



Development and initial validation of a postal survey evaluation of community pharmacists' opinion regarding falsified (counterfeit) medicines in Hampshire (UK)

[Desarrollo y validación inicial de evaluación de la opinión de los farmacéuticos de la comunidad con respecto a los medicamentos falsificados en Hampshire (Reino Unido)]

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Abstract

Context: Falsified-medicines pose a worldwide problem to patients, healthcare professionals, pharmaceutical companies, and governments. Community pharmacists are usually the last points of contact with patients and can protect them by quarantining falsified medicines. Hence, their opinions are valuable in exploring how the profession can combat this.

Aims: To explore the opinion of pharmacists with respect to falsified medicines.

Methods: A postal survey was developed and distributed to 359 pharmacies via the local pharmaceutical committee in Hampshire, UK. Descriptive statistics and hypothesis testing was conducted. Hypothesis testing (95% CI, $\alpha = 0.05$) will be conducted to identify any gender differences, differences based on years of experience and differences based on number of working hours per week.

Results: A 14% response rate was achieved. Pharmacists surveyed believe that falsified-medicines pose a significant problem to the profession on a five-point Likert scale (4.02 ± 1.078). A pharmacist's intervention can prevent or disrupt the supply to patients (4.12 ± 0.824) and training courses can improve pharmacist's knowledge (4.06 ± 0.843). Pharmacists are not confident and capable in identifying falsified-medicines (2.62 ± 1.105). This is surprising and unexpected because pharmacists are medicines-expert. A 10-item scale is validated (72.2% Cronbach alpha).

Conclusions: Falsified-medicines pose a small but significant and growing challenge to the profession. There is underutilization of the high street community pharmacist in identifying falsified-medicines. Healthcare professionals should report suspect counterfeits to the MHRA.

Keywords: counterfeit medicines; falsified medicines; pharmacists; survey.

Resumen

Contexto: Los medicamentos falsificados representan un problema mundial para los pacientes, los profesionales de la salud, las compañías farmacéuticas y los gobiernos. Los farmacéuticos en oficina de farmacia son el punto primario de contacto con los pacientes y pueden protegerlos detectando falsificaciones. Por lo tanto, sus opiniones son valiosas para explorar cómo la profesión puede combatir este problema.

Objetivos: Explorar la opinión de los farmacéuticos con respecto a los medicamentos falsificados.

Métodos: Se desarrolló una encuesta postal y se distribuyó a 359 farmacias a través del comité farmacéutico local en Hampshire, Reino Unido. Se realizaron cálculos estadísticos para refutar la hipótesis. Se estableció una hipótesis (95% IC, $\alpha = 0.05$) con respecto a la identificación de medicamentos falsos, con diferencias basadas en años de experiencia y número de horas de trabajo por semana.

Resultados: La tasa de respuesta fue del 14%. Los farmacéuticos encuestados creen que los medicamentos falsificados representan un problema importante para la profesión en una escala de Likert de cinco puntos (4.02 ± 1.078). La intervención de un farmacéutico puede prevenir o interrumpir el suministro a los pacientes (4.12 ± 0.824) y los cursos de capacitación pueden mejorar el conocimiento del farmacéutico (4.06 ± 0.843). Los farmacéuticos se consideran con limitada capacidad de identificar medicamentos falsificados (2.62 ± 1.105). Este resultado contrasta con la experiencia y conocimientos que presentan con respecto a medicamentos. Se valida una escala de 10 ítems (72.2% alfa de Cronbach).

Conclusiones: Los medicamentos falsificados representan un problema creciente para la profesión. Hay una subutilización del farmacéutico de oficina de farmacia para identificar medicamentos falsificados. Los profesionales de la salud deben ser capaces de identificar y reportar falsificaciones sospechosas a los organismos correspondientes.

Palabras Clave: encuesta; medicamentos falsificados; farmacéuticos.

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INTRODUCTION

One of the greatest challenges facing the pharmaceutical industry today is the international trade in counterfeit drugs (Bunker, 2007). Falsified medicines pose a major threat to public health and safety. As falsifications become more sophisticated, the risk that falsified medicines reach patients in the UK and European Union (EU) increases every year. Falsified medicines represent a serious threat to global health and a comprehensive strategy is needed at both the European and international level (European Commission, 2016). Falsified medicines are problematic in both primary and secondary care. Falsified medicines and medical devices are a health risk to patients because they circumvent the rigorous quality standards required of legitimate manufacture (MHRA, n.d.). The current evidence-based for this study is weak as this is an understudied area. There is also limited amount of information on the extent and prevalence of this problem due to underreporting in the public space by government agencies.

