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An evaluation of community pharmacists' perception of falsified medicines: An English cross-sectional survey.

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Keywords:

counterfeit drugs; falsified medicines; pharmacists; survey; public health; pharmacy; spatial analysis; medicine quality; procurement; substandard medicine

Abstract

Objectives: To evaluate perceptions and readiness to implement the European Falsified Medicines Directive (FMD) by 9 February 2019 by community pharmacists in England.

Setting: Community pharmacies from a single national chain.

Participants: We invited pharmacists from 501 pharmacies that contribute to the NHS Business Services Authority dispensing data across England to complete a survey. Non-NHS contractors, non-pharmacists or pharmacists practicing abroad were excluded. We selected them from a single national pharmacy chain, ensuring they were nationally representative.

Interventions: We conducted a mail shot with a single follow-up of non-responders from October 2018 to April 2019. Respondents were invited to provide self-reported answers. A prepaid self-addressed envelope was provided. We received favourable institutional ethical approval.

Results: 102 responses were received (95% confidence interval). Readiness to implement the directive was poor: 40 (39.2%) said not at all, 29 (28.4%) said not really (P<0.000 One sample chi square test). None had been involved in any public health campaigns regarding falsified medicines. Six (5.9%) had used the Yellow Card Scheme for this purpose (P<0.000 One sample binomial test). Five (4.9%) had identified falsified medicines, but only three (2.9%) had informed the national competent agency (P<0.000 One sample binomial test). Forty-seven comments were received on ways to reduce falsified medicines reaching the public. Thirty-seven comments were received on the role pharmacists can play in combating falsified medicines. Geospatial analysis shows pharmacists in deprived areas identified more falsified medicines.

Conclusions:
English pharmacists are not ready to implement FMD, potentially not capturing anticipated benefits of the directive, with greatest risk of harm in deprived area. Impact on workload and profitability were areas of concern, though improve patient safety was anticipated. We further validated a scale. Limited public health campaigns may result in a lack of awareness amongst pharmacy professionals and patients. Limited awareness of technologies to identify falsified medicines exist, though further training is welcome. A worrying trend of underreporting maybe prevalent. A larger sample study using this survey would be valuable.

Article Summary

- This study is needed because it seeks to understand the challenges faced by community pharmacists in implementing the Falsified Medicines Directive (FMD).
- We for the first time, evaluated experiences and perceptions of community pharmacists on falsified medicines in England.
- We for the first time, examined association with geospatial location and Index of Multiple Deprivation (IMD) score to assess in the context of deprivation.
- We report on a nationally representative sample examining readiness to implement FMD in England.
- Low respondent numbers and some missing information may make our findings unreliable.

3741 words

Introduction.

There is no universally agreed definition of counterfeit/falsified medication and jurisdictions around the world define these types of medicines in many different ways. The World Health Organization (WHO) identifies 'Substandard and Falsified (SF) Medical Products'(1,2) that demonstrate public harm (3). The European Union (EU) has a strong legal framework for the licensing, manufacturing and distribution of medicines supported by the EU Member States in implementing the falsified medicines Directive (4,5). At writing, the UK remains an EU member state. At the end of the distribution chain, only licensed pharmacies and approved retailers are allowed to offer medicines for sale, including legitimate sale via the internet (6,7).

No specific definition of counterfeit medical product exists within English law and the national competent agency (The Medicines and Healthcare products Regulatory Agency (MHRA)) adopts the definition contained within the European Falsified Medicines Directive (FMD) and has provided guidance on its implementation. The final part of the Directive, the 'safety features' Delegated Regulation (EU) 2016/161 comes into force on 9 February 2019 in the UK (8).

Falsified medicines and medical devices are problematic in both primary and secondary care as they are not subject to the rigorous quality standards and can create difficulty in identifying sources of contamination and public harm. The parallel import system in the EU also permit legitimate movement of medicines through the supply chain over large geographic territories, which is susceptible to infiltration by SF medicines.

Pharmacist's ability to identify SF medication can help in thwarting public harm alongside implementation of the FMD. No studies of English pharmacist's experiences of implementing FMD exist.

This study is needed because it seeks to understand the challenges faced by the healthcare team caring for NHS patients and other under pressure models of care in the Western world. Challenges include: growing patient demand, changing patterns of demand, insufficient funding in primary care, reduced access to GPs and addressing national health inequalities.

Objectives

The primary objective of this study is to evaluate perceptions and the readiness to implement FMD by 9 February 2019 by community pharmacists in England.. Secondary objectives are to use this data to examine its association with geospatial location and Index of Multiple Deprivation (IMD) score and to understand the cognitive and behavioural mechanisms underlying it.

Methods

We invited pharmacists from 501 pharmacies that contribute to the NHS Business Services Authority (BSA) dispensing data across England to complete a survey. Community pharmacies that are not NHS contractors, non-pharmacists or pharmacists practicing abroad were excluded. Addresses were taken from publicly available BSA website to gain a nationally representative sample. We selected them by a single national pharmacy chain, ensuring they were nationally representative with respect to the number of prescription forms (sample mean 5355, SD 2044 versus population mean 4895, SD

2630) and number of prescription items dispensed (sample mean 10817, SD 4611 versus population mean 9875, SD 5480). This permits comparison with like for like businesses (approximately equal burden of work, similar team size, and similar business complexity) across the country, therefore allowing fair comparison between pharmacies invited to study and the wider pharmacy population.

We conducted a mail shot with a single follow-up of non-responders from October 2018 to April 2019. Respondents were invited to provide self-reported answers. A prepaid self-addressed envelope was provided. We sought and received favourable institutional ethical approval. No financial (or similar) benefits were offered to minimise biased responses. A previously validated scale (9) was incorporated in this survey (see Appendix A).

There are 11,619 community pharmacies in England in 2017-18 (10). Assuming confidence level of 95%, confidence interval of 10%, a sample size of 95 is calculated. To achieve this, we invited 501 pharmacies as response ranges between 15% to 25% in similar studies (9,11,12). Analyses were undertaken using SPSS v 25 (13) to present proportions, descriptive statistics and hypothesis testing at 95% CI and 5% significance. Comments are thematically analysed.

Postcodes of pharmacies were linked with freely available data on IMD score (14), an estimate of the socioeconomic deprivation of the practice population and NHS dispensing data (15). We mapped our results using Arc GIS online (https://arcg.is/0q1mGf , legend: Yellow dot, red dot and green dot represents those who are somewhat or very much ready to implement FMD by the 9th Feb 2019, who said FMD would affect workload and those who said FMD would affect business profitability respectively. Orange dot represents those who had used the Yellow Card Scheme (YCS) for reporting SF, blue dot represents those who had ever identified SF and green dot represents all respondents). We created an app with several layers to visualize the data easily, freely and publically: https://portuni.maps.arcgis.com/apps/webappviewer/index.html?id=95497aeae0cf4411abd8433d736b8989

We mapped our responses alongside the IMD 2015 data (Ranks: every postcode has a rank from 1, which is the most deprived area up to 32,844 that is the least deprived area. Deciles are published alongside ranks to assess relative deprivation and we have used these).

At the end of our survey, we included brief guidance on reporting Counterfeit Products via the YCS (https://yellowcard.mhra.gov.uk/counterfeit-products/) operated by the MHRA. Participants can complete a two-page form to report a suspected counterfeit product (fake medicine or fake medical device) including any related side effects or safety concerns to the YCS. Participants can register on the Yellow Card reporting site when submitting a report, or can register in advance. Alternatively, participants can report a suspected counterfeit anonymously by contacting the 24-hour counterfeit hotline telephone number on 020 3080 6701.

Results

In total, 102 responses (20.44% response rate) were received (two closures and abatements), satisfying sample size needs. Higher response rates can be achieved with incentives, but may introduce bias. Demographic data are summarized in table 1.

Variables	**Respondent Frequency (Percentage) (n=102), p-value**
Sex	P<0.000 One sample chi square test
Male	46 (45.1)

Female	51 (50.0)
Preferred not to say	5 (4.9)
Years of registration experience	P<0.000 One sample chi square test
0-5	37 (36.3)
6-10	26 (25.5)
11-15	20 (19.6)
16-20	1 (1.0)
> 20 years	18 (17.6)
Working Hours (Per Week)	P<0.000 One sample chi square test
16 – 24	3 (2.9)
25 – 34	10 (9.8)
35 – 44	77 (75.5)
45 – 54	12 (11.8)

Table 1 Response frequency.

The deadline for full implementation is 9 February 2019. This requires every prescription only medicine and some pharmacy medicines to be scanned at point of dispensing (to check against a central database that they are not falsified, recalled or expired) at community pharmacy level across the EU, before supplying to the patients. We enquired how ready respondents were to implement this. 40 (39.2%) said not at all, 29 (28.4%) said not really, 14 (13.7%) were undecided, 12 (11.8%) said somewhat and 4 (3.9%) said very much, 3 (2.9%) missing, P<0.000 One sample chi square test.

We enquired if adequate equipment and expenses were prepared (e.g. computer terminals, scanners, compliance software, include initial set-up, IT, both software and hardware, plus ongoing operational costs). Twenty-two (21.6%) said not at all, 26 (25.5%) said not really, 12 (11.8%) were undecided, 31 (30.4%) said somewhat and 11 (10.8%) said very much, P<0.000 One sample chi square test.

We enquired how this affected workload: with Seven (6.9%) said not at all, 10 (9.8%) said not really, 24 (23.5%) were undecided, 35 (34.3%) said somewhat 26 (25.5%) said very much, P<0.000 One sample chi square test. A follow-on of how this affected profitability revealed 10 (9.8%) said not at all profitable, 13 (12.7%) said not really profitable, 65 (63.7%) were undecided, 9 (8.8%) said somewhat profitable, 4 (3.9%) said very much profitable, 1 (1.0%) missing, P<0.000 One sample chi square test. A further follow-on of how this affected patient safety showed 4 (3.9%) said does not improve patient safety, 14 (13.7%) were undecided, 41 (40.2%) said somewhat improves patient safety, 38 (37.3%) said very much improves patient safety, 5 (4.9%) missing, P<0.000 One sample chi square test.

We then enquired what percentage of medicines are believed to be falsified in the UK. Thirty-three (32.4%) said <1%, 33 (32.4%) said 1 - 5%, 20 (19.6%) said 6 - 10%, 12 (11.8%) said 11 - 20%, 2 (2.0%) said >21%, 2 (2.0%) missing, P<0.000 One sample chi square test. A follow-on of what percentage of medicines are believed to be falsified from online suppliers: 23 (22.5%) said 0 – 20%, 27 (26.5%) said 21 – 40%, 31 (30.4%) said 41 – 60%, 17 (16.7%) said 61 – 80%, 4 (3.9%) said 81-100%, P<0.000 One sample chi square test.

We enquired about the most likely sources of falsified medicine: 59 (56.2%) said Internet pharmacies, 21 (20.0%) said Personal Importation, 23 (21.9%) said professional falsifier, 2 (1.9%) said

'other' (of which 1 did not elaborate and another said "including illegal websites"), 1 missing. Three respondents gave combination-answers [first said Internet pharmacies & Professional falsifier, second said Internet pharmacies, Professional falsifier & other and third said Internet pharmacies & Personal Importation].

We asked what were the most commonly falsified medicines in the UK and invited multiple responses. 7 said Anti-cholesterol , 5 said Cancer , 77 said Erectile dysfunction , 5 said Heart problems , 32 said Weight loss, 6 said other (benzodiazepines, painkillers, anabolic steroids), 2 missing.

We asked what would raise suspicious of an SF. Forty said Different distribution route ,40 said Different labelling , 87 said Different packaging to original packaging, 26 said Different product composition (e.g. ingredients including excipients), 50 Different source (e.g. different manufacturer or country of origin), 3 said 'other' with reasons including cost, foreign text and medicine's appearance.

We enquired which national agency would they contact, if any. Nine *said Department of Health (DoH), 17 said European Medicines Agency (EMA), 7 said Royal Pharmaceutical Society (RPS), 74 said Medicines Healthcare Products Regulator y Agency (MHRA), 15 said General Pharmaceutical Council (GPhC) and 3 said 'other', with reasons including "Head office for advice, then appropriate agency", "company head office" and "[name] support office".*

Then we sought strength of opinion on a validated scale (9) on community pharmacists' opinion regarding falsified medicines, presented in table 2. We have also presented our and previously validated means and standard deviations to assess validity of our results and their relative difference. It is important to note that the scales was originally validated in a smaller sample (n=50) within the Hampshire, UK location.

For each of the statements below, tick the response that best characterises how you feel about the statement.	Strongly Disagree (coded as 1)	Disagree (coded as 2)	Uncertain (coded as 3)	Agree (coded as 4)	Strongly Agree (coded as 5)	Missing	Mean (current study, n=101)	Std. Deviation (current study, n=101)	Mean (initial scale, n=50)	Std. Deviation (initial scale, n=50)	Mean difference	SD difference
	n (%)	**n (%)**	**n (%)**	**n (%)**	**n (%)**	**n (%)**						
16. Falsified medicines pose a significant problem to the pharmacy profession	3, 2.9	10,	15, 14.7	40,	33,	1 (1.0	3.89	1.067	4.02	1.078	0.13	0.011

		9.8		39.2	32.4	%)						
17. Lack of knowledge is a barrier for detecting the presence of falsified medicines	0, 0	5, 4.9	8, 7.8	58, 56.9	30, 29.4	1, 1.0	4.12	0.752	4.14	0.948	0.02	0.196
18. Lack of resources is a barrier for detecting the presence of falsified medicines	0, 0	7, 6.9	7, 6.9	56, 54.9	31, 30.4	1, 1.0	4.1	0.806	3.94	1.077	-0.16	0.271
19. The dispensing pharmacist retains highest liability when falsified medicines reach patients	6, 5.9	24, 23.5	20, 19.6	22, 21.6	29, 28.4	1, 1.0	3.44	1.292	3.4	1.278	-0.04	-0.014
20. A pharmacists intervention can prevent or disrupt the supply of falsified medicines to patients	1, 1.0	3, 2.9	12, 11.8	54, 52.9	30, 29.4	2, 2.0	4.09	0.793	4.12	0.824	0.03	0.031
21. Training courses can improve pharmacists knowledge regarding falsified medicines	1, 1.0	1, 1.0	11, 10.8	48, 47.1	40, 39.2	1, 1.0	4.24	0.764	4.06	0.843	-0.18	0.079
22. Listening to patients could help identify falsified medicines	2, 2.0	15, 14.7	31,30.4	32, 31.4	21, 20.6	1, 1.0	3.54	1.044	3.63	1.035	0.09	-0.009
23. The majority of my fellow pharmacists in the UK are confident regarding falsified medicines	18, 17.6	43, 42.2	33,32.4	4, 3.9	3, 2.9	1, 1.0	2.32	0.916	2.74	0.853	0.42	-0.063
24. I'm confident and capable in identifying falsified medicines	18, 17.6	38, 37.3	29,28.4	14, 13.7	2, 2.0	1, 1.0	2.45	1.005	2.62	1.105	0.17	0.1
25. I'm constantly vigilant of encountering falsified medicines when checking prescriptions	12, 11.8	36, 35.3	22,21.6	25, 24.5	6, 5.9	1, 1.0	2.77	1.13	3.04	1.195	0.27	0.065
26. I have enough knowledge to identify falsified medicines	19, 18.6	39, 38.2	31,30.4	10, 9.8	2, 2.0	1, 1.0	2.38	0.968	2.72	1.179	0.34	0.211

Table 2 validated scale on community pharmacist's opinion regarding falsified medicines (P<0.000 One sample chi square test for all statements).

Our study provides further face validity to the scales (table 2), in a nationally representative sample.

None had been involved in any campaigns regarding SF, 91 (89.2%) said no, 11 (10.8%) missing. No campaign was named, though, 8 (7.8%) believed that the campaigns they encountered were effective, while 42 (41.2%) did not, 52 (51.0%) missing, P<0.000 One sample binomial test.

Six (5.9%) had ever used the YCS for SF, 84 (82.4%) had not, 12 (11.8%) missing, P<0.000 One sample binomial test. Thirty-seven (36.3%) said yes this scheme is useful in combating SF, 34 (33.3%) said no, 31 (30.4%) missing.

To try and corroborate our findings to a nationally representative sample, we separately placed a Freedom of Information Request (FOI) with the MHRA in October 2018 to request data regarding UK suspected Adverse Drug Reactions (ADRs) that have been reported with suspected counterfeit or SF (Query ref: GENQ-00131558).
Where a patient has experienced a suspected ADR to a medicine, even if the medicine is suspected to be counterfeit or falsified, this is recorded on their database. The MHRA has received a total of 70 UK spontaneous suspected ADR reports associated with SF for the period 01/07/1963 – 09/10/2018 (these include reports that suspect SF).

Three (2.9%) had seen the 'Postcard Guidance for Patients'(16) leaflet, 88 (86.3%) had not, 11 (10.8%) missing, P<0.000 One sample binomial test. Fourteen (13.7%) were aware of technologies in place to identify SF, 76 (74.5%) were not, 12 (11.8%) missing, P<0.000 One sample binomial test. Technologies quoted in 11 comments presented two themes of barcode scanning and hologram use, 91 missing. Thirty-six (35.3%) believed technologies were effective in combating SF, 28 (27.5%) did not, 38 (37.3%) missing. Three (2.9%) had received any training regarding SF, 88 (86.3%) had not, 11 (10.8%) missing, P<0.000 One sample binomial test. Seventy (68.6%) would participate in such training, 13 (12.7%) would not, 19 (18.6%) missing, P<0.000 One sample binomial test.

Five (4.9%) had identified SF, 86 (84.3%) had never, 11 (10.8%) missing, P<0.000 One sample binomial test. In such circumstance, three (2.9%) informed the MHRA and five explanatory comments received: "Patient didn't want to report it she bought it from online pharmacy, I would contact MHRA" (not reported to MHRA). "It was bought in by a patient who had bought it from a friend and wanted to check if it was genuine. Advised not to take" (not reported to MHRA). "Referred patient back to where they purchased it" (not reported to MHRA). "Yellow card" and "Melatonin" were both reported to MHRA.

Twenty-one (20.6%) kept records when encountering potential SF, 56 (54.9%) did not, 25 (24.5%) missing, P<0.000 One sample binomial test. Eight participants who kept records, went on to elaborate with comments (major theme of recording and reporting): "If we came across any on our [propritary] system", "Reporting on company system", "Online reporting tools of pharmacy events", "I would keep records", "In store records", "Hypothetically POM register, internal reporting system and Yellow card", "Details of the medicine, Name, manufacturer, distributor, strength, form", "Incident report sent online to headquarters"

We enquired how to reduce SF reaching the public. Forty-seven comments were received with the following major themes were: no idea, public education, regulatory control (with a sub theme of regulated online sales), supply chain, track & trace, training. Some illustrative comments: *"QC should be the watchword, enlightening the public to buy medicines only from approved pharmacy and use less internet pharmacies", "Reducing online sale of medicine or be more vigilant", "Government responsible to prevent if flow into the market either from Internet/EU imported medicines", "Impetus on suppliers and audit - award levels based on compliance (gold, silver, bronze et cetera)", "I think this should be the role of the manufacturers and wholesalers not pharmacists", "Verify medicines at every step of distribution from original source. Have one system only (very difficult to achieve)", "Each medicine box have unique code which keeps a history of where it has been and which can be viewed", "Public campaigns to raise awareness, training for pharmacists to be more confident to educate or give information to patients".*

Thirty-seven comments were received on the role pharmacists can play in combating SF. The major themes included to build checks into the accuracy checking process, by education, training and public awareness, that it was not the pharmacist's role but a regulators job, buy from reputable sources, have adequate resources, be vigilant and act on it. Some comments: *"If there was a procedure in place it would be part of dispensing procedure otherwise little time", "Embrace training and procedures, order through authorised suppliers, Learn through other's mistakes, public information campaign, check medicines waste returned to us could identify an issue", "With appropriate training able to identify these and intercept before reaching the patient", "Doing what is asked of us but training/information should be provided and we have received nothing at all", "Pharmacists already have their hands full with their every day job, so it is unrealistic for pharmacists to check whether it is a genuine medicine by naked eyes. Wholesaler should take responsibility in sourcing genuine medicines", "Crucial-all members of the healthcare team will be required to scan and verify medication", "I do not want to play a role in falsified medicines. Should be a government job", "Source trusted-products from valid/trusted wholesalers", "knowledge and resources", "being vigilant of falsified medicines and what to do in the event of finding one".*

Five comments were additionally received. These mainly re-iterated points already raised: *"Not sure YCS is a useful tool for SF"."Falsified meds should not have been able to reach community pharmacy in the first place. Any falsified meds should have been caught at the wholesaler but not at the pharmacy! The whole idea of scanning every box during dispensing is purely stupid. Waste of time and effort! Wholesalers should be the one making sure no falsified meds reach the pharmacy via delivery in the first place", "Being chain pharmacy our each item is coming from certified suppliers which make me think there shouldn't be any falsified medicine in my store", "Already the change of packaging has caused out of stocks of medicines, while they get the new boxes implemented which causes problems" and "To identify falsified meds. It shouldn't be left to the pharmacist, their jobs are hard enough!"*

Index of Multiple Deprivation Decile

We stratified the data by decile (table 2) and visually assessed on our maps.

		Decile (1, 2, 3) Total (n)	Decile (1, 2, 3) %
IMD Decile (1 poorest, 10 richest)		50	100%
Frequency of respondents		50	100%
Gender. (n = 102)	Male	23	46%
	Female	25	50%
	Other	2	4%
Years of registered experience. (n = 102)	0-5	17	34%
	6-10	11	22%
	11-15	11	22%
	16-20	1	2%
	20+	10	20%
Working hours per week. (n = 102)	16 – 24	1	2%
	25 - 34	8	16%
	35 - 44	32	64%
	45 - 54	9	18%
Ever used the YCS for SF. (n = 90)	Yes	3	7%
	No	42	93%
Ever used the Patients' leaflet? (n = 91)	Yes	1	2%
	No	45	98%
Seen the Postcard Guidance for identify SF? (n = 90)	Yes	6	13%
	No	39	87%
Aware of any technologies in place to identify SF? (n = 91)	Yes	2	4%
	No	44	96%
Ever received any training regarding SF? (n = 91)	Yes	4	9%
	No	42	91%
Ever identified SF? (n = 91)			

	Total (n)	Decile (4, 5, 6, 7, 8, 9, 10)	%	Decile (4, 5, 6, 7, 8, 9, 10)
	52		100%	
	23		45%	
	26		50%	
	3		5%	
	20		36%	
	15		25%	
	9		20%	
	0		1%	
	8		18%	
	2		3%	
	2		10%	
	45		75%	
	3		12%	
	3		7%	
	42		93%	
	2		3%	
	43		97%	
	8		16%	
	37		84%	
	1		3%	
	44		97%	
	1		5%	
	44		95%	

Table 3 Respondent's demographics vs IMD decile distribution.

The data were segregated in near-even portions representing deprived areas versus affluent areas (Table 3) for easy comparison. Appendix B provides a detailed breakdown.

Discussion

Table 1 shows a sex ratio in line with the latest census (17). Most (62%) responders had 10 years or less practice experience, with 75.5% working full-time hours.

Most responders were not ready to implement FMD on the deadline, except four pharmacies and many did not know that this implementation was imminent. Many did not have the resources nor equipment to deliver FMD implementation. These changes were perceived as disruptive to normal business flow and likely to negatively affect workloads. In turn, 22.5% perceived this to negatively impact profitability and 4.9% believes that it might increase profitability. Perhaps some limitation of this survey questions is that the participants were not themselves business owners, but employees within a larger business. We cautiously hypothesise that by their nature, they maybe more accurate at assessing impact to workload, but perhaps not to profitability. However, we do not know. Few (3.9%) perceived this did not improve patient safety and 42.2% believes that it might improve patient safety. Improved patient safety is the main purpose of FMD, so it is interesting to note that only 42.2% of practitioners were confident about this. This leads us to cautiously hypothesis that many participants believe this adds to the administrative burden, with some improved patient safety.

There was unimodal distribution in the opinion of the percentage of medicines believed to be falsified in the UK, with a mode around 1 - 5%. This matches WHO estimates (3). What percentage of medicines are believed to be falsified from online suppliers followed a near normal distribution with a mode around 41 – 60% from online suppliers. This reflects that responders believe the legitimate supply chain to be sufficiently protected, but have anxieties around online sources of medicines that are at a greater risk of falsification and may lead to greater public harm, which is supported by the wider literature(18–23). This phenomenon was supported in the answer around the most likely source of falsified medicine, which were identified as mainly originating from internet pharmacies.

