1   **Documentation of drug related problems and their management in community pharmacy:**

2   **data evolution over six years**

Abstract

Background

Documentation of pharmacists' activities, such as drug related problems (DRPs) management, is necessary to estimate fair remuneration but is rarely done in community pharmacies.

Objective

To document and evaluate the evolution of DRPs prevalence and management over six years.

Methods

Observational study carried out since 2016 in a community pharmacy. Documentation was made yearly for 21 days (depending on seasons, holidays and medical internship rotations) using the ClinPhADoc tool. Pharmacists documented: medication, DRP type, intervention, implied partner and time for DRP management. A subanalysis was made depending on the medical rotation.

Results

A total of 171 437 prescriptions were received and 6 844 (4.0%) documented with 1 550 DRPs. Most frequent DRPs were procedural (n=506, 32.6%), dosage/posology (n=263, 17.0%) and drug-drug interaction (n=153, 9.9%). Mean time dedicated to DRP management was 6.9 minutes, the longest time was for clinical DRPs (11.0 minutes, SD=6.6). Most DRPs (n=726, 44.6%) were managed by the pharmacist alone taking less working time than when involving other stakeholders ($p<0.01$). Statistically significant differences were found in DRPs between the beginning and end of medical rotation ($p<0.05$).

Conclusions

23 Documentation of DRP management allowed consistent results over the years. Patterns of DRPs

24 can be used to develop inter-professional interventions to prevent DRPs.

Keywords

26 Documentation; Community pharmacy services; Medication review; Drug related problem;

27 pharmaceutical intervention.

Introduction

A Drug-Related Problem (DRP) is an event or circumstance involving drug therapy that actually or potentially interferes with desired health outcomes (1). Its management involves pharmacists' activities and different partners (patients and/or other health professionals) (2, 3). Documentation of pharmacists' activities, particularly those targeting DRPs, has been recommended internationally to assess appropriately the impact on clinical outcomes (4, 5). However, the lack of standardized documentation systems inside community pharmacies presents a major obstacle for documenting clinical activities (5). The existing documentation tools have been deemed incompatible with the workflow in community pharmacies due to tools' complexity; omission of the actions taken by the pharmacist to resolve the DRP or its clinical significance (1). Furthermore, studies that report DRPs are normally transversal or carried out during short periods of time (6). The World Health Organization (WHO) included as one of the three actions its Global Patient Safety Challenge (7) "strengthening the quality of data to monitor medication-related harm; providing guidance and developing strategies, plans, and tools to ensure that the medication process has the safety of patients". As part of such initiative (7), it is also important to evaluate DRPs during long periods of time to monitor its evolution.

Pharmacists' roles as patient care providers is growing, but remuneration for activities apart from dispensing is not consistently offered (8). In Switzerland, payment schemes for pharmacist's services related to dispensing prescription drugs remunerate activities on a fee-for-service basis (9) that currently rely on drug validation which includes the identification, prevention and resolution of DRP such as drug-drug interactions or risk factors. In addition, documentation and consequently, their economic implications such as remuneration are rarely evaluated, particularly in the ambulatory context (10, 11). The development of quality indicators in primary care will be

51   closely related to future remuneration (12). Hence, the development and evaluation of such

52   indicators over time should be supported in community pharmacies.

53   Tools for documenting clinical activities related to DRPs in Swiss community pharmacies have

54   already been developed (13) but a simpler tool was needed to support a long-term use. For that,

55   the Clinical Pharmacy Activities Documented (ClinPhADoc) tool has been proven reliable and

56   acceptable in one study from 2019 but its implementation in daily practice needed evaluation (14).

57   It includes three categories of DRPs: (i) clinical (related to efficacy or toxicity); (ii) technical

58   (related to medication use); and (iii) procedural (related to renewals of expired prescriptions by

59   pharmacists to ensure continuity of treatment). The present study presents a first experience to

60   document DRPs using the ClinPhADoc tool and evaluate over six years the evolution of DRPs and

61   pharmacists' activities to manage them.

Methods

<u>Study design</u>

Observational prospective study carried out for six years (April'2016 – December'2021). Given its descriptive nature and the absence of patients' data, this study is excluded of the Swiss laws on clinical research by the Ethics Committee of Vaud (CERV-VD Req-2022-01021).