Global spending on medicines is forecast to reach nearly \$1.3 trillion by 2018, an increase of about 30% (\$290-320 billion) over the 2013 level, driven by population growth, an aging population, and improved access in pharmerging countries (China, Brazil, India, Russia, Poland, Argentina, Turkey, Mexico, Venezuela, Romania, Saudi Arabia, Colombia, Vietnam, South Africa, Algeria, Thailand, Indonesia, Egypt, Pakistan, Nigeria, and Ukraine) markets (Global Outlook for Medicines Through, 2018). The prevalence of counterfeit medicines ranges from less than 1% of sales in developed countries, to over 10% in developing countries, depending on the geographical area (WHO, 2006). The European Commission estimate that counterfeiting in general, represents around 5–7% of world trade and as much as 15% of the global medicines supply chain could, at any time, be counterfeit (Feldschreiber, 2009). Counterfeit medicine seizures by custom officials within the EU increased 384% between 2005 and 2006, with a further 51% increase in 2007; detentions increased by 118% in 2008 (Jackson, 2012).

According to the Medicines, and Healthcare Products Regulatory Agency (MHRA), counterfeiters now also target the most lucrative markets, cop-

ying high-value, high-turnover, high-demand drugs (WHO, n.d.). UK is one of several countries targeted by counterfeiters because of the potential for huge profits in these markets (Jackson et al., 2012). A June 2015 MHRA report identified £15.8 million seizure in global operation targeting counterfeit and unlicensed medicines and devices (MHRA, 2015). Spurious online sale and supply of medicines also contributes to the growing danger of falsified medicines.

Before considering the various elements of the problem, the term “falsified medicines” should be defined. There is no universally agreed definition of counterfeit medicines and jurisdictions around the world define counterfeit medicines in many ways. The World Health Organization (WHO) currently uses the term Substandard, Spurious, Falsely labeled, Falsified and Counterfeit (SSFFC) medical product until a new definition is agreed upon (WHO, 2017). The WHO defines counterfeit medication as: “A counterfeit medicine is one which is deliberately and fraudulently mislabelled with respect to identity and/or source. Counterfeiting can apply to both branded and generic products and counterfeit products may include products with the correct ingredients or with the wrong ingredients, without active ingredients, with insufficient (inadequate quantities of ingredient(s) or with fake packaging”. The WHO is a specialized agency of the United Nations that is concerned with international public health (WHO, 1948).

In the UK, the MHRA (a government agency) attempts to raise awareness and prevent the supply of falsified medicines via campaigns, law enforcement and investigations. No specific definition of counterfeit medical product exists within English law and the MHRA adopts the definition contained within the European Falsified Medicines Directive (EFMD) (European Commission, 2016). This is stated as “Any medicinal product with a false representation of: a) its identity, including its packaging, and labeling, its name or its composition as regards any of the ingredients including excipients and the strength of those ingredients; b) its source, including its manufacturer, its country of manufacturing, its country of origin or its marketing authorization holder; or c) its history, including the records and documents relating to the distribution channels used. The definition

does not include unintentional quality defects and is without prejudice to infringements of intellectual property rights" (MHRA, 2012).

'Falsified medicines' and 'counterfeit medicines' are terms used to address the deliberate imitation of authentic medicine. This study will use the latter definition as adopted by the MHRA.

UK community pharmacists are the final link in the supply chain to the patient, and therefore pharmacist's awareness and understanding of falsified medicines play a crucial role in combating this problem. Gaps in the current literature include documentation of pharmacist's opinion and current practice regarding falsified medicines in the UK. This provides an opportunity to explore the pharmacist's role in detecting and responding to counterfeit medication.

This study explores the opinion of practicing pharmacists regarding falsified medicines.

Hypothesis testing (95% CI, $\alpha = 0.05$) will be conducted to identify any gender differences, any differences based on years of registered experience and any differences based on number of working hours per week.

MATERIAL AND METHODS

Literature review

The following terms were used individually or in combination to support the literature review conducted on 7 November 2017: [(pharmacists) AND counterfeit medicines] AND falsified medicines in PubMed. Doctoral theses were also searched. Three articles were identified, which were unrelated to the aims of this study. Further hand searching was conducted on the PubMed Central® (PMC) database.

Due regard has been given to the cultural variations in adapting these studies. Other studies proved inappropriate for inclusion due to their focus on authentication technologies, significant geographical, political, economic, and cultural differences.