The most commonly falsified medicines in the UK, its physical appearance and who to report it to were in line with the wider literature (24,25). Table 2 shows slightly lower agreement in our sample with the statements: "The majority of my fellow pharmacists in the UK are confident regarding falsified medicines", "I'm constantly vigilant of encountering falsified medicines when checking prescriptions" and "I have enough knowledge to identify falsified medicines". This is normal and as expected because our sample is nearly double the original sample.

The messages raising public awareness of SF has not been reaching the public via pharmacy professionals, which raises important questions about promoting the message and getting it out to

front-line staff and patients. While all pharmacy undergraduates are taught about the YCS in UK universities, this does not translate into practice as evidenced by general underreporting(26) of adverse drug reactions (ADRs). Few respondents had reported SF but more believed it helped combat SF.

Six out of 500 of our respondents had reported SF. Therefore, nationally in 11,619 pharmacies, we anticipate 140 reports. Therefore, the 70 reports lodged with the MHRA, we believe, indicate an under-reporting. This is supported in comments relating to informing the MHRA.

Only three respondents had seen the 'Postcard Guidance for Patients' leaflet, which conflicts with their earlier responses to involvement in any campaigns regarding SF but can be explained by prior training. A sub-group analysis of these three responders revealed that they were two women and one man, with 0-5 years and 11-15 years of practice experience, working 25-34 hours and 35-44 hours per week and all believed that FMD would greatly improve patient safety. All had received training regarding SF and all would further seek such training. While most respondents were not aware of technologies in place to identify SF, a handful could name some strategies in place and overall envisaged them having a limited impact in combating SF. While most respondents did not receive training, 69% would participate in a training program regarding SF. Off the five people who had identified SF, two reported it to the MHRA and three did not. One individual who said they had not encountered SF, would inform the MHRA in such a circumstance. There seems to be a worrying practice of not reporting ADRs irrespective of point of purchase or local circumstance. This provides tentative support for our analysis on the FOI request, which indicates under-reporting of suspected ADRs related to SF.

Record keeping and ADR reporting is an essential and integral part of a pharmacist's duty. SF medicines pose an uncommon problem and so how professionals deal with this can be varied. However, more needs to be done to raise awareness of the need to report SF and the importance of reporting related ADRs. Reducing public harm is inherently acknowledged as key by responders, though a greater regulatory role and supply chain integrity is expected by pharmacists.

Analysing the data by geographical distribution shows more SF were identified in deprived areas, but otherwise uninteresting findings (table 3).

Strengths and limitations

We report on a nationally representative sample in the first study of its kind examining readiness to implement FMD by pharmacists in England. Low respondent numbers and some missing information may make our findings unreliable.

Future research

A larger sample study using this survey would be valuable. Qualitative studies with participants that have encountered SF may help identify why this maybe the case and to explore ways of dealing with such events better. More needs to be done at a national level about raising public awareness.

Conclusions

We find pharmacists less than ready to implement FMD. Impact on workload and profitability were areas of concern, though improve patient safety was anticipated. Of the total number of medicines dispensed in England, 1 to 5% are believed to be FS, with a greater proportion from online sources.

We further validated an established scale on community pharmacist's opinion regarding SF. Limited public health campaigns may result in a lack of awareness amongst pharmacy professionals and patients. Limited awareness of technologies in place identifying SF exist, though further training is welcome. A worrying trend of underreporting may be prevalent. Geospatial analysis revealed more SF were identified in deprived areas.

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Contributors

The author conceived, designed, acquired, analysed and interpreted data. They developed and approved the version to be published and is accountable for its accuracy and integrity.

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None

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Data sharing statement

No further data is available to protect participant anonymity.

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An evaluation of community pharmacists' perception of falsified medicines: An English cross-sectional survey.

INSTRUCTIONS: Please fill out the following questionnaire by ticking ☑ the box that is most applicable to you. Unless specified, tick one box only and where spaces are provided, please state your thoughts and opinions. The data submitted will be confidential and remain anonymous, so please be honest with your responses.

	Coded 1	Coded 2	Coded 3	Coded 4	Coded 5	Coded 6
1. What is your gender?	Male ☐	Female ☐	Other ☐	Prefer not to say ☐		
2. What type of pharmacy do you work in? (*Tick all that apply)*	Independent☐	Chain ☐	Online ☐	Other ☐		
3. How many years have you been a registered pharmacist?	0-5 ☐	6-10 ☐	11-15 ☐	16-20 ☐	20+ ☐	
4. What are your current working hours per week as a pharmacist (excluding lunch hour)?	16 – 24 ☐	25 - 34 ☐	35 - 44 ☐	45 - 54 ☐	55+ ☐	
5. The deadline for full implementation is 9 February 2019. This requires every prescription only medicine and some pharmacy medicines to be scanned at point of dispensing (to check against a central database that they are not falsified, recalled or expired) at community pharmacy level across	Not at all ☐	Not really ☐	Undecided ☐	Somewhat ☐	Very much ☐	
6. Have you adequate equipment (e.g. computer terminals, scanners, compliance software, include initial set-up, IT, both software and hardware, plus	Not at all ☐	Not really ☐	Undecided ☐	Somewhat ☐	Very much ☐	
7. How do you see this affecting your workload?	Not at all ☐	Not really ☐	Undecided ☐	Somewhat ☐	Very much ☐	
8. How do you see this affecting your business profitability?	Not at all profitable ☐	Not really profitable ☐	Undecided ☐	Somewhat profitable ☐	Very much profitable ☐	
9. How do you see this affecting patient safety?	Does not improve patient safety at all ☐	Does not improve patient safety ☐	Undecided ☐	Somewhat improves patient safety ☐	Very much improves patient safety ☐	
10. In your opinion, what percentage of medicines are believed to be falsified in the UK?	<1% ☐	1 - 5% ☐	6 - 10% ☐	11 - 20% ☐	>21% ☐	
11. In your opinion, what percentage of medicines are believed to be falsified from online suppliers?	0 – 20% ☐	21 – 40% ☐	41 – 60% ☐	61 – 80% ☐	81-100% ☐	
12. In your opinion, what is the most likely source of falsified medicine?	Internet pharmacies ☐	Personal Importation ☐	Professional falsifier ☐	Other (please state) ☐		

For each of the statements below, tick ☑ the response that best characterises how you feel regarding falsified medicines in the UK .

13. What are the most commonly falsified medicines in the UK? *(Tick most relevant)*	Anti-cholesterol ☐	Cancer ☐	Erectile dysfunction ☐	Heart problems ☐	Weight loss ☐	Other (please state) ☐
14. What would make you suspicious that a medicine is falsified? *(Tick all that apply)*	Different distribution route ☐	Different labelling ☐	Different packaging to original packaging ☐	Different product composition (e.g. ingredients including excipients)	Different source (e.g. different manufacturer or country of origin)	Other (please state) ☐
15. Which national agency would you contact, if any? *(Tick most relevant)*	Department of Health (DoH) ☐	European Medicines Agency (EMA) ☐	Royal Pharmaceutical Society (RPS) ☐	Medicines Healthcare Products Regulatory Agency (MHRA) ☐	General Pharmaceutical Council (GPhC) ☐	Other (please state) ☐

For each of the statements below, tick ☑	**Strongly Disagree**	**Disagree**	**Uncertain**	**Agree**	**Strongly Agree**
16. Falsified medicines pose a significant problem to the pharmacy profession.	☐	☐	☐	☐	☐
17. Lack of knowledge is a barrier for detecting the presence of falsified medicines.	☐	☐	☐	☐	☐
18. Lack of resources is a barrier for detecting the presence of falsified medicines.	☐	☐	☐	☐	☐
19. The dispensing pharmacist retains highest liability when falsified medicines reach patients.	☐	☐	☐	☐	☐
20. A pharmacists intervention can prevent or disrupt the supply of falsified medicines to patients.	☐	☐	☐	☐	☐
21. Training courses can improve pharmacists knowledge regarding falsified medicines.	☐	☐	☐	☐	☐
22. Listening to patients could help identify falsified medicines.	☐	☐	☐	☐	☐
23. The majority of my fellow pharmacists in the UK are confident regarding falsified medicines.	☐	☐	☐	☐	☐
24. I'm confident and capable in identifying falsified medicines.	☐	☐	☐	☐	☐

25. I'm constantly vigilant of encountering falsified medicines	☐	☐	☐	☐	☐
26. I have enough knowledge to identify falsified medicines.	☐	☐	☐	☐	☐

For each of the questions below please tick ☑ for either Yes or No.	**Yes**	**No**
27. a) Have you been involved in any campaigns regarding falsified medicines?	☐	☐
b) If yes, please state the name of the campaign.		
c) Do you believe that campaigns was effective?	☐	☐
28. a) Have you ever used the Yellow Card Scheme for falsified medicines?	☐	☐
b) Do you believe this scheme is useful in combating falsified medicines?	☐	☐
29. Have you seen the 'Postcard Guidance for Patients' leaflet?	☐	☐
30. a) Are you aware of any technologies in place to identify falsified medicines?	☐	☐
b) Which technologies?		
c) Do you believe this technology would be effective in combating falsified medicines?	☐	☐
31. a) Have you ever received any training regarding falsified medicines?	☐	☐
b) Would you participate in a training program regarding falsified medicines?	☐	☐

For each of the questions below please tick ☑ for either Yes or No.	**Yes**	**No**
32. a) Have you ever identified falsified medicines?	☐	☐
b) Did you inform the MHRA if you identified falsified medicines?	☐	☐
c) What did you do in that situation?		
33. a) Do you keep any records when encountering potential falsified medicines?	☐	☐
b) What records do you maintain when encountering falsified medicines?		
34. a) In your opinion, how can falsified medicines reaching the public be reduced?		
b) In your opinion, what role can pharmacists play in combating falsified medicines?		

Any additional comments:

END OF SURVEY. Thank you for completing this survey please return it in the prepaid, self-addressed envelope

Reporting a Counterfeit Product could not be easier via the Yellow Card Scheme:
https://yellowcard.mhra.gov.uk/counterfeit-products/

You can complete a two page form to report a suspected counterfeit product (fake medicine or fake medical device) including any related side effects or safety concerns to the Yellow Card Scheme. You can register on the Yellow Card reporting site when you submit a report, or you can register in advance.

Alternatively, you can report a suspected counterfeit anonymously by contacting our 24-hour counterfeit hotline telephone number on 020 3080 6701.

Appendix B

IMD Decile (1 poorest, 10 richest)	Frequency of respondents	Gender. (n = 102)			Years of registered experience. (n = 102)					Working hours per week. (n = 102)				Ever used the Yellow		Seen the 'Postcard		Aware of any		Ever received any		Ever identified falsified	
		Male	Female	Other	0-5	6-10	11-15	16-20	20+	16 – 24	25 - 34	35 - 44	45 - 54	Yes	No	Yes	No	Yes	No	Yes	No	Yes	No
1	17	7	10	0	6	4	2	0	5	0	2	11	4	1	14	1	15	1	14	1	15	2	14
2	17	7	8	2	6	2	7	1	1	1	4	9	3	2	15	0	17	2	15	0	17	1	16
3	16	9	7	0	5	5	2	0	4	0	2	12	2	0	13	0	13	3	10	1	12	1	12
Total	**50**	**23**	**25**	**2**	**17**	**11**	**11**	**1**	**10**	**1**	**8**	**32**	**9**	**3**	**42**	**1**	**45**	**6**	**39**	**2**	**44**	**4**	**42**
%	100%	46%	50%	4%	34%	22%	22%	2%	20%	2%	16%	64%	18%	7%	93%	2%	98%	13%	87%	4%	96%	9%	91%
4	15	7	7	1	5	5	2	0	3	2	1	11	1	1	12	1	12	3	10	1	12	0	13
5	4	3	1	0	0	0	2	0	2	0	0	4	0	0	4	0	4	0	4	0	4	0	4
6	7	3	3	1	4	3	0	0	0	0	0	7	0	0	6	1	5	1	5	0	6	0	6
7	11	4	7	0	5	1	2	0	3	0	0	9	2	1	7	0	8	3	5	0	8	1	7
8	5	2	3	0	2	2	1	0	0	0	0	5	0	1	4	0	5	0	5	0	5	0	5
9	4	2	2	0	1	1	2	0	0	0	0	4	0	0	3	0	3	1	2	0	3	0	3
10	6	2	3	1	3	3	0	0	0	0	1	5	0	0	6	0	6	0	6	0	6	0	6
Total	**52**	**23**	**26**	**3**	**20**	**15**	**9**	**0**	**8**	**2**	**2**	**45**	**3**	**3**	**42**	**2**	**43**	**8**	**37**	**1**	**44**	**1**	**44**
%	100%	44%	50%	6%	38%	29%	17%	0%	15%	4%	4%	87%	6%	7%	93%	4%	96%	18%	82%	2%	98%	2%	98%

Reporting checklist for cross sectional study.

Based on the STROBE cross sectional guidelines.

Instructions to authors

Complete this checklist by entering the page numbers from your manuscript where readers will find each of the items listed below.

Your article may not currently address all the items on the checklist. Please modify your text to include the missing information. If you are certain that an item does not apply, please write "n/a" and provide a short explanation.

Upload your completed checklist as an extra file when you submit to a journal.

In your methods section, say that you used the STROBE cross sectionalreporting guidelines, and cite them as:

von Elm E, Altman DG, Egger M, Pocock SJ, Gotzsche PC, Vandenbroucke JP. The Strengthening the Reporting of Observational Studies in Epidemiology (STROBE) Statement: guidelines for reporting observational studies.

		Reporting Item	Page Number
Title and abstract			
Title	#1a	Indicate the study's design with a commonly used term in the title or the abstract	1
Abstract	#1b	Provide in the abstract an informative and balanced summary of what was done and what was found	2
Introduction			
Background / rationale	#2	Explain the scientific background and rationale for the investigation being reported	3
Objectives	#3	State specific objectives, including any prespecified hypotheses	3
Methods			
Study design	#4	Present key elements of study design early in the paper	3
Setting	#5	Describe the setting, locations, and relevant dates, including periods of	3,4

		recruitment, exposure, follow-up, and data collection	
Eligibility criteria	#6a	Give the eligibility criteria, and the sources and methods of selection of participants.	3
	#7	Clearly define all outcomes, exposures, predictors, potential confounders, and effect modifiers. Give diagnostic criteria, if applicable	4-9
Data sources / measurement	#8	For each variable of interest give sources of data and details of methods of assessment (measurement). Describe comparability of assessment methods if there is more than one group. Give information separately for for exposed and unexposed groups if applicable.	9
Bias	#9	Describe any efforts to address potential sources of bias	3,4
Study size	#10	Explain how the study size was arrived at	4
Quantitative variables	#11	Explain how quantitative variables were handled in the analyses. If applicable, describe which groupings were chosen, and why	4-9
Statistical methods	#12a	Describe all statistical methods, including those used to control for confounding	4-9
Statistical methods	#12b	Describe any methods used to examine subgroups and interactions	9
Statistical methods	#12c	Explain how missing data were addressed	n/a
Statistical methods	#12d	If applicable, describe analytical methods taking account of sampling strategy	n/a
Statistical methods	#12e	Describe any sensitivity analyses	n/a
Results			
Participants	#13a	Report numbers of individuals at each stage of study—eg numbers potentially eligible, examined for eligibility, confirmed eligible, included in the study, completing follow-up, and analysed. Give information separately for for exposed and unexposed groups if applicable.	4-9
Participants	#13b	Give reasons for non-participation at each stage	n/a
Participants	#13c	Consider use of a flow diagram	n/a

Descriptive data	#14a	Give characteristics of study participants (eg demographic, clinical, social) and information on exposures and potential confounders. Give information separately for exposed and unexposed groups if applicable.	4-9
Descriptive data	#14b	Indicate number of participants with missing data for each variable of interest	9
Outcome data	#15	Report numbers of outcome events or summary measures. Give information separately for exposed and unexposed groups if applicable.	4-9
Main results	#16a	Give unadjusted estimates and, if applicable, confounder-adjusted estimates and their precision (eg, 95% confidence interval). Make clear which confounders were adjusted for and why they were included	4-9
Main results	#16b	Report category boundaries when continuous variables were categorized	4-9
Main results	#16c	If relevant, consider translating estimates of relative risk into absolute risk for a meaningful time period	n/a
Other analyses	#17	Report other analyses done—e.g., analyses of subgroups and interactions, and sensitivity analyses	4-9
Discussion			
Key results	#18	Summarise key results with reference to study objectives	10
Limitations	#19	Discuss limitations of the study, taking into account sources of potential bias or imprecision. Discuss both direction and magnitude of any potential bias.	11
Interpretation	#20	Give a cautious overall interpretation considering objectives, limitations, multiplicity of analyses, results from similar studies, and other relevant evidence.	11
Generalisability	#21	Discuss the generalisability (external validity) of the study results	11
Other Information			
Funding	#22	Give the source of funding and the role of the funders for the present study and, if applicable, for the original study on which the present article is based	1

This checklist was completed on 02. August 2019 using https://www.goodreports.org/, a tool made by the EQUATOR Network in collaboration with Penelope.ai

BMJ Open

An evaluation of community pharmacists' readiness to implement the Falsified Medicines Directive (Directive 2011/62/EC): An English cross-sectional survey with geospatial analysis.

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Primary Subject Heading:	General practice / Family practice
Secondary Subject Heading:	Public health, Evidence based practice, General practice / Family practice, Global health, Health policy
Keywords:	counterfeit drugs, falsified medicines, PUBLIC HEALTH, pharmacy, spatial analysis, substandard medicine

An evaluation of community pharmacists' readiness to implement the Falsified Medicines Directive (Directive 2011/62/EC): An English cross-sectional survey with geospatial analysis.

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Keywords:

counterfeit drugs; drug-related side effects and adverse reactions; falsified medicines; Falsified Medicines Directive (Directive 2011/62/EC); pharmacists; survey; public health; pharmacy; spatial analysis; medicine quality; procurement; substandard medicine

Abstract.

Objectives: to evaluate the readiness to implement the Falsified Medicines Directive (FMD) by community pharmacies in England. Eight secondary objectives were assessed.

Setting: Community/Retail pharmacies.

Participants: We invited pharmacists from 501 pharmacies to complete a survey. Non-contractors, non-pharmacists or pharmacists practising abroad were excluded. We randomly selected addresses, ensuring they were nationally representative.

Interventions: We mailed the survey in October 2018 with a single follow-up in January 2019. Respondents were invited to provide self-reported answers. A prepaid self-addressed envelope was provided. We received favourable ethical approval.

Results: 102 responses (20.44% response rate) were received. Readiness to implement was poor: 40 (39.2%) said not at all, 29 (28.4%) said not really. Increased workload and reduced profitability was anticipated, accompanied with improved patient safety. Prevalence of falsified medicines (SFs) was estimated at 1 to 5%, with erectile dysfunction at greatest risk of falsification. Different packaging would raise suspicions. Five (4.9%) had identified SFs ($p<0.001$ One sample binomial). Of these, three (2.9%) informed the medicines agency. None had been involved in any public health campaigns. Confidence and self-efficacy was low. Strategies to reduce SFs reaching the public are described. Pharmacist's role in combating SFs was elucidated. SFs were identified in deprived areas 4 (9%) more often than in affluent areas 1 (2%).

Conclusions: Many pharmacies are not ready to implement FMD, potentially not capturing anticipated benefits of the directive, with greatest risk of harm in deprived area. We further validated a confidence scale. Limited public health campaigns may result in a lack of awareness amongst pharmacy professionals and patients. Limited awareness of technologies to identify falsified medicines exist, though further training is welcome. A worrying trend of underreporting maybe prevalent. A larger sample study using this survey would be valuable.

Article Summary.

Strengths and limitations of this study

- This is the first study to evaluate the readiness of community pharmacies in England to implement the European Union's Falsified Medicines Directive (Directive 2011/62/EC) by 9 February 2019.
- We invited pharmacists from 501 pharmacies across England to complete a survey.
- We mailed the survey in October 2018 with a single follow-up of non-responders in January 2019.
- Postcodes of pharmacies were linked with freely available data on index of multiple deprivation (IMD) scores, which provides an estimate of the socioeconomic deprivation of the practice population.
- The interactive application helps to visualize the data easily: https://arcg.is/0q1mGf or https://portuni.maps.arcgis.com/apps/webappviewer/index.html?id=95497aeae0cf4411abd8433d736b8989

Introduction.

There is no universally agreed definition of counterfeit/falsified medication and jurisdictions around the world define these types of medicines in many different ways. The World Health Organization (WHO) identifies 'Substandard and Falsified (SF) Medical Products'[1,2] that demonstrate public harm.[3] The European Union (EU) has a strong legal framework for the licensing, manufacturing and distribution of medicines supported by the EU Member States in implementing the falsified medicines Directive.[4,5] At writing, the United Kingdom (UK) remains an EU member state. At the end of the distribution chain, only licensed pharmacies and approved retailers are allowed to offer medicines for sale, including legitimate sale via the internet.[6,7]

No specific definition of counterfeit medical product exists within English law and the national competent agency (The Medicines and Healthcare products Regulatory Agency (MHRA)) adopts the definition contained within the European Falsified Medicines Directive (FMD) and has provided guidance on its implementation. The final part of the Directive, the 'safety features' Delegated Regulation (EU) 2016/161 comes into force on 9 February 2019 in the UK.[8]

This requires every prescription only medicine and some pharmacy medicines to be scanned at point of dispensing (to check against a central database that they are not falsified, recalled or expired) at community pharmacy level across the EU, before supplying to the patients. The pharmacists' responsibilities are to 1) check that the anti-tampering device placed on the package by the manufacturer is intact before dispensing and 2) scan the 2D barcode and communicating with the National Medicine Verification System to change the status of the pack from 'active' to 'inactive-dispensed'. The first requires visual inspection while the second requires a scanning tool.

Falsified medicines and medical devices are problematic in both primary and secondary care as they are not subject to the rigorous quality standards and can create difficulty in identifying sources of contamination and public harm. The parallel import system in the EU also permit legitimate movement of medicines through the supply chain over large geographic territories, which is susceptible to infiltration by SF medicines.

Pharmacist's ability to identify SF medication can help in thwarting public harm alongside implementation of the FMD. No studies of English pharmacist's experiences of implementing FMD exist. This study is needed because it seeks to understand the challenges faced by the healthcare team caring for National Health Service (NHS) patients and other under pressure models of care in the Western world. Challenges include growing patient demand, changing patterns of demand, insufficient funding in primary care, reduced access to General practitioners (GPs) and addressing national health inequalities. From our 2016-17 SF study,[9] we hypothesise that the theme of 'lack of resources' may continue.

Objectives.

The primary objective of this study was to evaluate the readiness to implement FMD (Directive 2011/62/EC) by 9 February 2019 by community pharmacies in England. Secondary objectives were to:

a) assess the impact of change on current operations,
b) establish prior knowledge of prevalence of SF medicines,
c) determine what visual checks are done to identify SF medicines,
d) establish current practice around the identification and reporting of SF medicines,
e) establish current levels of awareness, involvement and training in public health by pharmacists with respect SF medicines,
f) explore pharmacists confidence of handling SF medicines,
g) seek opinions on policy and understand the pharmacist's role in combating SF medicines,
h) examine association with geospatial location and Index of Multiple Deprivation (IMD) scores.

Methods.

We invited pharmacists from 501 pharmacies that contribute to the NHS's Business Services Authority (BSA) dispensing data across England to complete a survey, as the BSA is responsible for pharmacy reimbursements and collates accurate prescription data on behalf of the NHS. Community pharmacies that are not NHS contractors, non-pharmacists or pharmacists practicing abroad were excluded. Addresses were taken from publicly available BSA website (March 2018) to gain a nationally representative sample.

We selected them randomly between contractor code (FAQ87 to FYR36), which resulted in recruiting a single large national pharmacy chain. We ensured they were nationally representative with respect to the number of prescription forms (invited sample mean 5355, SD 2044 versus English population mean 3564, SD 2692) and number of prescription items dispensed (invited sample mean 10817, SD 4611 versus English population mean 9875, SD 5480). This permits comparison with like for like businesses (approximately equal burden of work, similar team size, and similar business complexity) across the country, therefore allowing fair comparison between pharmacies invited to study and the wider pharmacy population.

We mailed the cross-sectional survey in October 2018 with a single follow-up of non-responders in January 2019. Respondents were invited to provide self-reported answers. A prepaid self-addressed envelope was included. We sought and received favourable institutional ethical approval. No financial (or similar) benefits were offered to minimise biased responses.[10]

Questionnaire.

The questionnaire was composed of items relating to the objectives. The full survey is available in Appendix A. A previously validated scale[9] was incorporated in this survey.

