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### CITATION

Obassi, Samuel; Doyle, Frank; Tinsley, Alan (2015): Prevalence and risk factors for modified prescriptions in an Irish community pharmacy.. figshare. Journal contribution. <https://hdl.handle.net/10779/rcsi.10773371.v1>

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## Prevalence and risk factors for modified prescriptions in an Irish community pharmacy



### Abstract

**Background:** Despite a dearth of knowledge on the causes of prescribing errors in medical practice, and the rates of prescribing errors among certain patient groups, little Irish research exists to address this issue. One possible reason for this is that the analysis of prescription modification is not part of the recognised job description of a pharmacist.

**Aims:** To investigate the prevalence, nature and risk factors for prescription modifications in an Irish community pharmacy.

**Methods:** A cross-sectional study was performed to examine prescriptions dispensed in an Irish community pharmacy over a period of five weeks.

**Results:** In total, 866 prescriptions were examined. The overall prevalence of prescribing errors and prescription modifications was 17.9% (155), with a mean of 31 modifications per week. Prescription only medicines (POM) comprised 94.8% (147) of the modifications, of which 87% (128/147) were prescription errors requiring a simple clerical clarification before dispensing could occur. The remaining 13% (19; average of 3.8 per week) were prescribing faults with potential clinical consequences if left unaltered. Half (51%) of all POM modifications occurred through consultation with the patient or their representative. The following factors were associated with increased risk of POM modifications: being a female patient (OR=1.605, 95% CI 1.104-2.333,  $p=0.013$ ); and, being prescribed drugs in the following therapeutic areas – musculoskeletal (OR=1.906, 95% CI 1.023-3.551,  $p=0.042$ ), and genitourinary system and sex hormones (OR=3.691, 95% CI 2.255-6.042,  $p<0.001$ ). Subsequent multivariate analysis confirmed these as significant independent risk factors for POM modifications.

**Conclusions:** The majority of prescribing errors modified involved non-serious clerical errors. However, an average of 3.8 POM prescriptions with potential clinical consequences were modified weekly.

*Royal College of Surgeons in Ireland Student Medical Journal 2015;(8)1:14-18.*

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## Introduction

Medicines should be prescribed only when they are necessary, and in all cases the benefit of administering the medicine should be considered in relation to the risk involved; these guidelines are stated in the British National Formulary, as well as being common sense to practitioners.<sup>1</sup> Even so, large-scale studies in the US<sup>2</sup> and the UK<sup>3</sup> by the Institute of Medicine (IOM) and the UK General Medical Council (GMC), respectively, have shown that medication errors, the most common of which are prescribing errors,<sup>4</sup> are common in practice. Jeffrey Aronson, a clinical pharmacologist based in Oxford University, devised a method for classifying incorrect prescriptions as either faults or errors based on psychological theory. Aronson's definitions aim to explain errors rather than merely describing them.<sup>5</sup>

Prescribing faults concern the decision-making process in writing a prescription (e.g., dose too high or low, or drug allergy or contraindication), while prescription errors concern the act of writing the prescription (e.g., absence of drug strength or number of tablets).<sup>5</sup> Prescription modifications, on the other hand, are interventions that prevent error occurrence and can be made through contact with the doctor about a query, checking the patient's medication history, or interviewing the patient or their representative.<sup>6</sup> They are required when there is a reduction in the probability of treatment being timely and effective, or an increase in the risk of harm to the patient when compared to generally accepted practice.<sup>7</sup>

The 2012 PRACTiCe study carried out by the GMC found that one in 20 prescriptions contained a prescribing or monitoring error, affecting one in eight patients, with severe errors (a score greater than 7 on a scale numbered from zero to 10) found in one in 550 prescription items.<sup>3</sup> Another UK study, the 2009 EQUIP study, looked at the causes of prescribing errors by foundation trainee doctors, and reported a mean of 8.9 errors per 100 medication orders.<sup>8</sup> These proportions may be even higher in Ireland. In 2013, more than 20 million prescriptions were filled in Ireland for over 60 million medical items, including medicines and medical devices.<sup>9</sup> In 2009, Sayers *et al.* found that 12.4% (491) of the prescriptions written by 28 general practitioners in Galway and Donegal contained one or more prescribing errors.<sup>10</sup> Much of the Irish research available has concentrated on the incidence or prevalence of prescribing errors. Several of these have focused on errors more common in specific patient groups (e.g., patients over 65 years) or in certain therapeutic classes of drugs.<sup>11,12,13,14</sup> There is, however, a gap in the literature with regard to studies that simultaneously take into account patient-, drug- and prescriber-related factors that contribute to prescription modifications as a result of prescribing errors.

