Patients' use of information about medicine side effects in relation to experiences of suspected adverse drug reactions: A cross-sectional survey in medical in-patients

J Krska, Professor of Pharmacy Practice, School of Pharmacy and Biomolecular Sciences, Liverpool John Moores University, Liverpool, UK

Charles W Morecroft, Principal Lecturer, School of Pharmacy and Biomolecular Sciences, Liverpool John Moores University, Liverpool, UK

Corresponding author:

Professor Janet Krska, Medway School of Pharmacy, The Universities of Greenwich and Kent, Chatham Maritime, Kent. ME4 4 TB

Tel: 01634 202950 **Fax:** 01634 883927

E-mail: j.krska@kent.ac.uk

Running title:

Medicines information use and experiences of ADRs

Acknowledgements

This study was funded by Liverpool John Moores University. The authors have no conflicts of interest to declare.

The authors are grateful to the following hospital pharmacists who facilitated the study: Lisa Ainsworth, Marianne Charlton, Chris Herring, Jennie Simpson, Heather Smith, David Thornton and to the undergraduate pharmacy students who administered the questionnaire. We also thank Julia Taylor for support with data entry and quality checking.

Word count 2992

Abstract

Background

Adverse drug reactions (ADRs) are common and information about medicines increasingly widely available to the public. However relatively little work has explored how people use medicines information to help them assess symptoms which may be suspected ADRs.

Objective

To determine how patients use patient information leaflets (PILs) or other medicines information sources and whether information use differs depending on experiences of suspected ADRs.

Method

This was a cross-sectional survey conducted in six National Health Service (NHS) hospitals in North West England involving medical in-patients taking at least two regular medicines prior to admission. The survey was administered by a questionnaire and covered: use of the PIL and other medicines information sources, perceived knowledge about medicines risks/ADRs, experiences of suspected ADRs, plus demographic information.

Results

There were 1218 respondents to the survey of whom 18.8% never read the PIL, whilst 6.5% only do so if something unexpected happens. Educational level was related to perceived knowledge about medicines risks, but not to reading the PIL or seeking further information about medicines risks. Over half the respondents (56.0%) never sought more information about possible side effects of medicines.

57.2% claimed they had experienced a suspected ADR. Of these 85.9% were either very sure or fairly sure this was a reaction to a medicine. Over half of those experiencing a suspected ADR (53.8%) had read the PIL, of whom 36.2% did so before the suspected ADR occurred, the remainder afterwards. Reading the PIL helped 84.8% of these respondents to decide they had experienced an ADR. Educational level, general knowledge of medicines risks and number of regular medicines used all increased the likelihood of experiencing an ADR.

Conclusion

More patients should be encouraged to read the PIL supplied with medicines. The results support the view that most patients feel knowledgeable about medicines risks and suspected ADRs and value information about side effects, but that reading about side effects in PILs or other medicines information sources does not lead to experiences of suspected ADRs.

Introduction

Adverse reactions to medicines are common. Two large prospective studies in Liverpool hospitals have shown that 6.5% out of 18,820 admissions to medical units were caused by adverse drug reactions (ADRs), that 2.3% of patients admitted with ADRs die [1] and that 14.7% of 3,695 medical or surgical in-patients experienced an ADR during their stay.[2] In primary care, studies which have relied on patients' reports of ADRs, either to postal questionnaires or telephone surveys suggest annual prevalence estimates of the order of 25-29% in the USA[3,4] and 30% in the UK.[5] Higher estimates were found in a Dutch study involving only anti-epileptic drugs.[6] Furthermore a survey of the general public found that 45% claimed to have experienced an ADR at some time.[7]

Members of the public in the UK can report suspected ADRs directly to the Medicines and Healthcare products Regulatory Agency (MHRA), through the Yellow Card Scheme (YCS). An evaluation of patient reporting to the YCS found that most reporters identified suspected ADRs through the timing of the event in relation to the medicine being used and/or written or verbal information about medicines.[8,9] However no research has explored this in detail. For example, are people more likely to seek and use medicines information after experiencing an unusual event which they perceive as an ADR?