We piloted the questionnaire via six steps. Questionnaire validation (pretesting) was achieved by researchers critically appraising the scale in a research-team focus-group. This comprised two external practicing community pharmacists, other academics with recent community and hospital practice experience, and student researchers. 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. To improve internal validity and reliability, the survey instrument was piloted with another external community pharmacist, and cognitive testing (read-aloud) was conducted. It took less than 10 minutes to complete the final survey.

There are 11,619 community pharmacies in England in 2017-18.[11] To be representative, (assuming confidence level of 95%, confidence interval of 10%, standard error of 5%, relative standard error of 10%), a minimum sample size of 95 was calculated. To achieve this, we invited 501 pharmacies as our previous response rates range between 15% to 25% in similar studies.[9,12,13] Analyses were undertaken using SPSS[14] to present proportions, descriptive statistics and hypothesis testing at 95% confidence level and 5% significance. Missing data are presented, any sub-group analysis will be descriptive. Comments are thematically analysed.[15,16]

Postcodes of pharmacies were linked with freely available data on IMD score,[17] an estimate of the socioeconomic deprivation of the practice population and NHS dispensing data.[18] The IMD, is the official measure of relative deprivation for small areas in England and the latest scores are presented in IMD 2015 data. It is a composite score of seven underlying domains related to income deprivation, employment deprivation, education, skills and training deprivation, health deprivation and disability, crime, barriers to housing and services, living environment deprivation.[17] We were interested to see if deprivation and SFs detection and reporting was linked in any way - which we find it is (as per our discussion and conclusion).

We mapped our results using Arc GIS online (https://arcg.is/0q1mGf , legend: Yellow dot, red dot and green dot represents those who are 'somewhat' and 'very much' ready to implement FMD by the 9th Feb 2019, who said FMD would affect workload and those who said FMD would affect business profitability respectively. Orange dot represents those who had used the Yellow Card Scheme (YCS) for reporting SF, blue dot represents those who had ever identified SF and green dot represents all respondents). We created an app with several layers to visualize the data easily, freely and publically:
https://portuni.maps.arcgis.com/apps/webappviewer/index.html?id=95497aeae0cf4411abd8433d736b8989

We mapped our responses alongside the IMD 2015 data (Ranks: every postcode has a rank from 1, which is the most deprived area up to 32,844 that is the least deprived area. Deciles are published alongside ranks to assess relative deprivation and we have used these).

At the end of our survey, we included brief guidance on reporting Counterfeit Products via the YCS (https://yellowcard.mhra.gov.uk/counterfeit-products/) operated by the MHRA. Participants can complete a two-page form to report a suspected counterfeit product (fake medicine or fake medical device) including any related side effects or safety concerns to the YCS. Participants can register on the site when submitting a report, or can register in advance. Alternatively, participants can report a suspected counterfeit anonymously by contacting the 24-hour counterfeit hotline telephone number on +44 (0)20 3080 6701.

No Patient and Public Involvement.

We did not involve patients or the public in our work. This is likely to be done in the future.

We used the STROBE cross sectional reporting guidelines.[19]

Results.

In total, 102 responses (20.44% response rate) were received (two closures and abatements), satisfying our sample size needs. Higher response rates can be achieved with incentives, but may introduce bias.[10] Demographic data are summarized in table 1.

Table 1 Characteristics of survey respondents (n=102).

Respondent Variables.	**Frequency (Percentage) (n=102).**
Sex	
Male	46 (45.1)
Female	51 (50.0)
Preferred not to say	5 (4.9)
Years of registration experience	
0-5	37 (36.3)
6-10	26 (25.5)
11-15	20 (19.6)
16-20	1 (1.0)
> 20 years	18 (17.6)
Working Hours (Per Week)	
16 – 24	3 (2.9)
25 – 34	10 (9.8)
35 – 44	77 (75.5)
45 – 54	12 (11.8)

We enquired how ready respondents were to implement this directive. Forty (39.2%) said not at all, 29 (28.4%) said not really, 14 (13.7%) were undecided, 12 (11.8%) said somewhat and 4 (3.9%) said very much, 3 (2.9%) missing.

We enquired if adequate equipment and expenses were prepared (e.g. computer terminals, scanners, compliance software, include initial set-up, IT, both software and hardware, plus ongoing operational costs). Twenty-two (21.6%) said not at all, 26 (25.5%) said not really, 12 (11.8%) were undecided, 31 (30.4%) said somewhat and 11 (10.8%) said very much.

a) Impact of change on current operations.

We enquired how this affected workload and profitability (table 2):

Table 2 Impact on workload and profitability.

n (%)	**Not at all**	**Not really**	**Undecided**	**Somewhat**	**Very much**	**Missing**
Affected workload	7 (6.9%)	10 (9.8%)	24 (23.5%)	35 (34.3%)	26 (25.5%)	-
n (%)	**Not at all profitable**	**Not really profitable**	**Undecided**	**Somewhat profitable**	**Very much profitable**	**Missing**
Affected profitability	10 (9.8%)	13 (12.7%)	65 (63.7%)	9 (8.8%)	4 (3.9%)	1 (1.0%) missing

We enquired how this might affected patient safety (table 3):

Table 3 Impact on patient safety.

n (%)	Does not improve patient safety at all	Does not improve patient safety	Undecided	Somewhat improves patient safety	Very much improves patient safety	Missing
Patient safety	-	4 (3.9%)	14 (13.7%)	41 (40.2%)	38 (37.3%)	5 (4.9%)

b) Prior knowledge of prevalence of SF medicines.

We then enquired what percentage of medicines are believed to be falsified in the UK (table 4 & 5).

Table 4 Perceived prevalence of SF medicines.

	<1%	1 - 5%	6 - 10%	11 - 20%	>21%	Missing
Perceived prevalence of SF medicines.	33 (32.4%)	33 (32.4%)	20 (19.6%)	12 (11.8%)	2 (2.0%)	2 (2.0%)

Table 5 Medicines believed to be falsified from online suppliers.

	0 – 20%	21 – 40%	41 – 60%	61 – 80%	81-100%
Medicines believed to be falsified from online suppliers.	23 (22.5%)	27 (26.5%)	31 (30.4%)	17 (16.7%)	4 (3.9%)

We enquired about the most likely sources of falsified medicine: 59 (56.2%) said 'internet pharmacies', 21 (20.0%) said 'personal importation', 23 (21.9%) said 'professional falsifier', 2 (1.9%) said 'other' (of which 1 did not elaborate and another said "including illegal websites"), 1 missing. Three respondents gave combination-answers.

We asked what were the most commonly falsified medicines in the UK and invited multiple responses. 7 said 'anti-cholesterol', 5 said 'cancer', 77 said 'erectile dysfunction', 5 said 'heart problems', 32 said 'weight loss', 6 said 'other' (benzodiazepines, painkillers, anabolic steroids), 2 missing.

c) Visual checks done to identify SF medicines.

We asked what would raise suspicions of an SF. Forty said 'different distribution route', 40 said 'different labelling', 87 said 'different packaging to original packaging', 26 said 'different product composition (e.g. ingredients including excipients), 50 'different source' (e.g. different manufacturer or country of origin), 3 said 'other' with reasons including cost, foreign text and medicine's appearance.

d) Practice around the identification and reporting of SF medicines.

Five (4.9%) had identified SF, 86 (84.3%) had never, 11 (10.8%) missing, $p<0.001$ One sample binomial test (95% CI: 1.95 ± 0.0471). In such circumstance, three (2.9%) informed the MHRA and five explanatory comments were received: *"Patient didn't want to report it she bought it from online pharmacy, I would contact MHRA"* (not reported to MHRA). *"It was bought in by a patient who had bought it from a friend and wanted to check if it was genuine. Advised not to take"* (not reported to

MHRA). *"Referred patient back to where they purchased it"* (not reported to MHRA). *"Yellow card"* and *"Melatonin"* were both reported to MHRA.

Twenty-one (20.6%) kept records when encountering potential SF, 56 (54.9%) did not, 25 (24.5%) missing, p<0.001 One sample binomial test (95% CI: 1.73 ± 0.1). Eight participants who kept records, went on to elaborate with comments (major theme of recording and reporting): *"If we came across any on our [proprietary] system", "Reporting on company system", "Online reporting tools of pharmacy events", "I would keep records", "In store records", "Hypothetically POM register, internal reporting system and Yellow card", "Details of the medicine, Name, manufacturer, distributor, strength, form", "Incident report sent online to headquarters".*

We enquired which national agency would they contact, if any. Nine said Department of Health (DoH), 17 said European Medicines Agency (EMA), 7 said Royal Pharmaceutical Society (RPS), 74 said Medicines Healthcare Products Regulator y Agency (MHRA), 15 said General Pharmaceutical Council (GPhC) and 3 said 'other', with reasons including *"Head office for advice, then appropriate agency", "company head office"* and *"[name] support office".*

e) Current awareness, involvement and training in public health.

None had been involved in any campaigns regarding SF, 91 (89.2%) said no, 11 (10.8%) missing. No campaign was named, though, 8 (7.8%) believed that the campaigns they encountered were effective, while 42 (41.2%) did not, 52 (51.0%) missing, p<0.001 One sample binomial test (95% CI: 1.91 ± 0.121).

Six (5.9%) had ever used the YCS for SF, 84 (82.4%) had not, 12 (11.8%) missing, p<0.001 One sample binomial test (95% CI: 1.93 ± 0.0519). Thirty-seven (36.3%) said yes this scheme is useful in combating SF, 34 (33.3%) said no, 31 (30.4%) missing.

To try and corroborate our findings to a nationally representative sample, we separately placed a Freedom of Information Request (FOI) with the MHRA in October 2018 to request data regarding UK suspected Adverse Drug Reactions (ADRs) that have been reported with suspected counterfeit or SF (Query ref: GENQ-00131558). Where a patient has experienced a suspected ADR to a medicine, even if the medicine is suspected to be counterfeit or falsified, this is recorded on their database. The MHRA has received a total of 70 UK spontaneous suspected ADR reports associated with SF for the period 01/07/1963 – 09/10/2018.

Three (2.9%) had seen the 'Postcard Guidance for Patients'[20] leaflet, 88 (86.3%) had not, 11 (10.8%) missing, p<0.001 One sample binomial test (95% CI: 1.97 ± 0.037). Fourteen (13.7%) were aware of technologies in place to identify SF, 76 (74.5%) were not, 12 (11.8%) missing, p<0.001 One sample binomial test (95% CI: 1.84 ± 0.0752). Technologies quoted in 11 comments presented two themes of barcode scanning and hologram use, 91 missing. Thirty-six (35.3%) believed technologies were effective in combating SF, 28 (27.5%) did not, 38 (37.3%) missing. Three (2.9%) had received any training regarding SF, 88 (86.3%) had not, 11 (10.8%) missing, p<0.001 One sample binomial test (95% CI: 1.97 ± 0.037). Seventy (68.6%) would participate in such training, 13 (12.7%) would not, 19 (18.6%) missing, p<0.001 One sample binomial test (95% CI: 1.12 ± 0.107).

f) Confidence regarding handling SF medicines.

Then we sought strength of opinion on a validated scale,[9] presented in figure 1. These cover statements 16 to 26 (Appendix A).

Figure 1 Confidence regarding handling falsified medicines (p<0.001 One sample chi square test for all statements), percentages have been rounded to whole numbers.

[Insert Fig 1 here]

We have also presented our and previously validated means and standard deviations to assess validity of our results and their relative difference in Table 6. It is important to note that the scales was originally validated in a smaller sample (n=50) within Hampshire, UK.

Table 6 Confidence regarding handling falsified medicines (p<0.001 One sample chi square test for all statements), percentages have been rounded to whole numbers.

	Mean (current study, n=101)	Std. Deviation (current study, n=101)	Mean (initial scale, n=50)	Std. Deviation (initial scale, n=50)	Mean difference	Std. Deviation difference
16. Falsified medicines pose a significant problem to the pharmacy profession.	3.89	1.067	4.02	1.078	0.13	0.011
17. Lack of knowledge is a barrier for detecting the presence of falsified medicines.	4.12	0.752	4.14	0.948	0.02	0.196
18. Lack of resources is a barrier for detecting the presence of falsified medicines.	4.1	0.806	3.94	1.077	-0.16	0.271
19. The dispensing pharmacist retains highest liability when falsified medicines reach patients.	3.44	1.292	3.4	1.278	-0.04	-0.014
20. A pharmacists intervention can prevent or disrupt the supply of falsified medicines to patients.	4.09	0.793	4.12	0.824	0.03	0.031
21. Training courses can improve pharmacists knowledge regarding falsified medicines.	4.24	0.764	4.06	0.843	-0.18	0.079
22. Listening to patients could help identify falsified medicines.	3.54	1.044	3.63	1.035	0.09	-0.009
23. The majority of my fellow pharmacists in the UK are confident regarding falsified medicines.	2.32	0.916	2.74	0.853	0.42	-0.063
24. I'm confident and capable in identifying falsified medicines.	2.45	1.005	2.62	1.105	0.17	0.1
25. I'm constantly vigilant of encountering falsified medicines when checking prescriptions.	2.77	1.13	3.04	1.195	0.27	0.065
26. I have enough knowledge to identify falsified medicines.	2.38	0.968	2.72	1.179	0.34	0.211

Table 6 shows small deviations from our original findings, except in statements 23, 25 and 26. Our study provides further face validity to this confidence scale (Figure 1, Table 6), in a nationally representative sample.

g) Opinions on policy and the pharmacists' role in combating SF medicines.

We enquired how we could reduce SF reaching the public. Forty-seven comments were received and are thematically analysed and presented in table 7.

Table 7 Respondent's opinions on how to reduce falsified medicines from reaching the public.

Major theme	Sub-theme	Exemplary comments
1. Public health education.	a. Public education.	• *"QC should be the watchword, enlightening the public to buy medicines only from approved pharmacy and use less internet pharmacies."* • *"More public campaigns to raise awareness, training for pharmacists to be more confident to educate or give information to patients."*
	b. Professional education (of all involved in supply chain).	• *"Education of how to recognise falsified meds - training of staff and what to do."* • *"Extra Information. Not had any information through."* • *"Better education to those involved in supply."*
2. (Government) Regulation and enforcement.	a. Regulated online sales.	• *"Reducing online sale of medicine or be more vigilant."* • *"Greater controls online purchasing. Less generics, so false medicines easier spotted."*
	b. Regulatory Control.	• *"Awareness and stricter consumer law in getting medication."* • *"Government responsible to prevent - if flow into the market either from Internet/EU imported medicines."*
	c. Reclassification.	• *"POM to P switches (e.g. Viagra)."*
d. Supply chain management.	a. Role of the manufacturers.	• *"I think this should be the role of the manufacturers and wholesalers not pharmacists."* • *"Monitoring of supply chains"* • *"Suppliers and wholesalers should be responsible and*

		have a system to check in place." • *"Controlling the supply chain, strict checks and audits."*
	b. Role of the wholesalers.	• *"Impetus on suppliers and audit - award levels based on compliance (gold, silver, bronze et cetera)."* • *"All medicines at wholesale level should be legitimate."* • *"The wholesaler needs to do these checks."* • *"Should be prevented at the wholesalers before reaching the pharmacy."* • *"Constant vigilance, using only reputable wholesalers, not using the Internet."*
	c. Role of all (manufacturers, wholesalers and pharmacy).	• *"Verify medicines at every step of distribution from original source. Have one system only (very difficult to achieve)."* • *"Checked at wholesalers as well as chemist level."*
e. Serialisation (Track & Trace).	• *"Each medicine box have unique code which keeps a history of where it has been and which can be viewed."* • *"Scanning the medicines prior to reaching patients."* • *"online central database and scanning are better options"* • *"To include a certified mark or sticker that is difficult to copy on the packaging."* • *"Electronic tagging."* • *"Scanning boxes."* • *"By original packaging and having hallmark. I don't think scanning a barcode will make any difference."*	
5. Reporting to the regulator, medical staff and internally to pharmacy.	• *"Yellow card, P.M.R [patient medical record], internal dispensing incident form."*	

We then asked what role can pharmacists play in combating falsified medicines. Thirty-seven comments were received and are thematically analysed (table 8).

Table 8 Pharmacist's role in combating falsified medicines.

Major themes	***Exemplary comments.***

Build into accuracy check	• *“Checking when completing accuracy check.”* • *“If we can use scanning method to check, then for sure we can improve.”* • *“Final Check and ensure dispenser check at point of assembly.”* • *“Scan items.”* • *“With enough training, pharmacists can play a strong role in identifying when dispensing.”* • *“If there was a procedure in place it would be part of dispensing procedure otherwise little time.”* • *"Crucial-all members of the healthcare team will be required to scan and verify medication."* • *“Scanning boxes.”*
Complex and multifactorial.	• *“Embrace training and procedures, order through authorised suppliers, learn through other's mistakes, public information campaign, check medicines waste returned to us could identify an issue.”*
Education and training.	• *"Be educated so that we can identify falsified medicines."* • *"With training - crucial role as gatekeeper."* • *"Being trained to recognise potential false medicines then using resources. To feedback and highlight common sources."* • *"With appropriate training able to identify these and intercept before reaching the patient."* • *"By right training, we can identify wrong/falsified medication."* • *"Undergo training."* • *"Doing what is asked of us but training/information should be provided and we have received nothing at all."* • *"The profession needs more awareness and knowledge in identifying falsified medication."*
Identify and report.	• *“Help identify and report them.”*
Not pharmacist's role.	• *"Would hope supply chain deals with this?"* • *"Pharmacists already have their hands [full] with their every day job, so it is unrealistic for pharmacists to check whether it is a genuine medicine [with their] naked eyes. Wholesaler should take responsibility in sourcing genuine medicines.”* • *"Better alerts issued to pharmacists, wholesalers BIG role to play."*
Public awareness.	• *"Advising the public and spotting counterfeit medication."* • *"Advise."* • *"Raise awareness among patients."*
Regulator’s job	• *“I do not want to play a role in falsified medicines. Should be a government job.”*
Reputable sources	• *"Only ordering from reputable sources."* • *"Source trusted products from valid/trusted wholesalers."* • *"Ensuring we never source or supply them and patient awareness."* • *"Use trustworthy wholesalers."*
Resources	• *“Knowledge and resources.”*
Vigilance and action	• *"Being vigilant of falsified medicines and what to do in the event of finding one.”* • *"Identify and improve patient safety."* • *"Be vigilant."* • *"Be vigilant and be trained."*

	• *"Be vigilant."* • *"Being diligent in spotting/ watching out for."*

Five comments were additionally received (Table 9).

Table 9 Additional comments.

Major themes	**Exemplary comments.**
Not a pharmacist's job	*"To identify falsified meds. It shouldn't be left to the pharmacist, their jobs are hard enough!"*
Quality Supply chain	*"Being chain pharmacy our each item is coming from certified suppliers which make me think there shouldn't be any falsified medicine in my store."*
Technical difficulties	*"Already the change of packaging has caused out of stocks of medicines, while they get the new boxes implemented which causes problems."*
Wholesalers duty	*"Falsified meds should not have been able to reach community pharmacy in the first place. Any falsified meds should have been caught at the wholesaler but not at the pharmacy! The whole idea of scanning every box during dispensing is purely stupid. Waste of time and effort! Wholesalers should be the one making sure no falsified meds reach the pharmacy via delivery in the first place."*
YCS ineffective	*"Not sure yellow card scheme is a useful tool for falsified medicines."*

h) Examine geospatial location and Index of Multiple Deprivation (IMD) by decile.

We stratified the data by decile (table 10) and visually assessed our maps. The data were segregated in near-even portions representing deprived areas versus affluent areas for easy comparison. Appendix B provides a detailed breakdown.

Table 10 Respondent's demographics vs IMD decile (1 poorest, 10 richest) distribution. Percentages (adjusted bases) have been rounded to whole numbers, small numbers may not add to 100%.

		Deprived Decile (1, 2, 3) n, %	Affluent Decile (4 to 10) n, %
Frequency of respondents	n, %	50, 100%	52, 100%
Gender. (n = 102)	Male	23, 46%	23, 44%
	Female	25, 50%	26, 50%
	Other	2, 4%	3, 6%
Years of registered experience. (n = 102)	0-5	17, 34%	20, 38%
	6-10	11, 22%	15, 29%
	11-15	11, 22%	9, 17%
	16-20	1, 2%	0, 0%

	> 20 years	10, 20%	8, 15%
Working hours per week. (n = 102)	16 – 24	1, 2%	2, 4%
	25 - 34	8, 16%	2, 4%
	35 - 44	32, 64%	45, 87%
	45 - 54	9, 18%	3, 6%
Ever used the YCS for SF. (n = 90)	Yes	3, 7%	3, 7%
	No	42, 93%	42, 93%
Seen the 'Postcard Guidance for Patients' leaflet? (n = 91)	Yes	1, 2%	2, 4%
	No	45, 98%	43, 96%
Aware of any technologies in place to identify SF? (n = 90)	Yes	6, 13%	8, 18%
	No	39, 87%	37, 82%
Ever received any training regarding SF? (n = 91)	Yes	2, 4%	1, 2%
	No	44, 96%	44, 98%
Ever identified SF? (n = 91)	Yes	4, 9%	1, 2%
	No	42, 91%	44, 98%

Discussion.

Table 1 shows a sex ratio in line with the latest census.[21] Most (62%) responders had 10 years or less practice experience, with 75.5% working full-time hours.

Most responders were not ready to implement FMD on the deadline, except four pharmacies and many did not know that this implementation was imminent.

a) Impact of change on current operations.

FMD related changes were perceived as disruptive to normal business flow and likely to negatively affect workloads (59.8%). In turn, 22.5% perceived this to negatively impact profitability and 12.7% believes that it might increase profitability. Perhaps some limitation of this survey question is that the participants were not themselves business owners, but employees within a larger business. We cautiously hypothesise that by their nature, they maybe are more accurate at assessing impact to workload, but perhaps not to profitability. However, we do not know. Few (3.9%) perceived this did not improve patient safety and 77.5% believes that it might improve patient safety. Improved patient safety is the main purpose of FMD, so it is interesting to note that more than 10% (13.7%) of practitioners were undecided about this. This leads us to cautiously hypothesise that many participants believe the FMD adds to the administrative burden, with some improved patient safety.

b) Prior knowledge of prevalence of SF medicines.

There was unimodal distribution in the opinion of the percentage of medicines believed to be falsified in the UK, with a mode around 1 to 5%, which matches WHO estimates.[3] Recent data shows the total number of items dispensed in 2017 was 1,105.8 million.[18] This represents 11.06 to 55.29 million dispensed items that could be falsified, each with a potential to harm patients.

The percentage of medicines believed to be falsified from online suppliers, followed a near-normal distribution with a mode around 41 – 60% from online suppliers. Responders believe the legitimate supply chain to be sufficiently protected, but have anxieties around online sources of medicines that are at a greater risk of falsification and may lead to greater public harm, which is supported by the wider literature.[22–27] This phenomenon was supported in the answer around the most likely source of SF, which were identified as mainly originating from internet pharmacies. The most commonly falsified medicines in the UK was perceived to be erectile dysfunction product followed by weight loss medication.

c) Visual checks are done to identify SF medicines.

Visual cues that would make pharmacists suspicious of a medicine being falsified, included different packaging to the original packaging and a different source. The most commonly falsified medicines in the UK, their physical appearance and who to report it to were in line with the wider literature.[28,29]

d) Practice around the identification and reporting of SF medicines.

Off the five people who had identified SF, two reported it to the MHRA and three did not. Four were from deprived postcodes, whereas one was from an affluent area. While five is a very small number, we do not know the frequency at which they detected SFs. Five respondents represent 1% of the invited sample and 4.9% of all respondents. Upscaling these numbers to a national level, would translate to 570 detections of SFs, without accounting for the cost of mitigating the damage to patients that may come from these SF medicines (While assuming: pharmacist detection of a single SF medicine, 11,619 pharmacies nationally, 5% identified SFs). We also do not know if there is likely to be a cluster effect (isolated to a specific area) or a nationwide effect of these detections. These findings are internationally relevant because of similar globally reported trends in major developed economies.[3,30]

There seems to be a worrying practice of not reporting ADRs irrespective of point of purchase or local circumstance. This provides tentative support for our FOI request analysis, which indicates under-reporting of suspected ADRs related to SFs. Record keeping and ADR reporting is an essential and integral part of a pharmacist's duty. SF medicines pose an uncommon problem and so how professionals deal with this can be varied. However, more needs to be done to raise awareness of the need to report SF to the appropriate agency (i.e. MHRA) and the importance of reporting related ADRs too. Reducing public harm is inherently acknowledged as key by responders.

e) Current awareness, involvement and training in public health.