Large-scale studies have been conducted in the US, the Netherlands and the UK to assess community pharmacy interventions intended to reduce prescribing errors, but data in this field is lacking thus far in Ireland.<sup>6,15,16</sup> Such research will provide a fuller picture of the risk factors for prescribing errors and prescription modifications in an Irish context, which may lead to new strategies aimed at reduction.

## Methods

### Study design

A cross-sectional study was performed to examine prescriptions dispensed in a community pharmacy in Leinster over a period of five weeks in winter 2012. All prescriptions were included and each was checked for prescribing errors by the supervising pharmacist. This included medications, as well as other healthcare products such as diabetes test strips, bandages, and needles. Inclusion criteria were based on the need for prescription modification.<sup>7</sup> The following were excluded from modification because of their lack of potential impact on patient care: address incorrect or absent; medical scheme data incorrect or absent; incorrect package size; product not in stock; unit of dosage or package specified incorrectly (e.g., mL instead of g); generic substitution; or, legal prescription requirements (e.g., for controlled drugs). Where there were two or more reasons given for a modification, the most relevant reason was selected based on the highest risk of harm to the patient.

### Classification of prescription items

Prescribed items were classified according to guidelines set out in the Irish Medicinal Products Regulations, as prescription only medicines (POM), over-the-counter medicines (OTC) or non-medicines. All medicines were classified into therapeutic groups using the Anatomical Therapeutic Chemical (ATC) classification given by the WHO Collaborating Centre for Drug Statistics Methodology.<sup>17</sup> During the data management process, prescribing errors were divided into two groups as per Aronson: prescription errors and prescribing faults.<sup>5</sup>

### Data collection and analysis

Data collected from eligible prescriptions included: the date the prescription in question was dispensed by the pharmacy; the therapeutic group of the prescribed drug; the age and gender of the patient; a description of the nature of the prescription (printed or handwritten, POM, OTC medicine or non-medicine); a description of the prescriber (the patient's own GP or another physician); and, a description of the modification type, if any was made.

Descriptive statistics were used to determine the prevalence of POM modifications, and logistic regression was used to estimate the association between prescription characteristics and modification. Multivariate logistic analysis was then performed combining the significant univariate predictors, to determine their independence or otherwise.

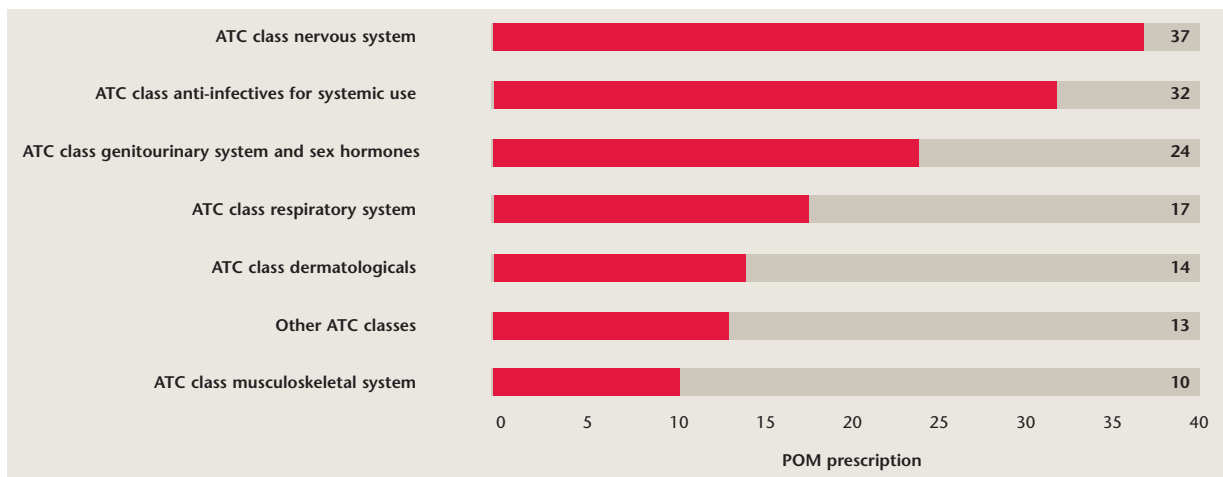
## Results

### Descriptive statistics

Over the five-week study period, 1,303 prescriptions were collected by the pharmacy and 66% (866) were analysed. Those excluded were collected on the days the supervising pharmacist was absent. Of the 866 prescriptions included, 17.8% (155) were modified, 94.8% (147) of which were due to