Furthermore, relatively little is known about the experiences of UK patients who do not report their suspected ADRs to the MHRA. The majority of reporters have relatively high levels of education, are likely to have high levels of health literacy and are thus unlikely to be representative of the majority of patients who experience adverse reactions to medicines. Studies have shown that not all patients inform health professionals about symptoms they suspect to be ADRs.[3,4] One potential reason for this may be that health professionals sometimes express dismissive attitudes about patients' judgements concerning symptoms they have experienced.[10-12]

It is important to explore further and in a wider, more representative population how patients use information about medicines, such as the patient information leaflet (PIL) or information provided by health professionals, to help them assess symptoms they suspect are ADRs and their experiences of discussing their views with health professionals. We have identified no

research which has specifically explored the relationship between use of medicines information and experiences of suspected ADRs.

Aim

To determine how medical in-patients use patient information leaflets (PILs) or other information sources about ADRs and whether use of information differs depending on experiences of suspected ADRs.

Methods

Approval to conduct the study was obtained from NHS and University Research Ethics Committees and the relevant NHS Trusts.

Questionnaire development

A questionnaire was devised for the study which consisted mainly of closed-ended questions covering: use of the PIL for medicines prescribed in primary care, other medicines information sources, perceived knowledge about medicines risks or ADRs, experiences of ADRs and reporting of these, plus demographic information covering use of prescribed and purchased medicines. Open-ended questions were also used to elicit most recent suspected ADR, how this was identified and what happened following reporting of this to a health professional. In the questionnaire the term 'side effect' was used throughout, as this term has been used in previous work.[8]

The questionnaires were piloted by 11 undergraduate pharmacy students with fifty individual members of the general public known personally to them to assess face validity and ease of completion, resulting inminor amendments to the wording of several questions to ensure greater clarity.

Setting

The study was conducted in between two and four medical wards in each of six hospitals in North West England, including teaching and non-teaching establishments in urban and semi-rural areas. Medical wards were selected because medical in-patients were likely to use medicines regularly and therefore had the potential to have experienced an ADR. Prior to data collection, the study was explained to the nurses-in-charge of the selected medical wards in each hospital, together with an information sheet and all gave written consent for the study to proceed.

Inclusion criteria

Potential participants were in-patients aged 18 or over, who were prescribed at least two medicines and taking at least two medicines prior to admission. Exclusion criteria were in-patients with cognitive impairment or confusion and those unable to communicate in English.

Recruitment

The nurse-in-charge identified patients who were well enough, with adequate English and were suitable to take part, who were then approached by a student researcher. Patients who agreed to consider participating were given an information sheet and at least thirty minutes to reflect on their decision. Those who were still willing to take part then gave written consent, before being given the questionnaire and instructions on how to complete it. The student researchers subsequently collected the questionnaire but were also available to clarify any questions to ensure its accurate completion. Training was provided on how to approach potential participants and respond to any concerns or queries.

Data analysis

All responses were entered into SPSS Version 17.0 (IBM Corporation, USA) for analysis and a quality check performed. To enable quantitative analysis of responses to the open questions, previously developed categories were used for how respondents identified suspected ADRs,[9] while categories for the remaining open questions were developed and agreed by the research team. Each response was categorised independently by the authors and cross-referenced. Independent associations between patient characteristics and experiences of suspected ADRs were assessed using chi-squared or Fisher's exact tests. Binary logistic regression analysis was used to identify the key factors associated with experiencing an ADR. Where relevant missing data were excluded from analysis.

Results

In total 1218 questionnaires were completed sufficiently for analysis. Demographic characteristics of the respondents and their self-reported medicines use are shown in Table 1.

Knowledge and use of information about suspected ADRs

Fewer than half of all respondents (508; 41.9%) indicated that they usually read the PIL for all medicines, but a further 397 (32.8%) claimed to read it only for new medicines (Table 2). Of the remainder, 228 (18.8%) indicated they never read the PIL, whilst 79 (6.5%) only do so

if something unexpected happens. Sections of the PIL selected as being most often read by respondents were 'possible side effects' (428; 37.7%), 'how to take the medicine' (268; 23.6%), 'advice before taking' (86; 7.6%), and 'what the medicine is for' (9; 0.5%). A further 242 (21.3%) respondents stated they read all sections.