Messages raising public awareness of SFs has not been reaching the public via pharmacy professionals, which raises important questions about promoting this message and getting it out to front-line staff and patients. While all pharmacy undergraduates are taught about the YCS in UK universities, this does not translate into practice as evidenced by general underreporting[31,32] of ADRs. Few respondents had reported SFs but more believed it helped to combat SFs. Six out of 501 of our respondents had reported SFs. Assuming our findings are nationally representative, we

anticipate 140 reports. Therefore, the 70 reports lodged with the MHRA, we believe, indicate an under-reporting (see Results, Sec e). This is supported in comments relating to informing the MHRA (see Results, Sec d).

Only three respondents had seen the 'Postcard Guidance for Patients' leaflet, which conflicts with their earlier responses to involvement in any campaigns regarding SF but can be explained by prior training. A sub-group analysis of these three responders revealed that they were two women and one man, with 0-5 years and 11-15 years of practice experience, working 25-34 hours and 35-44 hours per week and all believed that FMD would greatly improve patient safety. All had received training regarding SF and all would further seek such training. While most respondents were not aware of technologies in place to identify SF, a handful could name some strategies in place and overall envisaged them having a limited impact in combating SFs. While most respondents did not receive training, 69% would participate in a training program regarding SFs.

f) Confidence regarding handling SF medicines.

Pharmacists accepted that SF medicines pose a significant problem and that their lack of knowledge and resources was potentially detrimental. They accepted a degree of liability in such circumstances and that their intervention could disrupt use of SF medicines. Further training and listening to the patients could be useful in overcoming these barriers. Low scores were generally given for self and peer group for confidence, capability, vigilance and knowledge levels.

Table 6 shows slightly lower agreement in our sample with the statements: "The majority of my fellow pharmacists in the UK are confident regarding falsified medicines", "I'm constantly vigilant of encountering falsified medicines when checking prescriptions" and "I have enough knowledge to identify falsified medicines". This is normal and as expected because our sample is nearly double the original sample size.

g) Opinions on policy and the pharmacists' role in combating SF medicines.

Strong opinions on policy surrounding public health education, regulation and enforcement, supply chain management, product serialisation and reporting were made, though a greater regulatory role and supply chain integrity is expected by pharmacists. The role of the pharmacist was to build these checks into their accuracy checking, encourage education and training, identify and report SF medicines, raise public awareness, source medicines from reputable sources, have adequate resources and be vigilant and take action as necessary. Complex operational factors could make delivering all of these difficult. Some respondents did not believe that this was part of the pharmacist role and that it was the regulators job.

h) Examine geospatial location and Index of Multiple Deprivation (IMD) by decile.

Analysing the data by geographical distribution shows more SFs were identified in deprived areas (table 10).

Strengths and limitations.

We report on a nationally representative sample in the first study of its kind, examining readiness to implement FMD by pharmacies in England. Limitation of this study include those inherent to surveys, particularly those dependent on retrospective recall.

To assess non-respondent bias we examined dispensing statistics of the population, invited participants, respondents and non-respondents (table 11). Respondents tended to be from slightly

busier pharmacies than non-respondents, though by a small margin, making our findings nationally and internationally representative[30] and generalizable.

Table 11 Bias assessment.

NHS Dispensing Monthly (Mar 2018) Statistics		Number of Prescription Forms (nominal)	Number of Prescription Items (nominal)
Mean	England Population	3564 (3564±0)	7132 (7132±0)
	Invited	5355 (3564 +1,791)	10817 (7132+3,685)
	Respondent	5421 (3564 +1,857)	10953 (7132+3,821)
	Non-Respondent	5349 (3564 +1,785)	10800 (7132+3,668)
Standard deviation	England Population	2692 (2692±0)	5167 (5167±0)
	Invited	2044 (2692-648)	4611 (5167-556)
	Respondent	1918 (2692-774)	4302 (5167-865)
	Non-Respondent	2077 (2692-615)	4699 (5167-468)

Future research.

A larger study using our survey would be valuable to statistically validate our questionnaire. Qualitative studies with participants that have (and have not) identified and reported SFs may help explain why they reported it (or did not) and to explore ways of improving detection and reporting, in a bit to reduce public harm. More needs to be done at a national level about raising public awareness.

Conclusions.

We find pharmacies are not ready to implement FMD. Impact on workload and profitability were areas of concern, though improved patient safety was anticipated. Of the total number of medicines dispensed in England, 1 to 5% are believed to be falsified, with a greater proportion from online sources with erectile dysfunction and weight loss medicines at risk of falsification. Different packaging and different sources of medicine would raise suspicion among pharmacists. We found underreporting of detected SF medicines, with low confidence and self-efficacy on SFs among pharmacists. Limited public health campaigns may result in a lack of awareness amongst pharmacy professionals and patients. Limited awareness of technologies in place identifying SFs exist, though further training is welcome. Policy changes in the area of public health education, regulation and enforcement, supply chain management, serialisation and reporting are important. Geospatial analysis revealed more SFs were identified in deprived areas, potentially putting these patients at greater risk of harm from SF medicines.

Acknowledgments.

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Contributors.

The author conceived, designed, acquired, analysed and interpreted data. They developed and approved the version to be published and is accountable for its accuracy and integrity.

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Competing interests.

None

Patient consent.

Not required.

Ethics approval.

University of Portsmouth, Science Faculty Ethics Committee provided a favourable ethical review (reference SFEC 2018-086, Date Submitted: 28 September 2018).

Provenance and peer review.

Not commissioned, externally peer reviewed.

Data availability statement.

No further data is available to preserve participant anonymity.

Disclaimer.

The views expressed in this publication are those of the author(s) and not those of the University of Brighton, University of Portsmouth, nor the NHS.

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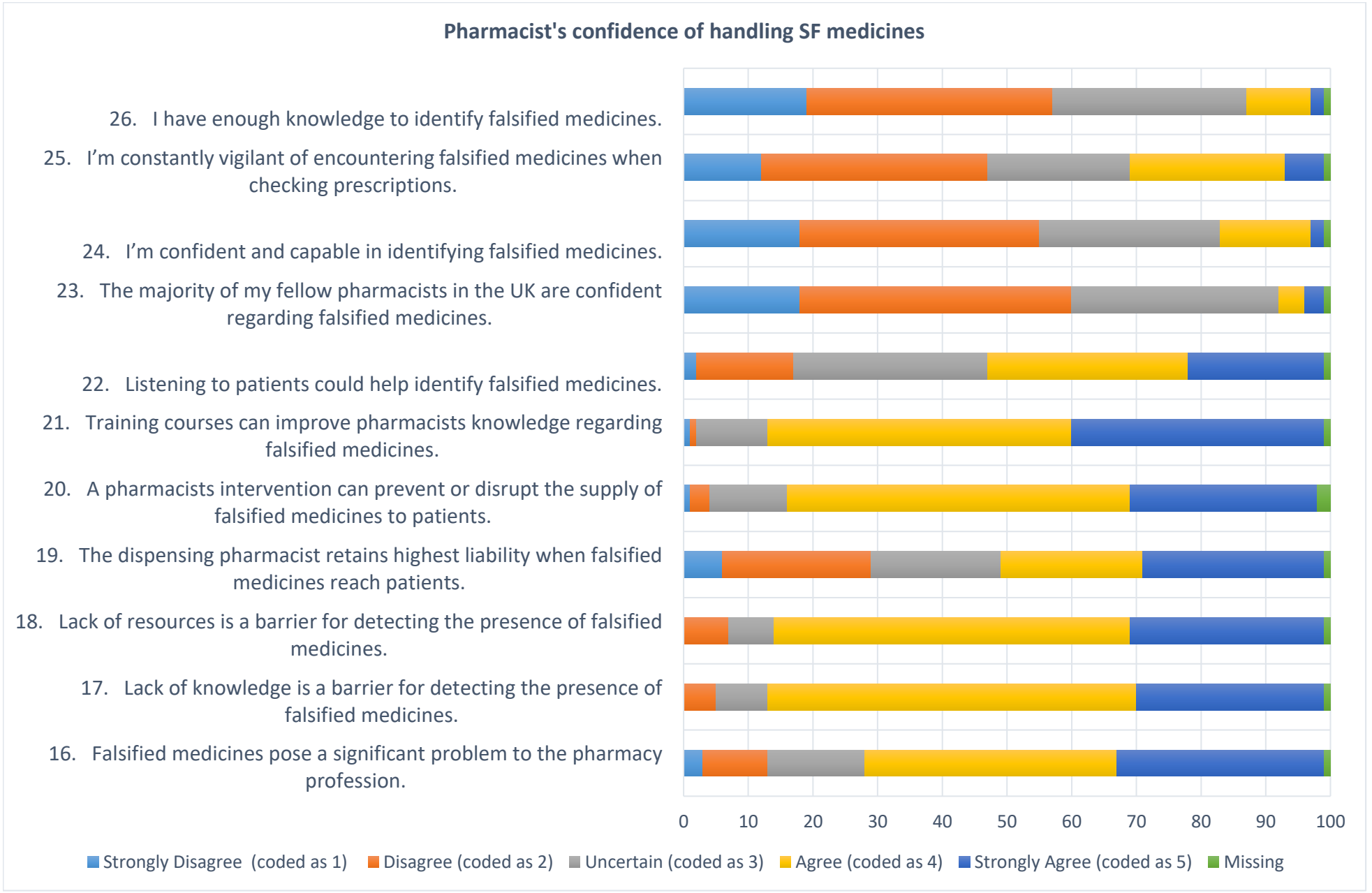
Pharmacist's confidence of handling SF medicines
26. I have enough knowledge to identify falsified medicines.
25. I'm constantly vigilant of encountering falsified medicines when checking prescriptions.
24. I'm confident and capable in identifying falsified medicines.
23. The majority of my fellow pharmacists in the UK are confident regarding falsified medicines.
22. Listening to patients could help identify falsified medicines.
21. Training courses can improve pharmacists knowledge regarding falsified medicines.
20. A pharmacists intervention can prevent or disrupt the supply of falsified medicines to patients.
19. The dispensing pharmacist retains highest liability when falsified medicines reach patients.
18. Lack of resources is a barrier for detecting the presence of falsified medicines.
17. Lack of knowledge is a barrier for detecting the presence of falsified medicines.
16. Falsified medicines pose a significant problem to the pharmacy profession.
0
10
20
30
40
50
60
70
80
90
100
Strongly Disagree (coded as 1)
Disagree (coded as 2)
Uncertain (coded as 3)
Agree (coded as 4)
Strongly Agree (coded as 5)
Missing

Appendix A_Survey

1.	What is your gender?	Male ☐	Female ☐	Other ☐		Prefer not to say ☐
2.	What type of pharmacy do you work in? (*Tick all that apply)*	Independent☐	Chain ☐	Online ☐	Other ☐	
3.	How many years have you been a registered pharmacist?	0-5 ☐	6-10 ☐	11-15 ☐	16-20 ☐	20+ ☐
4.	What are your current working hours per week as a pharmacist (excluding lunch hour)?	16 – 24 ☐	25 - 34 ☐	35 - 44 ☐	45 - 54 ☐	55+ ☐
5.	The deadline for full implementation is 9 February 2019. This requires every prescription only medicine and some pharmacy medicines to be scanned at point of dispensing (to check against a central database that they are not falsified, recalled or expired) at community pharmacy level across the EU, before supplying to the patients. How ready are you to implement this?	Not at all ☐	Not really ☐	Undecided ☐	Somewhat ☐	Very much ☐
6.	Have you adequate equipment (e.g. computer terminals, scanners, compliance software, include initial set-up, IT, both software and hardware, plus ongoing operational costs.) To enable you to fulfil this requirement?	Not at all ☐	Not really ☐	Undecided ☐	Somewhat ☐	Very much ☐
7.	How do you see this affecting your workload?	Not at all ☐	Not really ☐	Undecided ☐	Somewhat ☐	Very much ☐
8.	How do you see this affecting your business profitability?	Not at all profitable ☐	Not really profitable ☐	Undecided ☐	Somewhat profitable ☐	Very much profitable ☐
9.	How do you see this affecting patient safety?	Does not improve patient safety at all ☐	Does not improve patient safety ☐	Undecided ☐	Somewhat improves patient safety ☐	Very much improves patient safety ☐
10.	In your opinion, what percentage of medicines are believed to be falsified in the UK?	<1% ☐	1 - 5% ☐	6 - 10% ☐	11 - 20% ☐	>21% ☐

11. In your opinion, what percentage of medicines are believed to be falsified from online suppliers?	0 – 20% ☐	21 – 40% ☐	41 – 60% ☐	61 – 80% ☐	81-100% ☐
12. In your opinion, what is the most likely source of falsified medicine?	Internet pharmacies ☐	Personal Importation ☐	Professional falsifier ☐	Other (please state) ☐	

For each of the statements below, tick ☑ the response that best characterises how you feel regarding falsified medicines in the UK.

13. What are the most commonly falsified medicines in the UK? *(Tick most relevant)*	Anti-cholesterol ☐	Cancer ☐	Erectile dysfunction ☐	Heart problems ☐	Weight loss ☐	Other (please state) ☐
14. What would make you suspicious that a medicine is falsified? *(Tick all that apply)*	Different distribution route ☐	Different labelling ☐	Different packaging to original packaging ☐	Different product composition (e.g. ingredients including excipients)	Different packaging to original packaging	Different source (e.g. different manufacturer or country of origin)
15. Which national agency would you contact, if any? *(Tick most relevant)*	Department of Health (DoH) ☐	European Medicines Agency (EMA) ☐	Royal Pharmaceutical Society (RPS) ☐	Medicines Healthcare Products Regulator y Agency (MHRA) ☐	General Pharmaceutical Council (GPhC) ☐	Other (please state) ☐

For each of the statements below, tick ☑ the response that best characterises how you feel about the statement.

	Strongly Disagree	Disagree	Uncertain	Agree	Strongly Agree
16. Falsified medicines pose a significant problem to the pharmacy profession	☐	☐	☐	☐	☐
17. Lack of knowledge is a barrier for detecting the presence of falsified medicines	☐	☐	☐	☐	☐
18. Lack of resources is a barrier for detecting the presence of falsified medicines	☐	☐	☐	☐	☐
19. The dispensing pharmacist retains highest liability when falsified medicines reach patients	☐	☐	☐	☐	☐
20. A pharmacists intervention can prevent or disrupt the supply of falsified medicines to patients	☐	☐	☐	☐	☐
21. Training courses can improve pharmacists knowledge regarding falsified medicines	☐	☐	☐	☐	☐
22. Listening to patients could help identify falsified medicines	☐	☐	☐	☐	☐
23. The majority of my fellow pharmacists in the UK are confident regarding falsified medicines	☐	☐	☐	☐	☐

24. I'm confident and capable in identifying falsified medicines	☐	☐	☐	☐	☐
25. I'm constantly vigilant of encountering falsified medicines when checking prescriptions	☐	☐	☐	☐	☐
26. I have enough knowledge to identify falsified medicines	☐	☐	☐	☐	☐

For each of the questions below please tick ☑ for either Yes or No.	**Yes**	**No**
27. a) Have you been involved in any campaigns regarding falsified medicines?	☐	☐
b) If yes, please state the name of the campaign.		
c) Do you believe that campaigns was effective?	☐	☐
28. a) Have you ever used the Yellow Card Scheme for falsified medicines?	☐	☐
b) Do you believe this scheme is useful in combating falsified medicines?	☐	☐
29. a) Have you seen the 'Postcard Guidance for Patients' leaflet?	☐	☐
30. a) Are you aware of any technologies in place to identify falsified medicines?	☐	☐
b) Which technologies?		
c) Do you believe this technology would be effective in combating falsified medicines?	☐	☐
31. a) Have you ever received any training regarding falsified medicines?	☐	☐
b) Would you participate in a training program regarding falsified medicines?	☐	☐

For each of the questions below please tick ☑ for either Yes or No.	**Yes**	**No**
32. a) Have you ever identified falsified medicines?	☐	☐
b) Did you inform the MHRA if you identified falsified medicines?	☐	☐
c) What did you do in that situation?		
33. a) Do you keep any records when encountering potential falsified medicines?	☐	☐
b) What records do you maintain when encountering falsified medicines?		

34. a) In your opinion, how can falsified medicines reaching the public be reduced?

b) In your opinion, what role can pharmacists play in combating falsified medicines?

Any additional comments:

END OF SURVEY. Thank you for completing this survey please return it in the prepaid, self-addressed envelope provided.

Reporting a Counterfeit Product could not be easier via the Yellow Card Scheme:
https://yellowcard.mhra.gov.uk/counterfeit-products/
You can complete a two page form to report a suspected counterfeit product (fake medicine or fake medical device) including any related side effects or safety concerns to the Yellow Card Scheme. You can register on the Yellow Card reporting site when you submit a report, or you can register in advance.
Alternatively, you can report a suspected counterfeit anonymously by contacting our 24-hour counterfeit hotline telephone number on 020 3080 6701.

Appendix B

IMD Decile (1 poorest, 10 richest)	Frequency of respondents	Gender. (n = 102)			Years of registered experience. (n = 102)					Working hours per week. (n = 102)				Ever used the Yellow		Seen the 'Postcard		Aware of any		Ever received any		Ever identified falsified	
		Male	Female	Other	0-5	6-10	11-15	16-20	20+	16 – 24	25 - 34	35 - 44	45 - 54	Yes	No	Yes	No	Yes	No	Yes	No	Yes	No
1	17	7	10	0	6	4	2	0	5	0	2	11	4	1	14	1	15	1	14	1	15	2	14
2	17	7	8	2	6	2	7	1	1	1	4	9	3	2	15	0	17	2	15	0	17	1	16
3	16	9	7	0	5	5	2	0	4	0	2	12	2	0	13	0	13	3	10	1	12	1	12
Total	**50**	**23**	**25**	**2**	**17**	**11**	**11**	**1**	**10**	**1**	**8**	**32**	**9**	**3**	**42**	**1**	**45**	**6**	**39**	**2**	**44**	**4**	**42**
%	100%	46%	50%	4%	34%	22%	22%	2%	20%	2%	16%	64%	18%	7%	93%	2%	98%	13%	87%	4%	96%	9%	91%
4	15	7	7	1	5	5	2	0	3	2	1	11	1	1	12	1	12	3	10	1	12	0	13
5	4	3	1	0	0	0	2	0	2	0	0	4	0	0	4	0	4	0	4	0	4	0	4
6	7	3	3	1	4	3	0	0	0	0	0	7	0	0	6	1	5	1	5	0	6	0	6
7	11	4	7	0	5	1	2	0	3	0	0	9	2	1	7	0	8	3	5	0	8	1	7
8	5	2	3	0	2	2	1	0	0	0	0	5	0	1	4	0	5	0	5	0	5	0	5
9	4	2	2	0	1	1	2	0	0	0	0	4	0	0	3	0	3	1	2	0	3	0	3
10	6	2	3	1	3	3	0	0	0	0	1	5	0	0	6	0	6	0	6	0	6	0	6
Total	**52**	**23**	**26**	**3**	**20**	**15**	**9**	**0**	**8**	**2**	**2**	**45**	**3**	**3**	**42**	**2**	**43**	**8**	**37**	**1**	**44**	**1**	**44**
%	100%	44%	50%	6%	38%	29%	17%	0%	15%	4%	4%	87%	6%	7%	93%	4%	96%	18%	82%	2%	98%	2%	98%

Reporting checklist for cross sectional study.

Based on the STROBE cross sectional guidelines.

Instructions to authors

Complete this checklist by entering the page numbers from your manuscript where readers will find each of the items listed below.

Your article may not currently address all the items on the checklist. Please modify your text to include the missing information. If you are certain that an item does not apply, please write "n/a" and provide a short explanation.

Upload your completed checklist as an extra file when you submit to a journal.

In your methods section, say that you used the STROBE cross sectionalreporting guidelines, and cite them as:

von Elm E, Altman DG, Egger M, Pocock SJ, Gotzsche PC, Vandenbroucke JP. The Strengthening the Reporting of Observational Studies in Epidemiology (STROBE) Statement: guidelines for reporting observational studies.

		Reporting Item	Page Number
Title and abstract			
Title	#1a	Indicate the study's design with a commonly used term in the title or the abstract	1
Abstract	#1b	Provide in the abstract an informative and balanced summary	2

		of what was done and what was found	
Introduction			
Background / rationale	#2	Explain the scientific background and rationale for the investigation being reported	4
Objectives	#3	State specific objectives, including any prespecified hypotheses	4-5
Methods			
Study design	#4	Present key elements of study design early in the paper	5
Setting	#5	Describe the setting, locations, and relevant dates, including periods of recruitment, exposure, follow-up, and data collection	5-6
Eligibility criteria	#6a	Give the eligibility criteria, and the sources and methods of selection of participants.	5
	#7	Clearly define all outcomes, exposures, predictors, potential confounders, and effect modifiers. Give diagnostic criteria, if applicable	n/a
Data sources / measurement	#8	For each variable of interest give sources of data and details of methods of assessment (measurement). Describe comparability of assessment methods if there is more than one group. Give information separately for for exposed and unexposed groups if applicable.	6
Bias	#9	Describe any efforts to address potential sources of bias	5
Study size	#10	Explain how the study size was arrived at	6

Quantitative variables	#11	Explain how quantitative variables were handled in the analyses. If applicable, describe which groupings were chosen, and why	6
Statistical methods	#12a	Describe all statistical methods, including those used to control for confounding	6
Statistical methods	#12b	Describe any methods used to examine subgroups and interactions	6
Statistical methods	#12c	Explain how missing data were addressed	6
Statistical methods	#12d	If applicable, describe analytical methods taking account of sampling strategy	n/a
Statistical methods	#12e	Describe any sensitivity analyses	n/a
Results			
Participants	#13a	Report numbers of individuals at each stage of study—eg numbers potentially eligible, examined for eligibility, confirmed eligible, included in the study, completing follow-up, and analysed. Give information separately for for exposed and unexposed groups if applicable.	7-15
Participants	#13b	Give reasons for non-participation at each stage	n/a
Participants	#13c	Consider use of a flow diagram	n/a
Descriptive data	#14a	Give characteristics of study participants (eg demographic,	7

		clinical, social) and information on exposures and potential confounders. Give information separately for exposed and unexposed groups if applicable.	
Descriptive data	#14b	Indicate number of participants with missing data for each variable of interest	7-15
Outcome data	#15	Report numbers of outcome events or summary measures. Give information separately for exposed and unexposed groups if applicable.	7-15
Main results	#16a	Give unadjusted estimates and, if applicable, confounder-adjusted estimates and their precision (eg, 95% confidence interval). Make clear which confounders were adjusted for and why they were included	7-15
Main results	#16b	Report category boundaries when continuous variables were categorized	7-15
Main results	#16c	If relevant, consider translating estimates of relative risk into absolute risk for a meaningful time period	n/a
Other analyses	#17	Report other analyses done—e.g., analyses of subgroups and interactions, and sensitivity analyses	17
Discussion			
Key results	#18	Summarise key results with reference to study objectives	15-18
Limitations	#19	Discuss limitations of the study, taking into account sources of potential bias or imprecision. Discuss both direction and magnitude of any potential bias.	18

Interpretation	#20	Give a cautious overall interpretation considering objectives, limitations, multiplicity of analyses, results from similar studies, and other relevant evidence.	15-18
Generalisability	#21	Discuss the generalisability (external validity) of the study results	17
Other Information			
Funding	#22	Give the source of funding and the role of the funders for the present study and, if applicable, for the original study on which the present article is based	19

BMJ Open

An evaluation of community pharmacists' readiness to implement the Falsified Medicines Directive (Directive 2011/62/EC): An English cross-sectional survey with geospatial analysis.

Journal:	*BMJ Open*
Manuscript ID	bmjopen-2019-033405.R2
Article Type:	Original research
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Primary Subject Heading:	General practice / Family practice
Secondary Subject Heading:	Public health, Evidence based practice, General practice / Family practice, Global health, Health policy
Keywords:	counterfeit drugs, falsified medicines, PUBLIC HEALTH, pharmacy, spatial analysis, substandard medicine

An evaluation of community pharmacists' readiness to implement the Falsified Medicines Directive (Directive 2011/62/EC): An English cross-sectional survey with geospatial analysis.

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Keywords:

counterfeit drugs; drug-related side effects and adverse reactions; falsified medicines; Falsified Medicines Directive (Directive 2011/62/EC); pharmacists; survey; public health; pharmacy; spatial analysis; medicine quality; procurement; substandard medicine

Abstract.

Objectives: to evaluate the readiness to implement the Falsified Medicines Directive (FMD) by community pharmacies in England. Eight secondary objectives were assessed.

Setting: Community/Retail pharmacies.

Participants: We invited pharmacists from 501 pharmacies to complete a survey. Non-contractors, non-pharmacists or pharmacists practising abroad were excluded. We randomly selected addresses, ensuring they were nationally representative.

Interventions: We mailed the survey in October 2018 with a single follow-up in January 2019. Respondents were invited to provide self-reported answers. A prepaid self-addressed envelope was provided. We received favourable ethical approval.