<u>Setting</u>

The study was undertaken in a single community pharmacy (UP, Unisanté Pharmacy) (15-17). The UP is a community pharmacy located in a university hospital and serves an average of 28 600 prescriptions annually from patients coming mostly, but not exclusively, from the hospital (*Centre Hospitalier Universitaire Vaudois*) and an academic outpatient clinic (Unisanté). The UP clinical activities are alike those in other Swiss community pharmacies, but UP mainly serves chronic ambulatory patients followed by specialists (e.g., oncology or infectious diseases), whereas other community pharmacies manage more cases of general medicine diseases in collaboration with general practitioners. The UP has a total of 54 opening hours per week. Every working day, five pharmacists (among fourteen) and six pharmacy technicians (among eighteen) ensure the clinical activities with patients. For drug validation, pharmacy technicians welcome patients and contribute to the pre-identification of DRPs and to the collection of initial information from patients and then refer to the pharmacists to support their activities (Appendix 1).

Among such activities, drug validation according to the remuneration based on a fee-for-service basis (9) and documentation through ClinPhADoc tool is primarily performed by two pharmacists according to a daily work shift planning. In addition, the UP operates daily an Interdisciplinary Medication Adherence Program (IMAP) (17) where patients (approximately 250 patients) are seen

84 by one of the five pharmacists, hence this activity is not considered in the present study. The

85 characteristics of the UP have not changed throughout the duration of the study. Over this period,

86 16 pharmacists integrated the UP and 15 left the UP.

87 <u>Data collection</u>

88 Patients' fluctuation and activities in the UP depends on the following variables: seasons, school

89 holidays, fluctuation of the number of patients (according to specific days of activities at the UP)

90 and medical rotation (not only from general practitioners but from specialists changing setting to

91 gain knowledge in other medical specialty) at Unisanté (every year on May 1st and November 1st).

92 Thus, DRPs were documented during approximately 21 working days per year to assure a

93 systematic sampling considering the aforementioned variables (Appendix 2). In 2016, a double

94 number of days were selected for piloting the electronic tool. In 2020, the documentation in the

95 UP had to be reorganized due to the COVID-19 semi-containment (15).

96 Documentation of DRPs detected was made using Microsoft Access® v2016 document based on

97 the ClinPhADoc tool. Each year one pharmacist was responsible for managing the documentation

98 process and supporting involved pharmacist to ensure a systematic data collection. During the days

99 selected for documentation, two out of the five pharmacists working on drug validation evaluated

100 their respective prescriptions and documented DRPs. Documentation included: identification of

101 the prescription, identification of the DRP, medication involved (brand name, active substance,

102 Anatomical Therapeutic Chemical or ATC denomination), DRP type (clinical, technical,

103 procedural), its clinical consequence (increased toxicity, loss of efficacy), pharmacist's

104 intervention (prescription modified or not), implied partner in DRP management

105 (patient/caregiver, prescriber, none) and pharmacists' time to identify and manage DRPs.

106 According to the Swiss payment scheme for pharmacist's services, one patient could present more

107   than one prescription and one prescription could contain one or more medications and one or more

108   DRPs (time was considered separately for each DRP, because DRP type and implied partner when

109   managing them could differ in the same prescription).

110   Total number of prescriptions each day was extracted from the pharmacy software (GoldenGate®

111   v925.5.0).

112   Statistical analyses

113   A descriptive analysis was carried out evaluating frequencies, percentages and measures of central

114   tendency. Afterwards, Pearson's chi-square test was used to determine associations among

115   pharmacists' working time for DRPs management and other variables (type of DRP, implied

116   partner, working years). Pearson's chi-square test was used when dividing the pharmacists'

117   working time as categories (0-5min; 6-15min; 16-30min; >30min) and analysis of variance

118   (ANOVA) were used when evaluated as continuous variable (mean). In addition, inferential

119   analysis was made to evaluate the influence of the rotation of new assistant medical practitioners

120   to compare the beginning (May and November) and end of the rotation period (April and October)

121   on the number and type of DRP. P-value of <0.05 indicated statistically significance. Analyses

122   were performed using R Statistics® v4.0.5.