The majority of patients (676; 56.0%) never tried to find out more about possible side effects of their medicines, but 138 (11.4%) claimed they did so for all their medicines. In addition, 188 (15.6%) sought more information if the medicine was new and a further 205 (17.0%) only if something unexpected happened. There was no clear relationship between educational level and reading the PIL, as although 34.7% of those with lower educational qualifications claim never to read them, 26.7% of those completing further or higher education also made the same claim. The sources of additional information respondents indicated they used predominantly were health professionals (343; 50.7%) and the internet (193; 28.6%), with fewest using books, newspapers and magazines (33; 4.9%) and 57 (8.4%) preferring to ask friends or family members. Respondents were evenly divided between those who indicated they knew a great deal or a fair amount about the risks of medicines in general and those who knew not very much or nothing at all (Table 2). Over two-thirds of respondents felt they knew enough about the possible risks or side effects of the medicines they used. Educational level was significantly associated with perceived adequate knowledge about medicines risks in general ($p<0.001$), but not with possible risks or side effects about medicines used.

Experiences and identification of suspected ADRs

Over half (697; 57.2%) of all respondents claimed they had experience of a suspected ADR: 395 (32.4%) one and 302 (24.8%) more than one. The most common effects described by the respondents were nausea and/or vomiting (160), dizziness or drowsiness (105) and psychiatric problems, including hallucinations and mood changes (64). Severe allergic reactions, including anaphylaxis were described by 28 and other serious reactions, including liver damage, by 11.

The characteristics of respondents who had experienced a suspected ADR are shown in Table 3 in comparison to those who did not recall experiencing this. Sex was not related to experiencing a suspected ADR, but increasing age, higher educational levels, higher numbers of regular medicines and increasing frequency of prescribed medicines use were all independently associated with experiencing a suspected ADR, while use of over-the-counter medicines was not. Logistic regression analysis suggested that higher educational levels,

higher number of regular medicines and more frequent prescription use all increased the likelihood of experiencing an ADR (Table 3) Having a university education resulted in an odds ratio for experiencing an ADR of 2.7 (95% confidence intervals 1.6 – 4.4), whereas using eight or more medicines gave an odds ratio of 2.4 (1.8 – 3.3) over using four or fewer. Frequency of reading the PIL was only weakly associated with the risk of experiencing a suspected ADR, whereas seeking further information and general knowledge about risks of medicines showed stronger associations (Table 2). Logistic regression analysis controlling for all other factors found that lower levels of general knowledge reduced the likelihood of having a suspect ADR, with knowing nothing at all reducing the odds ratio to 0.2 (0.1 – 0.3), compared to knowing a great deal.

A substantial majority 599 (85.9%) of respondents who claimed to have experienced a suspected ADR were either very sure or fairly sure this was a reaction to a medicine. Of the 697 experiencing a suspected ADR, 375 (53.8% of those responding) claimed they had read the PIL, 252 (36.2%) before the suspected ADR occurred and 123 (17.7%) after the experience. The remaining 322 respondents indicated they had not read the PIL at all, could not remember or did not respond. Of the 375 who did read the PIL, 318 (84.8%) indicated that it had helped them to decide they had experienced an ADR, although 18 of these indicated the effect was not listed. There were 41 (10.9%) further respondents who indicated that the PIL was not helpful because the suspected ADR was not listed, whilst 16 (4.1%) indicated they could not understand the leaflet. The majority of those who experienced a suspected ADR (489; 70.2%) did not explore any other information sources regarding the symptom they experienced. However 172 did do so, 151 (87.8%) of whom found this helped them to decide their experience was related to their medicine.

Of the 697 respondents experiencing a suspected ADR, 562 provided an explanation of how they identified the problem as being related to a medicine. Similar proportions cited timing issues and being informed by a health professional (Table 4), with these factors accounting for over three-quarters of respondents (427; 76.0%). The proportion of respondents who cited the PIL as the method of identification was low (11.6%).