Results: 102 responses (20.44% response rate) were received. Readiness to implement was poor: 4 (3.9%) said very much, while 40 (39.2%) said not at all and 29 (28.4%) said not really. Increased workload and reduced profitability was anticipated, accompanied with improved patient safety. Prevalence of 'Substandard and Falsified (SF) Medical Products' was estimated at 1 to 5%, with erectile dysfunction at greatest risk of falsification. Different packaging would raise suspicions. Five (4.9%) had identified SFs ($p<0.001$ One sample binomial). Of these, three (2.9%) informed the medicines agency. None had been involved in any public health campaigns. Confidence and self-efficacy was low. Strategies to reduce SFs reaching the public are described. Pharmacist's role in combating SFs was elucidated. SFs were identified in deprived areas 4 (9%) more often than in affluent areas 1 (2%).

Conclusions: Many pharmacies are not ready to implement FMD, potentially not capturing anticipated benefits of the directive, with greatest risk of harm in deprived area. We further validated a confidence scale. Limited public health campaigns may result in a lack of awareness amongst pharmacy professionals and patients. Limited awareness of technologies to identify falsified medicines exist, though further training is welcome. A worrying trend of underreporting maybe prevalent. A larger sample study using this survey would be valuable.

Article Summary.

Strengths and limitations of this study

- This is the first study to evaluate the readiness of community pharmacies in England to implement the European Union's Falsified Medicines Directive (Directive 2011/62/EC) by 9 February 2019.
- We invited pharmacists from 501 pharmacies across England to complete a survey.
- Postcodes of pharmacies were linked with freely available data on index of multiple deprivation (IMD) scores, which provides an estimate of the socioeconomic deprivation of the practice population.
- The interactive application helps to visualize the data easily: https://arcg.is/0q1mGf or https://portuni.maps.arcgis.com/apps/webappviewer/index.html?id=95497aeae0cf4411abd8433d736b8989
- Limitation of this study include those inherent to surveys, particularly those dependent on retrospective recall.

Introduction.

There is no universally agreed definition of counterfeit/falsified medication and jurisdictions around the world define these types of medicines in many different ways. The World Health Organization (WHO) identifies 'Substandard and Falsified (SF) Medical Products'[1,2] that demonstrate public harm.[3] The European Union (EU) has a strong legal framework for the licensing, manufacturing and distribution of medicines supported by the EU Member States in implementing the falsified medicines Directive.[4,5] At writing, the United Kingdom (UK) remains an EU member state. At the end of the distribution chain, only licensed pharmacies and approved retailers are allowed to offer medicines for sale, including legitimate sale via the internet.[6,7]

No specific definition of counterfeit medical product exists within English law and the national competent agency (The Medicines and Healthcare products Regulatory Agency (MHRA)) adopts the definition contained within the European Falsified Medicines Directive (FMD) and has provided guidance on its implementation. The final part of the Directive, the 'safety features' Delegated Regulation (EU) 2016/161 comes into force on 9 February 2019 in the UK.[8]

This requires every prescription only medicine and some pharmacy medicines to be scanned at point of dispensing (to check against a central database that they are not falsified, recalled or expired) at community pharmacy level across the EU, before supplying to the patients. The pharmacists' responsibilities are to 1) check that the anti-tampering device placed on the package by the manufacturer is intact before dispensing and 2) scan the 2D barcode and communicating with the National Medicine Verification System to change the status of the pack from 'active' to 'inactive-dispensed'. The first requires visual inspection while the second requires a scanning tool.[9–11] This now forms a part of regulatory compliance inspections and can attract disciplinary actions against registered professionals and premises.[12,13]

Falsified medicines and medical devices are problematic in both primary and secondary care as they are not subject to the rigorous quality standards and can create difficulty in identifying sources of contamination and public harm. The parallel import system in the EU also permit legitimate movement of medicines through the supply chain over large geographic territories, which is susceptible to infiltration by SF medicines.

Pharmacist's ability to identify SF medication can help in thwarting public harm alongside implementation of the FMD. No studies of English pharmacist's experiences of implementing FMD exist. This study is needed because it seeks to understand the challenges faced by the healthcare team caring for National Health Service (NHS) patients and other under pressure models of care in the Western world. Challenges include growing patient demand, changing patterns of demand, insufficient funding in primary care, reduced access to General practitioners (GPs) and addressing national health inequalities. From our 2016-17 study,[14] we hypothesise that the theme of 'lack of resources' may continue.

Preparing for FMD implementation is a fundamental, structural change in an already well-established pharmacy dispensing and checking processes that risk-assesses and quality-assures the core pharmacy business. Inserting an additional stage of 'FMD compliance checking' is intended to further risk-reduce and safeguard the public.

Several change management theories exist[15–21] for sustaining positive change. Rogers' Diffusion of Innovation Theory[22] introduced five change phases: Knowledge (education and communication to expose staff to the change), Persuasion (use of change champions to pique staff interest; peers persuading peers), Decision (staff decide whether to accept or reject the change), Implementation

(putting new processes into practice) and Confirmation (staff recognize the value and benefits of the change and continue to use changed processes).

Change is inevitable in health care. A significant problem specific to health care is that almost two-thirds of all change projects fail for many reasons, such as poor planning, unmotivated staff, deficient communication, or excessively frequent changes.[23–25] The challenges relate to three features of their organizational environment: the fact that organizational change is mostly driven by external pressures; the speed with which change has to be implemented; and the frequency of change initiatives.[26]

The lack of research evidence suggests that the change process, up to the point of the research period, was managed using a largely directive approach in the UK. However, FMD poses a national and Europe wide 'change process' that is at risk of failure for the reasons identified. Assessing the geographic progress of implementation (and SFs detection rates inherent there) may inform policy and prevent health inequalities from emerging, because of this legislation.

The current study on FMD implementation, reflects how well the change process is fully characterised and supported by the many stakeholders, including retail pharmacy chains and employed pharmacists (especially financially in the workload and time allowance of the responsible staff). This includes the provision of additional resources (e.g. computers, employee time, etc.), preparedness and ongoing provision of training, and managing any unexpected, unintended, consequences of such a change.

This highlights the need to describe current practices around identifying and reporting of SFs, so that in time, we may be able to describe the impact of FMD on pharmacy services and its effectiveness. We hypothesise that pharmacist's confidence of handling SFs may change over time and so, capturing a snapshot now may be useful as a benchmark. The study also gives voice to the pharmacy professionals who are expected to deliver the implementation, in a naturalistic environment (not previously done). These concepts link our primary and secondary objectives to provide a coherent rationale to our study objectives.

Objectives.

The primary objective of this study was to evaluate the readiness to implement FMD (Directive 2011/62/EC) by 9 February 2019 by community pharmacies in England. Secondary objectives were to:

a) assess the impact of change on current operations,
b) establish prior knowledge of prevalence of SF medicines,
c) determine what visual checks are done to identify SF medicines,
d) establish current practice around the identification and reporting of SF medicines,
e) establish current levels of awareness, involvement and training in public health by pharmacists with respect SF medicines,
f) explore pharmacists confidence of handling SF medicines,
g) seek opinions on policy and understand the pharmacist's role in combating SF medicines,
h) examine association with geospatial location and Index of Multiple Deprivation (IMD) scores.

Methods.

We invited pharmacists from 501 pharmacies that contribute to the NHS's Business Services Authority (BSA) dispensing data across England to complete a survey, as the BSA is responsible for pharmacy reimbursements and collates accurate prescription data on behalf of the NHS. Community pharmacies that are not NHS contractors, non-pharmacists or pharmacists practicing abroad were excluded. Addresses were taken from publicly available BSA website (March 2018) to gain a nationally representative sample.

We selected them randomly between contractor code (FAQ87 to FYR36), which resulted in recruiting a single large national pharmacy chain. We ensured they were nationally representative with respect to the number of prescription forms (invited sample mean 5355, SD 2044 versus English population mean 3564, SD 2692) and number of prescription items dispensed (invited sample mean 10817, SD 4611 versus English population mean 9875, SD 5480). This permits comparison with like for like businesses (approximately equal burden of work, similar team size, and similar business complexity) across the country, therefore allowing fair comparison between pharmacies invited to study and the wider pharmacy population.

We mailed the cross-sectional survey in October 2018 with a single follow-up of non-responders in January 2019. Respondents were invited to provide self-reported answers. A prepaid self-addressed envelope was included. We sought and received favourable institutional ethical approval. No financial (or similar) benefits were offered to minimise biased responses.[27]

Questionnaire.

The questionnaire was composed of items relating to the objectives. The full survey is available in Appendix A. A previously validated scale[14] was incorporated in this survey.

We piloted the questionnaire via six steps. Questionnaire was pre-tested by researchers critically appraising the scale in a research-team focus-group. This comprised two external practicing community pharmacists, other academics with recent community and hospital practice experience, and student researchers. 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. To improve internal validity and reliability, the survey instrument was piloted with another external community pharmacist, and cognitive testing (read-aloud) was conducted. It took less than 10 minutes to complete the final survey.

There are 11,619 community pharmacies in England in 2017-18.[28] To be representative, (assuming confidence level of 95%, confidence interval of 10%, standard error of 5%, relative standard error of 10%), a minimum sample size of 95 was calculated. To achieve this, we invited 501 pharmacies as our previous response rates range between 15% to 25% in similar studies.[14,29,30] Analyses were undertaken using SPSS[31] to present proportions, descriptive statistics and hypothesis testing at 95% confidence level and 5% significance. Missing data are presented, any sub-group analysis will be descriptive. Comments are thematically analysed.[32,33]

Postcodes of pharmacies were linked with freely available data on IMD score,[34] an estimate of the socioeconomic deprivation of the practice population and NHS dispensing data.[35] The IMD, is the official measure of relative deprivation for small areas in England and the latest scores are presented in IMD 2015 data. It is a composite score of seven underlying domains related to income deprivation, employment deprivation, education, skills and training deprivation, health deprivation and disability, crime, barriers to housing and services, living environment deprivation.[34] We were interested to

see if deprivation and SFs detection and reporting was linked in any way - which we find it is (as per our discussion and conclusion).

We mapped our results using Arc GIS online (https://arcg.is/0q1mGf , legend: Yellow dot, red dot and green dot represents those who are 'somewhat' and 'very much' ready to implement FMD by the 9th Feb 2019, who said FMD would affect workload and those who said FMD would affect business profitability respectively. Orange dot represents those who had used the Yellow Card Scheme (YCS) for reporting SF, blue dot represents those who had ever identified SF and green dot represents all respondents). We created an app with several layers to visualize the data easily, freely and publically:
https://portuni.maps.arcgis.com/apps/webappviewer/index.html?id=95497aeae0cf4411abd8433d736b8989

We mapped our responses alongside the IMD 2015 data (Ranks: every postcode has a rank from 1, which is the most deprived area up to 32,844 that is the least deprived area. Deciles are published alongside ranks to assess relative deprivation and we have used these).

At the end of our survey, we included brief guidance on reporting Counterfeit Products via the YCS (https://yellowcard.mhra.gov.uk/counterfeit-products/) operated by the MHRA. Participants can complete a two-page form to report a suspected counterfeit product (fake medicine or fake medical device) including any related side effects or safety concerns to the YCS. Participants can register on the site when submitting a report, or can register in advance. Alternatively, participants can report a suspected counterfeit anonymously by contacting the 24-hour counterfeit hotline telephone number on +44 (0)20 3080 6701.

No Patient and Public Involvement.

We did not involve patients or the public in our work. This is likely to be done in the future.

We used the STROBE cross sectional reporting guidelines.[36]

Results.

In total, 102 responses (20.44% response rate) were received (two closures and abatements), satisfying our sample size needs. Demographic data are summarized in table 1.

Table 1 Characteristics of survey respondents (n=102).

Respondent Variables.	**Frequency (Percentage %) (n=102).**
Sex	
Male	46 (45.1%)
Female	51 (50.0%)
Preferred not to say	5 (4.9%)
Years of registration experience	
0-5	37 (36.3%)
6-10	26 (25.5%)
11-15	20 (19.6%)
16-20	1 (1.0%)
> 20 years	18 (17.6%)
Working Hours (Per Week)	
16 – 24	3 (2.9%)
25 – 34	10 (9.8%)
35 – 44	77 (75.5%)

45 – 54	12 (11.8%)

Table 1 shows a sex ratio in line with the latest census.[37] Most (62%) responders had 10 years or less practice experience, with 75.5% working full-time hours.

We enquired how ready respondents were to implement this directive. Forty (39.2%) said not at all, 29 (28.4%) said not really, 14 (13.7%) were undecided, 12 (11.8%) said somewhat and 4 (3.9%) said very much, 3 (2.9%) missing.

We enquired if adequate equipment and expenses were prepared (e.g. computer terminals, scanners, compliance software, include initial set-up, IT, both software and hardware, plus ongoing operational costs). Twenty-two (21.6%) said not at all, 26 (25.5%) said not really, 12 (11.8%) were undecided, 31 (30.4%) said somewhat and 11 (10.8%) said very much.

a) Impact of change on current operations.

We perceived changes to workload and profitability, as shown in Figure 1 and 2.

Figure 1 Impact on community pharmacy workload.

[Insert Fig 1 here]

Figure 2 Impact on community pharmacy profitability.

[Insert Fig 2 here]

Improved patient safety is the desired outcome of this directive, so we enquired how this might be impacted (Table 2).

Table 2 Impact on patient safety.

n (%)	Does not improve patient safety at all	Does not improve patient safety	Undecided	Somewhat improves patient safety	Very much improves patient safety	Missing
Patient safety	-	4 (3.9%)	14 (13.7%)	41 (40.2%)	38 (37.3%)	5 (4.9%)

b) Prior knowledge of prevalence of SF medicines.

We wanted to know what percentage of medicines are believed to be falsified in the UK, as an indicator of prior knowledge of prevalence of SF medicines (See Fig 3 & 4).

Figure 3 Perceived prevalence of SF medicines.

[Insert Fig 3 here]

Figure 4 Medicines believed to be falsified from online suppliers.

[Insert Fig 4 here]

We asked about the most likely sources of falsified medicine: 59 (56.2%) said 'internet pharmacies', 21 (20.0%) said 'personal importation', 23 (21.9%) said 'professional falsifier', 2 (1.9%) said 'other' (of which 1 did not elaborate and another said "including illegal websites"), 1 missing. Three respondents gave combination-answers.

Finally, we asked what were the most commonly falsified medicines in the UK and invited multiple responses. Seven said 'anti-cholesterol', 5 said 'cancer', 77 said 'erectile dysfunction', 5 said 'heart

problems', 32 said 'weight loss', 6 said 'other' (benzodiazepines, painkillers, anabolic steroids), 2 missing.

c) Visual checks done to identify SF medicines.

We asked what would raise suspicions of an SF. Forty said 'different distribution route', 40 said 'different labelling', 87 said 'different packaging to original packaging', 26 said 'different product composition (e.g. ingredients including excipients), 50 'different source' (e.g. different manufacturer or country of origin), 3 said 'other' with reasons including cost, foreign text and medicine's appearance.

d) Practice around the identification and reporting of SF medicines.

Five (4.9%) had identified SF, 86 (84.3%) had never, 11 (10.8%) missing, ($p<0.001$ One sample binomial test, 95% CI: 1.95 ± 0.0471). In such circumstance, three (2.9%) informed the MHRA and five explanatory comments were received: *"Patient didn't want to report it she bought it from online pharmacy, I would contact MHRA"* (not reported to MHRA). *"It was bought in by a patient who had bought it from a friend and wanted to check if it was genuine. Advised not to take"* (not reported to MHRA). *"Referred patient back to where they purchased it"* (not reported to MHRA). *"Yellow card"* and *"Melatonin"* were both reported to MHRA.

Twenty-one (20.6%) kept records when encountering potential SF, 56 (54.9%) did not, 25 (24.5%) missing, ($p<0.001$ One sample binomial test, 95% CI: 1.73 ± 0.1). Eight participants who kept records, went on to elaborate with comments (major theme of recording and reporting): *"If we came across any on our [proprietary] system", "Reporting on company system", "Online reporting tools of pharmacy events", "I would keep records", "In store records", "Hypothetically POM register, internal reporting system and Yellow card", "Details of the medicine, Name, manufacturer, distributor, strength, form", "Incident report sent online to headquarters".*

We enquired which national agency would they contact, if any. Nine said Department of Health (DoH), 17 said European Medicines Agency (EMA), 7 said Royal Pharmaceutical Society (RPS), 74 said Medicines Healthcare Products Regulator y Agency (MHRA), 15 said General Pharmaceutical Council (GPhC) and 3 said 'other', with reasons including *"Head office for advice, then appropriate agency", "company head office"* and *"[name] support office".*

e) Current awareness, involvement and training in public health.

None had been involved in any campaigns regarding SF, 91 (89.2%) said no, 11 (10.8%) missing. No campaign was named, though, 8 (7.8%) believed that the campaigns they encountered were effective, while 42 (41.2%) did not, 52 (51.0%) missing, ($p<0.001$ One sample binomial test, 95% CI: 1.91 ± 0.121).

Six (5.9%) had ever used the YCS for SF, 84 (82.4%) had not, 12 (11.8%) missing, ($p<0.001$ One sample binomial test, 95% CI: 1.93 ± 0.0519). Thirty-seven (36.3%) said yes this scheme is useful in combating SF, 34 (33.3%) said no, 31 (30.4%) missing.

To try and corroborate our findings to a nationally representative sample, we separately placed a Freedom of Information Request (FOI) with the MHRA in October 2018 to request data regarding UK suspected Adverse Drug Reactions (ADRs) that have been reported with suspected counterfeit or SF (Query ref: GENQ-00131558). Where a patient has experienced a suspected ADR to a medicine, even if the medicine is suspected to be counterfeit or falsified, this is recorded on their database. The MHRA has received a total of 70 UK spontaneous suspected ADR reports associated with SF for the period 01/07/1963 – 09/10/2018.

Three (2.9%) had seen the 'Postcard Guidance for Patients'[38] leaflet, 88 (86.3%) had not, 11 (10.8%) missing, (p<0.001 One sample binomial test, 95% CI: 1.97 ± 0.037). Fourteen (13.7%) were aware of technologies in place to identify SF, 76 (74.5%) were not, 12 (11.8%) missing, (p<0.001 One sample binomial test, 95% CI: 1.84 ± 0.0752). Technologies quoted in 11 comments presented two themes of barcode scanning and hologram use, 91 missing. Thirty-six (35.3%) believed technologies were effective in combating SF, 28 (27.5%) did not, 38 (37.3%) missing. Three (2.9%) had received any training regarding SF, 88 (86.3%) had not, 11 (10.8%) missing, (p<0.001 One sample binomial test, 95% CI: 1.97 ± 0.037). Seventy (68.6%) would participate in such training, 13 (12.7%) would not, 19 (18.6%) missing, (p<0.001 One sample binomial test, 95% CI: 1.12 ± 0.107).

f) Confidence regarding handling SF medicines.

Then we sought strength of opinion on a validated scale,[14] presented in figure 5. These cover statements 16 to 26 (Appendix A).

Figure 5 Confidence regarding handling falsified medicines (p<0.001 One sample chi square test for all statements), percentages have been rounded to whole numbers.

[Insert Fig 5 here]

It is important to note that the scales was originally validated in a smaller sample (n=50) within Hampshire, UK. Validity and reliability are two fundamental elements in the evaluation of a measurement instrument. Validity is concerned with the extent to which an instrument measures what it is intended to measure. Reliability is concerned with the ability of an instrument to measure consistently. It should be noted that the reliability of an instrument is closely associated with its validity. An instrument cannot be valid unless it is reliable.[39] Cronbach's alpha is the most widely used objective measure of reliability. There are different reports about the acceptable values of alpha, ranging from 0.70 to 0.95.[40–42]

Previously, we reported a 0.728 Cronbach's Alpha (on Standardized Items) of the 11 Item (Q16-26) scale.[14] Reliability Statistics were re-calculated here and a Cronbach's Alpha (on Standardized Items) of the scale was 0.675 in this study (n=100, 2 missing). This is very close to 0.70 and we accept this sufficiently demonstrates validity. We did a further Scale analysis with a Cronbach's Alpha Split-half in Part 1 (The items are: Q16, Q17, Q18, Q19, Q20, Q21.) and Part 2 (The items are: Q22, Q23, Q24, Q25, Q26.). We found the Cronbach's Alpha for Part 1 to be 0.672, and for Part 2 was 0.753. The Correlation Between Forms was 0.074, the Spearman-Brown Coefficient of Equal and Unequal Length was 0.138, the Guttman Split-Half Coefficient was 0.138, demonstrating good validity and reliability.

We have also presented current and previously validated means and standard deviations to assess validity of our results and their relative difference (See Table 1 of appendix B), which shows small deviations from our original findings, except in statements 23, 25 and 26. Our study provides further face validity to this confidence scale, in a nationally representative sample.

g) Opinions on policy and the pharmacists' role in combating SF medicines.

We enquired how we could reduce SF reaching the public. Forty-seven comments were received and present the following major and sub-themes: 1. Public health education, Sub-theme of a. Public education and b. Professional education (of all involved in supply chain). 2. (Government) Regulation and enforcement, Sub-theme of a. Regulated online sales and b. Regulatory Control. 3. Supply chain management, Sub-theme of a. Role of the manufacturers, b. Role of the wholesalers and c. Role of

all (manufacturers, wholesalers and pharmacy). 4. Serialisation (Track & Trace). 5. Reporting to the regulator, medical staff and internally to pharmacy. Detailed analysis is presented in Table 2 of appendix B.

We then asked what role can pharmacists play in combating falsified medicines. Thirty-seven comments were received with the major themes of 1. Build into accuracy check. 2. Complex and multifactorial. 3. Education and training. 4. Identify and report. 5. Not pharmacist's role. 6. Public awareness. 7. Regulator's job. 8. Reputable sources. 9. Resources. 10. Vigilance and action. Detailed analysis is presented in Table 3 of appendix B.

Five comments were additionally received (See Table 4 of appendix B) with a major themes: 1. Not a pharmacist's job. 2. Quality Supply chain. 3. Technical difficulties. 4. Wholesaler's duty. 5. YCS ineffective.

h) Examine geospatial location and Index of Multiple Deprivation (IMD) by decile.

We found that our sample was well distributed with good geographical representation of urban and rural residents, representing population densities fairly well: https://arcg.is/0q1mGf. We stratified the data by decile (table 3) and visually assessed our maps. The data were segregated in near-even portions representing deprived areas versus affluent areas for easy comparison. With respect to inequalities, there seem to be minimal except for the detection rates of SFs, which is higher in more deprived areas (See Q32a in Appendix C for details).

Table 3 Respondent's demographics vs IMD decile (1 poorest, 10 richest) distribution. Percentages (adjusted bases) have been rounded to whole numbers, small numbers may not add to 100%.

		Deprived Decile (1, 2, 3) n, %	Affluent Decile (4 to 10) n, %
Frequency of respondents	n, %	50, 100%	52, 100%
Gender. (n = 102)	Male	23, 46%	23, 44%
	Female	25, 50%	26, 50%
	Other	2, 4%	3, 6%
Years of registered experience. (n = 102)	0-5	17, 34%	20, 38%
	6-10	11, 22%	15, 29%
	11-15	11, 22%	9, 17%
	16-20	1, 2%	0, 0%
	> 20 years	10, 20%	8, 15%
Working hours per week. (n = 102)	16 – 24	1, 2%	2, 4%
	25 - 34	8, 16%	2, 4%
	35 - 44	32, 64%	45, 87%
	45 - 54	9, 18%	3, 6%

Ever used the YCS for SF. (n = 90)	Yes	3, 7%	3, 7%
	No	42, 93%	42, 93%
Seen the 'Postcard Guidance for Patients' leaflet? (n = 91)	Yes	1, 2%	2, 4%
	No	45, 98%	43, 96%
Aware of any technologies in place to identify SF? (n = 90)	Yes	6, 13%	8, 18%
	No	39, 87%	37, 82%
Ever received any training regarding SF? (n = 91)	Yes	2, 4%	1, 2%
	No	44, 96%	44, 98%
Ever identified SF? (n = 91)	Yes	4, 9%	1, 2%
	No	42, 91%	44, 98%

Discussion.

Most responders were not ready to implement FMD on the deadline, except four pharmacies and many did not know that this implementation was imminent.

a) Impact of change on current operations.