Results

From 2016 to 2021, a total number of 171 437 prescriptions were received at the UP. 14 651 prescriptions (8.5%) were received during the days selected for documentation, of which 6 844 (46.7%) were validated and documented by two of the five pharmacists. A total number of 1 550 DRPs were identified, therefore 22.6% of documented prescriptions presented DRPs (Table 1).

Regarding the ATC classification, 73 different groups were involved in DRPs. Three main groups accounted for the 23.9% of DRPs: analgesics (N02) were the most prevalent (10.7% of DRPs) followed by systemic antivirals (J05, 7.7% of DRPs) and psycholeptics (N05, 5.5% of DRPs).

131   **Table 1.** Total number of validated prescriptions, prescriptions considered for documentation and DRPs

Year	Prescriptions validated per year	Prescriptions validated during the documentation days n (%)[a]	Prescriptions validated and documented during the documentation days n (%)[b]	DRPs detected and documented n (%)[c]	DRPs documented per day Mean (SD)	Time for the management of the documented DRPs (min.) Mean (SD)
2016	32 200	5 068 (15.7)[d]	1 691 (33.4)	239 (14.1)	5.6 (4.9)	7.7 (6.1)
2017	28 248	2 091 (7.4)	1 248 (59.7)	300 (24.0)	13.4 (9.0)	5.6 (5.5)
2018	29 081	2 101 (7.2)	1 014 (48.3)	237 (23.4)	10.8 (6.0)	7.1 (7.4)
2019	30 012	2 021 (6.7)	1 014 (50.2)	281 (27.7)	11.7 (7.0)	8.4 (9.4)
2020	25 793[e]	1 553 (6.0)	849 (54.7)	224 (26.4)	10.7 (5.6)	6.0 (5.0)
2021	26 103	1 817 (7.0)	1 028 (56.6)	269 (26.2)	11.3 (6.8)	6.6 (5.3)
TOTAL	171 437	14 651 (8.5)	6 844 (46.7)	1 550 (22.6)	9.9 (6.9)	6.9 (6.7)

132
133   [a] Percentages are calculated considering the total number of prescriptions per year
134   [b] Percentages are calculated considering the total number of prescriptions validated
135   [c] Percentages are calculated considering the total number of prescriptions validated and documented
136   [d] Double number of days were selected for piloting the electronic tool in this first year
137   [e] Number of validated prescription s dropped due to COVID-19 semi-containment in Switzerland (15)

138   The most frequent DRP was of procedural type e.g. pharmacist prescription renewal (n=506,

139   32.6%). Followed by clinical DRPs: dosage/posology (n=263, 17.0%) and drug-drug interaction

140   (n=153, 9.9%). Overall mean time for the management of DRPs was 6.89 min (SD=6.74), the

141   longest time was for clinical DRPs: no indication (mean=15.8 min, SD=3.8) and side effect

142   (mean=12.6 min, SD=12.9) (Table 2). The majority of DRPs (n=1 008, 65.0%) were managed in

143   less than five minutes (Table 3). The difference in the time for DRP management was statistically

144   significant depending on DRP type and the implied partner (p<0.001) (Table 3).

145   **Table 2.** Mean time required for DRP management from 2016 to 2021 according to their type.

ClinPhADoc DRP category and type (14)		n (%)	Time dedicated to the management Mean (SD) (min.)
Procedural	Pharmacist prescription renewal	506 (32.6)	5.3 (4.6)
Clinical	Dosage/posology	263 (17.0)	7.3 (6.5)
	Drug-drug interaction	153 (9.9)	8.8 (9.4)
	Adherence, abuse, misuse	79 (5.1)	8.9 (6.4)
	Untreated problem	33 (2.1)	10.1 (8.8)
	Inadequate drug form	31 (2.0)	5.2 (3.8)
	Duration	22 (1.4)	7.1 (5.1)
	Contraindication	21 (1.4)	10.2 (8.0)
	Duplication	18 (1.2)	8.3 (5.9)
	Side effect	9 (0.6)	12.6 (12.9)
	Problem related to treatment effects	7 (0.5)	7.0 (2.2)
	No indication	6 (0.4)	15.8 (3.8)
Technical	Formal or regulatory reason	104 (6.7)	5.1 (4.2)
	Refund problem	89 (5.7)	6.5 (7.0)
	Problem of procurement	89 (5.7)	6.5 (5.0)
	Discordance with other medical data	81 (5.2)	10.7 (11.9)
	Inadequate quantity	17 (1.1)	4.8 (2.5)
	Unreadable prescription	16 (1.0)	5.7 (4.2)
	Problem related to treatment administration	4 (0.3)	6.8 (2.4)
	Problem of cost	2 (0.1)	3.5 (2.1)
TOTAL		1 550 (100.0)	6.9 (6.7)

146 **Table 3.** Prevalence of DRP from 2016 to 2021 as determined by management time dedicated by

147 the pharmacist.