Reporting suspected ADRs

Among the 697 who had experienced a side effect, 395 (56.7%) claimed to have informed a doctor, nurse or pharmacist about a side effect once, and a further 155 (22.2%) more than once. The outcomes of this were that 157 patients had their medicine changed, 136 had a

medicine discontinued, 36 had the dose of their medicine changed and 11 had changes made to formulation, timing or method of administration. In a further 39 respondents a medicine was added to provide symptom relief and 12 were admitted to hospital as a result of the problem. Seventy-nine respondents provided information about their experiences of discussing suspected ADRs with health professionals. These were categorised into positive or negative comments; examples of these are shown in Table 5.

Only 11 (0.9%) respondents in total had submitted a Yellow Card, five because a health professional suggested it and six who found out about the scheme themselves. There were a further 51 (4.2%) respondents who knew about the YC scheme but had not used it, whereas 1149 (94.9%) were not aware of it.

Discussion

Main findings

This survey found that while 74% of patients do usually read the PIL supplied with their medicines, the remainder do not or only do so if something unexpected happens, whereas over 40% seek information in addition to the PIL, mainly from health professionals or the internet. There were 57% of survey respondents who claimed to have experienced a suspected ADR, of whom 86% were sure of the causal association. The PIL was considered helpful by 85% of those who had used it in assisting identification of the suspected ADR, but only 11.6% of those experiencing a suspected ADR specifically cited the PIL as the method by which it was identified. Furthermore, only 36% of respondents who had experienced a suspected ADR had actually read the PIL before the event occurred. Factors strongly associated with having experienced a suspected ADR, were general knowledge about medicines risks, higher educational level and number of regular medicines used.

Strengths and limitations

The study involved only patients who were hospital in-patients on medical wards and had been taking prescribed medicines prior to and during admission, therefore were highly likely to have experienced a suspected ADR at some time. Participants were from six different hospitals covering a large geographical area and a wide range of medical services. Although surgical in-patients were excluded, there is no reason to suspect their experiences would differ from those of patients admitted to medical wards. The questions related to experiences of using medicines generally, incorporated many questions used successfully in previous surveys and was tested in a relevant population prior to use. Researchers ensured accurate completion of the questionnaire as far as possible, however a limited number of options were provided for closed questions. The questionnaire design incorporated questions about knowledge of medicines risks and use of information about medicines and side effects before questions about experiences of side effects, in an attempt to minimise bias resulting from recalling side effect experiences, however as most respondents completed the questionnaire without help, we cannot be assured that this was the case. The numbers of patients who were deemed by nursing staff to be unsuitable for inclusion or who refused to participate were not obtained, hence a response rate could not be calculated and there is also potential for self-selection bias. The design also has the potential for both recall bias and social desirability bias.

Comparison to the literature

Given the patient population in this study it is not surprising that such a high proportion (57%) had experienced a suspected ADR at some time. The proportion is higher than was found in a street survey of the general public asked the same question.[7] The finding that 19% of patients claim never to read the PIL is in line with a prospective study which found that 29% had not read the PIL within seven days of receiving a prescription for a new medicine and 13% had never read the PIL for a regular medicine.[13] Our results were also similar to this study in relation to the PIL sections most frequently read by patients, with the study by Raynor et al showing the side effects section being that which patients read in most detail. However a subsequent systematic review has shown that patients may not value the PIL and do not consider information written by medicine manufacturers as sufficiently independent.[14]

Awareness of medicines risks and experiences of side effects were related in our study, but a number of prospective studies have shown that informing patients about possible ADRs does not lead to their occurrence.[15-17] Indeed national guidance on how best to inform patients about side effects has been developed.[18] Most of the patients in our study had been informed about the possibility they had experienced an ADR by a health professional. This is in contrast to reporters of suspected ADRs using the YCS, who in the main identified the problem themselves through timing issues.[9] Only 11.6% of respondents to our survey had used the PIL to identify the experience as a suspected ADR, which is similar to the proportion of YCS reporters (8.5%). Furthermore the finding that that only 36% of respondents to our survey claimed they had read the PIL before they experienced the suspected ADR lends further weight to the view that patients' experiences of side effects are not due to awareness bias.