FMD related changes were perceived as disruptive to normal business flow and likely to negatively affect workloads (59.8%). In turn, 22.5% perceived this to negatively impact profitability and 12.7% believes that it might increase profitability. Perhaps some limitation of this survey question is that the participants were not themselves business owners, but employees within a larger business. We cautiously hypothesise that by their nature, they maybe are more accurate at assessing impact to workload, but perhaps not to profitability. However, we do not know. Few (3.9%) perceived this did not improve patient safety and 77.5% believes that it might improve patient safety. Improved patient safety is the main purpose of FMD, so it is interesting to note that more than 10% (13.7%) of practitioners were undecided about this. This leads us to cautiously hypothesise that many participants believe the FMD adds more to the administrative burden, than improved patient safety.

b) Prior knowledge of prevalence of SF medicines.

There was unimodal distribution in the opinion of the percentage of medicines believed to be falsified in the UK, with a mode around 1 to 5%, which matches WHO estimates.[3] Recent data shows the total number of items dispensed in 2017 was 1,105.8 million.[35] This represents 11.06 to 55.29 million dispensed items that could be falsified, each with a potential to harm patients.

The percentage of medicines believed to be falsified from online suppliers, followed a near-normal distribution with a mode around 41 – 60% from online suppliers. Responders believe the legitimate supply chain to be sufficiently protected, but have anxieties around online sources of medicines that

are at a greater risk of falsification and may lead to greater public harm, which is supported by the wider literature.[43–48] This phenomenon was supported in the answer around the most likely source of SF, which were identified as mainly originating from internet pharmacies. The most commonly falsified medicines in the UK was perceived to be erectile dysfunction product followed by weight loss medication.

c) Visual checks are done to identify SF medicines.

Visual cues that would make pharmacists suspicious of a medicine being falsified, included different packaging to the original packaging and a different source. The most commonly falsified medicines in the UK, their physical appearance and who to report it to were in line with the wider literature.[49,50]

d) Practice around the identification and reporting of SF medicines.

Off the five people who had identified SF, two reported it to the MHRA and three did not. Four were from deprived postcodes, whereas one was from an affluent area. While five is a very small number, we do not know the frequency at which they detected SFs. Five respondents represent 1% of the invited sample and 4.9% of all respondents. Upscaling these numbers to a national level, would translate to 570 detections of SFs, without accounting for the cost of mitigating the damage to patients that may come from these SF medicines (While assuming: pharmacist detection of a single SF medicine, 11,619 pharmacies nationally, 5% identified SFs). We also do not know if there is likely to be a cluster effect (isolated to a specific area) or a nationwide effect of these detections. These findings are internationally relevant because of similar globally reported trends in major developed economies.[3,51]

There seems to be a worrying practice of not reporting ADRs irrespective of point of purchase or local circumstance. This provides tentative support for our FOI request analysis, which indicates under-reporting of suspected ADRs related to SFs. Record keeping and ADR reporting is an essential and integral part of a pharmacist's duty. SF medicines pose an uncommon problem and so how professionals deal with this can be varied. However, more needs to be done to raise awareness of the need to report SF to the appropriate agency (i.e. MHRA) and the importance of reporting related ADRs too. Reducing public harm is inherently acknowledged as key by responders.

e) Current awareness, involvement and training in public health.

Messages raising public awareness of SFs has not been reaching the public via pharmacy professionals, which raises important questions about promoting this message and getting it out to front-line staff and patients. While all pharmacy undergraduates are taught about the YCS in UK universities, this does not translate into practice as evidenced by general underreporting[52,53] of ADRs. Few respondents had reported SFs but more believed it helped to combat SFs. Six out of 501 of our respondents had reported SFs. Assuming our findings are nationally representative, we anticipate 140 reports. Therefore, the 70 reports lodged with the MHRA, we believe, indicate an under-reporting (see Results, Sec e). This is supported in comments relating to informing the MHRA (see Results, Sec d).

Only three respondents had seen the 'Postcard Guidance for Patients' leaflet, which conflicts with their earlier responses to involvement in any campaigns regarding SF but can be explained by prior training. A sub-group analysis of these three responders revealed that they were two women and one man, with 0-5 years and 11-15 years of practice experience, working 25-34 hours and 35-44 hours per week and all believed that FMD would greatly improve patient safety. All had received

training regarding SF and all would further seek such training. While most respondents were not aware of technologies in place to identify SF, a handful could name some strategies in place and overall envisaged them having a limited impact in combating SFs. While most respondents did not receive training, 69% would participate in a training program regarding SFs.

f) Confidence regarding handling SF medicines.

Pharmacists accepted that SF medicines pose a significant problem and that their lack of knowledge and resources was potentially detrimental. They accepted a degree of liability in such circumstances and that their intervention could disrupt use of SF medicines. Further training and listening to the patients could be useful in overcoming these barriers. Low scores were generally given for self and peer group for confidence, capability, vigilance and knowledge levels.

Appendix B, Table 1 shows slightly lower agreement in our sample with the statements: "The majority of my fellow pharmacists in the UK are confident regarding falsified medicines", "I'm constantly vigilant of encountering falsified medicines when checking prescriptions" and "I have enough knowledge to identify falsified medicines". This is normal and as expected because our sample is nearly double the original sample size. In this study, heterogeneous constructs or some missing data may have contributed to the lower value of Cronbach's Alpha, but demonstrates criterion validity.

g) Opinions on policy and the pharmacists' role in combating SF medicines.

Strong opinions on policy surrounding public health education, regulation and enforcement, supply chain management, product serialisation and reporting were made, though a greater regulatory role and supply chain integrity is expected by pharmacists. The role of the pharmacist was to build these checks into their accuracy checking, encourage education and training, identify and report SF medicines, raise public awareness, source medicines from reputable sources, have adequate resources and be vigilant and act as necessary. Complex operational factors could make delivering all these difficult. Some respondents did not believe that this was part of the pharmacist role and that it was the regulators job.

h) Examine geospatial location and Index of Multiple Deprivation (IMD) by decile.

We achieved a well distributed sample, with good geographical representation. Analysing the data shows the following in deprived areas vs affluent counterparts: inadequate equipment (22.9% vs 22.5%), lower knowledge [Seen the 'Postcard Guidance for Patients' leaflet? (2% vs. 4%)], unawareness of technologies (87% vs 82%), slightly higher rates of training (4% vs 2%), higher rates of identifying SFs (9% vs 2%) (table 3 and Appendix C), though none were statistically significant.

Service inequalities by location were minimal, except for the detection rates of SFs, which is surprising in a single organisational structure. These premises may require more resources, time and support to meet compliance standards. This sub-analysis provides a snapshot of the deprivation landscape now and provides a benchmark for future evaluation to see if these pharmacies (and the communities they serve), get left-behind.

Strengths and limitations.

We report on a nationally representative sample in the first study of its kind, examining readiness to implement FMD by pharmacies in England. Limitation of this study include those inherent to surveys, particularly those dependent on retrospective recall.

To assess non-respondent bias we examined dispensing statistics of the population, invited participants, respondents and non-respondents (table 4). Respondents tended to be from slightly busier pharmacies than non-respondents, though by a small margin, making our findings nationally and internationally representative [51] and generalizable.

Table 4 Bias assessment.

NHS Dispensing Monthly (Mar 2018) Statistics		**Number of Prescription Forms (nominal)**	**Number of Prescription Items (nominal)**
Mean	England Population	3564	7132
	Invited	5355	10817
	Respondent	5421	10953
	Non-Respondent	5349	10800
Standard deviation	England Population	2692	5167
	Invited	2044	4611
	Respondent	1918	4302
	Non-Respondent	2077	4699

Future research.

A larger study using our survey would be valuable to further statistically validate our questionnaire (Appendix A) and we encourage the research community to use it to report their findings. The rollout of this implementation needs to be studied longitudinally to assess its full impact including on patient safety. Qualitative studies with participants that have (and have not) identified and reported SFs may help explain why they reported it (or did not) and to explore ways of improving detection and reporting, in a bid to reduce public harm. More needs to be done about raising public awareness.

Conclusions.

We find pharmacies are not ready to implement FMD and this remains an ongoing concern 9-months from implementation.[12,54,55] Impact on workload and profitability were areas of concern, though improved patient safety was anticipated. Of the total number of medicines dispensed in England, 1 to 5% are believed to be falsified, with a greater proportion from online sources with erectile dysfunction and weight loss medicines at risk of falsification. Different packaging and different sources of medicine would raise suspicion among pharmacists. We found underreporting of detected SF medicines, with low confidence and self-efficacy on SFs among pharmacists. Limited public health campaigns may result in a lack of awareness amongst pharmacy professionals and patients. Limited awareness of technologies in place identifying SFs exist, though further training is welcome. Policy changes in the area of public health education, regulation and enforcement, supply chain management, serialisation and reporting are important. Geospatial analysis revealed more SFs were identified in deprived areas, potentially putting these patients at greater risk of harm from SF medicines and not capturing the full benefits of FMD implementation.

In conclusion, pharmacies are not FMD compliant and limited practical help and support seems available. A lack of resources, knowledge, competency, training and confidence makes this a difficult directive to implement successfully. There is a risk that pharmacists maybe navigating this change in

isolation, potentially coming to innovative workarounds to meet ongoing business targets with untold consequences. At a pharmacy-corporate level, sanctions for non-compliance maybe stressful, costly, time-consuming and unattractive as these costs do not support business-operations (or profitability) and maybe perceived as bureaucratic. Improved patient safety is anticipated, but difficult to quantify. Our study provides much needed data for evidence-based decision making.

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Contributors.

The author conceived, designed, acquired, analysed and interpreted data. They developed and approved the version to be published and is accountable for its accuracy and integrity.

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No further data is available to preserve participant anonymity.

Disclaimer.

The views expressed in this publication are those of the author(s) and not those of the University of Brighton, University of Portsmouth, nor the NHS.

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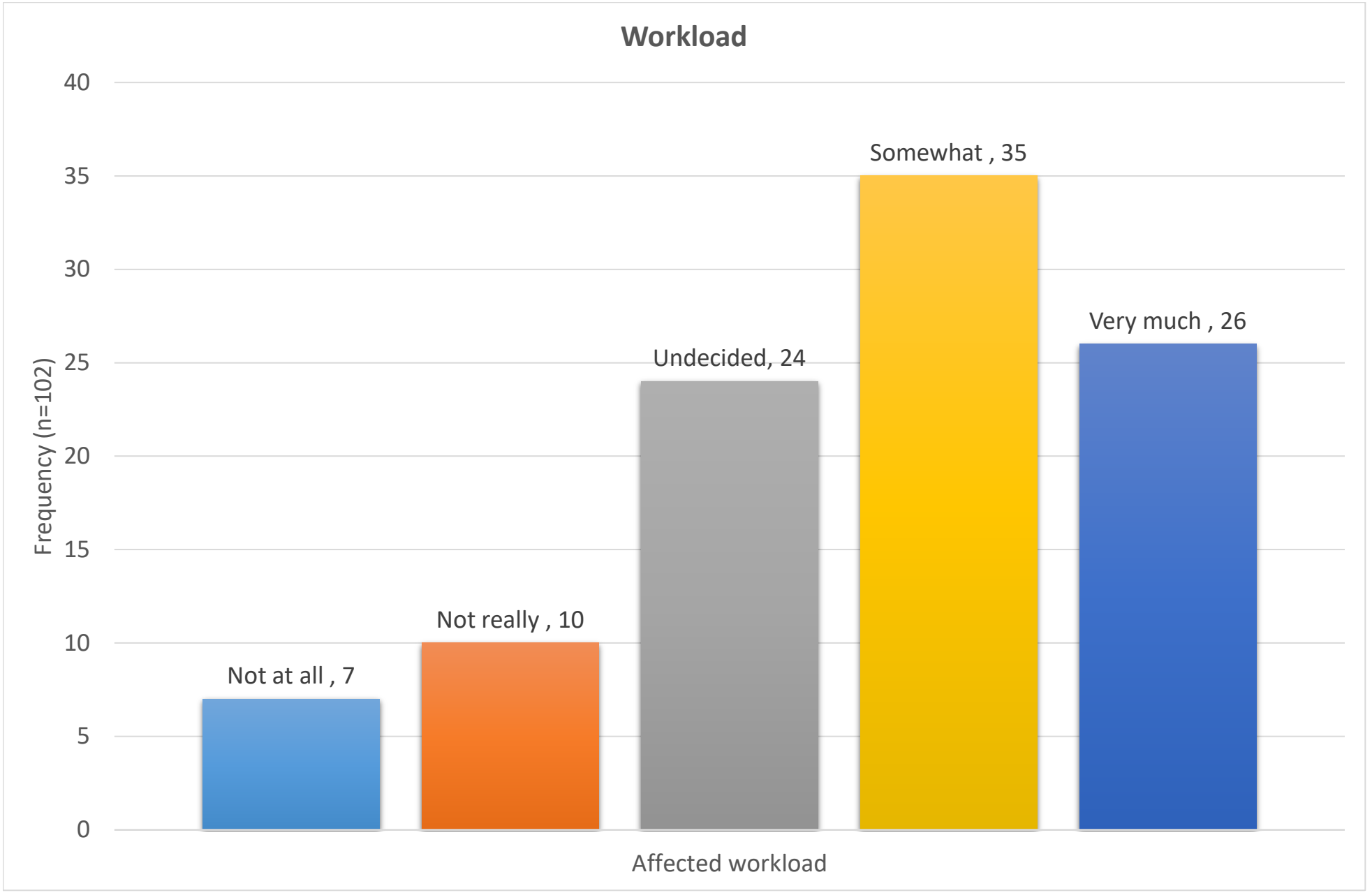
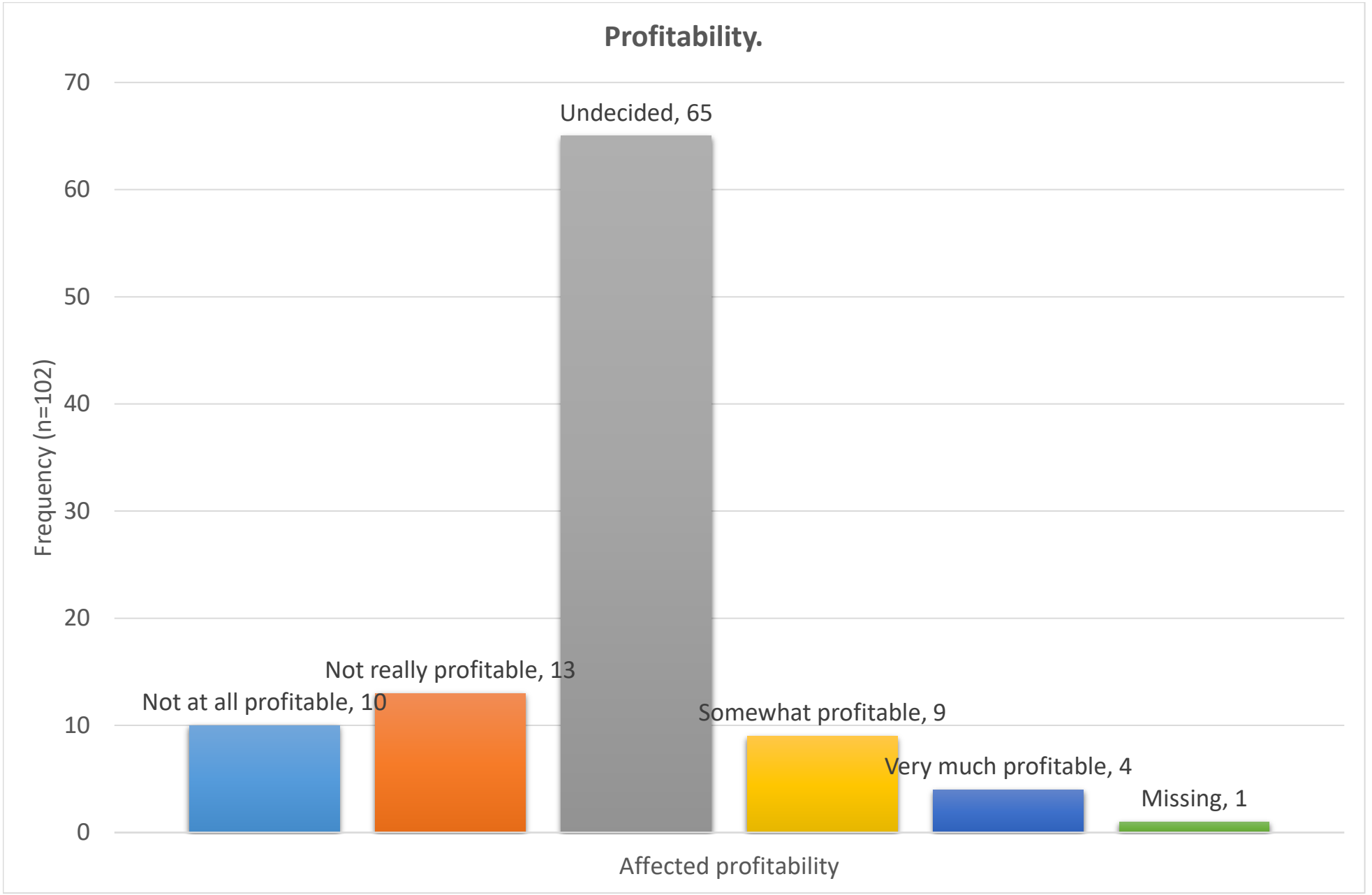
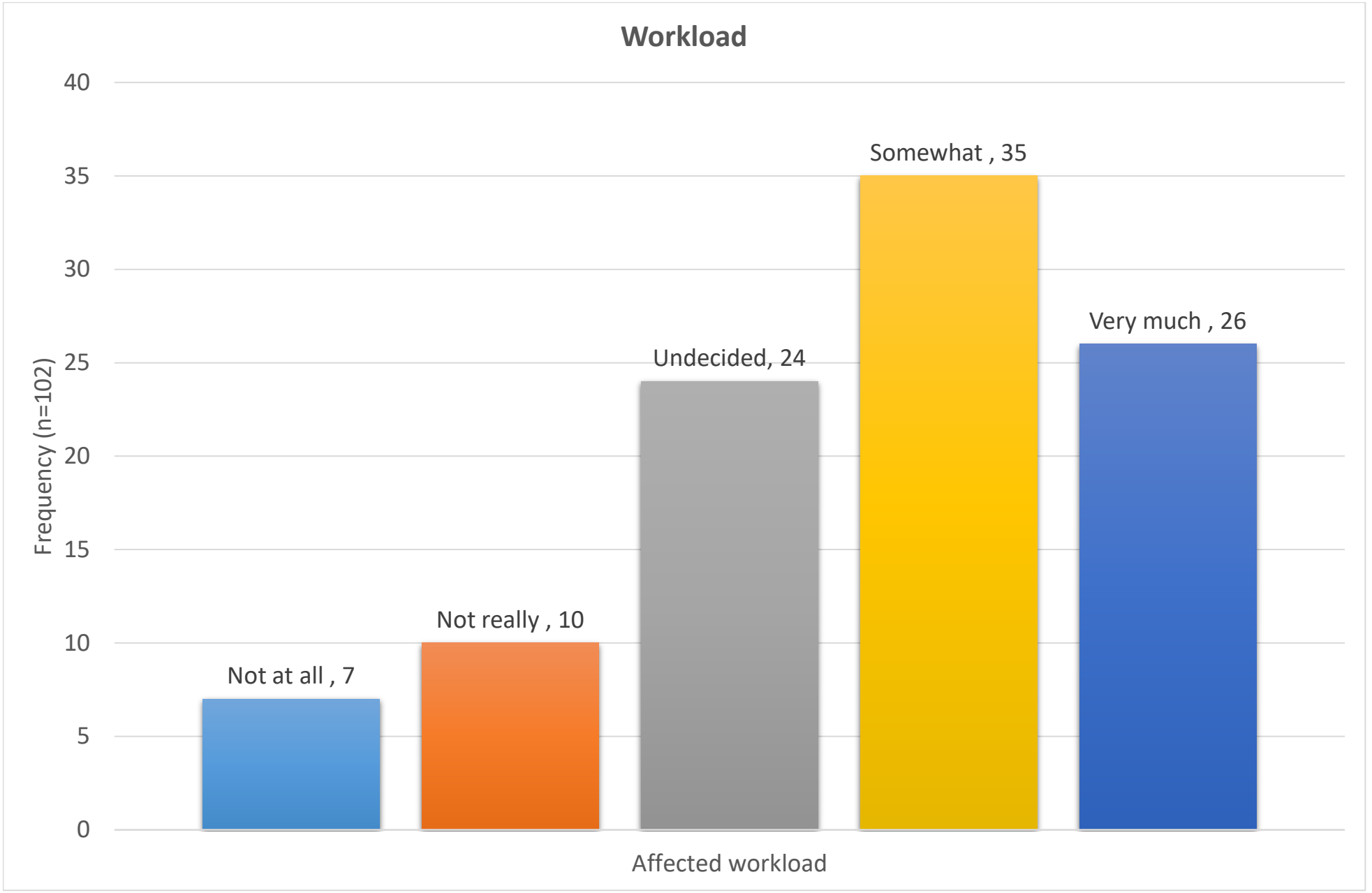
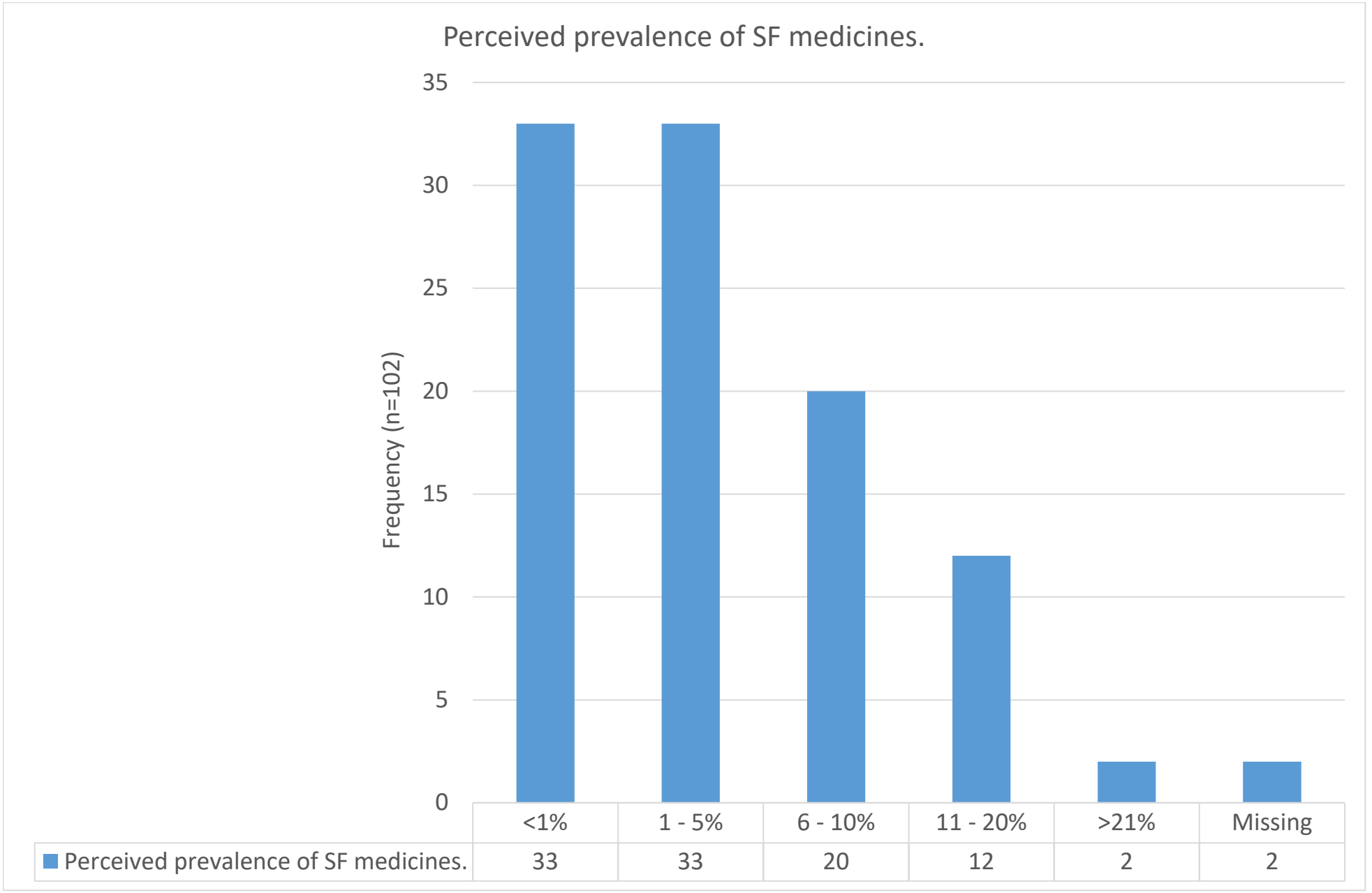
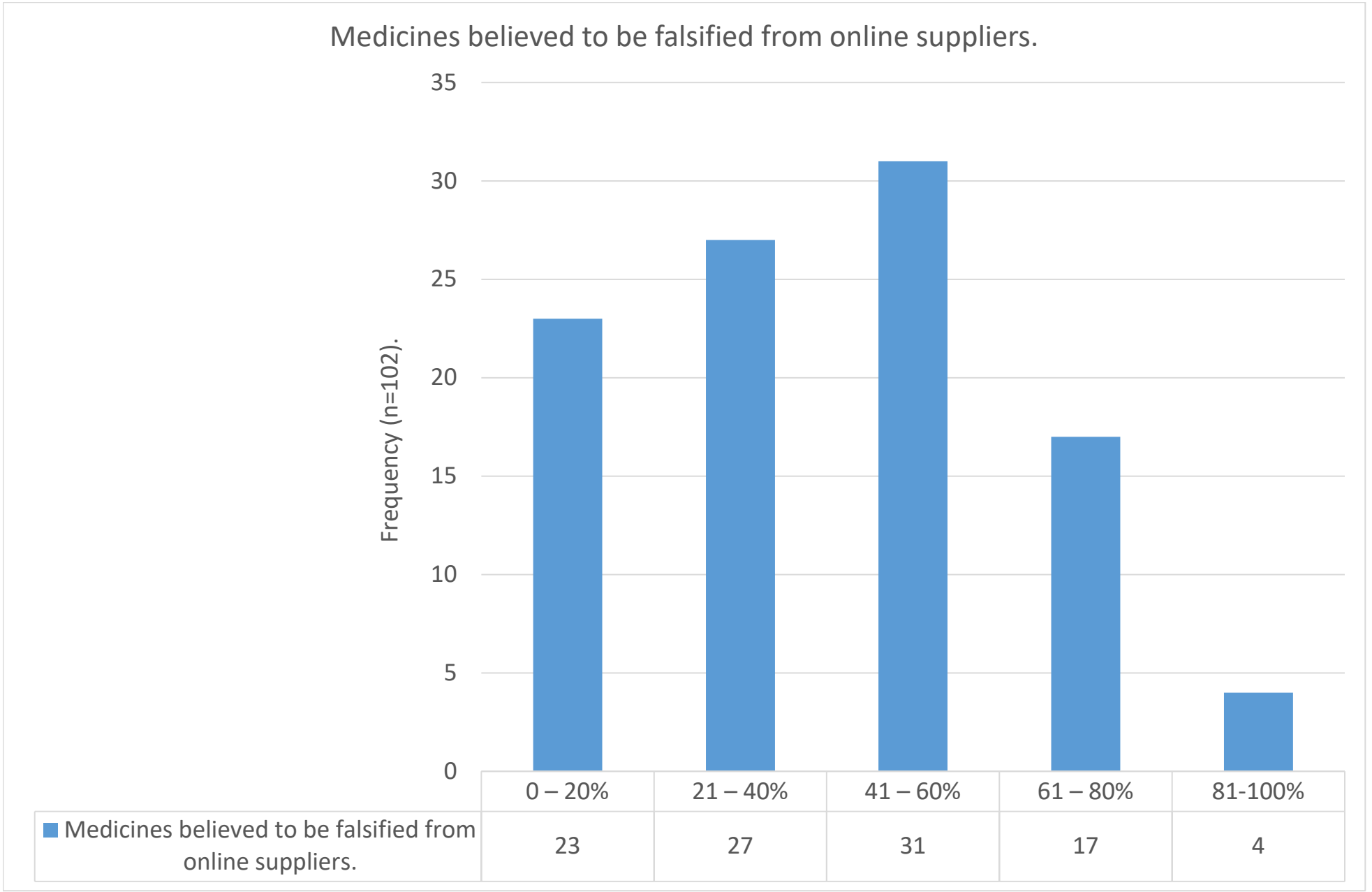
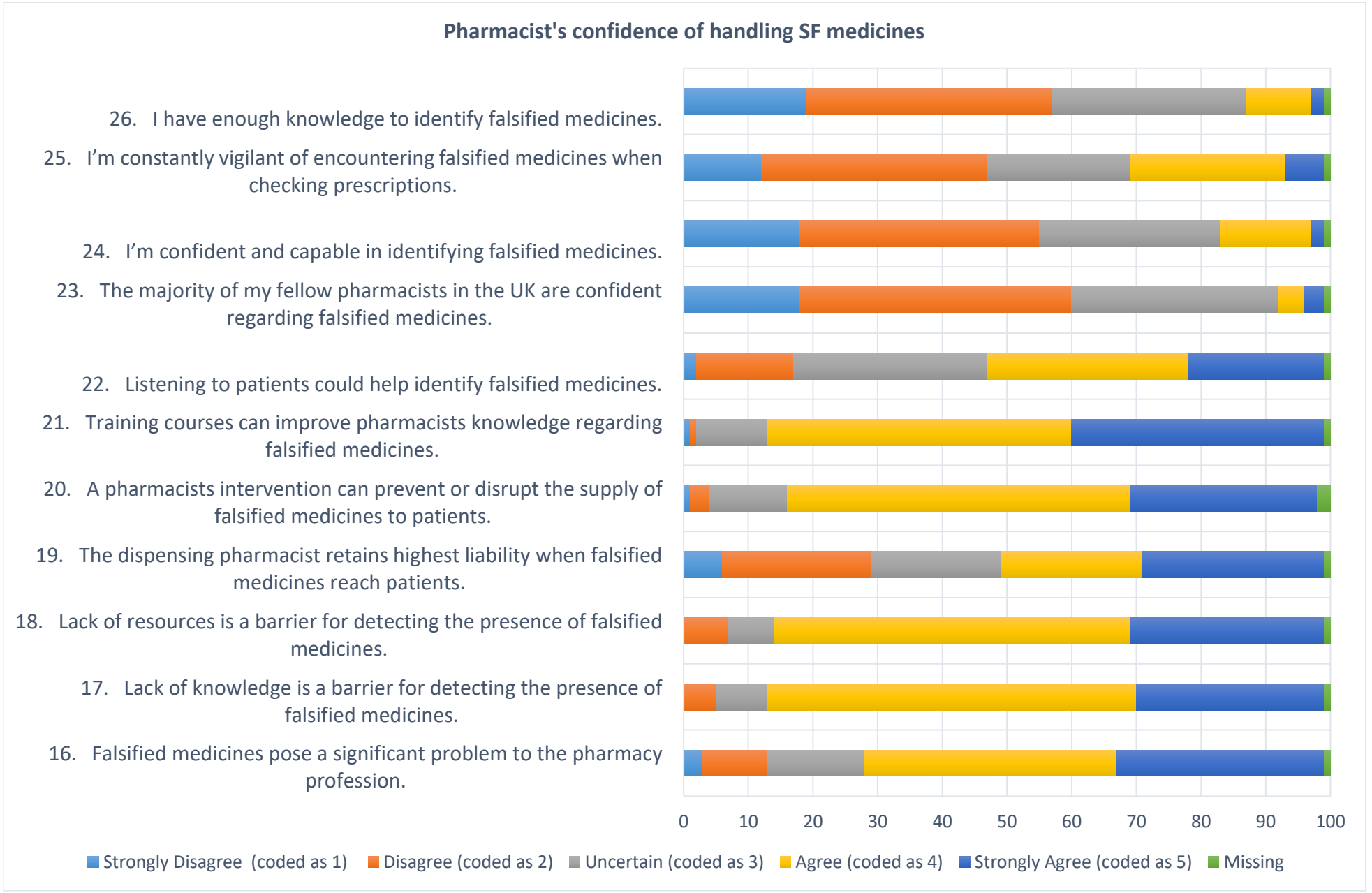