**Table 1: Analysis of prescriptions.**

	All prescriptions (n=866)	Modified prescriptions n (%) (n=155)	Non-modified prescriptions n (%) (n=711)
<b>Drug-related factors</b>			
Prescription only medicine (POM)	796 (92%)	147 (94.8%)	649 (91.2%)
Over-the-counter medicine (OTC)	42 (4.8%)	6 (3.9%)	36 (5.1%)
Non-medicine	28 (3.2%)	2 (1.3%)	26 (3.7%)
<b>Patient-related factors</b>			
Age, mean (SD)	43.01 (21.9)	40.15 (22.82)	43.64 (21.71)
Female	490 (56.6%)	99 (63.9%)	391 (55%)
<b>Prescriber-related factors</b>			
Handwritten prescriptions	263 (30.4%)	55 (35.5%)	208 (29.2%)
Own doctor/prescriber	725 (83.7%)	133 (85.8%)	592 (83.3%)



**FIGURE 1:** Therapeutic classes where POM modifications occurred with greater frequency.

POMs. The mean age of patients whose prescriptions required modification was 40.15 years and the majority were women (63.9%). Printed prescriptions accounted for 64.5% (100), while prescriptions written by the patient’s own doctor or prescriber accounted for 85.8% (133) (Table 1).

**Nature of prescription modifications**

The numbers of modified OTC (3.9%) and non-medicine prescriptions (1.3%) were too small for statistical analysis; as such, only POM modifications were considered further. POM modifications occurred with greater frequency in the following therapeutic classes: nervous system (ATC code N); anti-infectives for systemic use (ATC code J); genitourinary system and sex hormones (ATC code G); respiratory system (ATC code R); dermatologicals (ATC code D); and, musculoskeletal system (ATC code M) (Figure 1). The majority (87%; 128) of the POM

modifications concerned a prescription error where clarification of an insufficiently written prescription was needed (e.g., omitted drug dose), while the other 13% (19) were prescribing faults (e.g., dose too high). POM modifications after consultation with a patient or proxy, where the pharmacist identified a need for clarity, accounted for the greatest number of interventions. In 51% (75) of cases, the pharmacy consulted the patient or their proxy, either to clarify the doctor’s intentions or to establish their knowledge or need for additional medicines information. In 30% of cases (44), modifications of POM prescriptions were made after consultation with the prescriber or the prescriber’s assistant. These included instances where a drug was either out of stock or unavailable in Ireland, or where the strength or dose of a medicine was omitted. The remaining 19% (28) were made based on the patient’s medical history (e.g., where a contraindication/allergy was present).

**Table 2: Univariate and multivariate risk factors for prescription modification.**

	Univariate				Multivariate			
	Modified POM prescriptions (n=147, 100%)	Odds ratio (OR)	95% I (df)	p value	Modified POM prescriptions (n=147, 100%)	Odds ratio (OR)	95% I (df)	p value
<b>Drug related factors</b>								
ATC-code N	37 (25.2%)	1.098	0.762-1.578	0.619				
ATC-code J	32 (21.8%)	1.033	0.701-1.523	0.870				
ATC-code G	24 (16.3%)	3.691	2.255-6.042	<0.001	24 (16.3%)	3.531	2.095-5.952	<0.001
ATC-code R	17 (11.6%)	1.463	0.932-2.298	0.098				
ATC-code D	14 (9.5%)	1.169	0.646-2.116	0.606				
ATC-code M	10 (6.8%)	1.906	1.023-3.551	0.042	10 (6.8%)	2.408	1.248-4.645	0.009
<b>Patient-related factors</b>								
Age, mean (SD) (n=139)	39.6 (22.4)	0.993	0.985-1.001	0.081				
Female	99 (67.3%)	1.605	1.104-2.333	0.013	99 (67.3%)	1.595	1.073-2.372	0.021
<b>Prescriber-related factors</b>								
Handwritten	50 (34.0%)	1.247	0.855-1.818	0.253				
Own doctor/prescriber	125 (85.1%)	1.142	0.697-1.872	0.598				

**Univariate and multivariate risk factors for prescription modification**

Univariate analysis identified two therapeutic drug classes that exhibited significantly higher rates of POM modifications: the genito-urinary system and sex hormones therapeutic drug class (ATC code G), where modifications were almost three times more likely than in other therapeutic classes (OR=3.691, 95% CI [2.255-6.042], p<0.001), and the musculoskeletal system therapeutic class (ATC code M) (OR=1.906, 95% CI [1.023-3.551], p=0.042) (Table 2). Gender was also found to be a significant risk factor for POM modifications, with female patients significantly more likely to have their prescriptions modified (OR=1.605, 95% CI [1.104-2.333], p=0.013) than male patients. Multivariate analysis showed that these remained strong independent risk factors for POM modifications. Prescriber-related factors such as handwritten or typed prescriptions and the source of the prescription (patient’s own doctor/other prescriber) were not significant. This result was unusual but not unexpected, as low numbers of patients (16.2%; 141 of 866) in this study utilised a doctor or prescriber other than their own. Patient’s age was also not significant.