Ethics approval

University of Portsmouth, School of Pharmacy and Biomedical Sciences Ethics Committee approved this study (Reference number: 08.2016,

06.12.2016) using the Hampshire local pharmaceutical committee (LPC) list to invite recruitment. The UK Research Integrity Office checklist has been used to ensure good practice in research for this study (UKRIO Recommended Checklist for Researchers, n.d.).

Survey questionnaire development

Two research articles provided the foundation for development of the survey questionnaire (Law and Youmans, 2011; Shahverdi et al., 2012). Some statements from these surveys were adapted for this study and are clearly referenced. This study team inserted additional statements. The final instrument contained 11 statements (Table 1) with a 5-point Likert scale (strongly agree, agree, uncertain, disagree, and strongly disagree).

Questionnaire validation (pretesting)

The researchers critically appraised the scale in a research-team focus-group. This comprised two external practicing community pharmacists, supporting academics with recent community and hospital practice experience and student members. Necessary changes and improvements were made. This allowed for detection and deletion of ambiguous words, misinterpretation of questions, poor questions, and sensitive questions. Amendments and improvements were made to the format, structure, and content. It took less than 10 minutes to complete the final survey.

Participants recruitment

Pre-registration and registered pharmacists working in community pharmacy in Hampshire, UK were invited to recruitment. This included all pharmacists in Portsmouth, Southampton, and the Isle of Wight (n=359) on the LPC list.

The postal package was addressed to 'the pharmacist'. It included the survey scale, a participant information sheet (PIS) and a pre-paid self-addressed envelope. No personally-identifiable information was requested or provided, and anonymity and confidentiality were maintained throughout the study. All research data was stored in locked cupboards in locked offices and maintained securely on password protected university encrypted computers.

Informed consent was assumed once the questionnaire was completed and returned. The use of anonymous results for publication was made clear. Responses were invited between December, 2016 –

January, 2017. Withdrawal would prove difficult as no personally-identifiable data was collected and this was clearly stated in the PIS.

Table 1. Survey instrument. Summary of scale results.

Statement	N	Results (%)					Likert scale	
		Strongly disagree	Disagree	Uncertain	Agree	Strongly agree	Mean	SD
1 Falsified medicines pose a significant problem to the pharmacy profession	50	2	10	14	32	42	4.02	1.078
2 Lack of knowledge is a barrier for detecting the presence of falsified medicines	50	2	6	8	44	40	4.14	0.948
3 Lack of resources is a barrier for detecting the presence of falsified medicines	50	2	12	12	38	36	3.94	1.077
4 The dispensing pharmacist retains highest liability when falsified medicines reach patients	50	6	22	26	18	28	3.40	1.278
5 A pharmacist's intervention can prevent or disrupt the supply of falsified medicines to patients	50	0	2	22	38	38	4.12	0.824
6 Training courses can improve pharmacist's knowledge regarding falsified medicines	50	0	6	14	48	32	4.06	0.843
7 Listening to patients could help identify falsified medicines	49	4	10	22	44	18	3.63	1.035
8 The majority of my fellow pharmacists in the UK are confident regarding falsified medicines	50	8	24	58	6	4	2.74	0.853
9 I'm confident and capable in identifying falsified medicines	50	16	32	32	14	6	2.62	1.105
10 I'm constantly vigilant of encountering falsified medicines when checking prescriptions	50	6	36	20	24	14	3.04	1.195
11 I have enough knowledge to identify falsified medicines	50	16	32	22	24	6	2.72	1.179

Descriptive Statistics on Likert-scale (1=Strongly Disagree, 2=Disagree, 3=Uncertain, 4=Agree, 5=Strongly Agree). DS: Standard deviation.

Statistical analysis

Statistical Package for the Social Sciences (SPSS) was used to analyze the quantitative data (IBM Corp, 2014). Descriptive statistics was used to summarize and describe the data. Hypothesis testing was used to draw comparisons and establish relationships using variables such as gender, years of registration, and working hours per week. Non-parametric tests were used to accept or reject hypotheses at 95% confidence interval ($\alpha = 0.05$).

RESULTS

A low response rate of 14% (50 out of 359) was achieved which may be due to data collection over the busiest annual winter festive season. 'Missing' responses are clearly stated.

Questions 1 to 4 asked respondents about their gender, sector of work, number of registration years and working hours per week respectively. Table 2 summarize this demographics data.

Table 2. Pharmacists' gender and experience.