Workload
40
35
30
25
20
15
10
5
0
Frequency (n=102)
Not at all , 7
Not really , 10
Undecided, 24
Somewhat , 35
Very much , 26
Affected workload


Profitability.
70
60
50
40
30
20
10
0
Frequency (n=102)
Undecided, 65
Not really profitable, 13
Not at all profitable, 10
Somewhat profitable, 9
Very much profitable, 4
Missing, 1
Affected profitability


Workload
40
35
30
25
20
15
10
5
0
Frequency (n=102)
Not at all , 7
Not really , 10
Undecided, 24
Somewhat , 35
Very much , 26
Affected workload


Perceived prevalence of SF medicines.
Frequency (n=102)
35
30
25
20
15
10
5
0
<1%
1 - 5%
6 - 10%
11 - 20%
>21%
Missing
Perceived prevalence of SF medicines.
33
33
20
12
2
2


Medicines believed to be falsified from online suppliers.
Frequency (n=102).
35
30
25
20
15
10
5
0
0 – 20%
21 – 40%
41 – 60%
61 – 80%
81-100%
Medicines believed to be falsified from online suppliers.
23
27
31
17
4


Pharmacist's confidence of handling SF medicines
26. I have enough knowledge to identify falsified medicines.
25. I'm constantly vigilant of encountering falsified medicines when checking prescriptions.
24. I'm confident and capable in identifying falsified medicines.
23. The majority of my fellow pharmacists in the UK are confident regarding falsified medicines.
22. Listening to patients could help identify falsified medicines.
21. Training courses can improve pharmacists knowledge regarding falsified medicines.
20. A pharmacists intervention can prevent or disrupt the supply of falsified medicines to patients.
19. The dispensing pharmacist retains highest liability when falsified medicines reach patients.
18. Lack of resources is a barrier for detecting the presence of falsified medicines.
17. Lack of knowledge is a barrier for detecting the presence of falsified medicines.
16. Falsified medicines pose a significant problem to the pharmacy profession.
0 10 20 30 40 50 60 70 80 90 100
Strongly Disagree (coded as 1)
Disagree (coded as 2)
Uncertain (coded as 3)
Agree (coded as 4)
Strongly Agree (coded as 5)
Missing

Appendix A_Survey

1.	What is your gender?	Male ☐	Female ☐	Other ☐		Prefer not to say ☐
2.	What type of pharmacy do you work in? (*Tick all that apply)*	Independent☐	Chain ☐	Online ☐	Other ☐	
3.	How many years have you been a registered pharmacist?	0-5 ☐	6-10 ☐	11-15 ☐	16-20 ☐	20+ ☐
4.	What are your current working hours per week as a pharmacist (excluding lunch hour)?	16 – 24 ☐	25 - 34 ☐	35 - 44 ☐	45 - 54 ☐	55+ ☐
5.	The deadline for full implementation is 9 February 2019. This requires every prescription only medicine and some pharmacy medicines to be scanned at point of dispensing (to check against a central database that they are not falsified, recalled or expired) at community pharmacy level across the EU, before supplying to the patients. How ready are you to implement this?	Not at all ☐	Not really ☐	Undecided ☐	Somewhat ☐	Very much ☐
6.	Have you adequate equipment (e.g. computer terminals, scanners, compliance software, include initial set-up, IT, both software and hardware, plus ongoing operational costs.) To enable you to fulfil this requirement?	Not at all ☐	Not really ☐	Undecided ☐	Somewhat ☐	Very much ☐
7.	How do you see this affecting your workload?	Not at all ☐	Not really ☐	Undecided ☐	Somewhat ☐	Very much ☐
8.	How do you see this affecting your business profitability?	Not at all profitable ☐	Not really profitable ☐	Undecided ☐	Somewhat profitable ☐	Very much profitable ☐
9.	How do you see this affecting patient safety?	Does not improve patient safety at all ☐	Does not improve patient safety ☐	Undecided ☐	Somewhat improves patient safety ☐	Very much improves patient safety ☐
10.	In your opinion, what percentage of medicines are believed to be falsified in the UK?	<1% ☐	1 - 5% ☐	6 - 10% ☐	11 - 20% ☐	>21% ☐

11. In your opinion, what percentage of medicines are believed to be falsified from online suppliers?	0 – 20% ☐	21 – 40% ☐	41 – 60% ☐	61 – 80% ☐	81-100% ☐
12. In your opinion, what is the most likely source of falsified medicine?	Internet pharmacies ☐	Personal Importation ☐	Professional falsifier ☐	Other (please state) ☐	

For each of the statements below, tick ☑ the response that best characterises how you feel regarding falsified medicines in the UK.

13. What are the most commonly falsified medicines in the UK? *(Tick most relevant)*	Anti-cholesterol ☐	Cancer ☐	Erectile dysfunction ☐	Heart problems ☐	Weight loss ☐	Other (please state) ☐
14. What would make you suspicious that a medicine is falsified? *(Tick all that apply)*	Different distribution route ☐	Different labelling ☐	Different packaging to original packaging ☐	Different product composition (e.g. ingredients including excipients)	Different packaging to original packaging	Different source (e.g. different manufacturer or country of origin)
15. Which national agency would you contact, if any? *(Tick most relevant)*	Department of Health (DoH) ☐	European Medicines Agency (EMA) ☐	Royal Pharmaceutical Society (RPS) ☐	Medicines Healthcare Products Regulator y Agency (MHRA) ☐	General Pharmaceutical Council (GPhC) ☐	Other (please state) ☐

For each of the statements below, tick ☑ the response that best characterises how you feel about the statement.

	Strongly Disagree	Disagree	Uncertain	Agree	Strongly Agree
16. Falsified medicines pose a significant problem to the pharmacy profession	☐	☐	☐	☐	☐
17. Lack of knowledge is a barrier for detecting the presence of falsified medicines	☐	☐	☐	☐	☐
18. Lack of resources is a barrier for detecting the presence of falsified medicines	☐	☐	☐	☐	☐
19. The dispensing pharmacist retains highest liability when falsified medicines reach patients	☐	☐	☐	☐	☐
20. A pharmacists intervention can prevent or disrupt the supply of falsified medicines to patients	☐	☐	☐	☐	☐
21. Training courses can improve pharmacists knowledge regarding falsified medicines	☐	☐	☐	☐	☐
22. Listening to patients could help identify falsified medicines	☐	☐	☐	☐	☐
23. The majority of my fellow pharmacists in the UK are confident regarding falsified medicines	☐	☐	☐	☐	☐

24. I'm confident and capable in identifying falsified medicines ☐ ☐ ☐ ☐ ☐

25. I'm constantly vigilant of encountering falsified medicines when checking prescriptions ☐ ☐ ☐ ☐ ☐

26. I have enough knowledge to identify falsified medicines ☐ ☐ ☐ ☐ ☐

For each of the questions below please tick ☑ for either Yes or No.	**Yes**	**No**
27. a) Have you been involved in any campaigns regarding falsified medicines?	☐	☐
b) If yes, please state the name of the campaign.		
c) Do you believe that campaigns was effective?	☐	☐
28. a) Have you ever used the Yellow Card Scheme for falsified medicines?	☐	☐
b) Do you believe this scheme is useful in combating falsified medicines?	☐	☐
29. a) Have you seen the 'Postcard Guidance for Patients' leaflet?	☐	☐
30. a) Are you aware of any technologies in place to identify falsified medicines?	☐	☐
b) Which technologies?		
c) Do you believe this technology would be effective in combating falsified medicines?	☐	☐
31. a) Have you ever received any training regarding falsified medicines?	☐	☐
b) Would you participate in a training program regarding falsified medicines?	☐	☐

For each of the questions below please tick ☑ for either Yes or No.	**Yes**	**No**
32. a) Have you ever identified falsified medicines?	☐	☐
b) Did you inform the MHRA if you identified falsified medicines?	☐	☐
c) What did you do in that situation?		
33. a) Do you keep any records when encountering potential falsified medicines?	☐	☐
b) What records do you maintain when encountering falsified medicines?		

34. a) In your opinion, how can falsified medicines reaching the public be reduced?

b) In your opinion, what role can pharmacists play in combating falsified medicines?

Any additional comments:

END OF SURVEY. Thank you for completing this survey please return it in the prepaid, self-addressed envelope provided.

Reporting a Counterfeit Product could not be easier via the Yellow Card Scheme:
https://yellowcard.mhra.gov.uk/counterfeit-products/

You can complete a two page form to report a suspected counterfeit product (fake medicine or fake medical device) including any related side effects or safety concerns to the Yellow Card Scheme. You can register on the Yellow Card reporting site when you submit a report, or you can register in advance.

Alternatively, you can report a suspected counterfeit anonymously by contacting our 24-hour counterfeit hotline telephone number on 020 3080 6701.

Appendix B _ Detailed Results.

Table 1.

Table 1 Confidence regarding handling falsified medicines (p<0.001 One sample chi square test for all statements), percentages have been rounded to whole numbers.

	Mean (current study, n=101)	Std. Deviation (current study, n=101)	Mean (initial scale, n=50)	Std. Deviation (initial scale, n=50)	Mean difference	Std. Deviation difference
16. Falsified medicines pose a significant problem to the pharmacy profession.	3.89	1.067	4.02	1.078	0.13	0.011
17. Lack of knowledge is a barrier for detecting the presence of falsified medicines.	4.12	0.752	4.14	0.948	0.02	0.196
18. Lack of resources is a barrier for detecting the presence of falsified medicines.	4.1	0.806	3.94	1.077	-0.16	0.271
19. The dispensing pharmacist retains highest liability when falsified medicines reach patients.	3.44	1.292	3.4	1.278	-0.04	-0.014
20. A pharmacists intervention can prevent or disrupt the supply of falsified medicines to patients.	4.09	0.793	4.12	0.824	0.03	0.031
21. Training courses can improve pharmacists knowledge regarding falsified medicines.	4.24	0.764	4.06	0.843	-0.18	0.079
22. Listening to patients could help identify falsified medicines.	3.54	1.044	3.63	1.035	0.09	-0.009
23. The majority of my fellow pharmacists in the UK are confident regarding falsified medicines.	2.32	0.916	2.74	0.853	0.42	-0.063
24. I'm confident and capable in identifying falsified medicines.	2.45	1.005	2.62	1.105	0.17	0.1
25. I'm constantly vigilant of encountering falsified medicines when checking prescriptions.	2.77	1.13	3.04	1.195	0.27	0.065
26. I have enough knowledge to identify falsified medicines.	2.38	0.968	2.72	1.179	0.34	0.211

Table 2.

Table 2 Respondent's opinions on how to reduce falsified medicines from reaching the public.

Major theme	Sub-theme	Exemplary comments
1. Public health education.	a. Public education.	• *"QC should be the watchword, enlightening the public to buy medicines only from approved pharmacy and use less internet pharmacies."* • *"More public campaigns to raise awareness, training for pharmacists to be more confident to educate or give information to patients."*
	b. Professional education (of all involved in supply chain).	• *"Education of how to recognise falsified meds - training of staff and what to do."* • *"Extra Information. Not had any information through."* • *"Better education to those involved in supply."*
2. (Government) Regulation and enforcement.	a. Regulated online sales.	• *"Reducing online sale of medicine or be more vigilant."* • *"Greater controls online purchasing. Less generics, so false medicines easier spotted."*
	b. Regulatory Control.	• *"Awareness and stricter consumer law in getting medication."* • *"Government responsible to prevent - if flow into the market either from Internet/EU imported medicines."*
	c. Reclassification.	• *"POM to P switches (e.g. Viagra)."*
3. Supply chain management.	a. Role of the manufacturers.	• *"I think this should be the role of the manufacturers and wholesalers not pharmacists."* • *"Monitoring of supply chains"* • *"Suppliers and wholesalers should be responsible and have a system to check in place."*

		• *"Controlling the supply chain, strict checks and audits."*
	b. Role of the wholesalers.	• *"Impetus on suppliers and audit - award levels based on compliance (gold, silver, bronze et cetera)."* • *"All medicines at wholesale level should be legitimate."* • *"The wholesaler needs to do these checks."* • *"Should be prevented at the wholesalers before reaching the pharmacy."* • *"Constant vigilance, using only reputable wholesalers, not using the Internet."*
	c. Role of all (manufacturers, wholesalers and pharmacy).	• *"Verify medicines at every step of distribution from original source. Have one system only (very difficult to achieve)."* • *"Checked at wholesalers as well as chemist level."*
4. Serialisation (Track & Trace).	• *"Each medicine box have unique code which keeps a history of where it has been and which can be viewed."* • *"Scanning the medicines prior to reaching patients."* • *"online central database and scanning are better options"* • *"To include a certified mark or sticker that is difficult to copy on the packaging."* • *"Electronic tagging."* • *"Scanning boxes."* • *"By original packaging and having hallmark. I don't think scanning a barcode will make any difference."*	
5. Reporting to the regulator, medical staff and internally to pharmacy.	• *"Yellow card, P.M.R [patient medical record], internal dispensing incident form."*	

Table 3.

Table 3 Pharmacist's role in combating falsified medicines.

Major themes	***Exemplary comments.***
1. Build into accuracy check.	• *"Checking when completing accuracy check."* • *"If we can use scanning method to check, then for sure we can improve."* • *"Final Check and ensure dispenser check at point of assembly."* • *"Scan items."* • *"With enough training, pharmacists can play a strong role in identifying when dispensing."* • *"If there was a procedure in place it would be part of dispensing procedure otherwise little time."* • *"Crucial-all members of the healthcare team will be required to scan and verify medication."* • *"Scanning boxes."*
2. Complex and multifactorial.	• *"Embrace training and procedures, order through authorised suppliers, learn through other's mistakes, public information campaign, check medicines waste returned to us could identify an issue."*
3. Education and training.	• *"Be educated so that we can identify falsified medicines."* • *"With training - crucial role as gatekeeper."* • *"Being trained to recognise potential false medicines then using resources. To feedback and highlight common sources."* • *"With appropriate training able to identify these and intercept before reaching the patient."* • *"By right training, we can identify wrong/falsified medication."* • *"Undergo training."* • *"Doing what is asked of us but training/information should be provided and we have received nothing at all."* • *"The profession needs more awareness and knowledge in identifying falsified medication."*
4. Identify and report.	• *"Help identify and report them."*
5. Not pharmacist's role.	• *"Would hope supply chain deals with this?"* • *"Pharmacists already have their hands [full] with their every day job, so it is unrealistic for pharmacists to check whether it is a genuine medicine [with their] naked eyes. Wholesaler should take responsibility in sourcing genuine medicines."* • *"Better alerts issued to pharmacists, wholesalers BIG role to play."*
6. Public awareness.	• *"Advising the public and spotting counterfeit medication."* • *"Advise."* • *"Raise awareness among patients."*
7. Regulator's job.	• *"I do not want to play a role in falsified medicines. Should be a government job."*
8. Reputable sources.	• *"Only ordering from reputable sources."* • *"Source trusted products from valid/trusted wholesalers."* • *"Ensuring we never source or supply them and patient awareness."* • *"Use trustworthy wholesalers."*
9. Resources.	• *"Knowledge and resources."*

10. Vigilance and action.	• *"Being vigilant of falsified medicines and what to do in the event of finding one."* • *"Identify and improve patient safety."* • *"Be vigilant."* • *"Be vigilant and be trained."* • *"Be vigilant."* • *"Being diligent in spotting/ watching out for."*

Table 4.

Table 4 Additional comments.

Major themes	**Exemplary comments.**
1. Not a pharmacist's job.	*"To identify falsified meds. It shouldn't be left to the pharmacist, their jobs are hard enough!"*
2. Quality Supply chain.	*"Being chain pharmacy our each item is coming from certified suppliers which make me think there shouldn't be any falsified medicine in my store."*
3. Technical difficulties.	*"Already the change of packaging has caused out of stocks of medicines, while they get the new boxes implemented which causes problems."*
4. Wholesaler's duty.	*"Falsified meds should not have been able to reach community pharmacy in the first place. Any falsified meds should have been caught at the wholesaler but not at the pharmacy! The whole idea of scanning every box during dispensing is purely stupid. Waste of time and effort! Wholesalers should be the one making sure no falsified meds reach the pharmacy via delivery in the first place."*
5. YCS ineffective.	*"Not sure yellow card scheme is a useful tool for falsified medicines."*

Appendix C_Deprivation Analysis (geospatial location and Index of Multiple Deprivation (IMD) by decile)

Q1 * Index of Multiple Deprivation Decile Crosstabulation

		Index of Multiple Deprivation Decile											Percentages (unadjusted bases, n=102)	Percentages (adjusted bases)
		1	2	3	4	5	6	7	8	9	10	Total		
1. What is your gender?	1 Male	7	7	9	7	3	3	4	2	2	2	46	45%	
	2 Female	10	8	7	7	1	3	7	3	2	3	51	50%	
	4 Prefer not to say	0	2	0	1	0	1	0	0	0	1	5	5%	
Total		17	17	16	15	4	7	11	5	4	6	102	100%	

Q2 * Index of Multiple Deprivation Decile Crosstabulation

Count

		Index of Multiple Deprivation Decile										
		1	2	3	4	5	6	7	8	9	10	Total
What type of pharmacy do you work in? (Tick all that apply)	2 Chain	17	17	16	15	4	7	11	5	4	5	101
Total		17	17	16	15	4	7	11	5	4	5	101

All were invited from a chain, so this is 102.