**Discussion**

In this study, the overall prevalence of prescription modifications was 17.9%. As a measure of modification rate this is very high, especially when compared to results reported in similar studies performed in the US, the Netherlands by Buurma *et al.*, and the UK. These reported modification rates of 3.8% (102) from 2,690 prescriptions, 4.3% (2014) from 47,374 prescriptions, and 0.75% (1,500) from 201,000 prescribed medical items, respectively.<sup>6,15,16</sup> Differences in national healthcare programmes – for example the use of electronic prescribing, which has been associated with much lower error rates than handwritten prescriptions<sup>18</sup> – in the US, the UK and the Netherlands, may partly account for this difference in modification rates. In this study, there were far fewer modifications

of prescribing faults than there were of prescription errors, meaning that the majority of modifications were of errors that were unlikely to cause patient harm. There was a 2.2% (19 of 866) modification rate when it came to these prescribing faults, representing a mean of 3.8 POM prescribing faults in the pharmacy per week. In contrast, there was a 14.8% modification rate for prescription errors, a mean of 25.6 POM prescription errors in the pharmacy per week.

Drugs from the nervous system therapeutic class made up the highest source of POM modifications in this study, which is consistent with previous studies such as Buurma *et al.*<sup>15</sup> However, these results differ with regard to finding significant associations between drugs in both the genitourinary system and sex hormones therapeutic drug class and POM modifications. Our findings regarding drugs in the genitourinary system and sex hormones therapeutic class (ATC code G) were unexpected, as our literature review did not flag this drug class. It is important to mention that the majority of modifications for this drug class concerned clarifications about directions for use, where they were either missing or incomplete.

One possible reason for the incompleteness of the dose directions may be due to patients being already familiar with how to use their medicines. In this regard, individual experience about what constitutes a prescribing error may also have had consequences on error detection in this study.

There was also a significant association between POM modifications and female gender. This was at odds with our literature review, where associations between gender and prescribing errors were either insignificant<sup>15</sup> or found to be higher in male patients.<sup>3,19</sup> A number of factors may account for this finding; for example, all concerned drugs in the genitourinary system and sex hormones therapeutic drug class in this study were oral contraceptives. However, multivariate analysis shows both gender and drugs with ATC code G to be independent variables.

We found that printed prescriptions had a reduced frequency of errors, consistent with results by Buurma *et al.*<sup>15</sup> Most of our (51%) POM modifications were made based on consultation with the patient or their proxy. In contrast, Warholak and Rupp reported that the majority (64.1%) of their modifications were made based on consultation with the prescriber.<sup>6</sup> The biggest limitation in this research was regarding study design. As the research was cross-sectional, causality could not be inferred. Also, our study was conducted in just one pharmacy and may not be generalisable to others. We found a mean prescribing error rate of 17.9 errors per 100 prescriptions, corresponding to an average of 31 prescribing errors per week; a comparatively higher rate than that reported in the GMC PRACtICE study and the EQUIP study,<sup>3,8</sup> but within the range (12.4-27%) that has been reported across various healthcare settings in Ireland.<sup>10,11,20</sup>

### Conclusion

The majority of prescribing errors modified in this study involved non-serious clerical errors. However, an average of 3.8 POM

prescriptions with potential clinical consequences were modified weekly. Most were resolved through consultation with the patient or their representative, or checking the patient's medical history, more so than through contact with the doctor or the prescriber.

This study is important because it is the first Irish article that shines a light on the little-acknowledged phenomenon of prescription modification. Patient factors like female gender, as well drug factors such as the therapeutic class of drugs (e.g., genitourinary and sex hormones therapeutic class and musculoskeletal therapeutic class) have implications for the probability of prescription modifications, which suggests that focus must be put on ways to mitigate errors arising from patients and prescriptions that fit that profile.

Pharmacists and community pharmacies play a pivotal role in preventing prescribing errors. This study also illustrates the critical role that patient involvement can play in the prescribing process with regard to harm prevention and improved compliance. Future research should build upon this study and explore modification boundaries that should be removed or installed to advance patient safety.

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