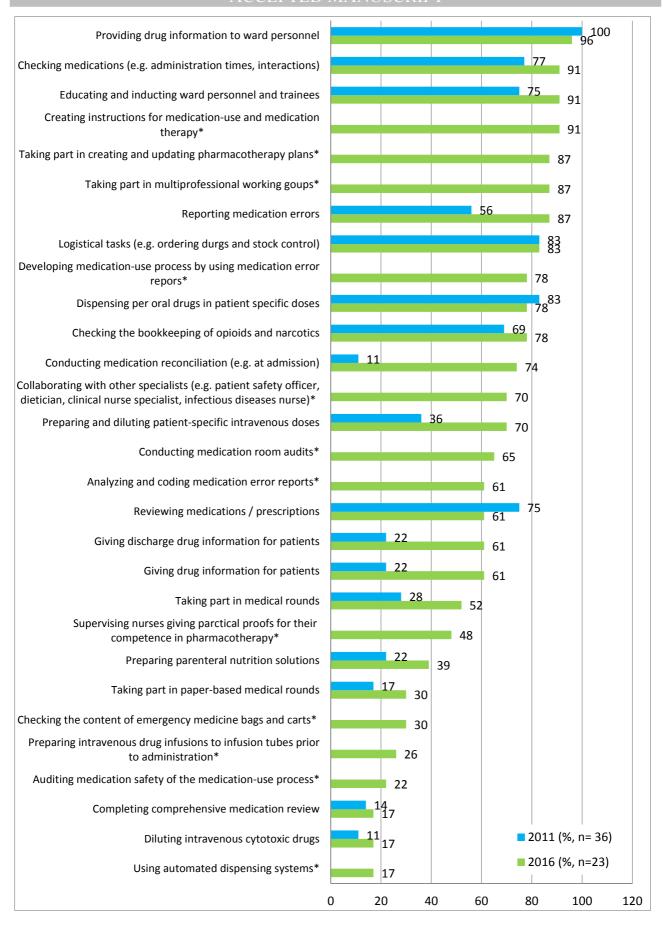


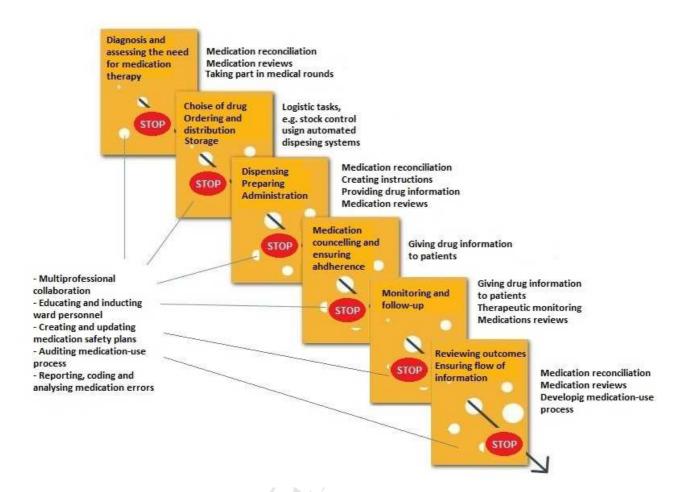
Figure 1. Content of the survey instrument in 2016.



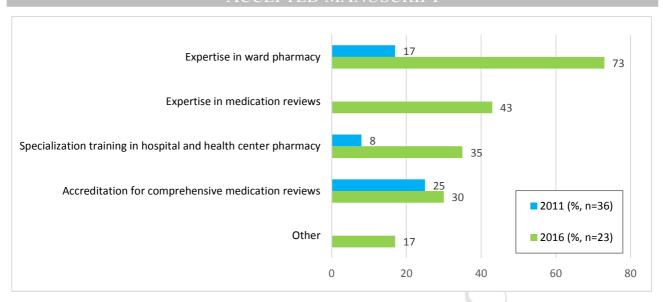
**Figure 2.** Location of the hospital pharmacies and medicine dispensaries that responded to the survey in 2016 (n=27/52) by county.



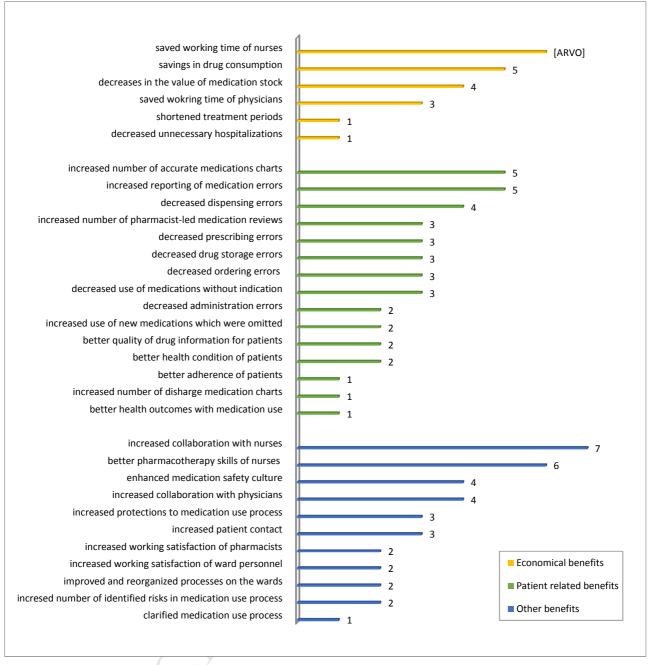
**Figure 3.** Reported tasks of clinical pharmacists (%) in 2011 and 2016. \*New tasks (n=12) added to the year 2016 survey.



**Figure 4.** Illustration of the evolution of the tasks of the clinical hospital pharmacists in Finland by 2016 as reported by the responding hospital pharmacies and medicine dispensaries. The figure illustrates the coverage of the clinical pharmacy services of the stages of medication use process by applying Reason's Swiss Cheese Model. 45



**Figure 5.** Participation in long-term continuing education and accreditation training of one or more of the clinical pharmacists in the responding units (%). Other (n=4): expertise in patient safety (n=2), master of clinical pharmacy (n=1), hospital's internal continuing education program (n=1). Training for expertise in medication reviews was not yet provided in 2011.



**Figure 6.** Benefits and outcomes of clinical pharmacy services that were reported to been assessed and achieved in 33% (n=9/27) of the responding units in 2016.