Experiences of perceived side effects were however related to educational level. It is possible that patients with higher educational levels may be more willing to ask for information and discuss any new symptoms with health professionals or indeed to search for further information to inform such discussions. Our results did show that educational levels were also positively associated with perceived general knowledge about medicines risks, but not to reading the PIL or knowledge about actual medicines being used. Previous work has shown that educational level and whether respondents had experienced frequent adverse effects in

the past were the most important predictors of wanting to know about all possible adverse effects of medicines.[19]

Given that 36% of our respondents cited a health professional as a method of identifying a suspected ADR, it is unsurprising that 57% of all those who had this experience claimed they had discussed their experience. Previous work has shown that in response to reporting of symptoms suspected by patients to be ADRs, the most common action of primary care physicians was to discontinue the offending medicine or to change therapy,[4] as was found here. However other work has suggested that physicians may sometimes be dismissive [11,12] and we also found a small number of patients who experienced this type of response.

Conclusion

These findings suggest that further support may be needed to encourage all patients to read the PIL supplied with medicines. The results add weight to other findings showing that most patients are knowledgeable about medicines risks and suspected ADRs, that they value information about medicines side effects and that reading about side effects in PILs or other medicines information sources does not lead to experiences of suspected ADRs.

References

1. Pirmohamed M, James S, Meakin S, Green C, Scott AK, Walley TJ, Farrar K, Park BK, Breckenridge AM. Adverse drug reactions as cause of admission to hospital: prospective analysis of 18 820 patients. *BMJ* 2004; 329: 15–19
2. Davies EC, Green CF, Taylor S et al. Adverse drug reactions in hospital in-patients: a prospective analysis of 3 965 patient-episodes. *PLoS one* 2009 4(2): e4439 doi: 10.1371/journal.pone.0004439
3. Ghandi TK, Weingart SN, Borus J et al. Adverse drug events in ambulatory care. *NEJM* 2003; 348(16): 1556-64
4. Weingart SN, Gandhi TK, Seger AC, Seger DL, Borus J et al. Patient-reported medication symptoms in primary care. *Arch Intern Med* 2005; 165: 234-240
5. Jarernsiripornkul N, Krska J, Capps PAG, Richards RME, Lee A. Patient reporting of potential adverse drug reactions: A methodological study. *Brit J Clin Pharmacol* 2002: 53: 318-25
6. Carpay JA, Aldenkamp AP, van Donselaar CA. Complaints associated with anti-epileptic drugs: results from a community–based study. *Seizure* 2005; 14: 198-206
7. Krska J, Jones L, McKinney J, Wilson C. Medicines safety: experiences and perceptions of the general public in Liverpool. *Pharmacoepidemiol Drug Saf* 2011; 20(10): 1098-1103