ClinPhADoc category		Time dedicated to the management, n (%)[a]				p-value
		01-05 min.	06-15 min.	16-30 min.	> 30 min.	
DRP type	Clinical	343 (22.1)	250 (16.1)	43 (2.8)	6 (0.4)	
	Procedural	388 (25.0)	103 (6.6)	14 (0.9)	1 (0.1)	<0.001[b]
	Technical	277 (17.9)	101 (6.5)	15 (1.0)	9 (0.6)	
Implied partner [c]	Patient/Caregiver	280 (18.1)	86 (5.6)	10 (0.6)	2 (0.1)	
	Prescriber	173 (11.2)	242 (15.6)	50 (3.2)	13 (0.8)	<0.001[b]
	Pharmacist alone	555 (35.8)	126 (8.1)	12 (0.8)	1 (0.1)	

148 [a] Percentages are calculated considering the total number of DRPs (n=1'550)
149 [b] Pearson's Chi-squared test
150 [c] Several partners may be selected

151 Most DRPs (n=726, 44.6%) were managed by the pharmacist alone. Mean time for DRP

152 management by the pharmacist alone was lower (4.84min., SD=4.17) than when implying the

153 patient/caregiver (5.87min., SD=5.76) or when the prescriber was also involved (10.73min.,

154 SD=8.67) with statistically significant differences ($p < 0.001$, ANOVA test).

155 For most clinical and technical DRPs, pharmacists modified the prescription (n=537, 49.2%), they

156 also refer the patient in 6.8% cases (n=74).

157 Subanalysis of the days when the rotation of assistant medical practitioners had place, showed that

158 clinical DRPs were the most frequent DRPs (42.5%) instead of procedural. Statistically significant

159 differences ($p < 0.05$) were found when the total number of observed DRPs (regardless the type)

160 was compared. No differences were found between the beginning and end of the rotation period

161 when stratified by the type of DRP ($p = 0.20$, Chi square test) (Figure 1).

162 **Figure 1**. Number of the three DRPs types depending on rotation of assistant medical practitioners
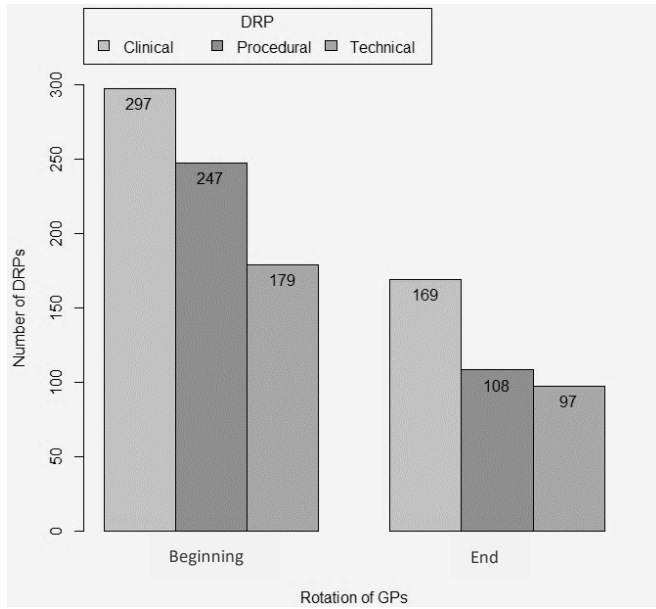
163
164 Inferential statistics were used to evaluate the influence of the rotation of assistant medical practitioners at Unisanté to compare the beginning (May
165 and November) and end of the rotation period (April and October) on the number and type of DRP.
166 P-value of <0.05 indicated statistically significance.

Discussion

The present study describes for almost six years the consistent and systematic documentation of DRPs detected and the related activities to manage them in a community pharmacy. The most frequent DRP was of procedural type and the primary action taken was management by the pharmacist alone.