Q3 * Index of Multiple Deprivation Decile Crosstabulation

Count

		Index of Multiple Deprivation Decile											
		1	2	3	4	5	6	7	8	9	10	Total	
How many years have you been a registered pharmacist?	0-5 •	6	6	5	5	0	4	5	2	1	3	37	36%
	6-10 •	4	2	5	5	0	3	1	2	1	3	26	25%
	11-15 •	2	7	2	2	2	0	2	1	2	0	20	20%
	16-20 •	0	1	0	0	0	0	0	0	0	0	1	1%
	20+ •	5	1	4	3	2	0	3	0	0	0	18	18%
Total		17	17	16	15	4	7	11	5	4	6	102	100%

Q4 * Index of Multiple Deprivation Decile Crosstabulation

Count

		Index of Multiple Deprivation Decile											
		1	2	3	4	5	6	7	8	9	10	Total	
What are your current working hours per week as a pharmacist (excluding lunch hour)?	16 – 24 •	0	1	0	2	0	0	0	0	0	0	3	3%
	25 - 34 •	2	4	2	1	0	0	0	0	0	1	10	10%
	35 - 44 •	11	9	12	11	4	7	9	5	4	5	77	75%
	45 - 54 •	4	3	2	1	0	0	2	0	0	0	12	12%
Total		17	17	16	15	4	7	11	5	4	6	102	100%

Q5 * Index of Multiple Deprivation Decile Crosstabulation

Count

		Index of Multiple Deprivation Decile												
		1	2	3	4	5	6	7	8	9	10	Total		
The deadline for full implementation is 9 February 2019. This requires every prescription only medicine and some pharmacy medicines to be scanned at point of dispensing (to check against a central database that they are not falsified, recalled or expired) at community pharmacy level across the EU, before supplying to the patients. How ready are you to implement this?	Not at all •	5	6	6	6	0	3	6	2	2	4	40	39%	40%
	Not really •	6	7	4	5	1	1	1	1	1	2	29	28%	29%
	Undecided •	3	1	2	2	2	2	1	1	0	0	14	14%	14%
	Somewhat •	3	1	2	2	0	1	2	0	1	0	12	12%	12%
	Very much •	0	1	1	0	1	0	0	1	0	0	4	4%	4%
Total		17	16	15	15	4	7	10	5	4	6	99	97%	100%

Q6 * Index of Multiple Deprivation Decile Crosstabulation

Count

		Index of Multiple Deprivation Decile											
		1	2	3	4	5	6	7	8	9	10	Total	
Have you adequate equipment (e.g. computer terminals, scanners, compliance software, include initial set-up, IT, both software and hardware, plus ongoing operational costs.) To enable you to fulfil this requirement?	Not at all •	2	2	6	3	0	2	5	0	1	1	22	22%
	Not really •	5	7	3	7	0	1	1	1	0	1	26	25%
	Undecided •	4	0	1	0	2	1	0	1	1	2	12	12%
	Somewhat •	5	4	4	4	1	2	5	2	2	2	31	30%
	Very much •	1	4	2	1	1	1	0	1	0	0	11	11%
Total		17	17	16	15	4	7	11	5	4	6	102	100%

Q7 * Index of Multiple Deprivation Decile Crosstabulation

Count

		Index of Multiple Deprivation Decile												
		1	2	3	4	5	6	7	8	9	10	Total		
Q7 How do you see this affecting your workload?	Not at all •	1	1	1	3	0	1	0	0	0	0	7	7%	
	Not really •	1	2	2	1	1	0	0	1	0	2	10	10%	
	Undecided •	5	4	3	3	0	0	3	2	2	2	24	24%	
	Somewhat •	7	6	5	6	2	2	4	1	1	1	35	34%	
	Very much •	3	4	5	2	1	4	4	1	1	1	26	25%	
Total		17	17	16	15	4	7	11	5	4	6	102	100%	

Q8 * Index of Multiple Deprivation Decile Crosstabulation

Count

		Index of Multiple Deprivation Decile												
		1	2	3	4	5	6	7	8	9	10	Total		
Q8 How do you see this affecting your business profitability?	Not at all profitable •	2	1	3	1	1	1	0	0	0	1	10	10%	10%
	Not really profitable •	3	1	1	2	0	1	1	1	3	0	13	13%	13%
	Undecided •	10	12	10	11	1	4	8	3	1	5	65	64%	64%
	Somewhat profitable •	1	2	2	1	1	1	1	0	0	0	9	9%	9%
	Very much profitable •	1	1	0	0	1	0	0	1	0	0	4	4%	4%
Total		17	17	16	15	4	7	10	5	4	6	101	99%	100%

Q9 * Index of Multiple Deprivation Decile Crosstabulation

Count

		Index of Multiple Deprivation Decile												
		1	2	3	4	5	6	7	8	9	10	Total		
Q9 How do you see this affecting patient safety?	Does not improve patient safety •	1	0	0	0	0	0	1	0	1	1	4	4%	4%
	Undecided •	4	2	2	1	1	0	2	2	0	0	14	14%	14%
	Somewhat improves patient safety •	8	6	8	9	0	3	3	0	1	3	41	40%	42%
	Very much improves patient safety •	4	8	6	5	3	3	3	3	2	1	38	37%	39%
Total		17	16	16	15	4	6	9	5	4	5	97	95%	100%

Q10 * Index of Multiple Deprivation Decile Crosstabulation

Count

		Index of Multiple Deprivation Decile												
		1	2	3	4	5	6	7	8	9	10	Total		
Q10 In your opinion, what percentage of medicines are believed to be falsified in the UK?	<1% •	6	5	7	5	2	1	3	1	1	2	33	32%	33%
	1 - 5% •	7	4	8	6	0	2	4	0	1	1	33	32%	33%
	6 - 10% •	2	3	1	3	1	2	2	2	1	3	20	20%	20%
	11 - 20% •	2	3	0	1	1	1	2	1	1	0	12	12%	12%
	>21% •	0	1	0	0	0	1	0	0	0	0	2	2%	2%
Total		17	16	16	15	4	7	11	4	4	6	100	98%	100%

Q11 * Index of Multiple Deprivation Decile Crosstabulation

Count

		Index of Multiple Deprivation Decile												
		1	2	3	4	5	6	7	8	9	10	Total		
Q11 In your opinion, what percentage of medicines are believed to be falsified from online suppliers?	0 – 20% •	5	2	6	4	1	1	2	1	0	1	23	23%	
	21 – 40% •	4	6	3	4	1	1	5	0	1	2	27	26%	
	41 – 60% •	6	2	6	5	1	3	3	2	1	2	31	30%	
	61 – 80% •	1	6	1	2	1	0	1	2	2	1	17	17%	
	81-100% •	1	1	0	0	0	2	0	0	0	0	4	4%	
Total		17	17	16	15	4	7	11	5	4	6	102	100%	

Q16 * Index of Multiple Deprivation Decile Crosstabulation

Count

		Index of Multiple Deprivation Decile												
		1	2	3	4	5	6	7	8	9	10	Total		
Q16 Falsified medicines pose a significant problem to the pharmacy profession	Strongly Disagree	0	0	0	1	0	0	1	0	0	1	3	3%	3%
	Disagree	0	2	4	1	0	1	1	1	0	0	10	10%	10%
	Uncertain	1	3	4	1	0	1	2	2	0	1	15	15%	15%
	Agree	11	4	4	8	2	1	3	1	4	2	40	39%	40%
	Strongly Agree	5	8	4	4	2	4	3	1	0	2	33	32%	33%
Total		17	17	16	15	4	7	10	5	4	6	101	99%	100%

Q17 * Index of Multiple Deprivation Decile Crosstabulation

Count

		Index of Multiple Deprivation Decile												
		1	2	3	4	5	6	7	8	9	10	Total		
Q17 Lack of knowledge is a barrier for detecting the presence of falsified medicines	Disagree	0	3	2	0	0	0	0	0	0	0	5	5%	5%
	Uncertain	2	1	2	0	0	0	2	0	0	1	8	8%	8%
	Agree	11	7	11	11	2	4	4	4	2	2	58	57%	57%
	Strongly Agree	4	6	1	4	2	3	4	1	2	3	30	29%	30%
Total		17	17	16	15	4	7	10	5	4	6	101	99%	100%

Q18 * Index of Multiple Deprivation Decile Crosstabulation

Count

		Index of Multiple Deprivation Decile												
		1	2	3	4	5	6	7	8	9	10	Total		
Q18 Lack of resources is a barrier for detecting the presence of falsified medicines	Disagree	0	1	4	1	1	0	0	0	0	0	7	7%	7%
	Uncertain	2	2	0	2	0	0	0	0	0	1	7	7%	7%
	Agree	11	6	11	7	0	5	6	4	2	4	56	55%	55%
	Strongly Agree	4	8	1	5	3	2	4	1	2	1	31	30%	31%
Total		17	17	16	15	4	7	10	5	4	6	101	99%	100%

Q19 * Index of Multiple Deprivation Decile Crosstabulation

Count

		Index of Multiple Deprivation Decile												
		1	2	3	4	5	6	7	8	9	10	Total		
Q19 The dispensing pharmacist retains highest liability when falsified medicines reach patients	Strongly Disagree	2	1	0	1	0	0	1	0	0	1	6	6%	6%
	Disagree	4	4	3	5	0	3	1	1	2	1	24	24%	24%
	Uncertain	5	3	4	3	0	1	1	1	0	2	20	20%	20%
	Agree	2	5	4	4	1	1	3	1	0	1	22	22%	22%
	Strongly Agree	4	4	5	2	3	2	4	2	2	1	29	28%	29%
Total		17	17	16	15	4	7	10	5	4	6	101	99%	100%

Q20 * Index of Multiple Deprivation Decile Crosstabulation

Count

		Index of Multiple Deprivation Decile												
		1	2	3	4	5	6	7	8	9	10	Total		
Q20 A pharmacists intervention can prevent or disrupt the supply of falsified medicines to patients	Strongly Disagree	0	0	0	0	0	0	0	0	0	1	1	1%	1%
	Disagree	0	2	0	0	0	0	0	0	1	0	3	3%	3%
	Uncertain	3	1	0	3	0	0	2	1	0	2	12	12%	12%
	Agree	10	7	13	10	2	4	3	3	1	1	54	53%	54%
	Strongly Agree	4	7	3	2	2	2	5	1	2	2	30	29%	30%
Total		17	17	16	15	4	6	10	5	4	6	100	98%	100%

Q21 * Index of Multiple Deprivation Decile Crosstabulation

Count

		Index of Multiple Deprivation Decile												
		1	2	3	4	5	6	7	8	9	10	Total		
Q21 Training courses can improve pharmacists knowledge regarding falsified medicines	Strongly Disagree	0	0	0	0	0	0	0	0	0	1	1	1%	1%
	Disagree	0	0	1	0	0	0	0	0	0	0	1	1%	1%
	Uncertain	1	1	4	1	0	0	3	0	1	0	11	11%	11%
	Agree	11	7	8	9	1	3	2	3	2	2	48	47%	48%
	Strongly Agree	5	9	3	5	3	4	5	2	1	3	40	39%	40%
Total		17	17	16	15	4	7	10	5	4	6	101	99%	100%

Q22 * Index of Multiple Deprivation Decile Crosstabulation

Count

		Index of Multiple Deprivation Decile												
		1	2	3	4	5	6	7	8	9	10	Total		
Q22 Listening to patients could help identify falsified medicines	Strongly Disagree	0	1	1	0	0	0	0	0	0	0	2	2%	2%
	Disagree	3	2	4	3	0	0	1	0	1	1	15	15%	15%
	Uncertain	4	6	3	3	1	2	5	2	2	3	31	30%	31%
	Agree	8	2	7	6	0	3	2	2	1	1	32	31%	32%
	Strongly Agree	2	6	1	3	3	2	2	1	0	1	21	21%	21%
Total		17	17	16	15	4	7	10	5	4	6	101	99%	100%

Q23 * Index of Multiple Deprivation Decile Crosstabulation

Count

		Index of Multiple Deprivation Decile												
		1	2	3	4	5	6	7	8	9	10	Total		
Q23 The majority of my fellow pharmacists in the UK are confident regarding falsified medicines	Strongly Disagree	2	1	3	3	0	3	1	0	2	3	18	18%	18%
	Disagree	7	7	4	7	3	2	6	4	2	1	43	42%	43%
	Uncertain	6	9	7	3	1	2	2	1	0	2	33	32%	33%
	Agree	2	0	1	1	0	0	0	0	0	0	4	4%	4%
	Strongly Agree	0	0	1	1	0	0	1	0	0	0	3	3%	3%
Total		17	17	16	15	4	7	10	5	4	6	101	99%	100%

Q24 * Index of Multiple Deprivation Decile Crosstabulation

Count

		Index of Multiple Deprivation Decile												
		1	2	3	4	5	6	7	8	9	10	Total		
Q24 I'm confident and capable in identifying falsified medicines	Strongly Disagree	2	2	3	0	1	3	2	0	2	3	18	18%	18%
	Disagree	5	8	4	7	2	2	3	4	2	1	38	37%	38%
	Uncertain	9	7	1	4	0	2	3	1	0	2	29	28%	29%
	Agree	1	0	8	3	1	0	1	0	0	0	14	14%	14%
	Strongly Agree	0	0	0	1	0	0	1	0	0	0	2	2%	2%
Total		17	17	16	15	4	7	10	5	4	6	101	99%	100%

Q25 * Index of Multiple Deprivation Decile Crosstabulation

Count

		Index of Multiple Deprivation Decile												
		1	2	3	4	5	6	7	8	9	10	Total		
Q25 I'm constantly vigilant of encountering falsified medicines when checking prescriptions	Strongly Disagree	0	1	1	2	0	2	1	1	1	3	12	12%	12%
	Disagree	8	5	5	6	1	1	5	1	3	1	36	35%	36%
	Uncertain	3	6	4	2	1	2	2	2	0	0	22	22%	22%
	Agree	5	4	6	4	1	1	1	1	0	2	25	25%	25%
	Strongly Agree	1	1	0	1	1	1	1	0	0	0	6	6%	6%
Total		17	17	16	15	4	7	10	5	4	6	101	99%	100%

Q26 * Index of Multiple Deprivation Decile Crosstabulation

Count

		Index of Multiple Deprivation Decile												
		1	2	3	4	5	6	7	8	9	10	Total		
Q26 I have enough knowledge to identify falsified medicines	Strongly Disagree	1	2	3	2	1	3	1	1	2	3	19	19%	19%
	Disagree	9	7	5	5	1	2	5	2	2	1	39	38%	39%
	Uncertain	5	7	5	4	1	2	3	2	0	2	31	30%	31%
	Agree	2	1	3	3	1	0	0	0	0	0	10	10%	10%
	Strongly Agree	0	0	0	1	0	0	1	0	0	0	2	2%	2%
Total		17	17	16	15	4	7	10	5	4	6	101	99%	100%

Q27a * Index of Multiple Deprivation Decile Crosstabulation

Count

		Index of Multiple Deprivation Decile												
		1	2	3	4	5	6	7	8	9	10	Total		
Q27a) Have you been involved in any campaigns regarding falsified medicines?	Yes	0	0	1	0	1	0	0	0	0	0	2	2%	2%
	No	16	17	12	13	3	6	8	5	3	6	89	87%	98%
Total		16	17	13	13	4	6	8	5	3	6	91	89%	100%

Q27c * Index of Multiple Deprivation Decile Crosstabulation

Count

		Index of Multiple Deprivation Decile												
		1	2	3	4	5	6	7	8	9	10	Total		
Q27c) Do you believe that campaigns was effective?	Yes	2	2	1	1	0	1	0	0	0	1	8	8%	16%
	No	8	8	5	5	3	1	5	2	3	2	42	41%	84%
Total		10	10	6	6	3	2	5	2	3	3	50	49%	100%

Q28a * Index of Multiple Deprivation Decile Crosstabulation

Count

		Index of Multiple Deprivation Decile												
		1	2	3	4	5	6	7	8	9	10	Total		
Q28a) Have you ever used the Yellow Card Scheme for falsified medicines?	Yes	1	2	0	1	0	0	1	1	0	0	6	6%	7%
	No	14	15	13	12	4	6	7	4	3	6	84	82%	93%
Total		15	17	13	13	4	6	8	5	3	6	90	88%	100%

Q28b * Index of Multiple Deprivation Decile Crosstabulation

Count

		Index of Multiple Deprivation Decile												
		1	2	3	4	5	6	7	8	9	10	Total		
Q28 b) Do you believe this scheme is useful in combating falsified medicines?	Yes	7	7	4	5	2	3	4	2	1	2	37	36%	52%
	No	6	5	4	7	2	1	4	1	2	2	34	33%	48%
Total		13	12	8	12	4	4	8	3	3	4	71	70%	100%

Q29 * Index of Multiple Deprivation Decile Crosstabulation

Count

		Index of Multiple Deprivation Decile												
		1	2	3	4	5	6	7	8	9	10	Total		
Q29 Have you seen the 'Postcard Guidance for Patients' leaflet?	Yes	1	0	0	1	0	1	0	0	0	0	3	3%	3%
	No	15	17	13	12	4	5	8	5	3	6	88	86%	97%
Total		16	17	13	13	4	6	8	5	3	6	91	89%	100%

Q30a * Index of Multiple Deprivation Decile Crosstabulation

Count

		Index of Multiple Deprivation Decile												
		1	2	3	4	5	6	7	8	9	10	Total		
Q30a) Are you aware of any technologies in place to identify falsified medicines?	Yes	1	2	3	3	0	1	3	0	1	0	14	14%	16%
	No	14	15	10	10	4	5	5	5	2	6	76	75%	84%
Total		15	17	13	13	4	6	8	5	3	6	90	88%	100%

Q30c * Index of Multiple Deprivation Decile Crosstabulation

Count

		Index of Multiple Deprivation Decile												
		1	2	3	4	5	6	7	8	9	10	Total		
Q30 c) Do you believe this technology would be effective in combating falsified medicines?	Yes	6	6	4	7	1	3	3	2	2	2	36	35%	56%
	No	4	5	4	6	3	0	4	0	1	1	28	27%	44%
Total		10	11	8	13	4	3	7	2	3	3	64	63%	100%

Q31a * Index of Multiple Deprivation Decile Crosstabulation

Count

		Index of Multiple Deprivation Decile												
		1	2	3	4	5	6	7	8	9	10	Total		
Q31. a) Have you ever received any training regarding falsified medicines?	Yes	1	0	1	1	0	0	0	0	0	0	3	3%	3%
	No	15	17	12	12	4	6	8	5	3	6	88	86%	97%
Total		16	17	13	13	4	6	8	5	3	6	91	89%	100%

Q31b * Index of Multiple Deprivation Decile Crosstabulation

Count

		Index of Multiple Deprivation Decile												
		1	2	3	4	5	6	7	8	9	10	Total		
Q31. b) Would you participate in a training program regarding falsified medicines?	Yes	11	13	10	11	3	6	6	4	3	3	70	69%	83%
	No	3	2	2	0	1	0	2	1	0	2	13	13%	15%
Total		14	15	12	12	4	6	8	5	3	5	84	82%	100%

Q32a * Index of Multiple Deprivation Decile Crosstabulation

Count

		Index of Multiple Deprivation Decile

		1	2	3	4	5	6	7	8	9	10	Total		
Q32. a) Have you ever identified falsified medicines?	Yes	2	1	1	0	0	0	1	0	0	0	5	5%	5%
	No	14	16	12	13	4	6	7	5	3	6	86	84%	95%
Total		16	17	13	13	4	6	8	5	3	6	91	89%	100%

Q32b * Index of Multiple Deprivation Decile Crosstabulation

Count

		Index of Multiple Deprivation Decile												
		1	2	3	4	5	6	7	8	9	10	Total		
Q32 b) Did you inform the MHRA if you identified falsified medicines?	Yes	2	0	0	0	0	0	1	0	0	0	3	3%	6%
	No	8	9	6	7	4	2	6	2	3	2	49	48%	94%
Total		10	9	6	7	4	2	7	2	3	2	52	51%	100%

Q33a * Index of Multiple Deprivation Decile Crosstabulation

Count

		Index of Multiple Deprivation Decile												
		1	2	3	4	5	6	7	8	9	10	Total		
Q33. a) Do you keep any records when encountering potential falsified medicines?	Yes	7	3	1	3	2	0	2	1	1	1	21	21%	27%
	No	6	11	9	9	2	5	6	3	2	3	56	55%	73%
Total		13	14	10	12	4	5	8	4	3	4	77	75%	100%

Reporting checklist for cross sectional study.

Based on the STROBE cross sectional guidelines.

Instructions to authors

Complete this checklist by entering the page numbers from your manuscript where readers will find each of the items listed below.

Your article may not currently address all the items on the checklist. Please modify your text to include the missing information. If you are certain that an item does not apply, please write "n/a" and provide a short explanation.

Upload your completed checklist as an extra file when you submit to a journal.

In your methods section, say that you used the STROBE cross sectionalreporting guidelines, and cite them as:

von Elm E, Altman DG, Egger M, Pocock SJ, Gotzsche PC, Vandenbroucke JP. The Strengthening the Reporting of Observational Studies in Epidemiology (STROBE) Statement: guidelines for reporting observational studies.

		Reporting Item	Page Number
Title and abstract			
Title	#1a	Indicate the study's design with a commonly used term in the title or the abstract	1
Abstract	#1b	Provide in the abstract an informative and balanced summary	2

		of what was done and what was found	
Introduction			
Background / rationale	#2	Explain the scientific background and rationale for the investigation being reported	4-5
Objectives	#3	State specific objectives, including any prespecified hypotheses	5
Methods			
Study design	#4	Present key elements of study design early in the paper	6
Setting	#5	Describe the setting, locations, and relevant dates, including periods of recruitment, exposure, follow-up, and data collection	6-7
Eligibility criteria	#6a	Give the eligibility criteria, and the sources and methods of selection of participants.	6
	#7	Clearly define all outcomes, exposures, predictors, potential confounders, and effect modifiers. Give diagnostic criteria, if applicable	5-7
Data sources / measurement	#8	For each variable of interest give sources of data and details of methods of assessment (measurement). Describe comparability of assessment methods if there is more than one group. Give information separately for exposed and unexposed groups if applicable.	6
Bias	#9	Describe any efforts to address potential sources of bias	6

Study size	#10	Explain how the study size was arrived at	6
Quantitative variables	#11	Explain how quantitative variables were handled in the analyses. If applicable, describe which groupings were chosen, and why	7-12
Statistical methods	#12a	Describe all statistical methods, including those used to control for confounding	7-12
Statistical methods	#12b	Describe any methods used to examine subgroups and interactions	6, 13, 14
Statistical methods	#12c	Explain how missing data were addressed	6
Statistical methods	#12d	If applicable, describe analytical methods taking account of sampling strategy	Appendix C
Statistical methods	#12e	Describe any sensitivity analyses	n/a
Results			
Participants	#13a	Report numbers of individuals at each stage of study—eg numbers potentially eligible, examined for eligibility, confirmed eligible, included in the study, completing follow-up, and analysed. Give information separately for for exposed and unexposed groups if applicable.	7-12
Participants	#13b	Give reasons for non-participation at each stage	n/a
Participants	#13c	Consider use of a flow diagram	n/a

Descriptive data	#14a	Give characteristics of study participants (eg demographic, clinical, social) and information on exposures and potential confounders. Give information separately for exposed and unexposed groups if applicable.	7-12
Descriptive data	#14b	Indicate number of participants with missing data for each variable of interest	7-12
Outcome data	#15	Report numbers of outcome events or summary measures. Give information separately for exposed and unexposed groups if applicable.	7-12
Main results	#16a	Give unadjusted estimates and, if applicable, confounder-adjusted estimates and their precision (eg, 95% confidence interval). Make clear which confounders were adjusted for and why they were included	7-12
Main results	#16b	Report category boundaries when continuous variables were categorized	7-12
Main results	#16c	If relevant, consider translating estimates of relative risk into absolute risk for a meaningful time period	n/a
Other analyses	#17	Report other analyses done—e.g., analyses of subgroups and interactions, and sensitivity analyses	7-12
Discussion			
Key results	#18	Summarise key results with reference to study objectives	12-14
Limitations	#19	Discuss limitations of the study, taking into account sources of	14

		potential bias or imprecision. Discuss both direction and magnitude of any potential bias.	
Interpretation	#20	Give a cautious overall interpretation considering objectives, limitations, multiplicity of analyses, results from similar studies, and other relevant evidence.	15
Generalisability	#21	Discuss the generalisability (external validity) of the study results	14
Other Information			
Funding	#22	Give the source of funding and the role of the funders for the present study and, if applicable, for the original study on which the present article is based	16