8. Avery AJ et al Evaluation of patient reporting of ADRs through the Yellow Card Scheme. Final report. *Health Technol Assess* 2011; 15: 20 http://www.hta.ac.uk/project/1628.asp
9. Krska J, Anderson CA, Murphy E, Avery AJ on behalf of the Yellow Card Study Collaboration. How Patient Reporters Identify Adverse Drug Reactions: A Qualitative Study of Reporting via the UK Yellow Card Scheme. *Drug Saf* 2011; 34(5): 429-436
10. van Grootheest AC, de Jong-van den Berg L. Review: Patients' role in reporting adverse drug reactions. *Exp Opin Drug Saf* 2004; 3: 363–368
11. Golomb BA, McGraw JJ, Evans MA et al. Physician response to patient reports of adverse drug effects. *Drug Saf* 2007; 30: 669-675
12. Anderson CA, Krska J, Murphy E, Avery AJ on behalf of the Yellow Card Study Collaboration. The importance of direct patient reporting of ADRs: a patient perspective. *Brit J Clin Pharmacol* 2011 doi: 10.1111/j.1365-2125.2011.03990.x
13. Raynor DK, Silcock J, Knapp P, Edmondson H. How do patients use medicine information leaflets in the UK? *Int J Pharm Pract* 2007; 15: 209-218
14. Raynor DK, Blenkinsopp A, Knapp P, Grime J, Nicolson DJ, Pollock K et al. A systematic review of quantitative and qualitative research on the role and effectiveness of written information available to patients about individual medicines. *Health Technol Assess* 2007; 11(5): 1-98
15. Lamb GC, Green SS, Heron J. Can physicians inform patients about potential side effects without fear of causing those side effects? *Arch Intern Med* 1994; 154: 2753-2756
16. Howland JS, Baker MG, Poe T. Does patient education cause side effects? A controlled trial. *J Fam Pract* 1990; 31: 62–64
17. Myers ED, Calvert EJ. The effect of forewarning on the occurrence of side effects and discontinuance of medication in patients on dothiepin. *J Int Med Res* 1976;4:237–240
18. Nunes V, Neilson J, O'Flynn N, Calvert N, Kuntze S, Smithson H, Benson J, Blair J, Bowser A, Clyne W, Crome P, Haddad P, Hemingway S, Horne R, Johnson S, Kelly S, Packham B, Patel M, Steel J (2009). Clinical Guidelines and Evidence Review for Medicines Adherence: involving patients in decisions about prescribed medicines and supporting adherence. London: National Collaborating Centre for Primary Care and Royal College of General Practitioners.
19. Ziegler DK, Mosier MC, Bauenaver M, Okuyemi K. How much information about adverse effects of medication do patients want from physicians? *Arch Intern Med* 2001; 161(5): 706-713

Table 1 Respondents' demographic characteristics and self-reported use of medicines

Characteristic		Number of respondents* (%)	Missing data
Gender	Female	625 (51.4)	2
Age	18 – 40	118 (9.7)	4
	41 – 64	400 (32.9)	
	65 – 80	485 (40.0)	
	Over 80	211 (17.4)	
Ethnicity	White	1201 (99.0)	6
	Asian	4 (0.3)	
	Mixed	4 (0.3)	
	Black	1 (0.1)	
	Other	2 (0.2)	
Educational level	Left school at 16	831 (68.5)	4
	Left school at 17 or 18	122 (10.0)	
	Further education	162 (13.3)	
	University	99 (8.2)	
Number of regular medicines	4 or fewer	500 (41.5)	12
	5 to 8	345 (28.6)	
	More than 8	361 (29.9)	
Obtain prescription medicines	At least monthly	851 (70.0)	3
	Every 2 – 3 months	266 (21.9)	
	Less than every 3 months	98 (8.0)	
Purchase over-the-counter medicines	At least monthly	98 (8.1)	6
	Every 2 – 3 months	114 (9.4)	
	Less than every 3 months	1000 (82.5)	

*missing data excluded from analysis

Table 2 Respondents' behaviours regarding side effect information-seeking and perceived knowledge

Measure	Categories	Had side effect (n=697)	No side effect (n =521)	Total	P value
Use of PIL	Always read	306 (44.2%)	202 (38.9%)	508 (41.9%)	0.007
	For new medicines	234 (33.8%)	163 (31.4%)	397 (32.8%)	
	If event occurs	46 (6.5%)	33 (6.4%)	79 (6.5%)	
	Never read	107 (15.4%)	121 (23.3%)	228 (18.8%)	
General knowledge about medicine risks	A great deal	72 (10.3%)	21 (4.0%)	93 (7.6%)	<0.001
	A fair amount	323 (46.4%)	194 (37.2%)	517 (42.5%)	
	Not very much	261 (38.5%)	224 (43.0%)	485 (39.9%)	
	Nothing at all	40 (5.7%)	82 (15.7%)	122 (10.0%)	
Sufficient knowledge of own medicines risks	Enough	467 (67.2%)	327 (63.0%)	794 (65.4%)	0.143
	Not enough	228 (32.8%)	192 (37.0%)	420 (34.6%)	
Seek further information in general	For all medicines	94 (13.6%)	48 (9.2%)	142 (11.7%)	<0.001
	For new medicines	130 (18.8%)	61 (11.8%)	191 (15.8%)	
	If event occurs	104 (15.0%)	48 (9.2%)	152 (12.6%)	
	Never	364 (52.6%)	362 (69.7%)	726 (60.0%)	
Seek further information about side effects	For all medicines	94 (13.6%)	44 (8.5%)	138 (11.4%)	<0.001
	For new medicines	123 (17.8%)	65 (12.6%)	188 (15.6%)	
	If event occurs	141 (20.4%)	64 (12.4%)	205 (17.0%)	
	Never	333 (48.2%)	343 (66.5%)	676 (56.0%)	