Although different pharmacists were involved in the documentation, the DRPs detected and the time required for management were similar along the years (some differences were found in 2016 when piloting). Nearly a quarter of the prescriptions validated and documented included DRPs. This result was higher than found by Nicolas et al (18) where it represented 11.2%, however they only considered clinical DRPs. Other studies have found higher number of DRPs (19-21) with lack of adherence being one of the most frequent DRP. Pharmacists in the UP participates in the IMAP, consequently, they proactively support patients' adherence. This probably explains why in our results, adherence was not the most common clinical DRP since lack of adherence is systematically prevented in the usual clinical approach (see Appendix 1). IMAP is not commonly introduced in community pharmacies in Switzerland: about 30 pharmacies (among 1'800) offer the same program throughout Switzerland. Likewise, in relation to the medications most frequently related to DRP, results could differ from other pharmacies due to most prescriptions in the UP being issued by specialists from the university hospital.

Medical rotation, for general practitioners and between different settings for different specialists, influenced the prevalence of DRPs, as significantly higher numbers were found at the beginning of the rotation. Therefore, documentation could be used to elaborate inter-professional coordinated interventions and training to ultimately optimize patient safety. While medical rotation has not

189 been studied in relation to DRPs, studies have shown (22, 23) that training and evaluation programs

190 improve the ability to prescribe.

191 Documentation is known to be a challenge in community pharmacies particularly due to lack of

192 time (5, 24). In order to develop effective clinical and administrative initiatives, documentation

193 should meet established criteria for legibility, clarity, and completeness(5, 11, 25). The ease of

194 completion of ClinPhADoc tool enabled the systematic documentation to compare pharmacists'

195 workload related to DRPs (14) and showed consistency among over the years. Its use should be

196 further evaluated in other community pharmacies.

197 The remuneration system in Switzerland already comprises the eventual DRPs detection and

198 management of drug validation. Pharmacists' remuneration for validating each drug is CHF4.30,

199 regardless if a DRP is present and the stakeholders involved (9). Pharmacists labor cost is estimated

200 in CHF87/hour (26) or CHF1.45/minute, which translates in remunerating 2.96 minutes for drug

201 validation. Results found a mean time of 6.9 minutes to manage a DRP, which is close to results

202 observed in another study carried out in Switzerland (27) that found out that drug validation was

203 completed in 5.4 minutes in the absence of DRPs and 6.8 minutes when a DRP was present (time

204 was determined based on observation by a pharmacy student). The time required to detect and

205 manage DRPs in Germany was four minutes (18). In addition, clinical DRPs required more

206 working time to be managed due to the involvement of other stakeholders. Therefore, DRPs

207 detection and management seem not completely remunerated.

208 International payment programs for pharmacy services have often offered flat fees per service (28).

209 It has also been suggested that remuneration should be based on the intensity of pharmaceutical

210 interventions (29). The use of documentation systems such as ClinPhADoc has improved

211 understanding of the frequency and nature of clinical interventions performed by pharmacists.

212   Studies like this have already contributed in Australia (5) for documentation to gain nationwide

213   acceptance and eventually develop better remuneration systems. The next revision of the Swiss

214   remuneration system will consider different situations to remunerate pharmacists (e.g., newly

215   added medication). In addition, further studies are necessary to evaluate the global time needed for

216   activities to better adapt the remuneration to services to avoid insufficient revenues as suggested

217   by Houle et al in a review carried out in 2019 (30).

Strengths and limitations

To our knowledge, this is the first study conducted in community pharmacy that has documented

the prevalence and management of DRPs during almost six years. The tool facilitated a systematic

documentation without increasing pharmacists' workload. Since the study was conducted in a

single pharmacy, external validity is limited. Further studies in several pharmacies would be

necessary to expand knowledge of DRPs identification and management (including management

time and implied partners). As this study only measured pharmacists' time, future research needs

to consider pharmacy technicians' time who are also involved in the process.

Conclusions

The systematic documentation of DRPs and their management showed that a documentation process based on ClinPhADoc allowed consistent results over the years (e.g., prevalence of DRP and time needed for their management). Documentation serves for the identification of patterns of DRPs that could be eventually used to elaborate professional coordinated interventions to prevent them with the ultimate aim of increasing patient safety.

Acknowledgements

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