Gender	% (n)	Number of years of registration (years)					
		Pre-reg.	0 - 1	2 - 3	4 - 5	6 - 7	8+
Male	42% (n=21)	1	2	2	1	1	14
Female	58% (n=29)	1	4	4	4	2	14
n	50	2	6	6	5	3	28
Total (%)	100	4	12	12	10	6	56

Demographic data

Males (21, 42%) and females (29, 58%) participate which accurately describes gender distribution within the UK pharmacy population (CfWI, 2013). All participants worked in community only, except for one (community and hospital). Most respondents were registered for 8 or more years, indicating they are experienced pharmacists. Most respondents worked 35-44 hours a week (mean 36.84 hours, SD 8.867), however more males worked 45-54 hours a week. This study shows both sexes work longer hours (Seston and Hassell, 2009).

Pharmacists' opinion of falsified medicines

Respondents were asked to rate the below statements on a 5-point Likert-scale (Strongly Disagree, Disagree, Uncertain, Agree, Strongly Agree). This data is summarized in Table 1.

In this study, 74% of respondents believed that 'falsified medicines posed a significant problem to the profession' (Statement 1) *versus* the California study, where 59.3% believed it (Law and Youmans, 2011).

In this study, 84% of respondents believed that a 'lack of knowledge is a barrier for detecting the presence of falsified medicines' (statement 2). This may indicate shortcomings in available pharmacy courses or education.

'Lack of resources is a barrier for detecting the presence of falsified medicines' (statement 3) was identified by 74% of respondents (36% strongly agreed and 38% agreed) *versus* 82.5% in the California study (29.2% strongly agreed and 53.3% agreed). The lack of resources or skills to detect counterfeit medicines has contributed in difficulty measuring the extent of the problem in many settings (WHO, 2010).

'The dispensing pharmacist retains highest liability when falsified medicines reach patients' (statement 4) was supported by 46% of respondents (28% disagree, 26% uncertain). Approximately half of the respondents felt they owed a duty of care to the individual patient. The balance of respondents may believe that the responsibility should be shared between various groups, such as other healthcare professionals, regulatory bodies, and the government. The largest standard deviation (1.28), indicates a wide spread of opinion.

'A pharmacist's intervention can prevent or disrupt the supply of falsified medicines to patients' (statement 5) was supported by 76% of respondents. This has a narrow standard deviation (0.824) indicating consensus around 'Agree'. As pharmacists are usually the last point of contact with patients in the UK, the respondents may feel that they can prevent falsified medicines reaching the public.

'Training courses can improve pharmacist's knowledge regarding falsified medicines' (statement 6) was supported by 80% of respondents with a narrow standard deviation (0.824) indicating consensus around 'Agree'.

'Listening to patients could help identify falsified medicines' (statement 7) was supported by 62% of respondents. Listening to patients' comments on clinical changes with a new batch of their medicines may help combat counterfeiting (Wright and Nicholson, 2009). Counterfeit medicines are often first detected by patients and therefore it's important to listen to them (MHPRA, Royal Pharmaceutical Society, & Dispensing Doctors' Association, n.d.).

'The majority of my fellow pharmacists in the UK are confident regarding falsified medicines' (statement 8) The majority (58%) of respondents are un-

certain about this statement, indicating that their colleagues might be just as 'lost' as they are. Similarly, consensus around 'disagree' with an SD of 0.853.

'I'm confident and capable in identifying falsified medicines' (statement 9) was supported by only 20% of respondents. Surprisingly, this statement has a higher SD than statement 8. This still indicates a majority opinion of 'disagree' but reveals a self-effacing bias (i.e. respondent believes others are more capable) with only a few respondents having a self-serving bias.

'I'm constantly vigilant to encountering falsified medicines when checking prescriptions' (statement 10) was supported by 38% of respondents, with 42% disagreeing with it. Overall the mean settles at 'uncertain', with the second largest SD spread around the mean.

'I have enough knowledge to identify falsified medicines' (statement 11) was supported by 30% of respondents, indicating that 48% of respondents did not believe that they have enough knowledge to identify falsified medicines. This suggests that pharmacists are underprepared when it comes to encountering counterfeit medicines.

The original 11 item scale had a Cronbach's alpha (a measure of internal consistency and reliability) of 69.4%. However, after running a bivariate Pearson correlation on the scale, two items (statement 2 and 3) were found to correlate by 0.768 indicating that they were measuring the same facet of construct. Hence by deleting statement 2, the empirical value of the scale was improved, which in turn improved the Cronbach's alpha to 72.2% (Cronbach's alpha based on standardized items 72.8%). A Cronbach's alpha above 70% indicates a 'good' internal consistency and reliability of the scale. This validates collectively the scale.