Table 3 Respondent characteristics in relation to experiences of suspected ADRs

Characteristic		Had suspected ADR n=697 (% of total)	No suspected ADR n =521 (% of total)	Individual association P value	Odds Ratio (95% CI)
Gender	Female	359 (51.6%)	267 (51.2%)	0.908	n/a
Age group	18 to 40	67 (9.6%)	51 (9.8%)	0.023	n/a
	41 to 64	237 (34.2%)	164 (31.2%)		
	65 to 80	289 (41.6%)	196 (37.8%)		
	Over 80	101 (14.5%)	110 (21.2%)		
Educational level	Left school at 16	450 (64.7%)	381 (73.4%)	<0.001	1.0
	Left school at 17 / 18	70 (10.1%)	52 (10.0%)		1.4 (0.9 – 2.0)
	Further education	103 (14.8%)	59 (11.4%)		1.7 (1.1 – 2.3)*
	University education	72 (10.4%)	27 (5.2%)		2.7 (1.6 – 4.4)*
Number of regular medicines	4 or fewer	238 (34.4%)	262 (50.8%)	<0.001	1.0
	5-8	203 (29.4%)	142 (27.5%)		1.5 (1.1 – 2.0)*
	>8	250 (36.1%)	112 (21.7%)		2.4 (1.8 – 3.3)*
Regular prescribed medicines	At least monthly	516 (74.2%)	335 (64.4%)	<0.001	1.0
	Every 1 to 3 months	143 (20.6%)	123 (23.7%)		0.8 (0.6 – 1.1)
	Less than every 3 months	36 (5.2%)	62 (12.0%)		0.4 (0.3 – 0.7)*

* $p<0.01$ logistic regression analysis, controlling for gender and age.

Table 4 Factors used to identify suspected ADRs by respondents (n = 562)

Factor		**Number citing (%)**
Timing issues	Not present before starting medicine	29 (5.2)
	Noted soon after starting medicines	124 (22.1)
	Disappeared when medicine stopped	19 (3.4)
	Change noted when dose changed	6 (1.1)
	Re-appeared on re-challenge	4 (0.7)
	Started after medicine stopped	1 (0.2)
	General timing	52 (9.3)
	New medicine	18 (3.2)
Information sources	Informed by health professional	221 (39.3)
	Used patient information leaflet	65 (11.6)
	Information other	31 (5.5)
Other reasons	Previous experience with this/similar medicine	6 (1.1)
	No other changes at the time	35 (6.2)
	Other reason given	12 (2.1)

Table 5 Respondents' experiences of reporting suspected ADRs to health professionals

Positive experiences			**Negative experiences**		
Outcome	Number reporting	Example	Outcome	Number reporting	Example
Record made in notes	5	"Informed doctor, who prescribed alternative and made record of allergy"	Dismissed	7	"The doctor thought I was being stupid"
Review of medicines	4	"Told by doctor to give it a few hours and then they would review it afterwards"	No action taken	20	"Nothing! not documented on drug chart"
Referral to other health professional	9	"Chemist told me to go to doctor"	Actions judged	3	"Doctor said I should've read the label"
Acceptance of patient report	7	"The doctor was very patient and explained well"	Told to continue	26	"I informed the Dr about an itch with a statin. The Dr told me to carry on taking the statin as it was doing me more good to take it than to stop."
Monitor symptoms	2	"I told the nurse who said they would monitor it"	Informed it's normal	7	"Told side effects were common and hair would grow back"