Hypothesis testing was done. Null hypothesis assumed that 'gender' made no difference in pharmacist confidence and capability. A significant difference ($p = 0.039$ Mann-Whitney U test) was found to statement 9: 38% of male respondents felt more confident and capable compared to 6.4% of female respondents. This could be a source of gender bias.

Similarly, the researcher hypothesized that work experience made no difference to the pharmacist's ability to make an intervention. A significant differ-

ence ($p = 0.017$ Kruskal-Wallis test) was found: Experienced pharmacists seem to 'agree strongly' with statement 5, indicating pharmacist's experience can disrupt the supply of falsified medicines.

Similarly, the researcher hypothesized that number of working hours per week made no difference to the pharmacist's ability to make an intervention. A significant difference was found to statement 5 ($p = 0.035$ Kruskal-Wallis test) where it examined perspectives regarding pharmacists' intervention that can prevent or disrupt the supply of falsified medicines. Those working 35-44 h were the smallest group that agreed (52.4%) compared to other working contracts. This indicates that full-time, experienced pharmacists were more confident in their ability to detect and disrupt the supply of falsified medicines.

DISCUSSION

Due to the limited information on UK pharmacist's opinion on falsified medications, results from the cross-sectional survey provide a unique perspective and extend the understanding of how practicing community pharmacists deal with these circumstances. However, a low response rate of 14% and a small sample size ($n=50$) may limit the generalizability of the study findings. However, this provides an up-to-date snapshot of the current pharmacy practice with respect to falsified medicines, which is under represented in the literature.

A total of 74% of respondents believed that falsified medicines pose a significant problem to the profession. Pharmacists are in the unique position of being the last line of defense in identifying counterfeit medications. Pharmacists already ensure that they order medications from legitimate sources, however, vigilance is always necessary. Possibly educating their patients on the risk of purchasing online medicines from unknown/disreputable sellers could be a solution. Evidence and experience shows that patients trust their pharmacists and are compelled to ask questions when their medications appear different. As an example, in a 2004 survey of patients that queried their knowledge of counterfeit medications, most patients (64%) said they would tell a pharmacist if they suspected they received or purchased a counterfeit drug (National Consumers League, 2004).

It is unknown how many pharmacists can properly recognize physical differences of counterfeit medications and whether they have adequate resources to help them overcome this barrier. A total of 84% of respondents believe the 'lack of knowledge is a barrier' and that 74% believe that a 'lack of resources is a barrier for detecting the presence of falsified medicines'. Many resources are available for medication identification (often used by specialist pharmacists in medicines information in major hospitals and pharmaceutical companies), but not all pharmacists may have access to these resources. In the UK, National Health Service (NHS) medicines information can help with these queries. The 'lack of resources' may indicate little or no governance consideration by commercial, nationwide, pharmacy chains or independent pharmacies. Simultaneously, the incentives to address this statistically improbable event is low for such commercial entities. Equally, it may be the case that individual respondents are not aware of the latest MHRA guidance regarding counterfeit medicines, medicines recall, updates to practice advice, licensing changes, etc. Nonetheless, the prevalence of falsified medicines is on the rise.

This study also found that 76% strongly agreed or agreed that pharmacist's intervention could prevent falsified medicines from reaching the patient. Therefore, providing some basic training could assist pharmacists in this vein. Training courses were also identified (80%) as a knowledge store to assist pharmacists in mitigating this risk. Pharmacy students and schools of pharmacies could provide such training, perhaps via collaborations with national pharmacy organizations and patient-safety agencies. Pharmacists should also be encouraged to subscribe to the MHRA updates as a cost-free alternative to get current up-to-date information.

CONCLUSIONS

The study found that falsified medicines pose a small but significant and growing challenge to the pharmacy profession. It also found that respondents believe that a lack of resources is a barrier in combating this problem. From the results, there is underutilization of the high street community pharmacists in identify falsified medications. Most community pharmacists agreed that a pharmacist's

intervention and their interaction with (listening to) patients may help in combating falsified medicines.

Improving pharmacist's knowledge regarding falsified medicines via education programs such as continuing education could be developed. Healthcare professionals should report suspected cases of counterfeit medication to the MHRA and be alert to threats to the medicine supply chain.

CONFLICT OF INTEREST

The authors declare no conflict of interest.

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Contribution	Barrett R	Al-Mousawi HA
Concepts or ideas	X	X
Design	X	X
Definition of intellectual content	X	X
Literature search	X	X
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Data analysis	X	X
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